Study on Enhancing implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU

Mapping and Analysis of Administrative Procedures: analytical report

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Mapping and Analysis of Administrative Procedures: draft analytical report

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LEGAL NOTICE

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Summary

The European Commission Directorate-General for Health and Food Safety (DG SANTE) has commissioned ECORYS Nederland B.V., Technopolis and Spark Legal Network to conduct a study to enhance the implementation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare. The aim of the study is to improve implementation in a number of areas, inter alia to reduce administrative obstacles for patients seeking prior authorisation and reimbursement of cross-border healthcare across the EU.

For that purpose, for all EU Member States and EEA EFTA countries, information was collected on the administrative procedures for prior authorisation and reimbursement of cross-border healthcare under Directive 2011/4/EU, in view of identifying any such potential barriers for patients, specifically in light of the requirements of Article 7(7) and Article 9(1) of the Directive.

The collection of data at national level was mainly performed by a network of national legal experts, through the completion of a template for the data collection which was specifically developed for this purpose. In particular, the national legal experts conducted two main activities:

1. Desk research and completion of a detailed questionnaire;
2. Verification calls with national/regional bodies (where possible), to verify and complement the data collected during the desk research task.

The outcome of the data collection task is a set of national country reports, which can be found in Annex A. A summary of the results of the data collection tasks is presented in this report. The results of the mapping served as a basis for their preliminary assessment against the requirements of Article 7(7) and 9(1) of the Directive.

Specifically, the data contained in the national country reports were analysed against the requirements of Article 7(7) and Article 9(1) of the Directive, in view of identifying whether any of the administrative procedures/requirements i) may appear to be or may be regarded as being discriminatory/based on non-objective or discriminatory criteria; ii) although non-discriminatory, may appear or may be regarded as being an obstacle to the free movement of patients, services or goods (and whether they may be objectively justified on the grounds provided by Article 7 of the Directive); and/or iii) although being based on objective or non-discriminatory criteria, may be regarded as not being necessary and proportionate to the objective to be achieved. Moreover, with specific regard to national reimbursement procedures, where applicable, the requirements of Article 7(4) of the Directive were also taken into account for the analysis.

The analysis of the data showed that certain administrative procedures/requirements across EU Member States and EEA EFTA countries may be regarded as creating potentially unjustified obstacles for patients seeking cross-border healthcare under the Directive. With regard to prior authorisation procedures, potential issues were identified in 21 countries (AT, BE, BG, CY, DE, DK, EL, FR, HR, HU, IE, IS, LI, LU, MT, NL, PL, PT, RO, SI, SK); with regard to reimbursement procedures, potential issues were also identified in 12 countries (AT, CY, EL, FI, HU, IE, IS, LI, NL, NO, PL, PT). The data collected on PA procedures informed the development of 'Guiding Principles for Information Provision on prior authorisation systems across Member States'.

1 Introduction

In March 2011, Directive 2011/24/EU on the application of patients' rights in cross-border healthcare[1] (hereafter "the Directive") was adopted. The Directive clarifies the rights of patients to seek reimbursement for healthcare received in another Member State and ensures that these rights can be used in practice. It provides a framework for cross-border healthcare and aims to "*establish rules for facilitating access to safe and high-quality cross-border healthcare in the Union and to ensure patient mobility in accordance with the principles established by the Court of Justice and to promote cooperation on healthcare between Member States, whilst fully respecting the responsibilities of the Member States for the definition of social security benefits relating to health and for the organisation and delivery of healthcare and medical care and social security benefits, in particular for sickness*."[2] As of its adoption in 2011, the Directive complements the framework established by the Regulations on the Coordination of Social Security Systems, namely Regulation (EC) No 883/2004[3], and the implementing Regulation (EC) No 987/2009[4] (hereinafter, 'the Regulations'). More background information on the framework for cross-border healthcare established by the Regulations, and the main difference with the Directive is provided in Annex B.

1.1 Administrative procedures for cross-border healthcare

Amongst others, the Directive sets out certain rules which EU Member States and EEA EFTA countries (hereafter, "the countries") must comply with when setting out the administrative procedures for cross-border healthcare under the Directive. In particular, these rules apply with regard to the administrative formalities required across the countries to request and obtain Prior Authorisation (hereafter, "PA") for cross-border healthcare under the Directive (where applicable), as well as those required to request/obtain reimbursement of the costs of cross-border healthcare upon return.

In this context **Article 9 (administrative procedures regarding cross-border healthcare)** of the Directive requires that "the Member State of affiliation shall ensure that administrative procedures regarding the use of cross-border healthcare and the reimbursement **are based on objective, non-discriminatory criteria which are necessary and proportionate to the objective to be achieved".** Moreover, according to this provision, administrative procedures "shall be easily accessible and publicly available and shall be capable of ensuring that requests are dealt with objectively and impartially" and "Member States shall also determine reasonable periods of time within which requests for cross-border healthcare must be dealt with and shall make them publicly available on time". The medical conditions of the patient and the urgency of the circumstances shall be taken into account while considering the request and the final individual decision could always be challenged in judicial proceedings.

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1 Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare.

2 Directive 2011/24/EU, recital 10.

3 Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems. Available at: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:166:0001:0123:en:PDF.

4 Regulation (EC) No 987/2009 of the European Parliament and of the Council of 16 September 2009 laying down the procedure for implementing Regulation (EC) No 883/2004 on the coordination of social security systems. Available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32009R0987.

Furthermore, **Article 7 (general principles for reimbursement of costs)** also contains relevant rules which specifically concern the procedures for reimbursement of the costs of cross-border healthcare under the Directive. In particular, Article 7(7) states that "*the Member State of affiliation may impose on an insured person seeking reimbursement of the costs of cross-border healthcare, including healthcare received through means of telemedicine,* ***the same conditions, criteria of eligibility and regulatory and administrative formalities, whether set at a local, regional or national level, as it would impose if this healthcare were provided in its territory.*** *This may include an assessment by a health professional or healthcare administrator providing services for the statutory social security system or national health system of the Member State of affiliation, such as the general practitioner or primary care practitioner with whom the patient is registered, if this is necessary for determining the individual patient's entitlement to healthcare*". Nevertheless, according to the same provision ***"no conditions, criteria of eligibility and regulatory and administrative formalities*** *imposed according to this paragraph* ***may be discriminatory or constitute an obstacle to the free movement of patients,*** *services or goods,* ***unless it is objectively justified*** *by planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources*". Additionally, it is worth noting that Article 7(4) states as a general rule that "*the costs of cross-border healthcare shall be reimbursed or paid directly by the Member State of affiliation* ***up to the level of costs that would have been assumed by the Member State of affiliation, had this healthcare been provided in its territory*** *without exceeding the actual costs of healthcare received*". According to the same provision, the reimbursement of additional costs is an option, and not a mandatory requirement.

1.2 Objectives of WP1.b.

In its Report on the operation of Directive 2011/24/EU of 2018 (COM(2018) 651 final)[5], the Commission identified administrative procedures regarding cross-border healthcare as one of the priority areas which had the greatest potential to act as barriers to patients if left unaddressed.

In this context, one of the aims of this study is to gain an overview of the administrative procedures regarding PA and reimbursement of cross-border healthcare costs under the Directive across the countries, in view of identifying any administrative procedures/requirements which, in light of the provisions of Article 7(7) and Article 9(1) of the Directive, may appear to be discriminatory, or based on non-objective or discriminatory criteria, or which may be regarded as disproportionate obstacles to the free movement of patients, services or goods.

In the following chapter, Chapter 2, we will elaborate on the data collection tasks. Thereafter, in Chapter 3, we will present a brief summary of the results of the data collection tasks. Finally, Chapter 4 will assess whether any of the administrative procedures/requirements identified during the data collection task: i) may appear to be or may be regarded as being discriminatory/based on non-objective or

[5] Report from the Commission on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare (COM(2018) 651 final). Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2018:651:FIN.

discriminatory criteria; ii) although non-discriminatory, may appear to be or may be regarded as being an obstacle to the free movement of patients, services or goods (and whether they may be objectively justified on the grounds provided by Article 7 of the Directive); and/or iii) although being based on objective or non-discriminatory criteria, may be regarded as not being necessary and proportionate to the objective to be achieved.

2 Data collection

In view of the objectives of WP1.b., information on the administrative procedures for cross-border healthcare was gathered through the following main activities:

- Succinct literature review;
- EU level scoping interviews;
- National data collection.

2.1 Succinct literature review

A succinct literature research was conducted in view of identifying any relevant sources providing information on the administrative procedures for cross-border healthcare across the countries. It should be noted that no sources covering specifically the topic of the administrative requirements/procedures for PA and reimbursement of cross-border healthcare costs under the Directive were identified during this research. Nonetheless, the documents consulted served the fine-tuning of the research protocol and the provision of relevant background information on the study to the network of national legal experts.

2.2 EU level scoping interviews

In view of gaining an understanding of pertinent issues at national level regarding the administrative procedures for PA and reimbursement of cross-border healthcare costs across the EU and EEA EFTA countries, several organisations[6] were contacted in order to seek their availability to conduct an interview. Amongst the ones contacted, one interview was conducted with AIM - *Association Internationale de la Mutualité* (International Association of mutual benefit societies).[7] No particular issues were identified by the interviewee with specific regard to the administrative procedures for cross-border healthcare as such, although further information was provided with regard to the overall application and use of the Directive across the countries.

2.3 National data collection

The detailed mapping of the administrative procedures for cross-border healthcare under the Directive across the countries has mainly been conducted by a network of national legal experts. For this activity, a detailed research protocol was developed, consisting of a template for the data collection and instructions for the national legal experts on how to conduct their task. The research protocol was dispatched to the network of national legal experts who performed the data collection tasks between 18 May 2021 and 23 July 2021.

In view of mapping the administrative procedures/requirements for cross-border healthcare set out in the national legislative/regulatory framework in each country, the national legal experts collected data through two main activities:
1. Desk research: under this activity, the national legal experts conducted research and completed the template for the data collection (Part 0 and Part 1). The research was primarily based on the legislative and regulatory sources governing the procedural aspects of cross-border healthcare in their respective countries. Secondly, the information gathered was supplemented by other complementary sources, such as

[6] HOPE - The European Hospital and Healthcare Federation; EURORDIS-Rare Diseases Europe; DKG - Deutsche Krankenhausgesellschaft (The German Hospital Federation); and AIM - Association Internationale de la Mutualité (International Association of mutual benefit societies).

[7] AIM was contacted following the suggestion provided by DG SANTE during a progress meeting held on 11 May 2021.

websites of the national social security bodies, insurance providers, National Contact Points (NCP), etc.;
2. Verification with national/regional bodies: under this activity, the national legal experts identified and contacted the relevant national/regional body in order to verify the accuracy and complement the data collected. Any feedback received was incorporated in the template for the data collection.[8]

In view of completing these activities, the template for the data collection presented three parts (Part 0, Part 1 and Part 2), each one respectively aimed at completing a specific step, as outlined here below:

> **Part 0: Preliminary assessment**: in this part the national legal experts identified: i) whether the rules establishing the administrative requirements for PA and reimbursement are set out at national level or at a decentralised/regional level; and ii) the most relevant body to be contacted for the verification of the data collected (e.g., national security body/insurance fund).
> **Part 1: Questionnaire:** in this part the national legal experts completed a detailed questionnaire, divided into the following two sections: **Section 1: Prior Authorisation (PA) procedures:** aimed at identifying and describing: i) the national rules and requirements concerning the procedures to request PA for cross-border healthcare under the Directive; ii) whether the national sources consulted provide a justification/purpose for the requirements identified. This part of the questionnaire was relevant only for countries which established a PA system under the Directive; **Section 2: Reimbursement:** aimed at identifying and describing: i) the national rules and requirements concerning the procedures to request reimbursement of cross-border healthcare costs under the Directive; ii) whether the requirements also apply domestically; and iii) whether the national sources consulted provide a justification/purpose for the requirements identified.
> **Part 2: Checklist for verification with national/regional body**: in this part national legal experts completed a checklist, with the aim of tracking whether the information contained in each question of Part 1 has been validated, verified and/or complemented during a verification call with the relevant body.

The output of the national data collection task is a set of 30 country reports, which are provided in Annex A.

It should be noted that in some countries (AT, CY, FR, LI, LU, PT) the verification of the data collected with the relevant national/regional bodies was not possible due to the lack of response or unavailability of the body contacted by the national legal experts. In four countries (BG, DK, ES, NL) the data collected were verified by more than one body in each country. An overview of the bodies contacted for each country, together with an indication of whether the data collected were verified or not during a verification call, is provided in Annex C.

[8] Please note that the data collected were also verified by national authorities (NCPs) in BE, DE, DK, EL, FI, HR, IE, IT, MT, NL, RO, on their own initiative, between 29 September 2021 and 8 October 2021 following the Workshop on Guiding Principles for Information Provision on prior-authorisation systems across Member States of 29 September 2021. The feedback received by Spark Legal Network from the national bodies was incorporated into the respective country reports (Annex A) and in the present report, where applicable.

3 Data collected at national level

This Chapter aims at providing an overview of the most pertinent data collected in the national country reports. This information is presented in three sections, as follows:

- **Section 3.1.** presents preliminary information concerning jurisdiction assessment (national/decentralised), implementation of PA systems and existence of domestic reimbursement procedures across the countries;
- **Section 3.2.** presents a summary of data collected with respect to PA procedures for cross-border healthcare under the Directive (Part 1, Section 1 of the national country reports);
- **Section 3.3.** presents a summary of data collected with respect to reimbursement procedures under the Directive (Part 1, Section 2 of the national country reports).

For a more in-depth overview on the information presented in this Chapter, please see Annexes D, E, F and G[9], where the most pertinent data collected in each country are presented in a comparative fashion. The data collected in the national country reports and summarised in this Chapter served as the basis for the assessment of the national administrative procedures against the requirements set out in Articles 7(7) and 9(1) of the Directive, the results of which are outlined in Chapter 4.

3.1. Preliminary information

3.1.1. Jurisdiction assessment

It should be noted that in the majority of countries the legislative and regulatory sources governing the administrative procedures for cross-border healthcare are enacted at national level. There are, however, some exceptions. In one country (ES), the rules governing the procedures are set out at decentralised level, as Autonomous Communities have competences to further regulate the procedures to request PA and reimbursement for cross-border healthcare costs. However, not all Autonomous Communities have exercised the delegated powers.[10] In another country (DK), the rules governing the administrative procedures for cross-border healthcare are enacted at national level, but they are practically implemented by five regional bodies instead.[11] Five countries (AT, BE, CZ, DE, FR) were found to have legislation enacted at national level, but also have a system of multiple social security institutions/health insurance funds in charge of handling the procedures and granting reimbursement, with some degree of autonomy in further defining these rules. Moreover, in Belgium, there are some differences between federal and regional level legislative competences. In particular, while the Federal Authority is generally competent for the reimbursement of healthcare services, the Regions have been provided with more

[9] Annex C: bodies contacted for the verification of the data collected; Annex D: bodies handling the procedures; Annex E: summarised overview of the data collected: PA procedures; and Annex F: summarised overview of the data collected: reimbursement procedures.

[10] For the purpose of the present study, Catalunya and Galicia were selected as examples: Catalunya is the second most populated region in the country and provides an example of a Community that did not further regulate the procedures at local revel (and in the absence of such regulation, the national legislation shall be held applicable); Galicia provides an example of a Community that did further regulate the procedures at local level. For this reason, the template for the data collection was completed (and the information collected was verified) twice, once for each respective Autonomous Community.

[11] The five regional bodies are the following: i) Søg forhåndsgodkendelse i Region Hovedstaden; ii) Søg forhåndsgodkendelse i Region Sjælland; iii) Søg forhåndsgodkendelse i Region Syddanmark; iv) Søg forhåndsgodkendelse i Region Midtjylland; v) Søg forhåndsgodkendelse i Region Nordjylland.

specific competences to regulate reimbursement for long-term revalidation care.[12] Lastly, in two countries (LI, NL), the procedures for cross-border healthcare do not appear to be regulated by national law, but are rather established by private insurance providers.[13] Moreover, national healthcare systems of these two countries do not seem to differentiate between healthcare service providers located domestically or abroad, but rather between contracted and non-contracted providers. Procedures and requirements, therefore, vary depending on the insurance provider. In the case of Liechtenstein, additionally, no information could be found on the effective implementation of a PA system, nor on how the reimbursement of cross-border healthcare costs is regulated.

3.1.2. Implementation of PA systems

It should be noted that most countries have implemented a PA system under the Directive, with solely 8 exceptions (CY[14], CZ, EE[15], FI, LT, LV, NO, SE). In one case (LI) it is not clear from the sources consulted whether a PA procedure has been implemented and whether it is mandatory. In one country (NL), although a PA system has not been officially implemented at national level, in practice each health insurance provider decides whether to implement a PA system or not.[16] Moreover, in one country (IE), a PA is optional, but nonetheless recommended for all inpatient healthcare abroad.[17] Finally, it should be noted that in certain countries not having a PA system, a voluntary prior notification system has been introduced (e.g., NO, SE).

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12 Please, note that only the Flemish Region and the German-speaking Region have enacted legislation on this matter. However, considering that the regional competences are very limited in scope, the national legislation can be considered as the relevant source. For more information, please consult the national country report for Belgium (Annex A).

13 Healthcare in the Netherlands is a free market system, based on multiple insurance providers with a high degree of discretion in setting out the rules applicable to their affiliates. On the basis of this, information with regards to the Netherlands have been gathered for two insurance providers, namely CZ and Menzis.

14 In Cyprus, the PA requirement under the Directive was recently removed (i.e., PA is currently not required by national legislation). Nonetheless, it should be noted that, at the time of the mapping of the data for WP1b, other sources (e.g., the website of the NCP in Cyprus) still seem to provide references to the PA requirement under the Directive.

15 In Estonia, although no PA system is implemented in practice, some rules on administrative requirements and procedures are set out in national legislation, should the PA be implemented in the future. Please note that Section 1 of Part 1 of the national report has been completed according to this legislation.

16 It should be reminded that the Dutch system does not differentiate systematically between cross-border and domestic healthcare, but rather between contracted and non-contracted healthcare.

17 The information contained in the PA application form indicates that PA is recommended "for inpatient care only - outpatient and daycase care do not require prior authorisation". The PA application form for Ireland is available at: https://www2.hse.ie/file-library/cross-border-directive/cbd-application-for-prior-authorisation.pdf. Moreover, the Irish NCP provided the following additional information to Spark Legal Network on 1/10/2021: "*Optional prior authorisation is designed to protect the patient as follows: 1) Gives the patient confidence he/she has followed public patient pathways and will be eligible for reimbursement (note: the care pathway that applies in Ireland, equally applies to any cross-border healthcare); 2) Requires the provider abroad to indicate the cost that will be charged and to identify the DRG so the patient also knows the reimbursement rate associated with that DRG; 3) Allows patients who have not followed public patient pathway to restart the process before they have committed large amounts of money for which they would not be eligible for reimbursement; 4) There is no obligation on the patient to use PA therefore no consequences concerning reimbursement entitlement. If the patient has not used PA, they are still entitled to reimbursement if they have followed the correct patient pathway. In Ireland patients must have a GP referral and a specialist consultation in person in order to be eligible for reimbursement. This is often not the case in other countries, so by using PA the patient can ensure he/she is entitled to reimbursement".*

3.1.3. Existence of domestic reimbursement procedures

As regards the reimbursement procedures, in the majority of countries (BG, CY, CZ, DK, EE, EL, ES, HR, HU, IE, IS, IT, LT, LV, MT, NO, PL, RO, SE, SI, SK), it has been noted that "*no reimbursement procedure applies domestically*". This means that patients receiving healthcare in the national territory do not have to ask to be reimbursed the costs of the service, as these are normally anticipated by the national healthcare system.[18] A minority of countries (AT, BE, DE, FI, FR, LI, LU, NL) was found to have a reimbursement procedure in place domestically.

3.2. PA procedures for cross-border healthcare

3.2.1. Entitlement to apply for PA and involvement of physicians in the PA application process

It should be noted that in all countries the patient (or the insured person) is entitled to file a request for PA. In Liechtenstein, it is not clear from the sources consulted whether a PA system has been implemented. For this reason, this country will not be considered in the information that will be provided in this Section. In five countries (BE[19], IE, IS, LU, PL), the assistance of a doctor is required to fill in a part of the application form. In one country (HU), the physician's intervention in the submission process is optional, meaning that both the patient and the doctor are entitled to complete and file the application form.[20] In turn, in the Netherlands, whether the assistance of a doctor is needed in the application process may depend on the insurance provider.[21] In addition, it seems that in six countries (AT, HR, HU, MT, RO[22], SI), the practitioner (who has to fill in the form and/or to provide a medical referral) should be a national/contracted doctor, whilst in two countries (BE, IT) the sources consulted were found to specify that the physician may be a practitioner from any EU/EEA country. In one country (IE), according to the information provided by the Irish NCP[23] "*Ireland accepts referrals submitted by a general practitioner (hereafter, "GP") in Ireland or abroad, but it is only a specialist doctor who knows the treatment he/she is going to provide who can assist the patient with the optional PA*". In all other countries, no specification on whether or not the doctor involved in the PA application process must be affiliated to the country where PA is requested was identified in the sources consulted.[24]

3.2.2. Application module

An overview of the availability of specific forms to be submitted for requesting PA under the Directive, and of the forms used for granting/issuing PA decisions, is provided in Annex E.

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18 See Part 1, Section 2, column 4 of the national country reports.

19 In Belgium, the doctor has to fill in the medical report which is a mandatory component of the PA application form. Based on the legislation, it is the responsibility of the patient to send the application together with the extensive medical report to the sickness fund to get PA (though, in practice, the specialised physician may also send the documentation directly to the sickness fund).

20 If the doctor proceeds to file the application, the patient's signature is mandatory. In addition, there is certain information that needs to be provided by the doctor.

21 The assistance of a doctor is necessary with the insurance provider CZ, but not with Menzis.

22 However, the national body consulted for the verification of the data collected indicated that, in practice, a referral from a doctor in any EU/EEA country is accepted.

23 This additional information was provided to Spark Legal Network by the Irish NCP on 1/10/2021. Moreover, the NCP noted that "In Ireland patients must have a GP referral and a specialist consultation in person in order to be eligible for reimbursement. This is often not the case in other countries, so by using PA the patient can ensure he/she is entitled to reimbursement".

24 More information on the involvement of the physicians in the PA application process is provided in Annex E, Section 4.

It should be noted that a majority of countries, where a PA system is implemented (BG, DK, EL, ES[25], HU, IE, IS, IT, LU, MT[26], PL, PT, SI, SK), has a specific form for PA application which is also available online. In three countries (IT, PL, SK), however, the template form for PA application is not available on the website of the national body in charge of handling the procedure, but it is contained directly in the relevant legislative/regulatory sources.[27] Hence, despite this not being the module directly accessible by the applicants online (i.e., in the case of Italy, the module still has to be requested from each local health unit), it is inferred that the bodies handling the procedure must adhere to the template forms for PA applications included in the respective legislative/regulatory framework. In other countries (AT or NL, for example), despite there not being a standardised application form, some indications on what type of information is to be included in the request were identified during the data collection tasks. Additionally, though the PA procedures in Belgium vary depending on the insurance providers, the funds have agreed to use a standardised template for the extensive medical report which needs to be filled in by the doctors and attached to the application request. Lastly, it should be underlined that in Bulgaria, forms for PA application are available for the procedures with two competent bodies, namely the National Health Insurance Fund (NHIF) and the Ministry of Health, with the exception of the PA procedure for transplantations, for which a specific application form is not used.[28]

3.2.3. Information to be included in the application module/attachments

With regard to the information to be included in the specific form or in the request, it should be noted that, in the majority of countries, the provision of general information is required for the identification of: (a) the patient, (b) the type of healthcare requested, (c) the foreign healthcare provider and (d) the reasons for the request. With regard to the documents required to accompany the PA application, in the majority of countries, applicants are required to submit medical documentation aimed at providing information on the patient's entitlement to and/or need of the particular healthcare, and/or on the state of health of the patient and his/her medical history.

In some countries, certain additional information or documentation is required to substantiate the request. In four countries (BE, EL, HU, IE), information on whether the healthcare for which PA is sought is available in the national territory must be

[25] This is the case for both Catalunya and Galicia.

[26] Please note that at the time of the data collection task, the link to the PA application form on the national authority's website redirected to an incorrect form (i.e., the specific module for the reimbursement request). The specific form for PA application was ultimately not identified during the national research conducted by the national legal expert. However, on 7/10/2021 the Maltese NCP informed Spark Legal Network that the mistaken link on the website has been corrected, and the form is therefore currently available online.

[27] In particular, in Italy, it is not properly contained in the legislation, but is annexed to the Guidelines on Cross-border Healthcare of 2017.

[28] In Bulgaria PA application procedures are handled by the National Health Insurance Fund (NHIF), with the exception of PA requests for specific types of healthcare (i.e., concerning assisted reproduction and transplantations), which are handled by the Ministry of Health. For more information see Annex A, national country report for Bulgaria, Part 1, Section 1.

provided.[29] Furthermore, in six countries (ES[30], IE, HR[31], PL, PT[32], SI), information on whether the patient is on a waiting list for some treatments, or the indication of the date of the scheduled treatment in the country of affiliation may be required. Amongst these, in one country (IE) the provision of this information with the application is an alternative requirement to the submission of a referral from a GP (from Ireland or abroad). Additionally, in one country (IS), information on whether there is comparable treatment available in that country and the length of the waiting time for the comparable treatment should be provided (whilst the indication on whether a patient is on a waiting list appears to be optional and not mandatory). In other countries (e.g., DK[33],FR, HR, LU), information on the dates of the planned treatment abroad also seems to be requested.

In three countries (BG[34], RO, SK), patients have to submit, together with the application, documentation issued directly by the foreign healthcare establishment providing information or confirming the availability to provide the service requested. In one country (PT), it is specified that the patient is required to consult a national hospital in order to obtain a so-called 'Hospital Clinical Assessment Report' to attach to the PA request, to assess the need of the treatment and surgical adequacy. In another country (EL), the patient needs to obtain documentation from at least two national hospitals certifying that the healthcare service cannot be provided in that country within a medically acceptable period. Moreover, it should be recalled that Ireland has an optional PA system.[35] If PA is requested, however, very extensive information has to be provided by the applicant, and in some instances proof of travel abroad and the certified translation is also required. Furthermore, it appears that the translation of the accompanying documentation is required in five countries (BG, IE[36], NL[37], PL, PT).

Finally, it should be noted that with regard to the means of submission of the applications for PA, in twelve countries (DK, EL, ES[38], HR[39], IE, IS, IT, LU, PL, PT, SI, SK) electronic submission of the request appears possible via email or other digital paths. Amongst these, for instance, one country (IT) allows electronic submission via

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29 Moreover, in the Netherlands, scientific proof of standards of the treatment might be requested for treatments not known domestically. In Luxembourg, indication/reasons why the treatment proves to be impossible or inadequate in Luxemburg or that it cannot be provided within a time limit should be provided 'where applicable'.

30 This was found to be the case in Catalunya, but not in Galicia. However, it appears that being on a waiting list is not a mandatory requirement, in the sense that it should solely be indicated 'whether or not' the patient is on a waiting list.

31 In Croatia, information is also to be provided on the dates available for the appointment or the possible date of admittance by the healthcare provider in another Member State.

32 In Portugal, this requirement only applies to surgery.

33 In Denmark, the price of the treatment abroad should also be indicated.

34 This is the case for the procedure with the NHIF only applicable to medical devices.

35 More information on whether patients must undergo additional steps and/or consultations also in view of obtaining additional documentation is provided in Annex E, Section 3 and Section 4.

36 In Ireland, the translation shall be certified. However, the Irish NCP communicated to Spark Legal Network on 1/10/2021 that "*It should further be noted that certified translations have only ever been requested where the documentation is such that it cannot easily be understood or is so voluminous that tools like Google Translate are not appropriate. The occasions where certified translations have been requested do not total any more than approximately 10 since 2014*".

37 This is the case for both CZ and Menzis.

38 This is the case for both Catalunya and Galicia.

39 This was confirmed by the Croatian NCP.

so-called certified email.[40] In two countries (NL, DE), this may vary depending on the health insurance providers.[41] In Malta, it is not clear from the sources consulted whether electronic submission is possible or not.

3.2.4. Costs associated with the handling of the applications

No direct costs for handling PA applications were identified across the countries. Conversely, in some countries (e.g., BE, FR, IS, IT, NL, PT, SI, SK) there might be indirect costs related to the submission of applications via post, depending on the modality of the submission, or for the initial consultation with a doctor. Translation costs were found to be relevant in six countries (BG, IE, NL[42], PL, PT, SI). In two of them (IE[43], PT), the costs seem to relate to the need of a certified translation; in five countries (BG, IE, PL, PT, SI), the translation requirement appeared to be mandatory, with the only exception of the Netherlands, where it is not required by law, but in practice, it may be asked by the health insurance provider. Finally, in Slovenia, potential indirect costs for the professional support by a lawyer or by other experts may be identified.

3.2.5. Time requirements for PA procedures

In relation to the time limits for the applicant to file a PA request, in one country (FR), PA requests must be submitted at least 14 days before departure. It should be noted that this time limit is equivalent to that set out for the responsible body in France to take a decision on the PA request. In all other countries, no specific time limits for applicants were identified. However, where specific time limits for the bodies to take a decision on the PA request exist, these should be considered by the applicant to allow enough time for the body to process the application before the planned treatment abroad. Regarding the time limits for the bodies to take a decision on the PA applications, it was found that in eleven countries (AT, DE, DK, FR, IE, LU, NL, PL, PT[44], RO[45], SK) a decision has to be taken in less than three weeks; in eight countries (BE, BG, EL, ES, HR, HU, MT, SI)[46], national authorities have between four weeks, up to a maximum of six months in Bulgaria.[47] Only in one country (IS), no specific time limit has been identified. As regards the consequences that could apply, if the deadlines are not respected, in the majority of countries (AT, BG, DK, EL, HR, HU, IE, IS, IT, LU, MT, NL[48], PT, RO, SK)[49], no specific direct consequences were found (besides the general right of the applicant to challenge the decision). In three

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40 Known as 'Posta Elettronica Certificata' in Italian (or PEC in short), certified email provides a legal equivalent of the traditional registered mail: by paying a small fee, users are able to legally prove that a given email has been sent and received.

41 As for the Netherlands, this is evident from the examples provided in Section 6 of Annex E.

42 This is the case for both CZ and Menzis.

43 However, the Irish NCP communicated to Spark Legal Network on 1/10/2021 that "It should further be noted that certified translations have only ever been requested where the documentation is such that it cannot easily be understood or is so voluminous that tools like Google Translate are not appropriate. The occasions where certified translations have been requested do not total any more than approximately 10 since 2014".

44 The time limit is set as of the completion of the investigation in the case (including obtaining the necessary medical opinions).

45 The time limit is set as of the registration of the request.

46 Please note that this would be the case in Estonia as well, if a PA system were introduced.

47 The six-month period applies only for the procedure with the Ministry of Health.

48 No consequences were found as for the procedure with CZ, while some consequences were found for the procedure with Menzis. For more information, please see Section 6 of Annex E.

49 Please note that this would be the case in Estonia as well, if a PA system was introduced.

countries (BE, ES[50], FR), if the authority does not respect the deadline, the applicant's request is assumed to be accepted and PA is considered to be granted. The same applies in Germany, if the health insurance provider does not provide reasons for not respecting the deadline. Lastly, in Poland, if the decision is not taken within the time limit, the patient does not lose the right to be reimbursed if the treatment abroad was received without PA for a matter of urgency.

3.2.6. Differences in the procedural/administrative requirements for requesting PA based on patient-related or treatment-related criteria

It should be noted that in the majority of countries (AT, DK, ES[51], FR, HR, HU, IE, IS, LU, MT, PL, PT, SI), no differences in the procedural and administrative requirements for PA requests based on patient-related or treatment-related criteria were found. In four countries (EL, NL, RO, SK), additional information may be requested (or the documentation may vary) depending on the treatment for which PA is sought. In Slovakia, for example, for procedures like transplantations, the decision of the apposite commission of the transplant centre shall be added to the application and, additionally, for scheduled healthcare connected with an accident at work or an occupational disease, the medical report of the accident or of the disease should also be submitted. In two countries (BE, BG), differences were found in the procedures. In Belgium, procedural differences are due to the competence of the Regions to regulate a particular type of healthcare, while Bulgaria has two different procedures depending on which body is in charge of handling the applications.[52] In Germany, it was noted that differences in the PA procedures may potentially exist depending on the type of health insurance provider/fund, as the national law does not provide for specific compulsory requirements for requesting PA. Moreover, in two countries (IT, EL), if a patient has a rare disease, a clinical evaluation may be performed, or an expert may be involved, should it be requested by the competent body. For this reason, time requirements are extended accordingly.[53]

3.3. Reimbursement procedures

3.3.1. Application module

An overview of the availability of specific forms to be submitted for requesting reimbursement under the Directive is provided in Annex F.

It should be noted that a majority of countries (BG, CY, DK, EE, EL, ES[54], FI, FR, IS, IT, LT, LV, MT, NL[55], NO, PL, PT, SE, SI, SK) have a specific form for reimbursement and in all of them, the form is available online. In three countries (IT, PL, SK), however, the template form is not always available on the website of the national

[50] This was found to be applicable both in Catalunya and in Galicia, the two examples considered for the purpose of the present study.

[51] This was found to be applicable both in Catalunya and in Galicia, the two examples considered for the purpose of the present study.

[52] As mentioned previously in Section 3.2.2, Bulgaria has two bodies in charge of the PA and reimbursement applications, the NHIF and the Ministry of Health. The NHIF covers applications concerning medical devices or certain types of treatments, while the Ministry of Health deals with assisted reproduction activities and transplantations. There are differences concerning the information and the documentation to be provided in the application, as outlined in Section 3 of Annex E, but it should be noted that the main difference is that for transplantations, there is no specific PA application form and the request can be submitted in free form.

[53] Differences in the time requirements related to the specific health situation of the patient, the specific circumstances or the urgency of the case, could be found in Estonia as well, if a PA system were introduced.

[54] This is the case for both Catalunya and Galicia.

[55] This is the case for both CZ and Menzis.

body in charge of handling the procedure, but it is contained directly in the relevant legislative/regulatory sources.[56] Hence, despite this not being the module to be directly accessible by the applicants online, it is inferred that the bodies handling the procedure must adhere to the templates included in the respective legislative/regulatory framework. In Bulgaria, a form is available for procedures handled by the National Health Insurance Fund (NHIF), but not for those handled by the Ministry of Health, where the request for reimbursement can be submitted in a free form. Some indications regarding which information should be contained in the reimbursement request are provided in the national legislation. In four countries (AT, BE, DE[57], NL[58]), the specific form has to be requested from the health insurance providers and there could be differences concerning the information required or the documentation to be attached.

Two countries (AT, IE) have only an optional request form for reimbursement. In Austria, in particular, forms are supporting and are different depending on the healthcare service requested to be reimbursed, while in Ireland, a template for the so-called "Pro-Forma Invoice" is available, but its submission is not mandatory.[59] In Belgium, some insurance providers have the form available online, others do not. Lastly, in Liechtenstein, it is not clear from the sources consulted which are the rules applicable to reimbursement procedures. For this reason, this country will not be considered in the information that will be provided in this Section.

3.3.2. Information to be included in the application module/attachments

With regards to the information to be included in the specific form or in the request, it should be noted that the majority of countries requires the provision of general information for the identification of (a) the patient; (b) the type and the description of the treatment received; (c) the foreign healthcare provider; (d) the costs of the treatment or the expenses incurred by the patient; and (e) the bank details for the reimbursement. In some countries (BG, CY, LU), an additional confirmation (normally from the bank) that the bank details are correct is demanded. Hungary does not regulate which information patients need to provide in order to apply for reimbursement, but it requires an evaluation of a physician of the effectiveness of the treatment to be attached to the reimbursement request and gives an indication on the information to be provided by the treating doctor in that evaluation. With regard to the documents required to accompany the application, it should be noted that in the majority of countries (BG[60], CY, CZ, EL, ES, FI, HR, IS, IT, LU, MT, SE, SI, SK), medical documentation or medical reports providing information on the healthcare service received abroad are normally required to substantiate the reimbursement request. The previous referral or the prescription of the treating doctor is also required

[56] In particular, in Italy, it is not properly contained in the legislation, but is annexed to the Guidelines on Cross-border Healthcare of 2017.

[57] An example of what type of information and documentation is required is provided in the national report, namely information from the Verband der Ersatzkassen e.V. (vdek) (Association of Substitute Funds e.V.). For more information, see Section 2 of Annex F.

[58] Two examples of reimbursement form have been provided in the national report, namely information from CZ and Menzis. For both health insurance providers, a specific reimbursement form was found.

[59] Please note that, however, the module contains the minimum data set necessary for processing the reimbursement request. The national report has therefore been filled in with the information gathered from this module.

[60] This is the case for both procedures handled by the NHIF and the Ministry of Health.

in some countries (BG[61], CY, DK[62], EE, IE[63], IT, LT, LV, MT, NL[64], NO, PL, SI). In addition, a vast majority of countries (BG, CY, CZ, DE[65], DK, EE, EL, ES, FR, IE, IS, LT, LV, LU, MT, NL[66], NO, PL, SI, SK) also require the originals of the payment documents or of the invoices. Furthermore, two countries (ES[67], PT) also require the submission of the previously obtained PA for those treatments where it should have been requested, and another two countries (IE[68], IS) demand the proof of travel. In four countries (EL, IS, IT, PT), the translation of the documents should be attached to the reimbursement request. Additionally, Greece requires all the documentation to be legally issued and certified by the respective Greek Consulate. Norway, on the other hand, demands a copy of the treatment provider's licence to practice or the specialist authorisation from the country of treatment.[69] Furthermore, it appears that the translation of the accompanying documentation is required in seventeen countries (AT, BG, CZ, DE, EE, IS, EL, ES[70], IE, IS, IT, LV, NL[71], NO, PL, PT, SI). Among these, in seven of them (AT, IE, EL, IT, LV, NO, PT), an official or certified translation may be needed.

Finally, it should be noted with regard to the means of submission of the reimbursement applications, in eighteen countries (AT, CY, CZ, DK, EL, ES[72], HR[73], IE, IS, IT, LV, MT[74], NL[75], NO, PL, PT, SE, SI, SK), the electronic submission of the request for reimbursement appears possible. Among these, for instance, in one country (IT), the electronic submission is possible only via so-called certified email ('PEC' in Italian).

3.3.3. Costs associated with the handling of the procedures

No direct costs for handling reimbursement procedures were identified across the countries. However, in some countries (BE, CY, CZ, EE, FI, FR, NL[76], PT, SI, SK), potential indirect costs related to the submission of the requests via post were identified. Translation costs were found to be relevant in a majority of countries (AT, BG, CZ, DE, EE, EL, ES[77], IE, IS, IT, LV, MT, NL[78], NO, PL, PT, SI). Among these, in four countries (IE, EL, NO[79], PT), an official or certified translation may be needed, while in three countries (AT, IT, LV), the translation of the documentation is a legal administrative requirement, but in practice it seems to be not requested for cross-

61 This is the case only for the procedures handled by the NHIF.
62 Please note that in Denmark the doctor referral only has to be submitted for reimbursement of costs of treatments which required PA, but for which PA was not requested (information provided to Spark Legal Network by the Danish coordinating NCP on 8 October 2021).
63 Please note that the reimbursement form in Ireland is optional.
64 This is the case for both CZ and Menzis.
65 According to the information provided on the website of the "Verband der Ersatzkassen e.V. (vdek) (Association of Substitute Funds e.V).
66 This is the case for both CZ and Menzis.
67 This is the case for both Catalunya and Galicia.
68 Please note that the reimbursement form in Ireland is optional.
69 This applies only for non-hospital healthcare services. For more information, see Section 2 of Annex F.
70 This is the case only for Galicia.
71 This applies to both CZ and Menzis.
72 This applies only to Catalunya.
73 This was confirmed by the Croatian NCP.
74 Information provided by the Maltese NCP to Spark Legal Network on 7/10/2021.
75 This is the case for both CZ and Menzis.
76 This applies to both CZ and Menzis.
77 This is the case only for Galicia.
78 This applies to both CZ and Menzis.
79 Please note that, however, as indicated by the National authority, this requirement is often not imposed. For more information, see Section 3 of Annex F.

border healthcare. In Greece, additional indirect costs relate to the certification by the respective Greek Consulate.

3.3.4. Time requirements for reimbursement procedures

In relation to the time limits for the applicant to submit a reimbursement request, specific time limits have been identified in a vast majority of countries (AT, BE, BG[80], DK, EL, ES[81], FI, FR, HR, HU, IT, LT, LV, LU, NL[82], NO, PL, PT, SK). In eleven countries (BG[83], EL, ES[84], FI, HU, IT, LT, LV, PL, PT, SK), applicants need to submit the request within a period of less than/equal to 1 year after the treatment has been received. Among these, for instance, Hungary and Portugal have a time limit of 30 days. In three countries (BE, FR, LU) applicants have up to two years to submit the request; in another three countries (DK, HR, NL[85]) applicants have up to three years, and in one country (BG), the request is possible up to 5 years after the cross-border healthcare has been provided. In relation to the time limits for the reimbursement decisions to be taken, once again specific limits are set in a vast majority of countries (CY, CZ, DE, EE, EL, ES[86], HR, IE, IT, NL[87], NO, PL, PT, RO, SI, SK). In seven countries (CZ, DE, HR, IE, NL[88], PL[89], RO), national authorities are required to take a decision within a period of less than/equal to 1 month from the receipt of the requests. In nine countries (CY, EE, EL, ES IT, NO, PT, SE, SI), requests need to be handled within a time frame of 3 months. In Slovakia, the limit is 6 months from the receipt of the request. In one country (MT) though the law does not provide a time frame for reimbursement, the Maltese NCP indicated that reimbursement requests are dealt with between a 6-to-12-month period.[90] As regards the consequences that could apply if the deadlines to submit a request are not respected by the applicants, generally the entitlement to the reimbursement is no longer valid.[91] With regard to the consequences if the deadlines of the authorities are not respected, in a vast majority of countries (AT, BE, BG, CY, DK, EE, FI, FR, HR, IE, IS, IT, LT, LV, LU, MT, NL[92], NO, RO, SE, SI, SK), no specific consequences have been identified. Generally, complaints may be filed.. Only in three countries (DE, ES, PL)[93], a system of "silent consent" was found.

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80 This is the case for both procedures with the NHIF and the Ministry of Health.
81 This is the case for both Catalunya and Galicia.
82 This is the case for both CZ and Menzis.
83 This is the case only for the procedure with the Ministry of Health.
84 This is the case for both Catalunya and Galicia.
85 This is the case for both CZ and Menzis.
86 This is the case for both Catalunya and Galicia.
87 This is the case for both CZ and Menzis.
88 This is the case for both CZ and Menzis. For the specific time limits, please see Section 4 of Annex F.
89 Please note that in Poland there is a time limit of 30 days for the standard procedure; 60 days apply instead where the examination of the application for reimbursement requires an explanatory procedure; 6 months where the examination of the application for reimbursement requires an explanatory procedure with the participation of a foreign NCP. For more information, please see Section 4 of Annex F.
90 Information provided to Spark Legal Network by the Maltese NCP on 7/10/2021.
91 In Hungary, the patient loses his right to receive reimbursement only if he/she does not provide a reasonable justification.
92 This is the case for both CZ and Menzis.
93 In Germany, the health insurance provider has to inform the applicant and to provide explanations for not respecting the deadline. If no reasons are provided, the request shall be considered approved. In Spain, if a deadline elapses without an express decision, the request is considered as accepted (this is the case for both Catalunya and Galicia). In Poland, if no arrangement is made by the national authority, the costs will be reimbursed immediately after the expiry of the deadline. For the specific time limits, please see Section 4 of Annex F.

3.3.5. Non-reimbursable thresholds

Non-reimbursable thresholds have been identified in five countries (AT, CY, FI, NL, IE).[94] In Austria, for example, for cross-border healthcare not subject to PA, patients will receive only a care cost allowance or a reimbursement of 80% of the tariff that insurance institutions would reimburse for domestic contracted care (the same thresholds seem to apply domestically when patients seek non-contracted care). A similar situation was identified in the Netherlands[95]. In Cyprus, some specific types of healthcare services are non-reimbursable. In Finland, there are thresholds for the reimbursement of medicines and some limitations to the reimbursement of dental services; travel costs are reimbursed, but only as if the trip would have been made to the closest healthcare establishment available for the treatment. Additionally, thresholds apply for all treatments received abroad, whether in a private or public establishment: the costs are reimbursed up to the amount as if the treatment had been provided in a private establishment in Finland.[96] Also in Ireland, there are non-reimbursable thresholds for treatments abroad and, in particular, for outpatient consultation in hospitals, for inpatient care and for orthodontic treatments.[97]

3.3.6. Simplified procedures[98]

It should be noted that in seventeen countries (AT, BE, CY, DE, DK, ES[99], FR, HR, HU, IE, IS, LU, MT, PL, PT, RO, SK), no specific simplified reimbursement procedures were found in cases where PA was previously granted. In three countries (IT, NL[100], SI), it was found that patients do not need to resubmit the referrals from the treating doctor when applying for reimbursement. Also, in two countries (BG, DK) patients are required to submit less documentation in case a PA was granted previously.[101] Though not specifically identified during the data collection tasks, this may be the case in practice in more countries.

3.3.7. Differences in the procedural/administrative requirements for reimbursement based on patient-related or treatment-related criteria

It should be noted that in a vast majority of countries (CY, CZ, FR, HR, IE, IS, IT, LV, LU, MT, NO, PL, PT, RO, SE, SI, SK), no differences in the procedural requirements for reimbursement, based on patient-related or treatment-related criteria, have been identified. In Belgium and Spain, differences can be found among regions, on the basis of their competences. Differences based on patient-related criteria have been

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94 For more information on non-reimbursable thresholds, see Section 5 of Annex F. In the case of the Netherlands, the existence of such thresholds was not identified by the national legal expert during the desk research phase, but nonetheless emerged via further research concerning infringement proceedings currently being carried out by the European Commission against the Netherlands. Further information on the infringement proceedings against Austria, Finland and the Netherlands is provided in Chapter 4.

95 INFR(2018)2328; MEMO-19-462 available at: https://ec.europa.eu/commission/presscorner/detail/EN/MEMO_19_462.

96 For more information, see Section 5 of Annex F.

97 For more information on the specific thresholds, see Section 5 of Annex F.

98 Simplified reimbursement procedures are not required by the Directive itself. The term 'simplified procedure' in the context of the present report refers to administrative procedures according to which, in cases when PA had been requested and previously obtained by the applicant, less documents and/or information has to be submitted to request and obtain reimbursement of the costs of the cross-border healthcare for which PA had been granted (i.e., due to the fact that, for instance, the body handling the application had already been provided with certain information for the purposes of issuing the PA).

99 This is the case for both Catalunya and Galicia.

100 For both CZ and Menzis, there is no need to submit again the documentation required for the PA (normally, referrals and treating plans).

101 This is the case for both procedures with the NHIF and the Ministry of Health. For more information, see Part 1 Section 2 of the national country report.

identified in Greece, where patients with disabilities can submit additional documents for the reimbursement of extra costs. Differences based on treatment-related criteria can be found in ten countries (AT, BG[102], DE, DK, EE, FI, HU, LT, NL, NO). In one country (HU), further documentation is required for those treatments that are not subject to PA, and for the reimbursement of medicinal products and medical devices. In another country (DK) additional documentation is required for reimbursement of costs of healthcare which would have required PA, but for which PA was not sought.[103] In two countries (FI, NO), patients shall provide further specifications in case of dentist visits, but those requirements also apply domestically, therefore, even if relevant, they are not specific to cross-border healthcare.

[102] Differences in the procedures have been identified between the treatments handled by the NHIF and those handled by the Ministry of Health. For more information, see Part 1 Section 2 of the national country report.

[103] Information provided to Spark Legal Network by the Danish coordinating NCP on 8/10/2021.

4 Assessment of the administrative procedures against the requirements of the Directive

The data collected at national level were analysed in view of identifying whether any of the administrative procedures/requirements for cross-border healthcare may be regarded as a potentially unjustified barrier to patients in light of Articles 7(7) and 9(1) of the Directive. In particular, those procedures/requirements which, on the basis of this assessment, appeared to be potentially discriminatory/based on discriminatory criteria, or unnecessary and disproportionate to the objective to be achieved, or potentially unjustified obstacles to the free movement of patients, services or goods, are outlined in this Chapter. Moreover, when assessing the data collected with regard to non-reimbursable thresholds for cross-border healthcare across the countries, the requirements of Article 7(4) of the Directive have also been considered.

With specific regards to reimbursement, it should be noted that the identification of potentially discriminatory requirements was carried out in light of Article 7(7), according to which Member States may apply the same administrative formalities as they would apply should the treatment be provided domestically. Moreover, where potential obstacles were identified, it was also considered whether they could be deemed objectively justified against the grounds provided by the same provision of the Directive.[104] For the identification of potential issues with regard to the administrative procedures, other factors were also taken into consideration. For instance, where only a few countries were found to impose certain additional requirements compared to others for the attainment of the same objective, further assessment of the necessity and proportionality of the former more burdensome requirements may be required. Moreover, administrative procedures/requirements which had already been regarded as barriers to patients in previous Commission reports on the topic of cross-border healthcare[105] have also been used as examples/benchmarks/indicators for this analysis. Where available, any justification or purpose for the identified burdensome requirements has also been considered.

4.1 Assessment of the procedural requirements for PA against the Directive

The analysis of the data collected at national level with regard to the administrative requirements concerning PA procedures across the countries has led to the identification of some potential issues in light of the requirements of the Directive.

Preliminary findings

It should be noted that with regard to one country **(LI)** no information on the administrative requirements for PA was available. Therefore, the detailed assessment against the requirements of the Directive was not possible for this country, though a potential lack of transparent information for patients may be pointed out as an issue. Moreover, it should be noted that in other countries where several insurance providers

[104] According to Article 7(7) of the Directive, such justification grounds may be "planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State/EEA EFTA country concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources".

[105] For instance, certified translations, excessive minimum thresholds, the requirement of a certificate from the foreign National Contact Point attesting that the healthcare to be provided within its territory would be compliant with the necessary safety and quality standards in place, have been identified as potentially disproportionate barriers in the Report from the Commission on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare (COM(2018) 651 final).

have a certain degree of autonomy in defining their own procedures (AT, BE, DE, FR, NL), the current assessment is not extensive, as the analysis has been conducted on the basis of the available data (e.g., in the case of the Netherlands, it is based on a sample of procedures set out by two insurance providers in that country).

In one country **(IE),** though PA is not mandatory, it is however recommended for patients.[106]

In particular, according to the Irish NCP [107], the "*Optional prior authorisation is designed to protect the patient as follows: 1) [It] gives the patient confidence he/she has followed public patient pathways and will be eligible for reimbursement; 2) [it] requires the provider abroad to indicate the cost that will be charged and identify the DRG so the patient also knows the reimbursement rate associated with that DRG; 3) [it] allows patients who have not followed [the] public patient pathway to restart the process before they have committed large amounts of money for which they would not be eligible for reimbursement; 4) there is no obligation on the patient to use PA, therefore no consequences concerning reimbursement entitlement. If patients have not used PA, they are still entitled to reimbursement if they have followed the correct patient pathway. In Ireland patients must have a GP referral and a specialist consultation in person in order to be eligible for reimbursement. This is often not the case in other countries, so by using PA the patient can ensure he/she is entitled to reimbursement".* Moreover, it was also noted that "*the care pathway that applies in Ireland, equally applies to any cross-border healthcare*". Nonetheless, further assessment would be appropriate on whether such an optional but nonetheless recommended system of PA is based on the objectives, for which PA or prior notification systems may be introduced under the Directive, and/or may generate uncertainty for patients with regard to the extent of their obligations, as well as on the necessity of the extensive information that applicants need to provide should they decide to apply for PA[108] (some of which may be more difficult for patients to obtain from foreign healthcare providers, compared to domestic providers).

In another country **(NL),** it was found that though a PA system has not officially been implemented at national level, each insurance provider has autonomy in deciding whether and under what conditions PA may be required.[109] On the one hand, this may generate uncertainty for patients and may potentially be considered as leading to discrimination between patients affiliated to different insurance providers within the same country. However, on the other hand, despite being potentially different across insurance funds, the PA procedures also seem to apply to domestic treatments, under the same conditions. This is due to the fact that in this country, the determination of whether PA is necessary does not depend on whether the healthcare for which PA is requested is provided domestically or abroad, but rather on whether the healthcare provider (in the country or abroad) is a contracted or non-contracted party, although it might be argued that foreign healthcare providers will more likely be non-contracted parties than national healthcare providers.

Finally, in one country **(CY)** though a PA system had been implemented in the past, PA is no longer required by national legislation for cross-border healthcare under the

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106 For more information, see Annex E, Section 3 and the national country report for Ireland, Part 1, Section 1.
107 This additional information was provided to Spark Legal Network by the Irish NCP on 1/10/2021.
108 For more information, please consult the national country report for Ireland (Annex A).
109 For more information, see, and the national country report for the Netherlands, Part 0.

Directive. However, certain sources other than national legislation (e.g., the website of the NCP for Cyprus) were found to still contain information concerning the fact that patients need to obtain PA in certain instances to obtain reimbursement of costs under the Directive. The publication of inconsistent information may generate uncertainty for patients on the extent of their obligations and the requirements they need to fulfil in order to access and obtain reimbursement for cross-border healthcare under the Directive.

Application module

The choice of certain countries to not provide a specific template form for PA applications and/or to not make such module available online,[110] does not appear to represent a self-standing compliance issue (i.e., the use of a standardised template is not required under the Directive, which only mandates that information for patients should be known in advance).[111] In this context, for instance, one of the national bodies contacted for the verification of the data collected **(RO)** specifically indicated that a standard form was deliberately not implemented, in consideration of the fact that "*It would have been more burdensome for patients to have to fill in a standard application form, as each patient has different justifying documents depending on the country where the documents were issued, and it would have been impossible to include all possible types of justifying documentation in a single form. What is important is for the patient to submit with its application all justifying documents it has in its possession*".[112]

It should however be noted that, in the same country **(RO)**, despite a specific form not being mandatory at national level, the regional bodies in charge of handling the procedures have (and in certain cases have made use of) the discretion to publish a template form.[113] In such cases, the national body contacted for the verification of the data collected has indicated that the forms available online do not always appear to be up-to-date, and therefore are not in line with the currently applicable legislative requirements. The publication of incorrect information may therefore be regarded as being a potential obstacle for patients seeking cross-border healthcare, for which corrective action should be considered in order to eliminate the ambiguity concerning the necessary procedural requirements.

With regard to the means by which it is possible to submit a PA application, no specific compliance issue was identified (i.e., electronic submission is not required under the Directive). It should nonetheless be noted that in countries where electronic submission is possible, the procedures appear less burdensome for patients (e.g., in terms of time, postage costs, etc.), compared to countries not providing digital means of submission of PA requests.[114]

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110 For more information, see Annex E, Section 3.

111 According to Recital 37 of the Directive "is thus appropriate to require that these general conditions, criteria and formalities should be applied in an objective, transparent and non-discriminatory way and should be known in advance, based primarily on medical considerations, and that they should not impose any additional burden on patients seeking healthcare in another Member State in comparison with patients being treated in their Member State of affiliation, and that decisions should be made as quickly as possible". More information on the application modules across the countries is provided in Annex E, Section 1.

112 For more information, see Part 1, Section 1, Question 5 of the national country report.

113 For more information, see Annex E, Section 3.

114 In some countries (e.g., AT, BE, BG, FR, HU, RO) the digital submission of a PA request does not seem possible. In Spain, electronic submission is not possible in Galicia. In some countries (e.g., DE, NL) whether or not the applications for PA can be submitted electronically varies depending on the different insurance providers. In other countries, electronic submission is possible only if the applicant has a

Information to be included in the module/application and documents required to substantiate a PA request

With regard to the information which must be included in a PA request, and the documentation which is needed to substantiate such request, it should be noted that though differences were identified across the countries, the requirements in the majority of the cases appear to be in line with the Directive, as they are aimed at determining the individual patient's entitlement to healthcare, and providing the bodies with the necessary data on the patient, the type of treatment for which PA is requested, etc. Such information appears necessary and proportionate in order to allow the bodies handling the procedures to make a decision on the case based on the Directive's criteria.[115]

However, in certain instances, specific requirements have been identified which may potentially be regarded as going beyond what may be strictly necessary and proportionate towards the aforementioned aim, also in consideration of the fact that they do not seem to be required for the same purpose in a majority of countries. Specifically:

In three countries **(BG, RO, SK)**, patients have to submit, together with the application, documentation issued directly by the foreign healthcare provider, either confirming information on the healthcare to be received abroad, or on the healthcare provider and/or its availability to provide the requested service.[116] It should be noted that these types of requirements had been identified as a potential barrier according to the Commission's Report on the operation of Directive 2011/24/EU of 2018 (COM(2018) 651 final). Though it is mentioned in this report that such requirements had been lifted in the respective countries, nonetheless the data collected at national level have led to the following findings:

- In **Bulgaria**, additional official documentation from the healthcare provider abroad seems to be requested when the PA concerns medical devices (i.e., an official document from the medical establishment abroad, indicating the type and price of the medical device, and technical specification, if possible, and information from the medical establishment abroad regarding: (a) the presence or absence of a label on the medical device; and (b) the possibility to provide a label of the medical device). Though it may be inferred that the latter requirements could be aimed at collecting proof on the safety of the medical devices for the use of which PA is requested, however, no such indication (i.e., no confirmation or indication of the specific justification/purpose for these requirements) was identified in the sources consulted. Therefore, further assessment on the necessity and proportionality of these requirements may be considered;
- Furthermore, in **Romania,** the modules published online by certain regional healthcare bodies require the submission of the following documents: i) Written confirmation from the medical assistance provider abroad of its availability to provide the service in the period indicated by the applicant; ii) Documents issued by the foreign NCP showing that the medical assistance provider does not give rise to serious and specific concerns relating to the observance of the standards and guidelines regarding the quality of medical assistance and safety of patients,

qualified electronic signature (e.g., PL), or has access to certified email (e.g., the so-called 'PEC' in Italy).

115 More information on the required information and documents across the countries is provided in Annex E, Sections 3 and 4.

116 For more information, see Annex E, Section 3 and the national country reports, Part 1, Section 1.

including provisions regarding supervision. It should be noted that (as confirmed by the national authority) this documentation is not required under the national legislative framework, and the templates available online are not up-to-date. Although, officially, such documentation is not required anymore, however, the fact that the online documentation is not up-to-date may still, in practice, generate an unjustified obstacle for patients who may wrongly believe that additional requirements are needed, and therefore could lead to patients abstaining from requesting PA;

- Similarly, in **Slovakia**, the submission of the following documents prepared by foreign healthcare providers appear mandatory: i) calculation of expected costs for the planned healthcare abroad prepared by the foreign healthcare provider which will provide healthcare; ii) confirmation of possible admission by the foreign healthcare provider after a positive decision of the health insurance company. Also in this case, the necessity and proportionality of these documents may require additional consideration.

In other countries **(BE[117], EL, IE, IS, HR, HU, PL, PT[118], SI)**, the patient seems to be required to provide in the application for PA information concerning the availability of the healthcare and/or the waiting time for the service in the country of affiliation.[119] Though the purpose of the requirement appears to be in line with the Directive (i.e., aimed at assessing whether the treatment could be provided in the country of affiliation within a reasonable time frame), however, the necessity and proportionality of requesting such information from the applicant should be further assessed. In fact, it should be noted that in a majority of countries, patients are not required to provide this information to substantiate PA requests, and it is rather for the body handling the applications to assess (and not for the applicant to prove) whether the requested healthcare could be provided in the country of affiliation within a reasonable timeframe (and, if so, to provide the patient with the details on the availability of the service in their country).

In this context, in one of the aforementioned countries **(EL),** besides a medical opinion of a specialised doctor, a certificate from "at least two hospitals" in the country confirming that the proposed healthcare cannot be provided in that country within a medically acceptable period has to be submitted with the PA request.[120] Besides the necessity and proportionality of this requirement being questionable for the reasons outlined above (i.e., the burden of proof of whether the treatment can be provided in the country of affiliation within the medically justifiable time limit should not as a rule be borne by the patients), the need to consult and receive documentation from several providers may also constitute a difficult and/or lengthy process and therefore, in practice, be perceived as an unjustified obstacle for patients seeking cross-border healthcare. However, it should be noted that according to the research conducted and

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[117] It should be noted that in Belgium, this information is to be provided in the medical report that needs to be submitted together with the application form. The medical report has to be filled in by the doctor.

[118] It should be noted that this is required in Portugal only for surgery treatments.

[119] In some instances, general information on the availability of the treatment in the country is requested (BE, EL, IE, IS, HU), whilst in other countries, patients need to demonstrate that they have been included on a waiting list or they need to provide an indication of the scheduled data of treatment in the country of affiliation (IE, HR, PL, PT, SI). In Ireland, the indication on whether the patient is included on a waiting list is an alternative requirement to the submission of a referral from the doctor. However, indication on the availability of the treatment in Ireland is still requested. In Spain (Catalunya), the inclusion on a waiting list, however, does not appear to be a mandatory requirement, but it is rather an option for the applicants to indicate whether or not they have been included on a waiting list. For more information see Annex E, Section 3.

[120] For more information see Annex E, Section 3.

the information provided by the national body contacted for the verification of the data collected, a reform of the procedural framework for cross-border healthcare is currently being carried out in Greece. Changes to the procedural rules and requirements are to be expected and therefore it will be reassessed whether such requirement will be lifted in the near future.[121]

In another of the aforementioned countries **(IE)** – where receiving PA is optional, though recommended – patients who exercise the option to request PA should also provide information concerning their inclusion on a waiting list. However, this requirement is only applicable if patients do not submit a GP referral to substantiate their application. Moreover, the national body contacted for the verification of the data collected indicated that "*such information is not collected for any [specific] purpose, only for office use as stated on the PA form. The reason [the national body] collects this information is [to] understand the reasons why patients are using the Directive. It has no bearing on any decision and is not used as a determining factor in relation to waiting time. Waiting time is not used as a determining factor*. *The only determining factor for eligibility in Ireland is residency and compliance with public patient pathways. Therefore, many patients using the Directive are not on waiting lists at all and used the Directive to avoid waiting lists*."[122] However, independently of the ultimate use that the body handling the PA procedure makes of the information collected (i.e., despite the 'inclusion in a waiting list' not being a determining factor in the decision-making process on PA), the Irish PA application form does not seem to provide an indication to patients that (in the absence of a doctor referral) the provision of such information is 'optional'. Therefore, the aforementioned reasoning concerning a further assessment on the aims, legal certainty, necessity and proportionality of this requirement may once again be taken into consideration, whilst recalling however that, in Ireland, patients are not obliged to request PA. Furthermore, always in Ireland, although PA is optional, if a patient decides to request PA, other very extensive information has to be provided by the patient and by the referring physician. More specifically, it appears that, amongst other things, the referring physician is also required to provide statements concerning information which may appear difficult to assess with certainty.[123] For instance, the physician must answer the following questions on the application form: *i) Is this treatment contrary to the Irish Constitution or any legislation to your knowledge? ii) Is the treatment regarded as a proven form of medical attention and not experimental or test treatment? Does the proposed healthcare pose any public health risks for the patient and/or the public in general?).* Moreover, the physician must also indicate very specific information on the healthcare provider abroad, such as: *i) whether the treatment abroad is being provided in a recognised hospital or other institution which is under the control of a Registered Medical Practitioner; and ii) whether that hospital is a public hospital available to National Health Agencies for Public Patients in that country*. Furthermore, where applicable (e.g., in cases where the medical documentation submitted to substantiate the request concerns medical consultations abroad), the applicants seem to be required to also submit proof of travel abroad (e.g., flight/ferry tickets, accommodation in patient's/applicant's name, toll/parking charges or a till receipt from a shop in the locality).

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[121] Moreover, according to the national body contacted by the national legal expert, the administrative procedures are considered necessary and proportionate to the objective to be achieved. For more information, please see the national country report for Greece, Part 1, Section 1.

[122] Information provided to Spark Legal Network by the Irish NCP on 1/10/2021.

[123] For more information, see Annex E, Section 3 and the national country report for Ireland, Part 1, Section 1.

In this context, it should be noted that in relation to the extensive information to be provided with the PA applications, according to the Irish NCP, the optional PA procedure is designed to give "*the patient confidence he/she has followed public patient pathways and will be eligible for reimbursement*", and "*requires the provider/doctor abroad to indicate the cost that will be charged and identify the DRG so the patient also knows the reimbursement rate associated with that DRG. This is to the patient's advantage".* Moreover, with regard to 'proof of travel', the national authority contacted for the verification of the data collected indicated that this requirement was introduced due to the fact that "*there were previously instances of consultants maintaining they had seen patients in their country, when they had not*".[124] Moreover, according to the Irish NCP, *"the collection of proof of travel should not be regarded as disproportionate [given that] the Directive is based on the patient travelling to another EU/EEA state to access the care".*[125] Nonetheless, as the requirements mentioned above do not appear to be requested in any other countries where a referral from a doctor abroad is also accepted, their necessity and proportionality may require reconsideration, in combination with the extensiveness of the aforementioned required information which must be provided by patients and physicians if the PA path is taken.

Finally, it is worth mentioning that with regard to the involvement of physicians in the PA application process, seven countries **(AT, HR, HU, IE[126], MT, RO[127], SI)** seem to require that the practitioner involved must be a national/contracted doctor, whilst in other countries **(BG, DE, DK, EL, ES, FR, IS, LU, NL, PL, PT, SK)**, the sources consulted do not seem to provide any indication on the country affiliation of the practitioner. In this context, it was previously noted in the Commission's Report on the operation of Directive 2011/24/EU of 2015 (COM(2015)421 final)[128] that "*according to the principle of mutual recognition of qualifications, Member States should recognise decisions about clinical need and appropriateness provided by an equivalent professional in another Member State*". Therefore, limiting the accepted documentation solely to the one provided by a national/contracted doctor could be regarded as a barrier for patients to access cross-border healthcare. Such a requirement could only be imposed based on the conditions in Article 7(7) of the Directive, *i.e.,* where the same requirement applies to healthcare provided in the country of affiliation and where it is objectively justified by the reasons listed therein. It has to be noted that Article 7(7) of the Directive expressly mentions a possibility to require an assessment of the general practitioner or primary care practitioner with whom the patient is registered in the country of affiliation, if this is necessary for determining the patient's entitlement to healthcare. However, this should not apply to specialist doctors. On the other hand, though it could be argued that a general reference to 'a practitioner' or 'a doctor' may be interpreted as to encompass physicians from any EU/EEA country, the lack of a clear specification thereof in the

[124] For more information, see national country report for Ireland, Part 1, Section 1.
[125] Information provided to Spark Legal Network by the Irish NCP on 1/10/2021.
[126] The doctor involved in the completion of the Irish PA application form should be a national one. The Irish NCP communicated to Spark Legal Network on 1/10/2021 that "*Ireland accepts referrals submitted by a general practitioner in Ireland or abroad, but it is only a specialist doctor who knows the treatment he/she is going to provide who can assist the patient with the optional PA".*
[127] In Romania the sources consulted seem to require that the practitioner involved has to be contracted with the national healthcare system. However, the national body contacted for the verification of the data collected has indicated that, in practice, referrals from any doctor within the EU/EEA is accepted.
[128] Available at: https://ec.europa.eu/health/sites/default/files/cross_border_care/docs/2015_operation_report_dir201124eu_en.pdf

national sources may also lead to uncertainty for patients with regards to which documents they should submit to substantiate a PA request (i.e., documents from a national or any doctor established in the EU/EEA).

Costs associated to the handling of the procedures

According to the Commission's findings in 2018 (COM(2018) 651 final), sworn translations can represent a disproportionate obstacle to free movement of services, due to the fact that, for example, the cost of the translation could be higher than the reimbursement of the outpatient services. Although in the 2018 report it was indicated that such requirements were lifted across the countries, the data collected at national level have found that amongst the countries in which costs for translations of application forms and/or documents were identified, in two countries **(IE, PT)**, these costs still related to official/certified translations, which in certain instances appear to be mandatory.[129] In the case of Ireland, it should nonetheless be noted that the Irish NCP indicated that: "*The documents in question are medical documents and it would be dangerous for translations to be carried out by unqualified personnel"*, and that "*it should further be noted that certified translations have only ever been requested where the documentation is such that it cannot easily be understood or is so voluminous that tools like 'Google Translate' are not appropriate. The occasions where certified translations have been requested do not total any more than approximately 10 since 2014".*[130] Nonetheless, as certified translations are listed as a mandatory requirement in the national sources, this may still be regarded as a potential obstacle for patients, and the proportionality and necessity of this requirement should be reconsidered, also in light of the fact that it is not requested in the majority of the countries.

4.2 Assessment of the procedural requirements for reimbursement against the Directive

The analysis of the data collected at national level with regard to the administrative requirements concerning reimbursement procedures across the countries has led to the identification of some potential issues, in light of the requirements of Article 7(7) and Article 9(1) of the Directive. With regard to non-reimbursable thresholds identified across the countries, the requirements of Article 7(4) of the Directive were also taken into account.

Preliminary remarks

With regard to one country **(LI)**, no information was available on the administrative requirements for the reimbursement. Therefore, as for PA, the detailed assessment against the requirements of the Directive was not possible for this country, though a potential lack of transparent information for patients may be pointed out as an issue. Moreover, it should be noted that in other countries where several insurance providers have a certain degree of autonomy in defining their own procedures (AT, BE, DE, FR, NL), the analysis has been conducted on the basis of the available data collected (e.g., in the case of the Netherlands, it is based on a sample of procedures set out by two insurance providers in that country).

Furthermore, it should be noted that in the majority of countries (e.g., BG, CY, CZ, DK, EE, EL, ES, HR, HU, IE, IS, IT, LT, LV, MT, NO, PL, RO, SE, SI, SK), the data collected have found that "*no reimbursement procedure applies domestically"* [131]. This

[129] More details on the procedural costs across the countries are available in Annex E, Section 5.
[130] Information provided to Spark Legal Network by the Irish NCP on 1/10/2021.
[131] See Annex A (national country reports), Part 1, Section 2.

means that normally patients receiving healthcare in the national territory do not have to ask reimbursement of the costs of the service, as these are normally anticipated by the national healthcare system. However, as the Directive explicitly allows Member States to opt for a prior authorisation system, the assessment of whether the administrative procedures/requirements may be considered as being discriminatory, based on the fact that they do not apply domestically, was not always applicable in these countries.

Application module

As explained for PA, also for reimbursement procedures the choice of certain countries not to provide a specific template form to be used for applications, and/or not to make such a module available online does not appear to represent a self-standing compliance issue (i.e., the use of a standardised template is not required under the Directive; it only requires that information for patients should be known in advance).[132] Similarly, with regard to the means by which it is possible to submit a reimbursement application, no specific compliance issue was identified (i.e., electronic submission is not required under the Directive). It should nonetheless be noted that in countries where electronic submission is possible, the procedures appear less burdensome for patients (e.g., in terms of time, postage costs, etc.), compared to countries not providing digital means of submission of reimbursement requests.[133] In Romania, though no particular issues were identified with respect to the reimbursement procedures/requirements, according to the information provided by the national body contacted for the verification of the data collected, the application forms available on some of the websites of the county insurance houses may not be up-to-date with the current legislative framework.[134]

Information to be included in the module/application and documents required to substantiate the reimbursement request

With regard to the information which must be included in the reimbursement application and the documentation needed to substantiate such requests, although differences were identified across the countries, the requirements in the majority of the cases appear to be aimed at allowing the body handling the procedure to obtain the necessary information to process the request. These requirements entail, for instance, details on the applicant and medical documentation to assess the patient's entitlement to reimbursement, to identify the type of healthcare and the healthcare provider abroad, as well as to ascertain the amount and proof of the costs actually borne by the patient abroad. Such requirements may be considered to be necessary and proportionate to the objective of assessing whether the patient is entitled to reimbursement, and to calculating the amounts to be reimbursed (i.e., according to the healthcare basket of the applicant and the costs of the healthcare in the country of

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[132] According to Recital 37 of the Directive "is thus appropriate to require that these general conditions, criteria and formalities should be applied in an objective, transparent and non-discriminatory way and should be known in advance, based primarily on medical considerations, and that they should not impose any additional burden on patients seeking healthcare in another Member State in comparison with patients being treated in their Member State of affiliation, and that decisions should be made as quickly as possible".

[133] In some countries (e.g., BE, BG, EE, FI, FR, HU, LT, RO), the digital submission of a reimbursement request does not seem possible. In Spain, electronic submission is not possible in Galicia. In Germany, whether or not the applications for reimbursement can be submitted electronically may vary depending on the different insurance providers. In other countries, electronic submission is possible only if the applicant has access to the certified email (e.g., the so-called 'PEC' in Italy). More information on the application modules across the countries is provided in Annex F, Section 1.

[134] For more information, see the national country report for Romania, Part 1, Section 2.

affiliation).[135] However, in some countries, some additional requirements were identified, the necessity and proportionality of which may require further assessment.

In particular, in one country **(EL)**, besides the fact that a certificate from the treating doctor regarding the legal status of the institution of treatment must also accompany the request (which may be regarded as difficult information to obtain in certain countries), it is further required that all documentation shall be legally issued and certified by the respective Greek Consulate and must be officially translated. Though no specific justification/purpose for these requirements was identified in the sources consulted, as mentioned above in Section 4.1., the national body contacted for the verification of the data collected indicated that a reform of the procedural framework for cross-border healthcare is currently being carried out in Greece, hence it will be reassessed whether such requirement(s) will be lifted in the near future.[136]

Furthermore, in one country **(HU)**, it was found that the reimbursement request should include an "evaluation of the treating physician on the effectiveness of the treatment".[137] Moreover, it is required that such physician should be a national doctor. It is not clear, however, whether the reimbursement of the cross-border healthcare costs is conditional upon the "effectiveness" of the treatment, which cannot be assessed *ex ante*. In any case, this requirement may be regarded as a disproportionate obstacle for patients, who may refrain from accessing cross-border healthcare should reimbursement of the costs be based on such aleatory assessment or, if the reimbursement does not depend on the "effectiveness" of the treatment, requiring additional documentation is burdensome for patients and does not seem to be necessary.

In two countries, together with the reimbursement application, patients are required to provide indications on whether they have applied for reimbursement at a private insurance company **(IS)** or whether they have travel insurance with medical coverage **(NL)**[138]. Though this requirement does not appear particularly burdensome, as patients should easily have access to information concerning their insurance coverage, the necessity of these requirements against the objective to be achieved may require further assessment, also in view of understanding if and to what extent they may impact the patients' entitlement to reimbursement, and also in consideration of the fact that patients are not required to provide such information in the majority of countries.

In one country **(PT)**, patients are also required to provide information on the "International Statistical Classification of Diseases and Related Health Problems or a similar classification adopted by the Member State of treatment" to substantiate the reimbursement request. Similarly, in another country **(PL)**, it is required that the invoice to be submitted to substantiate the reimbursement request contains "information enabling the identification of the codes of the International Classification of Medical Procedures ICD-9 and the International Statistical Classification of Diseases and Health Problems ICD-10 or data on medications". Once again, it should be further assessed whether such requirements may be regarded as disproportionate to the objective to be achieved, in consideration of the fact that patients may not be in the

[135] More information on the required information and documents across the countries is provided in Annex F, Section 2.
[136] For more information, see the national country report for Romania, Part 1, Section 2.
[137] For more information, see Annex F, Section 2, and the national country report for Hungary, Part 1, Section 2.
[138] CZ insurance provider.

position to provide such technical data, and/or may not be in control of the information which is provided in the invoice formats issued by foreign healthcare providers.

Moreover, in one country **(PT)**, it is indicated that "acceptable proof of payment" shall be submitted together with the reimbursement request. The national data collection activities have not revealed any additional rules clarifying this requirement. However, it should be noted that such a broad formulation may lead to a lack of clarity for patients on what will, in practice, be recognised as 'acceptable' proof upon their return, and therefore potentially constitute an unjustified barrier for patients attributable to the uncertainty concerning their reimbursement entitlements.

Finally, in one country **(IS)**, flight tickets must be submitted as a proof of travel abroad to substantiate reimbursement applications. Should it be confirmed that the lack of submission of flight tickets with the request leads to a rejection of the reimbursement application, such a requirement may be questioned as to its compatibility with the Directive.

Costs associated to the handling of the requests

As mentioned in relation to PA, sworn translations may represent a disproportionate obstacle to free movement of services, as the cost of the translation could be higher than the reimbursement of the outpatient services. With this in mind it should be noted that costs linked to official translation of documents have been identified in seven countries (AT, IE, IT, EL, NO[139], LV, PT)[140]. However, it should be noted that in three countries (AT, IT, LV), though the official translation is a general administrative requirement with a broader scope, the national authorities contacted for data verification claimed that in practice, the bodies handling the requests seem not to insist on compliance with such a requirement.[141] However, in one country **(NO)** the sources consulted specify that "*all documentation must be in Norwegian, Danish, Swedish or English. If the documents are in another language, [the body handling the procedure] may ask the individual to provide a state-authorised translation. In this assessment, emphasis shall be placed on the size of the claim amount. If it entails unreasonable costs for the user to translate the claim based on the amount to be reimbursed, [the body handling the procedure] shall assess whether there is a need for translation, or whether the documentation can still be understood by [the body]. In such cases, [the body handling the procedure] cannot demand that the user have the documents translated by a state-authorised translator*". The national body contacted for the verification of the data collected in Norway specified that it has "*caseworkers with expertise in many languages, so translations are often not required*".[142] Nonetheless, the existence of the official translation requirement may generate uncertainty for patients. Finally, for the remaining three countries **(IE, EL, PT)**, no such similar specification (i.e., that official translations may not be requested in practice) was identified in the sources consulted.

Non-reimbursable thresholds

With regard to non-reimbursable thresholds, it should be noted that, with only three exceptions **(AT, FI, NL),** in all other countries where specific limitations to the

[139] Please note that, however, as indicated by the National authority, this requirement is often not imposed. For more information, see Section 3 of Annex F.
[140] For more information, see Annex F, Section 3, and the national country reports, Part 1, Section 2.
[141] For more information, see Annex A (national country reports), Part 1, Section 2.
[142] Idem.

reimbursable amounts were identified, these were found to correspond to the same limits which would apply should the healthcare have been provided domestically. Therefore, such calculation methods appear to be in line with the requirements of the Directive, and in particular in line with Article 7(4) according to which "*the costs of cross-border healthcare shall be reimbursed or paid directly by the Member State of affiliation up to the level of costs that would have been assumed by the Member State of affiliation, had this healthcare been provided in its territory without exceeding the actual costs of healthcare received*".[143]

However, in **Finland**, national legislation differentiates domestically between treatment received in public and private establishments.[144] Any treatment sought in private establishments in Finland is reimbursed only partly. However, the data collected at national level found that in the case of healthcare received abroad, whether in a private or public establishment, cross-border healthcare is reimbursed only up to the partial amount that would be reimbursed domestically should the treatment be provided in a private establishment. This different method for the calculation of reimbursement may be regarded as being discriminatory based on the fact that it does not correspond to that applied domestically, whilst also appearing in contradiction with the requirements of Article 7(4) of the Directive. In this context, it was also found that the European Commission has started an infringement procedure against Finland regarding this issue for which a reasoned opinion was sent to Finland on 29 April 2016.[145] The infringement case is still pending. Moreover, no specific justification/purpose was provided by the national authority contacted for the verification of the data collected.

Similarly in **Austria**, the calculation of the reimbursement level was also found to be different for cross-border and domestic healthcare. In particular, for cross-border healthcare without PA, patients seeking reimbursement upon return will only receive 80% of the tariff that would be reimbursed had the healthcare been provided domestically by a contracted healthcare provided. Though it could be argued that the 80% threshold also applies domestically (i.e., for the reimbursement of healthcare services received from non-contracted healthcare providers in Austria), the application of the same calculation method to cross-border healthcare may be regarded as contrary to the non-discriminatory requirement contained in Article 7 of the Directive, also in view of the fact that, generally, foreign healthcare providers are not contracted parties to Austrian insurance providers. For this reason, infringement proceedings have been initiated against Austria for alleged failure to comply with the Directive regarding level of reimbursement.[146]

Similar infringement proceedings have also been initiated against the **Netherlands**, where the calculation methods for the amounts to be reimbursed appear to be different for domestic and cross-border healthcare, depending on whether patients seek healthcare from contracted or non-contract providers, therefore leading to potential non-compliance with Article 7 of the Directive.[147]

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[143] More information on the non-reimbursable thresholds across the countries is presented in Annex F, Section 5.
[144] For more information, see the national country report for Finland, Part 1, Section 2.
[145] See: European Commission, 'The April Infringements Package: Key decisions' 28 April 2016, available at https://ec.europa.eu/commission/presscorner/detail/EN/MEMO_16_1452.
[146] INFR(2018)2333; MEMO-19-462 available at: https://ec.europa.eu/commission/presscorner/detail/EN/MEMO_19_462.
[147] INFR(2018)2328; MEMO-19-462 available at: https://ec.europa.eu/commission/presscorner/detail/EN/MEMO_19_462.

Additionally, in one country **(CY)**, it appeared that for specific types of cross-border healthcare services, patients are not entitled to reimbursement at all, namely for: i) refractive surgery; ii) cosmetic surgery; iii) consumables (shoes, wheelchairs etc.). Though in principle this may not appear problematic, as countries have discretion in deciding what types of services may be considered as falling within the so-called "healthcare basket", it should be noted that such exclusions from the entitlement to reimbursement do not seem to apply for equivalent domestic services. Moreover, no specific justification/purpose was identified during the national data collection activities. For this reason, a further assessment of whether such exclusion with regard to cross-border healthcare is in line with the requirements of Article 7 of the Directive and/or other EU law provisions, may be appropriate.

Finally, in one country **(IE)**, there are non-reimbursable thresholds for specific types of treatments abroad and, in particular, for outpatient consultation in hospitals, for inpatient care and for orthodontic treatments.[148] According to the data collected, these thresholds do not appear to apply domestically, and no specific purpose for such thresholds has been identified in the sources consulted. Therefore, a further assessment on whether any objective justifications pursuant to Article 7 may be regarded as necessary.

[148] For more information, please see Annex F, Section 5 and the national country report for Ireland, Part 1, Section 2.

5 Conclusions and next steps

In light of our study to enhance the implementation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare we mapped:

1. The administrative procedures/requirements for PA for cross-border healthcare under the Directive;
2. The administrative procedures/requirements for reimbursement of costs of for cross-border healthcare under the Directive.

The data collection tasks showed that certain administrative procedures/requirements across the countries may be regarded as creating potential unjustified barriers for patients seeking cross-border healthcare under the Directive. Where potential issues have been identified, these have been outlined in Chapter 4.

With regard to PA procedures, for instance, potential issues were identified in 21 countries (AT, BE, BG, CY, DE, DK, EL, FR, HR, HU, IE, IS, LI, LU, MT, NL, PL, PT, RO, SI, SK);[149]

With regard to reimbursement procedures, potential issues were identified in 12 countries (AT, CY, EL, FI, HU, IE, IS, LI, NL, NO, PL, PT).

For these requirements, a further assessment of whether they constitute justified obstacles to patients seeking cross-border healthcare in practice may be appropriate.

Moreover, it should be noted that in certain countries, specifically those where the national healthcare system is based on a network of several health insurance funds (e.g., AT, BE, CZ, DE, FR, NL), the data collected with regard to the administrative procedures shall not be considered exhaustive as, in practice, insurance providers may apply different procedures and requirements according to the degree of autonomy which they may be granted within the specific national framework.

Finally, with regard to PA procedures, the findings of the data collected at national level fed into the 'Guiding Principles for Information Provision on prior authorisation systems across Member States' developed under WP1.a.

[149] Please note that in seven of these countries (AT, DE, DK, FR, IS, LU, MT) the conclusion on 'potential issues' is based solely on the fact that the national sources do not seem to specify whether the doctor providing a referral/involved in the PA process must be a national/contracted doctor or may be a doctor from another EU or EEA EFTA country (i.e., no other potential issue has been identified).

Annex A - National Country Reports

AUSTRIA – COUNTRY REPORT

Part 0: Preliminary Assessment

1. **Please indicate whether the rules governing the administrative procedures/requirements for requesting PA and reimbursement under Directive 2011/24/EU in your country are set out at:**

A. National level ☒

B. Decentralised/regional/local level ☐

In case (1.B): Please indicate the two most relevant jurisdictions in your country (i.e., in terms of population):

Region/jurisdiction: 1: N/A

Region/jurisdiction 2: N/A

NOTE: In case (1.B) the template for the data collection (Part 1) should be complete twice, once for each of the two most relevant regions/jurisdiction indicated above.

2. **Please indicate the national body best suited to verify the accuracy of the information collected in Part 1, and justify your selection.**
Depending on the characteristics of your national healthcare system, the relevant body may be: a) *the national social security body*; or b) *an insurance fund*. In the latter case, please indicate the most representative fund (e.g., the one with the highest number of affiliations).

Body to be contacted for Task 2:

Österreichische Gesundheitskasse (ÖGK) - Austrian Health Insurance Fund

Reasons for Selection:

The Austrian Health Insurance Fund is the largest Austrian federal social insurance institution with the most insured persons. It is technically responsible for pre-authorisation and reimbursement.

PRELIMINARY NOTE:

Introductory general overview of the **regulatory framework implementing** the Patient Mobility Directive in general.

Both prior authorisation (PA) and reimbursement according to Directive 2011/24/EU are regulated in the same provision (§ 7b Social Insurance Supplement Act [“Sozialversicherungs-Ergänzungsgesetz, hereinafter SV-EG]). The Directive 2011/24/EU was implemented in Austria after the official transposition deadline had expired. The law is called the "EU Patient Mobility Act" (“EU-Patientenmobilitätsgesetz” [hereinafter: EU-PMG]) and entered into force with the law number BGBl 2014 No. 32 on 25. 4. 2014.

The main regulatory contents of the EU-PMG are

- the introduction of a national contact point for cross-border healthcare (§ 15b Bundesgesetz über die Gesundheit Österreich GmbH),
- the introduction (here objective) of a system of prior authorisation (PA) for certain cross-border treatments (§ 7b of the SV-EG),
- the amendment of the Krankenhaus- und Kuranstaltengesetz to the effect that care patients are provided with clear price information and receive an invoice for the service (§§ 39 and 40 Krankenhaus- und Kuranstaltengesetz) as well as the
- introduction of mandatory professional liability insurance in the Pharmaziegesetz (§ 4a) and the Psychotherapiegesetz (§ 16b).

Within the framework of the implementation of the Directive, use was made of the possibility to introduce such a system of prior authorization (PA).

The reimbursement of costs for cases in which no PS is required was not newly regulated by the EU-PMG. Rather, the possibility of reimbursement under national law, which already existed before the introduction of the EU-PMG, continues to exist, namely under the provisions of §§ 131 and 150 of the "Allgemeines Sozialversicherungsgesetz" (ASVG - General Social Insurance Act); see below Question 2.

§ 7b (3) of the SV-EG now stipulates that in the cases of § 7b(4) (see below) there is an entitlement to special reimbursement of costs if there is also an entitlement to this benefit in Austria.

§ 7b(4) of the SV-EG lists those cases which open a claim for reimbursement according to § 7b(6) of the SV-EG, provided that the competent Austrian health insurance institution has granted a pre-authorisation (PA) to the entitled person.

These are:

- in-patient treatments,
- outpatient treatments (hospital outpatient and office-based) which require the use of highly specialised and cost-intensive medical infrastructure or medical equipment,
- treatments that are associated with a particular risk for patients or the population,
- treatments provided by healthcare providers that could give rise to serious specific concerns about the quality or safety of care in individual cases.

The obligation to obtain prior authorisation (PA) does not apply in medical emergencies where it can be demonstrated that it cannot be obtained or cannot be obtained in time.

According to the parliamentary material to the cited law, prior authorisation is not required if, for example, the victim of an accident in another Member State is admitted to a private hospital outside the local health insurance system and undergoes life-sustaining surgery there. However, if, for example, during a holiday, a general practitioner who has been consulted for another acute illness with the European Health Insurance Card diagnoses a cancer that could be treated immediately in a private hospital in the respective country of stay, a prior authorisation must indeed be obtained in these cases in order to ensure reimbursement of costs according to para 6 (see explanatory notes to government bill 33 of enclosures no. 25).

In turn, it follows from § 7b (5) SV-EG under which conditions an advance authorisation is to be granted, namely if this treatment cannot be provided within a medically reasonable period of time in Austria, taking into account the current state of health and the probable course of the disease, and the person entitled to benefits is entitled to this health service. Which period of time is considered reasonable results from a case-by-case assessment (see explanatory notes to government bill 33 of enclosures no. 25).

However, this does not apply if any of the following exceptions apply:

- the patient is exposed to an unacceptable safety risk; or
- the public is exposed to a significant safety risk, or
- this treatment is provided by a health care provider who raises serious concerns about compliance with quality standards and guidelines for care and patient safety.

When claiming benefits under the SV-EG, the patient is entitled to reimbursement of those costs which the Austrian social insurance institution would have charged to the competent foreign institution if the corresponding treatment had been provided in Austria by means of the European Health Insurance Card under the Regulation.

The reimbursement may not exceed the amount of the costs actually incurred by the health care (§ 7b(4) SV-EG).

In summary: PA for inpatient hospital treatment or outpatient treatment with large-scale equipment is required if the required services cannot be provided in Austria within a reasonable period of time. When assessing which period of time is to be considered "reasonable", a case-by-case consideration must be made, in which the subjective and objective state of health of the patient must be taken into account as well as the course of the disease to date and its probable further development. The insured person then has a claim for reimbursement amounting to 100% of the tariff that would have had to be paid in Austria.

If, on the other hand, hospital treatment is used without prior authorisation and the conditions of the Coordination Regulations (883/2004/EC) are not met, the insured person will only receive a care cost allowance (§ 150 ASVG) or the reimbursement of costs according to § 131 ASVG, i.e. 80% of the domestic tariff**.**

Part 1: Questionnaire

*__Note 1__: In cases where administrative requirements are set out in the legislative/regulatory framework at decentralised/regional/local level, please complete the template for the data collection twice, once for each of the two most relevant regions/jurisdictions (e.g., in terms population).

__*Note 2__: Setting out a Prior Authorisation (PA) system is optional for Member States. Should your country not have a system of PA in place under Directive 2011/24/EU, Section 1 will not need to be completed.

SECTION 1 PRIOR AUTHORISATION PROCEDURE(S)			
Questions	**Answer**	**Sources**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to PA procedures for a cross-border healthcare under Directive 2011/24/EU?	§ 7b Social Insurance Supplement Act ("Sozialversicherungs-Ergänzungsgesetz"), hereinafter 'SV-EG'. "EU Patient Mobility Act" ("EU-Patientenmobilitätsgesetz"), [hereinafter: 'EU-PMG'.	**Source(s):** General implementation: EU Patient Mobility Act[150] Relevant standard for prior authorisation (PA) and reimbursement under the Patient Mobility Directive:	N/A

[150] Bundesgesetz, mit dem das Bundesgesetz über die Gesundheit Österreich GmbH, das Sozialversicherungs-Ergänzungsgesetz, das Allgemeine Sozialversicherungsgesetz, das Gewerbliche Sozialversicherungsgesetz, das Bauern-Sozialversicherungsgesetz, das Beamten-Kranken- und Unfallversicherungsgesetz, das Bundesgesetz über Krankenanstalten und Kuranstalten, das Apothekengesetz, das Medizinproduktegesetz, das Ärztegesetz 1998, das Musiktherapiegesetz, das Psychotherapiegesetz, das EWR-Psychologengesetz, das EWR-Psychotherapiegesetz, das Psychologengesetz 2013, das Kardiotechnikergesetz, das Medizinische Assistenzberufe-Gesetz, das Medizinischer Masseur- und Heilmasseurgesetz, das Sanitätergesetz, das Zahnärztegesetz und das Familienlastenausgleichsgesetz 1967 geändert werden (EU-Patientenmobilitätsgesetz – EU-PMG) BGBl 32/2014, available at https://www.parlament.gv.at/PAKT/VHG/XXV/I/I_00033/index.shtml#, (last accessed 16/07/2021).

		§ 7b Social Insurance Supplement Act [151] § 15b Federal Act on Health Austria Ltd[152] <u>Previously relevant legislation</u>: §§ 131 and 150 of the "General Social Insurance Act"[153] Allgemeines Verwaltungsverfahrensgesetz[154]	
2. Is this the same procedure as for PA under the Social Security Coordination Regulations?	**Answer:** **Yes ☒ No ☐** The procedure is the same in some areas; the implementation of the Directive supplements the previous scope of the Coordination Regulations in some areas. The application forms do not seem to make a distinction between whether PA is requested under the Directive or under other legal bases; the patient does not really understand the legal basis of the reimbursement. Therefore, it could be concluded that the two procedures are 'substantially' equivalent. In addition, procedurally, the anyway applicable national law continues to exist, according to which any treatment received in another Member State against cash payment can be submitted to the competent Austrian health insurance institution for reimbursement without prior authorisation (PA) (§§ 131 and 150 ASVG; see point 1 above).		N/A

[151] Sozialversicherungs-Ergänzungsgesetz, available at https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10008889, (last accessed 16/06/2021).
[152] Bundesgesetz über die Gesundheit Österreich GmbH, available at https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20004884, (last accessed 16/06/2021).
[153] Allgemeines Sozialversicherungsgesetz", hereinafter ASVG, available at https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10008147 (last accessed 16/06/2021).
[154] Available at https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10005768 (last accessed 16/06/2021).

3. What body is in charge of handling the PA applications? *(e.g., where and to whom PA applications have to be submitted?)*	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations)* According to § 7b (4) SV-EG, the competent health insurance institution is responsible for issuing the prior authorisation (PA): • Austrian Health Insurance Fund (Österreichische Gesundheitskasse) • Insurance Institution for Public Employees, Railways and Mining (Versicherungsanstalt öffentlicher Bediensteter, Eisenbahn und Bergbau) • Social Insurance for the Self-Employed (Sozialversicherung der Selbständigen) The Austrian Health Insurance Fund has by far the highest amount of insured persons because it unites the employed, who naturally make up the largest group.[155]	**Source(s):** Social Insurance Supplement Act § 7b (4) SV-EG Prinzinger, Grenzüberschreitende Gesundheitsversorgung, DRdA 2015, page 472[156]	N/A

[155] Note of the National expert: Interesting and questionable in the light of a correct implementation of the Directive is the restriction of the competence to issue a prior authorisation (PA) to the health insurance institutions mentioned. There are other social insurance institutions in Austria that are responsible for medical services. Specifically, these are the accident insurance and the pension insurance, but also the In Vitro Fertilisation Fund (IVF).
The national contact point, on the other hand, is only to enable patients to make an informed choice when seeking health care in another Member State. Its tasks are limited to providing advice and information of a general nature. It is not intended to and cannot provide comprehensive care in individual cases. In particular, information regarding the quality of health care services is also limited to general information on the quality of the Austrian system.

[156] Available at www.rdb.at (last accessed 16/06/2021).

4. Who is entitled to apply for PA? *(e.g., can the patients apply themselves, or is treating doctor filing/partially filling the request, etc.)*	**Answer:** - *If there is a national doctor involved, is there a requirement that this doctor is contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA?* The patient himself can file the application; the intervention of a doctor or even a legal representative is not necessary. § 361 (2) sentence 1 of the General Social Insurance Act (ASVG) states: *"The claimant himself or his legal representative is entitled to file an application (...). Minors who have reached the age of 14 may also file the application themselves."* However, the national attending doctor/hospital or the respective treatment facility must consider the treatment abroad necessary and submit a written justification with the diagnosis to the competent social insurance institution (see point 3 above) (this should ideally be enclosed with the application). A specific treatment facility must already be indicated. In the Austrian health insurance system, the procedure is always initiated by a formal application for a benefit.[157] Applications for PA can be submitted to the competent	**Source(s):** § 361 Abs. 2 ASVG Kneihs in Mosler/Müller/Pfeil, Der SV-Kommentar § 361 ASVG (Stand 1.10.2019, rdb.at)	No specific purpose/justification identified in the sources consulted.

[157] Note of the National expert: For all Austrian administrative procedures a formal application has to be made (and healthcare is no exception).

	health insurance institution (see point 3 above) due to the so-called all-lines service. The social insurance institution responsible for the subject matter and the location must always apply the General Administrative Procedure Act (AVG)[158] when carrying out the procedure.		
5. Is there a specific application form/module which the person seeking PA needs to submit?	**Answer:** *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?* In principle, the individual social insurance institutions do not provide a separate form for applying for prior authorisation (PA) for treatment abroad (but there are separate forms for the reimbursement itself; see below). This means that the electronic submission of applications for the granting of prior authorisation (PA) with a form to be filled in is currently not possible.	**Source(s):** Österreichische Sozialversicherung (Austrian Social Insurance Fund)[159]	No specific purpose/justification identified in the sources consulted.

[158] Available at: https://www.refworld.org/docid/3ae6b5a7e.html, (last accessed 16/06/2021).

[159] Available at: https://www.sozialversicherung.at/cdscontent/?contentid=10007.820936&portal=svportal, (last accessed on 16.06.2021).

	In principle, electronic submission of applications (also with the help of a citizen card and mobile phone signature) is possible in other cases.		
6. What (other) documentation has to be submitted in order to substantiate a PA request?	**Answer:** *If applicable, please specify:* - *What documents and what particulars are required;* - *Whether there are requirements as to who has to issue the documents (e. g., a doctor contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA or any doctor);* - *Whether the submission of the documentation is optional, mandatory, or recommended.* If such prior authorisation (PA) is applied for, the competent health insurance institution (see above point 3.) must be provided with all documents on • the type of treatment, • the intended treatment objective, • the time of the treatment, • the health care provider from whom the treatment is to be received, as well as • the documents on the state of health which allow an assessment of the urgency of the treatment.	**Source(s):** Alexandra Brunner/Peter Wieninger, Die Interaktion zwischen den EU-Koordinierungsverordnungen und der nationalen Umsetzung der EU-Patientenmobilitätsrichtlinie im Bereich der Erstattungsverfahren (The interaction between EU coordination regulations and national implementation of the EU Patient Mobility Directive in the area of reimbursement procedures), Soziale Sicherheit (2014), p. 520.[160] General administrative Proceedings, Section 45 (2) AVG.	No specific purpose/justification identified in the sources consulted.

[160] Available at www.rdb.at (last accessed 16/06/2021).
Note of the National expert: In principle, according to Austrian administrative procedure, an application must be substantiated by suitable evidence. In administrative proceedings (such as those for PA or reimbursement of costs), the free assessment of evidence applies: The principle of the free assessment of evidence, which is standardized in Section 45 (2) AVG, means that the authority is not bound by fixed rules of evidence when assessing evidence, but must assess the value of the evidence taken to the best of its knowledge and belief according to its intrinsic truthfulness.
Therefore, there **is no legal basis** for what documents are required, but a case-by-case assessment is made.

	This documentation is not compulsory but recommended in order to prove eligibility		
7. Are there any costs associated with the handling of the PA request? - *Direct costs (e.g., fixed costs for submitting or filing a PA request).* - *Indirect costs* (*e.g., translations, stamps, etc).*	**Answer:** *Direct costs:* None identified. *Indirect costs:* None identified. Proceedings before the social insurance institutions are generally not subject to costs.[161]	**Source(s):** § 367 Abs. 1 Z 2 ASVG; § 70 ASGG Hengstschläger/Leeb, Kommentar zum Allgemeinen Verwaltungsverfahrensgesetz § 74 (Stand 1.4.2009).[162]	No specific purpose/justification identified in the sources consulted.
8. Are there any specific **time requirements** linked to a PA request? (*e.g., time within which a requesting person must submit the PA application and/or time within which the requested body must take a decision on the PA request, etc.*).	**Answer:** - *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* The patient only has to submit the application in time before the treatment. The competent social insurance institution shall decide on the approval (granting of the preliminary approval) within 2 weeks by means of a notice (§ 367 subsection 1 line 3 ASVG).	**Source(s):** § 367 Abs. 1 Z 3 ASVG	No specific purpose/justification identified in the sources consulted.

[161] However, in case of a rejection by means of a decision, the applicant may appeal against the decision of the social insurance institution (§ 367(1)(2) ASVG; § 70 ASGG). In this case, an appeal procedure is conducted according to the General Administrative Procedure Act (AVG). There are no court costs and stamp duties for proceedings before the Labour and Social Court. Medical reports by the court experts also cost nothing. Court fees may only be incurred at the highest court (Administrative Court). In any case, the ombudsman's offices of the respective social insurance institutions can be contacted free of charge

[162] Available at www.rdb.at, (last accessed 16/06/2021).

9. Are there **differences in the procedural/administrative requirements for requesting PA** based on, for instance, the type of treatment for which PA is requested, the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* No, but the required enclosures and justifications may vary (see point 6 above).	**Source(s):** See point 6 above	
10. Is there a specific PA form (i.e., form used for issuing/granting PA) and, if the answer is positive, what form?	**Answer:** No specific form is required(see point 5 above).	**Source(s):** Österreichische Gesundheitskasse (Austrian Health Insurance Fund)	No specific purpose/justification identified in the sources consulted.
11. Please list any other administrative requirements in your country in relation to the PA procedure for cross-border healthcare.	**Answer:** No further requirements identified.	**Source(s):** N/A	N/A

SECTION 2 **REIMBURSMENT PROCEDURE(S)**				
Questions	**Answer:**	**Sources**	**Does/do the identified requirement(s) also apply domestically?** **(i.e., is the requirement non-discriminatory?)**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory	**Answer:**	**Source(s):**	N/A	N/A

	provisions lay out the requirements related to reimbursement procedures for cross-border healthcare under Directive 201/24/EU?	As already described in the Preliminary note, the central norm is not only the prior authorisation (PA), but also for the reimbursement of costs § 7b SV-EG. The claims of the insured persons according to Regulation (EC) 833/2004 are not affected by this.	§ 7b SV-EG Wallner, Europäisches Gesundheitsrecht, in Resch/Wallner, in Handbuch Medizinrecht 2. Auflage (2015) Rz 127b.		
2.	**Is this the same procedure as for reimbursement under the Social Security Coordination Regulations?**	**Answer:** **Yes ☒ No ☐** See already point 1 question 2 above. There are no specific forms that differentiate the procedures.[163]		N/A	N/A
3.	**What body is/are responsible of handling the reimbursement applications?** (e.g., where and to whom reimbursement applications have to be submitted?)	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in*	**Source(s):** Alexandra Brunner/Peter Wieninger, Die Interaktion zwischen den EU-Koordinierungsverordnungen und der nationalen Umsetzung	N/A	N/A

[163] However, a fundamental distinction must be made in the procedures:

- In the case of treatments that **do not require authorisation (PA), the previously existing Coordination Regulations** for costs of medical treatment or the insurance provider's care cost subsidy in the case of institutional care are to be applied. In this area, the transposition of the Directive into national law does not lead to any changes.
- For treatments approved under the **Patient Mobility Directive, § 7b (6) SV-EG** provides for a special reimbursement of costs: The entitled person is reimbursed those costs which the competent Austrian health insurance institution would have charged to the competent foreign social insurance institution if the benefit had been claimed under the prescription (the condition is always that the benefit is included in the Austrian catalogue). This construction of the calculation of the reimbursement of costs, which was taken over from the Directive in the national implementation - without further clarification of the content - is, however, a great challenge in practice for all social insurance institutions concerned.

If, for example, in cases of approved inpatient treatment, costs are reimbursed according to § 7b (6) SV-EG, it must first be clarified which hospital is to be used as the reference hospital for the calculation, since on the one hand there is no uniform national rate and on the other hand different rates are applied depending on the hospital. It is also questionable how to proceed if the service rendered abroad is a treatment for which no "value" is provided in Austria. Whether this will be clarified by the legislator or whether objective criteria will have to be worked out in practice - such as the reference to the hospital nearest to the place of residence that could have provided the health care service used - is uncertain at present.

	your country (e.g., based on the number of affiliations). As already mentioned above (section 1 point 3), the respective social insurance institution is responsible. The so-called "medical service" of the respective social insurance institution decides to what extent the social insurance will cover the costs within the framework of the reimbursement procedure.	der EU-Patientenmobilitätsrichtlinie im Bereich der Erstattungsverfahren (The interaction between EU coordination regulations and national implementation of the EU Patient Mobility Directive in the area of reimbursement procedures), Soziale Sicherheit (2014), p. 520[164]		
4. Is there a specific application form/module which the person seeking reimbursement needs to submit?	**Answer:** *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?* No, but for reimbursement, the individual social security institutions provide specific forms for assistance. The form is supporting, but not mandatory. The invoice can be submitted online with a mobile phone signature. The treatment	**Source(s):** Österreichische Sozialversicherung (Austrian Insurance Fund).	**Yes** ☒ **No** ☐	

[164] Available at www.rdb.at (last accessed 16/06/2021).

	abroad must be indicated, and the invoice and proof of payment must be enclosed. The invoice can also be submitted by post or in person. There are separate, service-specific forms (e.g. elective doctor, hospital, physiotherapy, etc.) for reimbursement abroad.			
5. What (other) documentation has to be submitted in order to substantiate a reimbursement request?	**Answer:** *If applicable, please specify:* - *What documents are required;* - *Whether the submission of the documentation is optional, mandatory, or recommended.* The certificate can only be issued if it is known that the benefit can be settled with the insurance carrier abroad. You can ask the foreign insurance institution in advance whether this is the case (electronic process available). Subsequently, the person concerned can submit detailed invoices for the treatment provided to his or her competent health insurance institution for reimbursement and will be reimbursed for part or all of the costs incurred. In contrast to the ordinance, the benefits catalog of the insurance member state and its tariffs are decisive for the	**Source(s):** Alexandra Brunner/Peter Wieninger, Die Interaktion zwischen den EU-Koordinierungsverordnungen und der nationalen Umsetzung der EU-Patientenmobilitätsrichtlinie im Bereich der Erstattungsverfahren (The interaction between EU coordination regulations and national implementation of the EU Patient Mobility Directive in the area of reimbursement procedures), Soziale Sicherheit (2014), p. 520.	**Yes** ☐ **No** ☒	In principle, the national hospital does not have to issue confirmations for national circumstances, as the social security institutions are settled (in regular) directly.

	reimbursement of costs according to the directive. The method of documenting costs to obtain reimbursement is no different from any reimbursement under the coordination regulations (since pre-approval has been granted, no proof of entitlement is required, unlike under the regulations).[165]			
6. Are there any costs associated with the handling of the reimbursement request? - *Direct costs (e.g., fixed costs for submitting or filing a reimbursement request, proportion deducted from the reimbursable amount).* - *Indirect costs* (*e.g., translations, stamps, etc).*	**Answer:** *Direct costs:* None identified (see above Section 1 point 7). *Indirect costs*: Invoices and prescriptions must be translated by the applicant: In the case of a foreign fee invoice which is not issued in German or English, a translation must be attached. These translations must then be made at the applicant's own expense. No need for certified translation (the principle of free assessment of evidence applies).	**Source(s):** See above Section 1 point 7	**Yes** ☒ **No** ☐	Even in purely national situations, foreign-language invoices would theoretically have to be translated. Note from the National authority: According to the regulation, the patient may not be asked to provide a translation if it is an official language of the EU. The institution would have to do this at its own expense. Will this also apply to the directive? In practice, these cases are very rare and it is easy to read out what it is about from foreign-

[165] Note of the National expert: The use of health care services from private providers, as these are not covered by the coordination regulations. However, it should be emphasised here that, due to the national regulations already in force, an advantage arises for the individual insured person exclusively in those cases in which the possibility of special cost reimbursement opens up due to a previously granted prior authorization. The tariff in the Member State of insurance is higher than that in the Member State of treatment. In constellations in which deductibles are provided for insured persons in the Member State of treatment, there may be an advantage for the insured person, since deductibles provided for nationally are to be borne by the insured person according to the coordination regulations, while reimbursement according to the Directive is based on the regulations of the Member State of insurance.

				language invoices. Then no translation is requested.
7. Are there any specific time requirements linked to a reimbursement request? (*e.g., time within which the reimbursement requests must be submitted and/or time within the requested body must handle the request and/or reimburse the costs, etc.*).	**Answer:** *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* There are no specific rules for deadlines for reimbursement claims. Therefore, the general deadline for other reimbursements applies, according to which the fee notes with proof of payment must be submitted within 42 months (3 1/2 years) after the treatment.	**Source(s):** Österreichische Gesundheitskasse (Austrian Health Insurance Funds).	**Yes** ☒ **No** ☐	
8. Are there any non-reimbursable thresholds, deductions *(except the deductions for administrative costs mentioned above) etc.?*	**Answer:** *If yes, please specify the thresholds.* Not in general, deductibles that apply to treatment in Austria also apply to treatment abroad. Conversely, if deductibles are provided for and paid for treatment abroad for certain services, these are generally not reimbursed by the Austrian health insurance institution. If, on the other hand, hospital treatment is used without prior authorisation (and the conditions of the Coordination Regulations are not met), the insured person will only receive a care cost allowance (§ 150 ASVG)	**Source(s):** Felten in Mosler/Müller/Pfeil, Der Sozialversicherung-Kommentar § 135 ASVG (The Social Security Commentary).[166] Kietaibl, Sozialversicherungsrechtliche Beschränkung für wahlärztliche Honorarbemessung? (Social security restriction on elective physician fee assessment?) Wirtschaftsrechtliche Blätter 2006/502; Constitutional Court G 24/98, VfSlg 15.787).[167] Rebhahn in Pfeil/Prandtner (editors), Krankenversicherung	**Yes** ☒ **No** ☐ It should be noted in this context, however, that after the implementation of the Directive, a different reimbursement regime applies to treatments that do not require prior authorisation (PA) (which continues to be based on § 131 ASVG: 80% reimbursement, but no differentiation is made as to whether it is granted for domestic treatment or for treatment abroad) and to	A different regulation would discriminate against domestic matters.

[166] Stand/Actuality 1.1.2020, available at: www. rdb.at.
[167] Available at: www. rdb.at.

	or the reimbursement of costs according to § 131 ASVG, i.e. 80% of the domestic tariff.	zwischen Leistungsanspruch und Selbstbestimmung der Versicherten (Health insurance between entitlement to benefits and self-determination of insured persons) [2015] pages 4 ff.[168] Trauner/Weißenböck, Chefärztliche Bewilligung und Vorabgenehmigung im Kontext der europäischen Rechtsordnung (Chief medical officer authorization and prior authorization in the context of the European legal order), Zeitschrift Soziale Sicherheit 2019, pages 396 ff.[169]	treatments that require prior authorisation. Since no such differentiation can be found in the Patient Mobility Directive, it should be pointed out here. In Austria, the reduction of reimbursements to 80% is thus objectively justified in order to keep visits to elective physicians within limits. In the literature it is argued that a 100% reimbursement for foreign treatments would lead to a 100% requirement for domestic treatments as well, because otherwise there would be discrimination for domestic treatments.	
9. In instances where a PA (or prior-notification) has already been issued, is a separate/simplified procedure available for requesting reimbursement? **applicable only if the country has a PA system.*	**Answer:** *If yes, please describe the simplified procedure.* Yes, if pre-authorisation (PA) has been granted, the fee notes/cost notes must be attached as described above.	**Source(s):** Alexandra Brunner/Peter Wieninger, Die Interaktion zwischen den EU-Koordinierungsverordnungen und der nationalen Umsetzung der EU-Patientenmobilitätsrichtlinie im Bereich der Erstattungsverfahren (The interaction between EU coordination regulations and	**Yes** ☒ **No** ☐	

[168] Available at: www. rdb.at.
[169] Available at: www. rdb.at.

		national implementation of the EU Patient Mobility Directive in the area of reimbursement procedures), Soziale Sicherheit (2014), p. 520.		
10. Are there additional administrative/procedural requirements for reimbursement depending on, for instance, the type of treatment for which reimbursement is requested, or the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* A distinction must be made between inpatient hospital stays and doctor's visits; see point 3 above.	**Source(s):** See point 3 above.	**Yes** ☐ **No** ☒	See above point 5.
11. Please list any other administrative requirements in your country in relation to the procedures of reimbursement of cross-border healthcare.	**Answer:** None identified.[170]	**Source(s):** N/A	**Yes** ☐ **No** ☐	N/A

[170] Note of the National expert: In general, it can be said that a large part of the regulations on the use of cross-border health care providers laid down in the Directive were already applicable law in Austria before. This is based on the fundamental priority of application of the coordination ordinances, which, due to the principle of benefits in kind, often represent the more favourable variant for insured persons to make use of cross-border health care services, and the already existing possibility of reimbursement of costs when using elective service providers, which in Austria is not limited to the domestic market.
Only in the area of treatments requiring PA according to § 7b para 4 SV-EG, a new way of reimbursement for health treatments abroad was opened to insured persons. So far, however, this possibility has hardly been taken up by insured persons. The obligation of the insured to pay in advance as well as language barriers or access to information are certainly not insignificant.

Part 2: Checklist for verification with national/regional body

Name of the body: N/A
Country/Region: N/A
Date of verification call: N/A

Template for the Data Collection	**Aspects to be verified** *Tick the boxes if the information in the template for the data collection has been verified and/or complemented by the national body*		**Comments** *Include any additional comments and/or information provided by the contacted body*
Section 1 – Prior Authorisation			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Justification/purpose of the identified requirement(s) (Column 4)	☐ Question 1 ☐ Question 2 ☐ Question 3 ☐ Question 4 ☐ Question 5	☐ Question 6 ☐ Question 7 ☐ Question 8 ☐ Question 9 ☐ Question 10 ☐ Question 11	
Section 2 - Reimbursement			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Whether the requirement applies domestically (Discriminatory assessment) (Column 4) ▪ Justification/purpose of the identified requirement(s) (Column 5)	☐ Question 1 ☐ Question 2 ☐ Question 3 ☐ Question 4 ☐ Question 5	☐ Question 6 ☐ Question 7 ☐ Question 8 ☐ Question 9 ☐ Question 10 ☐ Question 11	

BELGIUM – COUNTRY REPORT

Part 0: Preliminary Assessment

1. Please indicate whether the rules governing the administrative procedures/requirements for requesting PA and reimbursement under Directive 2011/24/EU in your country are set out at:

A. National level ☒

B. Decentralised/regional/local level ☒

NOTE: Both boxes were checked. The reason for this is the following. The federal authority in Belgium is in general competent for the reimbursement of healthcare services, including reimbursement for cross-border healthcare. For that reason, the questionnaire was completed based on the federal regulation with regard to reimbursement.

However, following the last reform of the Belgian constitutional system in 2014, a very small part of this competence, including the reimbursement for the so-called 'long-term care revalidation', was given to the Regions.[171] This added a layer of complexity to the legislative framework given that, besides the general federal competence with regard to reimbursement, in parallel, and independently from the federal authority, the Regions are also – and solely for the specific matter of long-term care revalidation - competent to regulate the matters falling under the scope of Directive 2011/24/EU, including the administrative procedures for reimbursement. For a matter of clarity, 'long term care revalidation' is described in the legislation of the German speaking Regions as: "*non-acute or post-acute care provided in a multidisciplinary manner, regardless of the institution where this care is provided, in the context of disorders in the interaction between parents and children, in the context of mental, sensory, addiction, voice - and speech disorders, for cerebral palsy, in the context of children with respiratory and neurological disorders, as well as non-acute or post-acute care provided in a multidisciplinary manner for motor disorders outside general and university hospitals and hospitals where surgical and medical benefits in kind are provided exclusively for children or for the treatment of tumors*" [172]

However, it should also be noted that although the Regions have been provided with competences to regulate the matters concerning reimbursement of this specific type of care (long-term revalidation care), in practice only the Flemish Region and the German speaking Region have enacted regional legislation on the matter. Nor

[171] Other competences transferred to the Regions include mobility aids and elderly policy.

[172] 19 DECEMBRE 2019. - Arrêté du Gouvernement réglant de manière transitoire la procédure à suivre pour obtenir une autorisation préalable ou un accord aux fins de prise en charge des frais ou de participation aux frais engagés pour une revalidation long term care à l'étranger (Decree of the Government on the introduction of a transitional arrangement for the procedure to obtain prior permission for a cost transfer or an agreement to a contribution towards the costs in the context of long-term care rehabilitation abroad, Official Journal of 4 May 2019), page 30137, Article 2, 2°. Available at: http://www.ejustice.just.fgov.be/eli/arrete/2019/12/19/2020200927/justel (last accessed on 16 June 2021),

the Walloon Region, nor the Region of Brussels Capital have exercised their competence on the matter until now. Since the latter two Regions did not regulate enact such regulations (i.e. did not make use of their competence), the general rules set out by the federal authority still applies within the Region of Brussels Capital, as well as for the Walloon Region with regard to the long term care revalidation.

In any case, due to the fact that the scope of this exception (i.e., the competence of the regions) only covers a very small part of the functioning of the system of reimbursement of healthcare services in Belgium, as mentioned above, the questionnaire was completed based on the federal legislative/regulatory framework. In annex however, for a matter of completeness, an overview is given of the relevant, differing legislation in the Flemish, as well as in the German speaking Region.

In case (1.B): Please indicate the two most relevant jurisdictions in your country (i.e., in terms of population):

Region/jurisdiction: 1: N/A

Region/jurisdiction 2: N/A

NOTE: In case (1.B) the template for the data collection (Part 1) should be complete twice, once for each of the two most relevant regions/jurisdiction indicated above.

2. **Please indicate the national body best suited to verify the accuracy of the information collected in Part 1, and justify your selection.**
Depending on the characteristics of your national healthcare system, the relevant body may be: a) *the national social security body*; or b) *an insurance fund*. In the latter case, please indicate the most representative fund (e.g., the one with the highest number of affiliations).

Body to be contacted for Task 2: National Institute for Health and Disability Insurance (https://www.inami.fgov.be/fr/Pages/default.aspx)

(In case 1.B, please indicate two relevant bodies, one respectively for each Region/jurisdiction)

Reasons for Selection: This is the central (national) competent authority with regard to the regulation/policy on the reimbursement of costs of healthcare services in Belgium. The NIHDI has also the responsibility to collect statistic data with regard to cross-border healthcare.

Part 1: Questionnaire

*__Note 1__: In cases where administrative requirements are set out in the legislative/regulatory framework at decentralised/regional/local level, please complete the template for the data collection twice, once for each of the two most relevant regions/jurisdictions (e.g., in terms population).

__*Note 2__: Setting out a Prior Authorisation (PA) system is optional for Member States. Should your country not have a system of PA in place under Directive 2011/24/EU, Section 1 will not need to be completed.

SECTION 1 PRIOR AUTHORISATION PROCEDURE(S)			
Questions	**Answer**	**Sources**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to PA procedures for a cross-border healthcare under Directive 2011/24/EU?	**Answer:** Law on compulsory health care and compensation insurance, coordinated on 14 July 1994, Official Journal of 27 August 1994,[173] (**Law of 14 July 1994**), page 21524, Article 136. Royal Decree in execution of the law on compulsory health care and compensation insurance, coordinated of 14 July 1994, of 3 July 1996 - Official Journal of 31 July 1996[174] (**Royal Decree of 3 July**	**Source(s):** **Law of 14 July 1994** - Article 136. **Royal Decree of 3 July 1996** Articles 294, § 1, 14° & §§ 1, 2, 2/1- 2/2. **Ministerial Decree of 24 June 2014.**	N/A

[173] 14 JUILLET 1994. - Loi relative à l'assurance obligatoire soins de santé et indemnités coordonnée le 14 juillet 1994. Available at http://www.ejustice.just.fgov.be/eli/loi/1994/07/14/1994071451/justel (last accessed on 16 June 2021).
[174] 3 JUILLET 1996. - Arrêté royal portant exécution de la loi relative à l'assurance obligatoire soins de santé et indemnités, coordonnée le 14 juillet 1994. available at http://www.ejustice.just.fgov.be/eli/arrete/1996/07/03/1996022344/justel (last accessed on 16 June 2021).

	1996) page 20285 Articles 294, § 1, 14° & §§ 1, 2, 2/1- 2/2. Ministerial Decree to determine the list of medical interventions for which a prior authorization is necessary as mentioned in art. 294, § 1, 14° of Royal Decree of 3 July 1996 in execution of the law on compulsory health care and compensation insurance, coordinated on 14 July 1994 , of 24 June 2014, Official Journal of 22 July 2014[175] (**Ministerial Decree of 24 June 2014**), page 54874. Circular letter OA n° 2014/440 with regard to the Applications of the Regulations (CE) 883/2004, (CE) 987/2009 and of article 294 of Royal Decree of 3 July 1996 in execution of the law on compulsory health care and compensation insurance, coordinated on 14 July 1994, of 14 November 2014. Not officially available[176] (**Circular letter OA n° 2014/440**).	**Circular letter OA n° 2014/440.**	
2. Is this the same procedure as for PA under the Social Security Coordination Regulations?	**Answer:** **Yes ☒ No ☐**		N/A
3. What body is in charge of handling the PA applications?	**Answer:**	**Source(s):** Royal Decree of 3 July 1996 Article 294, § 2/1.	N/A

[175] 24 JUIN 2014. - Arrêté ministériel fixant la liste des prestations de santé soumises à une autorisation préalable en vertu de l'article 294, § 1er, 14°, deuxième alinéa, sous a), de l'arrêté royal du 3 juillet 1996 portant exécution de la loi relative à l'assurance obligatoire soins de santé et indemnités, coordonnée le 14 juillet 1994. Available at http://www.ejustice.just.fgov.be/eli/arrete/2014/06/24/2014022399/justel (last accessed on 16 June 2021).

[176] This Circular is not officially published. It is an internal document for use of the NIHDI which was provided (in its French version) to the national legal expert by the national body during the verification of the information during Task 2, for the specific purpose of this research. It only serves as a guiding document and in the most positive interpretation may be categorised as soft law.

(e.g., where and to whom PA applications have to be submitted?)	The bodies responsible for handling the applications for reimbursement are (the medical officer of the) sickness funds. Sickness funds are non-profit, private players that operate the reimbursement system of health care services covered by the compulsory health insurance for their members and the payment of a replacement income in case of long-term illness. All Belgian residents must be affiliated to a sickness fund of their choice or to the public institution for health and disability insurance. In Belgium multiple sickness funds exist, such as the union of Christian sickness funds, the union of neutral sickness funds, the union of socialist sickness funds, the union of liberal sickness funds, and the union of independent sickness funds. There is also a public sickness fund, i.e., the public institution for health and disability insurance (HZIV-CAAMI). Moreover, a designated sickness fund for people working for the Belgian Railway company also exists.	Information on the sickness funds and on how to apply for PA is available at the following links: https://www.riziv.fgov.be/fr/professionnels/autres/mutualites/Pages/contactez-mutualites.aspx https://www.health.belgium.be/en/how-should-you-apply-prior-authorisation	
4. Who is entitled to apply for PA? *(e.g., can the patients apply themselves, or is treating doctor filing/partially filling the request, etc.)*	**Answer:** *If there is a national doctor involved, is there a requirement that this doctor is contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA?* The patient, or his legal representative can apply himself. The application should contain an extensive medical report commissioned by a physician specialised in the treatment needed for the disease. This physician must be entitled to practice medicine in a member state of the EU or of the EER.	**Source(s):** Royal Decree of 3 July 1996 Article 294, § 2/1.	No additional information

	Based on the legislation, it is the responsibility of the patient to send the application together with the extensive medical report to the sickness fund to get PA. Despite this, it is also allowed that the specialised physician himself sends the documentation to the sickness fund. But this is not provided in the law. In practice it is often rather the physician who suggests to seek healthcare abroad (referring physician), than it is the patient who comes up with this plan and needs an extensive medical report in order the gain reimbursement.		
5. Is there a specific application form/module which the person seeking PA needs to submit?	**Answer:** *If yes, please specify:* *- What information is required* *- Is the information mandatory, optional, or recommended?* *- Is this application form/modules available online?* *- Does the form have to be submitted in paper or can it be submitted electronically?* There is no specific application form for seeking/requesting PA in execution of the Directive 2011/24/EU (nor available online, nor indicated in the legislative sources identified). However, a standardized document of the extensive medical report was agreed upon between the sickness funds. The document is rather a standardised file of the extensive medical report that needs to be submitted together with the application form (examples of the medical report template is provided in the column 'Sources'). It offers the referring physicians a guide to frame the motivation of the care abroad. It is	**Source(s):** Charter of the Social Insured Person Circular letter OA n° 2014/440. Not officially available, Title II, Chapter II, subtitle IV, A2.2 <u>Extensive medical report</u> Example for the Union of Christian healthcare funds.[177] <u>Way of submission</u> Royal Decree 3 July 1996 Article 294, § 2/1.	The form of extensive medical report offers the referring physicians a guide to frame the motivation of the care abroad. It is intended to avoid the questions for additional information.*Source: see introductory note* https://www.cm.be/media/Zorg-buitenland-application-for-healthcare-abroad_tcm47-17275.doc This information was confirmed by the contacted expert.

[177] Available at: https://www.cm.be/media/Zorg-buitenland-application-for-healthcare-abroad_tcm47-17275.doc.

	intended to avoid the questions for additional information. The form needs to be submitted by the patient through a registered letter or any way that allows to verify the date of submission (Royal Decree 3 July 1996, Article 294, § 2/1). In the form the following information needs to be provided 1. Patient details a. Name b. Belgian social security number c. Address 2. Referring doctor details a. Name + Number NIHDI b. Phone-number + e-mail address c. Address 3. Initiating applicant a. Myself as the referring doctor b. Myself at the suggestion of another doctor i. Name and address c. Myself at request of the patient 4. Medical problem a. Medical diagnosis/problem b. Relevant history c. Previous treatments and results d. Attached medical records 5. Requested healthcare a. Medical/technical description (as comprehensive as possible) b. Doctor abroad i. Name		

	ii. Credentials in terms of expertise (as comprehensive as possible) c. Name and address of the healthcare facility d. Care modalities i. Outpatient or day admission (no overnight stay) ii. Hospitalisation 1. Period: from – to 2. Hospital type: public/private e. Follow-up care i. No ii. Yes 1. Description 2. Frequency 3. Possible in Belgium a. Yes b. No c. Reason 6. Circumstances of application for care abroad Other doctors consulted in Belgium from the same field as the one in which the insured party is being referred abroad, and their written advice Name + advice		

	7. Medical/technical availability of the requested healthcare in Belgium a. Availability of requested healthcare in Belgium? i. Yes: corresponding (pseudo-) nomenclature number ii. No: Standard/alternative treatment in Belgium in comparable medical situation 8. Reasons for not utilising the healthcare available in Belgium In the case of 'more favorable medical circumstances', please give reasons why in this patient's situation there is a need to diverge from the healthcare available in Belgium. 9. Date + signature		
6. What (other) documentation has to be submitted in order to substantiate a PA request?	**Answer:** *If applicable, please specify:* *- What documents and what particulars are required;* *- Whether there are requirements as to who has to issue the documents (e. g., a doctor contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA or any doctor);* *- Whether the submission of the documentation is optional, mandatory, or recommended* See previous question n.5:	**Source(s):** Royal Decree of 3 July 1996 Article 294, § 2/1. <u>Extensive overview:</u> Circular letter OA n° 2014/440. Not officially available. Title II, Chapter II, subtitle IV. <u>Information on how to apply for PA:</u>	No additional information

	The application should contain an extensive medical report commissioned by a physician specialised in the treatment needed for the disease. This physician must be entitled to practice medicine in a member state of the EU or of the EER.	https://www.health.belgium.be/en/how-should-you-apply-prior-authorisation.	
7. **Are there any costs** associated with the handling of the PA request? - *Direct costs (e.g., fixed costs for submitting or filing a PA request).* - *Indirect costs* (*e.g., translations, stamps, etc).*	**Answer:** *Direct costs:* None identified. *Indirect costs:* 1. The application needs to be submitted to the sickness fund through a registered letter. The applicant must pay for the costs for this registered letter. 2. If for the drafting of the extensive medical report, a medical consultation is needed, the costs for this medical consultation.	**Source(s):** N/A	N/A
8. Are there any specific **time requirements** linked to a PA request? (*e.g., time within which a requesting person must submit the PA application and/or time within which the requested body must take a decision on the PA request, etc.*).	**Answer:** *- If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* **Time requirements**: the requested body needs to respond to the application within 45 calendar days after submission. This period of 45 days starts the day after the day that the requested body received the application. If the advisory physician needs additional information, the period of 45 days is suspended. It continues the day after receival of the additional information. (Royal Decree of 3 July 1996 Article 294, § 2/2). **Consequences if the deadlines are not met:**	**Source(s):** Royal Decree of 3 July 1996 Article 294, § 2/2.	No additional information

	If the deadline is missed by the requested body, the approval is assumed to be granted. (Royal Decree of 3 July 1996 Article 294, § 2/2).		
9. Are there **differences in the procedural/administrative requirements for requesting PA** based on, for instance, the type of treatment for which PA is requested, the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* No relevant procedural differences identified. Note: very limited exceptions apply with regards to long-term care revalidation due to the delegated competences of the Regions in this regard. For this type of care (only) procedural rules have been set out at regional level, solely by the following two regions, and respective regional regulations: **1. For the Flemish Region:** Decree of the Flemish Government of 7 December 208, implementing the Decree of 6 July 2018 on the takeover of the sectors of psychiatric care homes, sheltered housing initiatives, rehabilitation agreements, rehabilitation hospitals and multidisciplinary support teams for palliative care, Official Journal of 28 January 2019, page 8863[178] (**Decree of the Flemish Government 7 December 2018**) **2. For the German speaking Region:**	**Source(s):** **For the Flemish Region:** Decree of the Flemish Government 7 December 2018 Article 225, § 1. **For the German speaking Region:** Decree of the Government of 19 December 2019 Articles 12-16.	Dure to the system of federal/regional competence described in Part 0 of the present report. For more information on the differing regulations existing for the reimbursement of long-term care revalidation in the Flemish, as well as in the German speaking Region, please see the annex to this report.

[178] 7 DECEMBRE 2018. - Arrêté du Gouvernement flamand portant exécution du décret du 6 juillet 2018 relatif à la reprise des secteurs des maisons de soins psychiatriques, des initiatives d'habitation protégée, des conventions de revalidation, des hôpitaux de revalidation et des équipes d'accompagnement multidisciplinaires de soins palliatifs. Available at: http://www.ejustice.just.fgov.be/eli/arrete/2018/12/07/2019030061/justel (last accessed on 16 June 2021).

	Decree of the Government of 19 December 2019 on the introduction of a transitional arrangement for the procedure to obtain prior permission for a cost transfer or an agreement to a contribution towards the costs in the context of long-term care rehabilitation abroad, Official Journal of 4 May 2019, page 30137[179] (**Decree of the Government of 19 December 2019**). The text of the relevant legislation (cf. Sources) is provided as annex to this questionnaire.		
10. Is there a specific PA form (i.e., form used for issuing/granting PA) and, if the answer is positive, what form?	**Answer:** No. I However, between the NIHDI and the sickness funds it was agreed to use a document *ad hoc* that needed to contain certain minimal data based on the Law on the Charter of the Social Insured Person, of 11 April 1995, Official Journal 6 September 1995, page 25433[180] (**Charter of the Social Insured Person**). Based on the Circular Letter OA n° 2014/440 at least the following information is mentioned: - Personal data of the insured person - Reference to article 294, § 1, 14° - Description of the treatment with reference to the specialism - Duration of the treatment (date of begin and date of end) - Name of the hospital (and if possible the treating specialist-physician		

[179] 19 DECEMBRE 2019. - Arrêté du Gouvernement réglant de manière transitoire la procédure à suivre pour obtenir une autorisation préalable ou un accord aux fins de prise en charge des frais ou de participation aux frais engagés pour une revalidation long term care à l'étranger. Available at : http://www.ejustice.just.fgov.be/eli/arrete/2019/12/19/2020200927/justel (last accessed on 16 June 2021).

11. Please list any other administrative requirements in your country in relation to the PA procedure for cross-border healthcare.	**Answer:** In the document mentioned in "Sources" a chapter was written on the transposition of the Directive in Belgium in 2014 by an expert of the NIHDI, Chris Segaert. The text is only available in Dutch.[181] According to the expert, since 2014 some details in the procedures seem to have changed in a non-official way (inter alia not published agreement between sickness funds and NIHDI).	C. Segaert, "Toegang tot en terugbetaling van medisch noodzakelijke geneeskundige zorg gedurende een tijdelijk verblijf en geplande geneeskundige zorg in de Europese Economische Ruimte en Zwitserland voor Belgische verzekerden", Informatieblad bijzonder nummer.[182]	There are only very limited texts available in Belgium on the details of the transposition of Directive 2011/24/EU. Most texts only describe the general approach of the Directive. The transposition of Articles 7, 8 and 9 of Directive 2011/24/EU into Belgian law was done through a Royal Decree. Therefore, it was only a minimalized conversion, presented as an additional exception to the general rule of article 136 of the law on compulsory health care and compensation insurance, coordinated on 14 July 1994, executed in article 294 of the Royal Decree of 3 July 1996, that only national healthcare costs are reimbursed.

SECTION 2 REIMBURSMENT PROCEDURE(S)				
Questions	**Answer:**	**Sources**	**Does/do the identified requirement(s) also apply domestically? (i.e., is the requirement non-discriminatory?)**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions	**Answer:** Law on compulsory health care and compensation insurance, coordinated on 14 July 1994, Official	**Source(s):** Law of 14 July 1994	N/A	N/A

[181] Note of the National expert: Chris Segaert is also the person that was contacted as external expert for the verification of the information contained in the present report.
[182] C. Segaert, "Toegang tot en terugbetaling van medisch noodzakelijke geneeskundige zorg gedurende een tijdelijk verblijf en geplande geneeskundige zorg in de Europese Economische Ruimte en Zwitserland voor Belgische verzekerden", Informatieblad bijzonder nummer – Bulletin d'information hors série 2014, NIHDI, Brussels, 110-131, available online at: https://www.riziv.fgov.be/SiteCollectionDocuments/informatieblad-bijzonder-nummer-bulletin-information-hors-serie-2014.pdf, last accessed on 16 June 2021.

lay out the requirements related to reimbursement procedures for cross-border healthcare under Directive 201/24/EU?	Journal of 27 August 1994,[183] (**Law of 14 July 1994**), Article 136. Royal Decree in execution of the law on compulsory health care and compensation insurance, coordinated of 14 July 1994, of 3 July 1996 - Official Journal of 31 July 1996[184] (**Royal Decree of 3 July 1996**), Art. 294, § 1, 12°-14°, § 1/1, 2, 2/1 & 2/2	Article 136 Royal Decree of 3 July 1996 Articles 294, § 1, 12°-14° & §§ 1, 2, 2/1- 2/2		
2. Is this the same procedure as for reimbursement under the Social Security Coordination Regulations?	**Answer:** **Yes ☒ No ☐**		N/A	N/A
3. What body is/are responsible of handling the reimbursement applications? (e.g., where and to whom reimbursement applications have to be submitted?)	**Answer:** The sickness funds, as described in the answer to question 3 of Section 1 above.	**Source(s):** Law of 14 July 1994 Article 3. Royal Decree of 3 July 1996 Articles 294, § 1, 12°-14°. Law on the sickness funds and the unions of sickness funds of 6 August 1990, Official Journal of 28 September	N/A	N/A

[183] 14 JUILLET 1994. - Loi relative à l'assurance obligatoire soins de santé et indemnités coordonnée le 14 juillet 1994. Available at http://www.ejustice.just.fgov.be/eli/loi/1994/07/14/1994071451/justel (last accessed on 16 June 2021).
[184] 3 JUILLET 1996. - Arrêté royal portant exécution de la loi relative à l'assurance obligatoire soins de santé et indemnités, coordonnée le 14 juillet 1994. available at http://www.ejustice.just.fgov.be/eli/arrete/1996/07/03/1996022344/justel (last accessed on 16 June 2021).

		1990, page 18475[185] (**Law on the sickness funds**), Articles 3-6, §1 & 7 §.		
4. Is there a specific application form/module which the person seeking reimbursement needs to submit?	**Answer:** No not officially. *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?* A standardised specific form is not officially provided/available in the sources consulted. The patient must therefore request it to its insurance fund of affiliation. In some instances, the form seems to be available online (example of the Christian mutualite). And in that case you included the information that is requested by the Christian mutualite (name, etc etc). Where mandatory the information is indicated with (M). The information asked is: 1. Name 2. Nationality 3. National security number 4. Address 5. Telephone number 6. E-mail address	**Source(s):** For an example of the unofficial standard document of Christian healthcare funds.[186]	**Yes** ☐ **No** ☒ The requirements do not apply domestically (they vary depending on the insurance fund).	It was made clear by the contacted expert that the sickness funds have created an unofficial standard document that needs to be completed in order to get reimbursed for costs of healthcare services received abroad.

[185] 6 AOUT 1990. - Loi relative aux mutualités et aux unions nationales de mutualités. Available at: http://www.ejustice.just.fgov.be/eli/loi/1990/08/06/1990022427/justel (last accessed on 16 June 2021).
[186] Available at: https://www.cm.be/media/Aanvraag-tegemoetkoming-verzorging-buitenland_tcm47-24481.pdf.

	7. Country in which the healthcare services were provided (if cruise ship: place of departure and place of arrival) (M) 8. Period of visit (M) 9. Reason of visit (M) 10. Description of the circumstances of the treatment (M) 11. Name of medical advisor 12. Amount paid 13. Whether you have a private insurance (M)) and if so which 14. Proof of healthcare services 15. Date when the document was completed 16. Signature of the patient or representative. (M) The form has to be submitted to the insured person's sickness fund in paper.			
5. What (other) documentation has to be submitted in order to substantiate a reimbursement request?	**Answer:** *If applicable, please specify:* *- What documents and what particulars are required;* *- Whether there are requirements as to who has to issue the documents (e. g., a doctor contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA or any doctor);* *- Whether the submission of the documentation is optional, mandatory, or recommended* There is no clear information on which documents are required. The example module which was identified for one of the insurance providers (Cfr. Sources) only states that "proof that the costs for which reimbursement is asked, really cover costs for healthcare services provided" is to be submitted	**Source(s):** Law of 14 July 1994 Article 53, § 1.	**Yes** ☐ **No** ☒	This is the general approach towards reimbursement. This answer was provided based on e-mail contact with the Christian Sickness Fund. It was explained by the contacted expert that there are no concrete rules on which specific proof needs to be provided.

	together with the application, without specifying further what such proof consists of. Moreover, according to Article 53, § 1 of Law of 14 July 1994: "The sickness funds may not reimburse if a certificate of provided care, or equivalent, cannot be presented".			
6. Are there any costs associated with the handling of the reimbursement request? - *Direct costs (e.g., fixed costs for submitting or filing a reimbursement request, proportion deducted from the reimbursable amount).* - *Indirect costs* (*e.g., translations, stamps, etc).*	**Answer:** *Direct costs:* None identified. *Indirect costs:* Potential postal costs.	**Source(s):** N/A	**Yes** ☐ **No** ☒	No additional information
7. Are there any specific time requirements linked to a reimbursement request? (*e.g., time within which the reimbursement requests must be submitted and/or time within the requested body must handle the*	**Answer:** *- If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* **Time requirements:** time requirements are not indicated in the legislation with specific regards to reimbursement of cross-border healthcare. However, since the reimbursement conditions are the same as for healthcare services received in	**Source(s):** Law of 14 July 1994 Article 174, 3.	**Yes** ☒ **No** ☐	This is the general principle that applies in Belgium for reimbursement.

request and/or reimburse the costs, etc.).	Belgium, the general period of 2 years after having received the healthcare services applies. If the requesting person applies after two years, he will not get his costs reimbursed. In fact, according to Article 174, 3° of Law of 14 July 1994: "The claim for payment of medical benefits lapses two years after the end of the month in which the care was provided or whether or not these benefits were paid through the third-party payer scheme". **Consequences if deadlines are not met:** Not identified in the legislative/regulatory framework.			
8. Are there any non-reimbursable thresholds, deductions *(except the deductions for administrative costs mentioned above) etc.?*	**Answer:** *If yes, please specify the thresholds.* None identified.	**Source(s):** N/A	**Yes** ☐ **No** ☐ N/A	No additional information
9. In instances where a PA (or prior-notification) has already been issued, is a separate/simplified procedure available for requesting reimbursement? **applicable only if the country has a PA system.*	**Answer:** *If yes, please describe the simplified procedure.* No such procedure identified.	**Source(s):** N/A	**Yes** ☐ **No** ☒	No additional information

10. Are there additional administrative/procedural requirements for reimbursement depending on, for instance, the type of treatment for which reimbursement is requested, or the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* Cf. PA-procedure describe under Section 1.	**Source(s):** Royal Decree of 3 July 1996 Article 294, § 1, 14° & §§ 2/1- 2/2 **For the Flemish Region:** Decree of the Flemish Government 7 December 2018 Article 225, §2-238. **For the German speaking Region:** Decree of the Government of 19 December 2019 Articles 22-26.	**Yes** ☐ **No** ☒	With reference to the remark made with regard to the competence of the Regions in Belgium, a differing regulation exists for the reimbursement of long term care revalidation in the Flemish, as well as in the German speaking Region. The text of the relevant legislation is provided in annex.
11. Please list any other administrative requirements in your country in relation to the procedures of reimbursement of cross-border healthcare.	**Answer:** None identified.	**Source(s):** Circular letter OA n° 2014/440. Not officially available.	**Yes** ☐ **No** ☒	The contacted experts refers to the Circular Letter n° 2014/440 that provides an overview about the entire procedure.

Part 2: Checklist for verification with national/regional body

Name of the body: National Institute for Health and Disability Insurance
Country/Region: Belgium
Date of verification call: 14/06/2021

Template for the Data Collection	Aspects to be verified *Tick the boxes if the information in the template for the data collection has been verified and/or complemented by the national body*		Comments *Include any additional comments and/or information provided by the contacted body*
Section 1 – Prior Authorisation			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Justification/purpose of the identified requirement(s) (Column 4)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	With regard to the competent authority, the contacted body mentioned that a very small part of the federal competence on the reimbursement of health services was granted to the regions after the last constitutional reform in Belgium in 2014. It was explained by the contacted body how this small part of competence of the Regions should be interpreted. It was also made clear that due to lacking regulation for the Walloon Region as well as for the Region of Brussels Capital, this competence is very unclear. The feedback received by the contacted body has been incorporated in the questionnaire (Section 1).
Section 2 - Reimbursement			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Whether the requirement applies domestically (Discriminatory assessment) (Column 4) ▪ Justification/purpose of the identified requirement(s) (Column 5)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	

Belgium - Annex: legislation with regard to the reimbursement of long term care revalidation in the Flemish Region and the German speaking Region

German speaking region
http://www.ejustice.just.fgov.be/eli/arrete/2019/12/19/2020200927/justel
Art. 12-16 & 22-26

Art. 12: Previous inquiry
Before a planned long-term care rehabilitation abroad, the applicant submits an application to the administration with a view to taking over costs within the meaning of Article 5 for the costs associated with those rehabilitation benefits.
Art. 13: Application form
To this end, the Minister makes application forms available in which the following elements are requested:
1° surname, first name, national register number, nationality, date of birth, place of residence and address, telephone number, e-mail address and insurance status of the applicant;
2° a report drawn up, dated and signed by a specialist doctor who specializes in the treatment of the condition in question and who is legally authorized to practice medicine in Belgium. That report shall contain the following elements:
(a) surname and first name of the applicant;
b) name, first name and INAMI number of the doctor;
c) diagnosis showing that long-term care rehabilitation is necessary;
d) an indication of whether it is an initial application within the meaning of this Subsection or an application for renewal within the meaning of Subsection 2;
e) indication of the nature of the measure for long-term care rehabilitation within the meaning of Annex 1;
f) justification as to why a measure on long-term care rehabilitation within the meaning of Annex 1 is necessary;
g) probable duration of long-term care rehabilitation;
h) indication of the objectives aimed at with long-term care rehabilitation;
i) reasons why the rehabilitation measure should be provided in the specifically named institution abroad;
j) estimate whether the applicant will complete the measure so that the medical objectives can be achieved;
k) confirmation that the applicant does not have a contagious disease or multidrug-resistant infection;
3° a treatment plan drawn up, dated and signed by the foreign rehabilitation institution and comprising the following elements:
(a) surname and first name of the applicant;
b) contact details of the foreign institution;
c) nature of the measure;

d) indication of the objectives that are intended with the rehabilitation provision;
e) indication of the intended therapies and of the intended medical and medicinal benefits;
f) duration of the benefits in kind, number of benefits and scope of the benefits, as well as a description of the course of the day;
g) costs of long-term care rehabilitation measures.
The application is dated and signed by the applicant.

Art.14: Completeness check and administrative control

§ 1 - Within a period of ten working days from receipt of the application referred to in Article 13, the administration decides whether:
1° which is complete;
2° the applicant meets the conditions stated in Article 2, 1°.
§ 2 - If the application is complete, the administration will inform the applicant.
If the applicant has not submitted all the documents necessary to substantiate his application or if the application is incomplete, the administration shall inform him in writing of any additional information or documents he must submit within thirty working days of notification of the letter that are requested. The period for drawing up an opinion in accordance with Article 15 is suspended from that reminder until the requested documents are presented.
If the additional documents or information are not notified within the term stated in the second paragraph, the administration will declare the application inadmissible.
The applicant will be notified of the inadmissibility of the application by registered letter.
§ 3 - If the conditions stated in Article 2, 1°, are not met, the administration will refuse the application.
The administration will send the refusal decision to the applicant by registered letter. That decision shall state the following:
1° the possibility to lodge an appeal;
2° the competent authorities that take cognizance thereof;
3° the deadlines and formal requirements to be complied with.

Art 15: Drafting an advice

§ 1 - If it appears from the check referred to in Article 14, § 1, that the conditions stated therein are met, the administration shall draw up an opinion - within a period of thirty working days from the date on which the application is complete - on whether the conditions set out in Article 20 of Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems are fulfilled.
In drawing up the advice, the administration can base itself on the position of one or more external experts.
Within the period specified in the first paragraph, the administration may request other documents from the applicant or his attending physician that are necessary to draw up the advice or may invite them for an interview.
If the applicant and, where appropriate, his doctor do not appear at the interview or do not provide the requested documents, the administration will base its advice on the elements at its disposal.
§ 2 - If the conditions stated in paragraph 1, first paragraph, are fulfilled, the administration recommends granting a prior authorization in the form of an S2 form.

Art. 16: Decision of the Minister

§ 1 - Within a period of five working days after receipt of the advice from the administration, the Minister decides on the basis of that advice whether the requested prior authorization will be granted or refused.

The decision by which the Minister grants or refuses the prior permission will be sent to the applicant by the administration. A refusal decision is sent by registered mail and contains:

1° the possibility to lodge an appeal;

2° the competent authorities that take cognizance thereof;

3° the deadlines and formal requirements to be complied with.

§ 2 - If the conditions stated in Article 15, § 1, first paragraph, are fulfilled, the administration attaches the S2 form to the decision of the Minister.

§ 3 - If it appears from the advice that the benefits in kind for which a transfer of costs is requested are not benefits in kind for long-term care rehabilitation for which the German-speaking Community is competent in accordance with Article 6, second paragraph, 2°, but are benefits in kind for which the If the Federal State is competent, the Minister will refuse the application and the administration will forward the application to the competent health insurance fund, with the consent of the applicant and that competent health insurance fund.

Art. 22: Application

Either before or after long-term care rehabilitation abroad, the applicant can submit an application to the administration in order to obtain approval with a view to a contribution towards the costs within the meaning of Article 6 in connection with those rehabilitation benefits.

Art. 23: Application form

The Minister shall make application forms available for this purpose.

In addition to the elements mentioned in Article 13, the application forms request the following elements:

1° the applicant's account number;

2° invoices and proofs of payment regarding the treatment followed abroad

Art. 24: Completeness check and administrative control

§ 1 - Within a period of ten working days from receipt of the application referred to in Article 23, the administration decides whether:

1° which is complete;

2° the applicant meets the conditions stated in Article 2, 1°.

§ 2 - If the application is complete, the administration will inform the applicant.

If the applicant has not submitted all the documents necessary to substantiate his application or if the application is incomplete, the administration shall inform him in writing of any additional information or documents he must submit within thirty working days of notification of the letter that are requested. The period for drawing up an opinion in accordance with Article 25 is suspended from that notice until the requested documents are presented.

If the additional documents or information are not notified within the term stated in the second paragraph, the administration will declare the application inadmissible.

The applicant will be notified of the inadmissibility of the application by registered letter.

§ 3 - If the conditions stated in Article 2, 1°, are not met, the administration will refuse the application.

The administration will send the refusal decision to the applicant by registered letter. That decision shall state the following:

1° the possibility to lodge an appeal;

2° the competent authorities that take cognizance thereof;

3° the deadlines and formal requirements to be complied with.

Art. 25: Drafting an advice

§ 1 - If it appears from the check referred to in Article 24, § 1, that the conditions stated therein are fulfilled, the administration will draw up an opinion.

In the case of an application for prior consent, the administration checks within a period of thirty working days from the time when the application is complete, whether:

1° the conditions stated in Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems are met;

2° the conditions stated in Article 6, second paragraph, 1° to 5°, are fulfilled.

In the case of an application for subsequent consent, the administration checks, within a period of thirty working days from the moment the application is complete, whether the conditions stated in Article 6, second paragraph, 1° to 5° and 7° , be fulfilled.

§ 2 - For the preparation of the advice, the administration can base itself on the position of one or more external experts.

Within the time limits specified in § 1, paragraph 2 and paragraph 3, the administration may request other documents from the applicant or his attending physician that are necessary to prepare the advice or may invite them for an interview.

If the applicant and, where appropriate, his doctor do not appear at the interview or do not provide the requested documents, the administration will base its advice on the elements at its disposal.

§ 3 - If the conditions stated in § 1, second paragraph, 1°, are fulfilled, the administration recommends the granting of a prior authorization in the form of an S2 form, unless the applicant applies Articles 6 and 7 wishes.

If the conditions stated in § 1, second paragraph, 2°, are fulfilled, the advice of the administration shall contain:

1° the period to which the reimbursement of costs relates;

2° the name and address of the institution where the long-term care rehabilitation will take place;

3° the name and address of the responsible foreign doctor;

4° the description of the measures for long-term care rehabilitation;

5° the duration and frequency of the measures relating to long-term care rehabilitation;

6° the amount of the contribution towards the costs of the measures relating to long-term care rehabilitation.

If the conditions stated in § 1, third paragraph, are fulfilled, the advice of the administration shall contain:

1° the duration and frequency of the long-term care rehabilitation for which a contribution towards the costs is granted;

2° the amount of the contribution towards the costs of the measures relating to long-term care rehabilitation.

Art. 26. Decision of the Minister

§ 1 - Within a period of five working days after receipt of the advice from the administration, the Minister decides on the basis of that advice whether the requested contribution towards the costs will be granted in whole or in part, or whether the requested contribution towards the costs will be refused.

The decision whereby the Minister grants or refuses a full or partial contribution towards the costs will be sent to the applicant by the administration. A refusal decision is sent by registered mail and contains:

1° the possibility to lodge an appeal;

2° the competent authorities that take cognizance thereof;

3° the deadlines and formal requirements to be complied with.

§ 2 - If the conditions stated in Article 25, § 1, second paragraph, 1°, are fulfilled, the administration attaches the S2 form to the decision of the Minister.

If the conditions stated in Article 25, § 1, second paragraph, 2°, are fulfilled, the decision of the Minister contains the elements mentioned in Article 25, § 3, second paragraph.

If the conditions stated in Article 25, § 1, third paragraph, are fulfilled, the decision of the Minister contains the elements mentioned in Article 25, § 3, third paragraph.

§ 3 - If it appears from the advice that the benefits in kind for which an allowance is requested are not benefits in kind for long-term care rehabilitation for which the German-speaking Community is competent in accordance with Article 6, second paragraph, 2°, but are benefits in kind for which the Federal State is competent, then Article 16, § 3, applies mutatis mutandis.

Flemish region

http://www.ejustice.just.fgov.be/eli/arrete/2018/12/07/2019030061/justel

Art. 224-238

Art. 224: This title partially transposes the 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare.

Art 225: § 1. For planned rehabilitation services for which the care user must stay at least one night in a hospital in a Member State of the European Union other than Belgium, in Iceland, in Liechtenstein, in Norway and in Switzerland, a prior authorization for planned care in accordance with the 2011 Directive is required. /24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare. For all other forms of rehabilitation benefits abroad, prior permission is required, for which the same touchstone is used as for the decision to approve, referred to in Article 205.

§ 2. The care user can claim an allowance for planned rehabilitation benefits abroad if all of the following conditions are met:

1° the rehabilitation services are part of the care offer of the rehabilitation facilities, for which this Decree provides an allowance;

2° the care user meets the conditions that must be met on the basis of this Decree in order for an allowance for rehabilitation benefits to be granted;

3° the rehabilitation benefits are provided by a provider who is legally authorized to practice medicine in the country where the rehabilitation benefits take place, or in a facility that can be equated with a rehabilitation facility and that offers sufficient medical guarantees or is recognized by the government of the country where it is located;

4° the care user has submitted a prior application, in accordance with Articles 229 to 238 inclusive, and has obtained approval for the rehabilitation benefits in question from the insurance institution;

5° at the time the compensation is granted, the user has already paid the costs and provides proof thereof.

The minister may determine how the proof stated in the first paragraph, 5°, is to be provided.

Art. 226: The care user can claim an allowance for travel costs related to planned rehabilitation benefits abroad, if all the following conditions are met:

1° the care user meets the conditions that must be met on the basis of this Decree in order for an allowance for travel expenses to be granted;

2° the care user can claim an allowance for planned rehabilitation benefits abroad, to which the travel costs are related;

3° the healthcare user has submitted a prior application, in accordance with Articles 229 to 238 inclusive, and has obtained approval for the travel costs in question.

Art. 227: Except in cases where the conditions stated in Article 234, 1°, are met, the amount of the allowance for planned rehabilitation benefits abroad is the weighted average of the allowances granted for rehabilitation benefits provided in rehabilitation facilities. with a comparable rehabilitation program and a comparable target group. The allowance cannot be higher than the actual costs incurred.

Art. 228: For the calculation of the allowance for travel costs related to planned rehabilitation benefits abroad, only the distance, as the crow flies, there and back, between the center of Brussels and the place of treatment is taken into account. No allowance will be made for the first 350 kilometers of the outward and return journey.

The allowance for travel costs related to planned rehabilitation benefits abroad is calculated for each care user in accordance with the following formula: the amount of the allowance per kilometer stated in the third or fourth paragraph, multiplied by the number of kilometers stated in the first member.

If the care user is younger than eighteen and the rehabilitation program is comparable to the rehabilitation program of the rehabilitation facilities whose accreditation number starts with the number 7.74.6 or 9.69, the allowance is 0.25 euros per kilometre.

If it appears from a medical report that due to the nature and seriousness of his condition the care user can only be transported in his wheelchair in a vehicle that is adapted for transport in a wheelchair, the allowance amounts to:

1° 0.25 euros per kilometer if the care user is transported in his own vehicle that is adapted for transport in a wheelchair;

2° 1.30 euros per kilometer if the care user is transported by a professional carrier in a vehicle that is adapted for transport in a wheelchair.

This article does not apply in cases where the conditions stated in article 234, 1° are fulfilled.

The amounts stated in this article are, unless stated otherwise, linked to the pivot index figure 103.04 (basis 2013=100). These amounts are adjusted in accordance with the Act of 2 August 1971 establishing a system whereby salaries, wages, pensions, allowances and allowances charged to the public treasury, certain social benefits, the remuneration limits that must be taken into account when calculating certain contributions of the social security of workers, as well as the social obligations imposed on the self-employed, are linked to the consumer price index.

This link to the index, mentioned in the sixth paragraph, is calculated and applied in accordance with Article 2 of the Royal Decree of 24 December 1993 implementing the law of 6 January 1989 to safeguard the country's competitiveness.

Art. 229: In this chapter, the following definitions apply:

1° application: the application for the allowance for rehabilitation benefits abroad, to which, where appropriate, the application for an allowance for travel costs related to those rehabilitation benefits is attached;

2° date of receipt: the date on which the complete application was received. If sent by post, this is the post date of the letter with which the complete application was sent. If the postal date is missing, it is the date on which the insurance company received a complete application. An application is considered complete if the application form, stated in Article 231, has been completed in full.

Art 230: Prior to the planned rehabilitation benefits and travel costs abroad, the care user must submit an application for the allowance for rehabilitation benefits and, where appropriate, for the travel costs related to these rehabilitation benefits to the insurance institution with which he is affiliated or registered.

The application can only be submitted after the care user or his legal representative has taken cognizance of the rehabilitation agreements, whose rehabilitation program is comparable to the prescribed foreign rehabilitation program stated in the application.

Art 231: The agency makes an application form available on its website. The insurance institution also provides a French, English and German version of the application form.

The application form contains at least the following parts:

1° a detailed description of the foreign rehabilitation program that is prescribed;

2° which similar rehabilitation program consists of a rehabilitation facility as stated in the decree of 6 July 2018;

3° the motivation for not opting for a rehabilitation facility;

4° an additional document if an allowance for travel costs for transport in a vehicle that is adapted for transport in a wheelchair is requested: a standardized medical report showing that the care user is unable to leave his wheelchair due to the nature and seriousness of his condition during transport.

Documents motivating the application can be attached to the application form.

The application form is completed, signed and dated by a specialist doctor who specializes in the rehabilitation in question.

Art. 232: The insurance institution with which the healthcare user is affiliated or registered is charged with the administrative control of the application and checks:

1° the insurance status of the healthcare user, stated in Article 4 of the Decree of 6 July 2018;

2° compliance by the care user with the rules on cumulation, stated in the rehabilitation agreement and in Articles 28 to 38 of this Decree.

The cumulation of allowances is checked, among other things, on the basis of the cumulative provisions stated in the rehabilitation agreements, whose rehabilitation program is comparable to the prescribed foreign rehabilitation program stated in the application.

If necessary, the insurance institution will request missing information from the healthcare user.

If the conditions stated in the first paragraph are not met, the application will be administratively refused by the insurance institution with which the healthcare user is affiliated or registered. Contrary to article 233, the insurance institution takes the decision to refuse, without prior unanimous advice from the Expert Committee. The decision to refuse the application states the reason for the refusal, the options for appeal and the time limits within which the appeal must be lodged. The decision to refuse is sent to the care user by registered mail.

Art 233: The insurance statement sends the application to the Expert Committee within ten working days of the date of receipt.

The term stated in the first paragraph is suspended if the insurance institution requests missing information from the healthcare user. The period starts to run again on the working day after the day on which the insurance institution has received the additional information.

Art 234: The Expert Committee examines the file and decides whether the following conditions have been met:

1° the conditions stated in Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems;

2° the conditions stated in Article 225, first paragraph, 1° to 3°, of this Decree and, where appropriate, the conditions referred to in Article 226, 1° and 2°, of this Decree.

Art. 235: The Expert Committee issues a unanimous opinion to the insurance institution within fifteen working days of the day on which it has received the application from the insurance institution.

In the event of a positive advice in cases where the conditions stated in Article 234, 1°, are met, the Expert Committee recommends granting prior permission in the form of a form S2.

In the event of a positive advice in cases where the conditions stated in Article 234, 2°, are met, the advice of the Expert Committee shall state the following information:

1° the period of the allowance;

2° the name and address of the institution where the rehabilitation is provided;

3° the name and full address of the responsible foreign doctor;

4° a description of the rehabilitation benefits;

5° the period and frequency of the rehabilitation benefits;

6° the amount of the allowance for rehabilitation benefits and, where applicable, travel expenses.

The term stated in the first paragraph is suspended if the Expert Committee needs additional information from the healthcare user. The Expert Committee asks the insurance institution to request the missing information from the healthcare user. The period stated in the first paragraph starts again on the working day on which the application is re-processed by the Expert Committee.

Art 236: On the basis of the unanimous advice of the Expert Committee, the insurance institution with which the care user is affiliated or registered takes a decision to grant full or partial approval or to refuse the requested compensation.

Within five working days of the day on which the insurance institution has received the opinion of the Expert Committee, the insurance institution informs the healthcare user of the decision to approve or refuse the requested compensation in whole or in part and, if applicable, of the reasons for the refusal, the possibilities of appeal and the time limits within which the appeal must be lodged. The decision to refuse is sent to the care user by registered mail.

In cases in which the conditions stated in Article 234, 1°, are met, the insurance institution attaches form S2 to the decision for full or partial approval.

In cases in which the conditions stated in Article 234, 2°, are met, the decision to approve the insurance institution in whole or in part shall state the information included in the advice of the Expert Committee, referred to in Article 235, paragraph 3.

Art. 237: The period for which the requested allowance can be granted starts at the earliest on the day after the healthcare user has received the decision from the insurance institution with which the healthcare user is affiliated or registered.

If the insurance institution takes a decision for full or partial approval and does not provide that decision to the care user within thirty working days of the date of receipt, the period for which an allowance can be granted will start at the earliest on the day after a period of thirty working days that follows. on the date of receipt.

If the insurance institution takes a decision to refuse and does not provide that decision to the healthcare user within thirty working days of the date of receipt, the application is deemed to have been approved by the insurance institution. The period for which an allowance can be granted in that case starts at the earliest on the day after a period of thirty working days following the date of receipt, and ends after a period of ten working days following the day of the decision to refuse.

Art. 238: If the insurance institution, in accordance with Article 232, fourth paragraph, has taken a decision to refuse on the basis of an infringement of the prohibitions on cumulation stated in this Decree, and the healthcare user submits a new application for the same rehabilitation benefits and, where applicable, the same travel costs. as the original application, the healthcare user adds an additional statement of reasons for the cumulation of allowances to the application.

The insurance institution completes the new application, stated in the first paragraph, with information about the allowances for rehabilitation benefits that have already been awarded, on the basis of which the cumulative provisions can be re-evaluated. The insurance institution submits the new application to the agency within the term stated in Article 233, first paragraph. In derogation from article 232, it is not the insurance institution that assesses, but the Experts Committee compliance with the rule on cumulation. The Expert Committee carries out this assessment in the context of the investigation referred to in Article 234.

BULGARIA – COUNTRY REPORT

Part 0: Preliminary Assessment

1. **Please indicate whether the rules governing the administrative procedures/requirements for requesting PA and reimbursement under Directive 2011/24/EU in your country are set out at:**

A. National level ☒

B. Decentralised/regional/local level ☐

In case (1.B): Please indicate the two most relevant jurisdictions in your country (i.e., in terms of population):

Region/jurisdiction: 1:

Region/jurisdiction 2:

NOTE: In case (1.B) the template for the data collection (Part 1) should be complete twice, once for each of the two most relevant regions/jurisdiction indicated above.

2. **Please indicate the national body best suited to verify the accuracy of the information collected in Part 1, and justify your selection.**

Depending on the characteristics of your national healthcare system, the relevant body may be: a) *the national social security body*; or b) *an insurance fund*. In the latter case, please indicate the most representative fund (e.g., the one with the highest number of affiliations).

Body to be contacted for Task 2: Bulgarian National Health Insurance Fund (the NHIF) and Bulgarian Ministry of Healthcare

(In case 1.B, please indicate two relevant bodies, one respectively for each Region/jurisdiction)

Reasons for Selection:

The costs for cross-border healthcare are reimbursed either by the budget allocated to the NHIF or the Ministry of Healthcare, depending on the respective healthcare services/ products. The administrative requirements with regard to PA as well as with regard to reimbursement of costs differ depending on whether the procedure is before the NHIF or before the Ministry of Healthcare, therefore both were contacted with requests for assistance in the framework of the present study. Both the NHIF and the Ministry of Healthcare replied to our requests and provided us with clarifications and verification of the answers to the questions of the present questionnaire. Therefore, we have multiplied the table within Section 3 so as to be able to include the feedback from both the NHIF and the Ministry of Healthcare.

Part 1: Questionnaire

*__Note 1__: In cases where administrative requirements are set out in the legislative/regulatory framework at decentralised/regional/local level, please complete the template for the data collection twice, once for each of the two most relevant regions/jurisdictions (e.g., in terms population).

__*Note 2__: Setting out a Prior Authorisation (PA) system is optional for Member States. Should your country not have a system of PA in place under Directive 2011/24/EU, Section 1 will not need to be completed.

SECTION 1 PRIOR AUTHORISATION PROCEDURE(S)			
Questions	**Answer**	**Sources**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to PA procedures for a cross-border healthcare under Directive 2011/24/EU?	**Preliminary note:** In Bulgaria the PA procedures vary depending on the body which reimburses/ covers the costs for cross-border healthcare. Health insured persons may exercise their right to cross-border healthcare when the healthcare is included in the package of health activities, financed either by the budget of the **National Health Insurance Fund (the NHIF)**[187] or by the	**Source(s):** Article 80e(3) of the Health Insurance Act Article 80g(1) and (3) of the Health Insurance Act	N/A

[187] According to Article 19(1) of Ordinance No 5 of 21.03.2014 on the terms and conditions for exercising the rights of patients in cross-border healthcare (Ordinance No 5) the National Health Insurance Fund (NHIF) reimburses, subject to a PA, the costs for the following healthcare services, medicinal products, and medical devices, listed within Annex to Article 19(1) of Ordinance No 5:
o Healthcare services provided according to Ordinance No 9 of 2019 on Determining the Package of Healthcare Activities Guaranteed by the Budget of the National Health Insurance Fund (Ordinance No 9) - hospital treatment which requires hospital stay of more than 48 hours;
o Medical devices applied in the hospital medical care, according to the list under Article 13(2) of Ordinance No 10 of 2009 on the conditions, procedure, mechanism and criteria for payment by the National Health Insurance Fund of medicinal products and medical devices, and dietary foods for special medical purposes (Ordinance No 10) ;
o Medical healthcare provided in the framework of outpatient procedures for nuclear medical computed tomography imaging;
o Medicinal products included in Annex No 2 of the Positive Pharmaceutical List under Article 262(6), item 2 of the Pharmaceutical Products in Human Medicine Act , intended for treatment of malignant diseases in the hospital medical care and paid by the National Health Insurance Fund beyond the value of the respective clinical pathways and procedures;

	budget of the **Ministry of Healthcare.**[188] (Article 80e(3) of the Health Insurance Act[189]) The Minister of Healthcare, upon proposal of the Director of the NHIF, determines by an Ordinance the health services, medicinal products and medical devices for which reimbursement of the costs for cross-border healthcare requires PA, as well as the conditions and procedure for granting such prior authorisation. (Article 80g(1) of the Health Insurance Act). According to Article 80g(3) of the Health Insurance Act**, PA may be required in respect of healthcare which:** 1. depends on planning requirements related to the need to ensure sufficient and permanent access to certain high-quality treatment in the Republic of Bulgaria or in order to control costs and avoid waste of financial, technical and human resources, and includes placement of the patient in medical establishment for at least one night or require the use of highly specialised and associated with significant	Article 19 and following of the Ordinance No 5 Annex to Article 19(1) of Ordinance No 5 Article 33 and following of Ordinance No 5 Statute for the Organisation of Work and Activities of the Centre for Assisted Reproduction	

o Medical devices, paid according to Ordinance No 2 of 2019 for the medical and other services under Articles 82(1a) and 82(3) of the Health Act and for the terms and conditions for their approval, use and payment (Ordinance No 2) , necessary for the provision of healthcare services for which a prior authorisation for reimbursement has been obtained.
(Annex to Article 19(1) of Ordinance No 5).

[188] According to Article 33 of Ordinance No 5 the Ministry of Healthcare, on the other hand, covers, subject to a PA, certain healthcare costs related to:
o assisted reproduction activities; and
o transplantation of organs, tissues and cells paid in accordance with Ordinance No 29 of 2007 on the Reimbursement of Costs and the Relative Share of Funds for Labor for Transplantation Activities Financed by the Ministry of Health (Ordinance No 29).
See: Наредба № 29 от 2007 г. за възстановяване на разходите и за относителния дял на средствата за труд за дейности по трансплантация, финансирани от Министерството на здравеопазването (Ordinance No 29 of 2007 on the Reimbursement of Costs and the Relative Share of Funds for Labor for Transplantation Activities Financed by the Ministry of Health), last amended on 21.05.2019 with Official Journal issue No 41 of 21.05.2019, available here. Last accessed 16/06/21.

[189] Закон за здравното осигуряване (Health Insurance Act), last amended on 12.03.2021 with Official Journal issue No 21 of 12.03.2021, available on the official website of the NHIF here. Last accessed 16/06/21.

	costs medical infrastructure or medical equipment; 2. includes treatment that puts the patient or the population at risk; 3. is provided by a medical establishment, which in certain cases may raise serious and specific doubts about the quality or safety of the care, with the exception of healthcare, to which the EU law is applied, guaranteeing a minimum level of safety and quality. **Answer:** The provisions laying out the requirements related to **PA procedures for reimbursement of costs covered by the NHIF** are Article 19 and following of Ordinance No 5 and those related to **PA procedures for reimbursement of costs covered by the Ministry of Healthcare** are Article 33 and following of Ordinance No 5. The requirement pertaining to the **PA procedure for reimbursement of costs related to assisted reproduction activities** are also contained within the Statute for the Organisation of Work and Activities of the Centre for Assisted Reproduction[190].		
2. Is this the same procedure as for PA under the Social Security Coordination Regulations?	**Answer:** **Yes ☐ No ☒** **Additional clarifications:** PA procedures are conducted in accordance with the specifics and provisions of the two sets of acts – Directive 2011/24/EU of the European Parliament and of the Council		N/A

[190] Правилник за организацията на работа и дейността на Център за асистирана репродукция (Statute for the Organisation of Work and Activities of the Centre for Assisted Reproduction), last amended on 29.03.2019 with Official journal issue No 26 of 29.03.2019, available here. Last accessed 16/06/21.

	of 9 March 2011 on the application of patients' rights in cross-border healthcare (Directive 2011/24/EU)[191] and the Social Security Coordination Regulations (the Regulations).[192] Upon submission of a request for PA, the NHIF or the Ministry of Healthcare shall verify that the conditions set out in Regulation (EC) № 883/2004 of the European parliament and of the Council of 29 April 2004 on the coordination of social security systems (Regulation (EC) № 883/2004) are met in respect of the person's application for PA to receive cross-border healthcare. Where these conditions are met, **PA shall be granted in accordance with that Regulation, unless the patient requests otherwise** (Article 80g(4) of the Health Insurance Act, and Articles 24(1) and 38(10) of Ordinance No 5).		
3. What body is in charge of handling the PA applications? *(e.g., where and to whom PA applications have to be submitted?)*	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* **PA procedure for reimbursement of costs covered by the NHIF** (Article 20(1) and (2) of Ordinance No 5): • PA applications for reimbursement of costs covered by the NHIF shall be submitted to the central office of the NHIF or in the respective regional health insurance fund. In case the request is submitted to the regional health insurance fund, the latter is obliged to send it, in its original, to the central office of the NHIF within 2 (two) days from its receipt.	**Source(s):** Article 20(1) and (2) of Ordinance No 5 Article 34(1) of Ordinance No 5 Article 36(1) of Ordinance No 5	N/A

[191] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, OJ L 88, 4.4.2011, p. 45–65, available here.
[192] Regulation (EC) № 883/2004 of the European parliament and of the Council of of 29 April 2004 on the coordination of social security systems, OJ L 166/1, 30.4.2004, available here.

	PA procedures for reimbursement of costs covered by the Ministry of Healthcare: • PA applications for reimbursement of costs related to assisted reproduction activities shall be submitted to the Centre for Assisted Reproduction (Article 34(1) of Ordinance No 5). • PA applications for reimbursement of costs related to transplantation of organs, tissues and cells paid in accordance with Ordinance No 29 shall be submitted to the Ministry of Health (Article 36(1) of Ordinance No 5).		
4. Who is entitled to apply for PA? *(e.g., can the patients apply themselves, or is treating doctor filing/partially filling the request, etc.)*	**Answer:** *If there is a national doctor involved, is there a requirement that this doctor is contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA?* **PA procedure for reimbursement of costs covered by the NHIF:** • PA applications for reimbursement of costs covered by the NHIF shall be submitted by the person who will use the healthcare service in another Member state, respectively by his/her parent, guardian or custodian or by their proxy (Article 20(3) of Ordinance No 5). **PA procedures for reimbursement of costs covered by the Ministry of Healthcare:** • PA applications for reimbursement of costs related to assisted reproduction activities shall be submitted by the interested patient (i.e., the woman	**Source(s):** Article 20(3) of Ordinance No 5 Article 34(1) of Ordinance No 5 Article 36(1) of Ordinance No 5	No relevant information available, incl. within the Motives for adoption of Ordinance No 5.

	wishing to undergo in-vitro procedure in another Member state) (Article 34(1) of Ordinance No 5). • PA applications for reimbursement of costs related to transplantation of organs, tissues, and cells, paid in accordance with Ordinance No 29 shall be submitted by the interested patient (or in case the patient is a child, by the parent, guardian, trustee, or person with whom the child has been placed by the court) (Article 36(1) of Ordinance No 5).		
5. Is there a specific application form/module which the person seeking PA needs to submit?	**Answer:** *If yes, please specify:* *(1) What information is required;* *(2) Is the information mandatory, optional, or recommended?* *(3) Is this application form/modules available online?* *(4) Does the form have to be submitted in paper or can it be submitted electronically?* Generally, yes. **A) PA procedure for reimbursement of costs covered by the NHIF:** In order to obtain PA, a request shall be submitted using a template application form approved by the Director of the NHIF (Article 20(1) of Ordinance No 5). (1) The required information which shall be filled in the application form is the following:	**Source(s):** Article 20(1) of Ordinance No 5 Article 31(1) of the Statute for the Organisation of Work and Activities of the Centre for Assisted Reproduction Article 36(1) of Ordinance No 5	No relevant information available, incl. within the Motives for adoption of Ordinance No 5.

	○ Name, father's name and family name of the applicant; ○ National identification number of the applicant; ○ Capacity of the applicant (patient/ parent/ guardian/ custodian/ proxy); ○ Name, father's name and family name, and national identification number of the parent in case the application is filed by a person of age between 14 and 18 years old; ○ Type of the healthcare service, or type of the medical device paid according to Ordinance No 2; ○ Name and county of the healthcare establishment where the healthcare service will be provided; ○ National identification number of the patient; ○ Permanent and current address of the patient, as well as address for correspondence; ○ National ID/ passport details (number, date of issuance, body of issuance); ○ Telephone number; ○ Email address; ○ Date and place of signing; ○ Signature of the applicant and of the parent, where applicable. (2) The provision of all the information is mandatory. (3) Yes, the application forms are available online on the NHIF website. (4) The form and the additional documents attached thereto shall be submitted on paper (via post/courier services or in person) (Source: interview with expert from the NHIF).		

	B) PA procedure for reimbursement of costs covered by the Ministry of Healthcare: **Regarding PA applications for reimbursement of costs related to assisted reproduction activities**, (1) the required information is the following (as per Article 31(1) of the Statute for the Organisation of Work and Activities of the Centre for Assisted Reproduction): ○ Name, father's name and family name of the woman; ○ National identification number; ○ ID number and issuing body; ○ Permanent address; ○ Address for correspondence; ○ Telephone number; ○ Email address; ○ Citizenship; ○ Name, father's name and family name of the woman's husband or partner – this information is not required in certain cases related to the medical condition of the woman, as well as in cases where the woman does not have a husband or a partner at the time of filing the application; ○ National identification number of the woman's husband or partner – this information is not required in certain cases related to the medical condition of the woman, as well as in cases where the woman does not have a husband or a partner at the time of filing the application;		

	○ Name of the medical establishment chosen by the applicant; ○ Information related to the means by which the applicant wishes to receive the issued individual administrative act (i.e. via email, by post, etc.); ○ Data and place of signature; ○ Applicant's signature. (2) The only information marked as not required in certain specific cases is the information related to the woman's husband or partner. Therefore, it appears that all the rest of the information is mandatory. (3) The application form can be found online. (4) The application form shall be submitted either via post or courier service or in person at the Centre for Assisted Reproduction. • **Regarding PA applications for reimbursement of costs related to transplantation of organs, tissues, and cells, paid by the Ministry of Healthcare in accordance with Ordinance No 29**, the applicant submits a request to the Ministry of Healthcare. The request shall be submitted in a free form (meaning that there is no template application form), therefore there are no indications as to the content of the application or the way it shall be submitted (on paper/ electronically/ etc.) (Article 36(1) of Ordinance No 5).		
6. What (other) documentation has to be submitted in order to substantiate a PA request?	**Answer:** *If applicable, please specify:* *(1) What documents and what particulars are required;*	**Source(s):** Article 20(4) and (4a) of Ordinance No 5	No relevant information available, incl. within the Motives for adoption of Ordinance No 5.

	(2) Whether there are requirements as to who has to issue the documents (e. g., a doctor contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA or any doctor); *(3) Whether the submission of the documentation is optional, mandatory, or recommended.* **PA procedure for reimbursement of costs covered by the NHIF:** (1) In the general case, the required documents are the following (Article 20(4) of Ordinance No 5): - a copy of the ID document of the person who will use the health service, hand-certified with the stamp 'True to the original' and the stamp 'I agree with the copy made'; - medical documentation certifying the disease and the diagnosis made; the treatment carried out up to the time of submitting the application (if any); conclusions (recommendations) from medical specialists justifying the need for the treatment for which the PA is requested; - a template declaration regarding the fact that: (o) the person concerned is not insured in another Member state, a State party to the EEA or the Swiss Confederation; and (o) for persons up to 18 years of age – that the interested person has not applied / has not received approval for payment under Ordinance No 2 of 2019; - where applicable, a copy of a document certifying the quality of a parent, guardian, trustee or person with whom the child is	Article 31(1), (3), (5) and (14) of the Statute for the Organisation of Work and Activities of the Centre for Assisted Reproduction Article 36(1) of Ordinance No 5	

	placed by the court – hand-certified with the stamp 'True to the original'; - where applicable, power of attorney, which explicitly states that the proxy is authorized to submit a request and the necessary documents to the NHIF to obtain a PA for reimbursement of costs of cross-border health care; - personal data protection declaration – signed by the applicant. Regarding PA for reimbursement of cost of medical devices paid according to Ordinance No 2, the required documents are the following (Article 20(4a) of Ordinance No 5): - where applicable, a copy of document(s), certifying the quality of parent, guardian, custodian or person performing substitute care of the patient – relative, close or foster parent, with whom the child is accommodated under the Bulgarian Child Protection Act, respectively director of the Social Assistance Directorate (certificates from the municipality, including the child's birth certificate, orders from the social directorates, consents of the Social Assistance Directorates, court decisions, marriage certificates, etc.); - medical documentation, issued not more than 2 (two) months prior to the submission of the request, certifying for the disease, the condition and the diagnosis, the treatment carried out up until the submission of the request and a complex treatment plan, including the need to apply for the medical device for which the PA is requested (medical tests, conclusions, opinions, recommendations, and/or others);		

	- an official document (offer) from a medical establishment abroad, with indicated type and value of the medical device, and technical specification (if possible); - information from the medical establishment abroad regarding: (a) the presence or absence of a label on the medical device; and (b) possibility to provide a label of the medical device; - personal data protection declaration – signed by the applicant; - a template declaration by which the applicant declares that the patient is not using, at the moment of submitting the request, another instrument for financing with public funds for the same services; - where the submission of the application is made by a proxy - power of attorney, in which it is explicitly stated that the proxy is authorized to submit a request and the necessary documents to the NHIF for obtaining a PA for reimbursement of expenses for cross-border healthcare. (2) There are no specific requirements as to the doctor/s involved in the treatment and issuing the medical documentation. (3) The submission of the above documents is mandatory. **PA procedures for reimbursement of costs covered by the Ministry of Healthcare:** • **PA applications for reimbursement of costs related to assisted reproduction activities** (1) The required documents are the following (Article 31(1) of the Statute for the Organisation		

	of Work and Activities of the Centre for Assisted Reproduction): - medical documentation certifying the presence of indications and health condition requiring the assisted reproduction activities; - interim medical report in which the lack of contraindications pursuant to *Ordinance No 28 of 2007 for assisted reproduction activities* (Ordinance No 28)[193], and in case of indications for assisted reproduction of spontaneous cycle – a recommendation of a medical specialist in assisted reproduction for application of this method; - medical documentation, certifying the absence of certain circumstances preventing from applying the assisted reproduction method; - a copy of an ID card, certified by the applicant with the stamp 'True to the original'; - a template declaration certifying the lack of blood relationship in the direct line and in the collateral line up to the fourth degree between the applicant and her partner; - a template informed consent of the applicant and her partner; - a template declaration by the applicant that she has not been placed under guardianship; - a template declaration by the applicant's partner that he has not been placed under guardianship. The above documents are submitted when the woman applies for a first time. Next time the		

[193] Наредба № 28 от 20.06.2007 г. за дейности по асистирана репродукция (Ordinance No 28 of 2007 for assisted reproduction activities), last amended on 08.06.2012 with Official Journal issue No 43 of 08.06.2012, available on the official website of the Ministry of Healthcare here. Last accessed 16/06/21.

	woman files an application, the required documents are: application, interim medical report and declaration that there is no change in the circumstances, certified by the documents submitted with the first application (in case of changes in the circumstances, the documents related to the change shall be provided) (Article 31(14) and (5) of the Statute for the Organisation of Work and Activities of the Centre for Assisted Reproduction). (2) The medical documentation is prepared by a medical institution that has received a permit, respectively a certificate or registration for assisted reproduction activities. (Article 31(3) of the Statute for the Organisation of Work and Activities of the Centre for Assisted Reproduction) (3) The submission of the documents listed above is mandatory. • **PA applications for reimbursement of costs related to transplantation of organs, tissues, and cells, paid by the Ministry of Healthcare in accordance with Ordinance No 29** (1) The required documents are the following (Article 36(1) of Ordinance No 5): - copy of an ID document of the person who will use the healthcare service, hand-certified with the stamp 'True to the original' and stamp 'I agree with the copy made'; - where the submission of the application is made by a proxy - power of attorney, in which it is explicitly stated that the proxy is authorized to submit an application and the necessary documents to the Ministry of Healthcare for obtaining a PA for		

	reimbursement of expenses for cross-border healthcare; - medical documentation issued not more than 6 (six) months prior to the application, certifying for the disease and the diagnosis, the treatment carried out until the submission of the application, interim medical report, opinions, conclusions, recommendations of medical specialists regarding the condition and the necessary actions. (2) There are no specific requirements as to the doctor/s involved in the treatment and issuing the medical documentation. (3) The submission of the above documents is mandatory.		
7. Are there any costs associated with the handling of the PA request? - *Direct costs (e.g., fixed costs for submitting or filing a PA request).* - *Indirect costs* (*e.g., translations, stamps, etc).*	**Answer:** *Direct costs:* There are no costs for submitting a PA request. *Indirect costs:* All submitted documents shall be in Bulgarian language. In case documents are submitted in a foreign language, they should be accompanied by a translation into Bulgarian language. (Article 21(1) and 37(1) of Ordinance No 5).[194]	**Source(s):** Article 21(1) and 37(1) of Ordinance No 5	No relevant information available, incl. within the Motives for adoption of Ordinance No 5.
8. Are there any specific **time requirements** linked to a PA request? (*e.g., time within which a requesting person must submit the PA application and/or time within which the*	**Answer:** *- If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?*	**Source(s):** Article 23(1) of Ordinance No 5 Article 36(1), item 4 of Ordinance No 5	No relevant information available, incl. within the Motives for adoption of Ordinance No 5.

[194] In addition to being translated, previously there was a requirement that submitted documents shall also be legalised. However, with its decision No 6677 of 22.05.2018 on administrative case No 864/2018 the Bulgarian Supreme Administrative Court invalidated the requirement that documents shall be legalised.

	requested body must take a decision on the PA request, etc.).	**Regarding PA procedure for reimbursement of costs covered by the NHIF:** (Article 23(1) of Ordinance No 5) • In terms of **PA procedure for reimbursement, by the NHIF, of costs for medical devices paid according to Ordinance No 2**, the submitted medical documentation certifying for the disease, the condition and the diagnosis shall be issued **not more than 2 (two) months** prior to the submission of the request. • In cases when incompleteness or discrepancy is established with respect to the required documents, the NHIF shall notify the applicant in writing of this circumstance, setting a deadline for the submission of the relevant documents. **Regarding PA procedures for reimbursement of costs covered by the Ministry of Healthcare:** • In terms of **PA applications for reimbursement of costs related to transplantation of organs, tissues, and cells, paid in accordance with Ordinance No 29**, the submitted medical documentation certifying for the disease, the condition and the diagnosis shall be issued **not more than 6 (six) months** prior to the submission of the request. (Article 36(1), item 4 of Ordinance No 5)		
9.	Are there **differences in the procedural/administrative requirements for requesting PA** based on, for instance, the type of treatment for which PA is	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)*	**Source(s):** Ordinance No 5 Statute for the Organisation of Work and Activities of the Centre for Assisted Reproduction	No relevant information available, incl. within the Motives for adoption of Ordinance No 5.

requested, the profile of the insured person, or any other criterion?	Yes, different requirements are in place for the following: - medical devices paid according to Ordinance No 2 (covered, subject to PA, by the budget of the NHIF); - assisted reproduction activities (covered, subject to PA, by the budget of the Ministry of Healthcare); - transplantation of organs, tissues, and cells (covered, subject to PA, by the budget of the Ministry of Healthcare). **Regarding PA applications for reimbursement of costs related to transplantation of organs, tissues, and cells, paid by the Ministry of Healthcare in accordance with Ordinance No 29**, the applicant submits a request to the Ministry of Healthcare. The request shall be submitted in a free form (meaning that there is no template application form), therefore there are no indications as to the content of the application or the way it shall be submitted (on paper/ electronically/ etc.) (Article 36(1) of Ordinance No 5). The details of the requirements are presented in detail within the answers above.		
10. Is there a specific PA form (i.e., form used for issuing/granting PA) and, if the answer is positive, what form?	**Answer:** Yes. There is a **specific template** application forms for **requesting PA for reimbursement of costs covered by the Ministry of Healthcare**, more specifically for requesting PA for reimbursement of costs related to assisted reproduction activities. (Annex No 2	**Source(s):** Article 23(2) of Ordinance No 5 Article 25(1), (2) and (4) of Ordinance No 5	No relevant information available, incl. within the Motives for adoption of Ordinance No 5.

	to Article 31(1) of the Statute for the Organisation of Work and Activities of the Centre for Assisted Reproduction). There is **no specific template** form for **requesting PA for reimbursement of costs** related to transplantation of organs, tissues, and cells, paid by the **Ministry of Healthcare** in accordance with Ordinance No 29. **There are no indications on the form for the PA issued.** **Specifically, PA procedure for reimbursement of costs covered by the NHIF:** Within 1 month of the submission of the request and the necessary documents, the Director of the NHIF shall issue a PA for reimbursement of costs for healthcare in another Member state (Article 25(1) of Ordinance No 5) or shall refuse to issue a PA in certain cases (Article 25(2) of Ordinance No 5),or shall terminate the proceedings in case of incompleteness or discrepancies of the submitted documents (Article 23(2) of Ordinance No 5). The refusal to issue a PA is subject to appeal under the Administrative Procedure Code[195] (Article 25(4) of Ordinance No 5). **There are no further indications on the form of the issued PA, respectively the refusal to issue a PA.**	Article 39(10) of the Statute for the Organisation of Work and Activities of the Centre for Assisted Reproduction Article 39(1) and (5) of Ordinance No 5	

[195] Административнопроцесуален кодекс (Administrative Procedure Code), last amended on the 19.02.2021 with Official journal issue No 15 of 19.02.2021, available here.

	PA procedure for reimbursement of costs covered by the Ministry of Healthcare: - **Regarding PA applications for reimbursement of costs related to assisted reproduction activities:** The Director of the Centre for Assisted Reproduction issues a PA for reimbursement of the costs for assisted reproduction activities or makes a motivated refusal. The decision is subject to appeal under the Administrative Procedure Code (Article 39(10) of the Statute for the Organisation of Work and Activities of the Centre for Assisted Reproduction). **There are no further indications on its form**. - **Regarding PA applications for reimbursement of costs related to transplantation of organs, tissues, and cells, paid by the Ministry of Healthcare in accordance with Ordinance No 29:** The Minister of Health issues an order granting or refusing to grant a PA for reimburse the costs of organ, tissue and cell transplantation in another Member state (Article 39(1) of Ordinance No 5). The refusal is subject to appeal under the Administrative Procedure Code (Article 39(5) of Ordinance No 5). **There are no further indications on its form.**		
11. Please list any other administrative requirements in your country in relation to the	**Answer:** Regarding **PA applications for reimbursement of costs related to assisted reproduction activities**, there are more administrative requirements related to specific	**Source(s):** Article 32 of the Statute for the Organisation of Work and	No relevant information available.

PA procedure for cross-border healthcare.	medical condition of the woman and the healthcare service for which she is seeking PA. (Article 32 of the Statute for the Organisation of Work and Activities of the Centre for Assisted Reproduction) Due to the very specific character of these requirements, they are not included in the present questionnaire.	Activities of the Centre for Assisted Reproduction		
SECTION 2 REIMBURSMENT PROCEDURE(S)				
Questions	**Answer:**	**Sources**	**Does/do the identified requirement(s) also apply domestically? (i.e., is the requirement non-discriminatory?)**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to reimbursement procedures for cross-border healthcare under Directive 201/24/EU?	**Preliminary note:** Similarly to PA procedures, the administrative requirements related to reimbursement procedures differ depending on the body which reimburses the costs for the cross-border healthcare. This body could either be the NHIF or the Ministry of Healthcare. When exercising their right to cross-border healthcare, health insured persons shall pay to the medical establishment in the Member state of treatment the value of the healthcare provided to them. (Article 80f(1) of the Health Insurance Act) Health insured persons are entitled to reimbursement of the costs for the health care provided to them in the Member state of treatment up to the amount of the costs paid by the NHIF or the Ministry of Healthcare for the	**Source(s):** Article 80f(1), (2) and (4) of the Health Insurance Act Article 7(1) of Ordinance No 5 Article 27 of Ordinance No 5	N/A	N/A

	respective health care in the Republic of Bulgaria, but not more than the actually incurred costs. (Article 80f(2) of the Health Insurance Act) The conditions and the procedure for exercising the right to cross-border healthcare shall be determined by an Ordinance of the Minister of Healthcare. (Article 80f(4) of the Health Insurance Act) **Answer:** On the above legal grounds (i.e. Article 80f(4) of the Health Insurance Act), Ordinance No 5 regulates the conditions and procedure for reimbursement of costs for cross-border healthcare. The provisions laying out the requirements related to **procedures for reimbursement of costs covered by the NHIF** are Article 7 and following and Article 14 and following of Ordinance No 5 and those related to **procedures for reimbursement of costs covered by the Ministry of Healthcare** are Article 27 and following of Ordinance No 5**.** **The NHIF reimburses the costs for cross-border healthcare for the following:** (Article 7(1) of Ordinance No 5) - medical and dental activities for illness prevention; - medical and dental activities for early detection of illness; - outpatient and inpatient medical care for diagnosis and treatment due to illness;			

	- after-treatment, long-term treatment and medical rehabilitation; - emergency medical aid; - medical care during pregnancy, childbirth and maternity; - abortions on medical grounds and in case of pregnancy due to rape; - dental care; - medical care during home treatment; - prescription and dispensing of medicinal products intended for home treatment on the territory of Bulgaria; - prescription and dispensing of medical devices and dietary foods for special medical purposes, intended for home treatment on the territory of Bulgaria, as well as of medical devices, applied in the hospital medical care; - medical expertise of the working capacity; - transport services for medical indications **The Ministry of Healthcare reimburses the costs for cross-border healthcare for the following:** (Article 27 of Ordinance No 5) - one prophylactic medical check for pregnant women who do not have health insurance; - test reagents according to *Ordinance No 26 of 2007 on the provision of obstetric care to uninsured women and for the performance of research outside the scope of the compulsory health insurance for children and pregnant women* (Ordinance No 26)[196]; - health services paid according to *Ordinance No 3 of 2019 for the medical activities outside*			

[196] Наредба № 26 от 14.06.2007 г. за предоставяне на акушерска помощ на здравно неосигурени жени и за извършване на изследвания извън обхвата на задължителното здравно осигуряване на деца и бременни жени (Ordinance No 26 of 2007 on the provision of obstetric care to uninsured women and for the performance of research outside the scope of the compulsory health insurance for children and pregnant women), last amended on 30.12.2015 with Official Journal issue No 103 of 30.12.2015, available on the official website of the NHIF here. Last accessed 16/06/21.

	the scope of the obligatory health insurance, for which the Ministry of Health subsidises medical establishments, and for the criteria and the order for subsidising of medical establishments (Ordinance No 3)[197]; - health services related to diagnostics and medicinal monitoring of the recipient in the post-transplantation period; - medicinal products, included in Annex No 4 of the Positive Pharmaceutical List and for diseases which are paid according to *Ordinance No 34 of 2005 for the order of payment from the state budget of the treatment of the Bulgarian citizens for diseases outside the scope of the obligatory health insurance* (Ordinance No 34)[198].			
2. Is this the same procedure as for reimbursement under the Social Security Coordination Regulations?	**Answer:** **Yes ☒ No ☐** **Additional clarifications:** The regime under Directive 2011/24/EU (the Directive) provides for reimbursement of healthcare costs in the EU only up to the level of the costs paid by the competent institution (NHIF/ Ministry of Healthcare) for the same service in Bulgaria, whether it is outpatient treatment, highly specialised examination or treatment, or hospital treatment. Where the service used in another country is not provided in Bulgaria and therefore cannot be valued, the costs remain with the patient. According to the regime under the Social Security Coordination Regulations (the Regulations), the costs paid by patients for medical care provided during a temporary stay in another EU country, when the stay was not for medical purposes, can be reimbursed according to the law, and up to the amount of prices that local health funds		N/A	N/A

[197] Наредба № 3 от 05.04.2019 г. за медицинските дейности извън обхвата на задължителното здравно осигуряване, за които Министерството на здравеопазването субсидира лечебни заведения, и за критериите и реда за субсидиране на лечебни заведения (Ordinance No 3 of 2019 for the medical activities outside the scope of the obligatory health insurance, for which the Ministry of Health subsidises medical establishments, and for the criteria and the order for subsidising of medical establishments), last amended on 25.09.2020 with Official Journal issue No 83 of 25.09.2020, available on the official website of the Ministry of Healthcare here. Last accessed 16/06/21.

[198] Наредба № 34 от 25.11.2005 г. за реда за заплащане от държавния бюджет на лечението на българските граждани за заболявания, извън обхвата на задължителното здравно осигуряване (Ordinance No 34 of 2005 for the order of payment from the state budget of the treatment of the Bulgarian citizens for diseases outside the scope of the obligatory health insurance), last amended on 09.04.2021 with Official Journal issue No 29 of 09.04.2021, available on the official website of the Ministry of Healthcare here. Last accessed 16/06/21.

	pay for the same service for local insured persons. The health insurance fund in the other country should be formally asked by the competent insurance institution (the NHIF) about the level of payment for the used medical service. The foreign health insurance fund values the used health services at its prices and confirms in writing the amount that the local compulsory health insurance covers (or does not cover) for its insured persons. Upon receipt of PA for the use of planned medical care in accordance with the Regulations, the patient submits to the foreign medical institution Form S2, proving the consent of the NHIF/ Ministry of Healthcare to bear the costs for the planned treatment. User fees, regulated doctor's fees, additional tests and 'extras', such as transport and accommodation costs outside hospital stay (if any), which are not covered by compulsory health insurance in the country of treatment, remain at the expense of the patient. The price of the permitted medical activities is covered by the issued Form S2 for planned treatment in the other country. Notwithstanding the above differences in the criteria and the form, the procedures are similar, insofar as they both involve submitting an application form and a set of required documents in view of the reimbursement of costs for cross-border health care.			
3. What body is/are responsible of handling the reimbursement applications? (e.g., where and to whom reimbursement applications have to be submitted?)	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* **Applications for reimbursement of costs covered by the NHIF** shall be submitted to the central office of the NHIF or in the respective regional health insurance fund. In case the request is submitted to the regional health insurance fund, the latter is obliged to send it, in its original, to the central office of the NHIF within 3 (three) days from its receipt. (Article 7(1) and (2), and Article 14(2) of Ordinance No 5)	**Source(s):** Article 7(1) and (2), and Article 14(2) of Ordinance No 5 Article 28 of Ordinance No 5	N/A	N/A

	Applications for reimbursement of costs covered by the Ministry of Healthcare shall be submitted to the Ministry of Healthcare. (Article 28 of Ordinance No 5)			
4. Is there a specific application form/module which the person seeking reimbursement needs to submit?	**Answer:** *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?* Generally, yes. **Procedures for reimbursement of costs covered by the NHIF:** (1) The required information which shall be filled in the application form is the following (as per the Application form which is available on the website of the NHIF: ***<u>Identification information:</u>*** - Name, father's name and family name of the person who has benefited from the healthcare service; - National identification number of that person; - Name, father's name and family name of parent/ guardian/ trustee/ proxy submitting the application; - National identification number of the latter; - Postal address;	**Source(s):** Application form available on the website of the NHIF	**Yes** ☐ **No** ☒ **Preliminary note:** In Bulgaria mandatory health insurance guarantees free access of the insured persons to medical care through a package of health activities of certain type, scope and volume, as well as free choice of a healthcare provider who has concluded a contract with the regional health insurance fund (Article 4(1) of the Health Insurance Act). The financial relations between the NHIF and the providers of medical care are settled at two levels: nationally (when the NHIF concludes a National Framework Agreement (NDA) with the professional organisations of doctors and dentists), and individually (when the	No relevant information available, incl. within the Motives for adoption of Ordinance No 5.

	- Telephone number; - Bank and IBAN number of a bank account (serviced in BGN); ***Information on the received cross-border healthcare:*** - Country; - City; - Period of the stay; - Condition that required medical attention (diagnosis); - Type of medical care received (medical exam/ medical-diagnostic examination/ treatment and diagnostic procedures (diagnosis-type of desease)/ operations/ medicinal products/ other); - Period in which the medical care was received; - Information on the medical documentation attached to the application (interim medical report/ laboratory tests/ imaging tests (x-rays, scanner, etc.)/ other medical documents); - Information on the medical institution-provider of the medical care; - Information whether the medical care was received under the procedures for local insured persons or not; ***Information regarding the expenses made and basis for their reimbursement:*** - Information on the attached expenses-related supporting documents (invoices, payment documents, etc.); - Information on the medical institution-issuer of the documents; - Date; - Amount of the expense and currency;		NHIF signs individual contracts with the healthcare providers). The general principle is that for healthcare services, covered by the NHIF, health insured persons do not pay the costs at the time of the provision of the service, nor are required to ask for a PA. Patients are only due a user fee at the amount of BGN 2,90 (approx. EUR 1,50) when visiting their general practitioner or dentist. With view to the above, the answer to the question whether the requirements for reimbursement of costs for cross-border health care also apply domestically, is generally no – as the health insurance system in Bulgaria do not require health insured patients to pay for healthcare services at the time of the provision of the service, to eventually be reimbursed afterwards.	

	- Type of the medical care received (outpatient cross-border health services/ highly specialised and/or hospital cross-border health services); - Declaration on the truthfulness of the provided information; - Date and signature. (2) The provision of all the information is mandatory. (3) Yes, the application form is available online on the NHIF website. (4) The form and the additional documents attached thereto shall be submitted on paper (via post/courier services or in person) (Source: interview with expert from the NHIF). **Procedures for reimbursement of costs covered by the Ministry of Healthcare:** The provisions of Ordinance No 5 do not provide further details on what the content of the request shall be (i.e., (1) what information it shall contain, (2) whether the information is mandatory, optional, or recommended, (3) whether there is an application form which can be used for the request and (4) how the request shall be submitted). According to the feedback obtained from the Ministry of Healthcare: - the application shall be submitted in a free form (meaning that there is no template form which shall be used); - specific information requirements are contained within the documents which shall be attached to the application (see question below).			

5. What (other) documentation has to be submitted in order to substantiate a reimbursement request?	**Answer:** *If applicable, please specify:* *(1) What documents are required;* *(2) Whether the submission of the documentation is optional, mandatory, or recommended.* **Procedure for reimbursement of costs covered by the NHIF:** (1) The required documents are as follows (Article 7(7) of Ordinance No 5): - a copy of an ID document of the person who has used and paid for the health service, hand-certified with stamp 'True to the original' and stamp 'I agree to the copy made'; - originals of the expense-related and payment documents for the paid health services; - a copy of a document issued by a bank, in confirmation of the details on the personal IBAN number of the bank account, serviced in BGN, hand-certified with the stamp 'True to the original' and the stamp 'I agree with the copy made'; - a copy of a document certifying for the capacity of a parent, guardian, trustee or a person with whom the child has been placed by the court, hand-certified with the stamp 'True to the original'; - when the submission of the application is made by a proxy, power of attorney, in which it is explicitly stated that the proxy is authorised to submit to the NHIF an application and the required additional	**Source(s):** Article 7(7) of Ordinance No 5 Article 8(1) of Ordinance No 5 Article 14(2) and (3) of Ordinance No 5 Article 28(1) of Ordinance No 5	**Yes** ☐ **No** ☒* * Please, refer to our preliminary note under Section 2, question 4 above.	No relevant information available, incl. within the Motives for adoption of Ordinance No 5.

	documents for reimbursement of expenses; - where applicable, certificate for heirs (original or notarised copy) of the person who has used and paid for the health services. For reimbursement of costs for the provision of highly specialised outpatient healthcare and inpatient healthcare for the use of which on the territory of the Republic of Bulgaria it is required to obtain a referral / permission to perform, the following documents are also required Article 8(1) of Ordinance No 5): - original of the medical referral for performance of the health service, issued according to the conditions of the national framework contracts under Article 53(1) of the Health Insurance Act by a doctor / dentist working in a medical institution, which has a contract with the NHIF; - the medical documentation related to the results of the performance of the health service in the other Member state (interim reports, results of examination, etc.). For reimbursement of costs for medicinal products, dietary foods for special medical purposes and medical devices dispensed under medical prescriptions, the following documents are also required (Article 14(2) and (3) of Ordinance No 5): - a copy of the prescription form with all the requisites filled in it, including the date of dispensing of the medicinal product, dietary food or the medical device, hand-certified with the stamp 'True to the original'. The prescription form for a medicinal product may be issued by a			

	doctor/ dentist from a medical institution for outpatient care, which has a contract with the NHIF, or from a medical institution in another Member state. (2) The submission of the above documents is mandatory. **Procedure for reimbursement of costs covered by the Ministry of Healthcare:** (1) The required documents are as follows (Article 28(1) of Ordinance No 5): - a copy of an ID document of the person who has used and paid for the rendered health service, hand-certified with stamp 'True to the original' and stamp I agree to the copy made'; - a copy of a document certifying the quality of a parent, guardian, trustee or a person with whom the child has been placed by the court, hand-certified with the stamp 'True to the original'; - when the submission of the application is made by a proxy, power of attorney, in which it is explicitly stated that the proxy is authorized to submit to the Ministry of Healthcare an application and the necessary documents for reimbursement of expenses for cross-border healthcare; - medical documentation for conducted examinations with indicated type and scope of the tests and examinations; - where applicable, medical documentation, certifying for the performed examinations with medical conclusions;			

	- where applicable, medical documentation, certifying the performed diagnostic-medical activities; - where applicable, medical documentation, certifying for the performed diagnostics and medicinal monitoring in the post-transplantation period, and an opinion from a doctor that the provided health services are directly related to the performed transplantation; - where applicable, medical documentation, certifying for the disease, and prescription form; - detailed financial-reporting document; - a copy of a document issued by a bank, in confirmation of the details on the IBAN number of the person's bank account, serviced in BGN. (2) The submission of the above documents is mandatory.			
6. Are there any costs associated with the handling of the reimbursement request? - *Direct costs (e.g., fixed costs for submitting or filing a reimbursement request, proportion deducted from the reimbursable amount).* - *Indirect costs* (*e.g., translations, stamps, etc).*	**Answer:** *Direct costs:* There are no costs for submitting a reimbursement request. *Indirect costs:* All submitted documents shall be in Bulgarian language. In case documents are submitted in a foreign language, they should be accompanied by a translation. (Article 9(1) and Article 28(3) of Ordinance No 5).[199]	**Source(s):** Article 9(1) and Article 28(3) of Ordinance No 5	**Yes** ☐ **No** ☒***** * Please, refer to our preliminary note under Section 2, question 4 above.	No relevant information available, incl. within the Motives for adoption of Ordinance No 5.

[199] In addition to being translated, previously there was a requirement that submitted documents shall also be legalized. However, with its decision No 6677 of 22.05.2018 on administrative case No 864/2018 the Bulgarian Supreme Administrative Court invalidated the requirement that documents shall be legalised.

7. Are there any specific time requirements linked to a reimbursement request? (*e.g., time within which the reimbursement requests must be submitted and/or time within the requested body must handle the request and/or reimburse the costs, etc.*).	**Answer:** *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* **Procedure for reimbursement of costs covered by the NHIF:** • The application and the required additional documents shall be submitted not later than 5 (five) years after the provided health care. (Article 7(3) of Ordinance No 5) • In cases when incompleteness or discrepancy is established with respect to the required documents, the NHIF shall notify the applicant in writing of this circumstance, setting a deadline for the submission of the relevant documents. (Article 11(1) of Ordinance No 5) **Procedure for reimbursement of costs covered by the Ministry of Healthcare:** • The application and the required additional documents shall be submitted not later than 6 (six) months after the provided health care. (Article 28(2) of Ordinance No 5) • In cases when incompleteness or discrepancy is established with respect to the required documents, the Ministry of Healthcare shall notify the applicant in writing of this circumstance, setting a deadline for the submission of the relevant documents. (Article 30(1) of Ordinance No 5)	**Source(s):** Article 7(3) of Ordinance No 5 Article 11(1) of Ordinance No 5 Article 28(2) of Ordinance No 5 Article 30(1) of Ordinance No 5	**Yes** ☐ **No** ☒* * Please, refer to our preliminary note under Section 2, question 4 above.	No relevant information available, incl. within the Motives for adoption of Ordinance No 5.

8. Are there any non-reimbursable thresholds, deductions *(except the deductions for administrative costs mentioned above) etc.?*	**Answer:** *If yes, please specify the thresholds.* Yes. The general rule is as follows: When exercising their right to cross-border healthcare, health insured persons shall pay to the medical establishment in the Member state of treatment the value of the healthcare provided to them. (Article 80f(1) of the Health Insurance Act) Health insured persons are entitled to reimbursement of the costs for the health care provided to them in the Member state of treatment up to the amount of the costs paid by the NHIF or the Ministry of Healthcare for the respective health care in the Republic of Bulgaria, but not more than the actually incurred costs. (Article 80f(2) of the Health Insurance Act) **Procedure for reimbursement of costs covered by the NHIF:** • In terms of reimbursement of costs for outpatient cross-border health services – the costs are reimbursed up to the amount that the NHIF pays to its partners for similar treatment in Bulgaria; (Article 80f(2) of the Health Insurance Act) • In terms of reimbursement of costs for highly specialised and/or hospital cross-border health services – the costs are reimbursed according to the prices of the NHIF and according to the previously obtained PA; (Article 80f(2) of the Health Insurance Act)	**Source(s):** Article 80f(1) and (2) of the Health Insurance Act Article 15(1) of Ordinance No 5 Article 16(3) and (4) of Ordinance No 5 Article 32(1) of Ordinance No 5 Article 35(2) of Ordinance No 5	**Yes** ☐ **No** ☒* *Please, refer to our preliminary note under Section 2, question 4 above.	No relevant information available, incl. within the Motives for adoption of Ordinance No 5.

	• In terms of reimbursement of costs for medicinal products, the costs are reimbursed up to the amount that the NHIF pays for the respective medicinal product. (Article 15(1) of Ordinance No 5) • In terms of reimbursement of costs for dietary foods for special medical purposes, the costs are reimbursed up to the value determined for the dietary food with the list under Article 18(2) of *Ordinance No 10 of 2009 on the conditions, procedure, mechanism and criteria for payment by the National Health Insurance Fund of medicinal products, medical devices and dietary foods for special medical purposes, negotiating discounts and reimbursement of excess funds when applying a mechanism guaranteeing predictability and sustainability of the NHIF budget* (Ordinance No 10)[200] Article 16(4) of Ordinance No 5); • In terms of reimbursement of costs for medical devices dispensed under medical prescriptions, the costs are reimbursed up to the value determined by *Ordinance No 7 of 31.03.2021 for the conditions and the order for compiling a list of the medical devices under Article 30a of the Medical Devices Act and for determining the value*			

[200] Наредба № 10 от 2009 г. за условията, реда, механизма и критериите за заплащане от Националната здравноосигурителна каса на лекарствени продукти, медицински изделия и на диетични храни за специални медицински цели, договаряне на отстъпки и възстановяване на превишените средства при прилагане на механизъм, гарантиращ предвидимост и устойчивост на бюджета на НЗОК (Ordinance No 10 of 2009 on the conditions, procedure, mechanism and criteria for payment by the National Health Insurance Fund of medicinal products, medical devices and dietary foods for special medical purposes, negotiating discounts and reimbursement of excess funds when applying a mechanism guaranteeing predictability and sustainability of the NHIF budget), last amended on 08.12.2020 with Official Journal issue No 104 of 08.12.2020, available here. Last accessed 16/06/21.

	up to which they are paid (Ordinance No 7)[201]. (Article 16(3) of Ordinance No 5) **Procedure for reimbursement of costs covered by the Ministry of Healthcare:** The thresholds for reimbursement of costs by the Ministry of Healthcare, are as follows (Article 32(1) of Ordinance No 5): • In terms of prophylactic medical checks for pregnant women who do not have health insurance – up to the amount that the Ministry of Healthcare pays to the NHIF for prophylactic medical check of a health-uninsured woman in accordance with the Budget Act of the National Health Insurance Fund for the respective year; • In terms of test reagents according to Ordinance No 26 – at prices according to the public procurements conducted by the Ministry of Healthcare for the respective calendar year; • In terms of health services paid according to Ordinance No 3 – up to the value of the health services, specified with Ordinance No 3; • In terms of health services related to diagnostics and medicinal monitoring of the recipient in the post-transplantation period – up to the amount determined with Ordinance No 29; • In terms of medicinal products, included in Annex No 4 of the Positive Pharmaceutical List and for diseases			

[201] Наредба № 7 от 31.03.2021 г. за условията и реда за съставяне на списък на медицинските изделия по чл. 30а от Закона за медицинските изделия и за определяне на стойността, до която те се заплащат (Ordinance No 7 of 31.03.2021 for the conditions and the order for compiling a list of the medical devices under Article 30a of the Medical Devices Act and for determining the value up to which they are paid), Official Journal issue No 28 of 06.04.2021, available on the official website of the Ministry of Healthcare here. Last accessed 16/06/21.

	which are paid according to Ordinance No 34 – at prices according to the public procurements conducted by the Ministry of Healthcare for the respective calendar year. • In terms of reimbursement of costs for assisted reproduction activities for which a PA has been issued by the Center for Assisted Reproduction, the latter reimburses the costs of the person at prices determined by the commission who has issued the PA, but not more than BGN 5,000. (Article 35(2) of Ordinance No 5)			
9. In instances where a PA (or prior-notification) has already been issued, is a separate/simplified procedure available for requesting reimbursement? **applicable only if the country has a PA system.*	**Answer:** *If yes, please describe the simplified procedure.* Yes. Ordinance No 5 regulates a separate, simplified regime for reimbursement of costs under a PA issued by the relevant institution for the use of health services in another Member state under Directive 2011/24/EU. **For reimbursement of costs under a PA issued by the NHIF:** The NHIF shall reimburse the costs for the healthcare provided in another Member state for which the person has received a PA issued by the NHIF, after submission to the NHIF of an application to which the following documents shall be attached (Article 26(1) of Ordinance No 5): • copies of medical documents for the performed healthcare;	**Source(s):** Article 26(1) and (4) of Ordinance No 5 Article 35(1) of Ordinance No 5 Article 40 of Ordinance No 5	**Yes** ☐ **No** ☒* * Please, refer to our preliminary note under Section 2, question 4 above.	No relevant information available, incl. within the Motives for adoption of Ordinance No 5.

	• financial documentation for proving the payment of the costs directly related to the performed healthcare, respectively financial-reporting document with indicated the full name of the medical device and the manufacturer and with attached, if possible, the original stickers of the medical device; • a copy of a document issued by a bank, in confirmation of the information related to the personal IBAN number of a bank account serviced in BGN of the applicant, hand-certified with the stamp 'True to the original' and the stamp 'I agree with the copy made'. The costs shall be reimbursed to the applicant within 3 (three) months after presentation of the above documents, respectively after elimination of any incompleteness. (Article 26(4) of Ordinance No 5) **For reimbursement of costs under a PA issued by the Ministry of Healthcare:** • **Regarding the reimbursement of costs for assisted reproduction activities under a PA issued by the Center for Assisted Reproduction:** The Centre for Assisted Reproduction shall reimburse the costs for the performed activities for assisted reproduction under an already issued PA, within 3 (three) months after presentation of (Article 35(1) of Ordinance No 5): • detailed interim report, issued by the medical establishment; • medical documentation for the performed medical activities;			

	• a document signed by the person and the medical establishment, in which are indicated: (a) the types and volumes of examinations, tests, operations carried out, their unit price and total value; b) the attached medicinal products (distributed by type, quantity, unit price, total value and number of financial reporting document); • financial-reporting document, which contains full description and value of the performed medical activities and the used medicinal products; • a copy of a document issued by a bank, in confirmation of the information related to the personal IBAN number of a bank account, serviced in BGN, of the applicant. **Regarding the reimbursement of costs for transplantations under a PA issued by Ministry of healthcare:** The Ministry of Healthcare shall reimburse the costs for the performed transplantation of organs, tissues and cells in another Member state for which it has issued a PA, after submission to the Ministry of Healthcare of an application, to which the following documents shall be attached (Article 40 of Ordinance No 5): • copies of medical documents of the donor and the recipient; • financial documentation for proving the payment of the costs directly related to the performed healthcare activities; • a copy of a document issued by a bank, in confirmation of the information related to the personal IBAN number of a bank account, serviced in BGN, of the applicant.			

10. Are there additional administrative/procedural requirements for reimbursement depending on, for instance, the type of treatment for which reimbursement is requested, or the profile of the insured person, or any other criterion?	**Answer:** Yes. *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* All differences in the reimbursement procedures and the administrative requirements related thereto are presented in detail within the answers above.	**Source(s):**	**Yes** ☐ **No** ☒* * Please, refer to our preliminary note under Section 2, question 4 above.	No relevant information available.
11. Please list any other administrative requirements in your country in relation to the procedures of reimbursement of cross-border healthcare.	**Answer:** N/A	**Source(s):** N/A	**Yes** ☐ **No** ☐ N/A	N/A

Part 2: Checklist for verification with national/regional body

Name of the body: National Health Insurance Fund (the NHIF)

Country/Region: Bulgaria

Date of verification call: 15/06/2021

Template for the Data Collection	**Aspects to be verified** *Tick the boxes if the information in the template for the data collection has been verified and/or complemented by the national body*		**Comments** *Include any additional comments and/or information provided by the contacted body*
Section 1 – Prior Authorisation			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Justification/purpose of the identified requirement(s) (Column 4)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	Regarding whether the PA request and the additional documents shall be submitted on paper or electronically, the expert from the NHIF confirmed that the submission before the NHIF shall be on paper (via post/courier services or in person). The ratio behind this relates to the fact that certain documents shall be provided in their originals. The feedback received by the contacted body has been incorporated in the questionnaire (Section 1).
Section 2 - Reimbursement			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Whether the requirement applies domestically (Discriminatory assessment) (Column 4) ▪ Justification/purpose of the identified requirement(s) (Column 5)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10	Regarding whether the request for reimbursement and the additional documents shall be submitted on paper or electronically, the expert from the NHIF confirmed that the submission before the NHIF shall be on paper (via post/courier services or in person). The ratio behind this relates to the fact that certain documents shall be provided in their originals.

		☒ Question 11	The feedback received by the contacted body has been incorporated in the questionnaire (Section 2).

Name of the body: Ministry of Healthcare
Country/Region: Bulgaria
Date of verification call: Official letter received 16/06/2021

Template for the Data Collection	**Aspects to be verified** *Tick the boxes if the information in the template for the data collection has been verified and/or complemented by the national body*		**Comments** *Include any additional comments and/or information provided by the contacted body*
Section 1 – Prior Authorisation			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Justification/purpose of the identified requirement(s) (Column 4)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	Although the official letter received by the national legal expert in response to the request for assistance only contains comments, clarifications and remarks with regard to certain questions, the national legal expert's understanding is that all questions and answers were assessed and verified; the ones which were found correct and complete were simply left unmentioned. All clarifications and remarks contained within the official letter of the Ministry of Healthcare were incorporated and considered by the national legal expert while filling in the questionnaire.
Section 2 - Reimbursement			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Whether the requirement applies domestically (Discriminatory assessment) (Column 4) ▪ Justification/purpose of the identified requirement(s) (Column 5)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	Cf. comment above.

CROATIA – COUNTRY REPORT

Part 0: Preliminary Assessment

1. **Please indicate whether the rules governing the administrative procedures/requirements for requesting PA and reimbursement under Directive 2011/24/EU in your country are set out at:**

A. National level ☒

B. Decentralised/regional/local level ☐

In case (1.B): Please indicate the two most relevant jurisdictions in your country (i.e., in terms of population):

Region/jurisdiction: 1:

Region/jurisdiction 2:

NOTE: In case (1.B) the template for the data collection (Part 1) should be complete twice, once for each of the two most relevant regions/jurisdiction indicated above.

2. **Please indicate the national body best suited to verify the accuracy of the information collected in Part 1, and justify your selection.**
Depending on the characteristics of your national healthcare system, the relevant body may be: a) *the national social security body*; or b) *an insurance fund*. In the latter case, please indicate the most representative fund (e.g., the one with the highest number of affiliations).

Body to be contacted for Task 2:

Hrvatski Zavod za Zdravstveno Osiguranje (HZZO) / Croatian Health Insurance Fund (CHIF)

Reasons for Selection:

According to Croatian law, all matters relating to national and cross-border health are regulated by the CHIF, which also serves as a National Contact Point (NCA). Therefore, it is the most accurate national body to verify and provide the information.

Part 1: Questionnaire

*__Note 1__: In cases where administrative requirements are set out in the legislative/regulatory framework at decentralised/regional/local level, please complete the template for the data collection twice, once for each of the two most relevant regions/jurisdictions (e.g., in terms population).

__*Note 2__: Setting out a Prior Authorisation (PA) system is optional for Member States. Should your country not have a system of PA in place under Directive 2011/24/EU, Section 1 will not need to be completed.

SECTION 1 PRIOR AUTHORISATION PROCEDURE(S)			
Questions	**Answer**	**Sources**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to PA procedures for a cross-border healthcare under Directive 2011/24/EU?	**Answer:** Articles 26-31 of the CHIA and Article 7 of the Ordinance 160/13.	**Source(s):** *Primary Sources:* Ordinance 160/13.[202] The Compulsory Health Insurance Act (CHIA).[203] *Secondary Sources*:	The sources consulted did not identify any specific purpose or justification. However, according to Article 7(3) of the Ordinance 160/13, all the requirements are aimed to identify and assess whether Croatia can provide equal treatment within the same time limit.

[202] Pravilnik o pravima, uvjetima i načinu korištenja prekogranične zdravstvene zaštite 160/13 (the Ordinance on the rights, requirements and manner of utilizing cross-border healthcare (Ordinance 160/13)), Interni pročišćeni tekst – "Narodne novine", broj 160/13 (stupio na snagu 1 Siječnja 2014), 11/15, 16/15 ispravak, 113/16 i 34/18, available at https://hzzo.hr/wp-content/uploads/2013/10/PRAVILNIK-_prekogranicna_procisceni_tekst.pdf?b32def (last accessed on 16 June 2021), Article 7.

[203] Zakon o obveznom zdravstvenom osiguranju 80/13 (The Compulsory Health Insurance Act (CHIA)), Interni pročišćeni tekst - "Narodne novine" broj 80/13, te njegove izmjene I dopune objavljene u "Narodnim novinama" broj 137/13 i 98/19 (stupio na snagu 1 Srpnja 2013, uz napomenu: Odredbe Članka 2 i Članka 34 u dijelu koji se odnosi na primjenu Direktive 2011/24/EU kao i Članka 26-32 stupili su na snagu 25 Listopada 2013), available at https://hzzo.hr/wp-content/uploads/2013/10/ZOZO_PROCISCENI_TEKSTv2.pdf?b32def (last accessed on 16 June 2021), Articles 27,28 and 29.

		Iris Goldner Lang, "Patient Mobility in the European Union: Pushing for EU Internal Health Market", *Medicine and Law* (Journal of the World Association of Medical Law), Volume 28, Number 4, 2009, pp. 661-672. Iris Goldner Lang, "Pravo pacijenata na prekograničnu zdravstvenu skrb u Europskoj uniji" ("The Right of Patients to Cross-Border Healthcare in the European Union"), in *Liber Amicorum Prof.dr.sc. Petar Klarić* (*Essays in Honor of Prof. Dr. Petar Klarić*), Pravni fakultet u Zagrebu, 2013, pp. 859-875. Tomislav Sokol, Ljerka Mintas-Hodak, Ana Abramović, 'Patient Mobility Directive: One step forward or two steps back for cross-border healthcare?', CYELP 8 143-173 (2012).[204] Vedran Dodig, 'Integracije Direktive 2001/24/EU u Hrvatsko zdravstveno zakonodavstvo te njezina primjena', diplomski rad, Sveučilište u Zagrebu, Medicinski fakultet (2014)[205]	

[204] Available at https://www.cyelp.com/index.php/cyelp/article/view/134 (last accessed on 16 June 2019), p. 166.
[205] Available at https://zir.nsk.hr/en/islandora/object/mef%3A965/datastream/PDF/view (last accessed on 16 June 2021), p. 24-34.

		The Citizenship Network, 'Patients' rights have no borders': Traženje zdravstvene zaštite u drugoj zemlji (2016).[206] Dubravka Pezelj Duliba, 'Korištenje prekogranične zdravstvene zaštite' (2015).[207] Croatian Health Insurance Fund, National Contact Point (2021).[208] Croatian Health Insurance Fund, National Contact Point: Using Healthcare in Another Member State of The EU/EEA/Switzerland – Directive 2011/24/EU (2021).[209] Croatian Health Insurance Fund, National Contact point: Using Healthcare in Another Member State of The EU/EEA/Switzerland – Planned Treatment (2021).[210]	
2. Is this the same procedure as for PA under the Social Security Coordination Regulations?	**Yes ☒ No ☐**		The sources consulted did not identify any specific purpose or justification.

[206] Available at http://www.activecitizenship.net/files/patients_rights/patients-rights-have-no-borders/leaflets/opuscolo_HR_web.pdf (last accessed on 16 June 2019), p. 4-6.
[207] Available at http://zdravljezasve.hr/html/zdravlje07_pacijent.html (last accessed on 16 June 2019).
[208] Available at https://hzzo.hr/en/national-contact-point-ncp (last accessed on 16 June 2021).
[209] Available at https://hzzo.hr/en/national-contact-point-ncp/using-healthcare-another-member-state-eueeaswitzerland/planned-3 (last accessed on 16 June 2021).
[210] Available at https://hzzo.hr/en/national-contact-point-ncp/using-healthcare-another-member-state-eueeaswitzerland/planned-treatment (last accessed on 16 June 2021).

3. What body is in charge of handling the PA applications?	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations)* The body in charge of handling the prior authorization (PA) applications is the CHIF's regional or branch office (which the CHIF determines according to the place of residence).	**Source(s):** Article 7(1) and 7(3) of the Ordinance 160/13. Articles 28(1) and 28(5) of the CHIA.	The sources consulted did not identify any specific purpose or justification.
4. Who is entitled to apply for PA?	**Answer:** - *If there is a national doctor involved, is there a requirement that this doctor is contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA?* The insured person by the CHIA is entitled to apply for PA.	**Source(s):** Article 7(1) of the Ordinance 160/13. Articles 26(1) and 26(2) of the CHIA.	The sources consulted did not identify any specific purpose or justification.
5. Is there a specific application form/module which the person seeking PA needs to submit?	**Answer:** *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?* There is no specific application form or module which the person seeking PA needs to submit. The reason is that the insured person can submit an application in free form.	**Source(s):** Not applicable (N/A).	The sources consulted did not identify any specific purpose or justification.

	The submission can be done in paper format (in-hand) or via email.		
6. What (other) documentation has to be submitted in order to substantiate a PA request?	**Answer:** *If applicable, please specify:* - *What documents and what particulars are required;* - *Whether there are requirements as to who has to issue the documents (e. g., a doctor contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA or any doctor);* - *Whether the submission of the documentation is optional, mandatory, or recommended.* Other mandatory documentation that has to be submitted to substantiate a PA request is the: a.) medical indication for the solicited treatment (medical history and other medical documentation from which the established indication for the requested healthcare service is evident), b.) the scheduled date for the appointment in the contacted healthcare institution or contacted private practice physician or contracted supplier of orthopaedic and other prostheses in Croatia, and the c.) dates available for the appointment or the possible date of admittance to the healthcare provider in another Member State. Due to the nature of documents, a doctor contracted by the CHIF and treating the insured person in question in Croatia or the CHIF must issue most of the documentation. However, the healthcare authority of the Member State of treatment has to give the dates available for the	**Source(s):** Article 7(2) of the Ordinance 160/13. Croatian Health Insurance Fund, National Contact Point: Using Healthcare in Another Member State of The EU/EEA/Switzerland – Directive 2011/24/EU (2021).	The sources consulted did not identify any specific purpose or justification.

	appointment or the possible date of admittance to the healthcare provider in another Member State.		
7. Are there any costs associated with the handling of the PA request?	**Answer:** *Direct cost:* *Indirect cost:* There are no direct or indirect costs associated with the handling of the PA request.	**Source(s):** N/A.	The sources consulted did not identify any specific purpose or justification.
8. Are there any specific **time requirements** linked to a PA request?	**Answer:** - *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* There is no specific time within which a requesting person must submit the PA application. However, there is a time requirement within which the requested body must decide on the PA request. Namely, the CHIF must issue a decision and deliver it to the party without delay within 30 working dates in cases of direct resolution at the party's request. However, when conducting an investigation, the CHIF is obliged to issue a decision at the party's request and deliver it to the party no later than 60 days from the day of submitting a request. If the CHIF does not issue a decision within the prescribed time limit and delivers it, the party has the right to file an appeal (to initiate an administrative dispute).	**Source(s):** Zakon o općem upravnom postupku 49/09 (The Act on General Administrative Procedure 47/09), "Narodne novine" broj 47/09 (stupio na snagu 16 Travnja 2009).	The sources consulted did not identify any specific purpose or justification.

9. Are there **differences in the procedural/administrative requirements for requesting PA** based on, for instance, the type of treatment for which PA is requested, the profile of the insured person, or any other criterion?	**Answer:** - *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* There are no differences in the procedural/administrative requirements for requesting PA based on, for instance, the type of treatment for which PA is asked for, the profile of the insured person, or any other criterion.	**Source(s):** N/A.	The sources consulted did not identify any specific purpose or justification.
10. Is there a specific PA form (i.e., form used for issuing/granting PA) and, if the answer is positive, what form?	**Answer:** When issuing a PA, a specific PA form is used. Namely, the CHIF will issue a rješenje (decision) about the proceeding whose form prescribes the Act on General Administrative Procedure 47/09.	**Source(s):** Articles 96, 97(1) and 98 of the Act on General Administrative Procedure 47/09.	The sources consulted did not identify any specific purpose or justification.
11. Please list any other administrative requirements in your country in relation to the PA procedure for cross-border healthcare.	**Answer:** There are no other administrative requirements in Croatia concerning the PA procedure for cross-border healthcare. Nonetheless, it is essential to note that there is an obligation to request PA under Croatian law. Therefore, one should consult Article 28 of the CHIA, which indicates scenarios under which the insured person is obliged to acquire the PA. Likewise, one should consult the list of the highly specialized and expensive medical infrastructure or medical equipment established by the Decision on the list of treatment procedures provided as part of the cross-border healthcare.	**Source(s):** Article 28 of the CHIA. Odluka o popisu postupaka liječenja koji se provode u okviru planirane prekogranične zdravstvene zaštite 133/13 (the Decision on the list of treatment procedures provided as part of cross-border healthcare), "Narodne novine", broj 133/13 (stupio na snagu 6 Studenog 2013). Croatian Health Insurance Fund, National Contact Point: Using Healthcare in Another Member	The sources consulted did not identify any specific purpose or justification.

		State of The EU/EEA/Switzerland – Directive 2011/24/EU (2021).		
SECTION 2 REIMBURSMENT PROCEDURE(S)				
Questions	**Answer:**	**Sources**	**Does/do the identified requirement(s) also apply domestically? (i.e., is the requirement non-discriminatory?)**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to reimbursement procedures for cross-border healthcare under Directive 2011/24/EU?	**Answer:** Two national legislative acts lay out the requirements procedure for cross-border healthcare under the Directive 2011/24/EU, namely Article 31 of the CHIA and Articles 38 and 39 of the Ordinance 160/13.	**Source(s):** *Primary Sources*: Articles 38 and 39 of the Ordinance 160/13. Article 31 of the CHIA. *Secondary Sources*: Dubravka Pezelj Duliba, 'Korištenje prekogranične zdravstvene zaštite' (2015).[211] The Citizenship Network, 'Patients' rights have no borders': Traženje zdravstvene zaštite u drugoj zemlji (2016).[212] Croatian Health Insurance Fund, National Contact Point: Using	Croatia has a domestic system where reimbursement does not apply because there is no need to anticipate the money. Therefore, neither the procedure, formalities, nor the identified requirements apply domestically. However, the reason is not discriminatory in nature, but the national legal system does not require it domestically to begin with.	The sources consulted did not identify any specific purpose or justification.

[211] Available at http://zdravljezasve.hr/html/zdravlje07_pacijent.html (last accessed on 16 June 2019).
[212] Available at http://www.activecitizenship.net/files/patients_rights/patients-rights-have-no-borders/leaflets/opuscolo_HR_web.pdf (last accessed on 16 June 2019), p. 4-6.

		Healthcare in Another Member State of The EU/EEA/Switzerland – Directive 2011/24/EU (2021).[213] Croatian Health Insurance Fund, National Contact Point: Using Healthcare in Another Member State of The EU/EEA/Switzerland – The refund of costs (2021).[214]		
2. Is this the same procedure as for reimbursement under the Social Security Coordination Regulations?	**Answer:** **Yes ☐ No ☒** Note of the National body: The procedure is not the same when the matter relates to a planned treatment in another Member State under the Social Security Regulation, and that is so because in such a case, the reimbursement is issued directly by the CHIF.		Croatia has domestic system where reimbursement does not apply because there is no need to anticipate the money. Therefore, neither the procedure, formalities nor the identified requirements apply domestically. However, the reason is not discriminatory in nature, but the national legal system does not require it domestically to begin with.	The sources consulted did not identify any specific purpose or justification.
3. What body is/are responsible of handling the reimbursement applications?	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).*	**Source(s):** Articles 38(1) and 39 of the Ordinance 160/13. Article 31(3) of the CHIA.	Croatia has domestic system where reimbursement does not apply because there is no need to anticipate the money. Therefore, neither the procedure, formalities nor the	The sources consulted did not identify any specific purpose or justification.

[213] Available at https://hzzo.hr/en/national-contact-point-ncp/using-healthcare-another-member-state-eueeaswitzerland/planned-3 (last accessed on 16 June 2021).
[214] Available at https://hzzo.hr/en/national-contact-point-ncp/using-healthcare-another-member-state-eueeaswitzerland/necessary-3 (last accessed on 16 June 2021).

	The body responsible for handling the reimbursement applications is the CHIF regional or branch office (which the CHIF determines according to the place of residence).		identified requirements apply domestically. However, the reason is not discriminatory in nature, but the national legal system does not require it domestically to begin with.	
4. Is there a specific application form/module which the person seeking reimbursement needs to submit?	**Answer:** *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?* There is no specific application form or module which the person seeking reimbursement needs to submit. The reason is that the insured person can submit an application in free form. The submission can be done in paper format (in-hand) or via email.	**Source(s):** N/A.	**Yes** ☐ **No** ☒	The sources consulted did not identify any specific purpose or justification.
5. What (other) documentation has to be submitted in order to substantiate a reimbursement request?	**Answer:** *If applicable, please specify:* - *What documents are required;* - *Whether the submission of the documentation is optional, mandatory, or recommended.*	**Source(s):** Article 38(2) of the Ordinance 160/13. Croatian Health Insurance Fund, National Contact Point: Using Healthcare in Another Member State of The EU/EEA/Switzerland – Directive 2011/24/EU (2021).	**Yes** ☐ **No** ☒	The sources consulted did not identify any specific purpose or justification.

	The documentation that has to be submitted to substantiate a reimbursement request is the following: a.). the original medical documentation declaring the medical services obtained, b.) (i) the original receipt from which the CHIF can see that the receipt was issued to the insured person, and (ii) from which it can be explicitly seen what services were provided to the insured person seeking the reimbursement, and (iii) from which the CHIF can see that the receipt is fully paid. Also, the submission of the documentation is mandatory in a case where an insured person is seeking reimbursement.			
6. Are there any costs associated with the handling of the reimbursement request?	**Answer:** *Direct cost:* *Indirect cost:* There are no direct or indirect costs associated with the handling of the reimbursement request.	**Source(s):** N/A.	**Yes** ☐ **No** ☒	The sources consulted did not identify any specific purpose or justification.
7. Are there any specific time requirements linked to a reimbursement request?	**Answer:** *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* There are two specific time requirements liked to a reimbursement request. Namely, one relates to the time within which the insured person must submit the reimbursement request, and another	**Source(s):** Article 134(1) of the CHIA. Article 101 of the Act on General Administrative Procedure 47/09.	**Yes** ☐ **No** ☒	The sources consulted did not identify any specific purpose or justification.

	one relates to the time within which the requested body must handle the request. Regarding the first requirement linked to a reimbursement request, the insured party has three years from the date when the cost occurred (that is, from the date when the insured person gained the right to obtain reimbursement) to submit a reimbursement request (Article 134(1) of the CHIA). Secondly, there is a time requirement within which the requested body must decide on the reimbursement request. Namely, the CHIF must issue a decision and deliver it to the party without delay within 30 working dates in cases of direct resolution at the party's request. However, when conducting an investigation, the CHIF is obliged to issue a decision at the party's request and deliver it to the party no later than 60 days from the day of submitting a request. If the CHIF does not issue a decision within the prescribed time limit and delivers it, the party has the right to file an appeal (to initiate an administrative dispute). The individual can find this right in Article 101 of the Act on General Administrative Procedure 47/09.			
8. Are there any non-reimbursable thresholds, deductions *(except the deductions for administrative costs mentioned above) etc.?*	**Answer:** *If yes, please specify the thresholds.* The insured person is entitled to reimbursement of costs in accordance with the Croatian tariff for the equivalent service (Croatian price). Therefore, anything that goes beyond that is non-	**Source(s):** Article 31(2) and 31(4) of the CHIA.	**Yes** ☐ **No** ☒	The sources consulted did not identify any specific purpose or justification.

	reimbursable. Thus, for example, the insured person who used the right obtained under Article 27, 28 or 30 of the CHIA does not have the right to obtain reimbursement for travel or other related costs from the CHIF.			
9. In instances where a PA (or prior-notification) has already been issued, is a separate/simplified procedure available for requesting reimbursement?	**Answer:** *If yes, please describe the simplified procedure.* In instances where the CHIF has already issued the PA, there is no separate or simplified procedure available for requesting reimbursement. The reason is that there is no possibility to obtain reimbursement without PA because Croatia implemented the system of mandatory PA. Consequently, there is only one procedure available in Croatia.	**Source(s):** N/A.	**Yes** ☐ **No** ☒	The sources consulted did not identify any specific purpose or justification.
10. Are there additional administrative/procedural requirements for reimbursement depending on, for instance, the type of treatment for which reimbursement is requested, or the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* There are no additional administrative or procedural requirements for reimbursement depending on, for instance, the type of treatment for which reimbursement is requested, or the profile of the insured person or any other criterion.	**Source(s):** N/A.	**Yes** ☐ **No** ☒	The sources consulted did not identify any specific purpose or justification.
11. Please list any other administrative requirements in your country in relation to the procedures of reimbursement of cross-border healthcare.	**Answer:** In Croatia, no other administrative requirements were found concerning the procedure of reimbursement of cross-border healthcare.	**Source(s):** N/A.	**Yes** ☐ **No** ☒	The sources consulted did not identify any specific purpose or justification.

Part 2: Checklist for verification with national/regional body

Name of the body: CHIF
Country/Region: Croatia
Date of verification call: 15-16/06/2021

Template for the Data Collection	**Aspects to be verified** *Tick the boxes if the information in the template for the data collection has been verified and/or complemented by the national body*		**Comments** *Include any additional comments and/or information provided by the contacted body*
Section 1 – Prior Authorisation			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Justification/purpose of the identified requirement(s) (Column 4)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	The contacted body was extremely helpful, willing to cooperate, accurate, and verified all the information in detail. Also, during the verification call, the CHIF added a few explanations to answers which could not be found under Croatian law. For example, under question 5, the CHIF further specified and elaborated on why there is no specific application form or module which the person seeking PA needs to submit. The input provided has been incorporated in the questionnaire.
Section 2 - Reimbursement			
For each question verify the accuracy and/or fill the gaps for: Answers (Column 2) Sources (Column 3) Whether the requirement applies domestically (Discriminatory assessment) (Column 4) Justification/purpose of the identified requirement(s) (Column 5)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	The contacted body was extremely helpful, willing to cooperate, accurate, and verified all the information in detail. Also, during the verification call, the CHIF added a few explanations to answers which could not be found under Croatian law. For example, under question 2, the CHIF explained in detail why the procedure is not the same when the matter relates to a planned treatment in another Member State under the Social Security Regulation, and that is so because in such a case, the reimbursement is issued directly by the CHIF. The input provided has been incorporated in the questionnaire.

CYPRUS – COUNTRY REPORT

Part 0: Preliminary Assessment

1. **Please indicate whether the rules governing the administrative procedures/requirements for requesting PA and reimbursement under Directive 2011/24/EU in your country are set out at:**

A. National level ☒

B. Decentralised/regional/local level ☐

In case (1.B): Please indicate the two most relevant jurisdictions in your country (i.e., in terms of population):

Region/jurisdiction: 1:

Region/jurisdiction 2:

NOTE: In case (1.B) the template for the data collection (Part 1) should be complete twice, once for each of the two most relevant regions/jurisdiction indicated above.

2. **Please indicate the national body best suited to verify the accuracy of the information collected in Part 1, and justify your selection.**
Depending on the characteristics of your national healthcare system, the relevant body may be: a) *the national social security body*; or b) *an insurance fund*. In the latter case, please indicate the most representative fund (e.g., the one with the highest number of affiliations).

Body to be contacted for Task 2: Ministry of Health

(In case 1.B, please indicate two relevant bodies, one respectively for each Region/jurisdiction)

Reasons for Selection: The Ministry of Health is the competent social security body, as it has created and runs the general health system (Gesy) through which all residents of the Republic of Cyprus are compulsorily insured. Moreover, any requests for prior authorisation or reimbursement are handled by the Ministry of Health.

Part 1: Questionnaire

*__Note 1__: In cases where administrative requirements are set out in the legislative/regulatory framework at decentralised/regional/local level, please complete the template for the data collection twice, once for each of the two most relevant regions/jurisdictions (e.g., in terms population).

__*Note 2__: Setting out a Prior Authorisation (PA) system is optional for Member States. Should your country not have a system of PA in place under Directive 2011/24/EU, Section 1 will not need to be completed.

SECTION 1 PRIOR AUTHORISATION PROCEDURE(S)			
Questions	Answer	Sources	Purpose and/or justification of the requirements
1. Which national legislative and/or regulatory provisions lay out the requirements related to PA procedures for a cross-border healthcare under Directive 2011/24/EU?	Answer: For PA, a procedure seems to be in place because a module is available and there is information on the NCP website. However, the legislative sources consulted do not seem to refer to PA (Article 21 of the Law for the Application of Patients' Rights in Cross- border Healthcare (Law No. 149(I)/2013) which referred to prior authorisation has been removed in 2019), and that therefore Section 1 completed based on the available sources.	Source(s): Law for the Application of Patients' Rights in Cross- border Healthcare (Law No. 149(I)/2013).	N/A
2. Is this the same procedure as for PA under the Social Security Coordination Regulations?	Answer: Yes ☒ No ☐		N/A
3. What body is in charge of handling the PA applications?	Answer:	Source(s):	N/A

	(e.g., where and to whom PA applications have to be submitted?)	*Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations)* The Ministry of Health is in charge of handling PA applications. PA application form can be found online, and should be submitted to the NCP in the Ministry of Health, via email or in person at the Ministry.	Information on the official website of NCP.[215] Article 2 of the Law for the Application of Patients' Rights in Cross- border Healthcare (Law No. 149(I)/2013): '"Competent Authority" means the Ministry of Health'	
4.	Who is entitled to apply for PA? *(e.g., can the patients apply themselves, or is treating doctor filing/partially filling the request, etc.)*	Answer: - *If there is a national doctor involved, is there a requirement that this doctor is contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA?* Any person that is insured in the Republic of Cyprus may apply for PA.	Source(s): Article 17(B) of the Law for the Application of Patients' Rights in Cross- border Healthcare (Law No. 149(I)/2013).	N/A
5.	Is there a specific application form/module which the person seeking PA needs to submit?	Answer: *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?* Yes, there is a specific application form to be used. The Information required includes:	Source(s): Official PA application form found on the website of NCP.[217]	

[215] Available at: https://www.moh.gov.cy/Moh/cbh/cbh.nsf/page15_gr/page15_gr?OpenDocument.

[217] Available at: https://www.moh.gov.cy/Moh/cbh/cbh.nsf/page24_en/page24_en?OpenDocument.

	1) personal details of applicant (full name, DOB, ID number, Address, Telephone number); 2) Requested health service (short description of medical incident and health service for which prior authorisation is required); 3) Declaration (Signature, Full Name, Date) 4) Required Documents The information is mandatory as the form says "required documents". The application form can be found online, and should be submitted to the NCP in the Ministry of Health, via email or in person at the Ministry.[216]		
6. What (other) documentation has to be submitted in order to substantiate a PA request?	Answer: *If applicable, please specify:* - *What documents and what particulars are required;* - *Whether there are requirements as to who has to issue the documents (e. g., a doctor contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA or any doctor);* - *Whether the submission of the documentation is optional, mandatory, or recommended.* The following documents are required (mandatory): 1) Copy of medical ID card or relevant certificate issued by the Ministry of Health 2) Copy of the medical report, which shall include: I. The diagnosis / disease II. The history III. The current state of health	Source(s): Official PA application form found on the website of NCP.	

[216] Applicable forms available online can be found at the following: https://www.moh.gov.cy/Moh/cbh/cbh.nsf/page24_en/page24_en?OpenDocument.

	IV. The reasons for which the physician suggests the receiving of cross-border healthcare in another Member State		
7. Are there any costs associated with the handling of the PA request? - *Direct costs (e.g., fixed costs for submitting or filing a PA request).* - *Indirect costs* (*e.g., translations, stamps, etc).*	Answer: *Direct costs:* None identified. *Indirect costs:* None identified.	Source(s): N/A	N/A
8. Are there any specific time requirements linked to a PA request? (*e.g., time within which a requesting person must submit the PA application and/or time within which the requested body must take a decision on the PA request, etc.*).	Answer: - *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* Patients must submit the PA application to the NCP before their departure from the Republic of Cyprus for the purpose of receiving cross-border healthcare in another Member State. The NCP refers the applications meeting the required conditions to the Committee of Experts for clinical evaluation and must inform the applicant of the final decision of the Chief Executive within 30 days from the submission of the application. No consequences are specified in relation to missing deadlines.	Source(s): Law for the Application of Patients' Rights in Cross- border Healthcare (Law No. 149(I)/2013). Information on the official website of NCP.[218]	

[218] Available at: https://www.moh.gov.cy/Moh/cbh/cbh.nsf/page15_en/page15_en?OpenDocument.

9. Are there differences in the procedural/administrative requirements for requesting PA based on, for instance, the type of treatment for which PA is requested, the profile of the insured person, or any other criterion?	Answer: *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* There appear to be no differences.	Source(s): N/A	N/A
10. Is there a specific PA form (i.e., form used for issuing/granting PA) and, if the answer is positive, what form?	Answer: No specific PA issuing form has been identified.	Source(s): N/A	N/A
11. Please list any other administrative requirements in your country in relation to the PA procedure for cross-border healthcare.	Answer: N/A	Source(s): N/A	

SECTION 2 **REIMBURSMENT PROCEDURE(S)**				
Questions	**Answer:**	**Sources**	**Does/do the identified requirement(s) also apply domestically? (i.e., is the requirement non-discriminatory?)**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory	Answer:	Source(s):	N/A	N/A

	provisions lay out the requirements related to reimbursement procedures for cross-border healthcare under Directive 201/24/EU?	Articles 16- 17C of the Law for the Application of Patients' Rights in Cross- border Healthcare (Law No. 149(I)/2013)	Article 16 – 17C, Law for the Application of Patients' Rights in Cross- border Healthcare (Law No. 149(I)/2013).		
2.	Is this the same procedure as for reimbursement under the Social Security Coordination Regulations?	Answer: Yes ☒ No ☐		N/A	N/A
3.	What body is/are responsible of handling the reimbursement applications? (e.g., where and to whom reimbursement applications have to be submitted?)	Answer: *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* The Ministry of Health is in charge of handling reimbursement applications. Reimbursement application forms can be found online, and should be submitted to the NCP in the Ministry of Health, via email or in person at the Ministry.	Source(s): Article 5, Law for the Application of Patients' Rights in Cross- border Healthcare (Law No. 149(I)/2013). Official website of NCP.[219]	N/A	N/A
4.	Is there a specific application form/module which the person seeking reimbursement needs to submit?	Answer: *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?*	Source(s): Regulatory Administrative Act 16/2020[220]: Application form available online can be found online.[221]	Yes ☐ No ☒ The healthcare system in Cyprus does not require 'prior	

[219] Available at: https://www.moh.gov.cy/Moh/cbh/cbh.nsf/page24_en/page24_en?OpenDocument.

[220] Κ.Δ.Π. 16/2020, Οι περί εφαρμογής των δικαιωμάτων των ασθενών στο πλαίσιο της διασυνοριακής υγειονομικής περίθαλψης και για συναφή θέματα Νόμοι του 2013 εως 2019 (RAA 16/2020 of the Laws of 2013 to 2019 for the Application of Patients' Rights in Cross- border Healthcare and related issues), available at: http://www.cylaw.org/KDP/data/2020_1_16.pdf.

[221] Available at: https://www.moh.gov.cy/Moh/cbh/cbh.nsf/page24_en/page24_en?OpenDocument.

	- *Does the form have to be submitted in paper or can it be submitted electronically?* Yes, a specific application form exists. The information required therein is: 1) personal details of applicant (full name, DOB, ID number, Address, Telephone number); 2) Healthcare service provided; 3) Declaration (Signature, Full Name, Date); 4) Required Documents The information is mandatory as the form says "required documents". The application form can be found online (cfr. Sources), and should be submitted to the NCP in the Ministry of Health, via email or in person at the Ministry.		authorisation'. A referral from the GP would suffice for most treatments, and that would be at the discretion of the doctor. The social security system anticipates the costs of any treatment, through contributions that are taken from citizens' salaries on a monthly basis.	
5. What (other) documentation has to be submitted in order to substantiate a reimbursement request?	Answer: *If applicable, please specify:* - *What documents are required;* - *Whether the submission of the documentation is optional, mandatory, or recommended.* Documents required: 1) Copy of prior authorisation document (if applicable) 2) The original invoice / payment receipt / certified copy of the medical prescription and payment receipt from the Pharmacy (depending on the relevant Legal Order on reimbursement or not of pharmaceuticals and medical devices) 3) Copy of the medical report from the medical centre of the responsible healthcare provider in case of prior authorization	Source(s): Regulatory Administrative Act 16/2020.	Yes ☐ No ☒	

	4) The completed and signed authorisation form from Payments by FIMAS (Integrated Financial Management System), along with a written confirmation from the Bank stating the IBAN 5) Copy of Medical ID or relevant certificate issued by Ministry of Health.			
6. Are there any costs associated with the handling of the reimbursement request? - *Direct costs (e.g., fixed costs for submitting or filing a reimbursement request, proportion deducted from the reimbursable amount).* - *Indirect costs* (*e.g., translations, stamps, etc).*	Answer: *Direct costs:* None identified/ *Indirect costs:* None identified, besides possible postal costs for paper submission.	Source(s): N/A	Yes ☐ No ☒	
7. Are there any specific time requirements linked to a reimbursement request? (*e.g., time within which the reimbursement requests must be submitted and/or time within the requested body must handle the request and/or reimburse the costs, etc.*).	Answer: *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* No reference is made to specific time requirements for requesting a reimbursement. However, according to Article 17A, the requested body must issue a decision and reimburse the costs within 90 days of the request. As per Article 17Γ, the procedure is as follows:	Source(s): Article 17A, Article 17Γ, Law for the Application of Patients' Rights in Cross- border Healthcare (Law No. 149(I)/2013).	Yes ☐ No ☒	

	1) Any person insured in the Republic of Cyprus may submit a request for reimbursement for healthcare sought 2) The NCP received the request and once satisfied that the requirements of the Law are fulfilled, it refers the request to the "Committee of Specialists" with the required specialisation for a clinical evaluation of the healthcare service received by the requestor. 3) The NCP shall forward the opinion of the Committee to the Director-General. 4) The NCP shall notify the applicant, in writing, of the approval or rejection by the Director-General of the request for reimbursement of expenses within the period stated in Article 17A, from the date of submission of the request. No information is given in relation to failing to meet these deadlines.			
8. Are there any non-reimbursable thresholds, deductions *(except the deductions for administrative costs mentioned above) etc.?*	Answer: *If yes, please specify the thresholds.* The Law specifies that the following services are not reimbursable: 1) refractive surgery 2) cosmetic surgery 3) consumables (shoes, wheelchair) etc. Moreover, the NCP publishes a price list on its website which specifies the reimbursable amounts for specific procedures.	Source(s): Regulatory Administrative Act 16/2020. NCP price list (Regulatory Administrative Act 143/2013)[222]	Yes ☐ No ☒	

[222] Available at: http://www.cylaw.org/KDP/data/2013_1_143.pdf.

9. In instances where a PA (or prior-notification) has already been issued, is a separate/simplified procedure available for requesting reimbursement? **applicable only if the country has a PA system.*	Answer: *If yes, please describe the simplified procedure.* No, the same procedure applies with or without PA.	Source(s): Application forms on official website of NCP.	Yes ☐ No ☒	N/A
10. Are there additional administrative/procedural requirements for reimbursement depending on, for instance, the type of treatment for which reimbursement is requested, or the profile of the insured person, or any other criterion?	Answer: *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* None identified.	Source(s): N/A.	Yes ☐ No ☐	N/A
11. Please list any other administrative requirements in your country in relation to the procedures of reimbursement of cross-border healthcare.	Answer: None identified.	Source(s): N/A.	Yes ☐ No ☐	N/A

Part 2: Checklist for verification with national/regional body

Name of the body: N/A
Country/Region: N/A
Date of verification call: N/A

Template for the Data Collection	**Aspects to be verified** *Tick the boxes if the information in the template for the data collection has been verified and/or complemented by the national body*		**Comments** *Include any additional comments and/or information provided by the contacted body*
Section 1 – Prior Authorisation			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Justification/purpose of the identified requirement(s) (Column 4)	☐ Question 1 ☐ Question 2 ☐ Question 3 ☐ Question 4 ☐ Question 5	☐ Question 6 ☐ Question 7 ☐ Question 8 ☐ Question 9 ☐ Question 10 ☐ Question 11	
Section 2 - Reimbursement			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Whether the requirement applies domestically (Discriminatory assessment) (Column 4) ▪ Justification/purpose of the identified requirement(s) (Column 5)	☐ Question 1 ☐ Question 2 ☐ Question 3 ☐ Question 4 ☐ Question 5	☐ Question 6 ☐ Question 7 ☐ Question 8 ☐ Question 9 ☐ Question 10 ☐ Question 11	

CZECH REPUBLIC – COUNTRY REPORT

Part 0: Preliminary Assessment

1. **Please indicate whether the rules governing the administrative procedures/requirements for requesting PA and reimbursement under Directive 2011/24/EU in your country are set out at:**

A. National level ☒

B. Decentralised/regional/local level ☐

In case (1.B): Please indicate the two most relevant jurisdictions in your country (i.e., in terms of population):

Region/jurisdiction: 1: N/A

Region/jurisdiction 2: N/A

NOTE: In case (1.B) the template for the data collection (Part 1) should be complete twice, once for each of the two most relevant regions/jurisdiction indicated above.

2. **Please indicate the national body best suited to verify the accuracy of the information collected in Part 1, and justify your selection.** Depending on the characteristics of your national healthcare system, the relevant body may be: a) *the national social security body*; or b) *an insurance fund*. In the latter case, please indicate the most representative fund (e.g., the one with the highest number of affiliations).

Body to be contacted for Task 2: Všeobecná zdravotní pojišťovna České republiky

(In case 1.B, please indicate two relevant bodies, one respectively for each Region/jurisdiction)

Reasons for Selection: "Všeobecná zdravotní pojišťovna České Republiky" or (VZP ČR) is the insurance fund established by law (Act. No. 551/1991 Coll.). Even if the current legislation allows competing insurance funds (there are currently eight competing insurance funds in the market), the VZP is by all measures the only dominant player in the field of public health insurance. It represents approximately 6 million residents out of 10,7 million residents in total. In comparison, the second largest insurance fund has approximately 1,3 million affiliations.

The general public sees VZP ČR as a stable public corporation backed by the state. VZP ČR has wide territorial coverage and the network of its contracted healthcare providers covers all of the regions and districts of the Czech Republic.

It is important to mention, that VZP ČR is not the national contact point on the basis of Art. 14 of Public Health Insurance Act and EU Directive 24/2011 on Patients' Rights in Cross-Border Healthcare. This role is served by Health insurance bureau (Kancelář zdravotního pojištění), which is a non-profit institution founded jointly by several health insurance funds.

Part 1: Questionnaire

*__Note 1__: In cases where administrative requirements are set out in the legislative/regulatory framework at decentralised/regional/local level, please complete the template for the data collection twice, once for each of the two most relevant regions/jurisdictions (e.g., in terms population).

__*Note 2__: Setting out a Prior Authorisation (PA) system is optional for Member States. Should your country not have a system of PA in place under Directive 2011/24/EU, Section 1 will not need to be completed.

Note: in Czech Republic no PA system has been introduced under Directive 2011/24/EU. The national legislation regulates the PA procedure, but it also grants the Government the competence to issue a regulation listing the treatments for which PA is needed. It is worth noting that the Government has never used this competence, therefore this procedure is not used.
For this reason, Section 1 of the questionnaire below has not been completed.[223]

SECTION 1 PRIOR AUTHORISATION PROCEDURE(S)			
Questions	**Answer**	**Sources**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to PA procedures for a cross-border healthcare under Directive 2011/24/EU?	**Answer:** Act on public health insurance: - Section 2. This provision states, that every person with permanent residence, employment or self-employment in the Czech Republic have obligatory participation on the health insurance.	**Source(s):** In general, the provisions of: - Act on public health insurance, Section 14, 14a, 14b, 14c[225] - The Government Regulation on the accessibility of healthcare[226]	

[223] It is worth nothing that applying PA under the framework of the Directive 2011/24/EU remains only a theoretical possibility and is very rarely used by patients who seek to receive healthcare abroad.
[225] Zákon č. 48/1997 Sb. ze dne 7. března 1997 o veřejném zdravotním pojištění a o změně a doplnění některých souvisejících zákonů, částka 16/1997
[226] Nařízení vlády č. 307/2012 Sb. Nařízení vlády ze dne 29. srpna 2012 o místní a časové dostupnosti zdravotních služeb, částka 110/2012

	- Section 14, first paragraph. This provision states that public health insurance covers healthcare that is rendered on the territory of the Czech Republic. This is, however, a general rule, which needs to be interpreted together with special provisions in **sections 14 (remaining paragraphs), 14a, 14b, and 14c** - Section 14, third paragraph. This provision states that healthcare received abroad may be compensated up to the cost that would have been assumed in the Czech Republic. Ex post compensation, even without previously approved PA is possible. - Section 14b, first paragraph. This provision addresses the **Prior Authorisation procedure.** It gives the government explicit competence to select health services for which the prior authorisation will be necessary if the patient intends to have the cost of his/her treatment abroad reimbursed in the Czech Republic. The government is granted the authority to issue a regulation with the positive or negative list of services eligible or ineligible for PA. However, the services can be only picked from the already existing list of services contained in the regulation "307/2012 coll". This effectively limits the powers of the government to request PA to the care that can be planned in advance. **<u>NOTE:</u>** **It is important to mention that the Czech government has never used this**		

	competence, and the list of services, which can be reimbursed only upon prior authorsation does not exist.[224] - Section 14b, fifth paragraph. This provision states, that health insurance fund needs to assess whether the PA under Social Security Coordination Regulations does not give the applicant more benefits. If the procedure foreseen under Social Security Coordination Regulations is more favourable, the health Insurance Fund should follow the procedure under Social Security Coordination Regulations, unless the applicant insists on processing the application under the Section 14b. - Section 53. This provision states, that the PA requests under the section 14b (see point 1) are administered under general rules of Administrative procedure.		
2. Is this the same procedure as for PA under the Social Security Coordination Regulations?	**Answer:** **Yes ☒ No ☐** Section 14b, fifth paragraph: health insurance fund needs to assess whether the PA under Social Security Coordination Regulations does not give the applicant more benefits. They have jurisdiction to decide on requests of their clients. If the procedure foreseen under Social Security Coordination Regulations is more		The law does not contain any criteria restricting eligibility that have to be justified. Every insured person without restrictions has the right to apply for the PA.

[224] Note of the National expert: The PA under the Directive is in place, and it is integral part of our law (regulated by Act. 48/1997). According to the national legislation, the Government has the power to define the list of services that need PA. However, such a list has never been issued. As a result, the citizens/residents have a right to apply for PA under the Directive and if somebody does so, the insurance provider has to deal with the request. But there are very few reasons, why residents would apply for it, because the remaining two options (PA under social security directive or ex post reimbursement) are administratively simpler and more favourable. Therefore, insurance companies advise and nudge their clients to submit requests under SSC regulation.
However, if the government makes a decision and issues the list of services the situation will change.

	favourable, the health Insurance Fund should follow the procedure under Social Security Coordination Regulations, unless the applicant insists on processing the application under the Section 14b. This means that the insurance provider has an obligation to lead its client to a procedure that will have more favourable outcome. Therefore, the outcome of procedure should be **substantially** equivalent to procedure under the SSC Regulations, but the patient has a right to insist on remaining in the procedure under the Directive **Source(s):** Section 14b, third paragraph.		
3. What body is in charge of handling the PA applications? **3.** *(e.g., where and to whom PA applications have to be submitted?)*	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* The Czech Health insurance system is based on multiple insurance funds. Each provider is responsible for handling requests regarding PA and reimbursement of healthcare received abroad by the clients of the respective provider. The request can be filed at any of the 190 regional offices (contact points) but the decision is actually taken by the central administrative bodies (Czech name: "Ústředí" and "Krajská pobočka").	**Source(s):** Act on public health insurance: Section 14b, third paragraph: gives the Health Insurance Fund the jurisdiction to decide on requests of their clients	
4. Who is entitled to apply for PA?	**Answer:**	**Source(s):**	The law does not contain any criteria restricting eligibility that have to be justified. Every insured

4. (e.g., can the patients apply themselves, or is treating doctor filing/partially filling the request, etc.) **5.**	*If there is a national doctor involved, is there a requirement that this doctor is contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA?* Any client of the health insurance fund (any insured person) may file the request/application for PA.	Act on public health insurance: Section 2 – this provision states, that every person with permanent residence, employment or self-employment in the Czech Republic have obligatory participation on the health insurance.	person without restrictions has the right to apply for the PA.
5. Is there a specific application form/module which the person seeking PA needs to submit?	**Answer:** *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?* A form for PA under the Directive does not exist.[227] Insurance funds can accept PA applications under the Directive as well. However, considering the more favourable positions of patients under the Regulations, funds lead their clients to submit PA under the Regulations.[228]	**Source(s):**	
6. What (other) documentation has to be submitted in order	**Answer:** *If applicable, please specify:*	**Source(s):**	

[227] Note of the National expert: Because the government did not use its competence and did not narrow down the list of services that require PA, there is no major benefit of the client to ask for PA under the Directive 2011/24/EU. Asking for the reimbursement ex post brings the same outcome as applying for PA under directive 2011/24/EU.

[228] Note of the National expert: This procedure opens the possibility that reimbursement may be higher than the cost that would have been assumed in the Czech Republic. If the administrative procedure ends favourably, the clients are issued the form S2 (formerly E112).

to substantiate a PA request?	- *What documents and what particulars are required;* - *Whether there are requirements as to who has to issue the documents (e. g., a doctor contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA or any doctor);* - *Whether the submission of the documentation is optional, mandatory, or recommended.* As above, a form for PA under the Directive does not exist.		
7. Are there any costs associated with the handling of the PA request? - *Direct costs (e.g., fixed costs for submitting or filing a PA request).* - *Indirect costs* (*e.g., translations, stamps, etc).*	**Answer:** *Direct costs:* N/A *Indirect costs:* N/A	**Source(s):**	
8. Are there any specific **time requirements** linked to a PA request? 6. (*e.g., time within which a requesting person must submit the PA application and/or time within which the requested body must take a decision on the PA request, etc.*).	**Answer:** - *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* PA requests are regulated by general administrative rules. There are no specific deadlines. If there was the PA under the Directive, the health insurance fund (requested body) would have 30 days to process the application. Therefore,	**Source(s):** Act on public health insurance[1]: Section 53 Section 71 (contains general deadlines for administrative bodies to make a conclusion of an administrative procedure)	It can be concluded that general rules on administrative procedure apply to the submission and of requests and subsequent procedure. The decision-making procedure is a standard administrative procedure without any deviations from the other administrative procedures. This information is valid for PA application under the Directive (which is not used) and PA application under the Social Security Coordination regulations (which is the usual choice).

	submitting an application at least 30 days prior to the date of planned treatment is the usual procedure. If the deadline is missed, the applicant can file a complaint to the Ministry of Health of the CR.		
9. Are there **differences in the procedural/administrative requirements for requesting PA** based on, for instance, the type of treatment for which PA is requested, the profile of the insured person, or any other criterion?	**Answer:** - *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* N/A	**Source(s):** Not available	The process regarding PA is governed in accordance with general rules of administrative procedure.
10. Is there a specific PA form (i.e., form used for issuing/granting PA) and, if the answer is positive, what form?	**Answer:** N/A There is no specific PA form when it comes to PA under the Directive 2011/24/EU.	**Source(s):** Not available	Insurance funds can accept PA applications under Social Security Coordination Regulations as well as PA applications under Directive 2011/24/EU.
11. Please list any other administrative requirements in your country in relation to the PA procedure for cross-border healthcare.	**Answer:** Nothing worth mentioning.[229]	**Source(s):** See points 1., 4., 8.,	
SECTION 2 REIMBURSMENT PROCEDURE(S)			

[229] Note of the National expert: As was stated in points 1., 4., and 8., the PA procedure is not even necessary for reimbursement of healthcare received abroad.
If the applicant applies for PA, the process is governed in accordance with general rules of administrative procedure.

Questions	Answer:	Sources	Does/do the identified requirement(s) also apply domestically? (i.e., is the requirement non-discriminatory?)	Purpose and/or justification of the requirements
1. Which national legislative and/or regulatory provisions lay out the requirements related to reimbursement procedures for cross-border healthcare under Directive 2011/24/EU?	**Answer:** Act on public health insurance: - Section 14, third paragraph. This provision states that healthcare received abroad may be compensated up to the cost that would have been assumed in the Czech Republic. Ex post compensation, even without previously approved PA is possible. - Section 14c. This provision gives the Ministry of Health of the CR the competence to assign the duties of the National contact point. The ministry assigned the role of the National Contact Point to the entity named: "Health Insurance Bureau" (Czech: Kancelář zdravotního pojištění"). Health Insurance Bureau is a non-profit entity founded jointly by all health insurance funds in the country - Section 53. This provision states that the requests for reimbursement are administered under general rules of administrative procedure.	**Source(s):** Act on public health insurance[1]	N/A	N/A
2. Is this the same procedure as for reimbursement under	**Answer:** **Yes ☒ No ☐**		N/A	

the Social Security Coordination Regulations?	Even if the law recognizes each procedure as different, they are **substantially** equivalent.			
3. What body is/are responsible of handling the reimbursement applications? 7. (e.g., where and to whom reimbursement applications have to be submitted?)	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* The Czech Health Insurance System is based on multiple insurance funds. Therefore, each provider is responsible for handling requests regarding reimbursement of healthcare, which was received abroad by the clients of the respective provider. The request can be filed at any of the 190 regional offices (contact points) but the decision is taken by the central administrative bodies (Czech name: "Ústředí", "Regionální Pobočka").	**Source(s):** See point 3 in Section A.	N/A	N/A
4. Is there a specific application form/module which the person seeking reimbursement needs to submit? 8.	**Answer:** *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?*	**9. Source(s):** 10. 11. The English version of the form used by VZP ČR (largest insurance fund)[230] 12. 13. The recommended wording of the form by Health	14. **Yes** ☐ 15. **No** ☒ 16. 17. Patients recieving care in Czech facilities usually pays no cash and everything is cleared between provider and hospital.	18. The form itself is short and easy to fill in. 19. 20. The question whether the care received abroad can be reimbursed will be judged by the same criteria as the care received in the Czech Republic.

[230] Available at: https://media.vzpstatic.cz/media/Default/formulare/application-for-reimbursement-of-costs-of-health-en.pdf.

	Yes. Most insurance funds use similar forms in compliance with the recommendation of the Health Insurance Bureau (as a form of soft law). - *What information is required?* The form is quite simple. It involves the contact details, the details on the state where services were received and the sum that is requested to be reimbursed. - *Is the information mandatory, optional, or recommended?* Information mentioned above is mandatory, but it is important to note that the amount of requested information usually does not exceed one page. - *Is this application form/modules available online?* Yes. In Czech and English version. - *Does the form have to be submitted in paper or can it be submitted electronically?* Both methods of submission are possible.	Insurance Bureau (Czech only)[231]	The request for reimbursement of care within the borders of the Czech Republic is usually administered by the healthcare provider and not by the patient.[232] Therefore, this procedure is not applied domestically.	The care will be reimbursed up to the amount that equates the costs of the corresponding care in the Czech Republic.[233]
5. What (other) documentation has to be submitted in order to substantiate a reimbursement request?	**Answer:** *If applicable, please specify:* - *What documents are required;* - *Whether the submission of the documentation is optional, mandatory, or recommended.* *Compulsory attachments:*	**Source(s):** The English version of the form used by VZP ČR (largest insurance fund).	**Yes** ☐ **No** ☒	The attachments are deemed necessary to process the request. The amount of requested information is, in the opinion of the reviewer, proportionate

[231] Available at: https://www.kancelarzp.cz/images/cmu_documents/forms/zadost-refundace.pdf/.
[232] Section 11 of the Act on public health insurance.
[233] Note of the National expert: In case the Insurance fund issued PA under the SSR Regulation, the cost can be reimbursed, in certain cases, even to higher levels than are usual in the Czech Republic.

	(1) An original copy of the payment receipt (2) Medical reports issued abroad (a copy is sufficient), including their Czech translation (a certified translation is not necessary; translation is not necessary for the reports written in Slovak). If a legal representative files an Application, it is necessary to submit also their birth certificate or other document proving the respective family relation (a copy of the document is sufficient). If an authorised representative files an Application, it is necessary to submit also a power of attorney.			to the objective of administrative procedure.
6. Are there any costs associated with the handling of the reimbursement request? - *Direct costs (e.g., fixed costs for submitting or filing a reimbursement request, proportion deducted from the reimbursable amount).* - *Indirect costs* (*e.g., translations, stamps, etc).*	**Answer:** *Direct costs:* There are no direct costs. The submission of the application is free of charge. *Indirect costs:* Costs of translation of medical documentation (unless the documents are in Czech or in Slovak). The application may be submitted in person, by post or electronically. If the applicant decides to use land-mail, the actual costs of submission (paper, envelope, stamps) will usually not exceed 5 EURO.	**Source(s):** The English version of the form used by VZP ČR (largest insurance fund)	**Yes** ☒ **No** ☐	The major indirect costs may be the costs of translation of medical documentation. This cost is mitigated by the fact, that the translations do not have to be authorised by a certified translator.
7. Are there any specific time requirements linked to a reimbursement request?	**Answer:** *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?*	**Source(s):** Code on administrative procedure: [234] Section 71 – contains general deadlines for	**Yes** ☒ **No** ☐	The time requirements are no different to the general time requirements for submission and resolution of any formal

[234] Zákon č. 500/2004 Sb. Zákon ze ze dne 24. června 2004, správní řád. Částka 174/2004

21. (*e.g., time within which the reimbursement requests must be submitted and/or time within the requested body must handle the request and/or reimburse the costs, etc.*). 22.	There is no specific deadline for submission. The health insurance fund (requested body) has 30 days to process the application. In cases, where factual circumstances are exceptionally complicated, the deadline can be extended by another 30 days.- - *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* If the deadline is missed, the applicant can file a complaint to the supervisory body - the Ministry of Health of the CR.	administrative bodies to make a conclusion of an administrative procedure		application in the Czech Republic.
8. Are there any non-reimbursable thresholds, deductions *(except the deductions for administrative costs mentioned above) etc.?*	**Answer:** *If yes, please specify the thresholds* The non-reimbursable threshold is the actual cost of same healthcare in the Czech Republic.[235]	**Source(s):** Act on public health insurance (see sources in point 1. For more details).	**Yes** ☒ **No** ☐	
9. In instances where a PA (or prior-notification) has already been issued, is a separate/simplified procedure available for requesting reimbursement? **applicable only if the country has a PA system.*	**Answer:** No.	**Source(s):** N/A	**Yes** ☐ **No** ☐	As was described in detail in section 1, the Czech Republic has implemented the PA into its laws, but it is not used in general. 23. Clients are more likely to apply for PA under Social Security Coordination Regulations. In this case, healthcare is

[235] Note of the National expert: This threshold can be exceeded if the Insurance fund permitted so only in the PA procedure under Social Security Coordination Regulations.

				reimbursed without the direct involvement of the patient.
10. Are there additional administrative/procedural requirements for reimbursement depending on, for instance, the type of treatment for which reimbursement is requested, or the profile of the insured person, or any other criterion?	**Answer:** *-If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* In the application form, the patient is asked to clarify whether the received care was planned before arrival to a foreign country or whether it was necessary due to sudden events during the stay. The subsequent administrative procedure is, however, same for both cases.	**Source(s):** Act on public health insurance (48/1997 Coll): Section 53 – this provision states that the requests under the section 14 are administered under general rules of Administrative procedure.	**Yes** ☐ **No** ☒	No justification/purpose for the requirement was identified in the sources consulted.
11. Please list any other administrative requirements in your country in relation to the procedures of reimbursement of cross-border healthcare.	**Answer:** There are no other administrative requirements to mention.	**Source(s):** N/A	**Yes** ☐ **No** ☐	

Part 2: Checklist for verification with national/regional body

Name of the body: Všeobecná zdravotní pojišťovna České Republiky; Ústředí (central administrative body)
Country/Region: Czech Republic, Prague
Date of verification call: 14/06/2021; 15/06/2021

Template for the Data Collection	**Aspects to be verified** *Tick the boxes if the information in the template for the data collection has been verified and/or complemented by the national body*		**Comments** *Include any additional comments and/or information provided by the contacted body*
Section 1 – Prior Authorisation			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Justification/purpose of the identified requirement(s) (Column 4)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	Question 8 – the deadline of 30 days to process an application can be extended to 60 days in case of especially complicated cases.
Section 2 - Reimbursement			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Whether the requirement applies domestically (Discriminatory assessment) (Column 4) ▪ Justification/purpose of the identified requirement(s) (Column 5)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	Question 2 and 4 – it is worth noting, that the same form is used for Reimbursement under Social Security Coordination regulations and for Reimbursement under Directive 2011/24/EU. Question 7 – Even if there is no specific deadline for submission, the claims older than 3 years are considered expired under the general provisions of civil law and cannot be enforced. Question 8 – It may be important to note, that the payments that would go beyond standard treatment (i.e. cash payments for above-standard, or “extra paid” treatment or luxury rooms) are not reimbursed.

DENMARK – COUNTRY REPORT

Part 0: Preliminary Assessment

1. **Please indicate whether the rules governing the administrative procedures/requirements for requesting PA and reimbursement under Directive 2011/24/EU in your country are set out at:**

A. National level ☒

B. Decentralised/regional/local level ☐

In case (1.B): Please indicate the two most relevant jurisdictions in your country (i.e., in terms of population):

Region/jurisdiction: 1: N/A

Region/jurisdiction 2: N/A

NOTE: In case (1.B) the template for the data collection (Part 1) should be complete twice, once for each of the two most relevant regions/jurisdiction indicated above.

2. **Please indicate the national body best suited to verify the accuracy of the information collected in Part 1, and justify your selection.**

Depending on the characteristics of your national healthcare system, the relevant body may be: a) *the national social security body*; or b) *an insurance fund*. In the latter case, please indicate the most representative fund (e.g., the one with the highest number of affiliations).

Body to be contacted for Task 2: Regionsrådet, Region Syddanmark (The Regional Council, Region Syddanmark)

(In case 1.B, please indicate two relevant bodies, one respectively for each Region/jurisdiction)

Reasons for Selection: Although the rules governing the administration procedures for cross-border healthcare under Directive 2011/24/EU are set out in legislation enacted at national level, five regional bodies in Denmark implement them in practice. Therefore, the Regional body for the Syddanmark Region was contacted to verify the practical implications and implementation of the national rules and regulations outlined in this report.[236]

[236] The information collected was additionally verified by the Danish Patient Safety Authority (coordinating NCP) on 8 October 2021. Available at: https://stps.dk/da/eu-sygesikring/koeb-af-behandling-i-udlandet/.

Part 1: Questionnaire

*__Note 1__: In cases where administrative requirements are set out in the legislative/regulatory framework at decentralised/regional/local level, please complete the template for the data collection twice, once for each of the two most relevant regions/jurisdictions (e.g., in terms population).

__*Note 2__: Setting out a Prior Authorisation (PA) system is optional for Member States. Should your country not have a system of PA in place under Directive 2011/24/EU, Section 1 will not need to be completed.

SECTION 1 PRIOR AUTHORISATION PROCEDURE(S)			
Questions	**Answer**	**Sources**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to PA procedures for a cross-border healthcare under Directive 2011/24/EU?	**Answer:** The specific rules are contained in Arts. 31, 33 to 35 (Executive Order no. 657 of 28 June 2019) Guidance no. 9733 of July 5 2016 issued by the Ministry of Health Art. 89a of The Health Act, Statutory Order no. 903 of Statutory Order of 26 August 2019.	**Source(s):** The rules are encompassed in the following acts: Bekendtgørelse BEK nr 657 af 28/06/2019 om ret til sygehusbehandling m.v.[237] (Executive Order no. 657 of 28 June 2019 on right to medical treatment, etc. on special rules for reimbursement of expenditure of medical expenses incurred in other EU /EEA countries) ('**Executive Order no. 657 of 28 June 2019**').	N/A

[237] Available at: https://www.retsinformation.dk/eli/lta/2019/657 last accessed 23 June 2021.

		Vejledning vej nr. 9733 of 05/07/2016 om grænseoverskridende sundhedsydelser i EU/EØS-lande (regler i medfør af patientmobilitetsdirektivet),[238] (Guidance issued by Ministry of Health on cross-border healthcare in EU / EEA countries (rules pursuant to the Patient Mobility Directive) no. 9733 of 5 July 2016). ('**Guidance no. 9733 of July 5 2016 issued by the Ministry of Health**'). VEJ nr 10329 af 12/12/2016 ejledning om koordinering af sundhedsydelser og visse sociale ydelser for borgere, der rejser mellem EU/EØS-landene og Schweiz.[239] ('**Guidance no. 10329 of 12 December 2016'**) Bekendtgørelse BEK nr 1073 af 31/05/2021 om tilskud til sundhedsydelser uden for sygehusvæsenet købt i eller leveret fra andre EU/EØS-lande[240] (Executive Order no. 1073 of 31 May 2021 on subsidies for health services outside the hospital system	

[238] Available at: https://www.retsinformation.dk/eli/retsinfo/2016/9733 last accessed 23 June 2021.
[239] Available at: https://www.retsinformation.dk/eli/retsinfo/2016/10329#:~:text=VEJ%20nr%2010329%20af%2012%2F12%2F2016&text=Styrelsen%20for%20Patientsikkerhed%2C%20International%20Sygesikring%2C%20november%202016%2C%20J.,nr.%3A%202013%2F2908.&text=6.4.4.,af%20et%20EU%2Dsygesikringskort%20m.m. (last accessed 14 October 2021).
[240] Available at: https://www.retsinformation.dk/eli/lta/2021/1073 last accessed 23 June 2021.

		purchased in or delivered from other EU / EEA countries) ('**Executive Order no. 1073 of 31 May 2021'**). Bekendtgørelse LBK nr 903 af 26/08/2019 af sundhedsloven[241] (The Health Act, Statutory Order no. 903 of Statutory Order of 26 August 2019) ('**The Health Act, 2019'**). Lov nr 1638 af 26/12/2013 om ændring af sundhedsloven og lov om klage- og erstatningsadgang inden for sundhedsvæsenet[242] (Act No. 1638 of 26 December 2013 amending the Health Act and the Act on Access to Complaints and Compensation in the Health Service) ('**Act No. 1638 of 26 December 2013'**). All relevant legal acts and regulation above are accessible at: https://stps.dk/da/eu-sygesikring/lovgivning-om-eu-sygesikring/ last accessed 16 June 2021.	
2. Is this the same procedure as for PA under the Social Security Coordination Regulations?	**Answer:** **Yes ☐ No ☒**		The PD S2 under the SSC Regulations (art. 20) is issued by the Danish regional authorities, when the person is residing and insured in Denmark. When the person is residing in another Member State or Switzerland and insured at the expense of

[241] Available at: https://www.retsinformation.dk/eli/lta/2019/903 last accessed 23 June 2021.
[242] Available at: https://www.retsinformation.dk/eli/lta/2013/1638 last accessed 23 June 2021.

			Denmark, the Danish Patient Safety Authority is responsible for handling the procedure. The procedure for reimbursement is handled in accordance to the procedure laid down in the Implementing Regulation and claims settled between liaison bodies on behalf of the healthcare provider/institution. The Regulations etc. are complemented by the Danish Guidance no. 10329 of 12 December 2016.[243]
3. What body is in charge of handling the PA applications? (e.g., where and to whom PA applications have to be submitted?)	**Answer:** Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations). Pursuant to §89 (a) of the Health Act, 2019, the Regional Council of each region is in charge of handling PA applications. (There are 5 regions). Please see the links below. 1) Søg forhåndsgodkendelse i Region Hovedstaden 2) Søg forhåndsgodkendelse i Region Sjælland 3) Søg forhåndsgodkendelse i Region Syddanmark	**Source(s):** §89 (a) of the Health Act, 2019 The amendment to The Health Act to accommodate this specific provision was made through Act No. 1638 of 26 December 2013 amending the Health Act and the Act on Access to Complaints and Compensation in the Health Service. Executive Order no. 657 of 28 June 2019 on right to medical treatment, etc. on special rules for reimbursement of expenditure of medical expenses incurred in other EU /EEA countries.[244]	N/A

[243] Information provided by the Danish Patient Safety Authority (coordinating NCP) on 8 October 2021.
[244] Weblink to the information in the answer column: https://stps.dk/da/eu-sygesikring/koeb-af-behandling-i-udlandet/ (last accessed 16 June 2021).

	4) Søg forhåndsgodkendelse i Region Midtjylland 5) Søg forhåndsgodkendelse i Region Nordjylland		
4. Who is entitled to apply for PA? (e.g., can the patients apply themselves, or is treating doctor filing/partially filling the request, etc.)	**Answer:** If there is a national doctor involved, is there a requirement that this doctor is contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA? The patients can apply themselves. However the patients are required to submit a copy of the doctors' recommendation letter, as well as provide a consent form allowing the doctors and the authorities concerned to obtain information from the doctor/hospital who may be contacted directly by the Danish authorities to cross check validity and for other medical purposes.	**Source(s):** Art. 33, Executive Order no. 657 of 28 June 2019 on right to medical treatment, etc. on special rules for reimbursement of expenditure of medical expenses incurred in other EU /EEA countries. Danish Patient Safety Authority, information.[245] Patient guide regarding PA.[246]	Note from the National Body: To make the process as transparent as possible and also to make the procedure as streamlined, effective and quick.
5. Is there a specific application form/module which the person seeking PA needs to submit?	**Answer:** If yes, please specify: - What information is required; Is the information mandatory, optional, or recommended? - Is this application form/modules available online? - Does the form have to be submitted in paper or can it be submitted electronically?	**Source(s):** An example of the form is available online.[247] The information that is supposed to be stated in the application is mandatory and is stated in Art. 40, Executive Order no. 657 of 28 June 2019 on right to medical treatment, etc. on special rules for reimbursement of	The different regions are responsible for the administrative procedure. Each region has the same requirements since the rules and regulations are made at the central level and executed at the regional level. No further specific purpose for the requirements identified in the source consulted.

[245] Available at: https://stps.dk/da/eu-sygesikring/koeb-af-behandling-i-udlandet/ last accessed 16 June 2021.
[246] Available at: https://www.regionh.dk/Sundhed/Patientguiden/i-behandling-paa-hospital/rejse-og-ophold-i-udlandet/Sider/Forhaandsgodkendelse.aspx last accessed 16 June 2021.
[247] Available at: https://www.regionh.dk/Sundhed/Patientguiden/Documents/Ans%C3%B8gning%20om%20forh%C3%A5ndsgodkendelse.pdf, last accessed 16 June 2021.

	Yes. To obtain prior authorisation, the region must receive: - copy of the doctor's referral for treatment in a hospital; - patient's written consent for the region to obtain additional information about their health conditions and the like that is necessary to be able to assess the application; - the foreign hospital's description of the treatment for which the patient wants prior authorisation; - date of the treatment at the foreign hospital - the price offer from the foreign hospital - a copy of the special health card if the patient does not have the yellow health card. The information is mandatory. The form is available online. The patients have the option to submit the form either electronically or by regular post.	expenditure of medical expenses incurred in other EU /EEA countries.	
6. What (other) documentation has to be submitted in order to substantiate a PA request?	**Answer:** If applicable, please specify: - What documents and what particulars are required; - Whether there are requirements as to who has to issue the documents (e. g., a doctor contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA or any doctor);	**Source(s):** Art. 40, Executive Order no. 657 of 28 June 2019 on right to medical treatment, etc. on special rules for reimbursement of expenditure of medical expenses incurred in other EU /EEA countries.	In order to enable the Regional Council to make a decision, the documentation is necessary. The Regional Council needs to determine if the same treatment can be provided in Denmark at the same cost, without delay before they make their final decision. Such documentation is therefore, imperative. Article 35, Executive Order no. 657 of 28 June 2019.

	- Whether the submission of the documentation is optional, mandatory, or recommended The following documents need to be submitted to substantiate the PA. - copy of the doctor's referral for treatment in a hospital - Patients written consent for the region to obtain additional information about their health conditions and the like that is necessary to be able to assess the application; - the foreign hospital's description of the treatment for which the patient want prior approval - date of the treatment at the foreign hospital - the price offer from the foreign hospital - a copy of the special health card if the patient does not have the yellow health card The submission of the documentation is mandatory.	Danish Patient Safety Authority.	
7. **Are there any costs** associated with the handling of the PA request? - Direct costs (e.g., fixed costs for submitting or filing a PA request). - Indirect costs (e.g., translations, stamps, etc).	**Answer:** Direct costs: None identified. Indirect costs: None identified.	**Source(s):** Confirmed by the Patient Advisory body, Region Syddanmark. Danish Patient Safety Authority information. Patient guide regarding PA.	N/A
8. Are there any specific **time requirements** linked to a PA request?	**Answer:**	**Source(s):** Art. 33. Section 3 of the Executive Order no. 657 of 28	N/A

(e.g., time within which a requesting person must submit the PA application and/or time within which the requested body must take a decision on the PA request, etc.).	- If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body? The authorities are required to respond within 14 days of receipt of application. No consequences are indicated in the rules and regulations if this deadline is not met.	June 2019 on right to medical treatment, etc. on special rules for reimbursement of expenditure of medical expenses incurred in other EU /EEA countries. Danish Patient Safety Authority information.	
9. Are there **differences in the procedural/administrative requirements for requesting PA** based on, for instance, the type of treatment for which PA is requested, the profile of the insured person, or any other criterion?	**Answer:** None identified.	**Source(s):** Patient Guide made by the Danish Patient Safety Authority, information.[248]	N/A
10. Is there a specific PA form (i.e., form used for issuing/granting PA) and, if the answer is positive, what form?	**Answer:** There is no specific form. A letter is issued by the Regional Council accepting or rejecting the application.	**Source(s):** Regionsrådet, Patientkontoret, Region Syddanmark (The Regional Council, Patient Advisory body).	N/A
11. Please list any other administrative requirements in your country in relation to the PA procedure for cross-border healthcare.	**Answer:** None identified.	**Source(s):** Confirmed by the Regional Council, the Patient Advisory Body, Region Syddanmark. Patient Guide made by the Danish Patient Safety Authority.	N/A

[248] Available at: https://stps.dk/da/eu-sygesikring/koeb-af-behandling-i-udlandet/ last accessed 16 June 2021.

SECTION 2 **REIMBURSMENT PROCEDURE(S)**				
Questions	**Answer:**	**Sources**	**Does/do the identified requirement(s) also apply domestically?** **(i.e., is the requirement non-discriminatory?)**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to reimbursement procedures for cross-border healthcare under Directive 201/24/EU?	**Answer:** Hospital care Arts. 31-41, Executive Order no. 657 of 28 June 2019 on right to medical treatment, etc. on special rules for reimbursement of expenditure of medical expenses incurred in other EU /EEA countries. <u>Non-hospital healthcare (incl medicines)</u> Executive Order no. 1073 of 31 May 2021 on subsidies granted to healthcare services outside the hospital sector purchased in or delivered from other EU/EEA member states	**Source(s):** Bekendtgørelse BEK nr 657 af 28/06/2019 om ret til sygehusbehandling m.v.[249] (Executive Order no. 657 of 28 June 2019 on right to medical treatment, etc. on special rules for reimbursement of expenditure of medical expenses incurred in other EU /EEA countries). ('**Executive Order no. 657 of 28 June 2019**'). Vejledning vej nr. 9733 of 05/07/2016 om grænseoverskridende sundhedsydelser i EU/EØS-lande (regler i medfør af patientmobilitetsdirektivet)[250], (Guidance issued by Ministry of Health on cross-border	N/A	N/A

[249] Available at: https://www.retsinformation.dk/eli/lta/2019/657 last accessed 23 June 2021.
[250] Available at: https://www.retsinformation.dk/eli/retsinfo/2016/9733 last accessed 23 June 2021.

		healthcare in EU / EEA countries (rules pursuant to the Patient Mobility Directive) no. 9733 of 5 July 2016) ('**Guidance no. 9733 of July 5 2016 issued by the Ministry of Health**'). Bekendtgørelse BEK nr 1073 af 31/05/2021 om tilskud til sundhedsydelser uden for sygehusvæsenet købt i eller leveret fra andre EU/EØS-lande[251] (Executive Order no. 1073 of 31 May 2021 on subsidies for health services outside the hospital system purchased in or delivered from other EU / EEA countries) ('**Executive Order no. 1073 of 31 May 2021'**). Bekendtgørelse LBK nr 903 af 26/08/2019 af sundhedsloven[252] (The Health Act, Statutory Order no. 903 of Statutory Order of 26 August 2019) ('**The Health Act, 2019'**). Lov nr 1638 af 26/12/2013 om ændring af sundhedsloven og lov om klage- og erstatningsadgang inden for sundhedsvæsenet[253] (Act No. 1638 of 26 December 2013 amending the Health Act and the Act on Access to Complaints and		

[251] Available at: https://www.retsinformation.dk/eli/lta/2021/1073 last accessed 23 June 2021.
[252] Available at: https://www.retsinformation.dk/eli/lta/2019/903 last accessed 23 June 2021.
[253] Available at: https://www.retsinformation.dk/eli/lta/2013/1638 last accessed 23 June 2021.

		Compensation in the Health Service) ('**Act No. 1638 of 26 December 2013'**). All relevant legal acts and regulation above are accessible at: https://stps.dk/da/eu-sygesikring/lovgivning-om-eu-sygesikring/ last accessed 16 June 2021.		
2. Is this the same procedure as for reimbursement under the Social Security Coordination Regulations?	**Answer:** **Yes ☐ No ☒**		N/A	The health expenditure for treatment granted on the basis of a PD S2 form under the SSC Regulations is reimbursed via E125 – in accordance to the procedure in the Implementing Regulation When a PD S2 is issued by either a regional authority or municipality, the costs are settled via the liaison body (Danish Patient Safety Authority and the treating MS) via E125 system.

				Other healthcare received outside Denmark in accordance to the Regulation (art 19 – medically necessary treatment) will be reimbursed to the Danish insured person upon application if the person has paid the full amount for the treatment and provided that the treatment is possible to reimburse in accordance to the art. 19, 883/2004 cf. art 25(5), 987/2009. [254]
3. What body is/are responsible of handling the reimbursement applications? (e.g., where and to whom reimbursement applications have to be submitted?)	**Answer:** Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations). Pursuant to §89 (a) of the Health Act, 2019, the Regional Council of each region. (There are 5 regions). Please see the links below.	**Source(s):** §89 a of the Health Act, 2019. The amendment to The Health Act to accommodate this specific provision was made through Act No. 1638 of 26 December 2013 amending the Health Act and the Act on Access to Complaints and Compensation in the Health Service.	N/A	N/A

[254] Information provided by the Danish Patient Safety Authority (coordinating NCP) on 8 October 2021.

	1) Søg forhåndsgodkendelse i Region Hovedstaden 2) Søg forhåndsgodkendelse i Region Sjælland 3) Søg forhåndsgodkendelse i Region Syddanmark 4) Søg forhåndsgodkendelse i Region Midtjylland 5) Søg forhåndsgodkendelse i Region Nordjylland	Arts. 31-35, Executive Order no. 657 of 28 June 2019 on right to medical treatment, etc. on special rules for reimbursement of expenditure of medical expenses incurred in other EU /EEA countries.[255] Art. 17, Executive Order no.1073 of 31 May 2021 for re-imbursement of non-hospital treatments.		
4. Is there a specific application form/module which the person seeking reimbursement needs to submit?	**Answer:** If yes, please specify: - What information is required; - Is the information mandatory, optional, or recommended? Is this application form/modules available online? - Does the form have to be submitted in paper or can it be submitted electronically? YES. The conditions for reimbursement are the same as those in force for healthcare received in Denmark. Thus, if the patient is not entitled to reimbursement for the healthcare in Denmark, the patient is not entitled to reimbursement if the patient receives the healthcare in another EU/EEA state.	**Source(s):** Each region has a specific form which has the same content, since the requirements regarding rules and regulations are made at the national level. The information that is required to be filled in for obtaining reimbursement is specified under Arts. 40 and 41 of Executive Order no. 657 of 28 June 2019 on right to medical treatment, etc. on special rules for reimbursement of expenditure of medical expenses incurred in other EU /EEA countries.	**Yes** ☐ **No** ☒ Generally, Danish citizens do not have to pay for their cures, therefore normally they do not have to submit any reimbursement request.	

[255] Weblink to the information in the answer column: https://stps.dk/da/eu-sygesikring/koeb-af-behandling-i-udlandet/ last accessed 16 June 2021.

	Thus, for example: The requirements for a referral from the GP or a prescription are identical for treatment in another EU/EEA state and Denmark. You must therefore be referred from a GP to a specialist (except citizens covered by Group 2).[256] However, such a referral need not be obtained from the patient's own GP in Denmark. The referral may be obtained from a GP in another EU/EEA state. Please note that referral **is not required for treatment with an otorhinolaryngologist or an ophthalmologist.** If special rules apply as regards who may obtain reimbursement in Denmark, these rules also apply when you apply for reimbursement for treatment in another EU/EEA state. For example, rules may apply in relation to reimbursement of treatment rendered by psychologists, free physiotherapy or special reimbursement for dental care for cancer patients. You will only be entitled to reimbursement of the same number of treatments, etc. as you would be entitled to in Denmark. If your application concerns reimbursement of expenses for hospital treatment and **you have not obtained prior authorisation**, the following documents need to be submitted to substantiate the re-imbursement (The information that is required to be filled in for	Art. 17, Executive Order no.1073 of 31 May 2021 for re-imbursement of non-hospital treatments		

[256] Please note than in Denmark, citizens can chose to be part of Group 1 or Group 2. Group 1's citizens are attached to specific GPs and the citizen needs to have a referral from the GP in order to visit a specialist. Group 2's citizens, instead, do not need to be affiliated with a GP and also do not require a referral from a GP to visit a specialist. More information on it is available here: https://www.sundhed.dk/borger/behandling-og-rettigheder/sygesikring-og-laegevalg/sundhedskort-og-sikringsgrupper/, last accessed 23 June 2021.

	obtaining reimbursement is specified under Arts. 40 and 41 of Executive Order no. 657 of 28 June 2019): - copy of the doctor's referral for treatment in a hospital - Patients written consent for the region to obtain additional information about their health conditions and the like that is necessary to be able to assess the application; - the foreign hospital's description of the treatment for which the patient want prior approval - date of the treatment at the foreign hospital - r If you are not a resident of Denmark, please also enclose the following: - a copy of your special yellow health insurance card and - information about the account into which any reimbursement is to be paid. The information is mandatory; The application form/modules are available online. The form may be submitted in paper or electronically.			
5. What (other) documentation has to be submitted in order to substantiate a reimbursement request?	**Answer:** If applicable, please specify: - What documents and what particulars are required; - Whether the submission of the documentation is optional, mandatory, or recommended	**Source(s):** The information that is required to be filled in for obtaining reimbursement is specified under Arts. 40 and 41 of Executive Order no. 657 of 28 June 2019 on right to medical	**Yes** ☒ **No** ☐	The required documentation enables a comparison with the treatments for which reimbursement can

	1. The original invoice and receipt; 2. A description of the treatment purchased with specifications of where and when it was purchased 3. Copy of the referral from a doctor/GP or the prescription if relevant; 4. If not a resident of Denmark, please also enclose the following:**-** - A copy of your special yellow health insurance card and information about the account into which any reimbursement is to be paid. 5. The patient's statement as to whether full or partial public reimbursement has already been granted. 6. A description of the goods and services received, so that a comparison (equality) can be made with benefits for which subsidies are granted in accordance with health legislation or in agreements entered into pursuant thereto. When applying for a subsidy for medicinal products, cf. section 1, subsection 2, no. 23, a copy of the medicinal product package or a photograph thereof must be attached, in order to determine the substance's ingredient, package size, strength and pharmaceutical form. The Danish Medicines Agency may, in special cases, dispense with the requirement for a copy of the medicinal product package or a photograph thereof. 7. For the pensioners listed under § 4, no. 2, or their family members, a copy of the applicant's EU health insurance card must be attached to the	treatment, etc. on special rules for reimbursement of expenditure of medical expenses incurred in other EU /EEA countries. Art. 17, Executive Order no.1073 of 31 May 2021 for re-imbursement of non-hospital treatments		be obtained in Denmark.

	application. For the family members listed under § 4, no. 3 for a frontier worker, the application must be accompanied by a copy of the frontier worker's special health card and a copy of the applicant's EU health insurance card. If your application **concerns reimbursement of expenses for hospital treatment and you have not obtained prior authorisation**, the following documents must be enclosed with your application to the regional authorities: - a copy of the referral for hospital treatment from a doctor/GP - your permission for the regional authorities to seek further information about your health, etc. which are required in order to assess your application. - a description from the hospital abroad of the treatment you have received including the date of your treatment at the hospital. - The patient's statement as to whether full or partial public reimbursement has already been granted. - A description of the goods and services received (s), so that a comparison (equality) can be made with benefits for which subsidies are granted in accordance with health legislation or in agreements entered into pursuant thereto. When applying for a subsidy for medicinal products, cf. section 1, subsection 2, no. 23, a copy of the medicinal product package or a photograph thereof must be attached, in order to determine the substance's ingredient, package size, strength and pharmaceutical form. The			

	Danish Medicines Agency may, in special cases, dispense with the requirement for a copy of the medicinal product package or a photograph thereof. - - For the pensioners listed under § 4, no. 2, or their family members, a copy of the applicant's EU health insurance card must be attached to the application. For the family members listed under § 4, no. 3 for a frontier worker, the application must be accompanied by a copy of the frontier worker's special health card and a copy of the applicant's EU health insurance card. If you are not a resident of Denmark, please also enclose the following: - a copy of your special yellow health insurance card and - information about the account into which any reimbursement is to be paid.			
6. Are there any costs associated with the handling of the reimbursement request? - Direct costs (e.g., fixed costs for submitting or filing a reimbursement request, proportion deducted from the reimbursable amount). - Indirect costs (e.g., translations, stamps, etc).	**Answer:** Direct costs: None identified. Indirect costs: None identified. The patients are not charged for the handling of reimbursement requests and no costs are accrued to patients. The regions have to bear the costs of their residents.	**Source(s):** Confirmed by the Patient advisory Body, The Regional Council, Region Syddanmark.	**Yes ☒** **No ☐**	N/A
7. Are there any specific time requirements linked	**Answer:**	**Source(s):**	**Yes ☒**	N/A

to a reimbursement request? (e.g., time within which the reimbursement requests must be submitted and/or time within the requested body must handle the request and/or reimburse the costs, etc.).	If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body? Art. 3 of the Statute of limitations, Act no. 1238 of 9 November 2015.: The requests must be submitted within 3 years from the date of the treatment received abroad. The applications are usually attended to within a few months. No time limit is stipulated for feedback on the applications submitted. In case of medicines purchased in another EU/EEA member state, the Danish insured person must apply for reimbursement within one year from the purchase. If the application is received after the one-year deadline, the right to reimbursement according to the Danish provisions implementing the Directive, are deemed to have been expired.[257]	Statute of limitations, Act no. 1238 of 9 November 2015.[258]	**No** ☐	
8. Are there any non-reimbursable thresholds, deductions (except the deductions for administrative costs mentioned above) etc.?	**Answer:** None identified. The patient is only entitled to reimbursement of an amount corresponding to the reimbursement which the patient would have received if the healthcare was provided in Denmark.	**Source(s):** N/A	**Yes** ☒ **No** ☐	N/A

[257] Information provided by the Danish Patient Safety Authority (coordinating NCP) on 8 October 2021. For more information: the website of the Danish Medicines Agency https://laegemiddelstyrelsen.dk/en/reimbursement/bought-in-another-eueea-country/ last accessed October 14 2021

[258] Bekendtgørelse LBK nr 1238 af 09/11/2015 af lov om forældelse af fordringer (Statute of limitations, Act no. 1238 of 9 November 2015.) https://www.retsinformation.dk/eli/lta/2015/1238 last accessed 16 June 2021.

9. In instances where a PA (or prior-notification) has already been issued, is a separate/simplified procedure available for requesting reimbursement? *applicable only if the country has a PA system.	**Answer:** If yes, please describe the simplified procedure. No specific simplified procedure identified. The procedure is the same. It is only that there is guarantee of reimbursement of expenses because of prior authorisation and the patients do not need to submit certain documents again, while seeking reimbursement.	**Source(s):** Executive Order no. 657 of 28 June 2019 on right to medical treatment, etc. on special rules for reimbursement of expenditure of medical expenses incurred in other EU /EEA countries. Confirmed by Patient Advisory Body, The Regional Council, Region Syddanmark.	**Yes** ☒ **No** ☐	N/A
10. Are there additional administrative/procedural requirements for reimbursement depending on, for instance, the type of treatment for which reimbursement is requested, or the profile of the insured person, or any other criterion?	**Answer:** As indicated in Question 5, if your application concerns reimbursement of expenses for hospital treatment and you have not obtained prior authorisation, the following documents must be enclosed with your application to the regional authorities: - a copy of the referral for hospital treatment from a doctor/GP - your permission for the regional authorities to seek further information about your health, etc. which are required in order to assess your application. - a description from the hospital abroad of the treatment you have received including the date of your treatment at the hospital. If you are not a resident of Denmark, please also enclose the following: - a copy of your special yellow health insurance card and information about the account into which any reimbursement is to be paid.	**Source(s):** N/A	**Yes** ☒ **No** ☐	N/A

11. Please list any other administrative requirements in your country in relation to the procedures of reimbursement of cross-border healthcare.	**Answer:** N/A	**Source(s):** N/A	**Yes** ☒ **No** ☐	

Part 2: Checklist for verification with national/regional body[259]

Name of the body: Regionsrådet, Patientkontoret, Region Syddanmark (The Regional Council, Patient Advisory Body, Region Syddanmark).
Country/Region: Denmark
Date of verification call: 15/06/2021

Template for the Data Collection	Aspects to be verified *Tick the boxes if the information in the template for the data collection has been verified and/or complemented by the national body*		Comments *Include any additional comments and/or information provided by the contacted body*
Section 1 – Prior Authorisation			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Justification/purpose of the identified requirement(s) (Column 4)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	No additional comments. Where necessary, the feedback received during the verification call has been incorporated in answers to the questionnaire above.
Section 2 - Reimbursement			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Whether the requirement applies domestically (Discriminatory assessment) (Column 4) ▪ Justification/purpose of the identified requirement(s) (Column 5)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	No additional comments. Where necessary, the feedback received during the verification call has been incorporated in answers to the questionnaire above.

[259] The data collected was also verified by the Danish Patient Safety Authority (coordinating NCP) on 8 October 2021.

ESTONIA – COUNTRY REPORT

Part 0: Preliminary Assessment

1. **Please indicate whether the rules governing the administrative procedures/requirements for requesting PA and reimbursement under Directive 2011/24/EU in your country are set out at:**

A. National level ☒

B. Decentralised/regional/local level ☐

In case (1.B): Please indicate the two most relevant jurisdictions in your country (i.e., in terms of population):

Region/jurisdiction: 1: N/A

Region/jurisdiction 2: N/A

2. **Please indicate the national body best suited to verify the accuracy of the information collected in Part 1, and justify your selection.**

Depending on the characteristics of your national healthcare system, the relevant body may be: a) *the national social security body*; or b) *an insurance fund*. In the latter case, please indicate the most representative fund (e.g., the one with the highest number of affiliations).

Body to be contacted for Task 2:

The Estonian Health Insurance Fund (EHIF).

Reasons for Selection:

The EHIF is the respective state agency responsible for the reimbursement of treatment costs in the EU under § 66^2 of the Estonian Health Insurance Act[260].

[260] Ravikindlustuse seadus (Health Insurance Act). – RT I, 29.12.2020, 19. Available in English online at https://www.riigiteataja.ee/en/eli/530122020007/consolide (last accessed 21.05.2021).

Part 1: Questionnaire

***Note 1:** In cases where administrative requirements are set out in the legislative/regulatory framework at decentralised/regional/local level, please complete the template for the data collection twice, once for each of the two most relevant regions/jurisdictions (e.g., in terms population).

***Note 2:** Setting out a Prior Authorisation (PA) system is optional for Member States. Should your country not have a system of PA in place under Directive 2011/24/EU, Section 1 will not need to be completed.

Note: No PA system pursuant to Directive 2011/24/EU has been introduced in Estonia. However, certain rules on the administrative procedures concerning PA have been introduced nonetheless in the national legislative framework, should the PA system be regulated in the future. For this reason, and in order to provide a complete overview, Section 1 of this report has been completed with information on the aforementioned rules, though it should be borne in mind that these rules do not currently apply in practice in Estonia. Some of the relevant rules are already part of the current legislative framework (i.e., part of the law in force), and some (a draft procedural regulation to be adopted based on the law in force) are part of preparatory works.

SECTION 1 PRIOR AUTHORISATION PROCEDURE(S)			
Questions	**Answer**	**Sources**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to PA procedures for a cross-border healthcare under Directive 2011/24/EU?	**Answer:** At present, a PA system under Directive 2011/24/EU has not been introduced and regulated in Estonia. However**,** § 66^3(1) of the Health Insurance Act states that, on a proposal of the	**Source(s):** § 66^3(1) Health Insurance Act	According to the explanatory report of the legal act that was, amongst other things, the basis for implementing the relevant paragraphs concerning cross-border health service reimbursement into the Health Insurance Act, § 66^3 of the Health Insurance Act is tailored based on article 8 of Directive 2011/24/EU.[261]

[261] §§ 66^2-66^4 of the Health Insurance Act, which concern the reimbursement of cross-border health services, were introduced into the Health Insurance Act via the adoption of the Act amending the Health Services Organisation Act and other Acts related to these changes (*Tervishoiuteenuste korraldamise seaduse muutmise ja sellega seonduvalt teiste seaduste muutmise seadus*. – RT I, 29.11.2013, 1). Available at: https://www.riigiteataja.ee/akt/129112013001 (last accessed 21.05.2021). The explanatory report to the latter explains the aim and meaning behind §§ 66^2-66^4, which concern the

	supervisory board of the Estonian Health Insurance Fund (hereinafter 'EHIF'), the minister responsible for the field (Minister of Social Affairs) **may establish, by a regulation**, the prior authorisation requirement for provision of cross-border health services in a Member State of the European Union other than Estonia for purposes laid out in that paragraph. **However, as to date, no such regulation has been adopted. Hence, there is no PA procedure as of now.** **However, some principal rules for a PA have been established under § 66[3] of the Health Insurance Act, <u>should there ever be a PA procedure established.</u>** **These rules are described in the sections below for a matter of completeness (though, at present, they do not yet find practical application).**		The explanatory report refers to the case-law of the Court of Justice of the European Union (CJEU), which lays out the principle that Member States generally should not adopt a PA requirement but can do so when this is necessary to assure the maintenance of a balanced medical and hospital system. Based on this, § 66[3](1) of the Health Insurance Act allows the supervisory board of the EHIF to propose for the relevant minister to adopt a regulation, based on which a PA procedure can be adopted for specific health services along with the purpose/justification of the requirement (§ 66[3](3)).
2. Is this the same procedure as for PA under the Social Security Coordination Regulations?	**Answer:** **Yes ☒ No ☐** As noted, there is currently no PA procedure requirement. However, if there ever should be one, § 66[3](11) of the Health Insurance Act refers to Regulation (EC) No 883/2004 on Social Security Coordination, and states that if the terms and conditions of the Regulation have been fulfilled, prior authorisation will be granted in accordance with the Regulation, unless the person explicitly		N/A

reimbursement of cross-border health services. Both the act and explanatory report are only available in Estonian. Available at: https://www.riigikogu.ee/tegevus/eelnoud/eelnou/40cc4702-17f4-43e2-8a6a-cb438f885ab4 (last accessed 18.06.2021).

	requests otherwise. Hence, the procedures may be considered to correspond in substance.		
3. What body is in charge of handling the PA applications? *(e.g., where and to whom PA applications have to be submitted?)*	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* The Estonian Health Insurance Fund (EHIF).	**Source(s):** § 66^2 of the Health Insurance Act	N/A
4. Who is entitled to apply for PA? *(e.g., can the patients apply themselves, or is treating doctor filing/partially filling the request, etc.)*	**Answer:** *If there is a national doctor involved, is there a requirement that this doctor is contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA?* As noted, there is currently no PA procedure requirement. If there were to be a PA requirement, based on the wording of the law, it would presumably be the patient who can apply. However, the specific conditions and procedure for obtaining a PA would be set down in the ministerial regulation implementing a PA requirement for certain health services. No such regulation has been adopted as of yet.	**Source(s):** § 66^3(14) of the Health Insurance Act states that, the conditions of and procedure for obtaining prior authorization for cross-border health services in a Member State of the European Union other than Estonia and for application and granting of prior authorization will be established by a regulation of the minister responsible for the field. However, the wording of § 66^3(11) of the Health Insurance Act refers to the patient as the person applying for a PA.	There is no explicit reasoning in the explanatory report[264] as to why it is the patient who applies for the PA; however, this seems common sense as it is the patient who would otherwise have to cover the costs. A referral from a medical specialist licensed in Estonia would be needed.

[264] Supra n 261.

	Although, the explanatory note[262] included in its Annex II a draft for the relevant regulation, which makes it clear, that the patient would have to apply to the EHIF. A referral from a medical specialist licensed in Estonia would be required, but the patient would be the one to apply.	Confirmed in the Explanatory note to the Act amending the Health Services Organisation Act and other Acts related to these changes[263] (hereinafter 'the Explanatory Note'), Annex II.	
5. Is there a specific application form/module which the person seeking PA needs to submit?	**Answer:** *If yes, please specify:* *- What information is required;* *Is the information mandatory, optional, or recommended?* *- Is this application form/modules available online?* *- Does the form have to be submitted in paper or can it be submitted electronically?* See answer to question no 4. As noted, there is currently no PA procedure requirement. If there were to be a PA requirement, the specific conditions and procedure for obtaining a PA would be set down in the ministerial regulation implementing a PA requirement for certain health services.	**Source(s):** § 66[3](14) of the Health Insurance Act Annex II of the Explanatory Note	N/A

[262] Supra n 261.
[263] Supra n 261.

	No such regulation has been adopted as of yet. Although, the explanatory note[265] includes in its Annex II a draft for the relevant regulation.		
6. What (other) documentation has to be submitted in order to substantiate a PA request?	**Answer:** *If applicable, please specify:* *(4) What documents and what particulars are required;* *(5) Whether there are requirements as to who has to issue the documents (e. g., a doctor contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA or any doctor);* *(6) Whether the submission of the documentation is optional, mandatory, or recommended.* As noted, there is currently no PA procedure requirement. If there were to be a PA requirement, the patient would have to submit: (1) An application. (2) A referral from a provider of general medical care or a provider of specialised medical care with a license to provide the relevant healthcare service in Estonia.	**Source(s):** § 3(1), Annex II of the Explanatory Note, setting out the draft for the ministerial regulation and clarifies the requirement of submitting an application with a referral. § 66[3](13) of the Health Insurance Act gives the EHIF the right to request an expert evaluation.	Based on the explanatory note, the EHIF has the right to request an expert evaluation in order to get information on the patient's state of health, which would enable decision-making in regard to whether there truly is a need to receive medical care abroad.

[265] Supra n 261.

	In addition, the EHIF may require an expert evaluation in order to identify the need for provision of the health service applied for, and the term of provision of the service.		
7. **Are there any costs** associated with the handling of the PA request? - *Direct costs (e.g., fixed costs for submitting or filing a PA request).* - *Indirect costs* (*e.g., translations, stamps, etc).*	**Answer:** *Direct costs:* As noted, there is currently no PA procedure requirement. However, the draft of the ministerial regulation does not seem to establish any direct costs. *Indirect costs:* No indirect costs seem to be associated with the PA request if there ever should be a PA requirement.	**Source(s):** § 66[3] of the Health Insurance Act Annex II of the explanatory note	N/A
8. Are there any specific **time requirements** linked to a PA request? (*e.g., time within which a requesting person must submit the PA application and/or time within which the requested body must take a decision on the PA request, etc.*).	**Answer:** - *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* As noted, there is currently no PA procedure requirement. If there were a PA system in place, the EHIF would have to carry out the PA procedure within 60 days of receipt of the application. The applicant will be notified in writing about receiving or being denied a PA.	**Source(s):** § 3(3), Annex II of the Explanatory Note	N/A

9. Are there **differences in the procedural/administrative requirements for requesting PA** based on, for instance, the type of treatment for which PA is requested, the profile of the insured person, or any other criterion?	**Answer:** - *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* As noted, there is currently no PA procedure requirement. However, if there were to be one, when processing the PA application, the EHIF would have to take into account the state of health of the patient, the urgency and circumstances of the specific case. In case of applying a waiting period, the EHIF has to explain to the patient what the medically justified period for the wait is.	**Source(s):** § 3(2), Annex II of the Explanatory Note	The explanatory report refers to Recital 43 of Directive 2011/24/EU and the Guidelines[266] of the European Commission concerning regulations 883/2004 and 987/2009, and Directive 2011/24/EU, which emphasise the need for an individual case-by-case assessment, and in the case of a waiting period, the medical justification for it.
10. Is there a specific PA form (i.e., form used for issuing/granting PA) and, if the answer is positive, what form?	**Answer:** As noted, there is currently no PA procedure requirement. Hence, there is no form yet.	**Source(s):** N/A	N/A
11. Please list any other administrative requirements in your country in relation to the PA procedure for cross-border healthcare.	**Answer:** N/A	**Source(s):** N/A	N/A
SECTION 2 REIMBURSMENT PROCEDURE(S)			

[266] Unfortunately, it was not possible to confirm, which guidelines exactly were referenced, as the explanatory note did not include a proper citation for the referred guidelines of the European Commission.

Questions	Answer:	Sources	Does/do the identified requirement(s) also apply domestically? (i.e., is the requirement non-discriminatory?)	Purpose and/or justification of the requirements
1. Which national legislative and/or regulatory provisions lay out the requirements related to reimbursement procedures for cross-border healthcare under Directive 201/24/EU?	**Answer:** § 50^3(4) of the Health Services Organisation Act[267]; § 66^2 and § 66^4 of the Health Insurance Act; Regulation no 6 of the Minister of Social Affairs adopted 17.01.2014 "The procedure for application for reimbursement for cross-border health services, reviewing applications and payment of reimbursements"[268] (hereinafter 'Procedural Regulation').	**Source(s):** Health Services Organisation Act Health Insurance Act Procedural Regulation	N/A	N/A
2. Is this the same procedure as for reimbursement under the Social Security Coordination Regulations?	**Answer:** **Yes ☒ No ☐** In fact, the application form available online on the website of the EHIF (Cfr. answer to question 4 below) must contain "A clear indication whether the		N/A	N/A

[267] Tervishoiuteenuste korraldamise seadus (Health Services Organisation Act). – RT I 2001, 50, 284. Available in English at https://www.riigiteataja.ee/en/eli/530042021002/consolide (last accessed 31 May 2021).
[268] Sotsiaalministri 17.01.2014 määrus nr 6 "Piiriülese tervishoiuteenuse hüvitise taotlemise, taotluse menetlemise ja hüvitise maksmise kord" ("The procedure for application for reimbursement for cross-border health services, reviewing applications and payment of reimbursements"). – RT I, 21.01.2014, 9. Available only in Estonian.

	applicant wishes to be reimbursed based on § 662 of the Health Insurance Act or Regulation (EU) 883/2004*".*			
3. What body is/are responsible of handling the reimbursement applications? (e.g., where and to whom reimbursement applications have to be submitted?)	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* The Estonian Health Insurance Fund (EHIF).	**Source(s):** § 66[2] of the Health Insurance Act Procedural Regulation	N/A	N/A
4. Is there a specific application form/module which the person seeking reimbursement needs to submit?	**Answer:** *If yes, please specify:* *- What information is required;* *- Is the information mandatory, optional, or recommended?* *Is this application form/modules available online?* *- Does the form have to be submitted in paper or can it be submitted electronically?* **General information required (mandatory):** - First and last name. - Personal ID code. - Contact information. - Bank account information for the reimbursement.	**Source(s):** § 2 of the Procedural Regulation; Official website of the EHIF[269].	**Yes** ☐ **No** ☒ Estonia has state provided universal health insurance, which means that for domestically received health services the cost is directly covered by the EHIF. Reimbursement for purposes of domestically received health care services is defined in § 25(1) of the Health Insurance Act as a high quality and timely health service, necessary medicinal	No specific justification/purpose for each of the requirements of the application form was identified in the consulted sources. However, it appears to be the minimum information needed for the EHIF to assess the right of and calculate the sum of the reimbursement.

[269] EU-related applications are available online on the official website of the Estonian Health Insurance Fund at https://www.haigekassa.ee/en/kontaktpunkt/national-contact-point/european-union-forms (last accessed 1.06.2021).

	- Name of the insured person, personal ID code, contact information, if the application is submitted by the legal representative of the insured person. - Date of the application. - Signature of the applicant. **Questionnaire (mandatory):** - Description of the disease or trauma and the received health service. - Applicant's estimation whether the need for health services arose in Estonia or during a temporary stay in another EU country. - Date or time period of the provision of the health service. - The EU country and city, where the service was provided. - The name of the health care service provider (the facility). - Whether the health care service provider is a private or public service provider, if this fact is known to the applicant. - List of e-forms (E112/S2, E106, E109, E121) if such forms have been issued to the applicant or recipient of the service. - A clear indication whether the applicant wishes to be reimbursed based on § 66^2 of the Health Insurance Act or Regulation (EU) 883/2004.		product or medical device which is provided to an insured person under the conditions provided for in the Health Insurance Act by the EHIF or a person who has concluded a corresponding contract with the fund (benefit in kind), or a sum of money that the health insurance fund must pay to an insured person under the conditions provided for in the Health Insurance Act for the health care expenses incurred by the person or upon their temporary incapacity for work (pecuniary benefit). It is noted in the explanatory note[270] that the option of direct reimbursement (analogous to Estonia's domestic system) to health service providers in other EU countries would not have been possible, as	

[270] Supra n 261.

	The application form is available online on the website of the EHIF. The application can be submitted in person at the local EHIF office or via regular post.		that option would have presumed concluding contracts for financing medical treatments with virtually all health service providers across the EU. For this reason, the patient has to first cover the costs and can then receive reimbursement from the EHIF.	
5. What (other) documentation has to be submitted in order to substantiate a reimbursement request?	**Answer:** *If applicable, please specify:* *- What documents are required;* *- Whether the submission of the documentation is optional, mandatory, or recommended*. <u>Mandatory</u> documentation to be submitted: - Original receipts and documentation of proof regarding the payment of receipts for the health services received. - Copies of the prescriptions and documentation of proof regarding payment for medication bought with prescriptions received during the provision of the health service. - Original receipts from purchases of medical devices and documentation of proof regarding payment for such medical devices that were prescribed during the provision of the health service.	**Source(s):** § 66^4 of the Health Insurance Act § 2 of the Procedural Regulation	**Yes** ☐ **No** ☒ See explanation above in the (Question 4).	A referral is required in the same circumstances in which it is required in domestic cases. § 70(3) of the Health Insurance Act lists the cases in which a referral is <u>not</u> needed – this applies via § 66^4(1) of the Health Insurance Act also for purposes of reimbursement of costs incurred in cases of health services received in other EU countries. Thus, the requirement of a referral is equally applied in both cases. In terms of the referral requirement, See § 66^4(2) of the Health Insurance Act for cases where the insured person has insurance coverage on the basis of Article 17, 24 or 26 of Regulation (EC) No 883/2004 of the European Parliament and of the Council, or whose need to receive a cross-border health

	Additional documentation (if applicable): - In cases specified in § 66[4] clauses 1 and 2 of the Health Insurance Act the required referral or a copy of it.[271] Additional documentation (mandatory): A copy of the health records, medical records or other equivalent documentation from the health service provider who provided the health service in another EU country, which has to include at least the following information: - Data of the person who received the service. - Period of care and period of hospitalisation. - Name of the facility of the provider of health services, the relevant unit at the facility and name of the doctor in charge of care of the insured person. - The diagnosis of the person who received care (main diagnosis and associated diseases) with an explanation. - The state of health of the person at the arrival to receive care and the course of the disease during the provision of care. - Description of the health service provided to the recipient.			service arises during their stay in a Member State of the European Union other than Estonia.

[271] According to § 66[4] clauses, the referral from a general medical care is always needed except if:
- the specialist medical care is provided due to trauma, tuberculosis, eye disease, skin or STDs or
- if gynaecological or psychiatric care is provided
- or the provider of specialised medical care leaves the patient for monitoring or treatment leaves the patient under observation or treatment due to the state of health of the patient.

	- Tests, analyses and operations performed (incl. anaesthesia) on the recipient of care. - Medicinal products administered or prescribed to the recipient of care.			
6. Are there any costs associated with the handling of the reimbursement request? - *Direct costs (e.g., fixed costs for submitting or filing a reimbursement request, proportion deducted from the reimbursable amount).* - *Indirect costs* (*e.g., translations, stamps, etc).*	**Answer:** *Direct costs:* None identified. *Indirect costs:* Possible cost of postal services if the person does not want to or cannot hand in the application in person at the local EHIF office. Possible cost of translation for the documentation issued abroad, since the language of administrative proceedings is Estonian.	**Source(s):** § 66[2] of the Health Insurance Act Procedural Regulation § 20 of the Administrative Procedure Act[272]	**Yes** ☐ **No** ☒ See explanation above in the (Question 4).	As in domestic cases reimbursement happens without the involvement of the patient, the difference in terms of costs can be noted if the person applying for reimbursement in cross-border cases decides to submit the application and documentation via postal services, instead of in-person at the local EHIF office. In terms of translation of the documentation issued abroad, so far, the EHIF has not required official translations, as they have been able to handle it on their own – they aim to burden the applicant as little as possible with such translations. However, they have the right to require a translation of the documentation in the Estonian language.
7. Are there any specific time requirements linked to a reimbursement request?	**Answer:** *If yes, what are the consequences, if the deadlines are missed on the part of the*	**Source(s):**	**Yes** ☐ **No** ☒	In regard to the comparison to domestic cases, please see explanation provided in the answer block to Question no 4.

[272] Haldusmenetluse seadus (Administrative Procedure Act), RT I 2001, 58, 354. Available in English online at https://www.riigiteataja.ee/en/eli/527032019002/consolide#9da6f2c4-b02c-4a66-8120-e8c3e06bfa30 (last accessed 1 June 2021).

(*e.g., time within which the reimbursement requests must be submitted and/or time within the requested body must handle the request and/or reimburse the costs, etc.*).	*requesting person or the requested body?* There are no deadlines set for the applicant for submitting the application. Under general rules of administrative procedure, if the application does not include all the required information and associated documentation, then a deadline will be set for such errors to be rectified in the application. If this deadline is not met, the application may be dismissed. The EHIF has to process the application within 3 months, but this time period can be extended up to 6 months if this is necessary to establish relevant facts. The EHIF has to make a bank transfer for the reimbursement to the applicant within 15 days upon making a decision regarding the reimbursement. If the EHIF does not follow these deadlines, under general rules of administrative procedure, the applicant can initiate challenge proceedings by filing a challenge with EHIF.	§§ 3 and 4 of the Procedural Regulation § 15 and §§ 71 ff. Administrative Procedure Act	See explanation above in the (Question 4).	
8. Are there any non-reimbursable thresholds, deductions *(except the deductions for administrative costs mentioned above) etc.?*	**Answer:** Yes. The applicant has to make a clear choice, whether they want to receive reimbursement based on Regulation (EU)	**Source(s):** § 66^2 of the Health Insurance Act Procedural Regulation.	**Yes** ☒ **No** ☐	The aim of applying the Estonian price lists for health services, medicinal products and medical devices is to ensure equal treatment of patients whether they receive

	883/2004 or Directive 2011/24/EU via the Health Insurance Act. If reimbursement is based on Regulation (EU) 883/2004, there are no non-reimbursable thresholds. This is applicable where the need for care arises during a temporary stay in another EU country. If reimbursement is based on Directive 2011/24/EU via the Health Insurance act, reimbursement is limited by the price lists set in Estonia. This applies where the trip to another EU country is planned for purposes of receiving health services, i.e., the need for care arises in one EU country, but care is provided in another EU country. In either case, the insured person will not be reimbursed for the additional fee or additional cost-sharing established in the Health Insurance Act or on the basis thereof.			health services in Estonia or in another EU country. The rule of additional fees and cost-sharing not being covered applies equally in domestic and cross-border cases.
9. In instances where a PA (or prior-notification) has already been issued, is a separate/simplified procedure available for requesting reimbursement? **applicable only if the country has a PA system.*	**Answer:** There is no PA requirement yet, but as noted above, the basic principles have been set and there is a draft for the relevant ministerial regulation on the PA procedure. Based on this, the answer would be 'no' if there ever were to be a PA requirement.	**Source(s):** §§ 66^2 and 66^3 of the Health Insurance Act Annex II of the explanatory note	**Yes** ☐ **No** ☐ N/A	N/A

10. Are there additional administrative/procedural requirements for reimbursement depending on, for instance, the type of treatment for which reimbursement is requested, or the profile of the insured person, or any other criterion?	**Answer:** No additional administrative requirements identified. However, according to § 66[4] clauses, for some treatments the referral of the general or specialised medical doctor is not mandatory.[273]	**Source(s):** § 66[2] of the Health Insurance Act Procedural Regulation	**Yes** ☐ **No** ☐ N/A	N/A
11. Please list any other administrative requirements in your country in relation to the procedures of reimbursement of cross-border healthcare.	**Answer:** None identified.	**Source(s):** N/A	**Yes** ☐ **No** ☐ N/A	N/A

[273] These exceptions are specified above.

Part 2: Checklist for verification with national/regional body

Name of the body: Estonian Health Insurance Fund
Country/Region: Estonia
Date of verification call: 10.06.2021

Template for the Data Collection	Aspects to be verified *Tick the boxes if the information in the template for the data collection has been verified and/or complemented by the national body*		Comments *Include any additional comments and/or information provided by the contacted body*
Section 1 – Prior Authorisation			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Justification/purpose of the identified requirement(s) (Column 4)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	No additional comments and/or information.
Section 2 - Reimbursement			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Whether the requirement applies domestically (Discriminatory assessment) (Column 4) ▪ Justification/purpose of the identified requirement(s) (Column 5)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	No additional comments and/or information.

FINLAND – COUNTRY REPORT

Part 0: Preliminary Assessment

1. **Please indicate whether the rules governing the administrative procedures/requirements for requesting PA and reimbursement under Directive 2011/24/EU in your country are set out at:**

A. National level ☒

B. Decentralised/regional/local level ☐

In case (1.B): Please indicate the two most relevant jurisdictions in your country (i.e., in terms of population):

Region/jurisdiction: 1: N/A

Region/jurisdiction 2: N/A

NOTE: In case (1.B) the template for the data collection (Part 1) should be complete twice, once for each of the two most relevant regions/jurisdiction indicated above.

2. **Please indicate the national body best suited to verify the accuracy of the information collected in Part 1, and justify your selection.**

Depending on the characteristics of your national healthcare system, the relevant body may be: a) *the national social security body*; or b) *an insurance fund*. In the latter case, please indicate the most representative fund (e.g., the one with the highest number of affiliations).

Body to be contacted for Task 2: The national social security body (Kansaneläkelaitos, KELA)

(In case 1.B, please indicate two relevant bodies, one respectively for each Region/jurisdiction)

Reasons for Selection: KELA is the national authority responsible for granting prior authorisations as well as for the reimbursement of costs.

Part 1: Questionnaire

*__Note 1__: In cases where administrative requirements are set out in the legislative/regulatory framework at decentralised/regional/local level, please complete the template for the data collection twice, once for each of the two most relevant regions/jurisdictions (e.g., in terms population).

__*Note 2__: Setting out a Prior Authorisation (PA) system is optional for Member States. Should your country not have a system of PA in place under Directive 2011/24/EU, Section 1 will not need to be completed.

Note: in Finland, no PA system has been introduced under Directive 2011/24/EU. For this reason, Section 1 of the questionnaire below has not been completed.

SECTION 1 PRIOR AUTHORISATION PROCEDURE(S)			
Questions	**Answer**	**Sources**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to PA procedures for a cross-border healthcare under Directive 2011/24/EU?	**Answer:** **<u>Section 1 – not applicable to Finland.</u>** Finland has a prior authorisation (PA) procedure in place, but it corresponds to the PA procedure under the Social Security Regulation 883/2004 (Art. 20), not to the PA procedure under Directive 2011/24/EU (Art. 8). The Finnish PA procedure according to the aforementioned Regulation is in force since Finland's EEA membership (1994) and was not changed with the entry into force of Directive 2011/24/EU. The patient usually submits the PA application before seeking treatment	**Source(s):** Act on Cross-Border Healthcare of 30 December 2013 and subsequent amendments (Laki rajat ylittävästä terveydenhuollosta 30.12.2013/1201)[274] Section 13(6)	N/A

[274] Laki rajat ylittävästä terveydenhuollosta 30.12.2013/1201 (Act on Cross-Border Healthcare of 30 December 2013 and subsequent amendments), available at https://www.finlex.fi/fi/laki/ajantasa/2013/20131201 (last accessed on 15 June 2021), Section 13(6).

	abroad. However, he/she can submit the application also after having sought treatment abroad (i.e., retroactively). In case the patient applies for authorisation afterwards, KELA (the national social security body) will examine the prerequisites for the authorisation, and the authorisation must be granted in retrospect if the conditions for granting the authorisation were fulfilled prior to the provision of the health care service.		
2. Is this the same procedure as for PA under the Social Security Coordination Regulations?	**Answer:** **Yes ☐ No ☐**		
3. What body is in charge of handling the PA applications? *(e.g., where and to whom PA applications have to be submitted?)*	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* N/A	**Source(s):**	N/A
4. Who is entitled to apply for PA? *(e.g., can the patients apply themselves, or is treating doctor filing/partially filling the request, etc.)*	Answer: - *If there is a national doctor involved, is there a requirement that this doctor is contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA?* N/A	**Source(s):**	
5. Is there a specific application form/module which the person seeking PA needs to submit?	**Answer:** *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?*	**Source(s):**	

	- *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?* N/A		
6. What (other) documentation has to be submitted in order to substantiate a PA request?	**Answer:** *If applicable, please specify:* - *What documents and what particulars are required;* - *Whether there are requirements as to who has to issue the documents (e. g., a doctor contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA or any doctor);* - *Whether the submission of the documentation is optional, mandatory, or recommended.* - N/A	**Source(s):**	
7. Are there any costs associated with the handling of the PA request? - *Direct costs (e.g., fixed costs for submitting or filing a PA request).* - *Indirect costs* (*e.g., translations, stamps, etc).*	**Answer:** *Direct costs:* *Indirect costs:* N/A	**Source(s):**	
8. Are there any specific time requirements linked to a PA request? (*e.g., time within which a requesting person must submit the PA application*	**Answer:** - *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?*	**Source(s):**	

and/or time within which the requested body must take a decision on the PA request, etc.).	N/A			
9. Are there differences in the procedural/administrative requirements for requesting PA based on, for instance, the type of treatment for which PA is requested, the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* N/A	**Source(s):**		
10. Is there a specific PA form (i.e., form used for issuing/granting PA) and, if the answer is positive, what form?	**Answer:** N/A	**Source(s):**		
11. Please list any other administrative requirements in your country in relation to the PA procedure for cross-border healthcare.	**Answer:** N/A	**Source(s):**		
SECTION 2 REIMBURSMENT PROCEDURE(S)				
Questions	**Answer:**	**Sources**	**Does/do the identified requirement(s) also apply domestically? (i.e., is the requirement non-discriminatory?)**	**Purpose and/or justification of the requirements**

1. Which national legislative and/or regulatory provisions lay out the requirements related to reimbursement procedures for cross-border healthcare under Directive 201/24/EU?	**Answer:** Act on Cross-Border Healthcare.[275] Health Insurance Act of 21 December 2004 with later amendments (Health Insurance Act)[276]	**Source(s):** Act on Cross-Border Healthcare of 30 December 2013 with later amendments (Act on Cross-Border Healthcare) Health Insurance Act of 21 December 2004 with later amendments (Health Insurance Act) The online service EU-healthcare.fi (EU-healthcare.fi website)[277]	N/A	N/A
2. Is this the same procedure as for reimbursement under the Social Security Coordination Regulations?	**Answer:** **Yes ☒ No ☐** When a patient has a PA (under the Regulation only, as no PA system exists for PA under the Directive) he/she only pays the local client/patient fee for the treatment. He/she can claim reimbursement from KELA retrospectively for costs relating to trips, medication and accommodation, as well as for any other costs that the patient has exceptionally incurred above the applicable local patient fee. In some cases, reimbursement can also be claimed for the costs of an accompanying person. The reimbursement is applied with the same form as for any other treatment that has been received abroad. Patient must choose the applicable scenario from the different options on the form (in this case, treatment that has been received with PA). The reimbursement procedure and the form are relatively simple and there does not appear to be a justified need for a separate/simplified procedure for reimbursement relating to PA only.		N/A	N/A

[275] Laki rajat ylittävästä terveydenhuollosta 30.12.2013/1201 (Act on Cross-Border Healthcare of 30 December 2013 with later amendments), available at https://www.finlex.fi/fi/laki/ajantasa/2013/20131201 (last accessed on 15 June 2021), Chapter 3, Sections 9, 11, 12, 13.

[276] Sairausvakuutuslaki 21.12.2004/1224 (Health Insurance Act of 21 December 2004 with later amendments), available at https://finlex.fi/fi/laki/ajantasa/2004/20041224 (last accessed on 13 June 2021).

[277] The online service EU-healthcare.fi, maintained by the Finnish National Contact Point for Cross-Border Healthcare, available: https://www.eu-healthcare.fi/frequently-asked-questions/prior-authorisation/ (last accessed 15 June 2021).

3. What body is/are responsible of handling the reimbursement applications? (e.g., where and to whom reimbursement applications have to be submitted?)	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* The national social security body (Kansaneläkelaitos, KELA).	**Source(s):** Health Insurance Act, Chapter 1, Section 3	N/A	N/A
4. Is there a specific application form/module which the person seeking reimbursement needs to submit?	**Answer:** *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?* The patients apply for reimbursement by filling a form that is available online on KELA's website (form SV 128)[278]. The form must be submitted by post in paper. There is no possibility for electronic submission. The following information must be provided by the patient by filling out form SV 128 (all these details are set out on the form itself):	**Source(s):** Specific KELA Form (SV 128)[281]	**Yes ☒ No ☐** The information asked in the case of cross-border healthcare is more detailed compared to the information that is asked when a patient seeks treatment in private healthcare units situated in Finland (by form SV 127). However, this is not necessarily discriminatory as it is easier for KELA to verify the costs and information relating to domestic healthcare providers as compared to treatment received abroad. The deadline	

[278] 'Hoitoon hakeutuminen ulkomaille', website of KELA, available at https://www.kela.fi/sairaanhoito-kansainvalisissa-tilanteissa-hoitoon-hakeutuminen-ulkomaille (last accessed on 15 June 2021).
[281] Available at https://www.kela.fi/documents/10192/3861304/SV128.pdf (last accessed 13 June 2021).

	- Personal details (national identity number, name, phone number and email address); - Account number; - Details about the scenario in which the treatment was received: 1) Patient got suddenly ill during a temporary stay in the Nordic Countries (reimbursed in accordance with each Nordic state's national legislation in accordance with the Nordic Social Security Agreement). 2) Patient got suddenly ill during a temporary stay in an EU or EEA country or Switzerland. In this case the patient must choose whether he/she applies for reimbursement in accordance with the Finnish legislation or with other state's legislation. If neither option is chosen, the reimbursement is done in accordance with the Finnish legislation. 3) Patient independently sought treatment abroad in an EU or EEA country or Switzerland (reimbursement in accordance with the Health Insurance Act). 4) Patient sought treatment in an EU or EEA country or Switzerland with PA granted by KELA (no mention of applicable legislation on the form). 5) Patient got suddenly ill during a temporary stay outside an EU or EEA country or Switzerland (reimbursement in accordance with the Health Insurance Act). - The reason for which the costs were born: a transport accident, an occupational accident or illness, another reason.		to apply for reimbursement is the same for treatment received domestically and abroad (six months from the moment when the patient paid for the services). The form SV 127 simply requires the patient to fill in his/her personal and contact details and attach the medical reports and receipts. No further questions are asked.[282]	

[282] Note of the National expert: Moreover, usually it is not even necessary to apply for reimbursement using the SV 127 form, as most private healthcare suppliers in Finland reduce the KELA reimbursement automatically from the patients' bill in accordance with a direct reimbursement mechanism.

	- Has the patient obtained any reimbursement from elsewhere than KELA. If yes, from where. - Why the patient needed treatment abroad: illness or sudden attack, injury or accident, treatment relating to pregnancy or birth, treatment relating to an existing illness, another reason to be specified. - A description of the situation in which the treatment was sought (e.g. the symptoms and the course of events). If the treatment related to pregnancy or an existing illness, patient should specify why it was necessary to receive the treatment abroad. - In which country the treatment was received and in which currency. - The place of treatment and the type of doctor (a general practitioner or a specialist). - A breakdown of the treatments received (date, type of treatment, related cost). - A separate section for visits to a dentist. Patient must specify the place of treatment, the type of dentist (a dentist or a specialist dentist) as well as a breakdown of the treatments received (date, type of treatment, related cost).[279] - Purchased medications: information should be provided on the name of the medication, date of purchase, package size, strength and cost. - Travel costs relating to the treatment. Information should be provided on the dates, route, means of travel and cost. - Overnight accommodation costs and whether they were born by the patient or escort. Information should be provided for the date,			

[279] More specifications on this requirement are provided below at Question 10.

	place of accommodation, the reason for needing accommodation and cost.[280] - Annexes: copies of receipts, medical prescriptions and reports on the treatments that were received. Also other annexes can be attached. - Possible additional information if the patient wishes to provide it. - Date and signature. It is not specified which information is mandatory, optional or recommended.			
5. What (other) documentation has to be submitted in order to substantiate a reimbursement request?	**Answer:** *If applicable, please specify:* - *What documents are required;* - *Whether the submission of the documentation is optional, mandatory, or recommended.* All required documentation is explained under Question 4. In Annex to the form: - Copies of receipts, medical prescriptions and reports on the treatments that were received. Also other annexes can be attached.	**Source(s):** Specific KELA Form (SV 128)[283]	**Yes** ☒ **No** ☐	As above.
6. Are there any costs associated with the handling of the reimbursement request? - *Direct costs (e.g., fixed costs for submitting or*	**Answer:** *Direct costs:* No direct costs identified. *Indirect costs:* The patient must pay the postage fee to send the form and annexes to KELA.	**Source(s):** Information provided via call by the national body (KELA) during the verification of the data collected in this report.	**Yes** ☒ **No** ☐	Note from the National authority: The requirement also applies domestically, therefore it also applies for cross-border

[280] NB: the reimbursement of accommodation and escort costs is applicable only where a PA has been granted, therefore not for the reimbursement under the Directive 2011/24/EU.
[283] Available at https://www.kela.fi/documents/10192/3861304/SV128.pdf (last accessed 13 June 2021).

filing a reimbursement request, proportion deducted from the reimbursable amount). - *Indirect costs* (*e.g., translations, stamps, etc).*				healthcare. In fact, patients must pay the postage fee for any correspondence that they send to KELA, also for reimbursement applications for medical costs occurred in Finland.
7. Are there any specific time requirements linked to a reimbursement request? (*e.g., time within which the reimbursement requests must be submitted and/or time within the requested body must handle the request and/or reimburse the costs, etc.*).	**Answer:** *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* The patient must submit the form (SV 128) within six months from paying the associated medical costs.[284] However, a reimbursement or benefit can be granted in part or in full, even in the event that it has not been applied for within that time limit, if the withholding of such a benefit or reimbursement due to delay would constitute unreasonable practice.[285] There is no specific timeframe for KELA to make its decision. The general rules under the Administrative Procedure Act[286] apply. Under the said Act, all matters shall be considered 'without undue delay'. Moreover, upon the request of a party, the authority shall inform the party about the	**Source(s):** Specific KELA Form SV 128 Health Insurance Act, Chapter 15, Sections 3 and 7 Administrative Procedure Act[287]	**Yes** ☒ **No** ☐	There is no deadline for KELA to take its decision but this is the same for reimbursement decisions on domestic costs. The Administrative Procedure Act applies to all actions and omissions by Finnish authorities.

[284] Sairausvakuutuslaki 21.12.2004/1224 (Health Insurance Act of 21 December 2004 with later amendments), available at https://finlex.fi/fi/laki/ajantasa/2004/20041224 (last accessed on 13 June 2021), Chapter 15, Section 3.
[285] Health Insurance Act of 21 December 2004 with later amendments, Chapter 15, Section 7.
[286] Hallintolaki 6.6.2003/434 (Administrative Procedure Act of 6 June 2003, with later amendments), available at https://www.finlex.fi/fi/laki/ajantasa/2003/20030434 (last accessed on 14 June 2021), Section 23.
[287] Hallintolaki 6.6.2003/434 (Administrative Procedure Act of 6 June 2003, with later amendments), available at https://www.finlex.fi/fi/laki/ajantasa/2003/20030434 (last accessed on 14 June 2021), Section 23.

	estimated date of issue of a decision and respond to queries about the progress of consideration.			
8. Are there any non-reimbursable thresholds, deductions *(except the deductions for administrative costs mentioned above) etc.?*	**Answer:** *If yes, please specify the thresholds.* With regards to cross-border healthcare sought without PA under the Directive, a non-reimbursable threshold is applied for any treatment that has been received in EU/EEA countries and Switzerland without PA, both in private and in public establishments: the reimbursement covers the same amount as is covered for treatment received in private establishments in Finland. Additional thresholds exist in relation to the reimbursement of: - Medicines: for medicines, there is an initial deductible of 50 euros that is applied annually.[288] The deductible applies to all medicines bought by the patient. The deductible is not applied in the case of the underaged (the application of the threshold starts during the year when the patient turns 19 years). Once the threshold for the initial deductible is full, reimbursement is available. The rate of reimbursement depends on the reimbursement category to which the product belongs. Any prescription	**Source(s):** Act on Cross-Border Healthcare, Sections 9, 11 and 12 Health Insurance Act, Chapters 4 and 5 The website of KELA regarding reimbursement of medical costs[292] The website of KELA regarding reimbursement of medicines purchased abroad[293]	**Yes** ☐ **No** ☒ Differences identified with regards to the amounts to be reimbursed for healthcare provided in public establishments, compared to those reimbursed for healthcare provided in public establishments in Finland (Cfr. column 5).	The Finnish law differentiates domestically between treatment received in public and private establishments. Any treatment sought in private establishments in Finland is reimbursed only partly. Treatment received in private establishments abroad (in EU/EEA countries and Switzerland) is reimbursed with this same partial rate. However, there is a difference in treatment when a patient seeks treatment in public establishments abroad as compared to being treated in public establishments in Finland. In Finland, the patient pays the public healthcare's patient fee only, whereas any treatment received in

[288] The limitations apply both domestically and for treatments abroad.
[292] Website of KELA, 'Hoitoon hakeutuminen ulkomaille' (The website of KELA regarding reimbursement of medical costs), available at https://www.kela.fi/sairaanhoito-kansainvalisissa-tilanteissa-hoitoon-hakeutuminen-ulkomaille (last accessed on 15 June 2021).
[293] Website of KELA, 'Reimbursement of medicines purchased abroad' (The website of KELA regarding reimbursement of medicines purchased abroad), available at https://www.kela.fi/web/en/medicines-purchased-abroad (last accessed on 15 June 2021).

	medicine costs that the patient pays himself/herself (once the reimbursement has been applied) count towards an annual maximum limit on out-of-pocket costs. The initial deductible also counts towards the annual out-of-pocket maximum. In 2021 the annual maximum is set at EUR 579,78. - Dental expenses:[289] oral and dental care and examinations are reimbursed when the treatment concerned is necessary to cure an illness other than dental illness, and the reimbursement is not available for dental prosthetic procedures or dental technology expenses.[290] Additionally, travel costs incurred by a person seeking a health care service in another EU Member State are reimbursed as provided in Chapter 4 of the Health Insurance Act. Travel costs for treatment received in another EU Member State are reimbursed as if the trip would have been made to the closest healthcare establishment where the treatment was available in Finland.[291]			both private and public establishments abroad is reimbursed only to the same partial amount as treatment in private establishments domestically. This partial rate is typically only a fraction of the actual costs.[294] KELA did not provide a justification for the differential treatment in treatment received in public healthcare establishments during the verification call. For medicines, reimbursement is only provided for necessary medicines used in the treatment of an illness. This also applies domestically. To qualify

[289] According to Health Insurance Act, Chapter 3, Section 2.
[290] The limitations apply both domestically and for treatments abroad.
[291] Act on Cross-Border Healthcare, Section 11.
[294] The European Commission has started an infringement procedure against Finland regarding this issue. It concerns the implementation of Article 7(4) of Directive 2011/24. The Commission sent a reasoned opinion to Finland on 29 April 2016. The infringement case is still pending. The issue at stake is thus the rate with which medical costs are reimbursed when treatment abroad has been sought in public medical establishments without PA. In the Commission's view, treatment received in all healthcare establishments in other EU countries should be reimbursed up to the same amount as public healthcare treatment received in Finland. See: European Commission, 'The April Infringements Package: Key decisions' 28 April 2016, available at https://ec.europa.eu/commission/presscorner/detail/EN/MEMO_16_1452 (last accessed on 4 June 2021).
Regarding the state of play of the infringement procedure, see the Commission's answer to a parliamentary question at the European Parliament on 13 November 2020: Answer given by Ms Kyriakides on behalf of the European Commission, 13 November 2020, Question reference: P-005395/2020, available at https://www.europarl.europa.eu/doceo/document/P-9-2020-005395-ASW_EN.html (last accessed 4 June 2021).

				for reimbursement, the medicine must be equivalent to a medicine available and reimbursable in Finland. Whether it is equivalent is determined by reference to the pharmaceutical dosage form, substance and strength. Travel costs are reimbursed in accordance with the same principles as in Finland (to the closest treating establishment in Finland). There is no additional compensation for trips made abroad. This is not problematic under the Directive as the Directive does not require the compensation of travel costs.
9. In instances where a PA (or prior-notification) has already been issued, is a separate/simplified procedure available for requesting reimbursement?	**Answer:** *If yes, please describe the simplified procedure.* Not applicable (no PA system established in Finland according to Directive 2011/24/EU). Reimbursement of costs is applied for with the same form as reimbursement for any other costs	**Source(s):** The website of KELA regarding reimbursement of medical costs EU-healthcare.fi website	**Yes** ☐ **No** ☐	

**applicable only if the country has a PA system.*	related to treatment that has been received abroad (form SV 128).			
10. Are there additional administrative/procedural requirements for reimbursement depending on, for instance, the type of treatment for which reimbursement is requested, or the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* More specifications are needed for dentistry visits: patients must specify the place of treatment, the type of dentist (a dentist or a specialist dentist) as well as a breakdown of the treatments received (date, type of treatment, related cost).[295]	**Source(s):** N/A	**Yes** ☒ **No** ☐	
11. Please list any other administrative requirements in your country in relation to the procedures of reimbursement of cross-border healthcare.	**Answer:** No further administrative requirements.	**Source(s):**	**Yes** ☒ **No** ☐	

[295] Note of the National expert: The further specifications needed for dentists are needed as it might not always be clear, from the name of the provider, whether a dentist or a medical doctor is involved.

Part 2: Checklist for verification with national/regional body

Name of the body: Kansaneläkelaitos (KELA)
Country/Region: Finland
Date of verification call: 10 June 2021

Template for the Data Collection	**Aspects to be verified** *Tick the boxes if the information in the template for the data collection has been verified and/or complemented by the national body*		**Comments** *Include any additional comments and/or information provided by the contacted body*
Section 1 – Prior Authorisation			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Justification/purpose of the identified requirement(s) (Column 4)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	The body confirmed the findings on the lack of PA system in Finland under Directive 2011/24/EU.
Section 2 - Reimbursement			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Whether the requirement applies domestically (Discriminatory assessment) (Column 4) ▪ Justification/purpose of the identified requirement(s) (Column 5)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	The information and clarifications provided by KELA have been incorporated in the report above.

FRANCE – COUNTRY REPORT

Part 0: Preliminary Assessment

1. **Please indicate whether the rules governing the administrative procedures/requirements for requesting PA and reimbursement under Directive 2011/24/EU in your country are set out at:**

A. National level ☒

B. Decentralised/regional/local level ☐

In case (1.B): Please indicate the two most relevant jurisdictions in your country (i.e., in terms of population):

Region/jurisdiction: 1:

Region/jurisdiction 2:

NOTE: In case (1.B) the template for the data collection (Part 1) should be complete twice, once for each of the two most relevant regions/jurisdiction indicated above.

2. **Please indicate the national body best suited to verify the accuracy of the information collected in Part 1, and justify your selection.**

Depending on the characteristics of your national healthcare system, the relevant body may be: a) *the national social security body*; or b) *an insurance fund*. In the latter case, please indicate the most representative fund (e.g., the one with the highest number of affiliations).

Body to be contacted for Task 2: Caisse primaire d'assurance maladie (CPAM) (Primary health insurance fund)

(In case 1.B, please indicate two relevant bodies, one respectively for each Region/jurisdiction)

Reasons for Selection: The Social Security system in France is a national regime with a decentralised organisation. The CPAMs (Primary health insurance funds) are the local bodies in charge of the provision of public health insurance services, including issuing prior authorisation (PA) and handling reimbursement requests in the context of cross-border healthcare within the European Union. The CPAMs are also the main contact of the insured persons to get information about their rights, the public insurance procedures and formalities. There are 102 Primary health insurance funds in France, with at least one in each department. At the national level, the CNAM (National health insurance fund) ensures the effective and consistent implementation of the Social Security regime by coordinating the local CPAMs. The Ministry for Health and Solidarity is the top executive body which lays out the politic for public health insurance and works directly with the Parliament in the legislative process.

The national legal expert has contacted by phone and emails the CPAMs (decentralised funds) as well as the Ministry for Health and Solidarity for the verification of the data collected via desk research (Task 2). However, the national legal expert did not receive any answer, besides a general invitation to seek advice personally at the CPAMs premises for any query. There are no direct contact details available for contact persons in the CNAM.

Part 1: Questionnaire

*__Note 1__: In cases where administrative requirements are set out in the legislative/regulatory framework at decentralised/regional/local level, please complete the template for the data collection twice, once for each of the two most relevant regions/jurisdictions (e.g., in terms population).

__*Note 2__: Setting out a Prior Authorisation (PA) system is optional for Member States. Should your country not have a system of PA in place under Directive 2011/24/EU, Section 1 will not need to be completed.

SECTION 1 PRIOR AUTHORISATION PROCEDURE(S)			
Questions	**Answer**	**Sources**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to PA procedures for a cross-border healthcare under Directive 2011/24/EU?	Answer: Under Article R160-2 of the Code de la Sécurité Sociale (Social Security Code)[296], there are two cases in which a PA is required specifically in the context of cross-border healthcare[297]: • the healthcare involves at least one night of hospitalisation • the healthcare requires the use of highly specialised and cost-intensive medical infrastructure or equipment listed by	Source(s): • Article R160-2 of the Social Security Code (link) • Website of the CLEISS (French NCP) regarding the transposition of the Directive 2011/24/EU (link) and the PA procedure (link) • Website of the Social Security regarding the PA procedure (link)	N/A

[296] Code de la Sécurité Sociale, available at: https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000031795846/2016-01-01 (last accessed 28/06/2021).
[297] Note that a PA procedure is also required for the reimbursement of specific medical practices or treatments received in France, and *a fortiori* in another Member State, under Article L315-2 of the Social Security Code. This procedure does not fall within the scope of the Directive 2011/24/EU and is therefore not described in this study.

	Order of the Minister for Health and Solidarity[298] The same Article R160-2 of the Social Security Code lays out the procedure and administrative requirements for the PA application and the grant process.		
2. Is this the same procedure as for PA under the Social Security Coordination Regulations?	Answer: Yes ☒ No ☐		N/A
3. What body is in charge of handling the PA applications? *(e.g., where and to whom PA applications have to be submitted?)*	Answer: *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* Caisses primaires d'assurance maladie (CPAMs) (Primary health insurance funds). Each insured person is affiliated to a local CPAM which is in charge of all healthcare reimbursement requests and handles PA applications in the context of a cross-border healthcare. The PA application must be submitted by the insured person to the medical advisor of his/her CPAM of affiliation.	Source(s): • Article R160-2 of the Social Security Code (link) • Website of the CLEISS regarding the PA procedure (link) • Website of the Social Security regarding the PA procedure (link)	N/A

[298] Order in force on the 16 June 2021: Arrêté du 27 mai 2014 établissant la liste des soins hors de France nécessitant le recours à des infrastructures ou équipements médicaux hautement spécialisés et coûteux (Order of 27 May 2014 establishing the list of healthcare outside of France which require the use of highly specialised and cost-intensive medical infrastructure or equipment), available at https://www.legifrance.gouv.fr/loda/id/JORFTEXT000029054348/ (last accessed 28/06/2021).

4. Who is entitled to apply for PA? *(e.g., can the patients apply themselves, or is treating doctor filing/partially filling the request, etc.)*	Answer: *If there is a national doctor involved, is there a requirement that this doctor is contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA?* The insured persons apply themselves by submitting a PA application to the medical advisor of their CPAM of affiliation.	Source(s): • Article R160-2 of the Social Security Code (link) • Website of the CLEISS regarding the PA procedure (link) • Website of the Social Security regarding the PA procedure (link)	No specific justification/purpose identified in the sources consulted.
5. Is there a specific application form/module which the person seeking PA needs to submit?	Answer: *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?* There is no specific application form/module. The insured persons apply by sending a letter to the medical advisor of their CPAM of affiliation. The PA application cannot be submitted electronically.	Source(s): • Website of the CLEISS regarding the PA procedure (link) • Website of the Social Security regarding the PA procedure (link) • Decree No 2016-1494 of 4 November 2016 on the exceptions to the application of the right for users to electronically contact the administration regarding the procedures followed before the Social Security bodies (link)	No specific justification/purpose identified in the sources consulted.
6. What (other) documentation has to be submitted in order to substantiate a PA request?	Answer: *If applicable, please specify:* - *What documents and what particulars are required;*	Source(s): • Website of the CLEISS regarding the PA procedure (link)	No specific justification/purpose identified in the sources consulted.

	- *Whether there are requirements as to who has to issue the documents (e. g., a doctor contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA or any doctor);* - *Whether the submission of the documentation is optional, mandatory, or recommended.* It is a mandatory requirement to attach to the PA application a medical consultation issued by a doctor (general practitioner or specialist). This medical consultation must contain the following mandatory information: - the identity of the patient - the disease - the type of healthcare that needs to be performed - the reasons why this healthcare has to be performed abroad - the country where the planned healthcare will be performed - the name and contact details of the facility where the planned healthcare will be performed - the start and end dates of the planned healthcare	• Website of the Social Security regarding the PA procedure (link)[299]	

[299] Note of the National expert: No legislative source was found, but the websites of the CLEISS and the Social Security clearly state that these requirements are mandatory.

7. Are there any costs associated with the handling of the PA request? - *Direct costs (e.g., fixed costs for submitting or filing a PA request).* - *Indirect costs* (*e.g., translations, stamps, etc).*	Answer: Direct costs: No direct costs Indirect costs: • To receive the medical certificate that has to be attached to the PA request will involve medical consultation cost(s), which can be partially or fully covered by the public health insurance depending on the situation of the patient and the type of practitioner who issues the medical certificate. • If sent by post, the costs of the postage stamp for sending the PA application to the medical advisor of the CPAM.	Source(s): N/A	No specific justification/purpose identified in the sources consulted.
8. *Are there any specific time requirements linked to a PA request?* *(e.g., time within which a requesting person must submit the PA application and/or time within which the requested body must take a decision on the PA request, etc.).*	Answer: *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* The CPAM has to notify its decision in a time period compatible with the degree of urgency and availability of the planned healthcare, and at the latest 14 days after receiving the PA application. The absence of response from the CPAM within that 14 days period is considered equivalent to a tacit decision to grant the PA. There is no specific requirement of time to submit the PA application. It must be submitted early enough, and at least 14 days before departure, to make sure of getting the CPAM's decision before departure. However, if the insured person needs urgent healthcare abroad that	Source(s): • Article R160-2 of the Social Security Code (link) • Website of the CLEISS regarding the PA procedure (link) • Website of the Social Security regarding the PA procedure (link)	No specific justification/purpose identified in the sources consulted.

	cannot be postponed, and is not able to seek PA or wait for the CPAM's decision before departure, the decision to grant PA can be issue *a posteriori*.		
9. Are there differences in the procedural/administrative requirements for requesting PA based on, for instance, the type of treatment for which PA is requested, the profile of the insured person, or any other criterion?	Answer: *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* None identified.	Source(s):	*No specific justification/purpose identified in the sources consulted.*
10. Is there a specific PA form (i.e., form used for issuing/granting PA) and, if the answer is positive, what form?	Answer: Once the PA is granted the CPAM issues a Form S2 which contains the following information: - the covered prescribed healthcare - the country and the facility where the planned healthcare will be performed - the start and end dates of the planned healthcare Note: the same form (S2) is issued for both PA under the Social Security Coordination Regulations and PA under Directive 2011/24/EU.	Source(s): • Website of the CLEISS regarding the Form S2 (link) • Website of the Social Security regarding the PA procedure (link)	*No specific justification/purpose identified in the sources consulted.*
11. Please list any other administrative requirements in your country in relation to the PA procedure for cross-border healthcare.	Answer: None identified.	Source(s): N/A	N/A
SECTION 2 **REIMBURSMENT PROCEDURE(S)**			

Questions	Answer:	Sources	Does/do the identified requirement(s) also apply domestically? (i.e., is the requirement non-discriminatory?)	Purpose and/or justification of the requirements
1. Which national legislative and/or regulatory provisions lay out the requirements related to reimbursement procedures for cross-border healthcare under Directive 201/24/EU?	Answer: Article R160-1 of the Social Security Code provides the right of reimbursement of cross-border healthcare costs under Directive 2011/24/EU.	Source(s): • Article R160-1 of the Social Security Code (link) • Website of the CLEISS regarding the transposition of the Directive 2011/24/EU (link) and the reimbursement procedure (link) • Website of the Social Security regarding the reimbursement procedure (link)	N/A	N/A
2. Is this the same procedure as for reimbursement under the Social Security Coordination Regulations?	Answer: Yes ☒ No ☐		N/A	N/A
3. What body is/are responsible of handling the reimbursement applications? (e.g., where and to whom reimbursement applications have to be submitted?)	Answer: *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* Caisses primaires d'assurance maladie (CPAMs) (Primary health insurance funds).	Source(s): • Article R160-1 of the Social Security Code (link)	N/A	N/A

	The CPAMs are in charge of all healthcare reimbursement requests including in the context of a cross-border healthcare.			
4. Is there a specific application form/module which the person seeking reimbursement needs to submit?	Answer: *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?* In order to seek reimbursement, the insured person has to complete and submit a form S3125[300] to his/her CPAM of affiliation. This form is a mandatory requirement and it is available online. The information required in the form are: - the details of the patient: name, address, work situation, nationality, affiliation number ; - the details of the stay abroad: address, duration, purpose of the stay ; - the details regarding the healthcare performed abroad: reason for the healthcare, type of healthcare ; - if the insured person wants to be reimbursed under the French regime or the reimbursement regime of the	Source(s): • Website of the CLEISS regarding the reimbursement procedure (link) • Website of the Social Security regarding the reimbursement procedure (link) • Formulaire S3125 "Soins reçus a l'étranger" (Form S3125 "Healthcare provided abroad")	Yes ☐ No ☒ The form S3125 is specific to reimbursement of healthcare provided abroad. If healthcare is provided in France, the reimbursement request is sent either electronically through the patient's Security Social card (Carte Vitale), or by post through a form called "healthcare sheet" (feuille de soin) filled and signed by both the patient and the medical practitioner.	No specific justification/purpose identified in the sources consulted.

[300] Formulaire S3125 "Soins reçus a l'étranger" (Form S3125 "Healthcare provided abroad") available at: https://www.ameli.fr/sites/default/files/formualires/221/s3125.pdf

	country where the healthcare has been performed. If the insured person does not indicate his/her choice, the second option apply automatically ; - the sums already reimbursed by the country where the healthcare has been performed, if any. Note that this form has to be submitted to seek the reimbursement of any healthcare provided abroad, i.e. treatments provided inside or outside of the European Union, with or without prior authorization. The form has to be submitted in person or by post, as the original documents (form, invoices and payment receipts) are required.			
5. What (other) documentation has to be submitted in order to substantiate a reimbursement request?	Answer: *If applicable, please specify:* - *What documents are required;* - *Whether the submission of the documentation is optional, mandatory, or recommended.* It is a mandatory requirement to attach to the form S3125 the original copies of the invoices and payment receipts for which reimbursement is requested. The CPAM can also request additional documents such as medical reports or radiograph.[301]	Source(s): • Website of the CLEISS regarding the reimbursement procedure (link) • Website of the Social Security regarding the reimbursement procedure (link) • Formulaire S3125 "Soins reçus a l'étranger" (Form S3125 "Healthcare provided abroad")	Yes ☐ No ☒ These documents are not required for the reimbursement of healthcare provided in France. No documents are required if the reimbursement request is sent through the patient's Social Security	No specific justification/purpose identified in the sources consulted.

[301] Please note that these requirements are also included in pages 1 and 2 of the Form S3125: https://www.ameli.fr/sites/default/files/formualires/221/s3125.pdf.

			card (Carte Vitale). If the reimbursement request is made on paper and concerns a specialist consultation or the purchase of medicines, the insured patient must provide the prescriptions to the CPAM.	
6. Are there any costs associated with the handling of the reimbursement request? - *Direct costs (e.g., fixed costs for submitting or filing a reimbursement request, proportion deducted from the reimbursable amount).* - *Indirect costs* (*e.g., translations, stamps, etc).*	Answer: *Direct costs:* No direct costs *Indirect costs:* If sent by post, the costs of the postage stamp for sending the reimbursement request to the CPAM.	Source(s): N/A	Yes ☒ No ☐	N/A
7. Are there any specific time requirements linked to a reimbursement request? (*e.g., time within which the reimbursement requests must be submitted and/or time within the requested body must handle the request and/or reimburse the costs, etc.*).	Answer: *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* Under Article L332-1 of the Social Security Code, reimbursement requests must be submitted within 2 years. The computation of this period is different when the reimbursement request concerns medical expenses for a disease or for a pregnancy:	Source(s): • Article L332-1 of the Social Security Code (link) • Website of the CLEISS regarding the reimbursement procedure (link) • Website of the Social Security regarding the reimbursement procedure (link)	Yes ☒ No ☐	*No specific justification/purpose identified in the sources consulted.*

	- For the reimbursement of medical expenses regarding a disease, the 2 years period starts from the first day of the civil quarter which follows the quarter when the healthcare was provided. - For the reimbursement of maternity costs, the 2 years period starts from the date of the first medical confirmation of the pregnancy. Beyond this 2 year period, the insured persons lose the right to claim reimbursement. There is no mandatory deadline for the CPAM to handle the request and proceed to the reimbursement.			
8. Are there any non-reimbursable thresholds, deductions *(except the deductions for administrative costs mentioned above) etc.?*	Answer: *If yes, please specify the thresholds.* No specific thresholds identified. Costs are covered on the basis of the French social security tariffs, within the limit of the costs incurred. Therefore, some costs may only be partially covered depending on the French tariff applicable to each specific treatment or medicine.	Source(s): • Article R160-1 of the Social Security Code (link) • Website of the CLEISS regarding the reimbursement procedure (link) • Website of the Social Security regarding the reimbursement procedure (link)	Yes ☒ No ☐	No specific justification/purpose identified in the sources consulted.
9. In instances where a PA (or prior-notification) has already been issued, is a separate/simplified procedure available for requesting reimbursement?	Answer: *If yes, please describe the simplified procedure.*	Source(s): • Article R160-1 of the Social Security Code (link)	Yes ☒ No ☐	No specific justification/purpose identified in the sources consulted.

**applicable only if the country has a PA system.*	No, the procedure is the same.			
10. Are there additional administrative/procedural requirements for reimbursement depending on, for instance, the type of treatment for which reimbursement is requested, or the profile of the insured person, or any other criterion?	Answer: *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* None identified.	Source(s): N/A	Yes ☐ No ☐	N/A
11. Please list any other administrative requirements in your country in relation to the procedures of reimbursement of cross-border healthcare.	Answer: N/A	Source(s): N/A	Yes ☐ No ☐	N/A

Part 2: Checklist for verification with national/regional body

Name of the body: N/A
Country/Region: N/A
Date of verification call: N/A

Template for the Data Collection	Aspects to be verified *Tick the boxes if the information in the template for the data collection has been verified and/or complemented by the national body*		Comments *Include any additional comments and/or information provided by the contacted body*
Section 1 – Prior Authorisation			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Justification/purpose of the identified requirement(s) (Column 4)	☐ Question 1 ☐ Question 2 ☐ Question 3 ☐ Question 4 ☐ Question 5	☐ Question 6 ☐ Question 7 ☐ Question 8 ☐ Question 9 ☐ Question 10 ☐ Question 11	
Section 2 - Reimbursement			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Whether the requirement applies domestically (Discriminatory assessment) (Column 4) ▪ Justification/purpose of the identified requirement(s) (Column 5)	☐ Question 1 ☐ Question 2 ☐ Question 3 ☐ Question 4 ☐ Question 5	☐ Question 6 ☐ Question 7 ☐ Question 8 ☐ Question 9 ☐ Question 10 ☐ Question 11	

GERMANY – COUNTRY REPORT

Part 0: Preliminary Assessment

1. **Please indicate whether the rules governing the administrative procedures/requirements for requesting PA and reimbursement under Directive 2011/24/EU in your country are set out at:**

A. National level ☒

B. Decentralised/regional/local level ☐

In case (1.B): Please indicate the two most relevant jurisdictions in your country (i.e., in terms of population):

Region/jurisdiction 1: N/A

Region/jurisdiction 2: N/A

NOTE: In case (1.B) the template for the data collection (Part 1) should be complete twice, once for each of the two most relevant regions/jurisdiction indicated above.

2. **Please indicate the national body best suited to verify the accuracy of the information collected in Part 1, and justify your selection.**

Depending on the characteristics of your national healthcare system, the relevant body may be: a) *the national social security body*; or b) *an insurance fund*. In the latter case, please indicate the most representative fund (e.g., the one with the highest number of affiliations).

Body to be contacted for Task 2:

Bundesministerium für Gesundheit (Federal Ministry of Health)

Main Insurance fund: vdek - Verband der Ersatzkassen e. V.

Other insurance funds: AOK-Bundesverband; Interessenvertretung von Innungskrankenkassen (IKK e.V.) [302]

(In case 1.B, please indicate two relevant bodies, one respectively for each Region/jurisdiction)

Reasons for Selection: As the legal framework is regulated at a national level, the German Federal Ministry of Health is responsible.

[302] NB: The insurance funds have been contacted but no answer was received for the verification of the data collected.

Note: the data collected in the present documents has not yet been verified by the bodies/insurance funds contacted by the national legal expert.

Part 1: Questionnaire

*__Note 1__: In cases where administrative requirements are set out in the legislative/regulatory framework at decentralised/regional/local level, please complete the template for the data collection twice, once for each of the two most relevant regions/jurisdictions (e.g., in terms population).

__*Note 2__: Setting out a Prior Authorisation (PA) system is optional for Member States. Should your country not have a system of PA in place under Directive 2011/24/EU, Section 1 will not need to be completed.

SECTION 1 PRIOR AUTHORISATION PROCEDURE(S)			
Questions	**Answer**	**Sources**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to PA procedures for a cross-border healthcare under Directive 2011/24/EU?	**Answer:** The requirements related to PA procedures for a cross-border healthcare under Directive 2011/24/EU are indicated in the Fifth Book of the Social Code at Art. 13, paragraphs 4 and 5. Preliminary note: In Germany, patients can have statutory health insurance or a private one. If they	**Source(s):** § 13 Abs. 4 und 5 des Fünften Buches Sozialgesetzbuch - SGB V (Art. 13, paragraphs 4 and 5 of the Fifth Book of the Social Law). [305]	The German health system for legally insured persons distinguishes whether treatment is requested under EC Regulation No 883/2004 or under the Directive. Applications under EC Regulation 883/2004 are always subject to prior approval under this Regulation. For this purpose, the insured person does not have to make advance payments, but on the other hand he receives only the statutory benefits to the extent provided for by the scheme of the State of treatment. If he makes use of a benefit under Directive 2011/24/EU, Article 13, paragraphs 4 - 6 of the Fifth Book of the

[305] Sozialgesetzbuch (SGB) Fünftes Buch (V) - Gesetzliche Krankenversicherung - Artikel 1 des Gesetzes v. 20. Dezember 1988, BGBl. I S. 2477 (Social Code (SGB) Book Five (V) - Statutory Health Insurance - Article 1 of the law of December 20, 1988, Federal Law Gazette I, p. 2477), available at: https://www.gesetze-im-internet.de/sgb_5/__13.html (last accessed on 27.05.2021), Article 13(4-5).

	have a private health insurance, the health insurance determines the extent to which treatments can be obtained in another Member State (and the same applies to any cost reimbursement). If they have a statutory health insurance, the following rules apply.[303] According to the NCP portal, a patient can take up a treatment in another EU country where his/her health insurance fund would also assume the costs for persons in Germany who have statutory health insurance. According to this procedure, a PA is necessary if this would be the case under German law. Therefore, only in certain cases PA is needed. As provided for in German law, PA is always mandatory in case of hospital treatments. Services requiring prior authorisation by the health insurance fund include: - In-patient treatment (minimum 1 night in hospital); - Treatment provided in an hospital; - All treatment that would also require prior authorisation if carried out in Germany (such as dentures, rehabilitation services, psychotherapies and		Social Law of the German law governs the claim under German law. He first pays the benefit himself and receives a refund in the amount of German contract rates.[306]

[303] Before treatment in another EU country, National Contact Point for cross-border healthcare, EU-PATIENTEN.DE 2021, available at: https://www.eu-patienten.de/en/behandlung_ausland/geplante_behandlung_1/kostentraeger_eu/behandlung_wie_gesetzlich_krankenversicherte/behandlung_wie_gesetzlich_krankenversicherte_1.jsp, (last accessed on 01.06.2021).
[306] Information provided to Spark Legal Network by the German National Contact Point on 1 October 2021.

	behaviour therapies, orthodontic treatments, etc).[304]		
2. Is this the same procedure as for PA under the Social Security Coordination Regulations?	**Answer:** **Yes ☐ No ☒** The German healthcare system does not really differentiate between cases under Regulations and cases under the Directive, but more between whether the patient has statutory or private health insurance and whether it is a "planned treatment" (for which you have to ask for PA) or an "unplanned treatment" (so mostly for the cases under the Regulations). Explanatory note: According to the NCP portal, there are two procedures for healthcare abroad: - One for patients that want to be treated as if they have a statutory health insurance in the country of treatment (and in this case, their health insurance will pay the treatment). This is the procedure for exercising rights pursuant to the Regulation. - One for patients that want to have a benefit abroad which the health insurance would also pay for in Germany. In this case, patients would be treated as if they have private health insurance, meaning that they initially pay the costs incurred and then they can ask for reimbursement. This is the procedure for exercising rights pursuant to the Directive.[307]		N/A

[304] Treatment as if you had private health insurance, National Contact Point for cross-border healthcare, EU-PATIENTEN.DE 2021, available at: https://www.eu-patienten.de/en/behandlung_ausland/geplante_behandlung_1/kostentraeger_eu/behandlung_wie_privat_krankenversicherte/behandlung_patientenmobilitaet_1.jsp, (last accessed on 27.05.2021).
[307] Who pays for planned treatment in EU Member States?, National Contact Point for cross-border healthcare, EU.PATIENTEN.DE 2021, available at: https://www.eu-patienten.de/en/behandlung_ausland/geplante_behandlung_1/kostentraeger_eu/kostentraeger_eu_2.jsp (last accessed on 01.06.2021).

	When the health insurance fund is obliged to authorise a treatment (in case of hospital treatment) it is generally obliged to issue an E112 or S2 form (pursuant to the Regulation), which should entail a lower cost risk. If, instead, patients would like to take up a more specific hospital treatment, although it is also offered in Germany, the health insurance fund has discretion, which implies that it can grant authorisation, but it is not obliged to.[308]		
3. What body is in charge of handling the PA applications? *(e.g., where and to whom PA applications have to be submitted?)*	**Answer:** In case the PA system applies, PA applications should be submitted to public health insurance funds/providers (Gesetzliche Krankenversicherung (GKV), Statutory health insurance). *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* **Answer:**	**Source(s):** § 13 Abs. 5 des Fünften Buches Sozialgesetzbuch - SGB V (Art. 13, paragraphs 5 of the Fifth Book of the Social Law).[311] Assumption of costs if you are treated as if you had statutory health insurance (form E 112 or S2), National Contact Point for cross-border healthcare, EU-PATIENTEN.DE 2021.[312]	N/A

[308] Prior authorisation for treatment in another EU country in accordance with the Patient Mobility Directive, National Contact Point for cross-border healthcare, https://www.eu-patienten.de/en/behandlung_ausland/geplante_behandlung_1/kostentraeger_eu/behandlung_wie_privat_krankenversicherte/vorabgenehmigungspflichtige_behandlungen/vorabgenehmigungspflichtige_behandlungeen_nach_rl_2011_24_eu/vorabgenehmigungspflichtige_behandlung_2.jsp, (last accessed on 01.06.2021).

[311] Sozialgesetzbuch (SGB) Fünftes Buch (V) - Gesetzliche Krankenversicherung - Artikel 1 des Gesetzes v. 20. Dezember 1988, BGBl. I S. 2477 (Social Code (SGB) Book Five (V) - Statutory Health Insurance - Article 1 of the law of December 20, 1988, Federal Law Gazette I, p. 2477), available at: https://www.gesetze-im-internet.de/sgb_5/__13.html (last accessed on 27.05.2021), Article 13(5).

[312] Assumption of costs if you are treated as if you had statutory health insurance (form E 112 or S2), National Contact Point for cross-border healthcare, EU-PATIENTEN.DE 2021, available at: https://www.eu-patienten.de/en/behandlung_ausland/geplante_behandlung_1/kostentraeger_eu/behandlung_wie_gesetzlich_krankenversicherte/behandlung_wie_gesetzlich_krankenversicherte_1.jsp (last accessed on 28.05.2021).

	The German national healthcare system is based on multiple insurance providers.[309] A list of the German statutory Health insurance funds can be found here: Krankenkassenliste - GKV-Spitzenverband.[310]	Daten des Gesundheitswesens 2020, Bundesministerium für Gesundheit (Healthcare data 2020, Federal Ministry of Health), p. 112. [313]	
4. Who is entitled to apply for PA? *(e.g., can the patients apply themselves, or is treating doctor filing/partially filling the request, etc.)*	**Answer:** The patients can apply themselves and directly apply to their personal health insurance providers, because the patients are directly affiliated to the health insurance provider and have a direct contact with them. Moreover, they should take contact with the health insurance provider in order to clarify which costs can be reimbursed and in which cases there is a need of a prior authorisation system. - *If there is a national doctor involved, is there a requirement that this doctor is contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA?* **Answer:**	**Source(s):** § 13 Abs. 5 des Fünften Buches Sozialgesetzbuch - SGB V (Art. 13, paragraphs 5 of the Fifth Book of the Social Law).[314] Assumption of costs if you are treated as if you had statutory health insurance (form E 112 or S2), National Contact Point for cross-border healthcare, EU-PATIENTEN.DE 2021. [315]	Purpose of the requirement is to facilitate application for PA, enabling health insurance providers to provide information regarding cross-border healthcare to their affiliated members and to issue PA in cases provided for by national law.

[309] The most important/relevant insurance provider in Germany is the "Verband der Ersatzkassen e.V. (vdek)" (Association of Substitute Funds e.V.) with the highest number of affiliations (28.099.937 affiliations in August 2020).

[310] Information provided to Spark Legal Network by the German National Contact Point on 1 October 2021.

[313] Daten des Gesundheitswesens 2020, Bundesministerium für Gesundheit (Healthcare data 2020, Federal Ministry of Health), available at: https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/5_Publikationen/Gesundheit/Broschueren/Daten_des_Gesundheitswesens_2020.pdf (last accessed on 28.05.2021), p. 112.

[314] Sozialgesetzbuch (SGB) Fünftes Buch (V) - Gesetzliche Krankenversicherung - Artikel 1 des Gesetzes v. 20. Dezember 1988, BGBl. I S. 2477 (Social Code (SGB) Book Five (V) - Statutory Health Insurance - Article 1 of the law of December 20, 1988, Federal Law Gazette I, p. 2477), available at: https://www.gesetze-im-internet.de/sgb_5/__13.html (last accessed on 27.05.2021), Article 13(5).

[315] Assumption of costs if you are treated as if you had statutory health insurance (form E 112 or S2), National Contact Point for cross-border healthcare, EU-PATIENTEN.DE 2021, available at: https://www.eu-patienten.de/en/behandlung_ausland/geplante_behandlung_1/kostentraeger_eu/behandlung_wie_gesetzlich_krankenversicherte/behandlung_wie_gesetzlich_krankenversicherte_1.jsp (last accessed on 28.05.2021).

	There is no national doctor involved in the application phase as such, only the patient and the health insurance providers/funds.		
5. Is there a specific application form/module which the person seeking PA needs to submit?	**Answer:** The specific application form/module can vary depending on the health insurance provider/fund. The national federal law does not prescribe any specific requirements for application form/module that the person seeking PA needs to submit. *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?* **Answer:** As above, specific requirements for application form/modules that the person seeking PA should submit are not foreseen by the national law, so the health insurance providers/funds are free to determine these requirements, e.g., they can determine which requirements are compulsory or not, if the application form has to be submitted online or in paper etc.	**Source(s):** § 13 Abs. 5 des Fünften Buches Sozialgesetzbuch - SGB V (Art. 13, paragraphs 5 of the Fifth Book of the Social Law).[316]	A specific application form/module nor the information that must be indicated in such modules has not been provided by national law, so that health insurance providers/funds are free to indicate a particular application form/module for requesting PA.

[316] Sozialgesetzbuch (SGB) Fünftes Buch (V) - Gesetzliche Krankenversicherung - Artikel 1 des Gesetzes v. 20. Dezember 1988, BGBl. I S. 2477 (Social Code (SGB) Book Five (V) - Statutory Health Insurance - Article 1 of the law of December 20, 1988, Federal Law Gazette I, p. 2477), available at: https://www.gesetze-im-internet.de/sgb_5/__13.html (last accessed on 27.05.2021).
Article 13(5) states: "Insured persons can choose reimbursement of costs instead of goods or services (...) The statutes regulate the reimbursement procedure."
This provision is for the reimbursement procedure, but it actually also applies to PA requesting procedure.

6. What (other) documentation has to be submitted in order to substantiate a PA request?	**Answer:** As in mentioned above (Cfr. Answer to question n. 5), the specific application form/module can vary depending on the health insurance provider/fund. The national federal law does not prescribe any specific requirements for application form/module that the person seeking PA needs to submit. *If applicable, please specify:* - *What documents and what particulars are required;* - *Whether there are requirements as to who has to issue the documents (e. g., a doctor contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA or any doctor);* - *Whether the submission of the documentation is optional, mandatory, or recommended.* **Answer:** As above, specific requirements for application form/modules that the person seeking PA should submit are not foreseen by the national law, so the health insurance providers/funds are free to determine these requirements, e.g. they can determine which requirements are compulsory or not, if the application form has to be submitted online or in paper etc.	**Source(s):** § 13 Abs. 5 des Fünften Buches Sozialgesetzbuch - SGB V (Art. 13, paragraphs 5 of the Fifth Book of the Social Law).[317]	A specific application form/module has not been indicated by national law, so that health insurance providers/funds are free to indicate a particular application form/module and/or other documentation to be submitted in order to request PA.

[317] Sozialgesetzbuch (SGB) Fünftes Buch (V) - Gesetzliche Krankenversicherung - Artikel 1 des Gesetzes v. 20. Dezember 1988, BGBl. I S. 2477 (Social Code (SGB) Book Five (V) - Statutory Health Insurance - Article 1 of the law of December 20, 1988, Federal Law Gazette I, p. 2477), available at: https://www.gesetze-im-internet.de/sgb_5/__13.html (last accessed on 27.05.2021), Article 13(5).

7. Are there any costs associated with the handling of the PA request? - *Direct costs (e.g., fixed costs for submitting or filing a PA request).* - *Indirect costs* (*e.g., translations, stamps, etc).*	**Answer:** Affiliated persons can submit their PA request to their health insurance providers/funds without any additional costs, because the direct costs of the affiliation to the health insurance provider should also cover these kind of requests. Differences could be found between public and private health insurance providers. The national law does not prescribe any costs associated with the handling of the PA request. *Direct costs:* Affiliation fee (compulsory for the health insurance services in the country). *Indirect costs:* None identified.	**Source(s):** § 13 Abs. 5 des Fünften Buches Sozialgesetzbuch - SGB V (Art. 13, paragraphs 5 of the Fifth Book of the Social Law).[318]	National law does not prescribe any costs associated with the handling of the PA request.
8. Are there any specific **time requirements** linked to a PA request? (*e.g., time within which a requesting person must submit the PA application and/or time within which the requested body must take a decision on the PA request, etc.*).	**Answer:** In any case, PA should of course be requested before the healthcare service in another Member State has been provided, in order to get a reimbursement for the costs / in order not to pay the healthcare service in another Member State. *- If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* **Answer:** The following time limit applies: the health insurance fund shall decide at least within 3 weeks after receiving the application or, in	**Source(s):** § 13 Abs. 3(a), 5 des Fünften Buches Sozialgesetzbuch - SGB V (Art. 13, paragraphs 3(a) and 5 of the Fifth Book of the Social Law).[319]	National law does not seem to prescribe time requirements linked to a PA request.

[318] Sozialgesetzbuch (SGB) Fünftes Buch (V) - Gesetzliche Krankenversicherung - Artikel 1 des Gesetzes v. 20. Dezember 1988, BGBl. I S. 2477 (Social Code (SGB) Book Five (V) - Statutory Health Insurance - Article 1 of the law of December 20, 1988, Federal Law Gazette I, p. 2477), available at: https://www.gesetze-im-internet.de/sgb_5/__13.html (last accessed on 27.05.2021), Article 13(5).
[319] Sozialgesetzbuch (SGB) Fünftes Buch (V) - Gesetzliche Krankenversicherung - Artikel 1 des Gesetzes v. 20. Dezember 1988, BGBl. I S. 2477 (Social Code (SGB) Book Five (V) - Statutory Health Insurance - Article 1 of the law of December 20, 1988, Federal Law Gazette I, p. 2477), available at: https://www.gesetze-im-internet.de/sgb_5/__13.html (last accessed on 27.05.2021), Article 13(5).

	cases in which a decision of the medical service is needed, 5 weeks (Art. 13, paragraphs 3(a) of the Fifth Book of the Social Law). If the health insurance fund is unable to meet the deadlines, it shall inform the applicant accordingly explaining its reasons. If no adequate reason is notified, the benefit shall be considered to be approved/the decision to be taken on expiry of the deadline. In case, instead, the health service provider/fund provides for a deadline, the requesting person who misses the deadline should bear the costs himself/herself for receiving the healthcare service in another Member State.		
9. Are there **differences in the procedural/administrative requirements for requesting PA** based on, for instance, the type of treatment for which PA is requested, the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* Differences in the procedural/administrative requirements for requesting PA could be present depending on the type of health insurance provider/fund, as the national law does not provide for specific compulsory	**Source(s):** § 13 Abs. 5 des Fünften Buches Sozialgesetzbuch - SGB V (Art. 13, paragraphs 5 of the Fifth Book of the Social Law).[325] Treatment subject to prior authorisation, National Contact Point for cross-border healthcare, EU-PATIENTEN.DE 2021.[326]	Differences in the procedural/administrative requirements for requesting PA are not prescribed for by national law.

[325] Sozialgesetzbuch (SGB) Fünftes Buch (V) - Gesetzliche Krankenversicherung - Artikel 1 des Gesetzes v. 20. Dezember 1988, BGBl. I S. 2477 (Social Code (SGB) Book Five (V) - Statutory Health Insurance - Article 1 of the law of December 20, 1988, Federal Law Gazette I, p. 2477), available at: https://www.gesetze-im-internet.de/sgb_5/__13.html (last accessed on 27.05.2021), Article 13(5).

[326] Treatment subject to prior authorisation, National Contact Point for cross-border healthcare, EU-PATIENTEN.DE 2021, available at: https://www.eu-patienten.de/en/behandlung_ausland/geplante_behandlung_1/kostentraeger_eu/behandlung_wie_privat_krankenversicherte/vorabgenehmiguns__system/vorabgenehmigungspflichtige_behandlungen_uebersicht_2.jsp (last accessed on 27.05.2021).

	requirements for requesting PA. Anyway, the profile of the insured person and the type of treatment could provide for differences. PA should be requested only for some kind of treatments that are foreseen by the German national law. According to the NCP portal, some treatments may only be provided in Germany subject to specific conditions or in a certain form. Patients will need to make sure that these conditions are also met if they undergo treatment in another EU country.[320] Some of the treatments subject to certain preconditions under German law (also for treatments in Germany) are:[321] - Orthodontic treatment, - Psychotherapeutic and behavioural therapy, - Prosthetic treatment, - Medical rehabilitation benefits, - Out-patient preventive care services (spa treatments) - Artificial insemination. Moreover, a referral is always required under German law (also for treatments in Germany) for the following specialists:[322] - Laboratory medicine physicians, - Microbiologists and infection epidemiologists,		

[320] Treatment as if you had private health insurance, National Contact Point for cross-border healthcare, EU-PATIENTEN.DE 2021, available at: https://www.eu-patienten.de/en/behandlung_ausland/geplante_behandlung_1/kostentraeger_eu/behandlung_wie_privat_krankenversicherte/behandlung_patientenmobilitaet_1.jsp, (last accessed on 27.05.2021).
[321] Treatment subject to advance approval in accordance with the German legislation, National Contact Point for cross-border healthcare, EU-PATIENTEN.DE 2021, available at: https://www.eu-patienten.de/en/behandlung_ausland/geplante_behandlung_1/kostentraeger_eu/behandlung_wie_privat_krankenversicherte/vorabgenehmigungspflichtige_behandlungen/vorabgenehmigungspflicht_nach_deutschen_rechtsvorschriften/standard_8.jsp, (last accessed on 27.05.2021).
[322] Ibid.

	- Nuclear medicine, - Pathology, - Radiological diagnostics and radiology, - Radiotherapy and transfusion medicine. The NCP portal provides information regarding the specific preconditions for certain medical services, for example for prosthetic treatments.[323] Before undergoing treatment in another EU country, a patient must always enquire the health insurance fund to find out whether certain preconditions must be met.[324]		
10. Is there a specific PA form (i.e., form used for issuing/granting PA) and, if the answer is positive, what form?	**Answer:** The national law provides for a specific PA form, used for issuing/granting PA. If the answer to the request is positive, PA should be issued/granted. The form is called form E 112 or S2, when PA is asked for a planned treatment, falling into the legal categories that require PA. However, the S2 form is only for granted healthcare under the Regulation 883/2004 not for cases concerning the Directive.[327]	**Source(s):** Who pays for planned treatment in EU Member States?, National Contact Point for cross-border healthcare, EU-PATIENTEN.DE 2021.[328]	
11. Please list any other administrative	**Answer:**	**Source(s):** N/A	N/A

[323] See: Prosthetic treatment in another EU country, National Contact Point for cross-border healthcare, EU-PATIENTEN.DE 2021, available at: https://www.eu-patienten.de/en/behandlung_ausland/geplante_behandlung_1/kostentraeger_eu/behandlung_wie_privat_krankenversicherte/vorabgenehmigungspflichtige_behandlungen/vorabgenehmigungspflicht_nach_deutschen_rechtsvorschriften/zahnersatzbehandlung_im_eu_ausland_2.jsp, (last accessed on 27.05.2021).

[324] Treatment as if you had private health insurance, National Contact Point for cross-border healthcare, EU-PATIENTEN.DE 2021, available at: https://www.eu-patienten.de/en/behandlung_ausland/geplante_behandlung_1/kostentraeger_eu/behandlung_wie_privat_krankenversicherte/behandlung_patientenmobilitaet_1.jsp, (last accessed on 27.05.2021).

[327] Information provided to Spark Legal Network by the German National Contact Point on 1 October 2021.

[328] Who pays for planned treatment in EU Member States?, National Contact Point for cross-border healthcare, EU.PATIENTEN.DE 2021, available at: https://www.eu-patienten.de/en/behandlung_ausland/geplante_behandlung_1/kostentraeger_eu/kostentraeger_eu_2.jsp (last accessed on 01.06.2021).

requirements in your country in relation to the PA procedure for cross-border healthcare.	None identified.		

SECTION 2 **REIMBURSMENT PROCEDURE(S)**				
Questions	**Answer:**	**Sources**	**Does/do the identified requirement(s) also apply domestically?** **(i.e., is the requirement non-discriminatory?)**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to reimbursement procedures for cross-border healthcare under Directive 201/24/EU?	**Answer:** The requirements related to reimbursement procedures for cross-border healthcare under Directive 2011/24/EU are indicated in the Fifth Book of the Social Code at Art. 13 (paragraphs 4 and 5), Art. 18 (paragraphs 1 and 2), Art. 39 (paragraph 1), Art. 115 a (paragraphs 1 and 2) and Art. 115 b (paragraphs 1 and 2). Preliminary note: In Germany, patients can have statutory health insurance or a private one. If they have a private health insurance, the health	Source(s): § 13 Abs. 4 und 5 des Fünften Buches Sozialgesetzbuch - SGB V (Art. 13, paragraphs 4 and 5 of the Fifth Book of the Social Law).[330] § 18 Abs. 1 und 2 des Fünften Buches Sozialgesetzbuch - SGB V (Art. 18, paragraphs 1 and 2 of the Fifth Book of the Social Law).[331]	N/A	N/A

[330] Sozialgesetzbuch (SGB) Fünftes Buch (V) - Gesetzliche Krankenversicherung - Artikel 1 des Gesetzes v. 20. Dezember 1988, BGBl. I S. 2477 (Social Code (SGB) Book Five (V) - Statutory Health Insurance - Article 1 of the law of December 20, 1988, Federal Law Gazette I, p. 2477), available at: https://www.gesetze-im-internet.de/sgb_5/__13.html (last accessed on 27.05.2021), Article 13(4-5).
[331] Sozialgesetzbuch (SGB) Fünftes Buch (V) - Gesetzliche Krankenversicherung - Artikel 1 des Gesetzes v. 20. Dezember 1988, BGBl. I S. 2477 (Social Code (SGB) Book Five (V) - Statutory Health Insurance - Article 1 of the law of December 20, 1988, Federal Law Gazette I, p. 2477), available at: https://www.gesetze-im-internet.de/sgb_5/__18.html (last accessed on 01.06.2021), Article 18(1-2).

	insurance determines the extent to which treatments can be obtained in another Member State (and the same applies to any cost reimbursement). If they have a statutory health insurance, the following rules apply.[329]	§ 39 Abs. 1 und 2 des Fünften Buches Sozialgesetzbuch - SGB V (Art. 39, paragraphs 1 and 2 of the Fifth Book of the Social Law).[332] § 115 a Abs. 1 und 2 des Fünften Buches Sozialgesetzbuch - SGB V (Art. 115 a, paragraphs 1 and 2 of the Fifth Book of the Social Law).[333] § 115 b Abs. 1 und 2 des Fünften Buches Sozialgesetzbuch - SGB V (Art. 115 b, paragraphs 1 and 2 of the Fifth Book of the Social Law).[334]		
2. Is this the same procedure as for reimbursement under the Social Security Coordination Regulations?	**Answer:** **Yes ☐ No ☒** The German healthcare system does not really differentiate between cases under Regulations and cases under the Directive, but more between whether the patient has statutory or private health insurance and		N/A	N/A

[329] Before treatment in another EU country, National Contact Point for cross-border healthcare, EU-PATIENTEN.DE 2021, available at: https://www.eu-patienten.de/en/behandlung_ausland/geplante_behandlung_1/kostentraeger_eu/behandlung_wie_gesetzlich_krankenversicherte/behandlung_wie_gesetzlich_krankenversicherte_1.jsp, (last accessed on 01.06.2021).

[332] Sozialgesetzbuch (SGB) Fünftes Buch (V) - Gesetzliche Krankenversicherung - Artikel 1 des Gesetzes v. 20. Dezember 1988, BGBl. I S. 2477 (Social Code (SGB) Book Five (V) - Statutory Health Insurance - Article 1 of the law of December 20, 1988, Federal Law Gazette I, p. 2477), available at: https://www.gesetze-im-internet.de/sgb_5/__39.html (last accessed on 01.06.2021), Article 39(1).

[333] Sozialgesetzbuch (SGB) Fünftes Buch (V) - Gesetzliche Krankenversicherung - Artikel 1 des Gesetzes v. 20. Dezember 1988, BGBl. I S. 2477 (Social Code (SGB) Book Five (V) - Statutory Health Insurance - Article 1 of the law of December 20, 1988, Federal Law Gazette I, p. 2477), available at: https://www.gesetze-im-internet.de/sgb_5/__115a.html (last accessed on 01.06.2021), Article 115 a (1-2).

[334] Sozialgesetzbuch (SGB) Fünftes Buch (V) - Gesetzliche Krankenversicherung - Artikel 1 des Gesetzes v. 20. Dezember 1988, BGBl. I S. 2477 (Social Code (SGB) Book Five (V) - Statutory Health Insurance - Article 1 of the law of December 20, 1988, Federal Law Gazette I, p. 2477), available at: https://www.gesetze-im-internet.de/sgb_5/__115b.html (last accessed on 01.06.2021), Article 115 b (1-2).

	whether it is a “planned treatment” (for which you have to ask for PA) or an “unplanned treatment” (so mostly for the cases under the Regulations).			
3. What body is/are responsible of handling the reimbursement applications? (e.g., where and to whom reimbursement applications have to be submitted?)	**Answer:** Health insurance providers/ funds are responsible for handling the reimbursement applications. If the amount of the treatment costs covered by the health insurance in the state of treatment is lower than the amount the German health insurance fund would have covered for a treatment in Germany, the applicant may request reimbursement of the full cost from the health insurance fund. Conversely, in case the cost is higher abroad, the applicant may request the reimbursement up to the cost should the treatment have been provided in Germany. *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* **Answer:** The German national healthcare system is based on multiple insurance providers. The	**Source(s):** § 13 Abs. 4 und 5 des Fünften Buches Sozialgesetzbuch - SGB V (Art. 13, paragraphs 4 and 5 of the Fifth Book of the Social Law).[335] § 18 Abs. 1 und 2 des Fünften Buches Sozialgesetzbuch - SGB V (Art. 18, paragraphs 1 and 2 of the Fifth Book of the Social Law).[336] Advantages and disadvantages of the cost reimbursement methods in case of planned treatment as if you had statutory or private health insurance in Germany, National Contact Point for cross-border healthcare, EU.PATIENTEN.DE 2021.[337] Daten des Gesundheitswesens	N/A	N/A

[335] Sozialgesetzbuch (SGB) Fünftes Buch (V) - Gesetzliche Krankenversicherung - Artikel 1 des Gesetzes v. 20. Dezember 1988, BGBl. I S. 2477 (Social Code (SGB) Book Five (V) - Statutory Health Insurance - Article 1 of the law of December 20, 1988, Federal Law Gazette I, p. 2477), available at: https://www.gesetze-im-internet.de/sgb_5/__13.html (last accessed on 27.05.2021), Article 13(4-5).
[336] Sozialgesetzbuch (SGB) Fünftes Buch (V) - Gesetzliche Krankenversicherung - Artikel 1 des Gesetzes v. 20. Dezember 1988, BGBl. I S. 2477 (Social Code (SGB) Book Five (V) - Statutory Health Insurance - Article 1 of the law of December 20, 1988, Federal Law Gazette I, p. 2477), available at: https://www.gesetze-im-internet.de/sgb_5/__18.html (last accessed on 01.06.2021), Article 18(1-2).
[337] Advantages and disadvantages of the cost reimbursement methods in case of planned treatment as if you had statutory or private health insurance in Germany, National Contact Point for cross-border healthcare, EU.PATIENTEN.DE 2021, available at: https://www.eu-patienten.de/en/behandlung_ausland/geplante_behandlung_1/kostentraeger_eu/vor__und_nachteile_der_jeweiligen_kostenerstattung_2/standard_5.jsp (last accessed on 01.06.2021).

	most important/relevant insurance provider in Germany is the "Verband der Ersatzkassen e.V. (vdek)" (Association of Substitute Funds e.V.) with the highest number of affiliations (28.099.937 affiliations in August 2020).	2020, Bundesministerium für Gesundheit (Healthcare data 2020, Federal Ministry of Health), p. 112. [338]		
4. Is there a specific application form/module which the person seeking reimbursement needs to submit?	**Answer:** Specific application forms and modules which the person seeking reimbursement needs to submit can be freely determined by the insurance health providers/funds. An example of an application form has been found and provided for by the AOK (Allgemeine Ortskrankenkasse - General Regional Health Insurance), the details of which are provided below. *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?* **Answer:** The information required for reimbursement of the costs can vary depending on the	**Source(s):** § 18 Abs. 1 und 2 des Fünften Buches Sozialgesetzbuch - SGB V (Art. 18, paragraphs 1 and 2 of the Fifth Book of the Social Law).[339] Antrag auf Kostenerstattung bei einer Behandlung im Ausland (Application for reimbursement for treatment abroad), AOK Allgemeine Ortskrankenkasse - General Regional Health Insurance. [340]	**Yes ☒** **No ☐**	This requirement can also apply domestically in case of applications for receiving reimbursement for other costs, especially for healthcare services that are not included in the healthcare insurance, e.g., teeth cleaning.

[338] Daten des Gesundheitswesens 2020, Bundesministerium für Gesundheit (Healthcare data 2020, Federal Ministry of Health), available at: https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/5_Publikationen/Gesundheit/Broschueren/Daten_des_Gesundheitswesens_2020.pdf (last accessed on 28.05.2021), p. 112.
[339] Sozialgesetzbuch (SGB) Fünftes Buch (V) - Gesetzliche Krankenversicherung - Artikel 1 des Gesetzes v. 20. Dezember 1988, BGBl. I S. 2477 (Social Code (SGB) Book Five (V) - Statutory Health Insurance - Article 1 of the law of December 20, 1988, Federal Law Gazette I, p. 2477), available at: https://www.gesetze-im-internet.de/sgb_5/__18.html (last accessed on 01.06.2021), Article 18(1-2).
[340] Antrag auf Kostenerstattung bei einer Behandlung im Ausland (Application for reimbursement for treatment abroad), AOK Allgemeine Ortskrankenkasse - General Regional Health Insurance, available at: https://www.aok.de/pk/fileadmin/user_upload/AOK-Hessen/05-Content-PDF/aok-hessen_antrag-auf-kostenerstattung-bei-behandlung-im-ausland.pdf (last accessed on 28.05.2021).

	health insurance fund/provider. In the example provided above, <u>the AOK requests:</u> - Name and Surname of the affiliated person/requesting person; - Insurance affiliation number; - Permanent address; - Phone number; - Bank account references (IBAN, Name of the credit institute, BIC etc.); - Information regarding the visit abroad for receiving healthcare services (start and end date, country, health diseases etc.); - Information regarding the health insurance (presence of health insurance covering costs abroad, reimbursement of costs etc.); - Information regarding the healthcare service that should be receiving abroad (which kind of healthcare service, which costs have already been paid, was it a planned or unplanned treatment abroad etc.); - All proof of payment, medical prescriptions, doctor or hospital reports (original invoices); - Additional payments or co-payments customary in the country (that can only be reimbursed under certain conditions); - Medicines or remedies and aids can only be reimbursed if they have been prescribed by a doctor.			
5. What (other) documentation has to be submitted in order to substantiate a	**Answer:** The national federal law does not prescribe any specific documentation to be submitted to substantiate a reimbursement request; it can	**Source(s):** § 18 Abs. 1 und 2 des Fünften Buches Sozialgesetzbuch - SGB V	**Yes** ☒ **No** ☐	Health insurance providers can determine which other documentation has to be

reimbursement request?	vary depending on the health insurance provider/fund. Every health insurance provider/fund determines which documentation and additional documentation has to be submitted (see example in Question 4). *If applicable, please specify:* - *What documents are required;* - *Whether the submission of the documentation is optional, mandatory, or recommended.* **Answer:** As above, the national federal law does not prescribe any specific documentation to be submitted to substantiate a reimbursement request, it can vary depending on the health insurance provider/fund.	(Art. 18, paragraphs 1 and 2 of the Fifth Book of the Social Law).[341]		submitted in order to substantiate a reimbursement request at a domestical level too, in order to apply for reimbursement for costs that are not covered by the health insurance.
6. Are there any costs associated with the handling of the reimbursement request? - *Direct costs (e.g., fixed costs for submitting or filing a reimbursement request, proportion deducted from the reimbursable amount).*	**Answer:** The national federal law does not prescribe any direct costs associated with the handling of the reimbursement request; it can vary depending on the health insurance provider/fund. Anyway, indirect costs for translations of the medical documentation and stamps should be paid from the interested person in case of reimbursement under the Directive 2011/24/EU (treatment as a patient with private health insurance in another EU country, so for example unplanned treatment).	**Source(s):** § 18 Abs. 1 und 2 des Fünften Buches Sozialgesetzbuch - SGB V (Art. 18, paragraphs 1 and 2 of the Fifth Book of the Social Law).[343] Advantages and disadvantages of the cost reimbursement methods in case of planned treatment as if you had statutory or private health	**Yes** ☒ **No** ☐	Health insurance providers can determine if there are any costs associated with the handling of the reimbursement request also at a domestical level.

[341] Sozialgesetzbuch (SGB) Fünftes Buch (V) - Gesetzliche Krankenversicherung - Artikel 1 des Gesetzes v. 20. Dezember 1988, BGBl. I S. 2477 (Social Code (SGB) Book Five (V) - Statutory Health Insurance - Article 1 of the law of December 20, 1988, Federal Law Gazette I, p. 2477), available at: https://www.gesetze-im-internet.de/sgb_5/__18.html (last accessed on 01.06.2021), Article 18(1-2).
[343] Sozialgesetzbuch (SGB) Fünftes Buch (V) - Gesetzliche Krankenversicherung - Artikel 1 des Gesetzes v. 20. Dezember 1988, BGBl. I S. 2477 (Social Code (SGB) Book Five (V) - Statutory Health Insurance - Article 1 of the law of December 20, 1988, Federal Law Gazette I, p. 2477), available at: https://www.gesetze-im-internet.de/sgb_5/__18.html (last accessed on 01.06.2021), Article 18(1-2).

- *Indirect costs* (*e.g., translations, stamps, etc).*	In case of planned treatment with PA, no costs will incur for translations of invoices. *Direct costs:* No direct costs *Indirect costs:* Translation of invoices (in case of treatment as patient with private health insurance) indirect costs for administrative costs and co-payments that are provided for (in case of both treatments as statutory and private health insurance).[342]	insurance in Germany, National Contact Point for cross-border healthcare, EU-PATIENTEN.DE 2021.[344]		
7. Are there any specific time requirements linked to a reimbursement request? (*e.g., time within which the reimbursement requests must be submitted and/or time within the requested body must handle the request and/or reimburse the costs, etc.*).	**Answer:** *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* National law does not prescribe any specific time requirements linked to a reimbursement request. Anyway, in cases PA was not issued, reimbursement should be asked after receiving the cross-border healthcare service and providing receipt of the payment(s).	**Source(s):** § 18 Abs. 1 und 2 des Fünften Buches Sozialgesetzbuch - SGB V (Art. 18, paragraphs 1 and 2 of the Fifth Book of the Social Law).[345] § 13 Abs. 3(a) des Fünften Buches Sozialgesetzbuch - SGB V (Art. 13, paragraphs 3(a) of the Fifth Book of the Social Law).[346]	**Yes** ☒ **No** ☐	At a domestic level specific time requirements linked to a reimbursement request could be determined by the health insurance provider/fund.

[342] In case of patient with private health insurance, there are administrative non reimbursable fees explicitly provided. In case of patient with a statutory health insurance, it is specified that the health insurance provider shall provide for sufficient deductions from the reimbursement amount for administrative costs and the lack for a value-for-money audit and that co-payments shall be deducted too (Art. 13 paragraph 4 of the Fifth Book of the Social Code).

[344] Advantages and disadvantages of the cost reimbursement methods in case of planned treatment as if you had statutory or private health insurance in Germany, National Contact Point for cross-border healthcare, EU-PATIENTEN.DE 2021, available at: https://www.eu-patienten.de/en/behandlung_ausland/geplante_behandlung_1/kostentraeger_eu/vor__und_nachteile_der_jeweiligen_kostenerstattung_2/standard_5.jsp (last accessed on 02.06.2021).

[345] Sozialgesetzbuch (SGB) Fünftes Buch (V) - Gesetzliche Krankenversicherung - Artikel 1 des Gesetzes v. 20. Dezember 1988, BGBl. I S. 2477 (Social Code (SGB) Book Five (V) - Statutory Health Insurance - Article 1 of the law of December 20, 1988, Federal Law Gazette I, p.2477), available at: https://www.gesetze-im-internet.de/sgb_5/__18.html (last accessed on 01.06.2021), Article 18(1-2).

[346] Sozialgesetzbuch (SGB) Fünftes Buch (V) - Gesetzliche Krankenversicherung - Artikel 1 des Gesetzes v. 20. Dezember 1988, BGBl. I S. 2477 (Social Code (SGB) Book Five (V) - Statutory Health Insurance - Article 1 of the law of December 20, 1988, Federal Law Gazette I, p. 2477), available at: https://www.gesetze-im-internet.de/sgb_5/__13.html (last accessed on 27.05.2021), Article 13(5).

	The following time limit applies: the health insurance fund shall decide at least within 3 weeks after receiving the application or, in cases in which a decision of the medical service is needed, 5 weeks (Art. 13, paragraphs 3(a) of the Fifth Book of the Social Law) If the health insurance fund is unable to meet the deadlines, it shall inform the applicant accordingly explaining its reasons. If no adequate reason is notified, the benefit shall be considered to be approved/the decision to be taken on expiry of the deadline.			
8. Are there any non-reimbursable thresholds, deductions *(except the deductions for administrative costs mentioned above) etc.?*	**Answer:** *If yes, please specify the thresholds.* Deductions for administrative costs are not provided for by national law prescriptions. However, deductions for administrative costs can be provided for as indirect costs in case of reimbursement procedures for cross-border healthcare (as indicated above).	**Source(s):** § 18 Abs. 1 und 2 des Fünften Buches Sozialgesetzbuch - SGB V (Art. 18, paragraphs 1 and 2 of the Fifth Book of the Social Law).[347]	**Yes** ☐ **No** ☒	**N/A**
9. In instances where a PA (or prior-notification) has already been issued, is a separate/simplified procedure available	**Answer:** *If yes, please describe the simplified procedure.* There is no separate/simplified procedure.	**Source(s):** § 18 Abs. 1 und 2 des Fünften Buches Sozialgesetzbuch - SGB V (Art. 18, paragraphs 1 and	**Yes** ☐ **No** ☒	**N/A**

[347] Sozialgesetzbuch (SGB) Fünftes Buch (V) - Gesetzliche Krankenversicherung - Artikel 1 des Gesetzes v. 20. Dezember 1988, BGBl. I S. 2477 (Social Code (SGB) Book Five (V) - Statutory Health Insurance - Article 1 of the law of December 20, 1988, Federal Law Gazette I, p. 2477), available at: https://www.gesetze-im-internet.de/sgb_5/__18.html (last accessed on 01.06.2021), Article 18(1-2).

for requesting reimbursement? **applicable only if the country has a PA system.*		2 of the Fifth Book of the Social Law).[348] Advantages and disadvantages of the cost reimbursement methods in case of planned treatment as if you had statutory or private health insurance in Germany, National Contact Point for cross-border healthcare, EU.PATIENTEN.DE 2021.[349]		
10. Are there additional administrative/procedural requirements for reimbursement depending on, for instance, the type of treatment for which reimbursement is requested, or the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* Additional administrative or procedural requirements for reimbursement are not provided for by national law. Anyway, depending on the type of treatment for which reimbursement is requested or other criteria, the health insurance provider could ask for PA in advance, in mandatory cases provided for by national law.	**Source(s):** § 18 Abs. 1 und 2 des Fünften Buches Sozialgesetzbuch - SGB V (Art. 18, paragraphs 1 and 2 of the Fifth Book of the Social Law).[350]	**Yes ☒** **No ☐**	**N/A**

[348] Sozialgesetzbuch (SGB) Fünftes Buch (V) - Gesetzliche Krankenversicherung - Artikel 1 des Gesetzes v. 20. Dezember 1988, BGBl. I S. 2477 (Social Code (SGB) Book Five (V) - Statutory Health Insurance - Article 1 of the law of December 20, 1988, Federal Law Gazette I, p. 2477), available at: https://www.gesetze-im-internet.de/sgb_5/__18.html (last accessed on 01.06.2021), Article 18(1-2).

[349] Advantages and disadvantages of the cost reimbursement methods in case of planned treatment as if you had statutory or private health insurance in Germany, National Contact Point for cross-border healthcare, EU.PATIENTEN.DE 2021, available at: https://www.eu-patienten.de/en/behandlung_ausland/geplante_behandlung_1/kostentraeger_eu/vor__und_nachteile_der_jeweiligen_kostenerstattung_2/standard_5.jsp (last accessed on 01.06.2021).

[350] Sozialgesetzbuch (SGB) Fünftes Buch (V) - Gesetzliche Krankenversicherung - Artikel 1 des Gesetzes v. 20. Dezember 1988, BGBl. I S. 2477 (Social Code (SGB) Book Five (V) - Statutory Health Insurance - Article 1 of the law of December 20, 1988, Federal Law Gazette I, p. 2477), available at: https://www.gesetze-im-internet.de/sgb_5/__18.html (last accessed on 01.06.2021), Article 18(1-2).

11. Please list any other administrative requirements in your country in relation to the procedures of reimbursement of cross-border healthcare.	**Answer: N/A**	**Source(s): N/A**	**Yes ☐** **No ☐**	**N/A**

Part 2: Checklist for verification with national/regional[351]

Name of the body: EU-PATIENTEN.DE (NCP)
Country/Region: Germany
Date of verification call: 1 October 2021.

Template for the Data Collection	Aspects to be verified *Tick the boxes if the information in the template for the data collection has been verified and/or complemented by the national body*		Comments *Include any additional comments and/or information provided by the contacted body*
Section 1 – Prior Authorisation			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Justification/purpose of the identified requirement(s) (Column 4)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	
Section 2 - Reimbursement			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Whether the requirement applies domestically (Discriminatory assessment) (Column 4) ▪ Justification/purpose of the identified requirement(s) (Column 5)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	

[351] Data verified in writing by the German National Contact Point on 1 October 2021.

GREECE – COUNTRY REPORT

Part 0: Preliminary Assessment

1. **Please indicate whether the rules governing the administrative procedures/requirements for requesting PA and reimbursement under Directive 2011/24/EU in your country are set out at:**

   A. National level ☒

   B. Decentralised/regional/local level ☐

2. **Please indicate the national body best suited to verify the accuracy of the information collected in Part 1, and justify your selection.**
   Depending on the characteristics of your national healthcare system, the relevant body may be: a) *the national social security body*; or b) *an insurance fund*. In the latter case, please indicate the most representative fund (e.g., the one with the highest number of affiliations).

   Body to be contacted for Task 2: National Organisation for the Provision of Health Services (EOPYY-ΕΟΠΥΥ Ενιαίος Οργανισμός Παροχών Υπηρεσιών Υγείας) – -Directorate of International Relations-Unit for cross-border healthcare & National Contact Point for Cross-border Healthcare (Εθνικό Σημείο Επαφής Διασυνοριακής Περίθαλψης)[352]

   Reasons for Selection: The relevant body for the verification of data collected is the National Organisation for the Provision of Health Services (EOPYY-ΕΟΠΥΥ Ενιαίος Οργανισμός Παροχών Υπηρεσιών Υγείας) – Directorate of International Relations-Unit for cross-border healthcare & National Contact Point (NCP) for Cross-border Healthcare (Εθνικό Σημείο Επαφής Διασυνοριακής Περίθαλψης). EOPYY is the major statutory health insurance body in Greece (covering over 95% of the population) and undertakes issues related to patients' rights in cross-border healthcare, authorization for planned healthcare abroad and reimbursement of cross-border healthcare. EOPYY is also the liaison body for reimbursement of health benefits in kind as well as the competent institution for health benefits in kind for EU-insured persons who live temporarily or reside permanently in Greece under the Social Security Coordination Regulations. any issues related to social security and the relevant scheme are handled by the Unified Social Security Fund (EFKA-ΕΦΚΑ) which acts as the national social security body/insurance fund in Greece.[353] Moreover, the national legislation prescribes that the competent regional directorates of EOPYY along with the NCP provide information to patients, upon request, in

[352] See also https://eu-healthcare.eopyy.gov.gr/gr/Home.aspx (last accessed on 3 June 2021).
[353] See also https://ec.europa.eu/social/main.jsp?catId=1112&langId=en&intPageId=4562 (last accessed on 3 June 2021).

relation to healthcare rights and cross-border healthcare rights[354], whereas they are also in charge of relevant administrative procedures, such as the procedures of prior authorisation and reimbursement of the costs of cross-border healthcare[355] under Directive 2011/24/EU[356].

[354] Νόμος υπ' αριθμ. 4213/2013 Προσαρμογή της εθνικής νομοθεσίας στις διατάξεις της Οδηγίας 2011/24/ΕΕ του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 9ης Μαρτίου 2011 περί εφαρμογής των δικαιωμάτων των ασθενών στο πλαίσιο της διασυνοριακής υγειονομικής περίθαλψης (L88/45/ 4.4.2011) και άλλες διατάξεις (Law No. 4213/2013 Adaptation of national legislation to the provisions of Directive 2011/24 / EU of the European Parliament and of the Council of 9 March 2011 concerning implementation of patients' rights on the side cross-border healthcare (L 88/45 / 4.4.2011) and other provisions), Government Gazzette 261/A/3-12-2013, available at https://www.e-nomothesia.gr/kat-ygeia/perithalpse/n-4213-2013.html (last accessed on 3 June 2021), Article 5b.

[355] Υπουργική Απόφαση Υ9α/76908/2014 Διοικητικές διαδικασίες για τη χρήση της διασυνοριακής υγειονομικής περίθαλψης (άρθρο 9 του Ν. 4213/2013) (Ministerial Decision Y9a/76908/2014 Administrative procedures for the use of cross-border health care (article 9 of Law 4213/2013), Government Gazzette 2425/B/11-9-2014, available at https://www.e-nomothesia.gr/kat-ygeia/ya-y9a-76908-2014.html (last accessed on 3 June 2021), Article 2.1.

[356] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, available at https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:en:PDF (last accessed on 3 June 2021).

Part 1: Questionnaire

*__Note 1__: In cases where administrative requirements are set out in the legislative/regulatory framework at decentralised/regional/local level, please complete the template for the data collection twice, once for each of the two most relevant regions/jurisdictions (e.g., in terms population).

__*Note 2__: Setting out a Prior Authorisation (PA) system is optional for Member States. Should your country not have a system of PA in place under Directive 2011/24/EU, Section 1 will not need to be completed.

SECTION 1 PRIOR AUTHORISATION PROCEDURE(S)			
Questions	**Answer**	**Sources**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to PA procedures for a cross-border healthcare under Directive 2011/24/EU?	**Answer:** I) Law No. 4213/2013, Article 8 Adaptation of national legislation to the provisions of Directive 2011/24 / EU of the European Parliament and of the Council of 9 March 2011 concerning implementation of patients' rights on the side cross-border healthcare (L 88/45 / 4.4.2011) and other provisions II) Joint Ministerial Decision 80157/2018 Unified Regulation of Health Benefits (EKPY) of the National Organisation for the Provision of Health Services (EOPYY) III) Ministerial Decision Y9α /79323/2014 Determination of the cases of health care that may be subject to prior approval (article 8 of	**Source(s):** • Law No. 4213/2013 Adaptation of national legislation to the provisions of Directive 2011/24 / EU of the European Parliament and of the Council of 9 March 2011 concerning implementation of patients' rights on the side cross-border healthcare (L 88/45 /	N/A

	Law 4213/2013), as amended (Government Gazette B', 754/2021) IV) Ministerial Decision Y9a/76908/2014 Administrative procedures for the use of cross-border health care (article 9 of Law 4213/2013)	4.4.2011) and other provisions)[357] • Joint Ministerial Decision 80157/2018 Uniform Regulation 80157/2018 of Health Benefits (EKPY) of the National Organisation for the Provision of Health Services (EOPYY).[358] • Ministerial Decision Y9α /79323/2014 Determination of the cases of health care that may be subject to prior approval (article 8 of Law 4213/2013), as amended.[359] • Ministerial Decision Y9a/76908/2014 Administrative procedures for the use of cross-border health	

[357] Law No. 4213/2013 Adaptation of national legislation to the provisions of Directive 2011/24 / EU of the European Parliament and of the Council of 9 March 2011 concerning implementation of patients' rights on the side cross-border healthcare (L 88/45 / 4.4.2011) and other provisions) Νόμος υπ' αριθμ. 4213/2013, 'Αρθρο 8, Προσαρμογή της εθνικής νομοθεσίας στις διατάξεις της Οδηγίας 2011/24/ΕΕ του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 9ης Μαρτίου 2011 περί εφαρμογής των δικαιωμάτων των ασθενών στο πλαίσιο της διασυνοριακής υγειονομικής περίθαλψης (L88/45/ 4.4.2011) και άλλες διατάξεις) Government Gazette 261/A/3-12-2013, available at https://www.e-nomothesia.gr/kat-ygeia/perithalpse/n-4213-2013.html (last accessed on 3 June 2021).

[358] Κοινή Υπουργική Απόφαση Αριθμ. ΕΑΛΕ/Γ.Π. 80157/2018 Τροποποίηση και αντικατάσταση της με αριθμ. πρωτ. ΕΑΛΕ/Γ.Π. 46846/19-06-2018 (Β΄ 2315) κοινής υπουργικής απόφασης, με περιεχόμενο «Ενιαίος Κανονισμός Παροχών Υγείας (ΕΚΠΥ) του Εθνικού Οργανισμού Παροχών Υπηρεσιών Υγείας (ΕΟΠΥΥ)» (Joint Ministerial Decision 80157/2018 Uniform Regulation 80157/2018 of Health Benefits (EKPY) of the National Organisation for the Provision of Health Services (EOPYY), Government Gazzette 4898/B/1-11-2018, available at https://www.e-nomothesia.gr/kat-ygeia/perithalpse/koine-upourgike-apophase-ealegp-80157-2018.html (last accessed on 3 June 2021).

[359] Υπουργική Απόφαση Αριθ. Υ9α/79323/15.9.2014 Καθορισμός των περιπτώσεων υγειονομικής περίθαλψης που μπορεί να υπόκεινται σε προηγουμένη έγκριση (άρθρο 8 του Νόμου 4213/2013) (Ministerial Decision Y9α /79323/2014 Determination of the cases of health care that may be subject to prior approval (article 8 of Law 4213/2013), as amended), Government Gazzette B' 2459/16-09-2014, available at https://www.taxheaven.gr/circulars/19499/ario-y9a-79323-15-9-2014 (last accessed on 3 June 2021); amended version Government Gazette B' 754/2021, available at https://www.e-nomothesia.gr/kat-ygeia/perithalpse/upourgike-apophase-eale-gp-2281-2021.html (last accessed on 15 June 2021).

		care (article 9 of Law 4213/2013)[360]	
2. Is this the same procedure as for PA under the Social Security Coordination Regulations?	**Answer:** **Yes** ☒ [361] **No** ☐		N/A
3. What body is in charge of handling the PA applications? *(e.g., where and to whom PA applications have to be submitted?)*	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations)* The relevant body in charge of handling the PA applications is the National Organisation for the Provision of Health Services (ΕΟΡΥΥ-ΕΟΠΥΥ Ενιαίος Οργανισμός Παροχών Υπηρεσιών Υγείας). In particular, applications can be submitted at the Regional Directorates of EOPYY at the place of residence of the applicant.	**Source(s):** • Ministerial Decision Y9a/76908/2014 Administrative procedures for the use of cross-border health care (article 9 of Law 4213/2013), Articles 2.1, 2.2 and 2.3. • Law No. 4213/2013 Adaptation of national legislation to the provisions of Directive 2011/24 / EU of the European Parliament and of the Council of 9 March 2011	N/A

[360] I) Υπουργική Απόφαση Υ9α/76908/2014 Διοικητικές διαδικασίες για τη χρήση της διασυνοριακής υγειονομικής περίθαλψης (άρθρο 9 του Ν. 4213/2013) (Ministerial Decision Y9a/76908/2014 Administrative procedures for the use of cross-border health care (article 9 of Law 4213/2013), Government Gazzette 2425/B/11-9-2014, available at https://www.e-nomothesia.gr/kat-ygeia/ya-y9a-76908-2014.html (last accessed on 3 June 2021).

[361] Υπουργική Απόφαση Υ9α/76908/2014 Διοικητικές διαδικασίες για τη χρήση της διασυνοριακής υγειονομικής περίθαλψης (άρθρο 9 του Ν. 4213/2013) (Ministerial Decision Y9a/76908/2014 Administrative procedures for the use of cross-border health care (article 9 of Law 4213/2013), Government Gazzette 2425/B/11-9-2014, available at https://www.e-nomothesia.gr/kat-ygeia/ya-y9a-76908-2014.html (last accessed on 3 June 2021), Article 1.

	Following this, the applications are forwarded with a complete file to the headquarters of EOPYY to the Secretariat of the Supreme Health Council (AYS) for the examination of the request with notification of the relevant actions to the Directorate of International Insurance Relations, Department of Cross-Border Care - National Contact Point. The relevant decision of the AYS is then forwarded to the EOPYY Regional Directorate where the application was filed, in order to issue a decision of approval (or rejection) for cross-border healthcare in an EU/EEA Member State and to inform the applicant accordingly.	concerning implementation of patients' rights on the side cross-border healthcare (L 88/45 / 4.4.2011) and other provisions), Articles 8.1 and 8.2 • EOPYY, 'Guidelines on the implementation of Directive 2011/24 / EU on patients' rights in the context of Cross-border Health Care (Law 4213/2013)', available at https://aftodioikisi.gr/mediafiles/2016/06/ΕΓΚΥΚΛΙΟΣ-7.pdf (last accessed on 3 June 2021).	
4. Who is entitled to apply for PA? *(e.g., can the patients apply themselves, or is treating doctor filing/partially filling the request, etc.)*	**Answer:** - *If there is a national doctor involved, is there a requirement that this doctor is contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA?* Patients are entitled to apply for PA themselves. Doctors supply the medical diagnosis necessary. In particular, the applications are submitted at the Regional Directorates of EOPYY at the place of residence of the insured patient. No doctor is involved *per se* in the filling/submission of the	**Source(s):** • Ministerial Decision Y9a/76908/2014 Administrative procedures for the use of cross-border health care (article 9 of Law 4213/2013), Article 2.1. • Law No. 4213/2013 Adaptation of national legislation to the provisions of Directive 2011/24 / EU of the European Parliament	The set procedures reflect the administrative procedures in place for domestic patients when they address EOPYY for PA abroad. The repeated declaration in all the legal acts of the Directive's framework that reimbursement, procedures, PA etc are implemented proportionately pursuant to national law is assumed as sufficient justification. As for the justification for implementing a PA system when the Directive was transposed, it was the outcome of a consultation between the Ministry of Health and various stakeholders, and it was decided as the necessary and proportionate measure since according to EKPY the healthcare stipulated in Article 8 of the Directive requires PA in order for EOPYY to cover part or the total of healthcare costs incurred.

	request, but they are involved indirectly since they supply the necessary diagnosis/patient's history and recommended treatment.	and of the Council of 9 March 2011 concerning implementation of patients' rights on the side cross-border healthcare (L 88/45 / 4.4.2011) and other provisions), Article 8.1. • EOPYY, 'Guidelines on the implementation of Directive 2011/24 / EU on patients' rights in the context of Cross-border Health Care (Law 4213/2013);	
5. Is there a specific application form/module which the person seeking PA needs to submit?	**Answer:** *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?* There is a specific application form[362] that the person seeking PA needs to submit (signed and dated).	**Source(s):** • Ministerial Decision Y9a/76908/2014 Administrative procedures for the use of cross-border health care (article 9 of Law 4213/2013), Article 2.1. • EOPYY, 'Guidelines on the implementation of Directive 2011/24 / EU on patients' rights in the context of Cross-border Health	As above, the set procedures reflect the administrative procedures in place for domestic patients when they address EOPYY for PA abroad. The repeated declaration in all the legal acts of the Directive's framework that reimbursement, procedures, PA etc are implemented proportionately pursuant to national law is assumed as sufficient justification. As for the justification for implementing a PA system when the Directive was transposed, it was the outcome of a consultation between the Ministry of Health and various stakeholders, and it was decided as the necessary and proportionate measure since according to EKPY the healthcare stipulated in Article 8 of the Directive requires PA in order for EOPYY to cover part or the total of healthcare costs incurred.

[362] Αίτηση για προηγούμενη έγκριση χρήσης διασυνοριακής περίθαλψης (Application for prior approval for the use of cross-border healthcare), available at https://eu-healthcare.eopyy.gov.gr/gr/key_docs.aspx (last accessed on 3 June 2021).

	The following information is required in the application form: a. Name & Surname of the insured applicant (mandatory), b. Date of birth, c. Identity/Passport number (mandatory), d. Insurance type (insured/family member – mandatory), e. Social Security Insurance Fund (mandatory), f. Number of Medical Booklet (mandatory), g. Reference to disabilities (optional), h. Address (mandatory), i. Telephone number (mandatory), j. E-mail (mandatory), k. Member State of treatment (mandatory), l. Type of treatment (mandatory), m. Details of treatment provider (optional). The application form is available also online. The application along with the supporting documents can be submitted via email or registered post.	Care (Law 4213/2013);	In addition, the specific type of application forms that are required for PA is an internal matter regulated by EOPYY.
6. What (other) documentation has to be submitted in order to substantiate a PA request?	**Answer:** *If applicable, please specify:* - *What documents and what particulars are required;* - *Whether there are requirements as to who has to issue the documents (e. g., a doctor contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA or any doctor);* - *Whether the submission of the documentation is optional, mandatory, or recommended.* On top of the abovementioned application form, there are also a number of other	**Source(s):** • Ministerial Decision Y9a/76908/2014 Administrative procedures for the use of cross-border health care (article 9 of Law 4213/2013), Article 2.1. • Law No. 4213/2013 Adaptation of national legislation to the provisions of Directive 2011/24 / EU of the European Parliament and of the Council of 9 March 2011 concerning	The set procedures reflect the national law for healthcare stipulated in Article 8 of the Directive (hospital inpatient care + highly specialized and cost-intensive treatments) which also require referral by a public or private doctor or additional documentation related to the treatment's indications. The repeated declaration in all the legal acts of the Directive's framework that reimbursement, procedures, PA etc are implemented proportionately pursuant to national law is assumed as sufficient justification.

	documents that have to be submitted in order to substantiate a PA request. In particular: α) Opinion (medical & written) of a Director Doctor of a Clinic of a State Hospital or a Military Hospital or a University Clinic or of a Director of a Private Clinic of the corresponding medical specialty. The relevant opinion should describe in detail the type of disease with a short medical history and will adequately justify the need to address the patient's condition with the proposed treatment, which falls under the provisions of article 8 par. 1 of Law 4213/13 (mandatory documentation) b) Certificate from at least two hospitals in the country in case the proposed health care cannot be provided in Greece within a medically acceptable period based on an objective medical assessment of the patient's medical condition, history and possible progression of his disease, pain experienced and / or the nature of their disability when submitting or re-applying for approval (mandatory documentation) c) Disability certification decision (if applicable) d) Other supporting documentation (optional) **IMPORTANT: Greece is currently in the final stages of an impact assessment of the Directive's transposition framework and is reviewing the requirements for documentation in PA claims. Expected reforms will be realized shortly.**	implementation of patients' rights on the side cross-border healthcare (L 88/45 / 4.4.2011) and other provisions), Article 8.1. • EOPYY, 'Guidelines on the implementation of Directive 2011/24 / EU on patients' rights in the context of Cross-border Health Care (Law 4213/2013);	

7. Are there any costs associated with the handling of the PA request? - *Direct costs (e.g., fixed costs for submitting or filing a PA request).* - *Indirect costs* (*e.g., translations, stamps, etc).*	**Answer:** *Direct costs:* *Indirect costs:* There are no associated costs (direct or indirect) with the handling of the PA request.	**Source(s):** N/A	N/A
8. Are there any specific **time requirements** linked to a PA request? (*e.g., time within which a requesting person must submit the PA application and/or time within which the requested body must take a decision on the PA request, etc.*).	**Answer:** There are no specific time requirements linked to a PA request as far as the time within which a requesting person must submit the PA application, nonetheless, there are time requirements regarding the time within which the requested body must take a decision on the PA request. In this regard, the citizens' requests for cross-border healthcare have to be handled by the competent authorities within a reasonable time by their receipt, in accordance with the provisions of Article 4, par. 1 of Law 2690/1999 (Code of Administrative Procedure)[363], as in force,	**Source(s):** • Ministerial Decision Y9a/76908/2014 Administrative procedures for the use of cross-border health care (article 9 of Law 4213/2013), Article 7. • Law 2690/1999: Ratification of the Code of Administrative Procedure and other provisions)[364], Articles 4.1 and 4.2.	The set procedures reflect the national law (Code of Administrative procedures) as far as responding times for claims filed with public services. The repeated declaration in all the legal acts of the Directive's framework that reimbursement, procedures, PA etc are implemented proportionately pursuant to national law is assumed as sufficient justification.

[363] Νόμος 2690/1999 Κύρωση του Κώδικα Διοικητικής Διαδικασίας και άλλες διατάξεις (Law 2690/1999: Ratification of the Code of Administrative Procedure and other provisions), Government Gazzette 45/A/9-3-1999, available at https://www.e-nomothesia.gr/kat-demosia-dioikese/n-2690-1999.html (last accessed on 3 June 2021).
[364] Νόμος 2690/1999 Κύρωση του Κώδικα Διοικητικής Διαδικασίας και άλλες διατάξεις (Law 2690/1999: Ratification of the Code of Administrative Procedure and other provisions), Government Gazzette 45/A/9-3-1999, available at https://www.e-nomothesia.gr/kat-demosia-dioikese/n-2690-1999.html (last accessed on 3 June 2021).

	while in the cases of complex / specialised requests, the processing of which presupposes the involvement of other bodies, the laid down in Article 4, par. 1 c-d of Law 2690/1999 apply. In particular, the administrative authorities, when applications are submitted, must process the cases of the interested parties and decide on their requests within the deadline that may be determined by the relevant special provisions, otherwise within a period of sixty (60) days. The deadline starts from the submission of the application to the competent authority. If the application is submitted to an incompetent authority, this authority must, within five (5) days, forward it to the competent authority and notify the interested party. In this case, the deadline starts from the time the application was received by the competent authority. In addition, if a case cannot be processed within the previously mentioned deadline, the competent authority must notify the interested party in writing: a) the reasons for the delay, b) the official who has taken over the case and his telephone number, in order to provide information , c) any missing supporting documents, and d) any other useful information.		

9. Are there **differences in the procedural/administrative requirements for requesting PA** based on, for instance, the type of treatment for which PA is requested, the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* There are provisions for specific treatments (specialized and cost-intensive treatments) and categories of patients (with rare diseases or disabilities) in the procedural/administrative requirements for requesting PA. The national legislation lays down that, when a patient has or is suspected of having a rare disease[365] and submits an application for PA for cross-border healthcare, a clinical evaluation by experts in the field may be performed. If the experts cannot be identified or if the evaluation of the experts does not lead to a safe conclusion, the healthcare provider may seek scientific advice before deciding on PA request. Regarding the highly specialized and cost-intensive treatments, the PA claim is processed as for domestic healthcare administration. The reason for this is because PA is linked to specific indications, may require extra supporting documentation and is required irrelevant of the place (country)-of-service. Patients with disabilities (officially certified by state authority) are eligible for coverage	**Source(s):** • Law No. 4213/2013 Adaptation of national legislation to the provisions of Directive 2011/24 / EU of the European Parliament and of the Council of 9 March 2011 concerning implementation of patients' rights on the side cross-border healthcare (L 88/45 / 4.4.2011) and other provisions), Article 8.4 and 12. • Ministerial Decision Y9a/76908/2014 Administrative procedures for the use of cross-border health care (article 9 of Law 4213/2013), Article 7. • EOPYY, 'Guidelines on the implementation of Directive 2011/24 / EU on patients' rights in the context of Cross-border Health Care (Law 4213/2013);	The set procedures reflect the national law for healthcare stipulated in Article 8 of the Directive (hospital inpatient care + highly specialized and cost-intensive treatments) which also require referral by a public or private doctor or additional documentation related to the treatment's indications. The repeated declaration in all the legal acts of the Directive's framework that reimbursement, procedures, PA etc are implemented proportionately pursuant to national law is assumed as sufficient justification.

[365] See also EOPPY National Contact Point, 'Rare Diseases', available at https://eu-healthcare.eopyy.gov.gr/en/3_3.aspx (last accessed on 3 June 2021).

	of additional costs when granted a PA such as travel, accommodation expenses etc.		
10. Is there a specific PA form (i.e., form used for issuing/granting PA) and, if the answer is positive, what form?	**Answer:** The Regional Directorate of EOPYY where the application was field issues a reasoned decision of approval (rejection) for cross-border healthcare in an EU/EEA Member State and informs the applicant accordingly. The administrative acts of approval or rejection are issued in accordance with the Regulation of Communication for Public Services – Greek acronym KEDY (Ministry of Internal Affairs, Public Administration and Decentralization, General Secretariat of Public Administration, January 2003). Generally, when it is not specifically stipulated otherwise, the abovementioned Regulation is implemented as is the case for PA approvals/rejections.	**Source(s):** • Ministerial Decision Y9a/76908/2014 Administrative procedures for the use of cross-border health care (article 9 of Law 4213/2013), Article 2.3. • Law No. 4213/2013 Adaptation of national legislation to the provisions of Directive 2011/24 / EU of the European Parliament and of the Council of 9 March 2011 concerning implementation of patients' rights on the side cross-border healthcare (L 88/45 / 4.4.2011) and other provisions), Articles 8.3 and 9.2. • EOPYY, 'Guidelines on the implementation	The administrative acts of approval or rejection are issued in accordance with the Regulation of Communication for Public Services – greek acronym KEDY (Ministry of Internal Affairs, Public Administration and Decentralization, General Secretariat of Public Administration, January 2003). Generally, when it is not specifically stipulated otherwise, the abovementioned Regulation is implemented as is the case for PA approvals/rejections. The repeated declaration in all the legal acts of the Directive's framework that reimbursement, procedures, PA etc are implemented proportionately pursuant to national law is assumed as sufficient justification.

		of Directive 2011/24 / EU on patients' rights in the context of Cross-border Health Care (Law 4213/2013) • Regulation of Communication for Public Services, General Secretariat of Public Administration[366].	
11. Please list any other administrative requirements in your country in relation to the PA procedure for cross-border healthcare.	**Answer:** There are no further administrative requirements in Greece in relation to the PA procedure for cross-border healthcare under Directive 2011/24/EU.	**Source(s):** • Ministerial Decision Y9a/76908/2014 Administrative procedures for the use of cross-border health care (article 9 of Law 4213/2013), Article 2.1. • Law No. 4213/2013 Adaptation of national legislation to the provisions of Directive 2011/24 / EU of the European Parliament and of the Council of 9 March 2011 concerning implementation of	Greece decided to implement a PA system (Article 8 of the Directive) when the Directive was transposed, as the outcome of a consultation between the Ministry of Health and various stakeholders and it was decided as the necessary and proportionate measure since according to EKPY the healthcare stipulated in Article 8 of the Directive requires PA in order for EOPYY to cover part or the total of healthcare costs incurred.

[366] Κανονισμός Επικοινωνίας Δημοσίων Υπηρεσιών (Regulation of Communication for Public Services), General Secretariat of Public Administration, available at https://www.ypes.gr/UserFiles/f0ff9297-f516-40ff-a70e-eca84e2ec9b9/KanonEpikDhmYp.pdf (last accessed on 15 June 2021).

		patients' rights on the side cross-border healthcare (L 88/45 / 4.4.2011) and other provisions), Articles 8.1, 8.5, 8.6 and 9.2. • EOPYY, 'Guidelines on the implementation of Directive 2011/24 / EU on patients' rights in the context of Cross-border Health Care (Law 4213/2013)'.		
SECTION 2 **REIMBURSMENT PROCEDURE(S)**				
Questions	**Answer:**	**Sources**	**Does/do the identified requirement(s) also apply domestically?** **(i.e., is the requirement non-discriminatory?)**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to reimbursement procedures for cross-border healthcare under Directive 2011/24/EU?	**Answer:** I) Law No. 4213/2013 Adaptation of national legislation to the provisions of Directive 2011/24 / EU of the European Parliament and of the Council of 9 March 2011 concerning implementation of patients' rights on the side cross-border healthcare (L 88/45 / 4.4.2011) and other provisions	**Source(s):** Law No. 4213/2013 Adaptation of national legislation to the provisions of Directive 2011/24 / EU of the European Parliament and of the Council of 9 March 2011 concerning	N/A	N/A

	II) Joint Ministerial Decision 80157/2018 Uniform Regulation of Health Benefits (EKPY) of the National Organisation for the Provision of Health Services (EOPYY) III) Joint Ministerial Decision Y9α/87340/2014 General principles for calculating the costs incurred to be returned to an insured under of cross-border healthcare (article 7 of Law 4213/2013) IV) Ministerial Decision Y9a/76908/2014 Administrative procedures for the use of cross-border health care (article 9 of Law 4213/2013) V) EOPYY, 'Guidelines on the implementation of the Directive 2011/24/EU on patients' rights in the context of cross-border healthcare (Law 4213/13)	implementation of patients' rights on the side cross-border healthcare (L 88/45 / 4.4.2011) and other provisions)[367] • Joint Ministerial Decision 80157/2018 Uniform Regulation 80157/2018 of Health Benefits (EKPY) of the National Organisation for the Provision of Health Services (EOPYY).[368] • Joint Ministerial Decision Y9α/87340/2014 General principles for calculating the costs incurred to be returned to an insured under of cross-border healthcare (article 7 of Law 4213/2013)[369]		

[367] Law No. 4213/2013 Adaptation of national legislation to the provisions of Directive 2011/24 / EU of the European Parliament and of the Council of 9 March 2011 concerning implementation of patients' rights on the side cross-border healthcare (L 88/45 / 4.4.2011) and other provisions) Νόμος υπ' αριθμ. 4213/2013, 'Αρθρο 8, Προσαρμογή της εθνικής νομοθεσίας στις διατάξεις της Οδηγίας 2011/24/ΕΕ του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 9ης Μαρτίου 2011 περί εφαρμογής των δικαιωμάτων των ασθενών στο πλαίσιο της διασυνοριακής υγειονομικής περίθαλψης (L88/45/ 4.4.2011) και άλλες διατάξεις) Government Gazzette 261/A/3-12-2013, available at https://www.e-nomothesia.gr/kat-ygeia/perithalpse/n-4213-2013.html (last accessed on 3 June 2021).

[368] Κοινή Υπουργική Απόφαση Αριθμ. ΕΑΛΕ/Γ.Π. 80157/2018 Τροποποίηση και αντικατάσταση της με αριθμ. πρωτ. ΕΑΛΕ/Γ.Π. 46846/19-06-2018 (Β΄ 2315) κοινής υπουργικής απόφασης, με περιεχόμενο «Ενιαίος Κανονισμός Παροχών Υγείας (ΕΚΠΥ) του Εθνικού Οργανισμού Παροχών Υπηρεσιών Υγείας (ΕΟΠΥΥ)» (Joint Ministerial Decision 80157/2018 Uniform Regulation 80157/2018 of Health Benefits (EKPY) of the National Organisation for the Provision of Health Services (EOPYY), Government Gazzette 4898/B/1-11-2018, available at https://www.e-nomothesia.gr/kat-ygeia/perithalpse/koine-upourgike-apophase-ealegp-80157-2018.html (last accessed on 3 June 2021).

[369] Κοινή Υπουργική Απόφαση Αριθμ. Υ9α/87340/2014 Γενικές αρχές για τον υπολογισμό των εξόδων που πρόκειται να επιστραφούν σε ασφαλισμένο στα πλαίσια της διασυνοριακής υγειονομικής περίθαλψης (άρθρο 7 του Ν. 4213/2013) (Joint Ministerial Decision Y9α/87340/2014 General principles for calculating the costs incurred to be returned to an insured under of cross-border healthcare (article 7 of Law 4213/2013), Government Gazzette Β΄ 2774/16.10.2014, available at https://www.e-forosimv.gr/details.asp?ID=27258&cat=58 (last accessed on 3 June 2021).

		• Ministerial Decision Y9a/76908/2014 Administrative procedures for the use of cross-border health care (article 9 of Law 4213/2013). [370] • EOPYY, 'Guidelines on the implementation of Directive 2011/24 / EU on patients' rights in the context of Cross-border Health Care (Law 4213/2013).[371]		
2. Is this the same procedure as for reimbursement under the Social Security Coordination Regulations?	**Answer:** **Yes ☐ No ☒**[372]		N/A	N/A
3. What body is/are responsible of handling the reimbursement applications? (e.g., where and to whom reimbursement	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in*	**Source(s):** • Ministerial Decision Y9a/76908/2014 Administrative procedures for the use	N/A	N/A

[370] Υπουργική Απόφαση Υ9α/76908/2014 Διοικητικές διαδικασίες για τη χρήση της διασυνοριακής υγειονομικής περίθαλψης (άρθρο 9 του Ν. 4213/2013) (Ministerial Decision Y9a/76908/2014 Administrative procedures for the use of cross-border health care (article 9 of Law 4213/2013), Government Gazzette 2425/B/11-9-2014, available at https://www.e-nomothesia.gr/kat-ygeia/ya-y9a-76908-2014.html (last accessed on 3 June 2021).

[371] EOPYY, 'Guidelines on the implementation of Directive 2011/24 / EU on patients' rights in the context of Cross-border Health Care (Law 4213/2013)', available at https://aftodioikisi.gr/mediafiles/2016/06/ΕΓΚΥΚΛΙΟΣ-7.pdf (last accessed on 3 June 2021).

[372] The reimbursement of health services in kind under the Social Security Regulations is settled between the member states liaison bodies with the exchange of EU-invoices (E125, E127).

applications have to be submitted?)	*your country (e.g., based on the number of affiliations).* The relevant body in charge of handling the reimbursement applications is the National Organisation for the Provision of Health Services (ΕΟΡΥΥ-ΕΟΠΥΥ Ενιαίος Οργανισμός Παροχών Υπηρεσιών Υγείας). In particular, applications can be submitted at the Regional Directorates of EOPYY at the place of residence of the applicant.	of cross-border health care (article 9 of Law 4213/2013), Articles 2.4, and 3.1. • Law No. 4213/2013 Adaptation of national legislation to the provisions of Directive 2011/24 / EU of the European Parliament and of the Council of 9 March 2011 concerning implementation of patients' rights on the side cross-border healthcare (L 88/45 / 4.4.2011) and other provisions), Articles 5 and 9.1. • EOPYY, 'Guidelines on the implementation of Directive 2011/24 / EU on patients' rights in the context of Cross-border Health Care (Law 4213/2013).		

4. Is there a specific application form/module which the person seeking reimbursement needs to submit?	**Answer:** *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?* There are two types of application forms that the person seeking reimbursement may submit, depending on whether PA has been previously requested. For first type of application form where PA has not been previously requested[373], the following information are required: a. Name & Surname of the insured applicant (mandatory), b. Date of birth, c. Identity/Passport number (mandatory), d. Insurance type (insured/family member –	**Source(s):** • Ministerial Decision Y9a/76908/2014 Administrative procedures for the use of cross-border health care (article 9 of Law 4213/2013), Articles 2.4 and 3.1. • EOPYY, 'Guidelines on the implementation of Directive 2011/24 / EU on patients' rights in the context of Cross-border Health Care (Law 4213/2013).	**Yes** ☐ [375] [376] **No** ☒	It is important to know that EOPYY implements a third-party payment scheme domestically for health benefits provided to its beneficiaries which is fully electronic (e-prescriptions, e-referrals, e-auditing, e-remuneration of health providers etc). The patient doesn't pay anything besides his co-payment contribution directly at the point-of-service and the health care costs are settled between EOPYY and the contracted healthcare providers, whose tax status, licences etc are registered with EOPYY. In the context of cross-border care, the administrative procedures are based on the

[373] Αίτηση για επιστροφή εξόδων διασυνοριακής υγειονομικής περίθαλψης χωρίς προηγούμενη έγκριση (Application for reimbursement for cross-border healthcare expenditures without prior approval), available at https://eu-healthcare.eopyy.gov.gr/gr/key_docs.aspx (last accessed on 3 June 2021).

[375] Please also note that the requirement of no-discrimination regarding cross-border healthcare and the relevant reimbursement procedures is also foreseen; Νόμος υπ' αριθμ. 4213/2013 Προσαρμογή της εθνικής νομοθεσίας στις διατάξεις της Οδηγίας 2011/24/ΕΕ του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 9ης Μαρτίου 2011 περί εφαρμογής των δικαιωμάτων των ασθενών στο πλαίσιο της διασυνοριακής υγειονομικής περίθαλψης (L88/45/ 4.4.2011) και άλλες διατάξεις (Law No. 4213/2013 Adaptation of national legislation to the provisions of Directive 2011/24 / EU of the European Parliament and of the Council of 9 March 2011 concerning implementation of patients' rights on the side cross-border healthcare (L 88/45 / 4.4.2011) and other provisions), Government Gazzette 261/A/3-12-2013, available at https://www.e-nomothesia.gr/kat-ygeia/perithalpse/n-4213-2013.html (last accessed on 3 June 2021), Articles 4.2c, 5c, 7.1, 7.4, 7.5, 8.2; EOPYY, 'Guidelines on the implementation of Directive 2011/24 / EU on patients' rights in the context of Cross-border Health Care (Law 4213/2013)', available at https://aftodioikisi.gr/mediafiles/2016/06/ΕΓΚΥΚΛΙΟΣ-7.pdf (last accessed on 3 June 2021).

[376] In Greece, the compensation of health benefits is now based entirely on an electronic system (e-prescription, e-referrals, e-submissions, e-check / clearing, e-payments contracted with EOPYY providers) and the patient is not involved financially at any stage except for the payment of the possible participation depending on the provision of health, as defined by the EKPY. In the context of cross-border care, administrative procedures are based on the submission of proportional claims (prescriptions, referrals, medical history, detailed invoices, etc.), which are submitted in writing and are the responsibility of the insured, who is also charged with translation costs or document validation costs.

	mandatory), e. Social Security Insurance Provider (mandatory), f. Number of Medical Booklet (mandatory), g. Reference to disabilities (optional), h. Address (mandatory), i. Telephone number (mandatory), j. E-mail (mandatory), k. Member State of treatment (mandatory), l. Type of treatment (mandatory), m. Details of treatment provider (optional). For second type of application form where PA has been previously requested[374], the following information are required: a. Name & Surname of the insured applicant (mandatory), b. Date of birth, c. Identity/Passport number (mandatory), d. Insurance type (direct/indirect – mandatory), e. Social Security Insurance Provider (mandatory), f. Number of Medical Booklet (mandatory), g. Reference to disabilities (-if applicable), h. Address (mandatory), i. Telephone number (mandatory), j. E-mail (mandatory), k. Member State of treatment (mandatory), l. Type of treatment (mandatory), m. Details of treatment provider (optional). Both application forms must be signed and dated. Both application forms are available also online. Reimbursement claims can also be submitted electronically or sent by registered post.			presentation of the proportionate requirements (prescriptions, referrals, medical history, detailed invoices, etc.), which are provided and are the responsibility of the insured person to submit.

[374] Αίτηση για επιστροφή εξόδων διασυνοριακής υγειονομικής περίθαλψης κατόπιν προηγούμενης έγκρισης (Application for reimbursement for cross-border healthcare expenditures with prior approval), available at https://eu-healthcare.eopyy.gov.gr/gr/key_docs.aspx (last accessed on 3 June 2021).

5. What (other) documentation has to be submitted in order to substantiate a reimbursement request?	**Answer:** *If applicable, please specify:* - *What documents are required;* - *Whether the submission of the documentation is optional, mandatory, or recommended.* On top of one the abovementioned application forms, there are also a number of other documents that have to be submitted in order to substantiate a reimbursement request. In particular: i) For applications for reimbursement for cross-border healthcare expenditures without prior approval: a) Medical certificate/diagnosis of the treating physician for the medical operations performed or for the necessity of specific medication or for the necessity of additional care (or additional expenses, which may have been submitted by persons with one or more disabilities – mandatory documentation)	**Source(s):** • Ministerial Decision Y9a/76908/2014 Administrative procedures for the use of cross-border health care (article 9 of Law 4213/2013), Articles 2.4 and 3.1. • Law No. 4213/2013 Adaptation of national legislation to the provisions of Directive 2011/24 / EU of the European Parliament and of the Council of 9 March 2011 concerning implementation of patients' rights on the side cross-border healthcare (L 88/45 / 4.4.2011) and other provisions), Articles 7.1, 7.5 and 9.5.	**Yes** ☐[377] [378] **No** ☒	The set procedures reflect the national requirements as set in EKPY for the different types of health benefits which also require referrals or are linked to treatment's indications. When the healthcare is provided domestically, the whole remuneration system is electronic (e-prescriptions, e-referrals etc) so the patients have no administrative burdens. In the case of cross-border healthcare, EOPYY requires the patient to submit the proportionate documentation (proof of payment, referrals etc) to prove the administration of the healthcare abroad.

[377] Please also note that the requirement of no-discrimination regarding cross-border healthcare and the relevant reimbursement procedures is also foreseen; Νόμος υπ' αριθμ. 4213/2013 Προσαρμογή της εθνικής νομοθεσίας στις διατάξεις της Οδηγίας 2011/24/ΕΕ του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 9ης Μαρτίου 2011 περί εφαρμογής των δικαιωμάτων των ασθενών στο πλαίσιο της διασυνοριακής υγειονομικής περίθαλψης (L88/45/ 4.4.2011) και άλλες διατάξεις (Law No. 4213/2013 Adaptation of national legislation to the provisions of Directive 2011/24 / EU of the European Parliament and of the Council of 9 March 2011 concerning implementation of patients' rights on the side cross-border healthcare (L 88/45 / 4.4.2011) and other provisions), Government Gazzette 261/A/3-12-2013, available at https://www.e-nomothesia.gr/kat-ygeia/perithalpse/n-4213-2013.html (last accessed on 3 June 2021), Articles 4.2c, 5c, 7.1, 7.4, 7.5, 8.2; EOPYY, 'Guidelines on the implementation of Directive 2011/24 / EU on patients' rights in the context of Cross-border Health Care (Law 4213/2013)', available at https://aftodioikisi.gr/mediafiles/2016/06/ΕΓΚΥΚΛΙΟΣ-7.pdf (last accessed on 3 June 2021).

[378] In Greece, the compensation of health benefits is now based entirely on an electronic system (e-prescription, e-referrals, e-submissions, e-check / clearing, e-payments contracted with EOPYY providers) and the patient is not involved financially at any stage except for the payment of the possible participation depending on the provision of health, as defined by the EKPY. In the context of cross-border care, administrative procedures are based on the submission of proportional claims (prescriptions, referrals, medical history, detailed invoices, etc.), which are submitted in writing and are the responsibility of the insured, who is also charged with translation costs or document validation costs.

	b) Certificate from a treating doctor or from a Nursing Institution, from which derives its legal status of operation of the Institution (public/private or public benefit institution – mandatory documentation) c) Original payment receipts (mandatory documentation) d) Original proof of payment of medication, accompanied by a medical certificate for the necessity of the said medication (mandatory documentation) e) Original payment receipts for supply of additional care items (medical devices, etc.), accompanied by a medical certificate for the necessity of their immediate supply (mandatory documentation) ii) For applications for reimbursement for cross-border healthcare expenditures with prior approval: a) Certificate of complete medical history of hospitalisation, where a possible termination / continuation of hospitalisation will be recorded (mandatory documentation) b) Certificate from a private doctor or from a Nursing Institution, from which derives its legal status of operation of the Institution (public/private or public benefit institution – mandatory documentation) c) Original payment receipts for hospitalisation (mandatory documentation)	• EOPYY, 'Guidelines on the implementation of Directive 2011/24 / EU on patients' rights in the context of Cross-border Health Care (Law 4213/2013).		The repeated declaration in all the legal acts of the Directive's framework that reimbursement, procedures, PA etc are implemented proportionately pursuant to national law is assumed as sufficient justification**.**

	d) Original proof of payment of medication, accompanied by a medical certificate for the necessity of the medication (mandatory documentation) e) Original payment receipts for the supply of additional care items (medical devices, etc.), accompanied by a medical certificate for the necessity of their immediate supply (mandatory documentation) f) Especially for people with one or more disabilities who are presumed by a decision of an official Disability Certification body, and for whom the use of cross-border health care has been approved (mandatory documentation): - Original payment receipts for the transfer and return of the patient (also for his/her attendant) depending on the type of seat and means of transport used. In case of using airline tickets, electronic tickets or their excerpts and boarding passes must be also submitted. - Original payment receipts of residence. - Additional costs with corresponding original receipts which will be examined on a case-by-case basis. For either type of application, all supporting documents must be certified by the respective Greek Consulate and must be officially translated. The submitted documents (receipts, invoices) must be legally issued, original and must indicate number, date of issue, as well as an			

	analysis of all relevant medical procedures, drugs or items. The competent authority may request from the insured additional supporting documents as well as indicate to the applicant the correct completion of special (predefined) forms in order to facilitate the task of valid and timely reimbursement of the costs of medical and related acts. **IMPORTANT: Greece is currently in the final stages of an impact assessment of the Directive's transposition framework and is reviewing the requirements for documentation in cross-border healthcare reimbursement. Expected reforms will be realized shortly.**			
6. Are there any costs associated with the handling of the reimbursement request? - *Direct costs (e.g., fixed costs for submitting or filing*	**Answer:** *Direct costs:* *Indirect costs:*	**Source(s):** • Ministerial Decision Y9a/76908/2014 Administrative procedures for the use of cross-border health	**Yes** ☐[380] [381] **No** ☒	Προεδρικό Διάταγμα 16/2014 Προξενικά Τέλη και Δικαιώματα (Presidential Decree 16/2014 Consular Fees and Rights) - Θεώρηση βεβαιώσεων ή

[380] Please also note that the requirement of no-discrimination regarding cross-border healthcare and the relevant reimbursement procedures is also foreseen; Νόμος υπ' αριθμ. 4213/2013 Προσαρμογή της εθνικής νομοθεσίας στις διατάξεις της Οδηγίας 2011/24/ΕΕ του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 9ης Μαρτίου 2011 περί εφαρμογής των δικαιωμάτων των ασθενών στο πλαίσιο της διασυνοριακής υγειονομικής περίθαλψης (L88/45/ 4.4.2011) και άλλες διατάξεις (Law No. 4213/2013 Adaptation of national legislation to the provisions of Directive 2011/24 / EU of the European Parliament and of the Council of 9 March 2011 concerning implementation of patients' rights on the side cross-border healthcare (L 88/45 / 4.4.2011) and other provisions), Government Gazzette 261/A/3-12-2013, available at https://www.e-nomothesia.gr/kat-ygeia/perithalpse/n-4213-2013.html (last accessed on 3 June 2021), Articles 4.2c, 5c, 7.1, 7.4, 7.5, 8.2; EOPYY, 'Guidelines on the implementation of Directive 2011/24 / EU on patients' rights in the context of Cross-border Health Care (Law 4213/2013)', available at https://aftodioikisi.gr/mediafiles/2016/06/ΕΓΚΥΚΛΙΟΣ-7.pdf (last accessed on 3 June 2021).

[381] In Greece, the compensation of health benefits is now based entirely on an electronic system (e-prescription, e-referrals, e-submissions, e-check / clearing, e-payments contracted with EOPYY providers) and the patient is not involved financially at any stage except for the payment of the possible participation depending on the provision of health, as defined by the EKPY. In the context of cross-border care, administrative procedures are based on the submission of proportional claims (prescriptions, referrals, medical history, detailed invoices, etc.), which are submitted in writing and are the responsibility of the insured, who is also charged with translation costs or document validation costs.

a reimbursement request, proportion deducted from the reimbursable amount). - *Indirect costs* (*e.g., translations, stamps, etc).*	There are no associated direct costs with the handling of the reimbursement request, nonetheless, there are indirect costs. In particular, as the supporting documents that accompany an application form for reimbursement for cross-border healthcare expenditures (with or without prior approval) must be certified by the respective Greek Consulate and must be officially translated, the applicant bears the translation costs and any related costs to certification. **IMPORTANT: Greece is currently in the final stages of an impact assessment of the Directive's transposition framework and is reviewing the requirements for translation costs and consulate validation. Expected reforms will be realized shortly.**	care (article 9 of Law 4213/2013), Articles 2.4 and 3.1. • Law No. 4213/2013 Adaptation of national legislation to the provisions of Directive 2011/24 / EU of the European Parliament and of the Council of 9 March 2011 concerning implementation of patients' rights on the side cross-border healthcare (L 88/45 / 4.4.2011) and other provisions), Articles 7.1, 7.5 and 9.5. • EOPYY, 'Guidelines on the implementation of Directive 2011/24 / EU on patients' rights in the context of Cross-border Health Care (Law 4213/2013). • Presidential Decree 16/2014 Consular Fees and Rights), Government Gazzette 24 A/31-1-2014.[379]		αποδείξεων σχετικών με νοσήλια (Validation of certificates or receipts related to hospitalization). Greece is currently in the final stages of an impact assessment of the Directive's transposition framework and is reviewing the requirements for consulate validations. Expected reforms will be realized shortly.

[379] Προεδρικό Διάταγμα 16/2014 Προξενικά Τέλη και Δικαιώματα (Presidential Decree 16/2014 Consular Fees and Rights), Government Gazzette 24 A/31-1-2014, available at https://www.taxheaven.gr/law/%CE%A0.%CE%94.%2016/2014 (last accessed on 15 June 2021).

7. Are there any specific time requirements linked to a reimbursement request? (*e.g., time within which the reimbursement requests must be submitted and/or time within the requested body must handle the request and/or reimburse the costs, etc.*).	**Answer:** *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* Regarding the time within which the reimbursement claim must be submitted, it is a 6-month period after the date the invoice was issued (pursuant to Article 60 of EKPY).[382] The abovementioned deadline can only be exceeded following a decision of EOPYY Administrative Board in cases the delay is a result of objective difficulties (λόγοι ανωτέρας βίας) or EOPYY's responsibility. There are also time requirements regarding the time within which the requested body must take a decision on the reimbursement request. In this regard, the citizens' requests for cross-border healthcare have to be handled by the competent authorities within a reasonable time by their receipt, in	**Source(s):** • Joint Ministerial Decision 80157/2018 Uniform Regulation 80157/2018 of Health Benefits (EKPY) of the National Organisation for the Provision of Health Services (EOPYY), • Ministerial Decision Y9a/76908/2014 Administrative procedures for the use of cross-border health care (article 9 of Law 4213/2013), Article 7. • Law 2690/1999: Ratification of the Code of Administrative Procedure and other provisions), Articles 4.1 and 4.2	**Yes** ☐[384] [385] **No** ☒	The set procedures reflect the national law (Code of Administrative procedures) as far as responding times for claims filed with public services. The repeated declaration in all the legal acts of the Directive's framework that reimbursement, procedures, PA etc., are implemented proportionately pursuant to national law is assumed as sufficient justification.

[382] Information confirmed to Spark Legal Network by the EOPYY on 8 October 2021.

[384] Please also note that the requirement of no-discrimination regarding cross-border healthcare and the relevant reimbursement procedures is also foreseen; Νόμος υπ' αριθμ. 4213/2013 Προσαρμογή της εθνικής νομοθεσίας στις διατάξεις της Οδηγίας 2011/24/ΕΕ του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 9ης Μαρτίου 2011 περί εφαρμογής των δικαιωμάτων των ασθενών στο πλαίσιο της διασυνοριακής υγειονομικής περίθαλψης (L88/45/ 4.4.2011) και άλλες διατάξεις (Law No. 4213/2013 Adaptation of national legislation to the provisions of Directive 2011/24 / EU of the European Parliament and of the Council of 9 March 2011 concerning implementation of patients' rights on the side cross-border healthcare (L 88/45 / 4.4.2011) and other provisions), Government Gazzette 261/A/3-12-2013, available at https://www.e-nomothesia.gr/kat-ygeia/perithalpse/n-4213-2013.html (last accessed on 3 June 2021), Articles 4.2c, 5c, 7.1, 7.4, 7.5, 8.2; EOPYY, 'Guidelines on the implementation of Directive 2011/24 / EU on patients' rights in the context of Cross-border Health Care (Law 4213/2013)', available at https://aftodioikisi.gr/mediafiles/2016/06/ΕΓΚΥΚΛΙΟΣ-7.pdf (last accessed on 3 June 2021).

[385] In Greece, the compensation of health benefits is now based entirely on an electronic system (e-prescription, e-referrals, e-submissions, e-check / clearing, e-payments contracted with EOPYY providers) and the patient is not involved financially at any stage except for the payment of the possible participation depending on the provision of health, as defined by the EKPY. In the context of cross-border care, administrative procedures are based on the submission of proportional claims (prescriptions, referrals, medical history, detailed invoices, etc.), which are submitted in writing and are the responsibility of the insured, who is also charged with translation costs or document validation costs.

	accordance with the provisions of Article 4, par. 1 of Law 2690/1999 (Code of Administrative Procedure)[383], as in force, while in the cases of complex / specialised requests, the processing of which presupposes the involvement of other bodies, the laid down in Article 4, par. 1 c-d of Law 2690/1999 apply. In particular, the administrative authorities, when applications are submitted, must process the cases of the interested parties and decide on their applications within the deadline that may be determined by the relevant special provisions, otherwise within a period of sixty (60) days. The deadline starts from the submission of the application to the competent authority. If the application is submitted to an incompetent authority, this authority must, within five (5) days, forward it to the competent authority and notify the interested party. In this case, the deadline starts from the time the application was received by the competent authority. In addition, if a case cannot be processed within the previously mentioned deadline, the competent authority must notify the interested party in writing: a) the reasons for the delay, b) the official who has taken over the case and his telephone number, in order to provide information , c) any missing supporting documents, and d) any other useful information.			

[383] Νόμος 2690/1999 Κύρωση του Κώδικα Διοικητικής Διαδικασίας και άλλες διατάξεις (Law 2690/1999: Ratification of the Code of Administrative Procedure and other provisions), Government Gazzette 45/A/9-3-1999, available at https://www.e-nomothesia.gr/kat-demosia-dioikese/n-2690-1999.html (last accessed on 3 June 2021).

8. Are there any non-reimbursable thresholds, deductions *(except the deductions for administrative costs mentioned above) etc.?*	**Answer:** *If yes, please specify the thresholds.* As a rule, expenses incurred by the insured, who received cross-border health care, regardless of the place where the health care was provided, are reimbursed, if such health care is included in the benefits to which the insured is entitled, as defined by the applicable law, Greek legislation and the Regulation of health benefits. There are also co-payments for different types of health benefits stipulated in EKPY, which are proportionately deducted from the amount reimbursed to the patient. The costs of cross-border health care are reimbursed or paid directly up to the amount covered the statutory health insurance body, if this health care was provided in Greece, without the amount of their coverage exceeding the actual health care costs the patient. When the full costs of cross-border healthcare exceed the level of costs that the relevant statutory health insurance body	**Source(s):** • Ministerial Decision Y9a/76908/2014 Administrative procedures for the use of cross-border health care (article 9 of Law 4213/2013), Articles 2.4, 4 and 5. • Law No. 4213/2013 Adaptation of national legislation to the provisions of Directive 2011/24 / EU of the European Parliament and of the Council of 9 March 2011 concerning implementation of patients' rights on the side cross-border healthcare (L 88/45 / 4.4.2011) and other provisions), Articles 7.1, 7.2, 7.5 and 9.4.	**Yes** ☐[386] [387] **No** ☒	Please note that there are also co-payments for different types of health benefits stipulated in EKPY, which are proportionately deducted accordingly from the amount reimbursed to the patient who has received cross-border healthcare. Specifically, cross-border healthcare costs reimbursed to the insured amount to: (i) the current insurance price relating to medical acts or group of examination/diagnostic acts and in the absence of this value/price reference of the current State Tariff, ii) the Closed System of Consolidated

[386] Please also note that the requirement of no-discrimination regarding cross-border healthcare and the relevant reimbursement procedures is also foreseen; Νόμος υπ' αριθμ. 4213/2013 Προσαρμογή της εθνικής νομοθεσίας στις διατάξεις της Οδηγίας 2011/24/ΕΕ του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 9ης Μαρτίου 2011 περί εφαρμογής των δικαιωμάτων των ασθενών στο πλαίσιο της διασυνοριακής υγειονομικής περίθαλψης (L88/45/ 4.4.2011) και άλλες διατάξεις (Law No. 4213/2013 Adaptation of national legislation to the provisions of Directive 2011/24 / EU of the European Parliament and of the Council of 9 March 2011 concerning implementation of patients' rights on the side cross-border healthcare (L 88/45 / 4.4.2011) and other provisions), Government Gazzette 261/A/3-12-2013, available at https://www.e-nomothesia.gr/kat-ygeia/perithalpse/n-4213-2013.html (last accessed on 3 June 2021), Articles 4.2c, 5c, 7.1, 7.4, 7.5, 8.2; EOPYY, 'Guidelines on the implementation of Directive 2011/24 / EU on patients' rights in the context of Cross-border Health Care (Law 4213/2013)', available at https://aftodioikisi.gr/mediafiles/2016/06/ΕΓΚΥΚΛΙΟΣ-7.pdf (last accessed on 3 June 2021).

[387] In Greece, the compensation of health benefits is now based entirely on an electronic system (e-prescription, e-referrals, e-submissions, e-check / clearing, e-payments contracted with EOPYY providers) and the patient is not involved financially at any stage except for the payment of the possible participation depending on the provision of health, as defined by the EKPY. In the context of cross-border care, administrative procedures are based on the submission of proportional claims (prescriptions, referrals, medical history, detailed invoices, etc.), which are submitted in writing and are the responsibility of the insured, who is also charged with translation costs or document validation costs.

	would have incurred if the healthcare had been provided in Greece, then only the costs set out in the Regulation of health benefits are reimbursed. The statutory health insurance body is not obliged to reimburse related costs, such as accommodation and travel expenses, unless cross-border healthcare involves either the provision of prior authorisation of care or additional costs that may have been incurred by persons with one or more certified disabilities. The relevant statutory health insurance body shall also provide the patient with written notification of the estimated maximum amount to be reimbursed. This assessment takes into account the patient's clinical case, indicating the medical procedures that may be applied.	• EOPYY, 'Guidelines on the implementation of Directive 2011/24 / EU on patients' rights in the context of Cross-border Health Care (Law 4213/2013)' • Joint Ministerial Decision 80157/2018 Uniform Regulation 80157/2018 of Health Benefits (EKPY) of the National Organisation for the Provision of Health Services (EOPYY).		Hospitalisation Pricings (KEN/equivalent to DRG system) or in the absence of this to the Open System of Daily Hospitalisation Pricings fees for outpatient hospital care with the respective additional costs of items (e.g., medical devices, etc.), deducting in each case the patient's participation in diagnostic tests or hospitalisation, as provided in applicable national legislation and the Health Benefits Regulation of the statutory health insurance body. For the matching of the prices of the additional items/materials, the relevant statutory health insurance body may consult the Health Procurement Committee (EPY), while it shall not compensate in case the said materials have not been costed and are not included in the National Tariff Observatory.[388]

[388] Information confirmed to Spark Legal Network by the EOPYY on 8 October 2021.

9. In instances where a PA (or prior-notification) has already been issued, is a separate/simplified procedure available for requesting reimbursement? **applicable only if the country has a PA system.*	**Answer:** *If yes, please describe the simplified procedure.* In instances where a PA has already been issued, the patient submits a different application form and other supporting documents (+ EOPYY's PA approval decision + treatment history) to request reimbursement than in the case where a PA has not been requested. The procedure itself remains, nonetheless, almost identical. In particular, applications can be submitted at the Regional Directorates of EOPYY at the place of residence of the applicant. For the type of application form where PA has been previously issued[389], the following information are required: a. Name & Surname of the insured applicant (mandatory), b. Date	**Source(s):** • Ministerial Decision Y9a/76908/2014 Administrative procedures for the use of cross-border health care (article 9 of Law 4213/2013), Articles 2.4 and 3.1. • Law No. 4213/2013 Adaptation of national legislation to the provisions of Directive 2011/24 / EU of the European Parliament and of the Council of 9 March 2011 concerning implementation of patients' rights on the side cross-border healthcare (L 88/45 / 4.4.2011) and other	**Yes** ☐[390] [391] **No** ☒	The set procedures reflect the national requirements as set in EKPY and EOPYY circulars for the different types of health benefits which are audited and authorized by EOPYY-appointed medical staff before remunerating the costs. When the healthcare is provided domestically, the whole remuneration system is electronic (e-prescriptions, e-referrals etc) so the patients have no administrative burdens. In the case of cross-border healthcare EOPYY requires the patient to submit the proportionate documentation (proof of payment, referrals, treatment's history etc) to

[389] Αίτηση για επιστροφή εξόδων διασυνοριακής υγειονομικής περίθαλψης κατόπιν προηγούμενης έγκρισης (Application for reimbursement for cross-border healthcare expenditures with prior approval), available at https://eu-healthcare.eopyy.gov.gr/gr/key_docs.aspx (last accessed on 3 June 2021).

[390] Please also note that the requirement of no-discrimination regarding cross-border healthcare and the relevant reimbursement procedures is also foreseen; Νόμος υπ' αριθμ. 4213/2013 Προσαρμογή της εθνικής νομοθεσίας στις διατάξεις της Οδηγίας 2011/24/ΕΕ του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 9ης Μαρτίου 2011 περί εφαρμογής των δικαιωμάτων των ασθενών στο πλαίσιο της διασυνοριακής υγειονομικής περίθαλψης (L88/45/ 4.4.2011) και άλλες διατάξεις (Law No. 4213/2013 Adaptation of national legislation to the provisions of Directive 2011/24 / EU of the European Parliament and of the Council of 9 March 2011 concerning implementation of patients' rights on the side cross-border healthcare (L 88/45 / 4.4.2011) and other provisions), Government Gazzette 261/A/3-12-2013, available at https://www.e-nomothesia.gr/kat-ygeia/perithalpse/n-4213-2013.html (last accessed on 3 June 2021), Articles 4.2c, 5c, 7.1, 7.4, 7.5, 8.2; EOPYY, 'Guidelines on the implementation of Directive 2011/24 / EU on patients' rights in the context of Cross-border Health Care (Law 4213/2013)', available at https://aftodioikisi.gr/mediafiles/2016/06/ΕΓΚΥΚΛΙΟΣ-7.pdf (last accessed on 3 June 2021).

[391] In Greece, the compensation of health benefits is now based entirely on an electronic system (e-prescription, e-referrals, e-submissions, e-check / clearing, e-payments contracted with EOPYY providers) and the patient is not involved financially at any stage except for the payment of the possible participation depending on the provision of health, as defined by the EKPY. In the context of cross-border care, administrative procedures are based on the submission of proportional claims (prescriptions, referrals, medical history, detailed invoices, etc.), which are submitted in writing and are the responsibility of the insured, who is also charged with translation costs or document validation costs.

	of birth, c. Identity/Passport number (mandatory), d. Insurance type (insured/ family member – mandatory), e. Social Security Insurance body/fund(mandatory), f. Number of Medical Booklet (mandatory), g. Reference to disabilities (optional), h. Address (mandatory), i. Telephone number (mandatory), j. E-mail (mandatory), k. Member State of treatment (mandatory), l. Type of treatment (mandatory), m. Details of treatment provider (optional). The application form must be signed and dated and available also online The application can be submitted via email or registered post. Finally, for such applications the following documents are required: a) Certificate of complete medical history of hospitalisation, where a possible termination / continuation of hospitalisation will be recorded (mandatory documentation) b) Certificate from a treatingdoctor or from a hospital, from which derives its legal status of operation of the Institution (public/private or public benefit institution – mandatory documentation) c) Original payment receipts for hospitalisation (mandatory documentation) d) Original proof of payment of medication, accompanied by a medical certificate for the necessity of the medication (mandatory documentation)	provisions), Articles 5, 7.1, 7.5, 9.1 and 9.5. • EOPYY, 'Guidelines on the implementation of Directive 2011/24 / EU on patients' rights in the context of Cross-border Health Care (Law 4213/2013).		prove the administration of the healthcare abroad. EL has implemented the necessary and proportionate national measures for cross-border healthcare reimbursement. The repeated declaration in all the legal acts of the Directive's framework that reimbursement, procedures, PA etc., are implemented proportionately pursuant to national law is assumed as sufficient justification.

	e) Original payment receipts for the supply of additional care items (medical devices, etc.), accompanied by a medical certificate for the necessity of their immediate supply (mandatory documentation) f) Especially for people with one or more disabilities which are certified by a decision of an official Disability Certification body (KEPA), and for whom the use of cross-border health care has been approved (mandatory documentation): - Original payment receipts for the transfer and return of the patient (also for his/her attendant) depending on the type of seat and means of transport used. In case of using airline tickets, electronic tickets or their excerpts and boarding passes must be also submitted. - Original payment receipts of residence. - Additional costs with corresponding original receipts which will be examined on a case-by-case basis. All supporting documents must be certified by the respective Greek Consulate and must be officially translated. The submitted documents (receipts, invoices) must be legally issued, original and must indicate number, date of issue, as well as an analysis of all relevant medical procedures, drugs or items. The competent authority may request from the insured additional supporting documents as well as indicate to the applicant the correct			

	completion of special (predefined) forms in order to facilitate the task of valid and timely reimbursement of the costs of medical and related acts (see also question 5). **IMPORTANT: Greece is currently in the final stages of an impact assessment of the Directive's transposition framework and is reviewing the requirements for documentation in PA claims. Expected reforms will be realized shortly.**			
10. Are there additional administrative/procedural requirements for reimbursement depending on, for instance, the type of treatment for which reimbursement is requested, or the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* There are no further additional administrative/procedural requirements for reimbursements depending on the type of treatment for which reimbursement is requested, or the profile of the insured person,	**Source(s):** N/A	**Yes** ☐[392] [393] **No** ☒	N/A

[392] Please also note that the requirement of no-discrimination regarding cross-border healthcare and the relevant reimbursement procedures is also foreseen; Νόμος υπ' αριθμ. 4213/2013 Προσαρμογή της εθνικής νομοθεσίας στις διατάξεις της Οδηγίας 2011/24/ΕΕ του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 9ης Μαρτίου 2011 περί εφαρμογής των δικαιωμάτων των ασθενών στο πλαίσιο της διασυνοριακής υγειονομικής περίθαλψης (L88/45/ 4.4.2011) και άλλες διατάξεις (Law No. 4213/2013 Adaptation of national legislation to the provisions of Directive 2011/24 / EU of the European Parliament and of the Council of 9 March 2011 concerning implementation of patients' rights on the side cross-border healthcare (L 88/45 / 4.4.2011) and other provisions), Government Gazzette 261/A/3-12-2013, available at https://www.e-nomothesia.gr/kat-ygeia/perithalpse/n-4213-2013.html (last accessed on 3 June 2021), Articles 4.2c, 5c, 7.1, 7.4, 7.5, 8.2; EOPYY, 'Guidelines on the implementation of Directive 2011/24 / EU on patients' rights in the context of Cross-border Health Care (Law 4213/2013)', available at https://aftodioikisi.gr/mediafiles/2016/06/ΕΓΚΥΚΛΙΟΣ-7.pdf (last accessed on 3 June 2021).

[393] In Greece, the compensation of health benefits is now based entirely on an electronic system (e-prescription, e-referrals, e-submissions, e-check / clearing, e-payments contracted with EOPYY providers) and the patient is not involved financially at any stage except for the payment of the possible participation depending on the provision of health, as defined by the EKPY. In the context of cross-border care, administrative procedures are based on the submission of proportional claims (prescriptions, referrals, medical history, detailed invoices, etc.), which are submitted in writing and are the responsibility of the insured, who is also charged with translation costs or document validation costs.

	or any other criterion. The information provided in the responses above apply.			
11. Please list any other administrative requirements in your country in relation to the procedures of reimbursement of cross-border healthcare.	**Answer:** There are no other administrative requirements in Greece in relation to the procedures of reimbursement of cross-border healthcare. The information provided in the responses above apply.	**Source(s):** N/A	**Yes** ☐[394] [395] **No** ☒	N/A

[394] Please also note that the requirement of no-discrimination regarding cross-border healthcare and the relevant reimbursement procedures is also foreseen; Νόμος υπ' αριθμ. 4213/2013 Προσαρμογή της εθνικής νομοθεσίας στις διατάξεις της Οδηγίας 2011/24/ΕΕ του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 9ης Μαρτίου 2011 περί εφαρμογής των δικαιωμάτων των ασθενών στο πλαίσιο της διασυνοριακής υγειονομικής περίθαλψης (L88/45/ 4.4.2011) και άλλες διατάξεις (Law No. 4213/2013 Adaptation of national legislation to the provisions of Directive 2011/24 / EU of the European Parliament and of the Council of 9 March 2011 concerning implementation of patients' rights on the side cross-border healthcare (L 88/45 / 4.4.2011) and other provisions), Government Gazzette 261/A/3-12-2013, available at https://www.e-nomothesia.gr/kat-ygeia/perithalpse/n-4213-2013.html (last accessed on 3 June 2021), Articles 4.2c, 5c, 7.1, 7.4, 7.5, 8.2; EOPYY, 'Guidelines on the implementation of Directive 2011/24 / EU on patients' rights in the context of Cross-border Health Care (Law 4213/2013)', available at https://aftodioikisi.gr/mediafiles/2016/06/ΕΓΚΥΚΛΙΟΣ-7.pdf (last accessed on 3 June 2021).

[395] In Greece, the compensation of health benefits is now based entirely on an electronic system (e-prescription, e-referrals, e-submissions, e-check / clearing, e-payments contracted with EOPYY providers) and the patient is not involved financially at any stage except for the payment of the possible participation depending on the provision of health, as defined by the EKPY. In the context of cross-border care, administrative procedures are based on the submission of proportional claims (prescriptions, referrals, medical history, detailed invoices, etc.), which are submitted in writing and are the responsibility of the insured, who is also charged with translation costs or document validation costs.

Part 2: Checklist for verification with national/regional body

Name of the body: EOPYY (National Organisation for the Provision of Health Services – Directorate of International Affairs – Unit for cross-border healthcare & NCP
Country/Region: Greece
Date of verification call: 10 June2021*
**Please note that this body provided additional feedback in writing to Spark Legal Network on 8 October 2021.*

Template for the Data Collection	**Aspects to be verified** *Tick the boxes if the information in the template for the data collection has been verified and/or complemented by the national body*		**Comments** *Include any additional comments and/or information provided by the contacted body*
Section 1 – Prior Authorisation			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Justification/purpose of the identified requirement(s) (Column 4)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	The feedback and information received by the contacted body during the call has already been incorporated in the questionnaire. Nonetheless, the contacted body emphasised specifically the following points : - Greece is currently in the final stages of an impact assessment of the Directive's transposition framework and is currently reviewing the legal framework for transposing Directive 2011/24 / EU into national law, mainly in terms of administrative procedures relating to prior approval and reimbursement of cross-border care costs. At the same time, the website of the Cross-border care ERC (Eu-healthcare.eopyy.gov.gr) is being updated and revised, which will be published in June 2021. Greek authorities will soon be able to contact the European Commission about the relevant national measures. The questionnaire notes refer to the current context. - The transposition of the Directive into national law took place under the supervision of the General

			Secretariat of the Government and was the result of a consultation of the Ministry of Health with a wide range of stakeholders (health professionals, patient organizations, trade union representatives, public officials and stakeholders) and working parties in order to substantiate the transposition and comply with the commitments of the Directive. - The administrative procedures for the prior approval and the reimbursement procedures for cross-border healthcare pursuant to Law 4213/2013 (incorporation of Directive 2011/24/ EU) were deemed as necessary in proportion to the administrative procedures that apply when the insured receive care within the country. - The legal framework of Law 4213/13 is governed by the clear commitment of the country that the national legislation and the Regulations of Health Benefits of the health service providers are applied regarding the administrative procedures of prior approval and reimbursement of expenses. Given that the national legislation consists of a number of regulatory and administrative acts, is redefined and periodically reviewed, the above statement was considered as a sufficient and clear reference in the legal framework of Law 4213/13. - Regarding the deadlines for submitting requests and responding to those requests, national legislation is applied again, namely EKPY, Article 60 on limitation of the right to submit individual requests and the Code of Administrative Procedures (Law 2690/1999), Article 4. - Regarding the issuance of administrative acts of approval / rejection, the Regulation on Communication of Public Services (KEDY-Ministry of Interior, Public Administration & Decentralization, General Secretariat of Public Administration, January 2003) applies, in

			accordance with the national practice, where no other procedure is provided. - In Greece, the compensation of health benefits is now based entirely on an electronic system (e-prescription, e-referrals, e-submissions, e-check / clearing, e-payments contracted with EOPYY providers) and the patient is not involved financially at any stage except for the payment of the possible participation depending on the provision of health, as defined by the EKPY. In the context of cross-border care, administrative procedures are based on the submission of proportional claims (prescriptions, referrals, medical history, detailed invoices, etc.), which are submitted in writing and are the responsibility of the insured, who is also charged with translation costs or document validation costs.
Section 2 - Reimbursement			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Whether the requirement applies domestically (Discriminatory assessment) (Column 4) ▪ Justification/purpose of the identified requirement(s) (Column 5)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	The feedback and information received by the contacted body during the call has already been incorporated in the questionnaire. Nonetheless, the contacted body emphasised specifically the following points : - Greece is currently in the final stages of an impact assessment of the Directive's transposition framework and is currently reviewing the legal framework for transposing Directive 2011/24 / EU into national law, mainly in terms of administrative procedures relating to prior approval and reimbursement of cross-border care costs. At the same time, the website of the Cross-border care ERC (Eu-healthcare.eopyy.gov.gr) is being updated and revised, which will be published in June 2021. Greek authorities will soon be able to contact the European Commission about the

			relevant national measures. The questionnaire notes refer to the current context. - The transposition of the Directive into national law took place under the supervision of the General Secretariat of the Government and was the result of a consultation of the Ministry of Health with a wide range of stakeholders (health professionals, patient organizations, trade union representatives, public officials and stakeholders) and working parties in order to substantiate the transposition and comply with the commitments of the Directive. - The administrative procedures for the prior approval and the reimbursement procedures for cross-border healthcare pursuant to Law 4213/2013 (incorporation of Directive 2011/24/ EU) were deemed as necessary in proportion to the administrative procedures that apply when the insured receive care within the country. - The legal framework of Law 4213/13 is governed by the clear commitment of the country that the national legislation and the Regulations of Health Benefits of the health service providers are applied regarding the administrative procedures of prior approval and reimbursement of expenses. Given that the national legislation consists of a number of regulatory and administrative acts, is redefined and periodically reviewed, the above statement was considered as a sufficient and clear reference in the legal framework of Law 4213/13. - Regarding the deadlines for submitting requests and responding to those requests, national legislation is applied again, namely EKPY, Article 60 on limitation of the right to submit individual requests and the Code of Administrative Procedures (Law 2690/1999), Article 4. - Regarding the issuance of administrative acts of approval / rejection, the Regulation on Communication of Public Services (KEDY-

			Ministry of Interior, Public Administration & Decentralization, General Secretariat of Public Administration, January 2003) applies, in accordance with the national practice, where no other procedure is provided. - In Greece, the compensation of health benefits is now based entirely on an electronic system (e-prescription, e-referrals, e-submissions, e-check / clearing, e-payments contracted with EOPYY providers) and the patient is not involved financially at any stage except for the payment of the possible participation depending on the provision of health, as defined by the EKPY. In the context of cross-border care, administrative procedures are based on the submission of proportional claims (prescriptions, referrals, medical history, detailed invoices, etc.), which are submitted in writing and are the responsibility of the insured, who is also charged with translation costs or document validation costs.

HUNGARY – COUNTRY REPORT

Part 0: Preliminary Assessment

1. **Please indicate whether the rules governing the administrative procedures/requirements for requesting PA and reimbursement under Directive 2011/24/EU in your country are set out at:**

A. National level ☒

B. Decentralised/regional/local level ☐

In case (1.B): Please indicate the two most relevant jurisdictions in your country (i.e., in terms of population):

Region/jurisdiction: 1: N/A

Region/jurisdiction 2: N/A

NOTE: In case (1.B) the template for the data collection (Part 1) should be completed twice, once for each of the two most relevant regions/jurisdiction indicated above.

2. **Please indicate the national body best suited to verify the accuracy of the information collected in Part 1, and justify your selection.**
Depending on the characteristics of your national healthcare system, the relevant body may be: a) *the national social security body*; or b) *an insurance fund*. In the latter case, please indicate the most representative fund (e.g., the one with the highest number of affiliations).

Body to be contacted for Task 2: National Health Insurance Fund of Hungary (Hungarian acronym: NEAK)

(In case 1.B, please indicate two relevant bodies, one respectively for each Region/jurisdiction)

Reasons for Selection: The National Health Insurance Fund of Hungary is the responsible authority for PA and for reimbursement.

Part 1: Questionnaire

*__Note 1__: In cases where administrative requirements are set out in the legislative/regulatory framework at decentralised/regional/local level, please complete the template for the data collection twice, once for each of the two most relevant regions/jurisdictions (e.g., in terms population).

__*Note 2__: Setting out a Prior Authorisation (PA) system is optional for Member States. Should your country not have a system of PA in place under Directive 2011/24/EU, Section 1 will not need to be completed.

SECTION 1 PRIOR AUTHORISATION PROCEDURE(S)			
Questions	Answer	Sources	Purpose and/or justification of the requirements
1. Which national legislative and/or regulatory provisions lay out the requirements related to PA procedures for a cross-border healthcare under Directive 2011/24/EU?	Answer: Act 83. of 1997 on Health Care Insurance (1997. évi LXXXIII. törvény a kötelező egészségbiztosítás ellátásairól)[396]. Government Decree No. 340/2013. of December 25, 2013 on detailed regulations of medical treatment abroad (1997. évi LXXXIII. törvény a kötelező egészségbiztosítás ellátásairól)[397].	Source(s): Government Decree No. 340/2013. of December 25, 2013 on detailed regulations of medical treatment abroad. Act 83. of 1997 on Health Care Insurance.	N/A

[396] 1997. évi LXXXIII. törvény a kötelező egészségbiztosítás ellátásairól (Act 83. of 1997 on Health Care Insurance). Available at https://njt.hu/jogszabaly/1997-83-00-00, last accessed on 13 June2021.

[397] 340/2013. (IX. 25.) Korm. rendelet a külföldön történő gyógykezelések részletes szabályairól (Government Decree No. 340/2013. of December 25, 2013 on detailed regulations of medical treatment abroad). Available at https://njt.hu/jogszabaly/2013-340-20-22 , last accessed on 13 June2021.

2. Is this the same procedure as for PA under the Social Security Coordination Regulations?	Answer: Yes ☒ No ☐ Source(s): Government Decree No. 340/2013. of December 25, 2013 on detailed regulations of medical treatment abroad Art. 3. Sec. 1.		N/A
3. What body is in charge of handling the PA applications? *(e.g., where and to whom PA applications have to be submitted?)*	Answer: *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* National Health Insurance Fund of Hungary (Hungarian acronym: NEAK)	Source(s): Government Decree No. 340/2013. of December 25, 2013 on detailed regulations of medical treatment abroad Art. 3. Sec. 1.	N/A
4. Who is entitled to apply for PA? *(e.g., can the patients apply themselves, or is treating doctor filing/partially filling the request, etc.)*	Answer: *-If there is a national doctor involved, is there a requirement that this doctor is contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA?* There are 3 options. The entitlement to apply is given either to - the patient, or - his/her parent/guardian (in case of incompetence), or	Source(s): Government Decree No. 340/2013. of December 25, 2013 on detailed regulations of medical treatment abroad Art. 3. Sec. 2.	No specific purpose/justification identified in the sources consulted. In particular, there is no official preparatory document or explanatory memorandum to the Government Decree, therefore the justification/purpose of this section is not public. The official explanatory memorandum to the Act 83. of 1997 on Health Care Insurance Art. 27. (as amended by the Act 127. of 2013 on the Modification of Health Care and Health Insurance related Acts) is very concise and short so could not be used for this purpose.

	- the treating physician (who has to be contracted to the National Health Insurance Fund of Hungary) If the treating physician fills in the form, the patient/guardian/parent also has to sign it.		
5. Is there a specific application form/module which the person seeking PA needs to submit?	Answer: *If yes, please specify:* *- What information is required;* *- Is the information mandatory, optional, or recommended?* *- Is this application form/modules available online?* *- Does the form have to be submitted in paper or can it be submitted electronically?* Yes, there is a specific application module. The following information is required: - personal data of the patient (name, date of birth, postal address, social security number); - name and affiliation of the treating physician; - the planned treatment to be carried out abroad; - data of the chosen health care provider (if there is any) – country, name and address of the health care provider, name of the treating physician;	Source(s): Government Decree No. 340/2013. of December 25, 2013 on detailed regulations of medical treatment abroad Annex II. The application form is also available on the website of the National Health Insurance Fund of Hungary: http://www.neak.gov.hu/data/cms1010705/NEU.161.G.doc	No specific purpose/justification identified in the sources consulted.

	- if the applicant asks for the coverage of the transportation costs for himself/herself and an accompanying person, mode of transportation, cost of transportation. - the declaration of the patient/parent/guardian that s/he is aware of the fact that the costs of cross-border healthcare have to be paid by her/him, and will be reimbursed up to the level of costs that would have been assumed by NEAK, had this healthcare been provided in Hungary, without exceeding the actual costs of healthcare received. The following data should be given by the treating physician: - summary of the diagnostic evaluation related to the planned treatment (attaching the relevant documents); - main diagnosis related to the planned treatment; - if the planned treatment is available, standard and financed care in Hungary: when could the treatment be carried out and at which Hungarian health care provider, what is the medically acceptable waiting time for the applicant, if there is a waiting list, how long is the waiting time based on the available waiting list data and if the planned treatment is medically urgent; - if the planned treatment is not standard and financed care in Hungary: what is the most advanced standard and financed care available for the diagnosis of the patient in Hungary;		

	The information is mandatory in the sense that if the data provided are not sufficient for the approval, the PA will not be granted. The application form is available online on the website of the National Health Insurance Fund of Hungary The application form has to be submitted in paper		
6. What (other) documentation has to be submitted in order to substantiate a PA request?	Answer: *If applicable, please specify:* - *What documents and what particulars are required;* - *Whether there are requirements as to who has to issue the documents (e. g., a doctor contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA or any doctor);* - *Whether the submission of the documentation is optional, mandatory, or recommended.* Relevant health care files of the patient have to be submitted (the term "relevant" is not further specified). The documents and the information to be submitted are listed in Question 5 above.	Source(s): Government Decree No. 340/2013. of December 25, 2013 on detailed regulations of medical treatment abroad Art. 3. Sec. 2.	No specific purpose/justification identified in the sources consulted.

	There are no requirements as to who has to issue the documents (it does not have to be a doctor contracted by the NEAK). Submission is mandatory in the sense that if the data provided are not sufficient for the approval, the PA will not be granted.		
7. Are there any costs associated with the handling of the PA request? - *Direct costs (e.g., fixed costs for submitting or filing a PA request).* - *Indirect costs* (*e.g., translations, stamps, etc).*	Answer: *Direct costs:* None identified. *Indirect costs:* None identified. There are no direct or indirect costs associated with the handling of the PA request. Documents can be submitted in foreign language without official translation (a simple translation completed with the help of google translate is sufficient).	Source(s): According to the relevant legislation (specified above in Sec. 1.) there are no fees related to the submission of the application	N/A
8. Are there any specific time requirements linked to a PA request? (*e.g., time within which a requesting person must submit the PA application and/or time within which the requested body must*	*- If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* Answer: Yes, there are time requirements, as listed below.	Source(s): Act 150 of 2016 on Administrative Procedures[398] - Art. 50. Government Decree No. 340/2013. of December 25, 2013 on detailed regulations of medical	

[398] 2016. évi CL. törvény az általános közigazgatási rendtartásról (Act 150 of 2016 on Administrative Procedures). Available at https://njt.hu/jogszabaly/2016-150-00-00, last accessed on 13 June2021.

take a decision on the PA request, etc.).	The NEAK has to provide its decision within 60 days of receiving the application. If the NEAK misses the deadline, 10 000 HUF are to be paid to the patient. If the PA is granted, a time limit is set within which the health care abroad has to be performed. Missing this deadline without proper justification leads to the refusal of reimbursement. After completing the health care, the patient has to submit his/her medical documentation of the health care received abroad, together with the evaluation of the Hungarian treating physician. The deadline for the submission of the above documents is within 30 days of returning home. If the patient misses this deadline and cannot justify it, s/he receives no reimbursement.	treatment abroad Art. 4. Sec. 2., Art. 13. Sec. 2. Government Decree No. 340/2013. of December 25, 2013 on detailed regulations of medical treatment abroad Art. 12. Sec. 1. The evaluation form to be filled out by the Hungarian treating physician can be found in Annex 7. of Government Decree No. 340/2013. of December 25, 2013 on detailed regulations of medical treatment abroad.	
9. Are there differences in the procedural/administrative requirements for requesting PA based on, for instance, the type of treatment for which PA is requested, the profile of the insured person, or any other criterion?	Answer: *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* There are no differences in the procedural/administrative requirements for	Source(s): Government Decree No. 340/2013. of December 25, 2013 on detailed regulations of medical treatment abroad The list of the treatments/diagnostic procedures which are	N/A

	requesting PA either based on the type of treatment or the profile of the insured person, or any other criterion. There are some treatments/diagnostic procedures however, which are not subject to PA (mainly outpatient treatments).	subject to PA are listed in Annex 1. of Government Decree No. 340/2013. of December 25, 2013 on detailed regulations of medical treatment abroad. Therefore which are not listed here are not subject to PA.	
10. Is there a specific PA form (i.e., form used for issuing/granting PA) and, if the answer is positive, what form?	Answer: There is a specific PA form used for granting PA and it is available publicly. The following information has to be provided: - data of the patient - the data of the treatment for which PA is granted (diagnosis, treatment codes, Hungarian financing codes) - the costs of the treatment had it been carried out in Hungary - data of the PA procedure (beginning of the PA procedure, date of issuing the PA, timeframe set for the treatment)	Source(s): Annex 4. Of Government Decree No. 340/2013. of December 25, 2013 on detailed regulations of medical treatment abroad contains the form used for granting PA	N/A
11. Please list any other administrative requirements in your country in relation to the PA procedure for cross-border healthcare.	Answer: PA can be refused if the treatment can be carried out by a Hungarian contracted health care provider within reasonable time (taking into consideration the medical urgency of the treatment.) The refusal can be appealed.	Source(s): Government Decree No. 340/2013. of December 25, 2013 on detailed regulations of medical treatment abroad Art. 7.	N/A

SECTION 2 REIMBURSMENT PROCEDURE(S)				
Questions	Answer:	Sources	Does/do the identified requirement(s) also apply domestically? (i.e., is the requirement non-discriminatory?)	Purpose and/or justification of the requirements
1. Which national legislative and/or regulatory provisions lay out the requirements related to reimbursement procedures for cross-border healthcare under Directive 201/24/EU?	Answer: Act 83. of 1997 on Health Care Insurance[399]. Government Decree No. 340/2013. of December 25, 2013 on detailed regulations of medical treatment abroad[400]	Source(s): Act 83. of 1997 on Health Care Insurance Government Decree No. 340/2013. of December 25, 2013 on detailed regulations of medical treatment abroad	N/A	N/A
2. Is this the same procedure as for reimbursement under the Social Security Coordination Regulations?	Answer: Yes ☒ No ☐		N/A	N/A

[399] 1997. évi LXXXIII. törvény a kötelező egészségbiztosítás ellátásairól (Act 83. of 1997 on Health Care Insurance). Available at https://njt.hu/jogszabaly/1997-83-00-00, last accessed on 13 June2021.

[400] 340/2013. (IX. 25.) Korm. rendelet a külföldön történő gyógykezelések részletes szabályairól (Government Decree No. 340/2013. of December 25, 2013 on detailed regulations of medical treatment abroad). Available at https://njt.hu/jogszabaly/2013-340-20-22, last accessed on 13 June2021.

3. What body is/are responsible of handling the reimbursement applications? (e.g., where and to whom reimbursement applications have to be submitted?)	Answer: *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* National Health Insurance Fund (NEAK)	Source(s): Government Decree No. 340/2013. of December 25, 2013 on detailed regulations of medical treatment abroad Art. 7.	N/A	N/A
4. Is there a specific application form/module which the person seeking reimbursement needs to submit?	Answer: *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?* After completing the treatment, the patient has to submit the medical documentation of the treatment received abroad, together with the evaluation of the Hungarian treating physician. There is a specific form for this evaluation, but there is no specific form for the application for reimbursement. The documentation has to be submitted in paper.	Source(s): Government Decree No. 340/2013. of December 25, 2013 on detailed regulations of medical treatment abroad Art. 12. Sec. 1. and Annex 7.	Yes ☐ No ☒ According to the Hungarian health system, no PA and no reimbursement are needed for a treatment provided domestically.	

	The data to be provided by the Hungarian treating physician are the following: - data of the patient - data of the treatment provided abroad - the opinion of the treating physician on the issue if the treatment provided was the same as the treatment authorized - the evaluation of the treating physician on the effectiveness of the treatment - the further treatment to be carried out - name of the health care provider carrying out the further treatment of the patient.			
5. What (other) documentation has to be submitted in order to substantiate a reimbursement request?	Answer: *If applicable, please specify:* - *What documents are required;* - *Whether the submission of the documentation is optional, mandatory, or recommended.* The patient has to submit the medical documents s/he received abroad (preferably the discharge summary). The patient also has to submit the invoice he received abroad and the financial document proving that s/he paid the invoice. The submission is mandatory.	Source(s): Government Decree No. 340/2013. of December 25, 2013 on detailed regulations of medical treatment abroad Art. 8. Sec. 2.	Yes ☐ No ☒	

6. Are there any costs associated with the handling of the reimbursement request? - *Direct costs (e.g., fixed costs for submitting or filing a reimbursement request, proportion deducted from the reimbursable amount).* - *Indirect costs* (*e.g., translations, stamps, etc).*	Answer: *Direct costs:* none *Indirect costs:* none Note of the National body contacted for the verification of the data collected: The documentation can be submitted in the original language, no official translation is required, a simple translation (e.g. with Google translate) is sufficient.	Source(s): Government Decree No. 340/2013. of December 25, 2013 on detailed regulations of medical treatment abroad (it does not prescribe any fee to be paid).	Yes ☐ No ☒	
7. Are there any specific time requirements linked to a reimbursement request? (*e.g., time within which the reimbursement requests must be submitted and/or time within the requested body must handle the request and/or reimburse the costs, etc.*).	Answer: *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* After completing the treatment the patient has to submit his/her medical documentation of the treatment received abroad, together with the evaluation of the Hungarian treating physician. The deadline for the submission of the above documents: within 30 days of returning home. If the patient misses this deadline and cannot justify it, the res/he receives no reimbursement.	Source(s): Government Decree No. 340/2013. of December 25, 2013 on detailed regulations of medical treatment abroad Art. 12. Sec. 1.	Yes ☐ No ☒	

8. Are there any non-reimbursable thresholds, deductions *(except the deductions for administrative costs mentioned above) etc.?*	Answer: *If yes, please specify the thresholds.* *Yes.* The costs of the health care are reimbursed to the level of costs that would have been assumed by the National Insurance Fund of Hungary, had this healthcare been provided in Hungary, but it should not exceed the actual costs of the health care provided.	Source(s): Act 83. of 1997 on Health Care Insurance Art. 27. Sec. 6.	Yes ☐ No ☒	
9. In instances where a PA (or prior-notification) has already been issued, is a separate/simplified procedure available for requesting reimbursement? **applicable only if the country has a PA system.*	Answer: *If yes, please describe the simplified procedure.* There are no simplified procedure.	Source(s):	Yes ☐ No ☒	
10. Are there additional administrative/procedural requirements for reimbursement depending on, for instance, the type of treatment for which	Answer: *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)*	Source(s): - Government Decree No. 340/2013. of December 25, 2013 on detailed regulations of medical	Yes ☐ No ☒	

reimbursement is requested, or the profile of the insured person, or any other criterion?	In cases where there is no need for PA, there is one additional requirement: the patient has to submit his/her referral to the health care provided (if in Hungary this type of health care can be only provided if the patient has referral). If the patient seeks reimbursement for the purchase of medicinal products and medical devices in another Member State, the patient has to submit the following documents: - the prescription (or a copy of it) - the medical documents upon which the prescription was issued (e.g. discharge summary) - the invoice and the proof of payment. In case of transportation costs (for the patient and an accompanying person): these costs can be paid in advance (max. 12 days before the planned travel).	treatment abroad Art. 8. Sec. 1 and 3. Government Decree No. 340/2013. of December 25, 2013 on detailed regulations of medical treatment abroad Art. 11. Sec. 1.		
11. Please list any other administrative requirements in your country in relation to the procedures of reimbursement of cross-border healthcare.	Answer: Not identified	Source(s):-	Yes ☐ No ☐	

Part 2: Checklist for verification with national/regional body

Name of the body: National Health Insurance Fund of Hungary
Country/Region: Hungary
Date of verification call: 2021.06.21.

Template for the Data Collection	Aspects to be verified Tick the boxes if the information in the template for the data collection has been verified and/or complemented by the national body		Comments Include any additional comments and/or information provided by the contacted body
Section 1 – Prior Authorisation			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Justification/purpose of the identified requirement(s) (Column 4)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	The feedback received was incorporated in Part 1, Section 1.
Section 2 - Reimbursement			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Whether the requirement applies domestically (Discriminatory assessment) (Column 4) ▪ Justification/purpose of the identified requirement(s) (Column 5)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	The feedback received was incorporated in Part 1, Section 2.

ICELAND – COUNTRY REPORT

Part 0: Preliminary Assessment

1. **Please indicate whether the rules governing the administrative procedures/requirements for requesting PA and reimbursement under Directive 2011/24/EU in your country are set out at:**

A. National level ☒

B. Decentralised/regional/local level ☐

In case (1.B): Please indicate the two most relevant jurisdictions in your country (i.e., in terms of population):

Region/jurisdiction: 1: N/A

Region/jurisdiction 2: N/A

NOTE: In case (1.B) the template for the data collection (Part 1) should be complete twice, once for each of the two most relevant regions/jurisdiction indicated above.

2. **Please indicate the national body best suited to verify the accuracy of the information collected in Part 1, and justify your selection.**

Depending on the characteristics of your national healthcare system, the relevant body may be: a) *the national social security body*; or b) *an insurance fund*. In the latter case, please indicate the most representative fund (e.g., the one with the highest number of affiliations).

Body to be contacted for Task 2: The Icelandic Health Insurance (IHI).

(In case 1.B, please indicate two relevant bodies, one respectively for each Region/jurisdiction)

Reasons for Selection: This is the body handling the PA and reimbursement procedures in Iceland.

Part 1: Questionnaire

*__Note 1__: In cases where administrative requirements are set out in the legislative/regulatory framework at decentralised/regional/local level, please complete the template for the data collection twice, once for each of the two most relevant regions/jurisdictions (e.g., in terms population).

__*Note 2__: Setting out a Prior Authorisation (PA) system is optional for Member States. Should your country not have a system of PA in place under Directive 2011/24/EU, Section 1 will not need to be completed.

SECTION 1 PRIOR AUTHORISATION PROCEDURE(S)			
Questions	**Answer**	**Sources**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to PA procedures for a cross-border healthcare under Directive 2011/24/EU?	**Answer:** Directive no. 2011/24/EU was implemented in Iceland with a bill to amend the Health Insurance Act no. 112/2008 and the Medicinal Products Act no. 93/1994 with subsequent amendments (EEA rules), no. 13/2016. Article 23. a of the Health Insurance Act no. 112/2016 of 16 September 2008 (Health Insurance Act) contains provisions on	**Source(s):** Preparatory works to the amendment of the Health Insurance Act no. 112/2008 and the Medicinal Products Act no. 93/1994 with subsequent amendments (EEA rules), no. 13/2016.[403] Article 23. a of the Health Insurance Act.[404]	N/A

[403] Frumvarp til laga um breytingu á lögum um sjúkratryggingar, nr. 112/2008, og lyfjalögum, nr. 93/1994, með síðari breytingum (EES-reglur). A bill no. 13/2016 to the amendment of the Health Insurance Act no. 112/2008 and the Medicinal Products Act no. 93/1994 with subsequent amendments (EEA rules). Author: Kristján Þór Júlíusson, Minister of Health. Date of adoption: 1 March 2016. https://www.althingi.is/altext/pdf/145/s/0244.pdf, page 2 (last accessed 16 June 2021).

[404] Lög um sjúkratryggingar, nr. 112/2008. The Health Insurance Act, no. 112/2008. Author: Guðlaugur Þór Þórðarson, Minister of Health. Date of adoption: 10 September 2008. https://www.althingi.is/lagas/151b/2008112.html, (last accessed 16 June 2021).

	medical treatment abroad that can be provided in Iceland. Article 23. a (4) of the Health Insurance Act provides for an authorisation for the respective minister, by means of a regulation, to stipulate in more detail the implementation of Article 23. a, e.g., when to apply for PA for reimbursement on the basis of the first paragraph of Article 23. a of the Health Insurance Act.[401] Regulation no. 484/2016 of 1 June 2016 on Health Services applied for within the Member State of the EEA Agreement but can be Provided in Iceland and on the Role of a National Contact Person for Cross-Border Health Services (Regulation no. 484/2016) is based on Article 23. a of the Health Insurance Act and implements Directive 2011/24/EU on patient's rights regarding cross-border healthcare.[402]	Article 15 of Regulation no. 484/2016.[405]	
2. Is this the same procedure as for PA under the Social Security Coordination Regulations?	**Answer:** **Yes ☒ No ☐** The procedures are substantially the same (but the requirements are nonetheless different).		N/A

[401] Article 23. a (1) reads as follows: *If the health insured chooses to seek health care in another member state of the EEA Agreement, the health insurance reimburses the cost of the service as if it were health care within the country, provided that the service corresponds to the service that health insurance participates in paying in Iceland.*

[402] Reglugerð um heilbrigðisþjónustu sem sótt er innan aðildarríkis EES-samningsins en hægt er að veita hér á landi og um hlutverk innlends tengiliðar vegna heilbrigðisþjónustu yfir landamæri. Regulation no. 484/2016 of 1 June 2016 on Health Services applied for within the Member State of the EEA Agreement but can be Provided in Iceland and on the Role of a National Contact Person for Cross-Border Health Services. Author: Margrét Björnsdóttir, Ministry of Health. Date of adoption: 1 June 2016. https://www.reglugerd.is/reglugerdir/eftir-raduneytum/velferdarraduneyti/nr/20127, (last accessed 16 June 2021).

[405] https://www.stjornartidindi.is/DocumentActions.aspx?ActionType=Open&documentID=fbebb19e-0981-40cd-ae50-361d163c1f3d

3. What body is in charge of handling the PA applications? *(e.g., where and to whom PA applications have to be submitted?)*	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* The Icelandic Health Insurance oversees the handling of PA applications. PA applications should be submitted to the authority's address: Icelandic Health Insurance International Division Vínlandsleið 16 113 Reykjavík international@sjukra.is Phone: 515-0002 Fax: 515-0069 As per the IHI's website, the application (medical certificate) can be submitted both in paper and electronically. A person seeking PA can also submit the application through the IHI's web portal or the doctor's web portal as well as bring the application and documents to the IHI's service center every working day between 10-15. The IHI helps with filling out the application.	**Source(s):** Article 6 of Regulation no. 484/2016. The IHI's website.[406]	N/A

[406] https://www.sjukra.is/heilbrigdisthjonusta/rettindi-milli-landa/laeknismedferd-erlendis/langur-bidtimi-eftir-medferd-a-islandi/heilbrigdisthjonusta-yfir-landamaeri-innan-ees-landa/

4. Who is entitled to apply for PA? *(e.g., can the patients apply themselves, or is treating doctor filing/partially filling the request, etc.)*	**Answer:** *If there is a national doctor involved, is there a requirement that this doctor is contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA?* Before the insured person decides to seek health care in another member state of the EEA Agreement in accordance with Article 2 of Regulation no. 484/2016, he/she shall in the following cases apply for PA for reimbursement or participation in costs from the IHI: 1. When the treatment requires hospitalisation (inpatient care) for at least one night or continuous treatment for more than 24 hours. 2. When the treatment involves a special risk for the patient or the general public. 3. When there is reason to doubt the quality of the service sought. Furthermore, when a health insured person who has a rare disease or is considered to have a rare disease applies for PA, the IHI can have an assessment made by experts in that field. Based on Regulation no. 484/2016 the patients can apply for PA themselves. However, a patient must submit a medical certificate for medical treatment abroad and that can only be acquired by contacting a national doctor. That means that essentially the doctor will be filling/partially filling in the	**Source(s):** Articles 9(1) and 9(2) of Regulation no. 484/2016.	There are no explanations provided by the IHI or the legislative/executive regarding these specific requirements to apply for PA. **Directive 2011/24/EU is discussed in the preparatory works to the amendment of the Health Insurance Act, no. 13/2016. It reads as follows:** Directive 2011/24/EU legislates various rights within the European Union that have been recognised in judgments of the European Court of Justice concerning cross-border healthcare, in particular reimbursement for healthcare provided in a Member State other than the country where the recipient of the service resides. The purpose of the Directive is to facilitate access to safe, high-quality cross-border healthcare, to ensure the free movement of patients within the Union and to promote cooperation in healthcare between Member States, taking into account Member States' powers to plan and provide their own healthcare. The Directive does not affect the responsibility of the Member States to provide citizens in their territory with safe, efficient and adequate high-quality healthcare. The Directive applies to patients who decide to use healthcare in a Member State other than the one in which they are insured, but which is not intended to encourage patients to seek treatment abroad but only to guarantee their right to free movement between Member States to seek healthcare with the restrictions set in each state. The Directive applies in parallel with Regulation (EC) No 882/2004 of the European Parliament and of the Council on the coordination of social security systems, which has been included in VI. Annex I to the EEA Agreement, and the authorities are intended to guide the health insured on which act gives

	medical certificate, provided on IHI's website, and submit it to the IHI or give it to the patient who will hand it in to IHI.		the person in question a more favourable right at any given time.[407]
5. Is there a specific application form/module which the person seeking PA needs to submit?	**Answer:** *If yes, please specify:* ▪ *What information is required;* ▪ *Is the information mandatory, optional, or recommended?* ▪ *Is this application form/modules available online?* ▪ *Does the form have to be submitted in paper or can it be submitted electronically?* Yes, on three occasions, patients are required to submit a specific application form to the IHI which is accessible from the authority's website. Those three occasions are as follows: 1. When the treatment requires hospitalization (inpatient care) for at least one night or continuous treatment for more than 24 hours. 2. When the treatment involves a special risk for the patient or the general public.	**Source(s):** The IHI's website.[409] The Application for Cross-Border Treatment within EEA Countries (icel. Umsókn vegna meðferðar yfir landamæri innan EES landa), is available on the IHI's website.[410] Information from employees of the IHI.	

[407] Available at : https://www.althingi.is/altext/pdf/145/s/0244.pdf, p. 3.
[409] Available at : https://www.sjukra.is/heilbrigdisthjonusta/rettindi-milli-landa/laeknismedferd-erlendis/langur-bidtimi-eftir-medferd-a-islandi/heilbrigdisthjonusta-yfir-landamaeri-innan-ees-landa/.
[410] Availavle at: https://www.sjukra.is/media/althjodadeild/Umsokn-vegna-medferdar-yfir-landamaeri-innan-EES-landa.docx.

	3. When there is reason to doubt the quality of the service sought.[408] This application form is a medical certificate which needs to be (at least) partly filled and signed by a doctor. The submission of the application form to the IHI is a mandatory and a prerequisite for seeking PA. Every field needs to be filled in order for it to be processed. The following information is required: ▪ Name ▪ ID number (kennitala) ▪ Residence in Iceland ▪ Postal code ▪ Place ▪ Phone number ▪ Email ▪ Resident abroad ▪ ID number abroad The applicant/doctor shall also provide the following information: ▪ A short medical history – including the onset of the disease, its stage and the patient's state of health, as well as the probable progression of the disease should be described.		

[408] According to the national legal expert and the sources consulted, it appears that the majority of the applications approved are approved on the grounds of point 1, i.e., the treatment requires hospitalisation or is continuous for more than 24 hours. It is very rare that someone applies for PA in order to undergo a treatment that involves a special risk for the patient or the general public – the reason being that in most cases the treatment requires hospitalisation of the patient, and the application is therefore approved on the basis of point 1 of the above. As for point 3, it is appears to be very rare that an applicant seeks PA on the grounds that there is a reason to doubt the quality of the service sought.

	▪ What treatment/examination is recommended.
	  ▪ Name of treatment/examination in both Icelandic and English.
	  ▪ Registration number of the treatment according NCSP-IS.
	▪ Residence abroad (within the EEA) and planned treatment.
	  ▪ Name of hospital.
	  ▪ Address / location.
	  ▪ City and country.
	▪ If there is an appointment booked for the recommended treatment.
	▪ How urgent the need is:
	  ▪ Within a few days
	  ▪ Within a few weeks
	  ▪ Within a few months
	  ▪ Other
	▪ If there is a comparable treatment available in Iceland.
	▪ The length of the waiting time for comparable treatment in Iceland.
	▪ If there is a need for components for treatment and/or if there is a specialised aftercare.
	▪ Name of doctor, place of work, work phone, mobile phone, and e-mail address
	▪ Doctor's license number.
	▪ Date and doctor's signature.
	
	As per the IHI's website, the application (medical certificate) can be submitted both in paper and electronically. A person seeking PA can also submit the application through the IHI's web portal or the doctor's web portal as well as bring the application and documents to the IHI's service center		

	every working day between 10-15. The IHI helps with filling out the application.		
6. What (other) documentation has to be submitted in order to substantiate a PA request?	**Answer:** *If applicable, please specify:* - *What documents and what particulars are required;* - *Whether there are requirements as to who has to issue the documents (e. g., a doctor contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA or any doctor);* - *Whether the submission of the documentation is optional, mandatory, or recommended.* No other documentation has to be submitted in order to substantiate a PA request (see description of 'short medical history' above).	**Source(s):** Application for the Cross-Border Treatment within EEA Countries.[411]	
7. Are there any costs associated with the handling of the PA request? - *Direct costs (e.g., fixed costs for submitting or filing a PA request).* - *Indirect costs* (*e.g., translations, stamps, etc).*	**Answer:** *Direct costs:* No direct cost. *Indirect costs:* Applicants may need to pay for their doctor's appointment/assistance in the PA process.	**Source(s):** Article 13 of Regulation no. 484/2016.	

[411] Available at: https://www.sjukra.is/media/althjodadeild/Umsokn-vegna-medferdar-yfir-landamaeri-innan-EES-landa.docx

8. Are there any specific **time requirements** linked to a PA request? (*e.g., time within which a requesting person must submit the PA application and/or time within which the requested body must take a decision on the PA request, etc.*).	**Answer:** - *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* No, there are no specific time requirements put on the requesting person or the requested body. However, the IHI is required to process applications for PA as quickly as possible.[412] Moreover, once the PA applications have been submitted to the IHI, the authority has to prioritise the applications depending on the urgency of the treatment as required by Article 9(3) of Regulation no. 484/2016. The patient's health shall be taken into account when processing PA applications and the urgency of prompt processing for the patient's health. As for the patient, there seems to be no requirement to submit a PA request within a certain time frame.	**Source(s):** Article 9(3) and 11(3) of Regulation no. 484/2016.	

[412] As for the authority, an application for PA may not be rejected when the applicant is entitled to the healthcare, but the service cannot be provided within a time limit that can be medically justified if based on an objective medical assessment of the patient's health condition, medical history and probable progression of the disease, pain and in what way illness hinders the patient's life.

9. Are there **differences in the procedural/administrative requirements for requesting PA** based on, for instance, the type of treatment for which PA is requested, the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* None identified. There are no differences in the procedural/administrative requirements for patients who request PA on the basis of any of the three cases mentioned in question 5 above. The procedural/administrative requirements for patients who seek PA according to Article 9 of Regulation no. 484/2016 are the same.	**Source(s):** Article 9(3) of Regulation no. 484/2016.	
10. Is there a specific PA form (i.e., form used for issuing/granting PA) and, if the answer is positive, what form?	**Answer:** No, there is not a specific PA form used for issuing/granting PA.	**Source(s):** No information available regarding this question.	
11. Please list any other administrative requirements in your country in relation to the PA procedure for cross-border healthcare.	**Answer:** None identified.	**Source(s):** Articles 5, 7-8 of Regulation no. 484/2016. The Administrative Procedures Act no. 37/1993.[413]	

[413] The Administrative Procedures Act no. 37/1993. Available in English at: https://www.legislationline.org/download/id/4753/file/Iceland_Administrative_Procedures_Act_1993_en.pdf, (last accessed 16 June 2021).

SECTION 2 REIMBURSMENT PROCEDURE(S)				
Questions	**Answer:**	**Sources**	**Does/do the identified requirement(s) also apply domestically? (i.e., is the requirement non-discriminatory?)**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to reimbursement procedures for cross-border healthcare under Directive 2011/24/EU?	**Answer:** Directive no. 2011/24/EU was implemented in Iceland with a bill to amend the Health Insurance Act no. 112/2008 and the Medicinal Products Act no. 93/1994 with subsequent amendments (EEA rules).[414] Article 23. a of the Health Insurance Act contains provisions on medical treatment abroad that can be provided in Iceland. Article 23. a (4) of the Health Insurance Act provides for an authorization for the respective minister, by means of a regulation, to stipulate in more detail the implementation of Article 23. a, e.g., when to	**Source(s):** Preparatory works to the amendment of the Health Insurance Act no. 112/2008 and the Medicinal Products Act no. 93/1994 with subsequent amendments (EEA rules), no. 13/2016.[417] Article 23. a of the Health Insurance Act.[418]	N/A	N/A

[414] https://www.althingi.is/altext/145/s/0244.html
[417] Frumvarp til laga um breytingu á lögum um sjúkratryggingar, nr. 112/2008, og lyfjalögum, nr. 93/1994, með síðari breytingum (EES-reglur). A bill no. 13/2016 to the amendment of the Health Insurance Act no. 112/2008 and the Medicinal Products Act no. 93/1994 with subsequent amendments (EEA rules). Author: Kristján Þór Júlíusson, Minister of Health. Date of adoption: 1 March 2016. https://www.althingi.is/altext/pdf/145/s/0244.pdf, page 2 (last accessed 16 June 2021).
[418] Lög um sjúkratryggingar, nr. 112/2008. The Health Insurance Act, no. 112/2008. Author: Guðlaugur Þór Þórðarson, Minister of Health. Date of adoption: 10 September 2008. https://www.althingi.is/lagas/151b/2008112.html, (last accessed 16 June 2021).

	apply for PA for reimbursement on the basis of the first paragraph of Article 23. a of the Health Insurance Act.[415] Articles 10-13 of Regulation no. 484/2016 lay out requirements related to reimbursement procedures for cross-border healthcare.[416]	Articles 10-13 of Regulation no. 484/2016.[419]		
2. Is this the same procedure as for reimbursement under the Social Security Coordination Regulations?	**Answer:** **Yes ☒ No ☐** The procedures are substantially the same (but the requirements are nonetheless different).		N/A	N/A
3. What body is/are responsible of handling the reimbursement applications? (e.g., where and to whom reimbursement applications have to be submitted?)	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* The IHI is also responsible of handling the reimbursement applications. I refer to the answer to question 3 in Section 1.	**Source(s):** Article 10 of Regulation no. 484/2016. The IHI's website.[420]	N/A	N/A

[415] Article 23. a (1) reads as follows: *If the health insured chooses to seek health care in another member state of the EEA Agreement, the health insurance reimburses the cost of the service as if it were health care within the country, provided that the service corresponds to the service that health insurance participates in paying in Iceland.*

[416] Available at: https://www.reglugerd.is/reglugerdir/eftir-raduneytum/velferdarraduneyti/nr/20127

[419] Reglugerð um heilbrigðisþjónustu sem sótt er innan aðildarríkis EES-samningsins en hægt er að veita hér á landi og um hlutverk innlends tengiliðar vegna heilbrigðisþjónustu yfir landamæri. Regulation no. 484/2016 of 1 June 2016 on Health Services applied for within the Member State of the EEA Agreement but can be Provided in Iceland and on the Role of a National Contact Person for Cross-Border Health Services. Author: Margrét Björnsdóttir, Ministry of Health. Date of adoption: 1 June 2016. https://www.reglugerd.is/reglugerdir/eftir-raduneytum/velferdarraduneyti/nr/20127, (last accessed 16 June 2021).

[420] Available at: https://www.sjukra.is/heilbrigdisthjonusta/rettindi-milli-landa/laeknismedferd-erlendis/langur-bidtimi-eftir-medferd-a-islandi/heilbrigdisthjonusta-yfir-landamaeri-innan-ees-landa/

	The IHI reimburses health insured persons in Iceland as if it were domestic health services covered by health insurance, provided that the service corresponds to the service provided in Iceland, and where applicable, subject to the conditions of Article 9 of Regulation no. 484/2016. As per the IHI's website, the application and documents (for reimbursement) can be submitted both in paper and electronically. A person seeking reimbursement can also submit the application through the IHI's web portal or the doctor's web portal as well as bring the application and documents to the IHI's service center every working day between 10-15. The IHI helps with filling out the application. For electronic submissions, an application and documents shall be sent to international@sjukra.is.			
4. Is there a specific application form/module which the person seeking reimbursement needs to submit?	**Answer:** *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?*	**Source(s):** Information provided in the application for reimbursement of medical cost abroad, provided on the IHI's website.[422]	**Yes** ☐ **No** ☒ IHI: Icelandic residents do not have to apply for reimbursement of domestic medical cost. That is the	Based on the Application for reimbursement of domestic medical cost[423], the exact same information is required except for the following information: Resident abroad ID number abroad Country of stay Travel period

[422] Available at: https://www.sjukra.is/heilbrigdisthjonusta/rettindi-milli-landa/umsoknir/
[423] Available at: https://www.sjukra.is/media/althjodadeild/Endurgreidsla_innlends_sjukrakostnadar.doc.

	- *Does the form have to be submitted in paper or can it be submitted electronically?* Yes, a form is available online.[421] The following information is required (needs to be provided in the application): ▪ Name ▪ ID number (icel. kennitala) ▪ Residence in Iceland ▪ Postal code ▪ Place ▪ Phone number ▪ Email ▪ Resident abroad ▪ ID number abroad ▪ Country of stay ▪ Travel period ▪ Reasons of stay o 'Getting medical treatment abroad' is one option. ▪ Further explanation of medical treatment abroad ▪ If the patient has applied for reimbursement at a private insurance company – if yes, with whom. If someone other than the patient is to receive the reimbursement, then a power of attorney must be submitted. If the patient is a child under 18 years old, then the child's guardian will receive the reimbursement. If this is the case, the following information is needed: ▪ Name ▪ ID number		main principle and therefore the submission of the application provided on the IHI's website, concerning reimbursement of domestic medical cost, is not necessary.	Reasons of stay 'Getting medical treatment abroad' is an option. Further explanation of medical treatment abroad If the patient has applied for reimbursement at a private insurance company – if yes, with whom".

[421] The form is available online at the following; https://www.sjukra.is/media/althjodadeild/Application-for-reimbursement-of-medical-cost-abroad.docx

	▪ Residence, postal code, place etc. ▪ Bank information (bank, hb., account number). The applicant is required to sign name, place, and date and by signature; the applicant also gives the Icelandic Health Insurance authority to obtain the necessary information from the National Registry, insurance companies and tax authorities. As per the IHI's website, the application and documents (for reimbursement) can be submitted both in paper and electronically			
5. What (other) documentation has to be submitted in order to substantiate a reimbursement request?	**Answer:** *If applicable, please specify:* - *What documents are required;* - *Whether the submission of the documentation is optional, mandatory, or recommended.* Besides the application module, medical bills and receipt of payment must be submitted in English with the application, as well as plane tickets to confirm periods of temporary stay. Specifically, the following documents must be received by the IHI in order to substantiate a reimbursement request: ▪ Invoice breakdown. The invoice shall be numbered and approved from the service provider's accounting system. ▪ Payment confirmation. ▪ Medical certificate (especially in the case of inpatient care).	**Source(s):** The IHI's website.[424] Article 10(2) of Regulation no. 484/2016.	**Yes** ☐ **No** ☒	

[424] Available at: https://www.sjukra.is/heilbrigdisthjonusta/rettindi-milli-landa/laeknismedferd-erlendis/langur-bidtimi-eftir-medferd-a-islandi/heilbrigdisthjonusta-yfir-landamaeri-innan-ees-landa/

	▪ Flight tickets – back and forth confirming temporary stay. Also, if health insurance co-payments in the cost of domestic healthcare are conditional upon other requirements (e.g., that a doctor's referral is required) the same conditions shall apply to reimbursement for services applied for in another state of the EEA Agreement, *cf. Article 10(2) of Regulation no. 484/2016.* Therefore, in some cases, a patient might need to seek a doctor's referral in order to receive reimbursement or meet other conditions required domestically in Iceland (the conditions are not specified further in the Article). The submission of the documentation is mandatory.			
6. Are there any costs associated with the handling of the reimbursement request? - *Direct costs (e.g., fixed costs for submitting or filing a reimbursement request, proportion deducted from the reimbursable amount).* - *Indirect costs* (*e.g., translations, stamps, etc).*	**Answer:** *Direct costs:* There is no direct cost associated with the handling of the reimbursement request. *Indirect costs:* The IHI may require the applicant for reimbursement of the cost of health care applied for in another EEA member state that the documents be in the language requested by the institution. Translation costs are paid by the applicant.	**Source(s):** The IHI's website.[425] Article 13 of Regulation no. 484/2016.	**Yes** ☐ **No** ☒ No documents are required for reimbursement for domestic medical healthcare.	

[425] Available at: https://www.sjukra.is/heilbrigdisthjonusta/rettindi-milli-landa/laeknismedferd-erlendis/langur-bidtimi-eftir-medferd-a-islandi/heilbrigdisthjonusta-yfir-landamaeri-innan-ees-landa/

7. Are there any specific time requirements linked to a reimbursement request? (*e.g., time within which the reimbursement requests must be submitted and/or time within the requested body must handle the request and/or reimburse the costs, etc.*).	**Answer:** *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* There seems to be no specific time requirements linked to a reimbursement request. However, claims for reimbursement are subject to limitation periods in accordance with the rules of Act no. 150/2007 of 20 December 2007 on the Limitation Periods for Claims (Act no. 150/2007). Article 3 of the Act no. 150/2007, which states that the general limitation period for claims shall be four years, applies to claims for reimbursement. The IHI is required to process applications for reimbursement as quickly as possible in accordance with the 'prompt handling' principle, set out in Article 9 of the Administrative Procedures Act. However, there is no specific time requirements in the application or elsewhere which obliges the IHI to process a reimbursement request within a certain time frame.	**Source(s):** Administrative Procedures Act no. 37/1993. Act no. 150/2007 on the Limitation Periods for Claims.[426]	**Yes** ☒ **No** ☐	
8. Are there any non-reimbursable thresholds,	**Answer:**	**Source(s):**	**Yes** ☒	

[426] Act No. 150/2007 on the limitation periods for claims, https://www.stjornarradid.is/media/atvinnuvegaraduneyti-media/media/acrobat/act-no.-150-2007-on-the-limitation-periods-for-claims.pdf, , (last accessed 16 June 2021).

	deductions *(except the deductions for administrative costs mentioned above) etc.?*	None identified. The IHI reimburses health insured persons in Iceland as if it were domestic health services covered by health insurance, provided that the service corresponds to the service provided in Iceland, and where applicable, subject to the conditions of Article 9 of Regulation no. 484/2016. Reimbursement of cost for provided health services is based on what the service would have cost in Iceland but shall not amount to more than the actual cost. No travel and subsistence expenses or escort expenses are paid by the IHI. It is also a condition that there is co-payment in Iceland for comparable services. [427] The IHI shall set out the same requirements for reimbursement of costs when healthcare is sought in another member state of the EEA Agreement as to those set out for services sought in Iceland, e.g., in terms of quality and security of services provided.	Articles 10(3-5) and 11(1-2) of Regulation no. 484/2016. Application for reimbursement of medical cost abroad.[428]	**No** ☐	
9.	**In instances where a PA (or prior-notification) has already been issued, is a separate/simplified procedure available for**	**Answer:** *If yes, please describe the simplified procedure.*	**Source(s):** Not mentioned in the Health Insurance Act, Regulation no.	**Yes** ☒ **No** ☐	

[427] The IHI may refuse to reimburse costs in the following cases: 1. When it is possible to provide health care in Iceland within a time limit that can be medically justified when the patient's health condition and probable disease progression are taken into account; 2. When the safety of the patient or the general public is endangered by healthcare provided on the basis of Article 2. 3. When there is reason to doubt that healthcare providers comply with minimum quality and safety requirements. When a refund is refused according to paragraph 1, the refusal shall be based on considerations of public interest, e.g., to ensure adequate and sustainable use of the infrastructure of the health system and the need to control costs. The applicant of reimbursement of medical cost abroad is responsible for ensuring that the information is true and correct (cf. Article 34(4) of the Health Insurance Act). Inadequate and incorrect disclosure can result in a reimbursement claim by the IHI as well as the payment of penalty interest (cf. Articles 34 and 37 of the Health Insurance Act).

[428] https://www.sjukra.is/heilbrigdisthjonusta/rettindi-milli-landa/umsoknir/

requesting reimbursement? **applicable only if the country has a PA system.*	None identified. There does not seem to be a separate/simplified procedure in instances where a PA has already been issued.	484/2016 nor the applicable applications.		
10. Are there additional administrative/procedural requirements for reimbursement depending on, for instance, the type of treatment for which reimbursement is requested, or the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* No specific differences or additional requirements identified. As described in the answer to question 5, different documents may be requested to substantiate the reimbursement request, to the extent that these documents constitute a condition for the co-payment of the health insurance in the cost of domestic healthcare (i.e., where they also are required domestically). Therefore, in some cases, a patient might need to seek for, for instance, a doctor's referral in order to receive reimbursement or meet other conditions required domestically in Iceland (the conditions are not specified further in the legislative sources consulted).	**Source(s):** The IHI's website.[429] Article 10(2) of Regulation no. 484/2016.	**Yes** ☐ **No** ☐	Note of the National authority: Everyone gets the same treatment. No criteria.
11. Please list any other administrative requirements in your country in relation to the	**Answer:** None identified.	**Source(s):**	**Yes** ☒ **No** ☐	

[429] https://www.sjukra.is/heilbrigdisthjonusta/rettindi-milli-landa/laeknismedferd-erlendis/langur-bidtimi-eftir-medferd-a-islandi/heilbrigdisthjonusta-yfir-landamaeri-innan-ees-landa/

procedures of reimbursement of cross-border healthcare.		Articles 5, 7-8 of Regulation no. 484/2016.[430] The Administrative Procedures Act no. 37/1993.[431]		

[430] https://www.stjornartidindi.is/DocumentActions.aspx?ActionType=Open&documentID=fbebb19e-0981-40cd-ae50-361d163c1f3d
[431] https://www.legislationline.org/download/id/4753/file/Iceland_Administrative_Procedures_Act_1993_en.pdf

Part 2: Checklist for verification with national/regional body

Name of the body: Icelandic Health Insurance
Country/Region: Iceland
Date of verification call: 7/07/2021

Template for the Data Collection	**Aspects to be verified** *Tick the boxes if the information in the template for the data collection has been verified and/or complemented by the national body*		**Comments** *Include any additional comments and/or information provided by the contacted body*
24. Section 1 – Prior Authorisation			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Justification/purpose of the identified requirement(s) (Column 4)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	The feedback received have been incorporated in the questionnaire.
25. Section 2 - Reimbursement			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Whether the requirement applies domestically (Discriminatory assessment) (Column 4) ▪ Justification/purpose of the identified requirement(s) (Column 5)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	The feedback received have been incorporated in the questionnaire.

IRELAND – COUNTRY REPORT

1. **Please indicate whether the rules governing the administrative procedures/requirements for requesting PA and reimbursement under Directive 2011/24/EU in your country are set out at:**

A. National level ☒

B. Decentralised/regional/local level ☐

In case (1.B): Please indicate the two most relevant jurisdictions in your country (i.e., in terms of population):

Region/jurisdiction: 1: N/A

Region/jurisdiction 2: N/A

NOTE: In case (1.B) the template for the data collection (Part 1) should be completed twice, once for each of the two most relevant regions/jurisdiction indicated above.

2. **Please indicate the national body best suited to verify the accuracy of the information collected in Part 1, and justify your selection.**

Depending on the characteristics of your national healthcare system, the relevant body may be: a) *the national social security body*; or b) *an insurance fund*. In the latter case, please indicate the most representative fund (e.g., the one with the highest number of affiliations).

Body to be contacted for Task 2: Department of Social Protection. *Áras Mhic Dhiarmada, Store Street, Dublin 1, D01 WY03.*

Reasons for Selection: This is the national social security body in Ireland.

Part 1: Questionnaire

*__Note 1__: In cases where administrative requirements are set out in the legislative/regulatory framework at decentralised/regional/local level, please complete the template for the data collection twice, once for each of the two most relevant regions/jurisdictions (e.g., in terms population).

__*Note 2__: Setting out a Prior Authorisation (PA) system is optional for Member States. Should your country not have a system of PA in place under Directive 2011/24/EU, Section 1 will not need to be completed.

SECTION 1 PRIOR AUTHORISATION PROCEDURE(S)			
Questions	**Answer**	**Sources**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to PA procedures for a cross-border healthcare under Directive 2011/24/EU?	**Answer:** The national legislative provision in Ireland that lays out the requirements related to PA procedures is: **Regulation 12 of S.I. No. 203/2014** - European Union (Application of Patients' Rights in Cross-Border Healthcare) Regulations 2014. *(1) The Health Service Executive **may specify particular cross-border healthcare** to be subject to prior*	**Source(s):** S.I. No. 203/2014 - European Union (Application of Patients' Rights in Cross-Border Healthcare) Regulations 2014.[435] HSE, 'Cross-Border Directive: get healthcare abroad' (November 2018).[436]	N/A

[435] S.I. No. 203/2014 - European Union (Application of Patients' Rights in Cross-Border Healthcare) Regulations 2014, "*Iris Oifigiúil*" of 16th May 2014, available at: http://www.irishstatutebook.ie/eli/2014/si/203/made/en/print (last accessed 8 June 2021).
[436] HSE, 'Cross-Border Directive: get healthcare abroad' (November 2018), available at: https://www2.hse.ie/services/cross-border-directive/about-the-cross-border-directive.html (last accessed 8 June 2021).

	authorisation in order to be eligible for reimbursement under Regulation 10, where it considers that the healthcare— *(a) involves planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the State, or the wish to control costs or avoid, as far as possible, any waste of financial, technical and human resources, and—* *(i)involves overnight hospital accommodation of the insured person for at least one night, or* *(ii) requires the use of highly specialised and cost-intensive medical infrastructure or medical equipment,* *(b) involves treatments presenting a particular risk for a patient, or,* *(c) is provided by a healthcare provider that, on a case-by-case basis, could give rise to serious and specific concerns relating to the quality or safety of the care, with the exception of healthcare which is subject to European Union legislation ensuring a minimum level of safety and quality throughout the European Union.* *(2) Where a patient resident in the State is seeking to be provided with cross-border*	Prior Authorisation Application Form of the Health Service Executive Cross-Border Healthcare Directive[437]:	

[437] Available at: https://www2.hse.ie/file-library/cross-border-directive/cbd-application-for-prior-authorisation.pdf (last accessed 07/07/2021).

	healthcare in another Member State which is specified under paragraph (1) as being subject to prior authorisation from the Health Service Executive, he or she shall not be entitled to reimbursement under Regulation 10 unless he or she applies for, and is granted, prior authorisation from the Health Service Executive under this Regulation. *(3) The Health Service Executive shall decide and make available the form in which an application for prior authorisation must be made, and the information which must be provided in support of such an application.* *(4) Subject to subsection (5), the Health Service Executive shall grant prior authorisation for reimbursement in respect of the costs of cross-border healthcare to be provided to a patient resident in the State where the healthcare is specified under paragraph (1) as being subject to prior authorisation and the Health Service Executive is satisfied that—* *(a) the patient concerned is entitled under the Health Acts 1970 to 2013 (as amended) to the requested healthcare,* *(b) the requested healthcare is necessary to treat or diagnose a medical condition of the patient resident in the State, and* *(c) the requested healthcare is the same as, or equivalent to, healthcare that would have been made available to the patient in the State, in the particular circumstances of the patient.*		

	(5) The Health Service Executive may refuse to grant prior authorisation under this Regulation where it considers that— *(a) the patient will, according to a clinical evaluation, be exposed with reasonable certainty to a patient-safety risk that cannot be regarded as acceptable, taking into account the potential benefit for the person of the sought cross-border healthcare,* *(b) the general public will be exposed with reasonable certainty to a substantial safety hazard as a result of the cross-border healthcare in question,* *(c) the healthcare is to be provided by a healthcare provider that raises serious and specific concerns relating to the respect of standards and guidelines on quality of care and patient safety, including provisions on supervision, whether these standards and guidelines are laid down by laws and regulations or through accreditation systems established by the Member State of treatment, or* *(d) the Health Service Executive can provide healthcare that is the same as, or equivalent to, the healthcare sought by the patient within a time limit which is medically justifiable, taking into account the patient's current state of health at the time the decision under this Regulation is taken and*		

	the probable course of the medical condition to which the healthcare relates. *(6) Without prejudice to paragraph (5)(a) to (c), the Health Service Executive may not refuse to grant prior authorisation under this Regulation when the patient would otherwise be entitled to reimbursement for the healthcare in question in accordance with Regulation 10, and when the healthcare cannot be provided in the State within a time limit which is medically justifiable, based on an objective medical assessment of any or all of the following:* *(a) the insured person's medical condition;* *(b) the history and probable course of the insured person's illness;* *(c) the degree of the insured person's pain; and* *(d) the nature of the insured person's disability at the time when the request for authorisation is made or renewed.* *(7) When a patient affected, or suspected of being affected, by a rare disease, as referred to in the Directive, applies for prior authorisation under this Regulation, the Health Service Executive may require a clinical evaluation of the patient to be carried out by experts in that field in order to assist it in making a decision under this Regulation as to whether or not to grant prior authorisation.* *(8) Where an expert referred to in paragraph (7) cannot be found in the State or the expert's opinion is inconclusive, the Health Service Executive may request*		

	scientific advice in order to assist it in making a decision under this Regulation as to whether or not to grant prior authorisation. The Guidance, as provided on the HSE's website at 'Cross-Border Directive: get healthcare abroad', provides that: Healthcare must be planned. Patients need a valid referral and must qualify for healthcare as a public patient in Ireland. Once a patient goes abroad, they must pay for any healthcare that they get. This is then refunded under the Cross-Border Directive by applying to the HSE for reimbursement towards the cost of the healthcare. Patient's cannot claim reimbursement for the cost of any medicine needed afterwards or any travel costs. To get healthcare abroad and be refunded, a patient must: - Be ordinarily resident in Ireland;[432] - Be entitled to public healthcare in Ireland; - Not be in receipt of any state benefit from another EU or EEA member state; - Travel abroad for the healthcare; - Have a referral for public healthcare from a GP or hospital consultant in Ireland; - Provide a copy of a letter of referral or a letter from a hospital to say you're on a waiting list in Ireland; - Apply for repayment towards the cost of your healthcare abroad, after you have paid for it.		

[432] To be 'ordinarily resident' in Ireland, you must be prove that you've been living in Ireland for at least one year or can prove your intention to remain in Ireland for at least one year.

	Patients cannot use telemedicine[433] at any time during the process. This includes their outpatient appointment. (See answers to questions below for further information). **NOTE:** it should be noted that according to the information included in the Prior Authorisation Application Form of the Health Service Executive Cross-Border Healthcare Directive[434]: **"Prior Authorisation is optional but recommended". However, no further specification is provided in relation to the reasons and/or specific treatments for which it is recommended (and not mandatory), nor on the consequences for patients who do not apply for optional PA. Nonetheless, shall patients apply for PA, it appears that they must follow the procedure outlined in the present section of this report. Patients are also invited to contact the NCP to find out whether they should file a PA request in advance.**		
2. Is this the same procedure as for PA under the Social Security Coordination Regulations?	**Answer:** **Yes ☐ No ☒** Based on the main differences between the two, the system of PA in Ireland is in line with that of Directive 2011/24/EU instead of Regulation (EC) No 883/2004. This is because prior authorisation is optional and is not required as it would be under Regulation (EC) No 883/2004. This can be seen from Regulation 12 of S.I. No. 203/2014 - European Union (Application of Patients'		N/A

[433] Telemedicine is when you get a diagnosis, treatment or consultation using telecommunications technology.
[434] Available at: https://www2.hse.ie/file-library/cross-border-directive/cbd-application-for-prior-authorisation.pdf (last accessed 07/07/2021).

	Rights in Cross-Border Healthcare) Regulations 2014. Furthermore, the healthcare available under prior authorisation is not limited to those affiliated with the health system of the country of treatment and may be provided by public or private healthcare providers. It is not the same body that deals with both. The HSE Cross-Border Directive deals with those claims under Directive 2011/24/EU, while the Department of Social Protection deals with those procedures in Regulation (EC) No 883/2004.		
3. What body is in charge of handling the PA applications? *(e.g., where and to whom PA applications have to be submitted?)*	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations)* The Health Service Executive (HSE). These applications are to be submitted to the same NCP, established by HSE, as identified in Part 0, Question 2. Regulation 12(3) of S.I. No. 203/2014 maintains 'The Health Service Executive shall decide and make available the form in which an application for prior authorisation must be made, and the information which must be provided in support of such an application.'	**Source(s):** See: S.I. No. 203/2014 - European Union (Application of Patients' Rights in Cross-Border Healthcare) Regulations 2014. See also: Health Service Executive, 'Health Service Executive Cross-Border Healthcare Directive: Prior Authorisation Application Form.[438]	N/A

[438] Available at: https://www2.hse.ie/file-library/cross-border-directive/cbd-application-for-prior-authorisation.pdf (last accessed 8 June 2021).

4. Who is entitled to apply for PA? *(e.g., can the patients apply themselves, or is treating doctor filing/partially filling the request, etc.)*	**Answer:** - *If there is a national doctor involved, is there a requirement that this doctor is contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA?* The patient is entitled to apply for PA. A doctor must fill in part of the application form (i.e., Section A of the PA form must be completed by the patient, whilst Section B must be completed by the referring doctor). However, the doctor is not directly entitled to apply. See information provided in the answer to question 5 below.	**Source(s):** S.I. No. 203/2014 - European Union (Application of Patients' Rights in Cross-Border Healthcare) Regulations 2014. HSE, 'Cross-Border Directive: get healthcare abroad' (November 2018).	The care pathway that applies in Ireland, equally applies to any cross-border healthcare. **Additional information from the Irish NCP:** [439] Optional prior authorisation is designed to protect the patient as follows: •Gives the patient confidence he/she has followed public patient pathways and will be eligible for reimbursement. •Requires the provider abroad to indicate the cost that will be charged and identify the DRG so the patient also knows the reimbursement rate associated with that DRG. • Allows patients who have not followed public patient pathway to restart the process before they have committed large amounts of money for which they would not be eligible for reimbursement. • There is no obligation on the patient to use PA therefore no consequences concerning reimbursement entitlement. If the patient has not used PA, they are still entitled to reimbursement if they have followed the correct patient pathway. In Ireland patients must have a GP referral and a specialist consultation in person in order to be eligible for reimbursement. This is often not the case in other countries, so by using PA the patient can ensure he/she is entitled to reimbursement.
5. Is there a specific application form/module which	**Answer:**	**Source(s):**	These forms contain all of the information that are needed to confirm prior authorisation to a patient.

[439] This additional information was provided to Spark Legal Network by the Irish NCP on 1/10/2021.

the person seeking PA needs to submit?	*If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?* **Preliminary note:** Prior authorisation is optional but recommended for all inpatient healthcare abroad under the CBD**.** According to the information provided in the application form of the HSE: "Prior authorisation was introduced so that: • A patient can ensure he/she is compliant with public patient pathways and the necessary care requirement prior to incurring costs and thus make sure he/she will be eligible for reimbursement. • A patient can ensure he/she knows the costs and reimbursement of proposed healthcare prior to committing to expensive inpatient healthcare abroad. • A patient will have a cooling off period between his/her outpatient consultation and proceeding with inpatient care abroad	Health Service Executive, 'Health Service Executive Cross-Border Healthcare Directive: Prior Authorisation Application Form'.	**Additional information from the Irish NCP:** [440] • Ireland requires the provider/doctor abroad to indicate the cost that will be charged and identify the DRG, so the patient also knows the reimbursement rate associated with that DRG. This is to the patient's advantage (See also the additional information from the NCP above – question 4). • The context of the PA must be understood before making assertions that this should not apply to specialist doctors. Ireland accepts referrals submitted by a GP in Ireland or abroad, but it is only a specialist doctor who knows the treatment he/she is going to provide who can assist the patient with the optional PA.

[440] This additional information was provided to Spark Legal Network by the Irish NCP on 1/10/2021.

	If PA is requested, yes, there is a specific module. It is worth noting that the form itself is optional, however, if applying for prior authorisation, the form must be submitted as this information is necessary to process the request. This needs to be submitted to the NCP (HSE Cross Border Directive). This can be submitted by post or by e-mail. The patient/applicant must submit a fully completed application form accompanied by the appropriate referral letter, proof of travel abroad, and confirmation of the outpatient consultation which will be the basis of demonstrating necessary care. All parts of Section A must be complete; if a question is not relevant, it must be marked N/A. If a person is under 18 years of age or incapacitated, the application may be submitted on their behalf by a Parent/Guardian/Spouse/Partner. Section A requests the following information: - Patient details: name; address date of birth; mobile number; telephone number; personal public service number; medical card number (photocopy also); name of private health insurance company; membership number; have you applied to your health insurance company for funding?; if yes, has funding been approved by your health insurance company? Please submit a copy of the decision letter with your application. - GP's details: Name of patient's GP; GP's address; GP's telephone number.		

	- Parent/Guardian details (only complete the next section if you are making an application on behalf of a patient under 18 years of age or over 18 years of age and dependent): relationship to parent; address; name; telephone number; mobile number; name of private health insurance company; membership number; have you applied to your health insurance company for funding?; if yes, has funding been approved by your health insurance company? Please submit a copy of the decision letter with your application. - Please confirm the reason why you are/the patient is opting to travel abroad? (This information has no bearing on the application decision, it is just for the purposes of information on the reason why patients are opting for care under the CBD): o Length of wait for the treatment in Ireland; o Quality of the service abroad; o Proximity to my place of residence; o Other (if other, please provide details). Once Section A is complete, the applicant should present the application to their treating consultant to fully complete Section B. A copy of the original referral letter by which the patient accessed the assessment from the consultant should be submitted with this application form.		

	Section B must be completed in full by the treating consultant with the following information: - Details of Healthcare provider abroad (Name of Treating Consultant and Treating Hospital). - Name and date of birth of the patient; - Indication of whether the patient is attending the doctor in public or private capacity - Proposed Treatment - DRG Code of the proposed provider; - Summary of the condition from which the patient suffers: - Certification of the specific treatment that the patient requires outside the state; - Answers to the following questions (Yes/NO) *i. Is this treatment available within the State? (Only treatments that are available within the State qualify for reimbursement under the CBD.)* *ii. Is the patient currently receiving this treatment in Ireland?* *iii. Is the treatment medically necessary?* *iv. Will the treatment meet the patient's needs?* *v. Is this treatment contrary to the Irish Constitution or any legislation to your knowledge?* *vi. Is the treatment regarded as a proven form of medical attention and not experimental or test treatment?* *vii. Is the treatment required as a result of injuries received in a road traffic accident or other accidental injury?*		

	viii. *Does the proposed healthcare pose any public health risks for the patient and/or the public in general?* *(if yes, provision of further details)* - Name of accepting consultant (outside the State if different from the treating consultant): - Name of accepting hospital (outside the State if different from the treating consultant) - Indication of whether: i. *The treatment abroad is being provided in a recognised hospital or other institution which is under the control of a Registered Medical Practitioner?* ii. *That hospital a public hospital available to National Health Agencies for Public Patients in that country.* - Confirmed cost of treatment; - Date of Admission (if known); - Probable duration of stay; - Probable date(s) of Out-Patient Department visit(s); When the application form has been fully completed, it has to be returned completed with the referring clinician's letter of referral to the competent body (see documentation requested in the answer to question 6 below). The application will be assessed and a decision will be issued within 15 to 20 working days or as soon as possible thereafter.		

6. What (other) documentation has to be submitted in order to substantiate a PA request?	**Answer:** *If applicable, please specify:* - *What documents and what particulars are required;* - *Whether there are requirements as to who has to issue the documents (e. g., a doctor contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA or any doctor);* - *Whether the submission of the documentation is optional, mandatory, or recommended.* Besides the application form duly completed (Section A and Section B), the following documentation is mandatory to substantiate a PA request: ○ A valid referral letter* issued prior to and for the purpose of accessing the healthcare in question OR a copy of waiting list letter for a public hospital in Ireland. (*See below for clarification on a valid referral letter). ○ Evidence of the outpatient consultation with the consultant abroad OR a consultant treating the patient in a public capacity in Ireland at which the recommendation of inpatient care was determined. ○ A fully completed Application Form (Green in colour)	**Source(s):** Health Service Executive, 'Health Service Executive Cross-Border Healthcare Directive: Prior Authorisation Application Form'.	With regard to 'proof of travel', there were previously instances of consultants maintaining they had seen patients in their country, when they had not. **Additional information from the Irish NCP:** [441] With regards to 'proof of travel': according to the NCP, the collection of proof of travel should not be regarded as disproportionate: the Directive is based on the patient travelling to another EU/EEA state to access the care. According to the same NCP, the collection of evidence that the patient did travel to the other State is proportionate with this provision. With regards to information on the availability of the healthcare and/or the waiting time/list for the service: it should be noted that this information is not collected for any purpose, only for office use **as stated on the PA form**. The reason we collect this information is so that we can understand the reasons why patients are using the Directive. It has no bearing on any decision and is not used as a determining factor in relation to waiting time. Waiting time is not used as a determining factor. The only determining factor for eligibility in Ireland is residency and compliance with public patient pathways. Therefore, many patients using the Directive are not on waiting lists at all and used the Directive to avoid waiting lists.

[441] This additional information was provided to Spark Legal Network by the Irish NCP on 1/10/2021.

	○ Proof of travel abroad (e.g. flight/ferry tickets, accommodation in patients/applicants name, toll/parking charges or a till receipt from a shop in the locality). <u>More in detail:</u> **1.** *A valid GP/consultant (public) letter of referral: *a. Pre-dating your consultation abroad;* *b. To a name consultant;* *c. Addressed to a specific hospital;* *d. Signed by your GP/consultant (public)* **<u>OR</u>** **2.** A waiting list letter confirming that you are on a public waiting list in Ireland at the time of your consultation abroad. **3.** Evidence of your initial outpatient consultation with your treating clinician abroad on a date prior to your admission. *a. An invoice and receipt from your initial consultation;* <u>OR</u> *b. A medical report which includes the date of your initial consultation.* ➔ Proof of an initial consultation is not required where a person has already attended their public consultant in Ireland and subsequently been placed on an inpatient/day case treatment waiting list and where this waiting list letter is being submitted as your		

	path of referral for your treatment abroad.		
7. Are there any costs associated with the handling of the PA request? - *Direct costs (e.g., fixed costs for submitting or filing a PA request).* - *Indirect costs* (*e.g., translations, stamps, etc).*	**Answer:** *Direct costs:* There do not seem to be any direct costs. *Indirect costs:* If the application form is not completed in English the patient/applicant will be required to provide a certified translation at his/her own cost.	**Source(s):** Health Service Executive, 'Health Service Executive Cross-Border Healthcare Directive: Prior Authorisation Application Form.	With regard to 'proof of travel', there were previously instances of consultants maintaining they had seen patients in their country, when they had not. The Cross-Border Directive does not cover any translation costs. **Additional information from the Irish NCP:** [442] According to the NCP, the requiring certified translations is not disproportionate. The documents in question are medical documents and it would be dangerous for translations to be carried out by unqualified personnel. It should further be noted that certified translations have only ever been requested where the documentation is such that it cannot easily be understood or is so voluminous that tools like Google Translate are not appropriate. The occasions where certified translations have been requested do not total any more than approximately 10 since 2014.
8. Are there any specific **time requirements** linked to a PA request? (*e.g., time within which a requesting person must submit the PA application and/or time within which the requested body must take a decision on the PA request, etc.*).	**Answer:** - *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* There do not seem to be any explicit time requirements for the patients. According to the information provided in the HSE Application Form (page 1): "Valid	**Source(s):** HSE, 'Cross-Border Directive: get healthcare abroad' (November 2018). Health Service Executive, 'Health Service Executive Cross-Border Healthcare	The lack of time requirements for the patient to apply aims at allowing someone to still claim, even if they were unaware of the Directive at the time. Furthermore, under the Directive, there is no reference of time limits.

[442] This additional information was provided to Spark Legal Network by the Irish NCP on 1/10/2021.

	applications will be processed within 15-20 working days and a decision will be issued via letter". No specific consequences identified.	Directive: Prior Authorisation Application Form'.	
9. Are there **differences in the procedural/administrative requirements for requesting PA** based on, for instance, the type of treatment for which PA is requested, the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* No specific differences identified.	**Source(s):** HSE, 'Cross-Border Directive: get healthcare abroad' (November 2018).	N/A
10. Is there a specific PA form (i.e., form used for issuing/granting PA) and, if the answer is positive, what form?	**Answer:** Though PA form exists for requesting PA, according to the information provided in the HSE Application Form (page 1): "a decision will be issued via letter".	**Source(s):** Health Service Executive, 'Health Service Executive Cross-Border Healthcare Directive: Prior Authorisation Application Form'.	N/A
11. Please list any other administrative requirements in your country in relation to the PA procedure for cross-border healthcare.	**Answer:** No specific administrative requirement. However, it is worth noting that Consultants referring pediatric patients abroad must be satisfied as to the compliance of the service abroad with Children First guidelines and legislation. The services which they are referring must be in line with the Geneva Convention on the Rights of the Child.	**Source(s):** Health Service Executive, 'Health Service Executive Cross-Border Healthcare Directive: Prior Authorisation Application Form'.	N/A

SECTION 2 REIMBURSMENT PROCEDURE(S)				
Questions	**Answer:**	**Sources**	**Does/do the identified requirement(s) also apply domestically?** **(i.e., is the requirement non-discriminatory?)**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to reimbursement procedures for cross-border healthcare under Directive 2011/24/EU?	**Answer:** Regulations 10 and 11 of S.I. No. 203/2014 – European Union (Application of Patients' Rights in Cross-Border Healthcare) Regulations 2014. Regulation 10 focuses on the reimbursement of costs of treatment. *(1) Subject to the provisions of this Regulation and Regulation 11, and without prejudice to Regulation 883/2004, the Health Service Executive shall, on application by the person concerned, reimburse a patient resident in the State, in an amount determined in accordance with paragraph (4), in respect of expenditure he or she has incurred in relation to the provision, by a healthcare provider in a Member State other than the*	**Source(s):** S.I. No. 203/2014 - European Union (Application of Patients' Rights in Cross-Border Healthcare) Regulations 2014.[443]	N/A	N/A

[443] S.I. No. 203/2014 - European Union (Application of Patients' Rights in Cross-Border Healthcare) Regulations 2014, "*Iris Oifigiúil*" of 16th May 2014, available at: http://www.irishstatutebook.ie/eli/2014/si/203/made/en/print (last accessed 8 June 2021), Regulations 10 and 11.

	State, of cross-border healthcare which qualifies in accordance with paragraph (2). *(2) Cross-border healthcare qualifies for the purpose of paragraph (1) where the Health Service Executive is satisfied that—* *(a) the patient was entitled under the Health Acts 1970 to 2013 (as amended) to the healthcare in question,* *(b) the healthcare was necessary to treat or diagnose a medical condition of the patient,* *(c) the healthcare was the same as, or equivalent to, healthcare that would have been made available to the patient in the State, in the particular circumstances of the patient,* *(d) the healthcare has not been excluded under Regulation 11, and* *(e) where required, the Health Service executive granted prior authorisation in accordance with Regulation 12.* *(3) A patient seeking reimbursement under paragraph (1) shall provide to the Health Service Executive such evidence as the Health Service Executive considers necessary for it to establish the entitlement of the patient to the reimbursement, prior to the Health Service Executive making a reimbursement for any expenditure.* *(4) The level of expenditure that shall be reimbursed under paragraph (1), shall be*			

	the cost of treatment incurred by the patient in respect of qualifying cross-border healthcare or the cost of providing such healthcare in the State by the Health Service Executive, as determined by the Health Service Executive, whichever is the lesser. *(5) Paragraph (1) does not apply in circumstances where Article 20 or 27(3) of Regulation 883/2004 applies.* *(6) The Health Service Executive may impose on patients seeking reimbursement of the costs of cross-border healthcare under this Regulation, including healthcare received through means of telemedicine, the same conditions, criteria of eligibility and regulatory and administrative formalities as it would impose if the healthcare in respect of which reimbursement is sought was provided in the State, including an assessment by a health professional or healthcare administrator providing services for the statutory health system of the State, such as a general practitioner or primary care practitioner, if this is necessary for determining the patient's entitlement to healthcare.* *(7) Notwithstanding paragraph (6), the Health Service Executive shall not, unless it is objectively justified by planning requirements relating to—* *(a) the object of ensuring sufficient and permanent access to a balanced range of high quality treatment in the State, or* *(b) the wish to control costs or avoid, as far as possible, any waste of*			

	financial, technical and human resources, *impose other conditions, criteria of eligibility or regulatory and administrative formalities that are discriminatory or constitute an obstacle to the free movement of patients, services or goods.* *(8) The Health Service Executive shall not make the reimbursement of the costs of cross-border healthcare under this Regulation subject to prior authorisation, except where it has been made subject to prior authorisation under Regulation 12.* *(9) The Health Service Executive may deduct from any reimbursement made under this Regulation the amount of any charge which would have been payable by the patient resident in the State for the same or equivalent healthcare if that healthcare had been made available by, or on behalf of, the Health Service Executive in the State.* While, Regulation 11 focuses on exclusions of cross-border healthcare from reimbursement. *(1) Subject to this Regulation, the Health Service Executive may exclude certain cross-border healthcare from reimbursement under Regulation 10 based on overriding reasons of general interest, such as such as—* *(a) planning requirements relating to the aim of ensuring sufficient and permanent access to a balanced*			

	range of high quality treatment in the State, or *(b) the wish to control costs, or to avoid, as far as possible, any waste of financial, technical and human resources.* *(2) Any decision by the Health Service Executive to exclude cross-border healthcare under paragraph (1) shall be limited to what is necessary and proportionate and may not constitute a means of arbitrary discrimination or an unjustified obstacle to the free movement of goods, persons or services.* (3) *The Health Service Executive shall notify the Minister within 15 days of a decision under paragraph (1) to exclude cross-border healthcare from reimbursement, in order that the Minister may notify the European Commission of such decision in accordance with Article 11(7) of the Directive.*			
2. Is this the same procedure as for reimbursement under the Social Security Coordination Regulations?	**Answer:** **Yes ☐ No ☒** Based on the main differences between the two, the system of PA in Ireland is in line with that of Directive 2011/24/EU instead of Regulation (EC) No 883/2004. This is because the direct costs for the treatment are not required up front, but rather are anticipated and reimbursed later. This can be seen from Regulation 10 of S.I. No. 203/2014 - European Union (Application of Patients' Rights in Cross-Border Healthcare) Regulations 2014. It is not the same body that deals with both. The HSE Cross-Border Directive deals with those claims under Directive 2011/24/EU, while the		N/A	N/A

	Department of Social Protection deals with those procedures in Regulation (EC) No 883/2004.			
3. What body is/are responsible of handling the reimbursement applications? (e.g., where and to whom reimbursement applications have to be submitted?)	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* Health Service Executive (HSE). These applications are to be submitted to the same NCP, established by HSE, as identified in Part 0, Question 2. See: **Regulation 10(1)** of S.I. 203/2014, which provides: *"Subject to the provisions of this Regulation and Regulation 11, and without prejudice to Regulation 883/2004, the Health Service Executive shall, on application by the person concerned, reimburse a patient resident in the State, in an amount determined in accordance with paragraph (4), in respect of expenditure he or she has incurred in relation to the provision, by a healthcare provider in a Member State other than the State, of cross-border healthcare which qualifies in accordance with paragraph (2)."*	**Source(s):** S.I. No. 203/2014 - European Union (Application of Patients' Rights in Cross-Border Healthcare) Regulations 2014.	N/A	N/A

	Regulation 11(1) of S.I. 203/2014, which provides: *"Subject to this Regulation, the Health Service Executive may exclude certain cross-border healthcare from reimbursement under Regulation 10 based on overriding reasons of general interest […]"* It is worth noting that these Regulations (10 & 11) are exclusively addressed to the Health Service Executive and, therefore, this is evidently the body responsible for these applications.			
4. Is there a specific application form/module which the person seeking reimbursement needs to submit?	**Answer:** *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?* A pro-forma invoice template exists and is available on the HSE website. Submitting a 'Pro-Forma Invoice' is optional. However, the form contains the minimum data set necessary for processing a reimbursement request.	**Source(s):** S.I. No. 203/2014 - European Union (Application of Patients' Rights in Cross-Border Healthcare) Regulations 2014. Health Service Executive, 'Health Service Executive Cross-Border Healthcare Directive: Pro-Forma Invoice', available at: https://www2.hse.ie/file-library/cross-border-directive/cross-border-directive-pro-forma-invoice.pdf.	**Yes** ☐ **No** ☒ There is no need at the domestic level for those living in Ireland to be reimbursed for healthcare. This is because it is a tax-based system of public healthcare. Therefore, those resident in Ireland are not required to pay for their healthcare and, thus, would not be reimbursed for this either.	N/A

	It can be seen from Regulation 10(3) of S.I. 203/2014 that: *"A patient seeking reimbursement under paragraph (1) shall provide to the Health Service Executive such evidence as the Health Service Executive considers necessary for it to establish the entitlement of the patient to the reimbursement, prior to the Health Service Executive making a reimbursement for any expenditure."* To claim reimbursement in respect of CBD healthcare, the documentation outlined in the answer to question 6 below must be provided and, thus, is mandatory (this with the exception of the **pro-forma invoice**, which is optional but contains the data necessary to process a reimbursement claim and, therefore, even if the form is not submitted, the information contained in it will be requested in general). The pro-forma invoice form is available online and can be submitted by post or by e-mail to the HSE Cross Border Directive office (see NCP as provided in Task 0, Question 2). Note that if applying by email, the HSE may ask for copies of the documents provided if their legitimacy is doubtful. The following elaborates on the sections provided in this form:			

	Section A must be fully completed and if a question is not relevant, it must be marked as 'N/A'. If a patient is under 18 years of age or is incapacitated, the form may be submitted by a Parent/Guardian/Spouse/Partner. Patients seeking reimbursement for inpatient care or day case treatment abroad must provide evidence of assessment at an outpatient consultation on a date prior to the date of admission for the inpatient or day case treatment, either with the consultant abroad or with a consultant treating the patient in a public capacity in Ireland. **Section B** has to be fully completed by the patient's/applicants treating clinician. This must be accompanied by a copy of the detailed clinical referral letter from the referring clinician to the accepting clinician, outlining details and history of the patient's condition and the type of treatment envisaged. In the case of a reimbursement for inpatient or day case treatment evidence of the outpatient consultation which took place on a date prior to the inpatient or day case procedure and at which the medical necessity was determined must also be included for the purposes of reimbursement. Please note that the detailed information requested in Section B corresponds to that in the PA request (see Section 1).			
5. What (other) documentation has to be submitted in order	**Answer:**	**Source(s):**	**Yes** ☐	N/A

to substantiate a reimbursement request?	*If applicable, please specify:* - *What documents are required;* - *Whether the submission of the documentation is optional, mandatory, or recommended.* To claim reimbursement in respect of CBD healthcare, the documentation outlined in the list below must be provided and, thus, is mandatory (this with the exception of the **pro-forma invoice**, which is optional but contains the data necessary to process a reimbursement claim and, therefore, <u>even if the form is not submitted, the information contained in it will be requested in general</u>). o A valid path of referral i.e. a referral letter* OR a copy of a waiting list letter for a public hospital in Ireland if same has not already been provided at prior authorisation stage. *See below for clarification on a valid referral letter. o A fully completed Pro Forma Invoice** form (Pink in colour) in English only (optional) o The original invoice from the healthcare provider abroad. o The original receipt of payment from the healthcare provider abroad. o Proof of your payment of your healthcare costs e.g. Bank transfer, Credit Card Payment (statement) o Proof of travel abroad e.g. flight/ferry tickets, accommodation receipts in patients/applicants	Health Service Executive, 'Health Service Executive Cross-Border Healthcare Directive: Pro-Forma Invoice'.	**No ☒** There is no need at the domestic level for those living in Ireland to be reimbursed for healthcare. This is because it is a tax-based system of public healthcare. Therefore, those resident in Ireland are not required to pay for their healthcare and, thus, would not be reimbursed for this either.	

	name, toll/parking charges or a till receipt from a shop in the locality. More specifically, the documents are outlined as follows in the application form: **1.** *Path of referral: ○ A valid GP/Consultant (public) letter of referral: i. Pre-dating your consultation abroad; ii. To a name consultant abroad; iii. Addressed to the treating hospital abroad; iv. Signed by your GP/consultant (public). OR ○ A waiting list letter from a public hospital in Ireland (confirming that you are on the public waiting list in Ireland and the time of your consultation abroad) **2.** **Pro-forma invoice (Pink Form) (optional but recommended) a. Section A completed in full by applicant b. Section B completed in full by your treating consultant/clinician abroad. **3.** Invoice(s) for healthcare subject to claim for reimbursement.			

	4. Receipt(s) for each invoice submitted subject to claim for reimbursement. **5.** Proof of your payment of your healthcare costs. **6.** Proof of travel a. Flight/ferry tickets, accommodation receipts, toll/parking charges or till receipt from shop. **7.** Evidence of your initial outpatient consultation with your treating clinician abroad on a date prior to your admission. *a. An invoice & receipt from your initial consultation* b. *A medical report which includes the date of your initial consultation*. ➔ Proof of an initial consultation is not required where a person has already been assessed by their public consultant in Ireland and subsequently been placed on an inpatient treatment waiting list and where this waiting list letter is being submitted as your path of referral for your treatmentabroad. The initial consultation or outpatient consultation must pre-date any inpatient or day case treatment. **8.** Medical Card Details (photocopy of the medical card). a.			

6. Are there any costs associated with the handling of the reimbursement request? - *Direct costs (e.g., fixed costs for submitting or filing a reimbursement request, proportion deducted from the reimbursable amount).* - *Indirect costs (e.g., translations, stamps, etc).*	**Answer:** *Direct costs:* There do not seem to be any direct costs to be submitted for filing a reimbursement request. *Indirect costs:* Translation costs (if the pro-forma invoice is not completed in English). There may also be additional costs if the documents they submit are not comprehensive (e.g., need to post original documents)[444]	**Source(s):** Health Service Executive, 'Health Service Executive Cross-Border Healthcare Directive: Pro-Forma Invoice'.	**Yes** ☐ **No** ☒	Travel costs are required to minimize the likelihood of fraud. Translation costs are required, as these are not covered by the Cross-Border Directive. The additional costs for non-comprehensive documents are because this information is necessary for the claim to be substantiated.
7. Are there any specific time requirements linked to a reimbursement request? (*e.g., time within which the reimbursement requests must be submitted and/or time within the requested body must handle the request and/or reimburse the costs, etc.*).	**Answer:** *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* There do not seem to be any time requirements linked with a reimbursement request. The only mention of time is that the HSE aims to repay patients within 30 working days of getting all the completed documents.	**Source(s):** HSE, 'Cross-Border Directive: get healthcare abroad' (November 2018). Health Service Executive, 'Health Service Executive Cross-Border Healthcare Directive: Pro-Forma Invoice'.	**Yes** ☐ **No** ☒	N/A

[444] Please note that 'only the cost of the medical treatment provided' is eligible for reimbursement'. Hence, other costs such as travel costs are not reimbursed.

	No specific consequences identified.			
8. Are there any non-reimbursable thresholds, deductions *(except the deductions for administrative costs mentioned above) etc.?*	**Answer:** *If yes, please specify the thresholds.* As aforementioned, proof of travel has to be submitted in order for a reimbursement. However, an applicant/patient cannot be reimbursed for these travel costs. In addition, for outpatient healthcare claims (not involving an overnight stay), the maximum reimbursement for an outpatient consultation in a hospital abroad is €168 (as of March 2021). If a patient had inpatient care abroad, the HSE will deduct €80 per night, to a maximum of €800, from the amount to be repaid. However, a person will not have to pay the €80 per night if they either have a medical card or have already paid €800 for overnight stays in hospitals abroad or in Ireland in the last 12 months. If a patient is currently on an Orthodontic Assessment Waiting list in Ireland but has not yet been assessed, they can choose to have this assessment carried out abroad and claim up to €100.00 towards the cost of the assessment. The assessment abroad must be	**Source(s):** Health Service Executive, 'Health Service Executive Cross-Border Healthcare Directive: Pro-Forma Invoice'. HSE website.	**Yes** ☐ **No** ☒	N/A

	carried out in line with the HSE Orthodontic Assessment Tool.[445]			
9. In instances where a PA (or prior-notification) has already been issued, is a separate/simplified procedure available for requesting reimbursement? **applicable only if the country has a PA system.*	**Answer:** *If yes, please describe the simplified procedure.* There is no separate/simplified procedure available for requesting reimbursement. It is simply that PA will confirm you are eligible for repayment.	**Source(s):** HSE, 'Cross-Border Directive: get healthcare abroad' (November 2018).	**Yes** ☐ **No** ☒	N/A
10. Are there additional administrative/procedural requirements for reimbursement depending on, for instance, the type of treatment for which reimbursement is requested, or the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* None identified (see reimbursable thresholds, question 8).	**Source(s):** HSE, 'Cross-Border Directive: get healthcare abroad' (November 2018).	**Yes** ☐ **No** ☒	N/A
11. Please list any other administrative requirements in your country in relation to	**Answer:**	**Source(s):**	**Yes** ☐ **No** ☒	This mainly involves healthcare due in 2020 which was rescheduled

[445] The national authority contacted in te context of this report noted that patients cannot claim through the Cross-Border Directive for the cost of any prescription drugs after their healthcare. However, these can be claimed through the Drug Payment Scheme in Ireland.

the procedures of reimbursement of cross-border healthcare.	If a patient had been getting healthcare in the UK, they can apply for reimbursement if: - Healthcare began before 31 December 2020 – even if your care is not due to finish until later in 2021. - Upcoming treatment was booked before 31 December 2020. - Healthcare was due to happen in 2020, but was cancelled and rescheduled to 2021 by the provider. This may be due to the COVID-19 pandemic. In each case, the patient will need to provide evidence that their healthcare began or was scheduled to begin before 31 December 2020. This may include: - Confirmation that the healthcare was provided before 31 December 2020, such as a medical report, invoice or receipt; - Scheduled appointment letter dated in 2020.	HSE, 'Cross-Border Directive: get healthcare abroad' (November 2018).		and cancelled as a result of the COVID-19 pandemic. However, it can also apply in the sense of general delays.

Part 2: Checklist for verification with national/regional body

Name of the body: HSE Cross Border Directive
Country/Region: Ireland
Date of verification call: 21/06/2021

Template for the Data Collection	Aspects to be verified *Tick the boxes if the information in the template for the data collection has been verified and/or complemented by the national body*		Comments *Include any additional comments and/or information provided by the contacted body*
26. Section 1 – Prior Authorisation			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Justification/purpose of the identified requirement(s) (Column 4)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	Please those sections of the questionnaire that are highlighted in red.
27. Section 2 - Reimbursement			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Whether the requirement applies domestically (Discriminatory assessment) (Column 4) ▪ Justification/purpose of the identified requirement(s) (Column 5)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	Please those sections of the questionnaire that are highlighted in red.

ITALY – COUNTRY REPORT

Part 0: Preliminary Assessment

1. Please indicate whether the rules governing the administrative procedures/requirements for requesting PA and reimbursement under Directive 2011/24/EU in your country are set out at:

A. National level ☒

B. Decentralised/regional/local level ☐

NOTE: In Italy patients are affiliated to local health units, the so-called 'ASL' (Azienda Sanitaria Locale – Local Health Units). The ASL is a local unit which acts as the center of administrative operations related to Public Healthcare in Italy under the National Healthcare Service (SSN – Servizio Sanitario Nazionale). There are over 100 ASLs across the national territory. If a patient wants to seek prior-authorisation and/or claim reimbursement in Italy for cross-border healthcare under the Directive – as well as under the Social Security Coordination Regulations – the ASL of residence of the patient, to which he/she is registered, is the body in charge of handling the respective applications. Hence, in order to obtain information on the administrative procedures and requirements, a patient will have to refer to his/her territorially competent ASL. Nonetheless, it should be noted that despite the geographical decentralised distribution and structure of the Italian NHS, **the rules governing the administrative procedures are set out at national level and should therefore be followed and complied with uniformly by every ASL and local health unit across the national territory.** Specifically, Directive 2011/24/EU was transposed at national level by **Legislative Decree n.38/2014**[446] and **Ministerial Decree n.50/2018**[447]. The national transposing measures (specifically, Article 10 Legislative Decree n.38/2014) lay down rules on the administrative procedures, applicable throughout the entire national territory, concerning the prior authorisation and reimbursement procedures for cross-border healthcare under Directive 2011/24/EU. Moreover, in 2017, the Permanent Conference for relations between the State, the Regions and the Autonomous Provinces of Trento and Bolzano enacted a set of **Guidelines on Cross-border Healthcare**[448], with the aim of ensuring a harmonised application of the Directive across the entire national

[446] Legislative Decree March 4, 2014, n. 38 Implementation of Directive 2011/24 / EU concerning the application of patients' rights relating to cross-border healthcare, as well as Directive 2012/52/EU, involving measures intended to facilitate the recognition of medical prescriptions issued in another member state. (14G00050) (GU General Series n.67 of 21-03-2014) - Decreto Legislativo 4 marzo 2014, n. 38 Attuazione della direttiva 2011/24/UE concernente l'applicazione dei diritti dei pazienti relativi all'assistenza sanitaria transfrontaliera, nonche' della direttiva 2012/52/UE, comportante misure destinate ad agevolare il riconoscimento delle ricette mediche emesse in un altro stato membro. (14G00050) (GU Serie Generale n.67 del 21-03-2014). Available at: https://www.gazzettaufficiale.it/eli/id/2014/03/21/14G00050/sg. Last accessed 03/05/2021.

[447] Ministerial Decree 16 April 2018, n. 50 Regulation on cross-border healthcare subject to prior authorisation. (18G00075) (GU General Series n.117 of 22-05-2018) - DECRETO 16 aprile 2018, n. 50, Regolamento in materia di assistenza sanitaria transfrontaliera soggetta ad autorizzazione preventiva. (18G00075). Available at: https://www.gazzettaufficiale.it/eli/gu/2018/05/22/117/sg/pdf. Last accessed 11/05/2021.

[448] 21/12/2017 Guidelines of the Permanent Conference for relations between the State, the Regions and the Autonomous Provinces of Trento and Bolzano - Agreement pursuant to Art. 19 of the Legislative Decree 4 March 2014, n. 38, between the Government, the Regions and the Autonomous Provinces of Trento and Bolzano on the proposal of the Ministry of Health concerning the "Guidelines on cross-border healthcare" - Linee Guida della Conferenza permanente per i rapporti tra lo stato le regioni e le province autonome di Trento e Bolzano del 21/12/2017 - Intesa ai sensi dell'art. 19 del Decreto

territory (and clarifying its relationship with the Social Security Coordination Regulations). In particular, thought patients must request the forms for PA and reimbursement directly to their ASL of affiliation, the 2017 Guidelines contains specific template forms to be used by the ASLs which can be found annexes to the Guidelines on Cross-border Healthcare of 2017. **Hence, in Italy, the legislative and regulatory framework governing the administrative procedures for PA and reimbursement is considered to be set out at national level.** Besides Article 10 of Legislative Decree n.38/2014, Article 3(2) of Ministerial Decree n.50/2018 also confirms that "*The administrative procedures relating to the request for prior authorisation and those for the reimbursement of the costs of cross-border healthcare are governed by Article 10 of Legislative Decree no. 38 and the guidelines referred to in Article 19, paragraph 3, of the same legislative decree' [i.e., the Guidelines on Cross-border Healthcare of 2017].* The same provision specifies that the only "*The regions with special statute and the autonomous provinces of Trento and Bolzano*" – and not generally all regions – "*have the right maintain the administrative procedures defined by specific regulations in force on the date of entry into force of this regulation, without prejudice to the provisions of article 18, paragraph 1, last period of the aforementioned legislative decree*". The fact that this possibility and exception only applies to the 5 Italian regions which have a special statute and are granted particular conditions of autonomy (Friuli Venezia Giulia, Sardegna, Sicilia, Trentino-Alto Adige/Südtirol and Valle d'Aosta), indirectly confirms the general rule that all other (regular) regions do not have such autonomy and must comply with the procedural requirements set out at national level.

Moreover, for a sake of completeness, the following regional competences are worth mentioning – though they do not affect the conclusions on the 'national' scope of the research at hand. In Italy, with regards to healthcare matters, legislative and administrative competences are distributed at several levels (national, regional, local) depending on the specific cross-border healthcare matter to be regulated. With regards to the matters covered by the Directive, it is worth mentioning that:

1. Though the lists of healthcare subject to PA is set out at national level in transposing measures of the Directive (in particular, Ministerial Decree n.50/2018), the regions have the competence to subject additional treatments to PA, granted that the requirements of the Directive are met.[449] Determinations regarding these additional treatments are to be promptly published on the websites of the regions and communicated to the National Contact Point. After consulting the regional databases of the two most relevant regions in terms of population (i.e., Lazio and Lombardy), no specific regional measure making use of such option was identified. Hence, it appears that the list of treatments for which PA is required according to the national Ministerial Decree n.50/2018 applies uniformly across the two main regions, with no exceptions/differences.
2. With regards to the reimbursement of the expenses incurred, in Italy patients who have benefited from cross-border healthcare are entitled to reimbursement to the extent corresponding to the regional rates in force ('Tariffari Regionali'), net of the so called 'sharing of healthcare costs' (compartecipazione alla spesa

Legislativo 4 marzo 2014, n. 38, tra il Governo, le Regioni e le Province autonome di Trento e Bolzano sulla proposta del Ministero della salute concernente le "Linee guida sull'assistenza sanitaria transfrontaliera". Available at: https://www.trovanorme.salute.gov.it/norme/renderNormsanPdf?anno=2017&codLeg=63061&parte=1%20&serie=null . Last accessed 11/05/2021.

[449] According to Article 9(7) of Legislative Decree n.38/2014: *"[…] without prejudice to the possibility, for the regions and autonomous provinces of Trento and Bolzano, to submit further services to prior authorisation, in compliance with the conditions referred to in paragraph 2, letter a). The decisions relating to these additional services subject to prior authorisation are promptly published on the websites of the regions themselves and communicated to the National Contact Point".* Similarly, Article 1(2) of Ministerial Decree n.50/2018 reads as follows: "2. Without prejudice to the right, for the regions and autonomous provinces of Trento and Bolzano, to submit further services to prior authorisation, in compliance with the criteria referred to in paragraph 2, letter a), of article 9 of the legislative decree 4 March 2014, n. 38. The decisions relating to these additional services subject to prior authorisation are promptly published on the websites of the regions and communicated to the national contact point".

sanitaria', the Italian "Ticket") borne by the patients. Consequently, the amounts that a patient will receive as reimbursement for cross-border healthcare under the Directive may vary from region to region, as they are calculated according to specific Regional Tariffs ('Tariffari Regionali'). The Regional Tariffs are publicly available on the website of the Ministry of Health/NCP (https://www.salute.gov.it/portale/cureUE/dettaglioContenutiCureUE.jsp?lingua=italiano&id=3791&area=cureUnioneEuropea&menu=vuoto).

Nonetheless, the potential regional differences above relate to the lists of treatments for which PA is required and the tariffs for the calculation of the amounts to be reimbursed, and do not relate instead to the administrative procedures as such which are required in order to request the PA and reimbursement.

In case (1.B): Please indicate the two most relevant jurisdictions in your country (i.e., in terms of population):

Region/jurisdiction: 1: N/A

Region/jurisdiction 2: N/A

NOTE: for the reasons mentioned above, research has nonetheless been conducted in the two most relevant regions in terms of population, namely: **Lazio and Lombardy**

NOTE: In case (1.B) the template for the data collection (Part 1) should be completed twice, once for each of the two most relevant regions/jurisdiction indicated above.

2. **Please indicate the national body best suited to verify the accuracy of the information collected in Part 1, and justify your selection.**

Depending on the characteristics of your national healthcare system, the relevant body may be: a) *the national social security body*; or b) *an insurance fund*. In the latter case, please indicate the most representative fund (e.g., the one with the highest number of affiliations).

Body to be contacted for Task 2:

Ministry of Health: *Directorate-General for Health Programming* (*Direzione generale della programmazione sanitaria) Office 2 - National health plan and sector plans*[450] *https://www.salute.gov.it/portale/ministro/p4_5_2_4_2.jsp?menu=uffCentrali&label=uffCentrali&id=1196*

(In case 1.B, please indicate two relevant bodies, one respectively for each Region/jurisdiction)

1. **Regione Lombardia – most relevant Local health Unit:** ATS Milano Citta metropolitana – Corso Italia 52 (Milano), website: Info Contatti (ats-milano.it)
2. **Regione Lazio** – **most relevant Local Health Unit:** ASL Roma 1 – Borgo Santo Spirito 3 (Roma), website: Direttore Sanitario (aslroma1.it)

[450] The Directorate-General for Communication and European and International Relations was contacted in the first place, but they referred to the Directorate-General for Health Planning as the most competent department.

These local/regional bodies were also contacted for the verification of the information in Part 1, but indicated they were not in the position to do so. However, the local units provided information on the procedures (e.g., application modules where available) which was taken into account when answering the questions in Part 1 of the present report.

Part 1: Questionnaire

*__Note 1__: In cases where administrative requirements are set out in the legislative/regulatory framework at decentralised/regional/local level, please complete the template for the data collection twice, once for each of the two most relevant regions/jurisdictions (e.g., in terms population).

__*Note 2__: Setting out a Prior Authorisation (PA) system is optional for Member States. Should your country not have a system of PA in place under Directive 2011/24/EU, Section 1 will not need to be completed.

SECTION 1 PRIOR AUTHORISATION PROCEDURE(S)			
Questions	**Answer**	**Sources**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to PA procedures for a cross-border healthcare under Directive 2011/24/EU?	**Answer:** **<u>Transposing measures of Directive 2011/24/EU</u>:** ▪ Legislative Decree March 4, 2014, n. 38 Implementation of Directive 2011/24 / EU concerning the application of patients' rights relating to cross-border healthcare, as well as Directive 2012/52/EU, involving measures intended to facilitate the recognition of medical prescriptions issued in another member state. (14G00050) (GU	**Source(s):** ▪ Legislative Decree n.38/2014. ▪ Decree n.50/2018. ▪ Guidelines on Cross-border Healthcare of 2017. ▪ NCP website.[454]	N/A

[454] Available at: https://www.salute.gov.it/portale/cureUE/dettaglioContenutiCureUE.jsp?lingua=italiano&id=3791&area=cureUnioneEuropea&menu=vuoto .

	General Series n.67 of 21-03-2014) (**Legislative Decree n.38/2014**)[451] ▪ Ministerial Decree 16 April 2018, n. 50 Regulation on cross-border healthcare subject to prior authorisation. (18G00075) (GU General Series n.117 of 22-05-2018) (**Decree n.50/2018**)[452] **Other measures:** ▪ 21/12/2017 Guidelines of the Permanent Conference for relations between the State, the Regions and the Autonomous Pes of Trento and Bolzano - Agreement pursuant to Art. 19 of the Legislative Decree 4 March 2014, n. 38, between the Government, the Regions and the Autonomous Provinces of Trento and Bolzano on the proposal of the Ministry of Health concerning the "Guidelines on cross-border healthcare" (**Guidelines on Cross-border Healthcare of 2017**).[453] *Specifically:* **Legislative Decree n.38/2014** **Article 10 - 'Administrative procedures relating to the request for prior**		

[451] Decreto Legislativo 4 marzo 2014, n. 38 Attuazione della direttiva 2011/24/UE concernente l'applicazione dei diritti dei pazienti relativi all'assistenza sanitaria transfrontaliera, nonche' della direttiva 2012/52/UE, comportante misure destinate ad agevolare il riconoscimento delle ricette mediche emesse in un altro stato membro. (14G00050) (GU Serie Generale n.67 del 21-03-2014). Available at: https://www.gazzettaufficiale.it/eli/id/2014/03/21/14G00050/sg. Last accessed 03/05/2021.

[452] DECRETO 16 aprile 2018, n. 50, Regolamento in materia di assistenza sanitaria transfrontaliera soggetta ad autorizzazione preventiva. (18G00075). Available at: https://www.gazzettaufficiale.it/eli/gu/2018/05/22/117/sg/pdf. Last accessed 11/05/2021.

[453] Linee Guida della Conferenza permanente per i rapporti tra lo stato le regioni e le province autonome di Trento e Bolzano del 21/12/2017 - Intesa ai sensi dell'art. 19 del Decreto Legislativo 4 marzo 2014, n. 38, tra il Governo, le Regioni e le Province autonome di Trento e Bolzano sulla proposta del Ministero della salute concernente le "Linee guida sull'assistenza sanitaria transfrontaliera". Available at: https://www.trovanorme.salute.gov.it/norme/renderNormsanPdf?anno=2017&codLeg=63061&parte=1%20&serie=null . Last accessed 11/05/2021.

	authorisation and the request for reimbursement of the costs of cross-border healthcare'. 1. *The administrative procedures relating to the request for prior authorisation and the request for reimbursement of costs related to cross-border healthcare must be based on objective, non-discriminatory criteria, as well as necessary and proportionate to the objective to be achieved.* *2. All administrative procedures must be easily accessible and must guarantee the objective and impartial handling of requests relating to prior authorisation and reimbursement of costs. Information relating to these procedures must be made public.* *3. The application for the request for prior authorisation is presented, in the manner governed by this article, for the services referred to in Article 9, paragraph 8. In any case, the insured person who intends to benefit from cross-border assistance and of the consequent reimbursement pursuant to this decree,* ***submits a specific request to the territorially competent ASL****, so that it is verified whether the same service must be subject to prior authorisation pursuant to article 9, paragraph 2, letters b) and c), where applicable the conditions set out therein. The outcome of this verification is communicated to the interested party within 10 days and, if positive, the application referred to in the second period is intended as a request for prior authorisation pursuant to paragraph 4,*		

	and the terms referred to in paragraph 7 start from its reception. *4. The application for the request for prior authorisation must be presented by the insured person* ***to the ASL of residence on a specific form provided by the ASL itself*** *and* ***must be accompanied by medical certification****. The application* ***must indicate at least****:* ▪ *the diagnostic or therapeutic indication and the health service to be used;* ▪ *the place chosen for the service and the healthcare provider to which the insured person intends to go.* *5. The application* ***may*** *contain any other additional specifications necessary for the purpose of examining the request for prior authorisation.* *6. In the cases referred to in letters a), b) and d) referred to in paragraph 6 of article 9 of this decree, the application must be subjected to a clinical evaluation carried out by specialist operating units identified by the ASL.* *7. Upon receipt of the application, the ASL, within 30 days, must notify the insured person of the provision for granting or the refusal of prior authorisation. The term of 30 days is reduced by half in cases of particular urgency, which must be adequately motivated in the application for authorization referred to in paragraph 4.* *8. In the authorisation provision, the ASL specifies the cost of providing health assistance admitted to reimbursement. The*		

	refusal of the authorisation must be duly motivated by indicating one or more cases referred to in letters a), b), c) and d) referred to in paragraph 6 of article 9 of this decree. If the refusal is based on the existence of the conditions referred to in Article 9, paragraph 6, letter d), the ASL identifies and communicates to the person who submitted the application for authorisation the healthcare provider capable of providing the requested service. *9. In addition to the ordinary administrative and judicial protection tools, it is always possible to propose an application to the general manager of the ASL against the refusal provision within 15 days of receipt of the same. The general manager of the ASL expresses his opinion within 15 days of receipt of the request.* **Ministerial Decree n.50/2018** **Article 3(2)** "*The administrative procedures relating to the request for prior authorisation and those for the reimbursement of the costs of cross-border healthcare are governed by Article 10 of Legislative Decree no. 38 and the guidelines referred to in Article 19, paragraph 3, of the same legislative decree [Guidelines on Cross-border Healthcare of 2017*]" **Guidelines on Cross-border Healthcare of 2017 – Section 6.3. (pag. 30 and following):** provides additional details on the PA		

	administrative procedures and requirements (details provided in the answers below).		
2. Is this the same procedure as for PA under the Social Security Coordination Regulations?	**Answer:** Yes ☒ No ☐ **Formally no**: the procedures are not directly the same, as the forms to be submitted are different. **Substantially YES:** the procedures <u>are substantially equivalent</u> considering that, if the request for prior authorisation under the Directive meets the conditions set out in Art. 20 of EC Regulation 883/2004 (for example in the event that the chosen facility is a public facility or one accredited by the foreign country), the authorisation is granted pursuant to this Regulation, unless the patient requests otherwise. NOTE of the National Body: What prevails is the interest of the patient making the request, therefore this method simplifies the activities requested to the citizen. This is coherent with Article 8(3) of the Directive 2011/24. **Source(s):** Legislative Decree n.38/2014. Guidelines on Cross-border Healthcare of 2017 (section 6.3 and Annex A).		N/A
3. What body is in charge of handling the PA applications? *(e.g., where and to whom PA applications have to be submitted?)*	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in*	**Source(s):**	N/A

	your country (e.g., based on the number of affiliations) **Article 10(4) of Legislative Decree n.38/2014**, "*The application for the request for prior authorisation must be presented by the insured person* ***to the ASL of residence*** *on a specific form provided by the ASL itself and must be accompanied by medical certification*".6 **The competent bodies for handling a PA application are the local health units, the so-called 'ASL' (Azienda Sanitaria Locale)**. These are local health units to which patients are affiliated based on territorial criteria (e.g., residence). In Italy there are more than 100 ASLs. Lazio and Lombardy appear to be the regions with the highest number of affiliations (whilst the Piemonte Region appears to be the Region with the highest number of local healthcare units on its territory). Most relevant ASL for Lazio and Lombardy: - ATS Milano Citta metropolitana – Corso Italia 52 (Milano) - ASL Roma 1 – Borgo Santo Spirito 3 (Roma)	Article 10(4) of Legislative Decree n.38/2014.	

4. Who is entitled to apply for PA? *(e.g., can the patients apply themselves, or is treating doctor filing/partially filling the request, etc.)*	**Answer:** - *If there is a national doctor involved, is there a requirement that this doctor is contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA?* **The insured person (i.e., the patient) is entitled to apply for PA.** **Legislative Decree n.38/2014** **Article 10(4)** "*The application for the request for prior authorisation **must be presented by the insured person** to the ASL of residence on a specific form provided by the ASL itself and must be accompanied by medical certification*".	**Source(s):** Article 10(4) of Legislative Decree n.38/2014	
5. Is there a specific application form/module which the person seeking PA needs to submit?	**Answer:** *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?* **Yes. A specific module is to be requested to each ASL of affiliation.**	**Source(s):** Article 10(4) and 10(5) of Legislative Decree n.38/2014. **Section 6.3 and Annex A** - Guidelines on Cross-border Healthcare of 2017**.**	

	The information that must be included in the form and accompany the module is outlined in Article 10(4) and 10(5) of Legislative Decree n.38/2014. A template module to be used by each ASL is also provided in Annex A to the Guidelines on Cross-border Healthcare of 2017**.** - ***What information is required:*** **Legislative Decree n.38/2014 - Articles 10(4) and 10(5)** "4. *The application for the request for prior authorisation must be presented by the insured person to the ASL of residence on a specific form provided by the ASL itself and* ***must be accompanied by medical certification****.* The application **must** indicate at least: a) **the diagnostic or therapeutic indication** and the **health service to be used**; b) **the place** chosen for the service **and the healthcare provider to which the insured person intends to go.** **5.** The application *may* contain any other additional specifications necessary for the purpose of examining the request for prior authorisation". **Guidelines on Cross-border Healthcare of 2017 - Section 6.3 - Request for Prior Authorisation (page 30 and following):** *"The request for prior authorisation* ***must be submitted on the specific form (Annex A) of the ASL / Region****,* ***accompanied by an original medical prescription from the***		

	NHS** 'prescription pad'* [in IT: 'ricettario del SNN'] *or **by a prescription from a doctor or other professional qualified in another EU country** and **must contain: *- the diagnostic or therapeutic indication and the health service to be used;* *- the place chosen for the service and the healthcare provider where the patient intends to go.* *The application submission form follows the template attached to these guidelines (Annex A) […] – whilst being waived on the basis of specific regional / local health unit indications aimed at including additional information necessary for the purpose of examining the request prior authorisation.* *Specific details requested in the template module:* **Annex A of the Guidelines of 2017 (template module for the ASL)** • Particularities of the patient: *Name, surname, date and place of birth, place of residence, address, telephone number, email address, national social security number (i.e., 'codice fiscale')* • Indication of the type of service: *(i.e., regular hospitalisation, day hospitalisation, or outpatient service);* • The diagnostic or therapeutic indication; • Health service to be used; • Healthcare provider where the patient intends to go, including address;		

	• Urgency indication (yes/no). If yes, motivation for the urgency must be provided; • Indication (tick box) for the following attached documents: - Prescription of the doctor on the prescription pad of the NHS; *or* - Prescription of the doctor or other professional qualified in another EU State (which contains the essential elements for the identification of the patient; the identification of the prescriber with professional qualification, direct contact details, indication of the Member State in which he/she practices the profession, original legible signature and date of issue; indication of the health service); - Original clinical documentation; - Any documentation that legitimises the submission of the application on behalf of others (proxy with signed copy of the document currently valid delegating party; provision of appointment in the tutelary seat etc.). -***Is the information mandatory, optional, or recommended?*** The information listed above is mandatory (i.e., 'must be accompanied'). However, pursuant to Article 10(5) of Legislative Decree n.38/2014 the application *may* contain any other additional		

	specifications necessary for the purpose of examining the request for prior authorisation. - ***Is this application form/modules available online?*** **Generally, no.** Pursuant to Art.10(4) of Legislative Decree n.38/2014, the specific module has to be requested by the insured person to the local health unit of affiliation. However: 1. A template module that should be used by every local healthcare unite can be found in **Annex A** to the **Guidelines on Cross-border Healthcare of 2017.** The module is structured in such a way to collect the necessary information that must be provided pursuant to Article 10 of Legislative Decree n.38/2014, as described above. However, this is not the module that the patients can use directly, as its aim is to provide a guidance/template to the healthcare units. The patient wanting to request PA will have to request and use the specific module provided by the competent ASL. 2. Sample research has found that certain local healthcare units seem to provide the modules online (though this appears to be a minority of cases). For example: a. The module of the ASL3 of the city of Genova (http://www.asl3.liguria.it/components/com_publiccompetitions/		

	includes/ download.php?id=12379: domanda-assistenza-sanitaria-transfrontaliera.pdf); b. The module of the ASL3 of the city of Rome[455] (http://www.aslromad.it/PDFView.aspx?Organization=773&Progressive=1) Both modules are structured in a way to integrate both the PA request and/or reimbursement requests (as well as prior-verification requests) and they seem following the templates provided in Annex A and B of the Guidelines on Cross-border Healthcare. - ***Does the form have to be submitted in paper or can it be submitted electronically?*** The form and the attached documents may be submitted in **paper form** or by **means of certified email.** Applications via non-certified email are accepted in exceptional cases of urgency or impossibility to physically reach the ASL premises, in order to start the procedure. Nonetheless, the issuance of the PA will still be subject to the paper submission and/or submission via certified email. **Guidelines on Cross-border Healthcare of 2017:**		

[455] Please note that Rome is also one of the most relevant city in terms of population.

	Section 6.3 - Request for Prior Authorisation (page 30 and following) "*The request for prior authorisation* ***can also be submitted by sending certified e-mail (PEC)*** *to the valid PEC address of the competent ASL. The delivery receipt of the computer system of the ASL is valid for these purposes. In case of particular urgency, which does not allow to physically reach the offices of the competent ASL for filing the application in paper form, the member of the NHS who does not have a valid PEC address, can send the application for prior authorisation also by means of non-certified e-mail, at the address specifically indicated by the ASL. From the moment the non-certified email is actually received, the deadlines set for the conclusion of the authorisation procedure will begin to run. In any case, the issuant of the prior authorisation will remain subject to the formal submission of the application and its attachments, whether in paper form or by sending by means of certified email".*		
6. What (other) documentation has to be submitted in order to substantiate a PA request?	**Answer:** *If applicable, please specify:* - *What documents and what particulars are required;* - *Whether there are requirements as to who has to issue the documents (e. g., a doctor contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA or any doctor);*	**Source(s):** Article 10(4) and 10(5) of Legislative Decree n.38/2014. **Section 6.3 and Annex A** - Guidelines on Cross-border Healthcare of 2017**.**	

	- *Whether the submission of the documentation is optional, mandatory, or recommended.* The request for PA has to be submitted through the specific module (mentioned above) of the ASL of competence. A template model can be found in **Annex A** to the **Guidelines on Cross-border Healthcare of 2017.** According to Article 10(4) of the Legislative Decree n.38/2014, the model shall be accompanied by medical certification. More specifically, according to Section 6(3) of the **Guidelines on Cross-border Healthcare,** the medical certification shall be the original one on the NHS prescription pad or shall be made by a doctor or by another professional qualified in an EU Member State. The certificate shall contain the information outlined in the question above. According to Article 10(5) of the Legislative Decree n.38/2014, further specifications may be necessary for the examination of the request for PA. In case the patient has a rare disease or in case a specialist doctor has formulated a suspected diagnosis of a rare disease. In this case, the ASL may require the opinion of an expert in the field working at the National Network for rare disease. In this case, the patient has to undergo a clinical evaluation and the expert issue an opinion (and the time limits for the ASL to take a decision on the PA are suspended – see question 8 below).		

7. **Are there any costs** associated with the handling of the PA request? - *Direct costs (e.g., fixed costs for submitting or filing a PA request).* - *Indirect costs* (*e.g., translations, stamps, etc).*	**Answer:** <u>*Direct costs:*</u> There does not seem to be any direct cost for the submission of the request, provided under the national legislative and regulatory framework (e.g., no specific application fee, etc). <u>*Indirect costs:*</u> No particularly relevant indirect costs identified. In cases where the insured person may decide to submit the request in paper format, indirect costs may apply (e.g., posting costs). However, these costs do not appear relevant.	**Source(s):** Legislative Decree n.38/2014. Guidelines on Cross-border Healthcare of 2017**.** NCP website. Local Health Unit websites (ASL).	
8. Are there any specific **time requirements** linked to a PA request? (*e.g., time within which a requesting person must submit the PA application and/or time within which the requested body must take a decision on the PA request, etc.*).	**Answer:** *- If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* **Time requirements:** Following the receipt of the request, the local health unit has 30 days to take the decision to grant or refuse PA (15 days in case of motivated urgency). **Legislative Decree n.38/2014 - Article 10 (7):** "*Upon receipt of the application, the ASL, within 30 days, must notify the insured person of the provision for granting or the refusal of prior authorisation. The term of 30 days is*	**Source(s):** Article 10(7) of Legislative Decree n.38/2014.	

	reduced by half in cases of particular urgency, which must be adequately motivated in the application for authorisation referred to in paragraph 4." **Guidelines on Cross-border Healthcare of 2017 - Section 6.3.** "*Once the application has been assessed, the territorially competent ASL must communicate, within 30 days of receipt of the application for authorisation, the provision of refusal or granting of the authorisation. The term of 30 days is reduced to 15 days in cases of particular urgency which must be adequately motivated in the application for authorisation*". **Note:** besides the procedure to 'request' PA, **Article 10(3)** of **Legislative Decree n.38/2014** also foresees a so-called 'verification procedure'. This procedure is aimed at assisting patients to understand, in case of doubts, whether a specific healthcare requires prior-authorisation or not, due to the fact that it involves a particular risk for the patient or the population, or that the healthcare is provided by a healthcare provider who could raise specific and serious concerns about the quality and safety of the services. In such cases, the patient can submit a specific application to the territorially competent ASL, so that it is verified whether the healthcare must be subject to prior authorisation pursuant to Article 9, paragraph 2, letters b) and c) of the aforementioned legislative decree, where the conditions set out therein exist. The outcome of the verification procedure is communicated to the interested party **within 10 days** and, **if positive, the application is intended as a**		

	request for prior authorisation pursuant to paragraph 4 of Article 10, and the terms referred to in paragraph 7 of Article 7 start from its reception. **Consequences if deadlines are not met:** No direct/automatically applicable consequences. However, according to the **Section 6.5. of the Guidelines on Cross-border Healthcare of 2017:** *"In the event that the request for prior authorisation and / or reimbursement does not obtain any response of acceptance or rejection from the administration, within the term of 30 days indicated in art. 10 of the Legislative Decree. 38/2014, the patient may first of all address the same request to the holder of the substitute power in the event of inaction, which must be indicated by each administration pursuant to art. 2, paragraphs 9 bis and 9 ter of Law 241/1990. In this case, the deadline for the conclusion of the procedure will be halved compared to what was originally indicated. Pursuant to art. 20, paragraph 4, of Law 241/1990, dealing with the protection of health,* ***the general regime of silent consent is not applicable.*** *As long as the inertia persists and, in any case, no later than one year from the expiry of the deadline for the conclusion of the procedure,* ***it is also possible to seek the special judicial remedy for administrative inaction,*** *pursuant to art. 31 of Legislative Decree. 104/2010*		

	(Administrative Procedural Code), by proposing a specific appeal before the competent Regional Administrative Court. Any inaction on the administrative request concerning prior authorisation and reimbursement of services may, in any case, result in administrative and accounting responsibilities for the officer who is not properly activated in providing feedback to the patient.		
9. Are there **differences in the procedural/administrative requirements for requesting PA** based on, for instance, the type of treatment for which PA is requested, the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* **Yes. The time limits to grant PA may be extended in case the patient is carrier of a rare diseases (or a specialised doctor diagnosed a suspicion of a rare diseases). The reasons for the longer procedures are due to the fact that the local health unit may suspend the procedure to allow the receipt of clinical evaluations or opinions of experts in the sector.** **Legislative Decree n.38/2014 - Article 9(4):** *"When a patient suffering from a rare disease, or for whom a specialist doctor has formulated a diagnostic suspect of a rare disease, requests prior authorisation, he/she may undergo a clinical evaluation carried out by experts working at Presidium*	**Source(s):** Guidelines on Cross-border Healthcare of 2017 - Section 6.3.	

	of the national network for rare diseases identified according with the Decree of the Minister of Health of 18 May 2001, no. 279. If such experts cannot be found within the national territory or if the expert's opinion is not conclusive, a scientific opinion may be requested from the foreign facility where the patient intends to go to receive the treatment." **Guidelines on Cross-border Healthcare of 2017** **Section 6.3. (page 31):** "*If the patient for whom authorisation has been requested* ***is a carrier of a rare disease****,* ***or if a specialist doctor has formulated a diagnostic suspicion of a rare disease****, the ASL may request that it be subjected to clinical evaluation by experts in the sector operating at a Presidium of the national network for rare diseases. If no experts can be found within the national territory, or if the expert's opinion is not conclusive, a scientific opinion may be requested from the foreign facility where the patient intends to go to take advantage of the service. The relevant decisions are communicated to the applicant and* ***the terms of the procedure are suspended until the requested opinions are obtained*****"**		
10. Is there a specific PA form (i.e., form used for issuing/granting PA) and, if the answer is positive, what form?	**Answer:** Yes. The same form that used by the to apply for prior authorisation, contains a specific section to be completed by the competent body, which is to be returned to the applicant following the decision on the issuance or	**Source(s):** Article 10(8) of Legislative Decree n.38/2014 Guidelines on Cross-border Healthcare of 2017	

	refusal of PA (which must be duly motivated according in line with the requirements of the Directive (**Guidelines on Cross-border Healthcare of 2017 -** Section 6.3 and **Annex A**). Moreover, in case of a positive outcome, the ASL must also indicate in the authorisation decision the presumable amount of the cost that will be reimbursed (**Article 10(8) of Legislative Decree n.38/2014**). For this matter, the template form provided in Annex A of the aforementioned guidelines also specifically contains a section for the ASL to indicate the amount of the reimbursement (**Guidelines on Cross-border Healthcare of 2017- Annex A**). NOTE of the competent National Body: **Legislative Decree n.38/2014, Article 8(3):** *"If the refusal is based on the existence of the conditions of article 9, par. 6, letter d), the ASL shall identify the health care provider able to provide on the territory healthcare provider able to provide the requested service on the national territory and inform the person who has presented the request for authorisation accordingly. "* The refusal in itself contains also the indication of where it is possible to get the treatment needed on the national territory.	- Section 6.3. and Annex A.	

11. Please list any other administrative requirements in your country in relation to the PA procedure for cross-border healthcare.	**Answer:** Section 6(2) of the **Guidelines on Cross-border Healthcare** regulates the (prior)verification request, pursuant to Article 10(3) of the Legislative Decree n. 38/2014. According to this provision, a patient who wishes to benefit from cross-border healthcare can submit a verification request to the competent ASL in order to verify whether the healthcare must be subject to PA. The purpose of the verification request is to provide protection to patients according to Article 9(2) letter b) and c) of the Legislative Decree n. 38/2014, for cases where the intended treatment involves a particular risk for the patient or the population or for cases where there are serious and specific concerns about the quality or safety of the care of the intended healthcare provider. These treatments cannot be identified a priori, as the conditions affecting them are to be assessed on a case-by-case basis. The same module and the same documentation required for the PA are necessary. Once the request is received, the ASL verifies that (i) the conditions for the reimbursement of the treatment exist and (ii) that the treatment falls within the scope of the Legislative Decree n. 38/2014. If the conditions for reimbursement are not met, the ASL has to promptly inform the patient. Conversely, the ASL has to promptly verify the need for PA and has to inform the	**Source(s):** Article 10(3) of Legislative Decree n.38/2014 Guidelines on Cross-border Healthcare of 2017 - Section 6.2 and Annex A.	

	patient within 10 days after the receipt of the request. If the ASL does not find any risky conditions, but it finds that the circumstances for the PA exist according to Article 9(2) letter a), it has to notify the patient about the need for PA within 10 days after the receipt of the request. In this case, the verification request is considered to be a request for authorisation and the time limits for the authorisation procedure (30 days, reduced to 15 in urgent cases) are deemed to have elapsed from the date of receipt of the request. The ASL also provides information on the presumed amount of reimbursement. If, instead, the ASL does not find any risky conditions nor the existence of the circumstances for the PA, it has to inform the patient that no PA is needed and also provides information on the presumed amount of reimbursement. With such a procedure, the patient is, on the one hand, aware that on this return he will be reimbursed for the costs of the treatment he has received and, on the other hand, he will be sure on the absence of serious and specific concerns regarding the quality or safety of the healthcare provider. Thus, the procedure in question is intended to advise, and not to oblige, patients to contact their local health authority if they have doubts as to the reliability of the health care provider they intend to contact, or as to whether the service		

	they intend to receive is a risk to their own or the public's health.			
SECTION 2 REIMBURSMENT PROCEDURE(S)				
Questions	**Answer:**	**Sources**	**Does/do the identified requirement(s) also apply domestically? (i.e., is the requirement non-discriminatory?)**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to reimbursement procedures for cross-border healthcare under Directive 201/24/EU?	**Answer:** **<u>Transposing measures of Directive 2011/24/EU</u>:** ▪ Legislative Decree March 4, 2014, n. 38 Implementation of Directive 2011/24 / EU concerning the application of patients' rights relating to cross-border healthcare, as well as Directive 2012/52/EU, involving measures intended to facilitate the recognition of medical prescriptions issued in another member state. (14G00050) (GU General Series n.67 of 21-03-2014) (**Legislative Decree n.38/2014**)[456] ▪ Ministerial Decree 16 April 2018, n. 50 Regulation on cross-border healthcare subject to prior authorisation. (18G00075)	**Source(s):** Legislative Decree n.38/2014 Ministerial Decree n.50/2018 Guidelines on Cross-border Healthcare of 2017	N/A	N/A

[456] Decreto Legislativo 4 marzo 2014, n. 38 Attuazione della direttiva 2011/24/UE concernente l'applicazione dei diritti dei pazienti relativi all'assistenza sanitaria transfrontaliera, nonche' della direttiva 2012/52/UE, comportante misure destinate ad agevolare il riconoscimento delle ricette mediche emesse in un altro stato membro. (14G00050) (GU Serie Generale n.67 del 21-03-2014). Available at: https://www.gazzettaufficiale.it/eli/id/2014/03/21/14G00050/sg. Last accessed 03/05/2021.

	(GU General Series n.117 of 22-05-2018) (**Decree n.50/2018**)[457] **<u>Other measures:</u>** ▪ 21/12/2017 Guidelines of the Permanent Conference for relations between the State, the Regions and the Autonomous Pes of Trento and Bolzano - Agreement pursuant to Art. 19 of the Legislative Decree 4 March 2014, n. 38, between the Government, the Regions and the Autonomous Provinces of Trento and Bolzano on the proposal of the Ministry of Health concerning the "Guidelines on cross-border healthcare" (**Guidelines on Cross-border Healthcare of 2017**).[458] *<u>Specifically:</u>* **Legislative Decree n.38/2014** **Article 10 - 'Administrative procedures relating to the request for prior authorisation and the request for reimbursement of the costs of cross-border healthcare'.** *1. The administrative procedures relating to the request for prior authorisation **and the request for reimbursement** of costs related to cross-border healthcare must be based on objective, non-discriminatory criteria, as well*			

[457] DECRETO 16 aprile 2018, n. 50, Regolamento in materia di assistenza sanitaria transfrontaliera soggetta ad autorizzazione preventiva. (18G00075). Available at: https://www.gazzettaufficiale.it/eli/gu/2018/05/22/117/sg/pdf. Last accessed 11/05/2021.

[458] Linee Guida della Conferenza permanente per i rapporti tra lo stato le regioni e le province autonome di Trento e Bolzano del 21/12/2017 - Intesa ai sensi dell'art. 19 del Decreto Legislativo 4 marzo 2014, n. 38, tra il Governo, le Regioni e le Province autonome di Trento e Bolzano sulla proposta del Ministero della salute concernente le "Linee guida sull'assistenza sanitaria transfrontaliera". Available at: https://www.trovanorme.salute.gov.it/norme/renderNormsanPdf?anno=2017&codLeg=63061&parte=1%20&serie=null . Last accessed 11/05/2021.

	as necessary and proportionate to the objective to be achieved. *2. All administrative procedures must be easily accessible and must guarantee the objective and impartial handling of requests relating to prior authorisation and reimbursement of costs. Information relating to these procedures must be made public.* *[…]* *10.* ***In order to obtain reimbursement of the costs incurred for cross-border healthcare,*** *the insured person, within 60 days of the provision of the service, except for proven exceptional cases, submits a specific request for reimbursement to the ASL to which he belongs, attaching the original certificate and the original invoice issued by the healthcare provider.* *11. The ASL must pay the reimbursement within 60 days of receipt of the request.* **Ministerial Decree n.50/2018** **Article 3(2)** "*The administrative procedures relating to the request for prior authorisation and those for the reimbursement of the costs of cross-border healthcare are governed by Article 10 of Legislative Decree no. 38 and the guidelines referred to in Article 19, paragraph 3, of the same legislative decree [Guidelines on Cross-border Healthcare of 2017*]"			

	Guidelines on Cross-border Healthcare of 2017 – Section 6.4. (page 32 and following): provides additional details on the reimbursement administrative procedures and requirements (more detailed information provided in the sections below).			
2. Is this the same procedure as for reimbursement under the Social Security Coordination Regulations?	**Answer:** **Yes ☒ No ☐** **Formally no:** the modules to be submitted are different. **Substantially yes:** the procedures correspond substantially, in consideration of the fact that: in cases of urgency or necessity occurring during the temporary residence abroad of the client, the ASL also verifies whether the reimbursement can be paid pursuant to Article 19 of Regulation 883/2004 EC and art. 25 paragraph 5 of Regulation 987/2009 EC, and, if so, determines the reimbursement pursuant to this legislation, if the applicant does not ask otherwise. NOTE of the competent National body: The procedures correspond, but the criteria for the reimbursement are different under the Social Security Coordination Regulations and the Directive 2011/24. **Sources:** Legislative Decree n.38/2014. Guidelines on Cross-border Healthcare of 2017 (section 6.4 and Annex B).		N/A	N/A
3. What body is/are responsible of handling the	**Answer:**	**Source(s):**	N/A	N/A

reimbursement applications? (e.g., where and to whom reimbursement applications have to be submitted?)	*Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* As for the PA procedures, the competent bodies for handling reimbursement applications are the so-called 'ASL' (Azienda Sanitaria Locale) or 'ATS' (Agenzia di Tutela della Salute – Agencies for healthcare protection). These are Local Health Units to which patients are affiliated based on territorial criteria (e.g., Residence). In Italy there are more than 100 Local Health Units. The Piemonte Region appears to be the Region with the highest number of ASL, whilst the Lombardy Region and Lazio Region appear to be the ones with the highest number of affiliations. Most relevant ASL for Lazio and Lombardy: - ATS Milano Citta metropolitana – Corso Italia 52 (Milano) - ASL Roma 1 – Borgo Santo Spirito 3 (Roma)	Article 10(10) of Legislative Decree n.38/2014. Guidelines on Cross-border Healthcare of 2017 - Section 6.4 (page 32).		
4. Is there a specific application form/module which	**Answer:**	**Source(s):**	**Yes ☐**	

the person seeking reimbursement needs to submit?	*If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?* **Yes. A specific module is to be requested to each ASL of affiliation.** A **template module** to be used by each ASL is also provided in **Annex B** to the Guidelines on Cross-border Healthcare of 2017. The information that must be included in the form and accompany the module is outlined in **Article 10(10) of Legislative Decree n.38/2014.** ***- What information is required:*** **Legislative Decree n.38/2014 - Article 10(10): "***In order to obtain reimbursement of the costs incurred for cross-border healthcare, the insured person, within 60 days of the provision of the service, except for proven exceptional cases, **submits a specific request for reimbursement to the ASL** to which he belongs, **attaching the original certificate and the original invoice issued by the healthcare provider".***	Article 10(10) of Legislative Decree n.38/2014. Guidelines on Cross-border Healthcare of 2017 - Section 6.4.	**No ☒** Due to the free nature of the healthcare system in Italy. Specifically: the National Health Service is required to provide to all citizens the health services that fall under the Essential Levels of Assistance (so called 'LEA – Livelli Essenziali di Assistenza), **free of charge or upon payment of a participation fee (ticket).** The services included in the LEA are identified on the basis of principles of effective care need, effectiveness and appropriateness and represent the "essential" level of care guaranteed to all citizens. *As the essential healthcare is free of charge in Italy, it follows that there no 'reimbursement procedure' applies domestically.*	

	Guidelines on Cross-border Healthcare of 2017 – Section 6.4. (page 32 and following): "*The request for reimbursement of costs incurred for cross-border healthcare is presented by the patient and/or the entitled person by means of a specific form (**Annex B**) in cases where the patient has obtained the treatment and: i. has not submitted an application for prior authorisation or request for verification; ii. has submitted a request for verification with a negative result in the sense that prior authorisation by the ASL is not required; iii. has submitted a request for verification with a positive result and has received prior authorisation from the ASL; iv. has submitted an application for prior authorisation and received the relative authorisation; v. has obtained a judicial or administrative provision that has annulled the refusal of the ASL authorising him for treatment.* *[…]* *The reimbursement request must be submitted on the appropriate form of the ASL / Region, **accompanied by the following original documentation**:* - ***Prescription from a doctor or from a licensed professional in the country of origin, if not already presented during the authorisation or verification** (Except in cases of urgency or necessity occurring during the temporary residence abroad of the client, the prescriptions must be presented on the prescription*			

	pad of the NHS or medical prescription or other qualified professionals, valid in other member countries); - ***Original certification of the care provider, certifying the treatment provided with discharge diagnosis or the report of the diagnostic examination carried out****;* - ***Receipted invoices relating to the services provided;*** - ***Translation into Italian - at the client's expense - of the health and expense documentation.*** *<u>Specific details requested in the template module:</u>* **Annex B of the Guidelines of 2017 (template module for the ASL)** **<u>Particularities of the patient:</u>** *Name, surname, date and place of birth, place of residence, address, telephone number, email address, national social security number (i.e., 'codice fiscale')* **Indication of the:** - *Amounts of the costs sustained (in EUR);* - *List of original documents attached to the form;* - *Declaration of the reasons for which the applicant could not benefit of the 'direct contribution'.* - *Bank account details* - *Date and signature*			

	- Is the information mandatory, optional, or recommended? The information and documents to be submitted are mandatory. The only exception being the '*Prescription from a doctor or from a licensed professional in the country of origin'* which is not necessary if it had already been submitted during the authorisation or verification procedures**.** ***- Is this application form/modules available online?*** **Generally, no.** Pursuant to Art.10(10) of Legislative Decree n.38/2014, the specific module has to be provided by the local health unit of affiliation. <u>However:</u> 1. A template module that should be used by every local healthcare unit can be found in **Annex B** to the **Guidelines on Cross-border Healthcare of 2017.** The module is structured in such a way to collect the necessary information that must be provided pursuant to Article 10 of Legislative Decree n.38/2014, as described above. However, this is not the module that the patients can use directly, as its aim is to provide a guidance/template to the healthcare units. The patient wanting to request reimbursement of costs will have to			

	request and use the specific module provided by the competent ASL. 2. Sample research has found that certain local healthcare units seem to provide the modules online (though this appears to be a minority of cases). For example: a. A module is available on the website of the ASL3 of the city of Genova (http://www.asl3.liguria.it/components/com_publiccompetitions/includes/download.php?id=12379:domanda-assistenza-sanitaria-transfrontaliera.pdf); b. A module is available on the website of the ASL3 of the city or Rome (http://www.aslromad.it/PDFView.aspx?Organization=773&Progressive=1) Both modules are structured in a way to integrate both the PA request and/or reimbursement requests. ***-Does the form have to be submitted in paper or can it be submitted electronically?*** The forms by which the reimbursement request and necessary documents may be submitted is not specified in the legislative and regulatory sources. However, it can be inferred that the same rules for the submission of the documentation for PA request apply also for reimbursement, in			

	consideration of the fact that it is the same body handling both applications. Hence, the paper applications and those submitted via electronic certified post should be accepted (see answers above in Section 1 – Prior Authorisation).			
5. What (other) documentation has to be submitted in order to substantiate a reimbursement request?	**Answer:** *If applicable, please specify:* - *What documents are required;* - *Whether the submission of the documentation is optional, mandatory, or recommended.* **Legislative Decree n.38/2014, Article 10(10):** *"[…] the insured person, within 60 days from the date the healthcare was provided, except in exceptional cases, shall request the reimbursement to the competent ASL, attaching the original medical certificate and the original invoice issued by the healthcare provider."* More precisely, according to Section 6.2 of the **Guidelines on Cross-border Healthcare of 2017,** the reimbursement request must be submitted on the appropriate form of the ASL / Region, accompanied by the following original documentation: - Prescription from a doctor or from a licensed professional in the country of origin, if not already presented during the authorisation or verification (Except in cases of	**Source(s):** Article 10(10) of Legislative Decree n.38/2014. Guidelines on Cross-border Healthcare of 2017, Section 6.4.	**Yes** ☐ **No** ☒ *See above*	

	urgency or necessity occurring during the temporary residence abroad of the client, the prescriptions must be presented on the prescription pad of the NHS or medical prescription or other qualified professionals, valid in other member countries); - Original certification of the care provider, certifying the treatment provided with discharge diagnosis or the report of the diagnostic examination carried out; - Receipted invoices relating to the services provided; - Translation into Italian - at the client's expense - of the health and expense documentation.			
6. Are there any costs associated with the handling of the reimbursement request? - *Direct costs (e.g., fixed costs for submitting or filing a reimbursement request, proportion deducted from the reimbursable amount).* - *Indirect costs* (*e.g., translations, stamps, etc).*	**Answer:** *Direct costs:* Not identified. *Indirect costs:* Translation into Italian - at the client's expense - of the health and expense documentation. (**Guidelines on Cross-border Healthcare of 2017, Section 6.4**). NOTE of the competent National Body: The Italian translation is not mandatory according to the Decree 38/2014 and it is requested at the discretion of the single ASL. The legislative reference is the general law on	**Source(s):** Guidelines on Cross-border Healthcare of 2017, Section 6.4.	**Yes** ☐ **No** ☒ *See above*	

	administrative proceedings, Law No. 241/1990.[459]			
7. Are there any specific time requirements linked to a reimbursement request? (*e.g., time within which the reimbursement requests must be submitted and/or time within the requested body must handle the request and/or reimburse the costs, etc.*).	**Answer:** *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* **Legislative Decree n.38/2014** **Article 10(10) and (11)** ***10.*** *In order to obtain reimbursement of the costs incurred for cross-border healthcare,* ***the insured person, within 60 days of the provision of the service,*** *except for proven exceptional cases,* ***submits a specific request for reimbursement to the ASL*** *to which he belongs, attaching the original certificate and the original invoice issued by the healthcare provider.* ***11.*** *The ASL must pay the reimbursement* ***within 60 days*** *of receipt of the request.* **Guidelines on Cross-border Healthcare of 2017 – Section 6.4. (page 32 and following)** *The request for reimbursement must be submitted to the territorially competent ASL on a specific form of the ASL / Region* ***within 60***	**Source(s):** Legislative Decree n.38/2014 Article 10(10) and (11). Guidelines on Cross-border Healthcare of 2017 – Section 6.4.	**Yes** ☐ **No** ☒ *See above*	

[459] Legge 7 agosto 1990, n. 241, Nuove norme in materia di procedimento amministrativo e di diritto di accesso ai documenti amministrativi. Available at: https://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:legge:1990-08-07;241. Last accessed on: 21/06/2021.

	days of the provision of the service, *except in proven exceptional cases.* *[…]* *Once the application has been assessed, the ASL will* ***have to pay the reimbursement within 60 days of receipt of the request.****"* **Consequences if deadlines are not met:** No direct/automatically applicable consequences. However, according to the **Section 6.5. of the Guidelines on Cross-border Healthcare of 2017**: *"In the event that the request for prior authorisation and / or reimbursement does not obtain any response of acceptance or rejection from the administration, within the term of 30 days indicated in art. 10 of the Legislative Decree. 38/2014, the patient may first of all address the same request to the holder of the substitute power in the event of inaction, which must be indicated by each administration pursuant to art. 2, paragraphs 9 bis and 9 ter of Law 241/1990. In this case, the deadline for the conclusion of the procedure will be halved compared to what was originally indicated. Pursuant to art. 20, paragraph 4, of Law 241/1990, dealing in these with the protection of health,* ***the general regime of silent consent is not applicable.*** *As long as the inertia persists and, in any case, no later than one year from the expiry of the deadline for the conclusion of the procedure, it is also possible to seek the special judicial remedy*			

	for administrative inaction, pursuant to art. 31 of Legislative Decree. 104/2010 (Administrative Procedural Code), by proposing a specific appeal before the competent Regional Administrative Court. Any inaction on the administrative request concerning prior authorisation and reimbursement of services may, in any case, result in administrative and accounting responsibilities for the officer who is not properly activated in providing feedback to the patient.			
8. Are there any non-reimbursable thresholds, deductions (except the deductions for administrative costs mentioned above) etc.?	**Answer:** *If yes, please specify the thresholds.* No specific thresholds. **Legislative Decree n.38/2014, Article 8(3):** *"The costs of cross-border healthcare are reimbursed at the current regional tariffs, net of cost-sharing according to the regulations in force. […]"* In the Italian health system there is a cost-sharing between State and citizens with regards to health expenses, as patients are required pay a small amount for each treatments. This applies domestically and also for cross-border healthcare.	**Source(s):** Legislative Decree n.38/2014 Article 8(3). Opinion of the State-Regions Conference on the Draft Legislative Decree n.38/2014.[460]	**Yes** ☐ **No** ☒ *See above*	
9. In instances where a PA (or prior-notification) has already been issued,	**Answer:** *If yes, please describe the simplified procedure.*	**Source(s):**	**Yes** ☐ **No** ☒	

[460] Parere sullo schema di decreto legislativo di recepimento della direttiva 2011/24/UE concernante l'applicazione dei diritti dei pazienti relativi all'assistenza sanitaria transfrontaliera nonché della direttiva 2012/52/UE comportante misure destinate ad agevolare il riconoscimento delle ricette mediche emesse in un altro stato membro, available at: https://www.quotidianosanita.it/allegati/allegato5350415.pdf.

is a separate/simplified procedure available for requesting reimbursement? **applicable only if the country has a PA system.*	**No different/simplified procedure identified:** The Guidelines on Cross-border Healthcare of 2017 specify the instances where the form provided in Annex B must be submitted, and this list includes cases where PA has been granted. The only 'simplification' identified lays in the fact that, the 'pre*scription from a doctor or from a licensed professional in the country of origin'* does not have to be re-submitted during the reimbursement procedure, if it was already submitted during the PA or verification procedure. **Guidelines on Cross-border Healthcare of 2017 - Section 6.4.:** "*The request for reimbursement of costs incurred for cross-border healthcare is presented by the patient and/or the entitled person by means of a specific form (**Annex B)** in cases where the patient has obtained the treatment and: - has not submitted an application for prior authorisation or request for verification; has submitted a request for verification with a negative result in the sense that prior authorisation by the ASL is not required; - has submitted a request for verification with a positive result and has received prior authorisation from the ASL; - has submitted an application for prior authorisation and received the relative authorisation; - has obtained a judicial or administrative provision that has annulled the refusal of the ASL authorising him for treatment" […] "The reimbursement request must be submitted on the appropriate*	Guidelines on Cross-border Healthcare of 2017 - Section 6.4.	*See above*	

	form of the ASL / Region, accompanied by the following original documentation: *- Prescription from a doctor or from a licensed professional in the country of origin, **if not already presented during the authorisation or verification** […]".*			
10. Are there additional administrative/procedural requirements for reimbursement depending on, for instance, the type of treatment for which reimbursement is requested, or the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* Not identified	**Source(s):**	**Yes** ☐ **No** ☒ *See above*	
11. Please list any other administrative requirements in your country in relation to the procedures of reimbursement of cross-border healthcare.	Answer: Not identified	**Source(s):**	**Yes** ☐ **No** ☒ *See above*	

Part 2: Checklist for verification with national/regional body

Name of the body: Ministry of Health - Directorate-General for Health Programming
Country/Region: Italy
Date of verification call: 16/06/2020

Template for the Data Collection	**Aspects to be verified** *Tick the boxes if the information in the template for the data collection has been verified and/or complemented by the national body*		**Comments** *Include any additional comments and/or information provided by the contacted body*
Section 1 – Prior Authorisation			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Justification/purpose of the identified requirement(s) (Column 4)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	The feedback/comments received have been incorporated in the questionnaire.
Section 2 - Reimbursement			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Whether the requirement applies domestically (Discriminatory assessment) (Column 4) ▪ Justification/purpose of the identified requirement(s) (Column 5)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	The feedback/comments received have been incorporated in the questionnaire.

LATVIA – COUNTRY REPORT

Part 0: Preliminary Assessment

1. **Please indicate whether the rules governing the administrative procedures/requirements for requesting PA and reimbursement under Directive 2011/24/EU in your country are set out at:**

A. National level ☒

B. Decentralised/regional/local level ☐

In case (1.B): Please indicate the two most relevant jurisdictions in your country (i.e., in terms of population):

Region/jurisdiction: 1: N/A

Region/jurisdiction 2: N/A

NOTE: In case (1.B) the template for the data collection (Part 1) should be complete twice, once for each of the two most relevant regions/jurisdiction indicated above.

2. **Please indicate the national body best suited to verify the accuracy of the information collected in Part 1, and justify your selection.**

Depending on the characteristics of your national healthcare system, the relevant body may be: a) *the national social security body*; or b) *an insurance fund*. In the latter case, please indicate the most representative fund (e.g., the one with the highest number of affiliations).

Body to be contacted for Task 2: The National Health Service (Nacionālais veselības dienests).

(In case 1.B, please indicate two relevant bodies, one respectively for each Region/jurisdiction)

Reasons for Selection: In Latvia there is a centralised healthcare system; one institution at the national level. This derives from the respective provisions of Cabinet of Ministers: Regulation No.555 "Procedures for the Organisation of and Payment for Health Care Services" adopted on 28 August 2018 by the Cabinet of Ministers (further – Regulation No.555)[461]

[461] Ministru kabineta 2018.gada 28.augusta noteikumi Nr.555 "Veselības aprūpes pakalpojumu organizēšanas un samaksas kārtība" (Regulation No.555 "Procedures for the Organisation of and Payment for Health Care Services" adopted on 28 August 2018 by the Cabinet of Ministers), the official publisher of the Republic of Latvia "Latvijas Vēstnesis" 05 September 2018 No 176, available at: https://likumi.lv/ta/id/301399-veselibas-aprupes-pakalpojumu-organizesanas-un-samaksas-kartiba (LV) and https://likumi.lv/ta/en/en/id/301399-procedures-for-the-organisation-of-and-payment-for-health-care-services (ENG) (last accessed on 11 June 2021).

Part 1: Questionnaire

*__Note 1__: In cases where administrative requirements are set out in the legislative/regulatory framework at decentralised/regional/local level, please complete the template for the data collection twice, once for each of the two most relevant regions/jurisdictions (e.g., in terms population).

__*Note 2__: Setting out a Prior Authorisation (PA) system is optional for Member States. Should your country not have a system of PA in place under Directive 2011/24/EU, Section 1 will not need to be completed.

Note: in Latvia no PA system has been introduced under Directive 2011/24/EU. For this reason, Section 1 of the questionnaire below has not been completed.

SECTION 1 PRIOR AUTHORISATION PROCEDURE(S)			
Questions	**Answer**	**Sources**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to PA procedures for a cross-border healthcare under Directive 2011/24/EU?	Not applicable (N/A): in Latvia no PA system has been introduced under Directive 2011/24/EU.	Source(s):	N/A
2. Is this the same procedure as for PA under the Social Security Coordination Regulations?	**Answer:** **Yes ☐ No ☐** N/A		N/A

3. What body is in charge of handling the PA applications? *(e.g., where and to whom PA applications have to be submitted?)*	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* N/A	**Source(s):**	N/A
4. Who is entitled to apply for PA? *(e.g., can the patients apply themselves, or is treating doctor filing/partially filling the request, etc.)*	**Answer:** - *If there is a national doctor involved, is there a requirement that this doctor is contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA?* N/A	**Source(s):**	
5. Is there a specific application form/module which the person seeking PA needs to submit?	**Answer:** *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?* N/A	**Source(s):**	
6. What (other) documentation has to be submitted in order to	**Answer:** *If applicable, please specify:* - *What documents and what particulars are required;*	**Source(s):**	

substantiate a PA request?	- *Whether there are requirements as to who has to issue the documents (e. g., a doctor contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA or any doctor);* - *Whether the submission of the documentation is optional, mandatory, or recommended.* N/A		
7. Are there any costs associated with the handling of the PA request? - *Direct costs (e.g., fixed costs for submitting or filing a PA request).* - *Indirect costs* (*e.g., translations, stamps, etc).*	**Answer:** *Direct costs:* *Indirect costs:* N/A	**Source(s):**	
8. Are there any specific **time requirements** linked to a PA request? (*e.g., time within which a requesting person must submit the PA application and/or time within which the requested body must take a decision on the PA request, etc.*).	**Answer:** - *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* N/A	**Source(s):**	

9. Are there **differences in the procedural/administrative requirements for requesting PA** based on, for instance, the type of treatment for which PA is requested, the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* N/A	**Source(s):**	
10. Is there a specific PA form (i.e., form used for issuing/granting PA) and, if the answer is positive, what form?	**Answer:** N/A	**Source(s):**	
11. Please list any other administrative requirements in your country in relation to the PA procedure for cross-border healthcare.	**Answer:** N/A	**Source(s):**	

SECTION 2 **REIMBURSMENT PROCEDURE(S)**				
Questions	**Answer:**	**Sources**	**Does/do the identified requirement(s) also apply domestically?** **(i.e., is the requirement non-discriminatory?)**	**Purpose and/or justification of the requirements**

1. Which national legislative and/or regulatory provisions lay out the requirements related to reimbursement procedures for cross-border healthcare under Directive 201/24/EU?	**Answer:** Procedures for the Organisation of and Payment for Health Care Services" adopted on 28 August 2018 by the Cabinet of Ministers (further – Regulation No.555).[462]	**Source(s):** Regulation No.555.	N/A	N/A
2. Is this the same procedure as for reimbursement under the Social Security Coordination Regulations?	**Answer:** **Yes ☒ No ☐**		N/A	N/A
3. What body is/are responsible of handling the reimbursement applications? (e.g., where and to whom reimbursement applications have to be submitted?)	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* The National Health Service (Nacionālais veselības dienests)	**Source(s):** Applicable law: Regulation No.555, paragraph 205 (preamble of the Paragraph).	N/A	N/A
4. Is there a specific application form/module which the person seeking	**Answer:** *If yes, please specify:* - *What information is required;*	**Source(s):** Applicable law regarding the required information: Regulation No.555, paragraph 206.	**Yes ☐** **No ☒** At national level, comparable system of	No specific justification or purpose identified (besides the fact that there is no

[462] Regulation No.555 "Procedures for the Organisation of and Payment for Health Care Services" adopted on 28 August 2018 by the Cabinet of Ministers, the official publisher of the Republic of Latvia "Latvijas Vēstnesis" 05 September 2018 No 176; Ministru kabineta 2018.gada 28.augusta noteikumi Nr.555 "Veselības aprūpes pakalpojumu organizēšanas un samaksas kārtība", Latvijas Vēstnesis, 176, 05.09.2018, available at: https://likumi.lv/ta/id/301399-veselibas-aprupes-pakalpojumu-organizesanas-un-samaksas-kartiba (LV) and https://likumi.lv/ta/en/en/id/301399-procedures-for-the-organisation-of-and-payment-for-health-care-services (ENG) (last accessed on 11 June 2021).

reimbursement needs to submit?	- *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?* Yes, a specific application form (for the reimbursement of expenses) is available (Cfr. Sources). Information required: An application for reimbursement of expenses should be submitted. The following information shall be indicated in the application: - **Regarding the person seeking reimbursement**: name, surname, date of birth, personal identification code or taxpayer registration number assigned by the State Revenue Service, if the person is not registered in the Population Register, address, telephone number or electronic mail address;	Application form (for the reimbursement of expenses) at the official website of the competent institution – National Health Service (In Latvian: "Iesniegums izdevumu atmaksai par citā Eiropas Savienības, Eiropas Ekonomikas zonas dalībvalstī vai Šveicē saņemtiem un apmaksātajiem veselības aprūpes pakalpojumiem".[463] Applicable law regarding the person's right to submit an application (variety of submission methods): - Law on Submissions[464], Paragraph 3 of the Article 2 and Paragraph 3 of the Article 3; - Electronic Documents Law[465], Paragraph 2 and 5 of the Article 3. Applicable law regarding original documents: Law on Legal Force of Documents,[466] Paragraph 2 of the Article 1, Paragraph 2 of the Article 2, Paragraph 1 of the Article 4.	reimbursement does not exist, hence being the reason why the procedure does not apply domestically. **T**here is **no system for reimbursement** for the health care services received in the Republic of Latvia (only benefits in kind are available).	reimbursement system applicable domestically).

[463] The application is available only in Latvian at the following link: https://www.vmnvd.gov.lv/lv/pakalpojumi/iesniegumu-veidlapas (last accessed 07/07/2021).
[464] Law on Submissions, the official publisher of the Republic of Latvia "Latvijas Vēstnesis" 11 October 2007 No. 164. Iesniegumu likums, Latvijas Vēstnesis, 164, 11.10.2007, available at: https://likumi.lv/ta/id/164501-iesniegumu-likums (LV) and https://likumi.lv/ta/en/en/id/164501-law-on-submissions (ENG) (last accessed on 11 June 2021).
[465] Electronic Documents Law, the official publisher of the Republic of Latvia "Latvijas Vēstnesis" 20 November 2002 No. 169. Elektronisko dokumentu likums, Latvijas Vēstnesis, 169, 20.11.2002, available at: https://likumi.lv/ta/id/68521-elektronisko-dokumentu-likums (LV) and https://likumi.lv/ta/en/en/id/68521-electronic-documents-law (ENG) (last accessed on 11 June 2021).
[466] Law on Legal Force of Documents, the official publisher of the Republic of Latvia "Latvijas Vēstnesis" 19 May 2010 No. 78. Dokumentu juridiskā spēka likums, Latvijas Vēstnesis, 78, 19.05.2010, available at: https://likumi.lv/ta/id/210205-dokumentu-juridiska-speka-likums (LV) and https://likumi.lv/ta/en/en/id/210205-law-on-legal-force-of-documents (ENG) (last accessed on 14 June 2021).

	- **Regarding the rights to receive health care services**: information on whether the person was / was not considered to be insured under another social security system at the time of receiving the health care service;
	- **Regarding the received health care services**:
	  o the country where the health care services were received;
	  o a description of the reason for receiving the health care service in another EU Member State, EEA country or Switzerland.
	- **Personal current account details**;
	
	Specific documents (listed in the answer to Question 5 below) must be attached to the application form.
	
	The requested information is a legal requirement (i.e., mandatory).
	
	The application form is available on the website of the competent institution – National Health Service.
	
	With regards to the ways of submission: a specific application form is not approved at the level of regulatory enactments (there is no legally binding form). However, the regulatory enactment determines the amount of information to be provided (as explained			

	above). The application may be submitted in a free form, including the information specified in the regulatory enactment. The application can be submitted: - in electronic form with a secure electronic signature and time stamp; - in electronic form through the online forms available on the single State and local government services portal (www.latvija.lv); - in paper form by post; - in paper form, submitted in person to the competent authority; - the person has the right to ask the competent institution to make his or her oral application in writing (i.e., the person provides information in person, which is made in writing by the representative of the competent authority) and the person signs it.			
5. What (other) documentation has to be submitted in order to substantiate a reimbursement request?	**Answer:** *If applicable, please specify:* - *What documents are required;* - *Whether the submission of the documentation is optional, mandatory, or recommended.* **The following documents should be attached** to the application:	**Source(s):** Regulation No.555, paragraph 206. Applicable law regarding original documents: Law on Legal Force of Documents,[468] Paragraph 2 of the Article 1, Paragraph 2 of the Article 2, Paragraph 1 of the Article 4	**Yes** ☐ **No** ☒ Cfr. answer above to question 4 (i.e., no domestic system of reimbursement exists in Latvia);	No specific justification or purpose identified (besides the fact that there is no reimbursement system applicable domestically).

[468]Law on Legal Force of Documents, the official publisher of the Republic of Latvia "Latvijas Vēstnesis" 19 May 2010 No. 78. Dokumentu juridiskā spēka likums, Latvijas Vēstnesis, 78, 19.05.2010, available at: https://likumi.lv/ta/id/210205-dokumentu-juridiska-speka-likums (LV) and https://likumi.lv/ta/en/en/id/210205-law-on-legal-force-of-documents (ENG) (last accessed on 14 June 2021).

	○ a document certifying the payment, in which the information identifying the recipients of the service is indicated; ○ a document of the health care service provider which contains the following information: ▪ health care services provided to a person; ▪ the period of provision of health care services; ▪ the price of health care services provided to a person for each service separately; ▪ confirmation of payment for the provided health care services; ▪ the diagnosis on the basis of which the health care service has been provided to the person. ○ For those treatments subject to a prescription or referral (domestically)[467]: a prescription or referral from a family doctor or specialist for the relevant healthcare service or information on the prescription or referral number, the date of issue, the medical institution, and the medical practitioner who			

[467] Note of the National expert: The national legislation indicates in which cases specialists can be accessed directly without the referral (para 56.2 of the Regulation No. 555) and which medicines are subject to prescription (Regulation No. 855, "Procedure for the Classification of Medicinal Products"). The requirement of the prescription/referral always apply (with the exceptions just mentioned), both for national and cross-border heatlhcare.

	issued the prescription or referral if the person no longer has the prescription or referral, unless, if in accordance with the procedures specified in Regulation 555, a referral is not required for the receipt of the relevant health care service, as well as other documents certifying that the requirements for the receipt of health care services specified in regulatory enactments regulating the field of health care have been met. The documents to be submitted are specified in the Regulation No.555, so it is a legal requirement, therefore mandatory. In addition, it must be taken into account that the documents attached to the application must also be originals with legal force (a document of the health care service provider and a document certifying the payment). It follows from Regulation No. 555 that original documents must be submitted (it is not specified that a copy may be submitted or other types of derivatives). Namely, copies or other derivatives are not suitable.			
6. Are there any costs associated with the handling of the reimbursement request? - *Direct costs (e.g., fixed costs for submitting or*	**Answer:** *Direct costs:* None identified. *Indirect costs:* There could be indirect costs. An example of indirect costs is presented below. It does not, however, preclude other indirect costs in a different context. Without a particular	**Source(s):** Applicable law: Regulation No.555. Applicable law: Official Language Law.	**Yes** ☐ **No** ☒ Cfr. answer above to question 4 (i.e., no domestic system of	The competent authority (the National Health Service) has indicated that in practice (currently) **there are no indirect**

filing a reimbursement request, proportion deducted from the reimbursable amount). - *Indirect costs* (*e.g., translations, stamps, etc).*	case at hand, these costs are difficult to foresee. There are some legal administrative requirements for documents. In accordance with Paragraph 3 of the Article 10 of Official Language Law[469] (further – Official Language Law), (..) *Documents from persons in a foreign language shall be accepted if attached thereto is a translation into the official language, certified in accordance with the procedures prescribed by the Cabinet, or certified by a notary. Translation into the official language is not required for documents that have been issued in the territory of Latvia by the day this Law comes into force* (..). In accordance with Paragraph 4 of Regulation No.291 "Procedures for certifying translations of documents into the official language" adopted by the Cabinet of Minister on 22 August 2000 [470] (further – Regulation No.291), (..) *State and local government institutions, courts and the judicial system institutions as well as state and municipal enterprises (companies) (hereinafter - Office) shall examine a document in a foreign language only if a natural or legal person has submitted the document to the institution in accordance with its competence, together with a translation of the document in the official language*.(..) Paragraph 4 of the Section 10 of the Official Language Law allows an authority to accept	Applicable law: Regulation No.291.	reimbursement exists in Latvia);	**costs** for the person requesting reimbursement, as translation of documents is not required in practice. In the authority's view, the translation shall be provided or the costs thereof shall be borne by the competent authority. No other potential indirect costs have been identified by the competent authority (the National Health Service). Therefore, though the law requires the translation, there appear to be room to disapply the provisions based on discretion.

[469] Official Language Law, the official publisher of the Republic of Latvia "Latvijas Vēstnesis" 21 December 2019 No.428/433, Valsts valodas likums, Latvijas Vēstnesis, 428/433, available at: https://likumi.lv/ta/id/14740-valsts-valodas-likums (LV) and https://likumi.lv/ta/en/en/id/14740-official-language-law (ENG) (last accessed on 11 June 2021).

[470] Regulation No.291 "Procedure for certifying translations of documents into the official language" adopted on 22 August 2000 by the Cabinet of Ministers, the official publisher of the Republic of Latvia "Latvijas Vēstnesis" 29 August 2000 No.302. Ministru kabineta 2000.gada 22.augusta noteikumi Nr.291 "Kārtība, kādā apliecināmi dokumentu tulkojumi valsts valodā", Latvijas Vēstnesis, 302, 29.08.2000, available at: https://likumi.lv/doc.php?id=10127 (LV) and http://www.vvc.gov.lv/export/sites/default/docs/LRTA/MK_Noteikumi/Cab._Reg._No._291_-_Certification_of_Document_Translations_.doc (ENG) (last accessed on 11 June 2021).

	submissions that are received from foreign countries without the translation. Moreover, in the case of medical urgency, Paragraph 3 of the Section 10 of Official Language Law must be set aside (see Para 2 of Section 10). Note from the National body: Paragraph 3 of the Section 10 of Official Language Law is not enforced by the National Health Service. The authority accepts submissions in a foreign language.			
7. Are there any specific time requirements linked to a reimbursement request? (*e.g., time within which the reimbursement requests must be submitted and/or time within the requested body must handle the request and/or reimburse the costs, etc.*).	**Answer:** *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* Yes. The reimbursement request shall be submitted within one year after the completion of the medical treatment in another Member State. Failure to comply with the prescribed period risks resulting in loss of the right to receive reimbursement. No specific time requirement identified for the body to handle the procedure.	**Source(s):** Regulation No.555, paragraph 206 (preamble of the Paragraph).	**Yes** ☐ **No** ☒ Cfr. answer above to question 4 (i.e., no domestic system of reimbursement exists in Latvia);	No specific justification or purpose identified (besides the fact that there is no reimbursement system applicable domestically).
8. Are there any non-reimbursable thresholds, deductions *(except the deductions for administrative costs mentioned above) etc.?*	**Answer:** *If yes, please specify the thresholds.* No such thresholds identified. The amount of reimbursement is determined in accordance with the health care service tariffs set in Latvia. Reductions are not applied and	**Source(s):** N/A	**Yes** ☐ **No** ☐ N/A	N/A

	are not specified in Latvian regulatory enactments. However, it must be taken into account that traditionally tariffs for health care services in the other Member States are higher than tariffs for health care services in Latvia, as a result, the amount reimbursed by the National Health Service may be significantly lower than the amount paid by the patient for received health care services.			
9. In instances where a PA (or prior-notification) has already been issued, is a separate/simplified procedure available for requesting reimbursement? **applicable only if the country has a PA system.*	**Answer:** *If yes, please describe the simplified procedure.* Not applicable. There is no PA system.	**Source(s):** N/A	**Yes** ☐ **No** ☐	N/A
10. Are there additional administrative/procedural requirements for reimbursement depending on, for	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* There are no additional requirements.[471]	**Source(s):** N/A	**Yes** ☐ **No** ☐ N/A	N/A

[471] There are, in turn, some exceptional cases (which seem to apply also domestically) for which the requirement of a referral from a general doctor is not needed (para 56.2 of Regulation No. 555) :
56.2. by turning to the following direct access specialists upon his or her own initiative:
56.2.1. a psychiatrist or paediatric psychiatrist if the person is suffering from a mental illness (in accordance with the ICD-10, diagnosis codes F00-F09, F20-F62, F63.1-F99);
56.2.2. a narcologist;
56.2.3. a pneumonologist if the person is ill with tuberculosis (in accordance with the ICD-10, diagnosis codes A15-A19, B90, J65, P37.0, R76.1, Y58.0, Y60.3, Z03.0, Z20.1);
56.2.4. a dermatovenerologist if the person is ill with a sexually transmitted disease (in accordance with the ICD-10, diagnosis codes A50-A64, B35.0,4,8, B37.3,4, B86, L01.1, L08.0, L24.4, L30.2, Z11.3,4, Z20.2,6, Z22.4, Z29.2, Z86.1);

instance, the type of treatment for which reimbursement is requested, or the profile of the insured person, or any other criterion?				
11. Please list any other administrative requirements in your country in relation to the procedures of reimbursement of cross-border healthcare.	**Answer:** No other requirements identified.	**Source(s):** N/A	**Yes** ☐ **No** ☐	N/A

56.2.5. an endocrinologist if the person is ill with diabetes mellitus (in accordance with the ICD-10, diagnosis codes E10-E14.9);
56.2.6. an oncologist, oncologist-chemotherapist if the person is ill with an oncological disease (in accordance with the ICD-10, diagnosis codes C00-C97, D00-D09, D37-D48);
56.2.7. a gynaecologist;
56.2.8. an ophthalmologist;
56.2.9. a paediatric surgeon;
56.2.10. a paediatrician;
56.2.11. an infectologist if:
56.2.11.1. a person is ill with human immunodeficiency virus (hereinafter - HIV) infection (in accordance with the ICD-10, diagnosis codes B20-B24, Z21);
56.2.11.2. a person with the signs of HIV infection has undergone an HIV rapid test using capillary blood or saliva (in accordance with the ICD-10, diagnosis code Z20.6) at an HIV prevention point which has a cooperation contract with the Centre for Disease Prevention and Control;
56.2.11.3. he or she is a contact person (in accordance with the ICD-10, diagnosis code Z20.6) for a person with diagnosed HIV infection who receives medical treatment at an inpatient medical treatment institution;
56.2.12. a sports doctor in the State limited liability company Children's Clinical University Hospital;
56.3. by turning to medical treatment institutions upon his or her own initiative, including to emergency room in order to receive emergency medical assistance;
56.4. upon referral of an emergency medical assistance team;
56.5. within the scope of the State organised screening of breast and cervical cancer, by turning to a medical treatment institution implementing the screening programme upon her own initiative (if there is a valid letter of invitation in the management information system of the Service) or with the letter of invitation sent by the Service;
56.6. with the letter of invitation sent by the Service for the receipt of medically assisted insemination service.

Part 2: Checklist for verification with national/regional body

Name of the body: The National Health Service (Nacionālais veselības dienests).
Country/Region: Latvia
Date of verification call: 14/06/2021

Template for the Data Collection	**Aspects to be verified** *Tick the boxes if the information in the template for the data collection has been verified and/or complemented by the national body*		**Comments** *Include any additional comments and/or information provided by the contacted body*
Section 1 – Prior Authorisation			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Justification/purpose of the identified requirement(s) (Column 4)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Questio 11	The feedback received has been incorporated in the questionnaire.
Section 2 - Reimbursement			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Whether the requirement applies domestically (Discriminatory assessment) (Column 4) ▪ Justification/purpose of the identified requirement(s) (Column 5)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	**Regarding the application submission**: the National Health Service emphasised that the submission can be made trough www.latvija.lv. This information was incorporated for under question 4. **Regarding indirect costs**: The competent authority has indicated that in practice (currently) **there are no indirect costs** for the person requesting reimbursement, as translation of documents is not required. In its view, the translation shall be provided or the costs thereof shall be borne by the competent authority. No other potential indirect costs have been identified by the competent authority.[472]

[472] The researchers carrying out this study, however, would like to emphasise that the law requires the translation, but there is room to disapply the provisions based on discretion.

LICHTENSTEIN – COUNTRY REPORT

Part 0: Preliminary Assessment

1. **Please indicate whether the rules governing the administrative procedures/requirements for requesting PA and reimbursement under Directive 2011/24/EU in your country are set out at:**

A. National level ☒

B. Decentralised/regional/local level ☐

In case (1.B): Please indicate the two most relevant jurisdictions in your country (i.e., in terms of population):

Region/jurisdiction: 1:

Region/jurisdiction 2:

NOTE: In case (1.B) the template for the data collection (Part 1) should be complete twice, once for each of the two most relevant regions/jurisdiction indicated above.

2. **Please indicate the national body best suited to verify the accuracy of the information collected in Part 1, and justify your selection.**
Depending on the characteristics of your national healthcare system, the relevant body may be: a) *the national social security body*; or b) *an insurance fund*. In the latter case, please indicate the most representative fund (e.g., the one with the highest number of affiliations).

Body to be contacted for Task 2: "Amt für Gesundheit" (Office of Public Health), the higher-level contact point and where the "compulsory health insurance is located". It is also the National Contact Point for Directive 2011/24/EU.[473]

(In case 1.B, please indicate two relevant bodies, one respectively for each Region/jurisdiction)

Reasons for Selection:

PRELIMINARY NOTE:

[473] For more information: https://www.llv.li/inhalt/117345/amtsstellen/patientenmobilitat-im-eu-ewr-raum.

Directive 2011/24/EU has been transposed in the Health Act (Art. 50 para. 1a as well as Art. 20a) and in the Doctors Act (Art. 24 para. 3), introduced by the Government Report (BuA - Number 2016 / 103) on the legislative amendments required by the Patient Mobility Directive (implemented in LGBl. 2017 No. 35. The Government Report states:

"The provisions of Directive 2011/24/EU to be implemented in the Health Care Act and the Medical Practitioners Act are intended to benefit those patients who choose to receive health care in a country other than their country of insurance. Here, the approach of correct implementation, but not going beyond the minimum required by EEA law, is chosen."

In doing so, the government defined the following two substantive priorities:

- Establishment of a national contact point to ensure adequate information on all essential aspects of cross-border healthcare so that patients can exercise their right to cross-border healthcare in practice.

- Equal treatment with regard to applicable tariffs: The aim of this regulation is to ensure that all Liechtenstein healthcare providers apply the same tariff scale for the treatment of patients from other EEA countries as is applicable to domestic patients in a comparable medical situation.

It should be emphasised that a core element of Directive 2011/24/EU, namely the **entitlement to cross-border healthcare**, has in fact already been implemented, namely in the Law of 24 November 1971 on Health Insurance (KVG). This provides for a "two-tier model" for compulsory health care insurance in the outpatient sector, according to which insured persons can choose between an insurance model with a restricted choice of service providers (demand planning) and a model without restrictions within the compulsory health care insurance. The insured person has a choice between three approved health insurance companies, with uniform benefits and cost sharing but different premium options.

The insurance companies have contractual agreements with the health service providers, which allow direct billing between the two, without costs for the patients. Patients have the right to choose a service provider which is not a contractual partner (under the so called 'principle of the free choice of service providers'), and which can be located abroad. These type of service providers are accessible with an "extended OKP" (premium option). In this case, the bill is paid by the insured person, and it is submitted to the health insurance fund for reimbursement. There is no special form for such procedure.[474]

Note of the national legal expert:

[474] The homepage of the Liechtenstein "Office of Public Health" states:
"Any person who is compulsorily insured for health care in Liechtenstein may seek treatment not only from Liechtenstein contracted doctors, but also in other EU/EEA member states. However, whether your health insurance covers the costs of treatment abroad in the EU/EEA depends on certain conditions. You should therefore contact your health insurance fund before any treatment."
More detailed explanations are not provided by the Principality of Liechtenstein in the information available online.

For the sake of completeness, the government would like to note at this point that due to the current provisions of health insurance law and due to Liechtenstein's special situation in the area of inpatient care (Liechtenstein insured persons are dependent on hospitals in neighbouring countries), the possibility of introducing a system of prior authorisation should be dispensed with. According to Directive 2011/24/EU, such a prior authorisation procedure can be established to a limited extent for certain services, e.g. for inpatient treatment or for outpatient treatment that requires the use of highly specialised and cost-intensive medical infrastructure or medical equipment.

Part 1: Questionnaire

*__Note 1__: In cases where administrative requirements are set out in the legislative/regulatory framework at decentralised/regional/local level, please complete the template for the data collection twice, once for each of the two most relevant regions/jurisdictions (e.g., in terms population).

__*Note 2__: Setting out a Prior Authorisation (PA) system is optional for Member States. Should your country not have a system of PA in place under Directive 2011/24/EU, Section 1 will not need to be completed.

Note: in Liechtenstein it is unclear from the sources consulted whether a mandatory PA system has been introduced under Directive 2011/24/EU. For this reason, Section 1 of the questionnaire below has not been completed.

SECTION 1 PRIOR AUTHORISATION PROCEDURE(S)			
Questions	**Answer**	**Sources**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to PA procedures for a cross-border healthcare under Directive 2011/24/EU?	**Answer:** The implementation of Directive 2011/24/EU is without prejudice to the application of Regulation (EC) No 883/2004 on the coordination of social security systems and its implementing provisions.	**Source(s):** Health Act, Art. 50 para. 1a and Art. 20a.[475] Doctors Act, Art. 24 para. 3.[476]	N/A

[475] Liechtensteinsches Gesundheitsgesetz (GesG), available at: https://www.gesetze.li/konso/2008030000?search_text=gesundheitsgesetz&search_loc=titel&lrnr=&lgblid_von=&observe_date=22.07.2021, (last accessed on 22/07/2021).

[476] über die Ärzte (Ärztegesetz), available at: https://www.gesetze.li/konso/2003239000?search_text=%C3%A4rztegesetz&search_loc=titel&lrnr=&lgblid_von=&observe_date=22.07.2021, (last accessed on 22/07/2021).

	<u>The following provisions of the Liechtenstein Health Act were amended in 2017:</u> Art. 20a Health Act: Billing *In accordance with Directive 2011/24/EU, the holders of a professional licence are obliged to calculate the costs charged to the patient for treatment according to objective, non-discriminatory criteria.* Art. 50 para. 1a Health Act: *The Office of Public Health shall perform the task of the national contact point for cross-border healthcare in accordance with Directive 2011/24/EU. The contact point is responsible for cooperation with the contact points of other EEA member states and with the EFTA Surveillance Authority.* Art. 24 para. 3 Health Act *In analogy to Art. 20a of the Health Act, equality with regard to the applicable tariff system for patients from other EEA countries shall also be enshrined for medical services used in the context of cross-border healthcare.*	Government report (BuA - Number 2016 / 103) on the legislative amendments required by the Patient Mobility Directive (implemented in LGBl. 2017 No. 35).[477] § 6 Health Insurance Act.[478] Office of Public Health website.[479]	

[477] Available at: https://bua.regierung.li/BuA/default.aspx?year=2016&nr=103&content=1467458708, (last accessed on 22/07/2021).
[478] Liechtensteinisches Landesgesetzblatt, available at: https://www.gesetze.li/chrono/1971050000, (last accessed on 22/07/2021).
[479] Available at: https://www.llv.li/inhalt/117345/amtsstellen/patientenmobilitat-im-eu-ewr-raum.

2. Is this the same procedure as for PA under the Social Security Coordination Regulations?	**Answer:** **Yes ☐ No ☒**		N/A
3. What body is in charge of handling the PA applications? *(e.g., where and to whom PA applications have to be submitted?)*	**Answer:** It seems that no PA system is available in Liechtenstein.	**Source(s):** See above.	N/A
4. Who is entitled to apply for PA? *(e.g., can the patients apply themselves, or is treating doctor filing/partially filling the request, etc.)*	**Answer:** - *If there is a national doctor involved, is there a requirement that this doctor is contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA?* Information is missing; see above.	**Source(s):**	
5. Is there a specific application form/module which the person seeking PA needs to submit?	**Answer:** *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?* N/A	**Source(s):**	

6. What (other) documentation has to be submitted in order to substantiate a PA request?	**Answer:** *If applicable, please specify:* - *What documents and what particulars are required;* - *Whether there are requirements as to who has to issue the documents (e. g., a doctor contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA or any doctor);* - *Whether the submission of the documentation is optional, mandatory, or recommended.* N/A	**Source(s):**	
7. Are there any costs associated with the handling of the PA request? - *Direct costs (e.g., fixed costs for submitting or filing a PA request).* - *Indirect costs* (*e.g., translations, stamps, etc).*	**Answer:** *Direct costs:* *Indirect costs:* Information is missing; see above.	**Source(s):**	
8. Are there any specific **time requirements** linked to a PA request? (*e.g., time within which a requesting person must submit the PA application and/or time within which the requested body must take a decision on the PA request, etc.*).	**Answer:** - *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* N/A	**Source(s):**	

9. Are there **differences in the procedural/administrative requirements for requesting PA** based on, for instance, the type of treatment for which PA is requested, the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* N/A	**Source(s):**	
10. Is there a specific PA form (i.e., form used for issuing/granting PA) and, if the answer is positive, what form?	**Answer:** N/A	**Source(s):**	
11. Please list any other administrative requirements in your country in relation to the PA procedure for cross-border healthcare.	**Answer:** N/A	**Source(s):**	

SECTION 2 **REIMBURSMENT PROCEDURE(S)**				
Questions	**Answer:**	**Sources**	**Does/do the identified requirement(s) also apply domestically?** **(i.e., is the requirement non-discriminatory?)**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay	**Answer:** See above Point 1.	**Source(s):**	N/A	N/A

out the requirements related to reimbursement procedures for cross-border healthcare under Directive 201/24/EU?				
2. Is this the same procedure as for reimbursement under the Social Security Coordination Regulations?	**Answer:** **Yes ☐ No ☐** Unclear according to the available sources consulted.		N/A	N/A
3. What body is/are responsible of handling the reimbursement applications? (e.g., where and to whom reimbursement applications have to be submitted?)	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* The differnet health insurance providers, according to the health system as described in the preliminary note above.	**Source(s):**	N/A	N/A
4. Is there a specific application form/module which the person seeking reimbursement needs to submit?	**Answer:** *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?*	**Source(s):**	**Yes ☐** **No ☐**	

	No information available. As the procedures are handles by different insurance funds, and no procedural rules are established in the national legislative/regulatory sources consulted, it may be considered that such procedures differ from on insurance provider to another. Moreover, as far as domestic procedures are concerned, differences appear according to whether or not the general practitioner consulted has a contract with the health insurance funds.			
5. What (other) documentation has to be submitted in order to substantiate a reimbursement request?	**Answer:** *If applicable, please specify:* - *What documents are required;* - *Whether the submission of the documentation is optional, mandatory, or recommended.* No information available. See above answer to question 4.	**Source(s):**	**Yes ☐** **No ☐**	
6. Are there any costs associated with the handling of the reimbursement request? - *Direct costs (e.g., fixed costs for submitting or filing a reimbursement request, proportion*	**Answer:** *Direct costs:* *Indirect costs:* No information available. See above answer to question 4.	**Source(s):**	**Yes ☐** **No ☐**	

deducted from the reimbursable amount). - *Indirect costs (e.g., translations, stamps, etc).*				
7. Are there any specific time requirements linked to a reimbursement request? (*e.g., time within which the reimbursement requests must be submitted and/or time within the requested body must handle the request and/or reimburse the costs, etc.*).	**Answer:** *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* No information available. See above answer to question 4.	**Source(s):**	**Yes ☐** **No ☐**	
8. Are there any non-reimbursable thresholds, deductions *(except the deductions for administrative costs mentioned above) etc.?*	**Answer:** *If yes, please specify the thresholds.* No information available. See above answer to question 4.	**Source(s):**	**Yes ☐** **No ☐**	
9. In instances where a PA (or prior-notification) has already been issued, is a separate/simplified procedure available for requesting reimbursement? **applicable only if the country has a PA system.*	**Answer:** *If yes, please describe the simplified procedure.* *N/A*	**Source(s):**	**Yes ☐** **No ☐**	

10. Are there additional administrative/procedural requirements for reimbursement depending on, for instance, the type of treatment for which reimbursement is requested, or the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* No information available. See above answer to question 4.	**Source(s):**	**Yes ☐** **No ☐**	
11. Please list any other administrative requirements in your country in relation to the procedures of reimbursement of cross-border healthcare.	**Answer:** No information available. See above answer to question 4.	**Source(s):**	**Yes ☐** **No ☐**	

Part 2: Checklist for verification with national/regional body

Name of the body: N/A
Country/Region: N/A
Date of verification call: N/A

Template for the Data Collection	**Aspects to be verified** *Tick the boxes if the information in the template for the data collection has been verified and/or complemented by the national body*		**Comments** *Include any additional comments and/or information provided by the contacted body*
Section 1 – Prior Authorisation			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Justification/purpose of the identified requirement(s) (Column 4)	☐ Question 1 ☐ Question 2 ☐ Question 3 ☐ Question 4 ☐ Question 5	☐ Question 6 ☐ Question 7 ☐ Question 8 ☐ Question 9 ☐ Question 10 ☐ Question 11	
Section 2 - Reimbursement			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Whether the requirement applies domestically (Discriminatory assessment) (Column 4) ▪ Justification/purpose of the identified requirement(s) (Column 5)	☐ Question 1 ☐ Question 2 ☐ Question 3 ☐ Question 4 ☐ Question 5	☐ Question 6 ☐ Question 7 ☐ Question 8 ☐ Question 9 ☐ Question 10 ☐ Question 11	

LITHUANIA – COUNTRY REPORT

Part 0: Preliminary Assessment

1. **Please indicate whether the rules governing the administrative procedures/requirements for requesting PA and reimbursement under Directive 2011/24/EU in your country are set out at:**

A. National level ☒

B. Decentralised/regional/local level ☐

In case (1.B): Please indicate the two most relevant jurisdictions in your country (i.e., in terms of population):

Region/jurisdiction: 1: N/A

Region/jurisdiction 2: N/A

NOTE: In case (1.B) the template for the data collection (Part 1) should be complete twice, once for each of the two most relevant regions/jurisdiction indicated above.

2. **Please indicate the national body best suited to verify the accuracy of the information collected in Part 1, and justify your selection.**
Depending on the characteristics of your national healthcare system, the relevant body may be: a) *the national social security body*; or b) *an insurance fund*. In the latter case, please indicate the most representative fund (e.g., the one with the highest number of affiliations).

Body to be contacted for Task 2: National Health Insurance Fund under the Ministry of Health.

In case (1.B): Please indicate the two most relevant jurisdictions in your country (i.e., in terms of population):

Region/jurisdiction: 1: N/A

Region/jurisdiction 2: N/A

Reasons for Selection: Part 1 Section 2 provides information about the reimbursement procedures. In Lithuania, the cross-border health care costs of the insured are reimbursed from the National Health Insurance Fund under the Ministry of Health and territorial health insurance funds. In addition to this, the National Health Insurance Fund under the Ministry of Health advises the territorial health insurance funds on the reimbursement of cross-border health care

and prepares the draft report for the European Commission (that is sent to the European Commission by the Ministry of Health). In view of this, this body was selected as most relevant to verify the accuracy of the information collected in Part 1.

Part 1: Questionnaire

*__Note 1__: In cases where administrative requirements are set out in the legislative/regulatory framework at decentralised/regional/local level, please complete the template for the data collection twice, once for each of the two most relevant regions/jurisdictions (e.g., in terms population).

__*Note 2__: Setting out a Prior Authorisation (PA) system is optional for Member States. Should your country not have a system of PA in place under Directive 2011/24/EU, Section 1 will not need to be completed.

Note: in Lithuania, no PA system has been introduced under Directive 2011/24/EU. For this reason, Section 1 of the questionnaire below has not been completed.

SECTION 1 PRIOR AUTHORISATION PROCEDURE(S)			
Questions	**Answer**	**Sources**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to PA procedures for a cross-border healthcare under Directive 2011/24/EU?	**Answer:** Lithuania has no PA procedures for a cross-border healthcare under Directive 2011/24/EU in place. While implementing the Directive 2011/24/EU, a working group was established under the Ministry of Health. The analysis of the situation at that time showed that the application of the prior authorisation system was not necessary and proportionate to the objective pursued (it would constitute an unjustified obstacle to the timely availability of the necessary services in other EEA States). The introduction of a system of prior authorisation would impose additional administrative	**Source(s):** Explanatory report to the draft law amending and supplementing Articles 1, 2, 6, 21 of the Law on Health Insurance and supplementing the Law with Article 12 (1) and the Annex), 27 August 2013.[480]	N/A

[480] Available at https://e-seimas.lrs.lt/portal/legalAct/lt/TAK/TAIS.454934?jfwid=xqazkyx8w.

	burdens on both patients, as it would make it more difficult for them to exercise their right to receive healthcare in another Member State, and on the licensing authority (it would require additional human and financial resources).		
2. Is this the same procedure as for PA under the Social Security Coordination Regulations?	**Answer:** **Yes ☐ No ☐** N/A		N/A
3. What body is in charge of handling the PA applications? *(e.g., where and to whom PA applications have to be submitted?)*	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* N/A	**Source(s):**	N/A
4. Who is entitled to apply for PA? *(e.g., can the patients apply themselves, or is treating doctor filing/partially filling the request, etc.)*	**Answer:** - *If there is a national doctor involved, is there a requirement that this doctor is contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA?* N/A	**Source(s):**	
5. Is there a specific application form/module which the person seeking PA needs to submit?	**Answer:** *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?*	**Source(s):**	

	N/A		
6. What (other) documentation has to be submitted in order to substantiate a PA request?	**Answer:** *If applicable, please specify:* - *What documents and what particulars are required;* - *Whether there are requirements as to who has to issue the documents (e. g., a doctor contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA or any doctor);* - *Whether the submission of the documentation is optional, mandatory, or recommended.* N/A	**Source(s):**	
7. Are there any costs associated with the handling of the PA request? - *Direct costs (e.g., fixed costs for submitting or filing a PA request).* - *Indirect costs* (*e.g., translations, stamps, etc).*	**Answer:** *Direct costs:* *Indirect costs:* N/A	**Source(s):**	
8. Are there any specific **time requirements** linked to a PA request? (*e.g., time within which a requesting person must submit the PA application and/or time within which the requested body must*	**Answer:** *- If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* N/A	**Source(s):**	

take a decision on the PA request, etc.).			
9. Are there **differences in the procedural/administrative requirements for requesting PA** based on, for instance, the type of treatment for which PA is requested, the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* N/A	**Source(s):**	
10. Is there a specific PA form (i.e., form used for issuing/granting PA) and, if the answer is positive, what form?	**Answer:** N/A	**Source(s):**	
11. Please list any other administrative requirements in your country in relation to the PA procedure for cross-border healthcare.	**Answer:** N/A	**Source(s):**	

SECTION 2 **REIMBURSMENT PROCEDURE(S)**				
Questions	**Answer:**	**Sources**	**Does/do the identified requirement(s) also apply domestically?** **(i.e., is the requirement non-discriminatory?)**	**Purpose and/or justification of the requirements**

1. Which national legislative and/or regulatory provisions lay out the requirements related to reimbursement procedures for cross-border healthcare under Directive 201/24/EU?	**Answer:** Lithuanian Law on Health Insurance (hereinafter also referred to as: the **'Law'**), Article 12[1]. The Description of the procedure for the reimbursement of cross-border health care costs (Decree of the Minister of Health 15 October 2013 No. V-957) (hereinafter also referred to as: '**the Procedure**')	**Source(s):** Lithuanian Law on Health Insurance (hereinafter also referred to as: the Law).[481] Decree of the Minister of Health 15 October 2013 No. V-957 "On the approval of the Description of the procedure for the reimbursement of cross-border health care costs" (hereinafter also referred to as: the Procedure).[482]	N/A	N/A
2. Is this the same procedure as for reimbursement under the Social Security Coordination Regulations?	**Answer:** **Yes ☒ No ☐** Note: The Authority contacted for the verification of the data collected confirmed that in cases of urgency for which it is not possible to ask PA in advance under the Regulations, the reimbursement procedure for these exceptional cases, corresponds to the procedure for reimbursement under the Directive.		N/A	N/A
3. What body is/are responsible of handling the reimbursement applications? (e.g., where and to whom reimbursement	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).*	**Source(s):** The Law Article 12[1] part 2. The Procedure, paragraph 9.	N/A	N/A

[481] Lietuvos Respublikos sveikatos draudimo įstatymas, Valstybės žinios, 1996, No. 55-1287, available at https://www.e-tar.lt/portal/lt/legalAct/TAR.94F6B680E8B8/asr, last accessed on 2 June 2021.

[482] Sveikatos apsaugos ministro 2013 m. spalio 15 d. įsakymas Nr. V-957 "Dėl Tarpvalstybinės sveikatos priežiūros išlaidų kompensavimo tvarkos aprašo patvirtinimo" available at https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.458118/asr last accessed on 2 June 2021.

	applications have to be submitted?)	Reimbursement applications must be submitted to any of the five territorial health insurance funds (e.g., Vilnius Territorial Health Insurance Fund, Kaunas Territorial Health Insurance Fund). The application is addressed to the territorial health insurance fund, however, inside the fund, there is a commission established to examine the application.			
4.	**Is there a specific application form/module which the person seeking reimbursement needs to submit?**	**Answer:** *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?* Yes, a specific form is to be submitted (Website of the National Health Insurance Fund under the Ministry of Health, No.11) The specific application form (request for reimbursement of cross-border healthcare costs) contains the following information that is mandatory: • Information about the insured with compulsory health insurance (hereinafter - the insured): name(s), last name(s), personal code, date of birth. • Bank details of the insured (his/her representative): the name of the bank, personal account number or BIC code and IBAN code in case the applicant does not have a personal account with banks operating in the Republic of Lithuania.	**Source(s):** - The Procedure, Annex 1. - Website of the National Health Insurance Fund under the Ministry of Health.[483]	**Yes** ☐ **No** ☒ The reimbursement procedure does not apply domestically, because the Lithuanian national health care system is structured so that the cost of the treatment is already covered for the patient, if the person was insured at the time he or she was receiving health care.	No justification/purpose for the requirement was identified in the sources consulted (besides noting the fact that the reimbursement procedure does not apply domestically as the healthcare costs are directly anticipated for insured patients in Lithuania).

[483] Available at https://ligoniukasa.lrv.lt/lt/paslaugos/paslaugu-aprasymai/tarpvalstybines-sveikatos-prieziuros-islaidu-kompensavimas-paslauga-teikia-teritorines-ligoniu-kasos-1).

	• Address of the residence of the insured (his/her representative): country, municipality, town / village, house number, apartment number and postal code. • Contact details of the insured (his/her representative): phone number and e-mail address. • Data of the representative of the insured who has received cross-border health care: name(s), last name(s), personal code and date of birth (these data must be submitted if: 1) the application of the insured under 16 years of age is submitted by one of the parents (adoptive parents), guardian (custodian) or a representative of a social care institution; or 2) the application of the insured who is a disabled person is submitted by his / her guardian (caregiver) or other legal representative.(The Procedure, Annex 1, sections 1-5). This form is available online (it can be downloaded).(Website of the National Health Insurance Fund under the Ministry of Health, No.11). The form cannot be submitted electronically. It can only be submitted in paper. (Website of the National Health Insurance Fund under the Ministry of Health, No.6)			
5. What (other) documentation has to be submitted in order to substantiate a reimbursement request?	Answer: *If applicable, please specify:* - *What documents are required;* - *Whether the submission of the documentation is optional, mandatory, or recommended.* Other documents that are required are the following: • An identity document; • Medical documents or copies thereof, including:	**Source(s):** - The Procedure, paragraph 9.	**Yes** ☐ **No** ☒ Cfr. explanation on the national healthcare system provided above for question 4.	No justification/purpose for the requirement was identified in the sources consulted (besides noting the fact that the reimbursement procedure does not apply domestically as the healthcare costs are directly anticipated for

	1. if the insured person was provided with specialised outpatient or inpatient personal health care services in the country of treatment – a copy of the referral of a doctor of the personal health care institution of the Republic of Lithuania having concluded an agreement with the territorial insurance fund (except for primary personal health care services); 2. copies of documents and prescriptions confirming the prescription and receipt of reimbursable medicines, medical aids[i] or medical devices (if reimbursement of the purchase costs of medicines, medical aids or medical devices is requested); 3. if the insured has been prescribed reimbursable medicines or medical aids in the Republic of Lithuania - copies of Form 3 (in exceptional cases)[484] prescriptions according to which these medicines or medical aids were provided in the country of treatment. • original financial documents (invoices, cashier's checks, cash receipt receipts, etc.); • for the application of the insured under 16 years of age that must be completed and submitted to the territorial insurance fund by one of the parents (adoptive parents), guardian (custodian) or a representative of the social care institution - the documents confirming the appointment as guardian (custodian) or documents confirming the			insured patients in Lithuania).

[484] Form 3 refers to the specific prescription form for reimbursable medicinal products and reimbursable medical aid where: 1) the Insured does not have a Reimbursement Passport and the territorial insurance funds cannot immediately issue a Reimbursement Passport due to a malfunction of the Compulsory Health Insurance Computerized Information System or other reasonable reasons, and failure to grant a reimbursable medicinal product reimbursable medical aid may endanger his/her health or life; 2) the Insured plans to purchase reimbursable medicinal products, except narcotic medicinal products, or reimbursable medical aid in another EU country; 3) reimbursable medicines or reimbursable medical aid are prescribed to an Insured of another EU country. (Decree of the Minister of Health of the Republic of Lithuania, 2002 March 8 No. 112 "On the Rules of Issuance of Prescriptions and Provision of Medicinal Products, Medical Aids (Medical Devices) and reimbursable Medical Aids in Pharmacies to the population and Storage of Paper Prescriptions after dispensing (selling) Medicinal Products, Medical Aids (Medical Devices) and reimbursable Medical Aids in a Pharmacy"), available at https://www.e-tar.lt/portal/lt/legalAct/TAR.8268A928D936/asr, last accessed 7 June 2021.

	representation, or official copies of these documents as well as the identity document. • For the application of the disabled insured person that must be completed and submitted to the territorial insurance fund by his/her guardian (custodian) or other legal representative - the documents confirming the appointment as guardian (custodian), or documents confirming the representation, or official copies thereof as well as the identity document. The submission of the documentation is mandatory.			
6. Are there any costs associated with the handling of the reimbursement request? - *Direct costs (e.g., fixed costs for submitting or filing a reimbursement request, proportion deducted from the reimbursable amount).* - *Indirect costs* (*e.g., translations, stamps, etc).*	**Answer:** *Direct costs:* None identified (there are no direct costs associated with the handling of the reimbursement request). *Indirect costs:* None identified (there are no indirect costs associated with the handling of the reimbursement request). The handling of the reimbursement request is provided free of charge (Website of the National Health Insurance Fund under the Ministry of Health, No.7; the Procedure, paragraph 9).	**Source(s):** - Website of the National Health Insurance Fund under the Ministry of Health. - The Procedure.	**Yes** ☐ **No** ☒ Cfr. explanation on the national healthcare system provided above for question 4.	N/A
7. Are there any specific time requirements linked to a reimbursement request? (*e.g., time within which the reimbursement requests must be submitted and/or time within the requested*	**Answer:** *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* The reimbursement requests must be submitted no later than within one year of the provision of personal health care services and/or provision of medicines	**Source(s)** - The Law. - The Procedure.	**Yes** ☐ **No** ☒ Cfr. explanation on the national healthcare system provided above for question 4.	A 1-year deadline for applying for reimbursement of cross-border healthcare costs from the provision of personal healthcare services and / or medicines and / or medical devices and / or medical aids allow the National

body must handle the request and/or reimburse the costs, etc.).	and/or medical aids and/or medical devices. (The Law, Article 12[1] part 2) Territorial health insurance funds must handle the request no later than within 20 working days from the date of receipt of the documents specified in the answers to the questions 4 and 5 of this questionnaire. (The Procedure, paragraph 12) For cross-border healthcare, the territorial health insurance funds shall within 30 days from the date of the decision, transfer the reimbursable amount to the bank account specified in the application from the budget of the Compulsory Health Insurance Fund to reimburse healthcare costs. The shorter timeframe (10 working days from the date of the decision) is only established for transfer of the reimbursable amount for the purchase of orthopedic technical devices and joint endoprostheses in the country of treatment. The Procedure, paragraph 15).[485] Note: The National body contacted for the verification of the information collected in this questionnaire, indicated that, as for the consequences if the deadlines are missed, if the application is submitted by the insured person later than one year, the application is not considered. No other consequences identified.			Health Insurance Fund or territorial health insurance funds to make a reasoned decision. In case of doubts about the documents confirming the provision of personal health care services, the scope of services and / or the issuance of medicines and / or medical devices and / or medical aids, etc., the National Health Insurance Fund or territorial health insurance funds are able to apply to health care professionals of the European Economic Area country which have provided personal health care services and / or dispensed medicines and / or medical devices and / or medical aids. Given that the market for healthcare providers is constantly evolving, setting a deadline of 1 year from the provision of personal healthcare and / or medicines and / or medical devices and / or medical devices is likely to result in

[485] Note of the National expert: This is because only the Compulsory Health Insurance Fund owns funds to compensate for orthopaedic technical devices and joint endoprostheses (they are not distributed to territorial health insurance funds. The Compulsory Health Insurance Fund purchases endoprostheses centrally and distributes them to the territorial health insurance funds). However, from 1 January 2022, The Compulsory Health Insurance Fund will not be involved in the compensation of orthopedic technical devices and joint endoprostheses. Everything will be reimbursed through the territorial health insurance funds.

				the possibility for the National Health Insurance Fund or territorial health insurance funds to obtain the necessary and accurate information necessary for making a lawful decision. Both the one-year deadline for claiming reimbursement and 30 working days for reimbursement are linked to the very original idea behind the Directive: its purpose was to create an instrument that allows patients to receive the healthcare they need and compensation for such services as quickly as possible, without delay.[486]
8. Are there any non-reimbursable thresholds, deductions *(except the deductions for administrative costs mentioned above) etc.?*	**Answer:** *If yes, please specify the thresholds* No, the costs are reimbursed according to the basic prices of reimbursable medicines, medical aids, medical devices and health care services set by the	**Source(s):** - The Law, Article 12[1] part 2. - The Procedure, paragraph 8.	**Yes** ☒ **No** ☐ Cfr. explanation on the national healthcare system	No justification/purpose for the requirement was identified in the sources consulted.

[486] See the Explanatory report to the draft law amending and supplementing Articles 1, 2, 6, 21 of the Law on Health Insurance and supplementing the Law with Article 12 (1) and the Annex), 27 August 2013, available at https://e-seimas.lrs.lt/portal/legalAct/lt/TAK/TAIS.454934?jfwid=xqazkyx8w.

	Minister of Health, not exceeding the actual costs of the borne by the insured person.[487]		provided above for question 4.	
9. In instances where a PA (or prior-notification) has already been issued, is a separate/simplified procedure available for requesting reimbursement? **applicable only if the country has a PA system.*	**Answer:** *If yes, please describe the simplified procedure.* Not applicable as there is no PA system in Lithuania under the Directive.	**Source(s):** N/A	**Yes** ☐ **No** ☐	N/A
10. Are there additional administrative/procedural requirements for reimbursement depending on, for instance, the type of treatment for which reimbursement is requested, or the profile of the insured	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* There are no additional requirements other than those already mentioned above (i. e., obligation to provide a copy of the referral of a doctor of the personal health care institution of the Republic of Lithuania having	**Source(s):** N/A	**Yes** ☐ **No** ☐	N/A

[487] Specifically, the following costs of the Insured for cross-border healthcare are not reimbursed: 1) costs related to cross-border healthcare: travel, accommodation, meals, transport, translation, etc; 2) the patient's fees and bonuses which he/she pays to the healthcare provider in the country of treatment; 3) expenses for personal health care services provided in the country of treatment, which are not included in the lists of personal health care services approved by the Minister of Health of the Republic of Lithuania, the costs of which are paid from the budget of the Compulsory Health Insurance Fund, or which do not substantially correspond to the content of personal health care services; 4) expenditure on medicines, medical aids and medical devices intended for outpatient treatment, if they are not included in the List of Diseases and Compensatory Medicinal Products for Their Treatment (List A) or the List of Reimbursable Medicinal Products (List B) approved by the Minister of Health of the Republic of Lithuania on 28 January 2000 by the Decree No. 49 "On the Approval of the Lists of Reimbursable Medicinal Products" or the List of Reimbursable Medical Aids (List C) approved by the Minister of Health of the Republic of Lithuania on 6 October 2000 by the Decree No. 529 "On the Approval of the List of Reimbursable Medical Aids (List C)" or the List of Orthopedic Technical Measures Reimbursed from the Budget of the Compulsory Health Insurance Fund and their Basic Prices, approved by the Minister of Health of the Republic of Lithuania on 5 July 2012 by the Decree No. V-698 "On the Approval of the List of Orthopedic Technical Devices and their Basic Prices Reimbursed from the Budget of the Compulsory Health Insurance Fund".

person, or any other criterion?	concluded an agreement with the territorial insurance fund if the insured person was provided with specialised outpatient or inpatient personal health care services in the country of treatment); different timeframe for transfer of the reimbursable amount for the purchase of orthopedic technical devices and joint endoprostheses in the country of treatment or additional documents (i.e., documents confirming the representation of the insured))			
11. Please list any other administrative requirements in your country in relation to the procedures of reimbursement of cross-border healthcare.	**Answer:** There are no additional administrative requirements in place.	**Source(s):** N/A	**Yes** ☐ **No** ☐	N/A

Part 2: Checklist for verification with national/regional body

Name of the body: National Health Insurance Fund under the Ministry of Health.
Country/Region: Lithuania.
Date of verification call: 9 June 2021.

Template for the Data Collection	**Aspects to be verified** *Tick the boxes if the information in the template for the data collection has been verified and/or complemented by the national body*		**Comments** *Include any additional comments and/or information provided by the contacted body*
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Justification/purpose of the identified requirement(s) (Column 4)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	All the input provided has been included in the questionnaire.[488] The answers in the questionnaire were adjusted accordingly to the feedback received, which was duly incorporated throughout the report
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Whether the requirement applies domestically (Discriminatory assessment) (Column 4) ▪ Justification/purpose of the identified requirement(s) (Column 5)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	Comments were provided for the Section 2, questions 1 to 8. Key comments were made on answers 2, 7 and 8. Specifically, I the national legal expert was informed about the procedure as for PA under the Social Security Coordination Regulations (see the answer 2), the consequences of missing the deadline, the changes from 2022 January 1 (see the answer 7), and it was confirmed that there are no non-reimbursable thresholds, deductions (see the answer 8), no indication of which – in fact - had been identified in the sources consulted.

[488] Additional comment: One more expert - Ausrine Storpirstiene (Advisor of the Law Division of the Ministry of Health) also participated in the call and provided valuable feedback.

LUXEMBOURG – COUNTRY REPORT

Part 0: Preliminary Assessment

1. **Please indicate whether the rules governing the administrative procedures/requirements for requesting PA and reimbursement under Directive 2011/24/EU in your country are set out at:**

A. National level ☒

B. Decentralised/regional/local level ☐

In case (1.B): Please indicate the two most relevant jurisdictions in your country (i.e., in terms of population):

Region/jurisdiction: 1: N/A

Region/jurisdiction 2: N/A

NOTE: In case (1.B) the template for the data collection (Part 1) should be complete twice, once for each of the two most relevant regions/jurisdiction indicated above.

2. **Please indicate the national body best suited to verify the accuracy of the information collected in Part 1, and justify your selection.**
Depending on the characteristics of your national healthcare system, the relevant body may be: a) *the national social security body*; or b) *an insurance fund*. In the latter case, please indicate the most representative fund (e.g., the one with the highest number of affiliations).

Body to be contacted for Task 2: Caisse nationale de santé - D'Gesondheetskeess (CNS) (National Health Fund)

(In case 1.B, please indicate two relevant bodies, one respectively for each Region/jurisdiction)

Reasons for Selection: The CNS is the national body in charge of issuing the prior authorisation (PA) in the context of cross-border healthcare within the European Union. It is also in charge of handling the reimbursement requests for the private sector. The CNS is the main contact to inform patients about their rights and is one of the two NCPs for Luxembourg. The body was contacted for the verification of the data collects by the national legal expert, but no response has been yet received.

Part 1: Questionnaire

*__Note 1__: In cases where administrative requirements are set out in the legislative/regulatory framework at decentralised/regional/local level, please complete the template for the data collection twice, once for each of the two most relevant regions/jurisdictions (e.g., in terms population).

__*Note 2__: Setting out a Prior Authorisation (PA) system is optional for Member States. Should your country not have a system of PA in place under Directive 2011/24/EU, Section 1 will not need to be completed.

SECTION 1 PRIOR AUTHORISATION PROCEDURE(S)			
Questions	**Answer**	**Sources**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to PA procedures for a cross-border healthcare under Directive 2011/24/EU?	Answer: Under Article 20 of the Code de la Sécurité Sociale (Social Security Code), a PA is required in the context of cross-border healthcare if: • the healthcare involves at least one night of hospitalisation in a hospital infrastructure • the healthcare requires the use of highly specialised and cost-intensive hospital equipment as listed by the Law of 8	Source(s): • Social Security Code[490], Article 20 • Statutes of the CNS[491], Articles 26 to 28 • Website of the CNS regarding the PA procedure[492]	N/A

[490] Code de la sécurité sociale (Social Security Code), available at: https://www.secu.lu/assurance-maladie/livre-i/ (last accessed on 30 June 2021)
[491] Statuts de la Caisse nationale de santé (CNS) – D'Gesondheetskeess (Statutes of the National Health Fund), available at: https://cns.public.lu/dam-assets/legislations/statuts/cns-statuts-actuels.pdf (last accessed on 30 June 2021)
[492] Website of the Caisse nationale de santé (CNS) – D'Gesondheetskeess (Statutes of the National Health Fund), available at: https://cns.public.lu/en/assure/vie-privee/a-etranger/traitement-etranger/pays-membre-ue-eee-suisse.html (last accessed on 30 June 2021)

	March 2018 on hospital facilities and hospital planning[489]. The Articles 26 to 28 of the Statutes of the CNS lay out the procedure and administrative requirements for the PA application and the granting process.		
2. Is this the same procedure as for PA under the Social Security Coordination Regulations?	Answer: Yes ☒ No ☐		N/A
3. What body is in charge of handling the PA applications? *(e.g., where and to whom PA applications have to be submitted?)*	Answer: *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* The Caisse nationale de santé - D'Gesondheetskeess (CNS) (National Health Fund) is in charge of handling the PA applications. The CNS checks that the application satisfies the formal requirements before referring it to the Contrôle medical de la sécurité sociale(CMSS) (Medical Board of the Social Security) for a medical assessment. The PA is granted by the CNS based on a favourable opinion from the CMSS.	Source(s): • Social Security Code, Article 20 • Statutes of the CNS, Articles 26 to 28 • Website of the CNS regarding the PA procedure.	N/A
4. Who is entitled to apply for PA? *(e.g., can the patients apply themselves, or is treating*	Answer: *If there is a national doctor involved, is there a requirement that this doctor is contracted by*	Source(s): • Statutes of the CNS, Article 27 and Annex L	No specific purpose for the requirements was identified in the sources consulted.

[489] Law in force on the 16 June 2021: Loi du 8 mars 2018 relative aux établissements hospitaliers et à la planification hospitalière (Law of 8 March 2018 on hospital facilities and hospital planning), available at: http://legilux.public.lu/eli/etat/leg/loi/2018/03/08/a222/jo (last accessed on 17/06/2021).

	doctor filing/partially filling the request, etc.)	*the national insurance provider in the EU/EEA EFTA State issuing the PA?* The PA application must be filled by a doctor specialised in the pathology involved. The PA application is then submitted to the CNS by the patient.	• Website of the CNS regarding the PA procedure	
5.	Is there a specific application form/module which the person seeking PA needs to submit?	Answer: *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?* The Annex L of the Statutes of the CNS, which is available online[493], is a standard form used by doctors to fill the PA application. The PA application is submitted by the patient, either by mail to the Service Transfert à l'Étranger (Service for Transfers Abroad), by fax or by e-mail. The PA application must contain at least the following mandatory information: - the details of the patient (name, address and affiliation number),	Source(s): • Statutes of the CNS, Article 27 and Annex L	No specific purpose for the requirements was identified in the sources consulted.

[493] Form for PA request available at: https://cns.public.lu/dam-assets/formulaires/transfert-a-etranger/Demande_Transfert_Etranger_FR_07_2017_.pdf

	- the details of the doctor filling the PA application; - the diagnosis; - the type of healthcare that need to be performed; - the start date and the expected duration of the planned healthcare; - the reasons why this healthcare has to be performed; - the details of the healthcare provider who will be performing the planned healthcare; - if applicable, the type of highly specialised and cost-intensive hospital equipment that will be used; - if applicable, the reasons why a treatment in Luxembourg proves to be impossible or inadequate, or that the patient cannot be given such treatment within a time limit that is medically justifiable, taking account of his/her current state of health and the probable course of the condition; - if the insured person seeks the transport cost to be covered, the details regarding the type of transport and the reason why this transport is needed.		
6. What (other) documentation has to be submitted in order to substantiate a PA request?	Answer: *If applicable, please specify:* - *What documents and what particulars are required;* - *Whether there are requirements as to who has to issue the documents (e. g., a doctor contracted by the national insurance provider in the EU/EEA*	Source(s): N/A	N/A

	EFTA State issuing the PA or any doctor); - *Whether the submission of the documentation is optional, mandatory, or recommended.* No other documentation required.		
7. Are there any costs associated with the handling of the PA request? - *Direct costs (e.g., fixed costs for submitting or filing a PA request).* - *Indirect costs* (*e.g., translations, stamps, etc).*	Answer: *Direct costs:* None identified. *Indirect costs:* None identified.	Source(s): N/A	N/A
8. Are there any specific time requirements linked to a PA request? (*e.g., time within which a requesting person must submit the PA application and/or time within which the requested body must take a decision on the PA request, etc.*).	Answer: - *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* The PA application must be submitted before the start of the planned healthcare. No reimbursement will be made without the PA. The CNS has to notify its decision in a time period compatible with the degree of urgency and availability of the planned healthcare, and at the latest 3 weeks after receiving the PA application. If the CNS is not able to take a decision within the 3 weeks period, it notifies to the insured person the reason for the delay.	Source(s): • Statutes of the CNS, Article 28 • Website of the CNS regarding the PA procedure	No specific purpose for the requirements was identified in the sources consulted.

	No specific consequences identified if the deadlines are not met.		
9. Are there differences in the procedural/administrative requirements for requesting PA based on, for instance, the type of treatment for which PA is requested, the profile of the insured person, or any other criterion?	Answer: *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* No such differences identified.	Source(s): N/A	N/A
10. Is there a specific PA form (i.e., form used for issuing/granting PA) and, if the answer is positive, what form?	Answer: The CNS usually grants PA by using the Form S2. However, if the healthcare falls outside the scope of the Social Security Coordination Regulations, namely, if the application does not fulfill the requirements of the Regulation, the PA under the Directive is granted. This implies that the CNS issues a certificate of coverage ("titre de prise en charge"). indicating the reimbursement to be requested from the competent fund in Luxembourg, according to the tariffs or fixed amounts specified.	Source(s): • Statutes of the CNS, Article 28 • Website of the CNS regarding the PA procedure	No specific purpose for the requirements was identified in the sources consulted.
11. Please list any other administrative requirements in your country in relation to the PA procedure for cross-border healthcare.	Answer: None identified.	Source(s): N/A	N/A
SECTION 2 **REIMBURSMENT PROCEDURE(S)**			

Questions	Answer:	Sources	Does/do the identified requirement(s) also apply domestically? (i.e., is the requirement non-discriminatory?)	Purpose and/or justification of the requirements
1. Which national legislative and/or regulatory provisions lay out the requirements related to reimbursement procedures for cross-border healthcare under Directive 201/24/EU?	Answer: Article 20 of the Social Security Code and the Articles 20 and 29bis of the Statutes of the CNS provide the right and the procedural rules of reimbursement of cross-border healthcare costs under Directive 2011/24/EU.	Source(s): • Social Security Code, Article 20 • Statutes of the CNS, Articles 20 and 29bis • Website of the CNS regarding the procedure for the reimbursement by cheque[494] or by bank transfer[495]	N/A	N/A
2. Is this the same procedure as for reimbursement under the Social Security Coordination Regulations?	Answer: Yes ☒ No ☐		N/A	N/A
3. What body is/are responsible of handling the reimbursement applications? (e.g., where and to whom reimbursement applications have to be submitted?)	Answer: *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).*	Source(s): • Social Security Code, Articles 44 and 48	N/A	N/A

[494] Available at: https://cns.public.lu/en/assure/vie-privee/depenses-sante/avance-frais/remboursement-cheque.html (last accessed on 30 June 2021)
[495] Available at: https://cns.public.lu/en/assure/vie-privee/depenses-sante/avance-frais/remboursement-virement.html (last accessed on 30 June 2021)

	The relevant public health fund responsible of handling the reimbursement applications depends on the socio-professional regime of the insured person: - Caisse nationale de santé - D'Gesondheetskeess (CNS) (National Health Fund) for the private sector, which is the main public health fund based on the number of affiliations. - Caisse de maladie des fonctionnaires et employés publics (CMFEP) (Health Insurance Fund for Civil Servants and Public Employees) and Caisse de maladie des fonctionnaires et employés communaux (CMFEC) (Health Insurance Fund for Communal Civil Servants and Employees) for the public sector. - Entraide médicale des CFL (EMCFL) (CFL Health Insurance Fund) for the employees of the Luxembourg Rail Company.			
4. Is there a specific application form/module which the person seeking reimbursement needs to submit?	Answer: *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?* There is no specific form for requesting reimbursement. Reimbursement can be done in person of by post.	Source(s): • Website of the CNS regarding the procedure for the reimbursement by cheque or by bank transfer	Yes ☒ No ☐ In case the patient anticipates the costs of a treatment provided in Luxembourg, the reimbursement procedure will be the exact same.	No specific purpose for the requirements was identified in the sources consulted.

	The insured person has to submit the invoices and payment receipts (see question 5). The request must also contain the insured's surname, first name, address and 13-digit identification number. If it is the first reimbursement request from this insured person, he/she should also provide a bank account statement to receive the payment.		However, a "third party payment system" between the healthcare providers and the CNS exists for specific types of medical care, hospital fees, physiotherapy, laboratory tests, medicines, etc. For these specific medical expenses, the patient needs to present his/her public health insurance card and will only pay the part of the expense that is not covered by the public health insurance, if any. Therefore, there is no reimbursement procedure in this case.	

5. What (other) documentation has to be submitted in order to substantiate a reimbursement request?	Answer: *If applicable, please specify:* - *What documents are required;* - *Whether the submission of the documentation is optional, mandatory, or recommended.* It is a mandatory requirement to submit the original copies of the invoices and payment receipts to request their reimbursement.	Source(s): • Social Security Code, Article 84 • Statutes of the CNS, Article 20 • Website of the CNS regarding the procedure for the reimbursement by cheque or by bank transfer	Yes ☒ No ☐	No specific purpose for the requirements was identified in the sources consulted.
6. Are there any costs associated with the handling of the reimbursement request? - *Direct costs (e.g., fixed costs for submitting or filing a reimbursement request, proportion deducted from the reimbursable amount).* - *Indirect costs* (*e.g., translations, stamps, etc).*	Answer: *Direct costs:* None identified. *Indirect costs:* None identified.	Source(s): N/A	Yes ☒ No ☐	No specific purpose for the requirements was identified in the sources consulted.
7. Are there any specific time requirements linked to a reimbursement request? (*e.g., time within which the reimbursement requests must be submitted and/or time within the requested body must handle the request and/or reimburse the costs, etc.*).	Answer: *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* Under Article 84 of the Social Security Code, the insured person must submit a reimbursement request within 2 years following the payment of the invoices. Beyond this 2 years period, the insured person loses the right to claim reimbursement.	Source(s): • Social Security Code, Article 84 • Statutes of the CNS, Article 23	Yes ☒ No ☐	No specific purpose for the requirements was identified in the sources consulted.

	There is no mandatory deadline for the CNS to handle the request and reimburse the costs.			
8. Are there any non-reimbursable thresholds, deductions *(except the deductions for administrative costs mentioned above) etc.?*	Answer: *If yes, please specify the thresholds.* None identified. Costs are covered on the basis of the Luxembourg Social Security tariffs, within the limit of the costs incurred. The Annex K of the Statutes of the CNS lists the maximum amount covered for each specific treatment or medicine requiring a PA under Directive 2011/24/EU.	Source(s): • Social Security Code, Article 84 • Statutes of the CNS, Article 23 and Annex K	Yes ☒ No ☐	N/A
9. In instances where a PA (or prior-notification) has already been issued, is a separate/simplified procedure available for requesting reimbursement? **applicable only if the country has a PA system.*	Answer: *If yes, please describe the simplified procedure.* No such simplified procedure identified.	Source(s): • Statutes of the CNS, Article 23	Yes ☐ No ☐ N/A	N/A
10. Are there additional administrative/procedural requirements for reimbursement depending on, for instance, the type of treatment for which reimbursement is requested, or the profile of	Answer: *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* None identified.	Source(s): N/A	Yes ☐ No ☐ N/A	No specific purpose for the requirements was identified in the sources consulted.

the insured person, or any other criterion?				
11. Please list any other administrative requirements in your country in relation to the procedures of reimbursement of cross-border healthcare.	Answer: None identified.	Source(s): N/A	Yes ☐ No ☐ N/A	N/A

Part 2: Checklist for verification with national/regional body

Name of the body: N/A
Country/Region: N/A
Date of verification call: N/A

Template for the Data Collection	**Aspects to be verified** *Tick the boxes if the information in the template for the data collection has been verified and/or complemented by the national body*		**Comments** *Include any additional comments and/or information provided by the contacted body*
Section 1 – Prior Authorisation			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Justification/purpose of the identified requirement(s) (Column 4)	☐ Question 1 ☐ Question 2 ☐ Question 3 ☐ Question 4 ☐ Question 5	☐ Question 6 ☐ Question 7 ☐ Question 8 ☐ Question 9 ☐ Question 10 ☐ Question 11	
Section 2 - Reimbursement			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Whether the requirement applies domestically (Discriminatory assessment) (Column 4) ▪ Justification/purpose of the identified requirement(s) (Column 5)	☐ Question 1 ☐ Question 2 ☐ Question 3 ☐ Question 4 ☐ Question 5	☐ Question 6 ☐ Question 7 ☐ Question 8 ☐ Question 9 ☐ Question 10 ☐ Question 11	

MALTA – COUNTRY REPORT

Part 0: Preliminary Assessment

1. **Please indicate whether the rules governing the administrative procedures/requirements for requesting PA and reimbursement under Directive 2011/24/EU in your country are set out at:**

A. National level ☒

B. Decentralised/regional/local level ☐

In case (1.B): Please indicate the two most relevant jurisdictions in your country (i.e., in terms of population):

Region/jurisdiction: 1: N/A

Region/jurisdiction 2: N/A

NOTE: In case (1.B) the template for the data collection (Part 1) should be complete twice, once for each of the two most relevant regions/jurisdiction indicated above.

2. **Please indicate the national body best suited to verify the accuracy of the information collected in Part 1, and justify your selection.**

Depending on the characteristics of your national healthcare system, the relevant body may be: a) *the national social security body*; or b) *an insurance fund*. In the latter case, please indicate the most representative fund (e.g., the one with the highest number of affiliations).

Body to be contacted for Task 2: Department of Social Security, 38 Ordnance Street, Valleta VLT 1021.Telephone number: +356 21255153. **(**No e-mail address available – only an online contact form). The body was contacted for the verification of the data collected by the national legal expert, but no answer was received.

Reasons for Selection: This is the national social security body of Malta. They have information on EU Coordination Rules, in particular with regards to the coordination of social security schemes, as per EU Social Security Coordination Regulations (EC) Nos. 883/2004 and 987/2009.

Part 1: Questionnaire

*__Note 1__: In cases where administrative requirements are set out in the legislative/regulatory framework at decentralised/regional/local level, please complete the template for the data collection twice, once for each of the two most relevant regions/jurisdictions (e.g., in terms population).

__*Note 2__: Setting out a Prior Authorisation (PA) system is optional for Member States. Should your country not have a system of PA in place under Directive 2011/24/EU, Section 1 will not need to be completed.

SECTION 1 PRIOR AUTHORISATION PROCEDURE(S)			
Questions	**Answer**	**Sources**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to PA procedures for a cross-border healthcare under Directive 2011/24/EU?	**Answer:** The legislative provision that lays out the requirements related to PA procedures for cross-border healthcare under Directive 2011/23/EU in Malta is S.L. 528.03 Cross-Border Healthcare Regulations 2013. See **Regulation 10:** *(1) No insured person seeking to exercise his rights under these regulations shall be required to seek prior authorisation for the treatment sought save under the following circumstances:*	**Source(s):** S.L. 528.03 Cross-Border Healthcare Regulations 2013[496]	N/A

[496] S.L. 528.03 Cross-Border Healthcare Regulations 2013, available at: https://legislation.mt/eli/sl/528.3/eng (last accessed 9 June 2021).

	(a) if it involves hospital accommodation of the patient in question for at least one night; or *(b) if it requires use of highly specialised and cost-intensive medical infrastructure or medical equipment; or* *(c) if it involves treatments presenting a particular risk for the patient or the population, or* *(d) if it is provided by a healthcare provider that could give rise to serious and specific concerns relating to the quality or safety of the care, with the exception of healthcare which is subject to European Union legislation ensuring a minimum level of safety and quality throughout the European Union.* *(2) For the purpose of this regulation, the Directorate for Policy in Health shall publish a list of procedures which shall be known as the List of Procedures Requiring Prior Authorisation for Cross-Border Healthcare, and which may be updated from time to time, that require prior authorisation under sub-regulation (1).* See also **Regulation 11:** *(1) Prior authorisation may be refused for the following reasons:* *(a) the patient will, according to a clinical evaluation, be exposed with reasonable certainty to a patient-safety risk that cannot be regarded as acceptable, taking*		

	into account the potential benefit for the patient of the sought cross-border healthcare; *(b) the general public will be exposed with reasonable certainty to a substantial safety hazard as a result of the cross-border healthcare in question;* *(c) this healthcare is to be provided by a healthcare provider that raises serious and specific concerns relating to the respect of standards and guidelines on quality of care and patient safety, including provisions on supervision, whether these standards and guidelines are laid down by laws and regulations or through accreditation systems established by the Member State of treatment;* *(d) this healthcare can be provided in Malta within a time limit which is medically justifiable, taking into account the current state of health and the probable course of the illness of each patient concerned.* *(2) Without prejudice to the provisions of paragraphs (a) to (c) of sub-regulation (1), prior authorisation may not be refused when this healthcare cannot be provided in Malta within a time-limit which is medically justifiable, based on an objective medical assessment of the patient's medical condition, the history and probable course of the patient's illness, the degree of the patient's pain and, or the nature of the patient's disability*		

	at the time when the request for authorisation was made or renewed. *(3) There shall be established a Committee, to be appointed by the Minister and to be known as the Cross-Border Prior Authorisations Committee, whose function shall be to ascertain whether all the conditions laid down under the Act and under these regulations have been met and to decide whether such prior authorisations shall be granted.* *(4) Any request for cross-border healthcare shall be dealt with within a period of six weeks from the date such request is received, unless the urgency of the case or the particular medical condition requires a shorter period* (5) *Any decision taken regarding the use of cross-border healthcare and, or reimbursement, shall be properly reasoned and forwarded to the patient, and subject to appeal under the provisions of the Act.*		
2. Is this the same procedure as for PA under the Social Security Coordination Regulations?	**Answer:** **Yes ☐ No ☒** The procedures appear to be different (it is unclear whether they may correspond substantially).[497]		The legislation mentioned above concerns Cross-border Healthcare only. The procedure for PA under the Regulation is similar in the sense that the Treatment Abroad Committee assesses the application that is done by the clinician and raised to the committee. Decisions are taken within at most a week or so.[498]
3. What body is in charge of handling the PA applications?	**Answer:** *Should your national healthcare system be based on multiple insurance*	**Source(s):**	Health care in MT is centralised onto the Government National Health Service that is free of charge at the service-patient interface. The

[497] See Health.gov.mt – FAQ. Available at :https://deputyprimeminister.gov.mt/en/cbhc/Documents/frequently_asked_questions_1.pdf (last accessed 9 June 2021). See also ***information on the Social Security Regulations***: ***https://socialsecurity.gov.mt/en/international-relations/eu-coordination-rules/ - (***last accessed 9 June 2021).

[498] Information provided to Spark Legal Network by the Maltese Ministry of Health on 7 October 2021.

(e.g., where and to whom PA applications have to be submitted?)	*providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations)* Applications shall be submitted to: The Office of the Chief Medical Officer of the Ministry of Health (the National Contact Point) Palazzo Castellania 15, Merchants Street, Valletta VLT 1171. Telephone number: (+356) 22992381. E-mail: crossborderhealth@gov.mt	Health.gov.mt, 'Cross Border Health Care' (September 2020)[499]	national health service is supported by a National Insurance fund collected by the tax department from every employee in the country. Any private healthcare insurers in MT support private health care only and are not concerned with the Regulation or the Directive. Private health care insurance is a personal choice and does not remove or replace one's rights on the National Healthcare Service.[500]
4. Who is entitled to apply for PA? *(e.g., can the patients apply themselves, or is treating doctor filing/partially filling the request, etc.)*	**Answer:** - *If there is a national doctor involved, is there a requirement that this doctor is contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA?* Patients are entitled to apply for PA. Their treatment must in accordance with **Regulation 10 of S.L. 528.03** involve hospital accommodation for at least one night; or require the use of highly specialised and cost-intensive medical infrastructure or medical equipment; or it involves treatments	**Source(s):** Department of Health, 'Claim Form for Reimbursement of Treatment / Health Care Service(s) Sought Under Cross-Border Regulations'[501] S.L. 528.03 Cross-Border Healthcare Regulationss 2013,	N/A

[499] Health.gov.mt, 'Cross Border Health Care' (September 2020), available at: https://deputyprimeminister.gov.mt/en/cbhc/Pages/Cross-Border.aspx (last accessed 9 June 2021).
[500] Information provided to Spark Legal Network by the Maltese Ministry of Health on 7 October 2021.
[501] Department of Health, 'Claim Form for Reimbursement of Treatment / Health Care Service(s) Sought Under Cross-Border Regulations', available at: https://deputyprimeminister.gov.mt/en/cbhc/Documents/ClaimFormForReimbursement.pdf (last accessed 9 June 2021).

	presenting a particular risk for the patient or the population; or if it is provided by a healthcare provider that could give rise to serious and specific concerns relating to the quality or safety of the care, with the exception of health care which is subject to EU standards. The person seeking healthcare abroad must be covered by the National Insurance scheme in Malta. However, they do need a ticket of referral from a Specialist, indicating their medical condition(s)/diagnosis, time-line of events and the medical need for the treatment prior to it being sought. This Specialist must be on the 'Specialist Accreditation Register'.	National Contact Point Cross-border Healthcare Malta, 'Processing of requests for treatment abroad algorithm' REF: NCP 02/19[502]	
5. Is there a specific application form/module which the person seeking PA needs to submit?	**Answer:** *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?* There appears to be specific application form which needs to be submitted by someone	**Source(s):** Department of Health, 'Claim Form for Reimbursement of Treatment / Health Care Service(s) Sought Under Cross-Border Regulations', available at: https://deputyprimeminister.gov.mt/en/cbhc/Documents/ClaimFormForReimbursement.pdf (last accessed 9 June 2021).	N/A

[502] National Contact Point Cross-border Healthcare Malta, 'Processing of requests for treatment abroad algorithm' REF: NCP 02/19, available at: https://deputyprimeminister.gov.mt/en/cbhc/Documents/Cross_Border_Health_Care/Processing_of_Requests_for_Treatment_Abroad_SOP.pdf (last accessed 10 June 2021).

	seeking PA, which can be found online.[503] However, though it is referred to as "Prior Authorisation Form' on the Health.gov.mt website, at the time of the present legal research the accessible form actually appeared to be the one to be used for a 'Claim Form for Reimbursement of Treatment / Health Care Service(s) Sought Under Cross-Border Regulations'.[504] In consideration of the fact that the information requested therein is, indeed, relevant for the time period 'after' the treatment abroad has been received (i.e., see Section 2 – information required in the application module), and that the actual PA form does not seem to be accessible, it is not possible to answer the question with regards to the information required in the application form for PA. Moreover, it was not clear whether the form can be submitted online, or whether this can only be submitted via post. The website simply states that the NCP should be contacted. [505]	Health.gov.mt, 'Cross Border Health Care' (September 2020)	

[503] Please note that the link to this form actually leads to the form for the 'Claim Form for Reimbursement of Treatment / Health Care Service(s) Sought Under Cross-Border Regulations' (see: Health.gov.mt, 'Cross Border Health Care' (September 2020), available at: https://deputyprimeminister.gov.mt/en/cbhc/Pages/Cross-Border.aspx (last accessed 9 June 2021)). Morevover, PA does not seem to be always mandatory, but recommended as it is mentioned that 'It is in your best interest to obtain prior approval from the Department of Health as this allows continuity of care and organisation of aftercare on your return.' There is, however, a list of services for which PA is mandatory. Please, find the list at the following: https://deputyprimeminister.gov.mt/en/cbhc/Documents/Cross_Border_Health_Care/Prior_Authorisation.pdf, (last accessed 9 June 2021). In particular, according to Regulation 10 of S.L. 528.03 Cross-Border Healthcare Regulations 2013, and as indicated on the Health.gov.mt website, PA is mandatory in the following cases: i) If the healthcare involves overnight hospital stay of at least one night; ii) If the healthcare involves highly specialized/cost-intensive healthcare; iii) If there are concerns regarding the quality and safety of the healthcare provider; iii) If the treatment carries a particular risk.

[504] According to the information provided to Spark Legal Network by the Maltese Ministry of Health on 7 October 2021, the link on the website has been corrected to address this issue.

[505] According to the information provided to Spark Legal Network by the Ministry of Health on 7 October 2021, the website will be updated in the coming months. .

6. What (other) documentation has to be submitted in order to substantiate a PA request?	**Answer:** *If applicable, please specify:* - *What documents and what particulars are required;* - *Whether there are requirements as to who has to issue the documents (e. g., a doctor contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA or any doctor);* - *Whether the submission of the documentation is optional, mandatory, or recommended.* According to the information extracted from the Reimbursement Form (see explanation in Question 5 above) the following documentation seems to be required in order to substantiate a PA request: - Ticket of referral: a ticket of referral from the patient's clinician, indicating the patient's medical condition(s)/diagnosis, time-line of events and the medical need for the treatment prior to it being sought, must be attached. This needs to be done by a Specialist (as per Specialist Accreditation Register) if prior authorisation is sought;	**Source(s):** Department of Health, 'Claim Form for Reimbursement of Treatment / Health Care Service(s) Sought Under Cross-Border Regulations' National Contact Point Cross-border Healthcare Malta, 'Standard Operating Procedure for the processing of requests for prior authorization for treatment abroad under Articles 10 and 11 of the national Cross Border Healthcare Regulations (S.L 528.03)' REF: NCP 03/19[506]	A ticket of referral is required where PA is necessary. The ticket of referral is to be issued and signed by a Specialist in the respective field of specialisation and who is in government service.[507]

[506] National Contact Point Cross-border Healthcare Malta, 'Standard Operating Procedure for the processing of requests for prior authorization for treatment abroad under Articles 10 and 11 of the national Cross Border Healthcare Regulations (S.L 528.03)' REF: NCP 03/19, available at: https://deputyprimeminister.gov.mt/en/cbhc/Documents/Cross_Border_Health_Care/Requests_for_Cross_Border_SOP.pdf (last accessed 9 June 2021).
[507] Information provided to Spark Legal Network by the Maltese Ministry of Health on 7 October 2021.

	This document appears to be mandatory in applying for prior authorisation. However, given that the PA form is not available, it is unclear whether other documentation is requested to substantiate the request.		
7. Are there any costs associated with the handling of the PA request? - *Direct costs (e.g., fixed costs for submitting or filing a PA request).* - *Indirect costs* (*e.g., translations, stamps, etc).*	**Answer:** *Direct costs:* There are no direct costs for the handling of the PA request. *Indirect costs:* There are no indirect costs for the handling of the PA request. [508]	**Source(s):** N/A	N/A
8. Are there any specific **time requirements** linked to a PA request? (*e.g., time within which a requesting person must submit the PA application and/or time within which the requested body must take a decision on the PA request, etc.*).	**Answer:** According to Regulation 11(4) of Cross-Border Healthcare Regulations: 'Any request for cross-border healthcare shall be dealt with within a period of six weeks from the date such request is received, unless the urgency of the case or the particular medical condition requires a shorter period'. Moreover, there appears to be a general commitment requirement for the Ministry of Health to address any queries and requests for information within the shortest possible time and not more than seven working days. If a case is urgent, a decision could be taken within 24-48 hours.[509]	**Source(s):** Health.gov.mt, 'Cross Border Health Care' (September 2020) S.L. 528.03 Cross-Border Healthcare Regulations 2013	

[508] Both answers were confirmed by the Maltese Ministry of Health on 7 October 2021.
[509] This was confirmed by the Maltese Ministry of Health on 7 October 2021.

	No consequences if the deadlines are not met were identified.		
9. Are there **differences in the procedural/administrative requirements for requesting PA** based on, for instance, the type of treatment for which PA is requested, the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* There do not seem to be any differences in the procedural/administrative requirements for requesting PA.	**Source(s):** N/A	N/A
10. Is there a specific PA form (i.e., form used for issuing/granting PA) and, if the answer is positive, what form?	**Answer:** Approvals of PA are issued as soon as the Treatment Abroad Committee issues its approval, and an official letter of approval is sent. There are no specific form, but a letter.[510]	**Source(s):** N/A	N/A
11. Please list any other administrative requirements in your country in relation to the PA procedure for cross-border healthcare.	**Answer:** There does not seem to be any other administrative requirements in your country in relation to the PA procedure for cross-border healthcare.	**Source(s):** N/A	N/A

SECTION 2 **REIMBURSMENT PROCEDURE(S)**				
Questions	**Answer:**	**Sources**	**Does/do the identified requirement(s) also apply domestically?**	**Purpose and/or justification of the requirements**

[510] Information provided to Spark Legal Network by the Maltese Ministry of Health on 7 October 2021.

			(i.e., is the requirement non-discriminatory?)	
1. Which national legislative and/or regulatory provisions lay out the requirements related to reimbursement procedures for cross-border healthcare under Directive 201/24/EU?	**Answer:** The national legislative provision laying out the requirements related to reimbursement procedures for cross-border healthcare is S.L. 258.03 Cross-Border Healthcare Regulations. **Regulation 8** (on conditions for reimbursement) maintains the following: *(1) The costs related to cross-border healthcare shall only be reimbursed to an insured person after all the conditions laid down in these regulations have been satisfied and if the healthcare for which reimbursement is being requested forms part of the Register provided for in the Act.* *Provided that notwithstanding the above, for the purpose of cross-border care, organ transplants, vaccination programmes against infectious diseases, long-term and community care services are excluded. In respect of medicines, medicinal products and medical devices, reimbursement of cross-border health care shall refer only to those instances where these are provided in the context of a health service and where such products form part of the Government Formulary List.* *(2) An insured person who is resident in a Member State other than in Malta, and for*	**Source(s):** S.L. 528.03 Cross-Border Healthcare Regulations 2013[511]	N/A	N/A

[511] S.L. 528.03 Cross-Border Healthcare Regulations 2013, available at: https://legislation.mt/eli/sl/528.3/eng (last accessed 10 June 2021).

	whom Malta is the competent Member State under Regulation (EC) No. 883/2004, shall be entitled to the services offered by the Maltese public healthcare system at the same conditions of other insured persons residing in Malta, if such a service: *(a) is not a service requiring prior authorisation in the Member State where the insured person resides; and* *(b) is not provided in accordance with Chapter 1 of Title III of Regulation (EC) No 883/2004.* *(3) No costs shall be reimbursed in relation to healthcare provided by local private healthcare providers.* **Regulation 9** (on maximum reimbursement) provides: *(1) The maximum amount of costs to be reimbursed shall be either the amount of the relative healthcare service or services costs according to the Register provided for in the Act, or the actual costs of the healthcare service or services received, whichever is the lowest. No ancillary or related costs shall be reimbursed.* *(2) Reimbursement of the costs of cross-border healthcare shall be subject to the same conditions, criteria of eligibility and regulatory and administrative formalities, as applicable if this healthcare was provided under the Maltese public healthcare system: Provided that notwithstanding the above, the Directorate for Policy in Health shall retain*			

	the right to limit the application of the rules on reimbursement for cross-border healthcare based on overriding reasons of general interest, such as planning requirements relating to the aim of ensuring sufficient and permanent access to a balanced range of high-quality treatment in Malta or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources: Provided further that the same conditions, criteria of eligibility, tariffs and regulatory and administrative formalities shall apply in the case of a person insured in a Member State, other than Malta, seeking cross-border healthcare under the Maltese public healthcare system. *(3) Notwithstanding anything contained in these regulations, any cross-border healthcare for which a prior authorisation has already been granted, even before the entry into force of these regulations, shall be reimbursed in accordance with that same authorisation.* *(4) Notwithstanding the provisions of this regulation, the Minister shall retain the right to adopt measures regarding access to treatment aimed at fulfilling the fundamental responsibility to ensure sufficient and permanent access to healthcare within Malta and that are justified by overriding reasons of general interest.*			
2. Is this the same procedure as for reimbursement under the Social Security Coordination Regulations?	**Answer:** **Yes ☐ No ☒**		N/A	N/A

3. What body is/are responsible of handling the reimbursement applications? (e.g., where and to whom reimbursement applications have to be submitted?)	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* Applications shall be submitted to: The Office of the Chief Medical Officer of the Ministry of Health (the National Contact Point) Palazzo Castellania 15, Merchants Street, Valletta VLT 1171. Telephone number: (+356) 22992381. E-mail: crossborderhealth@gov.mt See: **Regulation 7(4)** of S.L. 528.03 Cross-Border Healthcare Regulations 2013: (4) The national contact point shall be responsible to receive claims for reimbursement and for determining whether such claims fulfil conditions for reimbursement under these regulations.	**Source(s):** S.L. 528.03 Cross-Border Healthcare Regulations 2013	N/A	N/A
4. Is there a specific application form/module which the person seeking reimbursement needs to submit?	**Answer:** *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?*	**Source(s):** Department of Health, 'Claim Form for Reimbursement of Treatment / Health Care	**Yes** ☐ **No** ☒ If a person is registered for state healthcare in Malta, most public	In practice, patients are asked to send in electronic format all necessary documentation and the

	- *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?* Yes, there is a specific application form which needs to be submitted by someone seeking reimbursement, which can be found online.[512] It is not clear whether this can be submitted online, or whether this can only be submitted via post. The website simply states that the NCP should be contacted. The following information must be completed in the form: • **Section 1** involves patient details: surname; name; gender; date of birth; I.D. number; telephone number; mobile number; email; address; is the patient entitled to healthcare from the Public Health Care System in Malta?; and national insurance number. • **Section 2** involves health care service/s: what is the diagnosed medical condition for which the patient has received treatment abroad?; Was prior authorisation of treatment sought?; and details of the health care service(s) / treatment(s) received abroad. • **Section 3** involves details of Health Care Provider(s) where patient received treatment: name of health care facility;	Service(s) Sought Under Cross-Border Regulations'. Health.gov.mt, 'Cross Border Health Care' (September 2020)	healthcare services are free of charge. Therefore, for such services a corresponding reimbursement procedure does not exist domestically.	reimbursement form is not always used. In the absence of the form once all documents (invoices, medical reports and payment receipts) are sent the case is accepted. In relation to private healthcare, this is not reimbursed because all MT citizens and foreigners paying National Insurance are entitled to free health care at the point of care except some dental procedures. It also follows from article 8 (3) of S.L. 528.03 that states: No costs shall be reimbursed in relation to healthcare provided by local private healthcare providers.[513]

[512] Please note that this form, despite having the name 'Claim Form for Reimbursement of Treatment / Health Care Service(s) Sought Under Cross-Border Regulations' is referred to as 'Prior Authorisation Form' on the Health.gov.mt website (see: Health.gov.mt, 'Cross Border Health Care' (September 2020), available at: https://deputyprimeminister.gov.mt/en/cbhc/Pages/Cross-Border.aspx (last accessed 9 June 2021)). And https://deputyprimeminister.gov.mt/en/cbhc/Documents/ClaimFormForReimbursement.pdf (last accessed 9 June 2021)).

[513] Information provided to Spark Legal Network by the Maltese Ministry of Health on 7 October 2021.

	name of treating clinician; address of health care facility; country; telephone number; email address; whether the health care provider is in the public or private sector; and whether they were satisfied with the service and quality of the health care service(s) received abroad. If medications/drugs were prescribed and dispensed: name of pharmacy that dispensed drugs; address of pharmacy; country; telephone number; and e-mail address. • **Section 4** involves the expenditure for which reimbursement is being claimed: date of receipt, establishment paid, treatment covered, and receipt amount paid. It also requests the attachment of required documentation (further specified in below, see answer to question5). • **Section 5 requests the patient's signature and date, or a signature of a parent, legal guardian, and custodian of a minor if needs be.**			
5. What (other) documentation has to be submitted in order to substantiate a reimbursement request?	**Answer:** *If applicable, please specify:* - *What documents are required;* - *Whether the submission of the documentation is optional, mandatory, or recommended.* According to Section 4 of the application module concerning the expenditure for which reimbursement is being claimed: the **following documents shall also be attached:**	**Source(s):** Department of Health, 'Claim Form for Reimbursement of Treatment / Health Care Service(s) Sought Under Cross-Border Regulations'	**Yes** ☐ **No** ☒ If a person is registered for state healthcare in Malta, most public healthcare services are free of charge. Therefore, for such services a corresponding reimbursement	N/A

	• **Ticket of referral:** a ticket of referral from the patient's clinician, indicating the patient's medical condition(s)/diagnosis, time-line of events and the medical need for the treatment prior to it being sought, must be attached (This needs to be done by a Specialist (as per Specialist Accreditation Register) if prior authorisation is sought). • **Medical Summary:** a letter/report from the health care facility where treatment was received must be attached. This should include a description of the treatment(s) received, date(s) treatment(s) was received, any diagnostic tests performed and any medication/drug(s) used as part of the treatment. • **Copy of Schedule V form (yellow card)** (if applicable)[514] • **Original itemised receipts.** These documents seem to be a mandatory requirement.		procedure does not exist domestically.	
6. Are there any costs associated with the handling of the reimbursement request? - *Direct costs (e.g., fixed costs for submitting or filing a reimbursement*	**Answer:** *Direct costs:* There are no direct costs involved in handling the reimbursement request. *Indirect costs:* None identified.	**Source(s):** 'Frequently Asked Questions about the EU cross-border healthcare Directive'[515] S.L. 528.03 article 9 (1).	**Yes** ☐ **No** ☒ If a person is registered for state healthcare in Malta, most public healthcare services are	Reimbursement process does not carry any charges to the patient or relatives of a minor. Most documents are received in English, but it is up to the patient

[514] Any patient suffering from a chronic condition which is listed under the second part of the Fifth Schedule of the Social Security Act is entitled to free medication for that specific disease and entitlement is based solely upon the presence of disease irrespective of means, income or age. See health.gov.mt, 'Schedule V', available at: https://deputyprimeminister.gov.mt/en/poyc/Pages/Schedule-V.aspx (last accessed 9 June 2021).

[515] 'Frequently Asked Questions about the EU cross-border healthcare Directive', available at: https://deputyprimeminister.gov.mt/en/cbhc/Documents/frequently_asked_questions_1.pdf (last accessed 10 June 2021).

request, proportion deducted from the reimbursable amount). - *Indirect costs (e.g., translations, stamps, etc).*	Note that no ancillary or related costs shall be reimbursed, e.g. accommodation and travel.		free of charge. Therefore, for such services a corresponding reimbursement procedure does not exist domestically.	to arrange the translation.[516]
7. Are there any specific time requirements linked to a reimbursement request? (*e.g., time within which the reimbursement requests must be submitted and/or time within the requested body must handle the request and/or reimburse the costs, etc.*).	**Answer:** *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* Reimbursement requests are dealt within a period of 6 to 12 months. Consequences of missed deadlines are not yet listed but in a few cases the person concerned reached out to the ombudsman.[517]	**Source(s):** Health.gov.mt, 'Cross Border Health Care' (September 2020)	**Yes** ☐ **No** ☒ If a person is registered for state healthcare in Malta, most public healthcare services are free of charge. Therefore, for such services a corresponding reimbursement procedure does not exist domestically.	N/A
8. Are there any non-reimbursable thresholds, deductions *(except the deductions for administrative costs mentioned above) etc.?*	**Answer:** *If yes, please specify the thresholds.* There are no thresholds or deductions in relation to reimbursement requests for cross-border healthcare.[518]	**Source(s):**	**Yes** ☒ **No** ☐ If a person is registered for state healthcare in Malta, most public healthcare services are free of charge. Therefore, for such services a corresponding	There is no domestic reimbursement procedure for treatment done in Malta, on the assumption that all healthcare is available on the national health service. A person may choose to undertake healthcare in the

[516] Information provided to Spark Legal Network by the Maltese Ministry of Health on 7 October 2021.
[517] Information provided to Spark Legal Network by the Maltese Ministry of Health on 7 October 2021.
[518] Information provided to Spark Legal Network by the Maltese Ministry of Health on 7 October 2021.

			reimbursement procedure does not exist domestically. However, domestic private hospital care is not covered by the national social security public system in Malta. Hence, it could be concluded that the same limitation applies domestically.	private sector such as a GP attendance or a hospital care out of own pocket and if privately insured to raise the reimbursement to one's insurance agency.[519]
9. In instances where a PA (or prior-notification) has already been issued, is a separate/simplified procedure available for requesting reimbursement? **applicable only if the country has a PA system.*	**Answer:** *If yes, please describe the simplified procedure.* There does not seem to be any separate/simplified procedure available for requesting reimbursement.	**Source(s):** N/A	**Yes** ☐ **No** ☐	N/A
10. Are there additional administrative/procedural requirements for reimbursement depending on, for instance, the type of treatment for which reimbursement is requested, or the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* There does not seem to be any additional administrative/procedural requirements for reimbursement.	**Source(s):** N/A	**Yes** ☐ **No** ☐	N/A

[519] Information provided to Spark Legal Network by the Maltese Ministry of Health on 7 October 2021.

11. Please list any other administrative requirements in your country in relation to the procedures of reimbursement of cross-border healthcare.	**Answer:** There do not seem to be any other administrative requirements in Malta in relation to the procedures of reimbursement of cross-border healthcare.	**Source(s):** N/A	**Yes** ☐ **No** ☐	N/A

Part 2: Checklist for verification with national/regional body[520]

Name of the body: Ministry of Health
Country/Region: Malta
Date of verification call: 7 October 2021

Template for the Data Collection	**Aspects to be verified** *Tick the boxes if the information in the template for the data collection has been verified and/or complemented by the national body*		**Comments** *Include any additional comments and/or information provided by the contacted body*
Section 1 – Prior Authorisation			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Justification/purpose of the identified requirement(s) (Column 4)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	
Section 2 - Reimbursement			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Whether the requirement applies domestically (Discriminatory assessment) (Column 4) ▪ Justification/purpose of the identified requirement(s) (Column 5)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	

[520] Data verified in writing on 7 October 2021.

NETHERLANDS – COUNTRY REPORT

1. **Please indicate whether the rules governing the administrative procedures/requirements for requesting PA and reimbursement under Directive 2011/24/EU in your country are set out at:**

A. National level ☒

B. Decentralised/regional/local level ☒

Note: both boxes were ticked as the legislative framework is national. However, healthcare in the Netherlands is a free market system, based on multiple insurance providers with a high degree of discretion in setting out the rules applicable to their affiliates (see explanatory note below). For this reason, the following two main insurance providers were indicated below.

In case (1.B): Please indicate the two most relevant jurisdictions in your country (i.e., in terms of population):

Region/jurisdiction: 1: One of the largest insurance providers in the border areas is CZ, which is especially operative in the border region with Belgium;

Region/jurisdiction 2: The second of the largest insurance providers in the border areas is Menzis, which is especially operative in the border region with Germany

NOTE: In case (1.B) the template for the data collection (Part 1) should be complete twice, once for each of the two most relevant regions/jurisdiction indicated above.

EXPLANATORY NOTE:

The Netherlands health care insurance system is a free market system. There are multiple private insurance providers active on the market and citizens can chose which one to use. Clients pay a periodic (monthly) fee to be insured which covers treatments/ types of care which are specified in the terms and conditions of the insurance contract.[521] Next to that there is also the contractual determined 'eigen risico' (own risk), an amount of costs that has to be reached before the insurance provider starts covering costs and that has to be carried by the client[522]. For some treatments or types of care there is also

[521] This is applicable from the age of 18 and older. Clients with an income (work, cash benefits, pension) need also to pay an income-related contribution. Information provided to Spark Legal network by CAK on 7 October 2021.

[522] For example: The client pays a monthly fee of 125€. Next to that the contract foresees in an 'eigen risico' of 385€. When the client needs health care, the first 385€ will be covered by the client and not by the insurance company, except for some costs that are always covered such as a visit to the general practitioner. The treatments that legally fall outside of the scope of 'eigen risico' can be found in Chapter 2, §2, Besluit van 28 juni 2005, houdende vaststelling van een algemene maatregel van bestuur als bedoeld in de artikelen 11, 20, 22, 32, 34 en 89, van de Zorgverzekeringswet (Decree of 28 June 2005, holding the determination of a general measure as refered to in the articles 11, 20, 22, 32, 34 and 89 of the Care insurance law) (Besluit

'eigen bijdrage' (own contribution) which means that for those treatments the insurance company only partially covers the costs, and the client is also expected to cover for part of the treatment[523]. The insurance companies list these also in their terms and conditions. Both 'eigen risico' and 'eigen bijdrage' are always to be paid by the client regardless of it concerns a contracted or non-contracted care provider or whether it concerns domestic or cross-border health care.

Each of the insurance providers has contracts with health care providers. When a client makes use of a health care provider that has a contract with their insurance company (contracted health care provider) a system of direct cost coverage applies. When a client wants to make use of a health care provider that does not have a contract with their insurance company (non-contracted health care provider), generally a prior authorisation is needed and the client will have to request a reimbursement of the costs afterwards.[524] Some of the insurance providers also have contracted healthcare providers abroad. **This system makes that there is no systematic difference between cross-border health care and domestic health care but rather a difference between contracted and non-contracted health care.**

The legal framework for health care insurance and health care insurance providers can be found in 'Zorgverzekeringswet'[525], 'Besluit zorgverzekering'[526] and 'Regeling zorgverzekering'[527]. These three documents set out the general outline of the insurance system and set requirements for insurance providers, what they minimally need to cover and what they minimally need to provide in information and documents, and lay down the general rules governing insurance providers. There are no specific rules for cross-border healthcare within the legal framework.

Given the above, and thus the possibility of each insurance provider to set out their own PA systems and reimbursement procedures for cross-border healthcare, the questionnaire below has been completed twice, based on data collected via desk research and interviews with contact persons from the following two health insurance bodies in the Netherlands:

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zorgverzekering) Official Journal 2015 No 389, available at https://wetten.overheid.nl/jci1.3:c:BWBR0018492&z=2021-01-01&g=2021-01-01 (last accessed at 6/6/2021), hereafter Besluit zorgverzekering.

[523] Article 11, Wet van 16 juni 2005, houdende regeling van een sociale verzekering voor geneeskundige zorg ten behoeve van de gehele bevolking (Law of 16 June 2015 on the regulation of a social insurance for medical care for the benefit of the whole population), Official Journal 2015 No 358, available at https://wetten.overheid.nl/jci1.3:c:BWBR0018450&z=2021-01-01&g=2021-01-01 (last accessed 6/6/2021).

[524] Reimbursement of non-contracted care is in general limited to 70-80% of the Dutch legal tariff.
Information provided to Spark Legal Network by CAK on 7 October 2021.

[525] Wet van 16 juni 2005, houdende regeling van een sociale verzekering voor geneeskundige zorg ten behoeve van de gehele bevolking (Law of 16 June 2015 on the regulation of a social insurance for medical care for the benefit of the whole population), Official Journal 2015 No 358, available at https://wetten.overheid.nl/jci1.3:c:BWBR0018450&z=2021-01-01&g=2021-01-01 (last accessed 6/6/2021), hereafter Zorgverzekeringswet.

[526] Besluit van 28 juni 2005, houdende vaststelling van een algemene maatregel van bestuur als bedoeld in de artikelen 11, 20, 22, 32, 34 en 89, van de Zorgverzekeringswet (Decree of 28 June 2005, holding the determination of a general rule as reffered to in articles 11, 20, 22, 32, 34 and 89 of the Care Insurance Law), Official Journal 2015 No 389, available at https://wetten.overheid.nl/jci1.3:c:BWBR0018492&z=2021-01-01&g=2021-01-01 (last accessed at 6/6/2021), hereafter Besluit zorgverzekering.

[527] Regeling van de Minister van Volksgezondheid, Welzijn en Sport van 1 september 2005, nr. Z/VV-2611957, houdende regels ter zake van de uitvoering van de Zorgverzekeringswet (regulation of the Minister of Public health,Wellb-being and Sports of 1 September 2005, nr. Z/VV-2611957, holding the rules on the execution of the Care Insurance Law), Government Gazete 2015 No. 171, p.15), available at https://wetten.overheid.nl/jci1.3:c:BWBR0018715&z=2021-05-12&g=2021-05-12 (Last accessed at 6/6/2021), hereafter Regeling zorgverzekering.

CZ – the most relevant insurance provider in the border region with Belgium
Menzis – the most relevant insurance provider in the border region with Germany

2. **Please indicate the national body best suited to verify the accuracy of the information collected in Part 1, and justify your selection.**
Depending on the characteristics of your national healthcare system, the relevant body may be: a) *the national social security body*; or b) *an insurance fund*. In the latter case, please indicate the most representative fund (e.g., the one with the highest number of affiliations).

Body to be contacted for Task 2: CZ and Menzis

(In case 1.B, please indicate two relevant bodies, one respectively for each Region/jurisdiction)

Reasons for Selection: In the Dutch system it is in first instance the private health care insurance companies that process the requests for permission for cross border health care. Even though all insurance providers are active in the complete Dutch territory, in the border region with Belgium CZ is the largest operative one and Menzis is the largest one in the border region with Germany. Thus those two are the most interesting for this research.

Part 1: Questionnaire

*__Note 1__: In cases where administrative requirements are set out in the legislative/regulatory framework at decentralised/regional/local level, please complete the template for the data collection twice, once for each of the two most relevant regions/jurisdictions (e.g., in terms population).

__*Note 2__: Setting out a Prior Authorisation (PA) system is optional for Member States. Should your country not have a system of PA in place under Directive 2011/24/EU, Section 1 will not need to be completed.

Questionnaire N.1 – Administrative procedures set out by **CZ Insurance provider**

SECTION 1 PRIOR AUTHORISATION PROCEDURE(S)			
Questions	**Answer**	**Sources**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to PA procedures for a cross-border healthcare under Directive 2011/24/EU?	**Answer:** None **There are no legislative provisions that lay out the requirements related to PA procedures for cross-border healthcare thus insurance providers can set up their own.** Requirements related to PA procedures for a cross-border healthcare under Directive	**Source(s):** Website CAK 'Meer over behandeling in een ander EU land'(more on treatment in a different EU country).[528] Law of 16 June 2015 on the regulation of a social insurance for medical care for the benefit of the whole population.[529]	N.B: Health care insurance providers in the Netherlands work with specified contracted health care providers. When patients go to health care providers that do not have a contract with their insurance provider, PA is often a requirement to be able to get reimbursement domestically as well. When patients go to health care providers that are contracted, PA is not required; a referral by a contracted health care provider to a contracted health care provider is considered a PA.

[528] Meer over behandeling in eer ander EU-land, available at: https://cbhc.hetcak.nl/nl/meer-over-behandeling-in-een-ander-eu-land, (last accessed 6/6/2021).

[529] Wet van 16 juni 2005, houdende regeling van een sociale verzekering voor geneeskundige zorg ten behoeve van de gehele bevolking (Law of 16 June 2015 on the regulation of a social insurance for medical care for the benefit of the whole population), Official Journal 2015 No 358, hereafter **'Zorgverzekeringswet'.**

	2011/24/EU for insurance provider CZ are laid out in their terms and conditions. CZ does not make PA for cross border healthcare mandatory, but does advise to obtain it as to make sure the patients know the financial consequences of getting planned cross-border healthcare. Furthermore, in order to obtain reimbursement, it is necessary to obtain PA when the healthcare will be provided by a non-contracted party. CZ gives patients the option to follow the rules as set out in their terms and conditions or to rely upon the Social Security Coordination Regulations.	Decree of 28 June 2005, holding the determination of a general rule as reffered to in articles 11, 20, 22, 32, 34 and 89 of the Care Insurance Law.[530] Regulation of the Minister of Public health,Wellb-being and Sports of 1 September 2005, nr. Z/VV-2611957, holding the rules on the execution of the Care Insurance Law.[531] Website CZ, Insurance conditions Care insurances and additional insurances as of 1 January 2021 (Verzekeringsvoorwaarden).[532] Insurance conditions Care insurances and additional insurances as of 1 January 2021, B.2 Buitenlandzorg (treatment abroad), p.41.	CZ also has some contracted healthcare providers in Belgium and Germany.[533]

[530] Besluit van 28 juni 2005, houdende vaststelling van een algemene maatregel van bestuur als bedoeld in de artikelen 11, 20, 22, 32, 34 en 89, van de Zorgverzekeringswet (Decree of 28 June 2005, holding the determination of a general rule as reffered to in articles 11, 20, 22, 32, 34 and 89 of the Care Insurance Law), Official Journal 2015 No 389, hereafter **'Besluit zorgverzekering'.**

[531][531] Regeling van de Minister van Volksgezondheid, Welzijn en Sport van 1 september 2005, nr. Z/VV-2611957, houdende regels ter zake van de uitvoering van de Zorgverzekeringswet (Regulation of the Minister of Public health,Wellb-being and Sports of 1 September 2005, nr. Z/VV-2611957, holding the rules on the execution of the Care Insurance Law), Government Gazete 2015 No. 171, p.15), hereafter **'Regeling zorgverzekering'.**

[532] 'Verzekeringsvoorwaarden Zorgverzekeringen en Aanvullende Verzekeringen per 1 januari 2021, available at Verzekeringsvoorwaarden 2021 (cz.nl) (last accessed 5/6/2021), hereafter **'Verzekeringsvoorwaarden',** A.18 Akkoordverklaring, p31-32.

[533] NB: as already explained, the main difference in the Dutch national system, is between contracted and non-contracted healthcare providers. Therefore, whether abroad or domestically, when a healthcare provider is contracted, the system of direct coverage of the cost applies, while when it is non-contracted, PA and reimbursement have to be requested both for domestic and cross-border healthcare.

2. Is this the same procedure as for PA under the Social Security Coordination Regulations?	**Answer:** **Yes ☒ No ☐**		N.B. Depends on whether it concerns a contracted health care provider or a non- contracted health care provider. For a contracted care provider, no PA is necessary and there is a direct coverage system, for a non-contracted care provider PA and reimbursement request are required.
3. What body is in charge of handling the PA applications? *(e.g., where and to whom PA applications have to be submitted?)*	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* **The legislative framework does not appoint any body to handle the PA applications, which allows the insurance providers to handle these.** The private insurance providers are in charge of handling the PA applications in first instance. This version is answered with regards to CZ, the most relevant insurance provider in the border region with Belgium.	**Source(s):** **Website SGKZ (Foundation complaints and** conflicts care insurances), 'Geplande zorg in het buitenland' (Planned health care abroad).[534] Law of 16 June 2015 on the regulation of a social insurance for medical care for the benefit of the whole population.	N/A

[534] Available at: Geplande zorg in het buitenland - SKGZ (last accessed 05/06/2021).

4. Who is entitled to apply for PA? *(e.g., can the patients apply themselves, or is treating doctor filing/partially filling the request, etc.)*	**Answer:** *- If there is a national doctor involved, is there a requirement that this doctor is contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA?* The health care provider (mostly the treating doctor)[535] is normally the one applying for the PA but the insurance takers (i.e., the patients) are also able to apply for PA.	**Source(s):** Website CZ, 'Een akkoordverklaring aanvragen'(request a prior authorisation).[536] Verzekeringsvoorwaarden, A.18.1.3 Niet-gecontracteerde zorgverlener en akkoordverklaring(non-contracted health care provider and prior authorisation), p. 32.	No specific purpose or justification identified in the sources consulted.
5. Is there a specific application form/module which the person seeking PA needs to submit?	Answer: *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?* No specific requirements are indicated in the legislative/regulatory sources consulted. For CZ, there is no available form, but there is only a list online of information that has to be provided by mail (see question 6 below).	**Source(s):** Website CZ, request a prior authorisation). Verzekeringsvoorwaarden, A.18.1.3 (non-contracted health care provider and prior authorisation), p. 32.	No specific purpose or justification identified in the sources consulted.

[535] Note of the National expert: Usually, it is the contracted doctor who applies for the PA for cross-border healthcare. In case of a non-contracted doctor, there would have already been the PA requirement before accessing the non-contracted doctor, therefore he could also have filed the PA for cross-border healthcare.
[536] Available at: Een akkoordverklaring aanvragen - CZ (last accessed 05/06/2021).

6. What (other) documentation has to be submitted in order to substantiate a PA request?	**Answer:** *If applicable, please specify:* - *What documents and what particulars are required;* - *Whether there are requirements as to who has to issue the documents (e. g., a doctor contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA or any doctor);* - *Whether the submission of the documentation is optional, mandatory, or recommended.* **The following information has to be submitted to the insurer provider CZ:** - Personal information: name, address, birthdate and relation number; - referral of treating doctor; - medical indication of treating doctor with treatment plan; - if possible, an estimate or quotation of the costs; - if applicable, depending on treatment, a request form; The patient needs to submit the information if their treating health care provider does not do this automatically. This can be done either by the treating and referring contracted health care provider in the Netherlands or by the non-contracted health care provider abroad. The condition being that the non-contracted doctor does meet the standards and terms in the	**Source(s):** Website CZ, request a prior authorisation. Verzekeringsvoorwaarden, A.18.1.3, non-contracted health care provider and prior authorisiation, p. 32, J° 17.4.b, p. 30 J°17.2, last bullet point, p.30.	No specific purpose or justification identified in the sources consulted.

	country of operation for the profession they practice.		
7. Are there any costs associated with the handling of the PA request? - *Direct costs (e.g., fixed costs for submitting or filing a PA request).* - *Indirect costs* (*e.g., translations, stamps, etc).*	**Answer:** *Direct costs:* None identified. *Indirect costs:* Stamps and translation for any other language than Dutch, English, German, French or Spanish. This requirement is not indicated in the law, but is required by CZ.	**Source(s):** Website CZ, request a prior authorisation. Verzekeringsvoorwaarden, A.18.1.3, non-contracted health care provider and prior authorisiation, last bullet point, p. 32.	No specific purpose or justification identified in the sources consulted.
8. Are there any specific **time requirements** linked to a PA request? (*e.g., time within which a requesting person must submit the PA application and/or time within which the requested body must take a decision on the PA request, etc.*).	**Answer:** *- If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* For the insurer CZ, there are no specific time requirements issued in the terms and conditions of this insurance provider. When PA is required, the request should be submitted beforehand leaving time for assessment by CZ. The website does foresee a reaction from the insurance provider within 10 days after the request by the patient is submitted, this is a target, not a guarantee. Once obtained, the PA is valid for 365 days.	**Source(s):** Website CZ, request a prior authorisation. Verification call with Sonja Drenovec, Kenniscentrum buitenland, CZ, 15/06/2021.	No specific purpose or justification identified in the sources consulted.

9. Are there **differences in the procedural/administrative requirements for requesting PA** based on, for instance, the type of treatment for which PA is requested, the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* For some specific treatments, a request form is required.[537] This is then also the case in order to receive the treatment from a contracted health care provider. For some treatments extra information may be required, e.g. radiological report.	**Source(s):** Website CZ, request a prior authorisation). Verzekeringsvoorwaarden, care included in care insurance, pp. 41 – 90.	No specific purpose or justification identified in the sources consulted.
10. Is there a specific PA form (i.e., form used for issuing/granting PA) and, if the answer is positive, what form?	**Answer:** There are two options: either a letter will be sent or an S2-form will be provided.[538]	**Source(s):** Verification call with Sonja Drenovec, Kenniscentrum buitenland, CZ, 15/06/2021.	No specific purpose or justification identified in the sources consulted.
11. Please list any other administrative requirements in your country in relation to the PA procedure for cross-border healthcare.	**Answer:** N/A.	**Source(s):** Verification call with Sonja Drenovec, Kenniscentrum buitenland, CZ, 15/06/2021.	No specific purpose or justification identified in the sources consulted.

[537] Note of the National expert: The specific conditions or extra requirements for all the treatments covered by the insurance are listed in the general terms and conditions.
[538] The second option is only for the PA requested pursuant the Social Security Regulations.

SECTION 2 REIMBURSMENT PROCEDURE(S)				
Questions	**Answer:**	**Sources**	**Does/do the identified requirement(s) also apply domestically? (i.e., is the requirement non-discriminatory?)**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to reimbursement procedures for cross-border healthcare under Directive 201/24/EU?	**Answer:** **There are no legislative provisions that specify the requirements or procedures of reimbursement of cross-border healthcare costs. As such the private insurance providers can install such procedures.** The Dutch system lets private insurance providers determine the requirements for reimbursement procedures. CZ also has contracts with health care providers in Belgium and Germany, if cross-border healthcare was obtained from these contracted health care providers, the reimbursement procedure is the same as domestically obtained health care. The requirements related to reimbursement procedures for cross-border health care as determined by CZ are laid down in their general	**Source(s):** Website CAK (Central administration office), 'Meer over behandeling in een ander EU land'(More on treatment in a different EU Country). Law of 16 June 2015 on the regulation of a social insurance for medical care for the benefit of the whole population). Decree of 28 June 2005, holding the determination of a general rule as reffered to in articles 11, 20, 22, 32, 34 and 89 of the Care Insurance Law. Regulation of the Minister of Public health,Wellb-being and Sports of 1 September 2005, nr. Z/VV-2611957, holding the rules	N.B. In the Netherlands the difference is more distinct between health care providers that are contracted by the insurance company and health care providers that are not contracted by the insurance company than between cross-border and domestic health care providers. Whenever a health care provider is contracted by the insurance company (cross-border or domestically) the insurance company will be billed directly so there is no reimbursement procedure.	N/A

	terms and conditions under title A.19.2 Rekeningen, p. 32	on the execution of the Care Insurance Law. Website CZ, Insurance conditions Care insurances and additional insurances as of 1 January 2021, ('Verzekeringsvoorwaarden').[539] Verzekeringsvoorwaarden, A.19.2 Rekeningen (bills), p. 32.		
2. Is this the same procedure as for reimbursement under the Social Security Coordination Regulations?	**Answer:** **Yes ☒ No ☐**			N/A
3. What body is/are responsible of handling the reimbursement applications? (e.g., where and to whom reimbursement applications have to be submitted?)	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* The private health care insurance providers are responsible for handling the reimbursement applications in first instance. CZ is the most relevant one in relation to the border region with Belgium.	**Source(s):** Website SGKZ (Foundation complaints and conflicts care insurances), 'Geplande zorg in het buitenland'(planned care abroad).[540]		N/A

[539] 'Verzekeringsvoorwaarden Zorgverzekeringen en Aanvullende Verzekeringen per 1 januari 2021, available at Verzekeringsvoorwaarden 2021 (cz.nl) (last accessed 5/6/2021), hereafter **'Verzekeringsvoorwaarden',** A.18 Akkoordverklaring, p31-32.

[540] Available at: Geplande zorg in het buitenland - SKGZ (last accessed 05/06/2021).

4. Is there a specific application form/module which the person seeking reimbursement needs to submit?	Answer: *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?* With regards to CZ, there are several ways reimbursement can be sought: through an app, online or via mail. In the latter case, a specific form has to be filed. The form requires: - Name, birth date and relation number of the patient - Date of bill, name of doctor or institute, valuta and amount - Country of made costs - Reason of being abroad - Period of stay abroad - Type of care received - Whether and if so, how long there was a hospitalisation - Whether there was a treatment plan - In case of planned health care, whether there was a referral - Whether or not the patient has notified the CZ helpline or the alarm central of the travel insurance provider	**Source(s):** Website CZ, 'Buitenlandse zorgkosten declareren' (declaring foreign health care costs). Verzekeringsvoorwaarden, A.19.2 Rekeningen, p. 32. Website CZ, Declaratieformulier buitenland (declaration form abroad).[541]	**Yes** ☒ **No** ☐ In general yes, the documents/requiements are the same as those that apply domestically, with slight differences to the specifics of the care abroad (e.g. country, valuta, etc)	

[541] Form available at: 476.808.001.001.2007_Declaratieformulier_Buitenland CZ_V2.indd (last accessed 04/06/2021).

	- Whether the patient had given the health care provider a S2, EHIC or a treaty form 111 - Whether the patient had a travel insurance with medical coverage at the time of the treatment abroad and if so with which provider and policy number.			
5. What (other) documentation has to be submitted in order to substantiate a reimbursement request?	**Answer:** *If applicable, please specify:* - *What documents are required;* *Whether the submission of the documentation is optional, mandatory, or recommended.* When seeking reimbursement through the app or online a digital photo of the bills or a scan of the bills has to be submitted. In case of the form by mail, the original bills have to be sent along. If applicable, the treatment plan. If applicable, the referral. In case of planned health care in a hospital or with a specialist, a referral is obligatory.	**Source(s):** Website CZ, To declare international care costs. Verzekeringsvoorwaarden, A.19.2 Rekeningen (bills), p. 32. Website CZ, declaration form abroad.	**Yes** ☒ **No** ☐	No specific purpose or justification identified in the sources consulted.
6. Are there any costs associated with the handling of the reimbursement request? - *Direct costs (e.g., fixed costs for submitting or filing a reimbursement request, proportion*	**Answer:** *Direct costs:* None identified. *Indirect costs:* Translation when it concerns another language than Dutch, English, German, French or Spanish. Stamps in case of applying by mail instead of through the app or internet**.**	**Source(s):** Verzekeringsvoorwaarden, A.19.2, title 2 Eisen aan rekeningen (requirements for bills), bullet 3, p.33.	**Yes** ☒ **No** ☐	No specific purpose or justification identified in the sources consulted.

deducted from the reimbursable amount). - *Indirect costs (e.g., translations, stamps, etc).*	These requirements are not indicated in the law, but are required by CZ.			
7. Are there any specific time requirements linked to a reimbursement request? (*e.g., time within which the reimbursement requests must be submitted and/or time within the requested body must handle the request and/or reimburse the costs, etc.*).	**Answer:** *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* The reimbursement has to be requested within 36 months after receiving the health care. If the deadline is missed the costs will not be reimbursed. CZ sets the target of handling requests at within 10 days ,but this is a target, not a guarantee.	**Source(s):** Verzekeringsvoorwaarden, A.19.2, title 2 Eisen aan rekeningen (requirements for bills), bullet 2, p.33. Verification call with Sonja Drenovec, Kenniscentrum buitenland, CZ, 15/06/2021.	**Yes** ☒ **No** ☐	No specific purpose or justification identified in the sources consulted.
8. Are there any non-reimbursable thresholds, deductions *(except the deductions for administrative costs mentioned above) etc.?*	**Answer:** *If yes, please specify the thresholds.* - The threshold of 'Eigen risico' is applicable which means that the first contractual determined amount will be paid by the patient and only after reaching that threshold the insurance company covers the costs. - In some cases, there is an 'eigen bijdrage' which means that a treatment is only	**Source(s):** Website CZ, 'Compensation non-emergency (planned) care abroad. Verzekeringsvoorwaarden, B2.2 Zorg buiten het land waarin u woont (care outside of the country where you live) p.41-42. Verzekeringsvoorwaarden, A.20. Tarieven (tariffs) p.34.	**Yes** ☒ **No** ☐	No specific purpose or justification identified in the sources consulted.

	partially covered by the insurance provider and the patient will pay a part themselves - The reimbursement happens according to the Dutch tariffs and conditions if no S2 form was obtained.			
9. In instances where a PA (or prior-notification) has already been issued, is a separate/simplified procedure available for requesting reimbursement? **applicable only if the country has a PA system.*	**Answer:** *If yes, please describe the simplified procedure.* Not really, but when a PA was granted, referrals and treatment plans were already provided so there is no need to submit those again.	**Source(s):** Source(s): Verification call with Sonja Drenovec, Kenniscentrum buitenland, CZ, 15/06/2021.	**Yes** ☒ **No** ☐	No specific purpose or justification identified in the sources consulted.
10. Are there additional administrative/procedural requirements for reimbursement depending on, for instance, the type of treatment for which reimbursement is requested, or the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* No such differences identified., except for some extra requirements such as: - The treatment plan, if applicable - The referral, if applicable	**Source(s):** Source(s): Verification call with Sonja Drenovec, Kenniscentrum buitenland, CZ, 15/06/2021.	**Yes** ☒ **No** ☐	N/A
11. Please list any other	**Answer:**	**Source(s):**	**Yes** ☐	N/A

administrative requirements in your country in relation to the procedures of reimbursement of cross-border healthcare.	None identified.	Source(s): Verification call with Sonja Drenovec, Kenniscentrum buitenland, CZ, 15/06/2021.	**No** ☐	

Questionnaire N.2 – Administrative procedures set out by MENZIS Insurance provider

SECTION 1 PRIOR AUTHORISATION PROCEDURE(S)			
Questions	**Answer**	**Sources**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to PA procedures for a cross-border healthcare under Directive 2011/24/EU?	**Answer: None** There are no legislative provisions that lay out the requirements related to PA procedures for cross-border healthcare thus insurance providers can set up their own. Requirements related to PA procedures for a cross-border healthcare under Directive 2011/24/EU for insurance provider Menzis are laid out in their terms and conditions and on their website. Menzis requires PA for cross-border health care with a stay of at least one night.	**Source(s):** Website CAK 'Meer over behandeling in een ander EU land' (more on treatments in a different EU country).[542] Law of 16 June 2015 on the regulation of a social insurance for medical care for the benefit of the whole population.[543] Decree of 28 June 2005 holding the determination of a general rule as referred to in the artiles 11, 20, 22, 32, 34	N.B: Health care insurance providers in the Netherlands work with specified contracted health care providers. When patients go to health care providers that don't have a contract with their insurance provider PA is often a requirement to be able to get reimbursement domestically as well. When patients go to health care providers that are contracted, PA is not required; a referral by a contracted health care provider to a contracted health care provider is considered a PA. Menzis also has some contracted healthcare providers abroad.[547]

[542] Meer over behandeling in eer ander EU-land, available at: https://cbhc.hetcak.nl/nl/meer-over-behandeling-in-een-ander-eu-land, (last accessed 6/6/2021).

[543] Wet van 16 juni 2005, houdende regeling van een sociale verzekering voor geneeskundige zorg ten behoeve van de gehele bevolking (Law of 16 June 2015 on the regulation of a social insurance for medical care for the benefit of the whole population), Official Journal 2015 No 358, hereafter **'Zorgverzekeringswet'.**

[547] NB: as already explained, the main difference in the Dutch national system, is between contracted and non-contracted healthcare providers. Therefore, whether abroad or domestically, when a healthcare provider is contracted, the system of direct coverage of the cost applies, while when it is non-contracted, PA and reimbursement have to be requested both for domestic and cross-border healthcare.

		and 89 of the Care Insurance Law.[544] Regulation of the Minister of public health, well-being and sports of 1 September 2005 nr Z/VV-2611957, holding the rules on execution of the Care Insurance Law.[545] Menzis, Verzekeringsvoorwaarden Menzis Basis (Terms and Conditions Menzis Basis).[546]	
2. Is this the same procedure as for PA under the Social Security Coordination Regulations?	**Answer:** **Yes ☒ No ☐**		N/A
3. What body is in charge of handling the PA applications? *(e.g., where and to whom PA applications have to be submitted?)*	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* **The legislative framework does not appoint anybody to handle the PA**	**Source(s):** Website SGKZ (Foundation complaints and conflicts care insurances), 'Geplande zorg in het buitenland' (planned care abroad).[548] Law of 16 June 2015 on the regulation of a social insurance	N/A

[544] Besluit van 28 juni 2005, houdende vaststelling van een algemene maatregel van bestuur als bedoeld in de artikelen 11, 20, 22, 32, 34 en 89, van de Zorgverzekeringswet (Decree of 28 June 2005, holding the determination of a general rule as reffered to in articles 11, 20, 22, 32, 34 and 89 of the Care Insurance Law), Official Journal 2015 No 389, hereafter **'Besluit zorgverzekering'.**

[545]Regeling van de Minister van Volksgezondheid, Welzijn en Sport van 1 september 2005, nr. Z/VV-2611957, houdende regels ter zake van de uitvoering van de Zorgverzekeringswet (Regulation of the Minister of Public health,Wellb-being and Sports of 1 September 2005, nr. Z/VV-2611957, holding the rules on the execution of the Care Insurance Law), Government Gazete 2015 No. 171, p.15), hereafter **'Regeling zorgverzekering'.**

[546] Available at: Verzekeringsvoorwaarden Menzis Basis 2021 (last accessed 06/06/2021), hereafter 'verzekeringsvoorwaarden, 'Buitenland'.

[548] Available at: Geplande zorg in het buitenland - SKGZ (last accessed 05/06/2021).

	applications which allows the insurance providers to handle these. The private insurance providers are in charge of handling the PA applications in first instance. This version is answered with regards to Menzis, the most relevant insurance provider in the border region with Germany.	for medical care for the benefit of the whole population..	
4. Who is entitled to apply for PA? *(e.g., can the patients apply themselves, or is treating doctor filing/partially filling the request, etc.)*	**Answer:** *If there is a national doctor involved, is there a requirement that this doctor is contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA?* For the insurance provider Menzis, the application is done by the patient. The patient can give authorisation to anyone who knows their name and insurance number to apply for them, but it is ultimately the responsibility of the patient.	**Source(s):** Website Menzis, 'Vergoeding medische behandeling buitenland' (compensation medical treatment abroad). Verification call with Louise ten Veen, authorisations, Menzis, 16/06/2021**.**	No specific purpose or justification identified in the sources consulted
5. Is there a specific application form/module which the person seeking PA needs to submit?	**Answer:** *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?*	**Source(s):** Website Menzis, 'Vergoeding medische behandeling buitenland' (compensation medical treatment abroad).	No specific purpose or justification identified in the sources consulted

	- *Does the form have to be submitted in paper or can it be submitted electronically?* Yes, for the insurance provider Menzis there is an online module. The module should be filled in with the following information: - Name and policy number - Birth date and address - Date of the treatment - Country of the treatment - Reason for treatment abroad - Information of provider abroad The information is mandatory. The module can be submitted online only.	Verification call with Louise ten Veen, authorisations, Menzis, 16/06/2021.	
6. What (other) documentation has to be submitted in order to substantiate a PA request?	**Answer:** *If applicable, please specify:* - *What documents and what particulars are required;* - *Whether there are requirements as to who has to issue the documents (e. g., a doctor contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA or any doctor);* - *Whether the submission of the documentation is optional, mandatory, or recommended.* **The following documents are to be provided with the form:**	**Source(s):** Website Menzis, 'Vergoeding medische behandeling buitenland' (compensation medical treatment abroad). Verification call with Louise ten Veen, authorisations, Menzis, 16/06/2021.	No specific purpose or justification identified in the sources consulted

	- referral of specialist - statement of reasons of treatment abroad - treatment plan - estimate or quotation of the costs - date of treatment - In case of a treatment that is impossible or non-existent in the Netherlands, scientific proof of standards of the treatment may be asked in the form of e.g. scientific articles.		
7. **Are there any costs** associated with the handling of the PA request? - *Direct costs (e.g., fixed costs for submitting or filing a PA request).* - *Indirect costs* (*e.g., translations, stamps, etc).*	**Answer:** *Direct costs:* None identified. *Indirect costs:* Translation for any other language than Dutch and English. This requirement is not indicated in the law, but is required by Menzis.	**Source(s):** Website Menzis, 'Vergoeding medische behandeling buitenland' (Compensation medical treatment abroad), Toestemming (authorisation).	No specific purpose or justification identified in the sources consulted.
8. Are there any specific **time requirements** linked to a PA request? (*e.g., time within which a requesting person must submit the PA application and/or time within which the requested body must take a decision on the PA request, etc.*).	**Answer:** - *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* According to the information available for Menzis, the PA request has to be requested 'far before' the treatment date.	**Source(s):** Website Menzis, 'Vergoeding medische behandeling buitenland'(compensation medical treatment abroad), Verification call with Louise ten Veen, authorisations, Menzis, 16/06/2021.	No specific purpose or justification identified in the sources consulted.

	There is no strict requirement, but it is best requested 10 to 15 days before the treatment as that is the time necessary to process the request. If the deadline is missed, the PA cannot be delivered in time. It is then up to the patient to decide whether to waits untill Menzis answers the request or whether to undergo the treatment nonetheless and then file a request for reimbursement afterwards without the certainty of the reimbursement request being granted. However, If Menzis is not able to process the request in 10-15 working days, they will notify the patient.		
9. Are there **differences in the procedural/administrative requirements for requesting PA** based on, for instance, the type of treatment for which PA is requested, the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* None specifically identified. However, in case the treatment is impossible or unknown in the Netherlands, there might be a request for additional scientific proof or information (Cfr. answer to question 6).	**Source(s):** Verification call with Louise ten Veen, authorisations, Menzis, 16/06/2021.	No specific purpose or justification identified in the sources consulted.

10. Is there a specific PA form (i.e., form used for issuing/granting PA) and, if the answer is positive, what form?	**Answer:** In principle a S2 form will be issued.[549] Otherwise a letter.	**Source(s):** Verification call with Louise ten Veen, authorisations, Menzis, 16/06/2021.	No specific purpose or justification identified in the sources consulted.
11. Please list any other administrative requirements in your country in relation to the PA procedure for cross-border healthcare.	**Answer:** N/A	**Source(s):** Verification call with Louise ten Veen, authorisations, Menzis, 16/06/2021.	No specific purpose or justification identified in the sources consulted.

SECTION 2 REIMBURSMENT PROCEDURE(S)				
Questions	**Answer:**	**Sources**	**Does/do the identified requirement(s) also apply domestically? (i.e., is the requirement non-discriminatory?)**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to reimbursement procedures for cross-border healthcare	**Answer:** **There are no legislative provisions that specify the requirements or procedures of reimbursement of cross-border healthcare costs. As such the private insurance providers can install such procedures.**	**Source(s):** Website CAK, 'Meer over behandeling in een ander EU land' (More on treatment in a different EU country). Law of 16 June 2015 on the regulation of a social insurance	N.B. In the Netherlands the difference is more distinct between health care providers that are contracted by the insurance company and health care providers that are not contracted by the insurance company than between cross-border and	N/A

[549] The S2 form is available **only** for the PA requested pursuant the Social Security Regulations.

under Directive 201/24/EU?	None, the Dutch system lets private insurance providers determine the requirements for reimbursement procedures. For Menzis these requirements are laid out in the general terms and conditions of Menzis Basis.	for medical care for the benefit of the whole population. Decree of 28 June 2005, holding the determination of a general rule as referred to in articles 11, 20, 22, 32, 34 and 89 of the Care Insurance Law , Official Journal 2015 No 389. Regulation of the Minister of public health, well-being and sports of 1 September 2005 nr Z/VV-2611957, holding the rules on execution of the Care Insurance Law. Menzis, Verzekeringsvoorwaarden Menzis Basis.	domestic health care providers. Whenever a health care provider is contracted by the insurance company (cross-border or domestically) the insurance company will be billed directly so there is no reimbursement procedure.	
2. Is this the same procedure as for reimbursement under the Social Security Coordination Regulations?	**Answer:** **Yes ☒ No ☐**		N/A	N/A
3. What body is/are responsible of handling the reimbursement applications? (e.g., where and to whom reimbursement	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in*	**Source(s):** Website SGKZ (Foundation complaints and conflicts care insurances), 'Geplande zorg in het buitenland'('planned care abroad').	N/A	N/A

applications have to be submitted?)	*your country (e.g., based on the number of affiliations).* The private health care insurance providers are responsible for handling the reimbursement applications in first instance. Menzis is the most relevant one in relation to the border region with Belgium			
4. Is there a specific application form/module which the person seeking reimbursement needs to submit?	**Answer:** *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?* For Menzis, there is a specific form for the declaration of cross-border health care costs. It is available online and it has to be sent by mail. **The form requires:** - Policy number, birth date, name, address, phone number and e-mail address of the patient. - Name of doctor or institute, date of treatment, amount, country, valuta, whether the amount has been paid by	**Source(s):** Website Menzis, declaratieformulier ziektekosten buitenland (declaration form medical costs abroad).[550]	**Yes ☐** **No ☒** The difference is not between cross-border and domestic healthcare but between contracted and non-contracted health care providers. For non-contracted healthcare providers abroad, the reimbursement request has to be made by email and no electronic form is available. On the contrary, for domestic non-contracted healthcare providers, there is the possibility to use an app or to make the request online.	

[550] Form available at: Declaratieformulier-ziektekosten-buitenland-menzis.pdf (last accessed 06/06/2021).

	the patient or not, whether it concerns an accident or not. - Period of stay abroad - Reason of being abroad - Whether the care could be deferred till return to the Netherlands - Description of what happened and care received - Type of health care provider - Whether there was a hospitalisation - Whether the patient showed the EHIC - Whether or not the patient has notified a helpline and if so, which one - Whether the complaints were already known in the Netherlands and if so the treating doctor and health care provider/institute - Whether the patient had a travel insurance with medical coverage at the time of the treatment abroad and if so with which provider and policy number.			
5. What (other) documentation has to be submitted in order to substantiate a reimbursement request?	**Answer:** *If applicable, please specify:* - *What documents are required; Whether the submission of the documentation is optional, mandatory, or recommended.* The following documents have to accompany the form mentioned in question 5: - The original bills.	**Source(s):** Website Menzis, declaratieformulier ziektekosten buitenland (declarationform care costs abroad).	**Yes** ☐ **No** ☒ See Question 4.	

	- For a language other than Dutch, English and German, a translation of the bills. - If applicable, a copy of the policy of the travel insurance. - If applicable, the treatment report of the specialist of the treatment in the Netherlands and the referral to the cross-border health care provider.			
6. Are there any costs associated with the handling of the reimbursement request? - *Direct costs (e.g., fixed costs for submitting or filing a reimbursement request, proportion deducted from the reimbursable amount).* - *Indirect costs* (*e.g., translations, stamps, etc).*	**Answer:** *Direct costs:* None identified. *Indirect costs:* Stamps and translation when it concerns another language than Dutch, Engish, German. This requirement is not indicated in the law, but is required by Menzis.	**Source(s):** Verzekeringsvoorwaarden, A16 Als u nota indient (when you declare a bill). Website Menzis, declaratieformulier ziektekosten buitenland (declarationform care costs abroad).	**Yes** ☒ **No** ☐	No specific purpose or justification identified in the sources consulted.
7. Are there any specific time requirements linked to a reimbursement request? (*e.g., time within which the reimbursement requests must be submitted and/or time within the requested body must handle the*	**Answer:** *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* The reimbursement has to be requested within 3 years after receiving the invoice (the invoice date being the date of	**Source(s):** Verzekeringsvoorwaarden, A16 Als u nota indient. Website Menzis, declaratieformulier ziektekosten buitenland (declarationform care costs abroad).	**Yes** ☒ **No** ☐	No specific purpose or justification identified in the sources consulted.

request and/or reimburse the costs, etc.).	application). If the deadline is missed the costs will not be reimbursed. Menzis will reimburse the costs within two weeks if the declaration of costs was made as soon as possible.			
8. Are there any non-reimbursable thresholds, deductions *(except the deductions for administrative costs mentioned above) etc.?*	**Answer:** *If yes, please specify the thresholds* - **'The threshold of '**Eigen risico' is applicable which means that the first contractual determined amount will be paid by the patient and only after reaching that threshold the insurance company covers the costs In some cases, there is an 'eigen bijdrage' which means that a treatment is only partially covered by the insurance provider and the patient will pay a part themselves The reimbursement happens according to the Dutch tariffs and conditions if no S2 form was obtained.	**Source(s):** Verzekeringsvoorwaarden, buitenland.	**Yes** ☒ **No** ☐	No specific purpose or justification identified in the sources consulted.
9. In instances where a PA (or prior-notification) has already been issued, is a separate/simplified procedure available	**Answer:** *If yes, please describe the simplified procedure.* No specific simplified procedures seems to apply, with the exception that	**Source(s):** Website Menzis, 'Vergoeding medische behandeling buitenland'(compensation medical treatment abroad).	**Yes** ☒ **No** ☐	No specific purpose or justification identified in the sources consulted.

for requesting reimbursement? **applicable only if the country has a PA system.*	documents which were already submitted for the PA may not be submitted again.	Verification call with Louise ten Veen, authorisations, Menzis, 16/06/2021.		
10. Are there additional administrative/procedural requirements for reimbursement depending on, for instance, the type of treatment for which reimbursement is requested, or the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* Only if there is any doubt about the scientific basis of the treatment in which case extra information will be requested.	**Source(s):** Verification call with Louise ten Veen, authorisations, Menzis, 16/06/2021.	**Yes** ☐ **No** ☒	If a treatment that is covered under the insurance is given in the Netherlands, it is assumed there is sufficient medical basis.
11. Please list any other administrative requirements in your country in relation to the procedures of reimbursement of cross-border healthcare.	**Answer:** N/A	**Source(s):** Verification call with Louise ten Veen, authorisations, Menzis, 16/06/2021.	**Yes** ☒ **No** ☐	No specific purpose or justification identified in the sources consulted.

Part 2: Checklist for verification with national/regional body[551]

Name of the body: Checklist for questionnaire n.1 (CZ)
Country/Region: Netherlands
Date of verification call: 15/06/2021

Template for the Data Collection	**Aspects to be verified** *Tick the boxes if the information in the template for the data collection has been verified and/or complemented by the national body*		**Comments** *Include any additional comments and/or information provided by the contacted body*
Section 1 – Prior Authorisation			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Justification/purpose of the identified requirement(s) (Column 4)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	Q 8: When PA is required, the request should be submitted beforehand leaving time for assessment by CZ. The website does foresee a reaction from the insurance provider within 10 days after the request by the patient is submitted, this is a target, not a guarantee. Q 9: For some treatments extra information may be required, e.g., radiological report. Q 10: There are two options: either a letter will be sent or an S2-form will be provided Justification or purpose: there is no preparatory works as it is a private company but the required information is necessary to assess whether or not it falls within the scope of the treatments covered by the insurance. **All the information provided in the comments below have been incorporated by the national legal expert in the answers of the questionnaires above,**

[551] Data also verified in writing by CAK on 7 October 2021.

<table>
<tr><th>Template for the Data Collection</th><th colspan="2">Aspects to be verified
Tick the boxes if the information in the template for the data collection has been verified and/or complemented by the national body</th><th>Comments
Include any additional comments and/or information provided by the contacted body</th></tr>
<tr><td colspan="4">Section 1 – Prior Authorisation</td></tr>
<tr><td colspan="4">Section 2 - Reimbursement</td></tr>
<tr><td>For each question verify the accuracy and/or fill the gaps for:
Answers (Column 2)
Sources (Column 3)
Whether the requirement applies domestically (Discriminatory assessment) (Column 4)
Justification/purpose of the identified requirement(s) (Column 5)</td><td>☒ Question 1
☒ Question 2
☒ Question 3
☒ Question 4
☒ Question 5</td><td>☒ Question 6
☒ Question 7
☒ Question 8
☒ Question 9
☒ Question 10
☒ Question 11</td><td>Q 7: CZ sets the target of handling requests at within 10 days but this is a target, not a guarantee.

Q 8: Not really, but when a PA was granted, referrals and treatment plans were already provided so there is no need to submit those again.

Q 9: No, but for some treatments extra information might be requested but this can be considered as part of the treatment plan or referral. All the information provided in the comments below have been incorporated by the national legal expert in the answers of the questionnaires above,</td></tr>
</table>

Name of the body: Checklist for questionnaire n.2 (Menzis)
Country/Region: The Netherlands
Date of verification call: 16/06/2021

Template for the Data Collection	**Aspects to be verified** *Tick the boxes if the information in the template for the data collection has been verified and/or complemented by the national body*		**Comments** *Include any additional comments and/or information provided by the contacted body*
Section 1 – Prior Authorisation			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Justification/purpose of the identified requirement(s) (Column 4)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	Q 4 : The patient can give authorisation to anyone who knows their name and insurance number to apply for them, but it is ultimately the responsibility of the patient. Q 5 : Date of the treatment, Country of the treatment, Reason for treatment abroad, Information of provider abroad Q 8 : If the deadline is missed, the PA cannot be delivered in time. It is then up to the patient whether he waits till Menzis answers the request or whether he undergoes the treatment and then files a request for reimbursement afterwards without the certainty of the reimbursement request being granted. If Menzis is not able to process the request in 10-15 working days, they will notify the patient. Q9 : Not really but in case the treatment is impossible or unknown in the Netherlands, there might be a request for additional scientific proof or information. Q10 : In principle a S2 form will be issued. Otherwise a letter.
Section 2 - Reimbursement			

For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Whether the requirement applies domestically (Discriminatory assessment) (Column 4) ▪ Justification/purpose of the identified requirement(s) (Column 5)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	Q9 : the health care provider will settle the costs with Menzis according to the tariffs of the country of the received health care Q 10 : Only if there is any doubt about the scientific basis of the treatment in which case extra information will be requested. Q11 : no additional requirements

NORWAY – COUNTRY REPORT

Part 0: Preliminary Assessment

1. **Please indicate whether the rules governing the administrative procedures/requirements for requesting PA and reimbursement under Directive 2011/24/EU in your country are set out at:**

A. National level ☒

B. Decentralised/regional/local level ☐

In case (1.B): Please indicate the two most relevant jurisdictions in your country (i.e., in terms of population):

Region/jurisdiction: 1: N/A

Region/jurisdiction 2: N/A

NOTE: In case (1.B) the template for the data collection (Part 1) should be completed twice, once for each of the two most relevant regions/jurisdiction indicated above.

2. **Please indicate the national body best suited to verify the accuracy of the information collected in Part 1, and justify your selection.**

Depending on the characteristics of your national healthcare system, the relevant body may be: a) *the national social security body*; or b) *an insurance fund*. In the latter case, please indicate the most representative fund (e.g., the one with the highest number of affiliations).

Body to be contacted for Task 2: The Norwegian Ministry of Health and Care Services and the Norwegian Directorate of Health.

Reasons for Selection: The Norwegian Ministry of Health and Care Services is responsible for the legal implementation of Directive 2011/24/EU in Norway, and the Norwegian Directorate of Health is responsible for the reimbursement procedures.

Part 1: Questionnaire

*__Note 1__: In cases where administrative requirements are set out in the legislative/regulatory framework at decentralised/regional/local level, please complete the template for the data collection twice, once for each of the two most relevant regions/jurisdictions (e.g., in terms population).

__*Note 2__: Setting out a Prior Authorisation (PA) system is optional for Member States. Should your country not have a system of PA in place under Directive 2011/24/EU, Section 1 will not need to be completed.

Note: in Norway no PA system has been introduced under Directive 2011/24/EU. For this reason, Section 1 of the questionnaire below has not been completed.

SECTION 1 PRIOR AUTHORISATION PROCEDURE(S)			
Questions	**Answer**	**Sources**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to PA procedures for a cross-border healthcare under Directive 2011/24/EU?	**Answer:** Norway does not have a system of PA in place under Directive 2011/24/EU.	**Source(s):**	N/A
2. Is this the same procedure as for PA under the Social Security Coordination Regulations?	**Answer:** **Yes ☐ No ☐** **N/A**		N/A

3. What body is in charge of handling the PA applications? *(e.g., where and to whom PA applications have to be submitted?)*	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* **N/A**	**Source(s):**	N/A
4. Who is entitled to apply for PA? *(e.g., can the patients apply themselves, or is treating doctor filing/partially filling the request, etc.)*	**Answer:** - *If there is a national doctor involved, is there a requirement that this doctor is contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA?* **N/A**	**Source(s):**	
5. Is there a specific application form/module which the person seeking PA needs to submit?	**Answer:** *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?* **N/A**	**Source(s):**	

6. What (other) documentation has to be submitted in order to substantiate a PA request?	**Answer:** *If applicable, please specify:* - *What documents and what particulars are required;* - *Whether there are requirements as to who has to issue the documents (e. g., a doctor contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA or any doctor);* - *Whether the submission of the documentation is optional, mandatory, or recommended.* **N/A**	**Source(s):**	
7. Are there any costs associated with the handling of the PA request? - *Direct costs (e.g., fixed costs for submitting or filing a PA request).* - *Indirect costs* (*e.g., translations, stamps, etc).*	**Answer:** *Direct costs:* *Indirect costs:* **N/A**	**Source(s):**	
8. Are there any specific **time requirements** linked to a PA request? (*e.g., time within which a requesting person must submit the PA application and/or time within which the requested body must take a decision on the PA request, etc.*).	**Answer:** *- If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* **N/A**	**Source(s):**	

9. Are there **differences in the procedural/administrative requirements for requesting PA** based on, for instance, the type of treatment for which PA is requested, the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* **N/A**	**Source(s):**	
10. Is there a specific PA form (i.e., form used for issuing/granting PA) and, if the answer is positive, what form?	**Answer:** **N/A**	**Source(s):**	
11. Please list any other administrative requirements in your country in relation to the PA procedure for cross-border healthcare.	**Answer:** **N/A**	**Source(s):**	

SECTION 2 **REIMBURSMENT PROCEDURE(S)**				
Questions	**Answer:**	**Sources**	**Does/do the identified requirement(s) also apply domestically?** **(i.e., is the requirement non-discriminatory?)**	**Purpose and/or justification of the requirements**

1. Which national legislative and/or regulatory provisions lay out the requirements related to reimbursement procedures for cross-border healthcare under Directive 201/24/EU?	**Answer:** In Norway, the National Insurance Act § 5-24a, the Regulation on benefits for health services received in another EEA country (Regulation 22 November 2010 No. 1466), and a Circular to this Regulation (Circular 16 April 2015 R05-24A-FOR), lay out the requirements related to reimbursement procedures for cross-border healthcare under Directive 2011/24/EU.	**Source(s):** National Insurance Act 18 February 1997 No. 19552, § 5-24a. Regulation on benefits for health services received in another EEA country 22 November 2010 No. 1466553 (hereinafter, 'Regulation 22 November 2010 No. 1466'). Circular to the regulation on benefits for health services received in another EEA country (F22.11.2010 No. 1466) 16 April 2015 R05-24A-FOR), The Norwegian Directorate of Health554 (hereinafter, 'Circular 16 April 2015 R05-24A-FOR').	N/A	N/A
2. Is this the same procedure as for reimbursement under the Social Security	**Answer:** **Yes ☒ No ☐**		N/A	N/A

[552] Lov om folketrygd 28. februar 1997 nr. 19, available at https://lovdata.no/dokument/NL/lov/1997-02-28-19/KAPITTEL_5-1#§5-24a (last accessed on 16 June 2021).
[553] Forskrift om stønad til helsetjenester mottatt i et annet EØS-land 22. november 2010 nr. 1466, available at https://lovdata.no/dokument/SF/forskrift/2010-11-22-1466 (last accessed on 16 June 2021).
[554] Rundskriv til forskrift om stønad til helsetjenester mottatt i et annet EØS-land (F22.11.2010 nr. 1466) 16. april 2015 R05-24A-FOR, available at https://lovdata.no/nav/rundskriv/r05-24a-for (last accessed on 16 June 2021).

Coordination Regulations?	Note from the National body contacted for the verification of the data collected at national level: The same reimbursement application form is used, and it is submitted to the same body, however, the case handling procedures necessarily vary in accordance to whether Regulation 883/2004 or Directive 2011/24/EU is applied. This is because reimbursement in accordance with Regulation 883/2004 is based on the legislation of the country of treatment, whereas reimbursement in accordance with Directive 2011/24/EU is based on national Norwegian legislation.555			
3. What body is/are responsible of handling the reimbursement applications? (e.g., where and to whom reimbursement applications have to be submitted?)	**Answer:** Helfo (The Norwegian Health Economics Administration in the Directorate of Health) is responsible for handling the reimbursement applications.556 The National Office for Health Service Appeals is responsible for handling appeals.557	**Source(s):** Regulation 22 November 2010 No. 1466 § 10(2). Circular 16 April 2015 R05-24A-FOR Pt. 9. Thorough step-by-step information is provided in both Norwegian and English at the National Contact Point's webpages.558	N/A	N/A
4. Is there a specific application form/module which the person seeking	**Answer:** *If yes, please specify:* - *What information is required;*	**Source(s):** Regulation 22 November 2010 No. 1466 § 11.	**Yes** ☐ **No** ☒	As for whether the identified requirements also apply domestically / whether the requirement

555 The national bodies provided this information.
556 Helfo, available at https://www.helfo.no (last accessed 16 June 2021).
557 The National Office for Health Service Appeals, available at https://www.helseklage.no (last accessed 16 June 2021).
558 HelseNorge. Hospital treatment and other specialist health services in EU/EEA countries, available at https://www.helsenorge.no/en/treatment-abroad/hospital-treatment-and-other-specialist-health-services-in-eea-countries/ (last accessed 16 June 2021).

reimbursement needs to submit?	- *Is the information mandatory, optional, or recommended?* The following information is required (mandatory): <u>Personal details</u> National ID No. (11 digits) First name, last name Telephone number Postal address Postal code, town/city and country Municipality of residence at time of treatment Nationality Bank account number If you have a minimum pension. <u>Which healthcare you received</u> - Hospitalisation - Medical care - Physiotherapy	Circular 16 April 2015 R05-24A-FOR Pt. 10. The application form for reimbursement of healthcare services received in an EEA country in English and Norwegian.559,560 Digital application forms are also available through a secure log-in portal.561	Norway has universal healthcare therefore there is a lack of an equivalent procedure at domestic level.	is non-discriminatory: Norway has universal healthcare. The described procedures are not discriminatory **though they lack a domestic equivalent**. Regulation 22 November 2010 No. 1466 § 2(2) clearly states that the same conditions apply as for corresponding health care at the expense of the public sector in Norway. The benefit is in both cases linked to the patient and the patient's rights. In Norway, there is **direct settlement** between Helfo/the State and the health service providers. Hence, as the benefit the individual patient is entitled to is usually **paid directly to the health service provider, the patient does not need to pay and afterwards**

[559] Helfo. Application for reimbursement of healthcare services received in an EEA country/Switzerland. In English, available at: https://www.helfo.no/skjema/Søknad%20om%20refusjon%20for%20helsetjenester%20mottatt%20i%20et%20annet%20EØS-land%20Sveits-05-24a.10-engelsk.pdf/ (last accessed on 16 June 2021).

[560] Helfo. Søknad om refusjon for helsetjenester mottatt i et annet EØS-land/Sveits. In Norwegian, available at: https://www.helfo.no/skjema/Søknad%20om%20refusjon%20for%20helsetjenester%20mottatt%20i%20et%20annet%20EØS-land%20Sveits-05-24a.10-bokmål.pdf/ (last accessed on 16 June 2021).

[561] Difi. ID-porten, available at: https://idporten.difi.no/opensso/UI/Login?realm=/norge.no&spEntityID=sp.altinn.no&service=IDPortenLevel3List&goto=http://idporten.difi.no/opensso/SSORedirect/metaAlias/norge.no/idp4?ReqID%3D637592246337270035100470%26index%3Dnull%26acsURL%3Dhttps://www.altinn.no:443/ui/Authentication/LoginIDPorten%26spEntityID%3Dsp.altinn.no%26binding%3Durn:oasis:names:tc:SAML:2.0:bindings:HTTP-POST (last accessed on 16 June 2021).

	- Ambulance Medication - Laboratory tests - X-rays *Description if other healthcare* If the treatment is related to an administrative decision for approved occupational injury or illness from NAV (the Norwegian Labour and Welfare Administration) <u>Connection to the country in which treatment was provided</u> How many weeks a year do you spend in the country of treatment (estimate)? (This year: Last year:) Are you employed or self-employed in Norway? Are you receiving welfare benefits such as sick pay, unemployment benefit, parental benefit or work assessment allowance from Norway? Are you receiving an old age pension or disability pension from Norway? Are you employed or self-employed in another EEA country? If yes, which? Are you studying in another EEA country? If yes, which? Do you have a spouse or partner in the country of treatment?			**apply to Helfo for reimbursement**. The entitlement to benefits is nevertheless based on the same requirements/conditions when health care is received in another EEA country, and the benefit provided is the same in both cases.

	Do you have any children under the age of 18 in the country of treatment? Do you have housing in the country of treatment? <u>Need for treatment</u> Did you plan this treatment before travelling abroad? If not, what type of healthcare institution abroad did you first contact for medical care (for example, a general practitioner, emergency room, hospital)? <u>Referral</u> Did you have a referral for the treatment? Was the referral made by a healthcare professional in Norway? Was the referral made by a healthcare professional abroad? <u>Details of healthcare provider and the treatment you are applying for</u> Name of healthcare institution(s) *Address* *Country* Did you use your European Health Insurance Card? Did you pay the full amount? Have you applied reimbursement of expenses, or had such expenses reimbursed elsewhere (for example, through student insurance, through an			

	insurer or a Norwegian hospital scheme that arranges for treatment abroad)? <u>List of the healthcare you received</u> *Date* *Details of treatment* *Amount paid in local currency* <u>Any other information</u> Any other health data which might be of relevance to the healthcare you have received. **<u>Documentation</u>** Tick each to confirm required documentation to support your application. (The list of documents that can be ticked is the one in the answer to Q5 below.) <u>For treatment at a hospital or outpatient clinic</u> Did you receive prior notification from Helfo? I give my consent for my application and supporting documentation to be transmitted to the specialist healthcare if Helfo requires assistance in determining my entitlement to reimbursement and the amount of any reimbursement. I also give my consent for Helfo, the Norwegian specialist health service and regional health authority units to exchange relevant health data on me or the status of other claims if necessary for processing my claim. In signing this form, I consent to			

	procurement and use of my health data; see the Norwegian Health Registry Act and Personal Data Protection Act. Signature I confirm that the information in the form is accurate and complete. I agree to notify Helfo if my circumstances change. Date and place Signature (of guardian for children under age 16) - *Is this application form/modules available online?* Yes. The form is available online. - *Does the form have to be submitted in paper or can it be submitted electronically?* One has the option to submit the form either in paper or electronically.			
5. What (other) documentation has to be submitted in order to substantiate a reimbursement request?	**Answer:** *If applicable, please specify:* - *What documents are required;* - *Whether the submission of the documentation is optional, mandatory, or recommended.* Required documentation: - Referral letter. (Not required for emergency medical care, from a general practitioner, for manual therapy or chiropractic therapy. If the application concerns emergency	**Source(s):** Regulation 22 November 2010 No. 1466 §§ 5, 6, and 11. Circular 16 April 2015 R05-24A-FOR Pts. 4, 5, and 10.	**Yes** ☐ **No** ☒ Cfr. Question 4 above.	As stated above under Q4, Norway has universal healthcare. The described procedures are not discriminatory **though they lack a domestic equivalent.** Regulation 22 November 2010 No. 1466 § 2(2) clearly states that the same conditions apply as for corresponding health

	healthcare without a referral, this must be clearly evident from the enclosed discharge summary.) - A copy of the treatment provider's licence to practice or specialist authorisation from the country of treatment (only for non-hospital treatment). - Relevant summary patient care record/discharge summary from specialist healthcare provider (only for treatment at a hospital or from a specialist). - For expenses on medication: prescription, pharmacy receipt and packaging or copy of the packaging stating the active ingredient(s). - For laboratory tests: requisition and documentation of the types of tests done. - For scans/X-rays: requisition. - Original itemised bills. - Original itemised receipt or other proof of payment such as a bank statement. The following documentation must be enclosed if relevant for the application: - For treatment at a hospital or from a specialist: If the individual has been assessed by the Norwegian specialist health service for the medical condition, a copy of the assessment should be enclosed. - The letter confirming entitlement to treatment within the specialist healthcare or the letter advising of the date of the appointment.			care at the expense of the public sector in Norway. The benefit is in both cases linked to the patient and the patient's rights. In Norway, there **is direct settlement** between Helfo/the State and the health service providers. Hence, **as the benefit the individual patient is entitled to is usually paid directly to the health service provider, the patient does not need to pay and afterwards apply to Helfo for reimbursement.** The entitlement to benefits is nevertheless based on the same requirements/conditions when health care is received in another EEA country, and the benefit provided is the same in both cases. It is stated in Regulation 22 November 2010 No. 1466 § 5(1) that when a referral from a health professional is a condition

	- If the treatment is for an occupational injury: NAV (the Norwegian Labour and Welfare Administration) decision confirming the occupational injury/illness. - Other documentation the individual believes to be relevant for the application.			for the right to benefits to cover expenses for health services in Norway or the right to receive health care at the expense of the public sector in Norway, the condition correspondingly applies to benefits for health care received in another EEA country. However, it is also acknowledged that this may in some instances be difficult, hence, Regulation 22 November 2010 No. 1466 § 5(3) provides that the condition of referral may in special cases be waived altogether if the need for health care arose during the stay abroad and it would, depending on the circumstances, be unreasonable to demand that the conditions are met.
6. Are there any costs associated with the handling of the reimbursement request? - *Direct costs (e.g., fixed costs for submitting or filing a reimbursement*	**Answer:** *Direct costs:* None. *Indirect costs:*	**Source(s):** Regulation 22 November 2010 No. 1466 § 11. Circular 16 April 2015 R05-24A-FOR Pt. 10.	**Yes** ☒ **No** ☐ Cfr. Question 4 above.	Helfo has caseworkers with expertise in many languages, so translations are often not required.

request, proportion deducted from the reimbursable amount). - *Indirect costs* (*e.g., translations, stamps, etc).*	All documentation must be in Norwegian, Danish, Swedish or English. If the documents are in another language, Helfo may ask the individual to provide a state-authorised translation. In this assessment, emphasis shall be placed on the size of the claim amount. If it entails unreasonable costs for the user to translate the claim based on the amount to be reimbursed, Helfo shall assess whether there is a need for translation, or whether the documentation can still be understood by Helfo. In such cases, Helfo cannot demand that the user have the documents translated by a state-authorised translator. The individual must pay for the translation. The application can either be submitted by mail or digitally, thereby avoiding the cost of stamps.			
7. Are there any specific time requirements linked to a reimbursement request? (*e.g., time within which the reimbursement requests must be submitted and/or time within the requested body must handle the request and/or reimburse the costs, etc.*).	**Answer:** *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* The reimbursement request must be submitted within six months after the earliest the claim could have been submitted. The six months are counted from the date of treatment. Claims for benefits are made after the health care has been received and paid for.	**Source(s):** National Insurance Act 18 February 1997 No. 19 § 22-13. Regulation 22 November 2010 No. 1466 § 10. Circular 16 April 2015 R05-24A-FOR pt. 9.	**Yes** ☒ **No** ☐	All administrative bodies in Norway shall prepare and decide cases without undue delay, subject to § 11a of the Act relating to procedures in cases concerning the public administration 10 February 1967[562]. Helfo is subject to these rules, assuring that the claim procedures are equivalent to other public

[562] Lov om behandlingsmåten i forvaltningssaker 10. februar 1967, available at https://lovdata.no/dokument/NL/lov/1967-02-10 (last accessed 16 June 2021), § 11a.

	If the deadline is missed, the costs will not be reimbursed. However, benefit can be granted for up to three years before the claim was made, if the person entitled to the benefit has obviously not been able to make a claim before. The same applies if the person in question has not submitted a claim before because the social security bodies have provided misleading information. The processing time for a treatment expenses reimbursement claim is up to 12 weeks. Helfo shall prepare and decide the case without undue delay. It is possible to appeal the decision within 6 weeks.			administration claims in Norway.
8. Are there any non-reimbursable thresholds, deductions *(except the deductions for administrative costs mentioned above) etc.?*	**Answer:** *If yes, please specify the thresholds.* No specific thresholds identified besides the domestic thresholds, namely: - the user fee corresponding to what the user fee would have been if the treatment had been received in Norway, unless an exemption card has been issued by Helfo. Exemption cards are issued once a user fee limit is reached. This corresponds to the domestic system). - Travel costs which are only covered for the proportion of the travel expenses corresponding to what the individual would	**Source(s):** Regulation 22 November 2010 No. 1466 §§ 8 and 9, and 13. Circular 16 April 2015 R05-24A-FOR Pts. 6, 7 and 12.	**Yes** ☒ **No** ☐	The thresholds correspond to the domestic thresholds. The individual will only need to cover costs that exceed the costs in Norway.

	have received if the treatment had been received in Norway.			
9. In instances where a PA (or prior-notification) has already been issued, is a separate/simplified procedure available for requesting reimbursement? **applicable only if the country has a PA system.*	**Answer:** *If yes, please describe the simplified procedure.* Norway does not have a PA system, but it does have voluntary prior notification. There is not a separate/simplified procedure available for requesting reimbursement.	**Source(s):** Regulation 22 November 2010 No. 1466 § 9a. Circular 16 April 2015 R05-24A-FOR Pt. 8.	**Yes** ☒ **No** ☐	Harmonisation between the voluntary prior notification and the reimbursement application must be ensured, but prior notification may decrease the processing time.
10. Are there additional administrative/procedural requirements for reimbursement depending on, for instance, the type of treatment for which reimbursement is requested, or the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* Information tailored to each main category of treatment is provided. In Norway, as a rule, individuals are liable for their own dental costs. However, there are some exceptions, and these exceptions also apply within the EEA. There are 15 dental conditions, that subject to certain requirements, may be eligible for reimbursement. There is a limit for the amount that can be reimbursed, equivalent to the estimated cost that the Norwegian	**Source(s):** Dental Health Services Act 3 June 1983 No. 54563, § 1-3. National Insurance Act 18 February 1997 No. 19 § 5-6. Regulation on benefits to cover the costs of examination and treatment by a dentist and dental nurse for illness 16 December 2014 No. 1702.564	**Yes** ☒ **No** ☐	The national exceptions are mirrored in the procedures for dental treatments in another EEA country.

[563] Lov om tannhelsetjenesten 3. juni 1983 nr. 54, available at https://lovdata.no/dokument/NL/lov/1983-06-03-54 (last accessed 2 July 2021).

1 [564] **Forskrift om stønad til dekning av utgifter til undersøkelse og behandling hos tannlege og tannpleier for sykdom 16. desember 2014 nr. 1702, available at https://lovdata.no/dokument/SF/forskrift/2014-12-16-1702 (last accessed 2 July 2021).**

	health service would have incurred had the dental treatment been received in Norway. One must pay the same patient contribution/user fee as one would have paid if the treatment had been provided in Norway. Additionally, certain groups are entitled to necessary dental care within the public dental health service in Norway, and may be able to transfer their right to treatment to other EEA countries: children and young people under the age of 18; people with mental disabilities, living in or outside of institutions; senior citizens with chronic illness or disabilities in institutional care or receiving home nursing; and young people who turn 19 or 20 in the year of treatment (user fee of 25 per cent of the fixed rates in Norway). The reimbursement is provided up to the same amount as the fixed rate in Norway. Where no rate has been set, the reimbursement is limited to an amount corresponding to the estimated costs the public sector would have been charged if the dental care had been received in Norway.	Regulation 22 November 2010 No. 1466 §§ 3(1)(c), 4(3), 7(1), 7(3), 8, 9(4), 11(2), and 13(6). Circular 16 April 2015 R05-24A-FOR Pts. 2, 5, and 6 HelseNorge. Treatment abroad.565 Information on dental treatment in another EEA country.566 Application form for reimbursement of the cost of dental treatment received in another EEA country.567 Documentation form for reimbursement of dental expenses incurred in another EEA-Country.568		

[565] HelseNorge. Treatment abroad, available at https://www.helsenorge.no/en/treatment-abroad/ (last accessed 16 June 2021).
[566] HelseNorge, Dental treatment in the EU/EEA, available at https://www.helsenorge.no/en/treatment-abroad/dental-treatment-in-the-eu-eea/ (last accessed 16 June 2021).
[567] Helfo. Application for reimbursement of the cost of dental treatment received in another EEA country, available at https://www.helfo.no/skjema/Søknad%20om%20refusjon%20for%20tannbehandling%20i%20EØS-pasient-05-24a.02-engelsk.pdf/_/attachment/inline/7370678f-43d4-420a-91d1-a754ea97f6a3:2b6bc0aeaa8bff1c6a58a7a372a5bdf147007a44/Søknad%20om%20refusjon%20for%20tannbehandling%20i%20EØS-pasient-05-24a.02-engelsk.pdf (last accessed 16 June 2021).
[568] Helfo. Documentation for reimbursement of dental expenses incurred in another EEA-Country, available at https://www.helfo.no/skjema/Dokumentasjon%20på%20utgifter%20til%20tannbehandling%20utført%20i%20EØS-behandler-05-24a.03-engelsk.pdf/_/attachment/inline/bc6b7e82-f0a4-4ac8-885d-18ab9a575212:09fbc9c5f7628c6b0f5cce5f2f27708dc550fc7f/Dokumentasjon%20på%20utgifter%20til%20tannbehandling%20utført%20i%20EØS-behandler-05-24a.03-engelsk.pdf (last accessed 2 July 2021).

	To account for the rules relating to dental health, the reimbursement application form for dental treatment differs from the regular reimbursement application form, as follow. A documentation form must be completed by the dentist/orthodontist after each treatment procedure. For the initial assessment for orthodontic work, one must also ensure that a diagnostic form is filled in. The orthodontist must furthermore document the treatment that has been performed, by filling in a new description of treatment for each visit. These forms must be enclosed with the claim form together with X-rays and the treatment plan. These must be sent to Helfo within 6 months of each individual treatment date together with itemised receipts.	Diagnostic form for reimbursement of the cost of orthodontic treatment abroad.569 Orthodontic treatment abroad form.570		
11. Please list any other administrative requirements in your country in relation to the procedures of reimbursement of cross-border healthcare.	**Answer:** Norway has voluntary prior notification. As treatment within a specialised health service abroad may prove costly, individuals have the option of applying to Helfo for prior notification to reduce their financial risk. The application can either be submitted by mail	**Source(s):** Regulation 22 November 2010 No. 1466 § 9a. Circular 16 April 2015 R05-24A-FOR Pt. 8.	**Yes** ☐ **No** ☒	As stated above under Q4, Norway has universal healthcare. The described procedures are not discriminatory though **they lack a domestic equivalent**. Regulation

[569] Helfo. Diagnostic form for reimbursement of the cost of orthodontic treatment abroad, available at https://www.helfo.no/skjema/Diagnostic%20form%20for%20reimbursement%20of%20the%20cost%20of%20orthodontic%20treatment%20abroad-05-24.12-engelsk.pdf/_/attachment/inline/ab056b15-0d82-47a1-99a4-a6447ecebb8c:46610333849ac948375426745961 1bee83e84bf4/Diagnoseskjema%20for%20kjeveortopedisk%20behandling%20i%20utlandet-05-24.12-engelsk.pdf (last accessed 2 July 2021).

[570] Helfo. Orthodontic treatment abroad, available at https://www.helfo.no/skjema/Takstskjema%20for%20Kjeveortopedisk%20behandling%20i%20utlandet-05-24.15-engelsk.pdf/_/attachment/inline/ec176843-868d-4e21-9a31-ba5c412cdf4a:01410c357fc33e8d8170baa0f2c379a5d4251491/Takstskjema%20for%20Kjeveortopedisk%20behandling%20i%20utlandet-05-24.15-engelsk.pdf (last accessed 2 July 2021).

	or digitally through a secure log-in portal. Normal processing time for a prior notification is up to 4 weeks. Prior notification is issued in a decision letter from Helfo granting economic support for the actual costs of the planned healthcare, up to a maximum reimbursement amount. A prior notification may be staged, meaning that it can be granted at different stages of the treatment, that is, diagnostics, treatment, follow-up care and so forth. The prior notification is legally binding on Helfo, but is valid only for the healthcare specified in the decision letter. One needs to pay for the treatment up front, and apply to Helfo for the reimbursement afterwards. Applying is voluntary, and only priority patients (those whose referral have been assessed by the specialised health service as warranting treatment by a specialist) are eligible for prior notification. To apply, one must first obtain a formal offer to provide medical treatment from another EEA country. When considering whether to grant an application for prior notification, Helfo will decide if the treatment sought abroad is equivalent to the treatment one would have received from the public health service in Norway. One must document that one is a priority patient, and that one has	Prior notification application form.571		22 November 2010 No. 1466 § 2(2) clearly states that the same conditions apply as for corresponding health care at the expense of the public sector in Norway. Voluntary prior notification has been implemented as an extra service to those seeking healthcare in another EEA country to reduce their financial risk.

[571] Helfo. Application for prior authorisation (S2) or prior notification of planned treatment in an EEA country or Switzerland, available at https://www.helfo.no/skjema/Søknad%20om%20forhåndsgodkjenning%20(S2)%20eller%20forhåndstilsagn%20for%20planlagt%20behandling%20i%20et%20EØS-land%20eller%20Sveits-05-24a.04-engelsk/_/attachment/inline/a2a17d1b-fbf2-4a76-ac98-ca7231b4d4b9:7e9f8c877065457abccb5e534f6fba5885839c88/Søknad%20om%20forhåndsgodkjenning%20(S2)%20eller%20forhåndstilsagn%20for%20planlagt%20behandling%20i%20et%20annet%20EØS-land-sykehusbehandling-05-24a.04-engelsk.pdf (last accessed 2 July 2021).

	received an offer of treatment in another EEA country, showing the type of treatment and the anticipated cost. If one has been evaluated by the specialised health service in Norway, one should also submit a copy of this evaluation. Prior notification is not a condition for reimbursement.			

Part 2: Checklist for verification with national/regional

Name of the body: The Norwegian Ministry of Health and Care Services and the Norwegian Directorate of Health.
Country/Region: Norway.
Date of verification call: 14 June 2021.

Template for the Data Collection	**Aspects to be verified** *Tick the boxes if the information in the template for the data collection has been verified and/or complemented by the national body*		**Comments** *Include any additional comments and/or information provided by the contacted body*
Section 1 – Prior Authorisation			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Justification/purpose of the identified requirement(s) (Column 4)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	It was verified that Norway does not have a PA system.
Section 2 - Reimbursement			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Whether the requirement applies domestically (Discriminatory assessment) (Column 4) ▪ Justification/purpose of the identified requirement(s) (Column 5)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	All the information provided in the comments below have been incorporated by the national legal expert in the answers of the questionnaires above.

POLAND – COUNTRY REPORT

Part 0: Preliminary Assessment

1. **Please indicate whether the rules governing the administrative procedures/requirements for requesting PA and reimbursement under Directive 2011/24/EU in your country are set out at:**

A. National level ☒

B. Decentralised/regional/local level ☐

In case (1.B): Please indicate the two most relevant jurisdictions in your country (i.e., in terms of population):

Region/jurisdiction: 1: N/A

Region/jurisdiction 2: N/A

NOTE: In case (1.B) the template for the data collection (Part 1) should be completed twice, once for each of the two most relevant regions/jurisdiction indicated above.

2. **Please indicate the national body best suited to verify the accuracy of the information collected in Part 1, and justify your selection.**
Depending on the characteristics of your national healthcare system, the relevant body may be: a) *the national social security body*; or b) *an insurance fund*. In the latter case, please indicate the most representative fund (e.g., the one with the highest number of affiliations).

Body to be contacted for Task 2:

The National Health Fund, Central National Health Fund (also NCP).

(In case 1.B, please indicate two relevant bodies, one respectively for each Region/jurisdiction)

Reasons for Selection: National Health Fund (hereinafter also referred to as: the NHF) is a national social security body in Poland and the main payer in the health care system. The NHF is responsible for concluding contracts with public and non-public service providers and for financing services.[572]

[572] Dobrochna Bach-Golecka, Obawy rządu, oczekiwania pacjentów. O implementacji dyrektywy o transgranicznej opiece zdrowotnej w Polsce, paragraph III, available at [in Polish]: http://forum-pl-cz.com/index.php/cs/home/22-polska/polityki-publiczne/54-dobrochna-bach-golecka-obawy-rzadu-oczekiwania-pacjentow-o-implementacji-dyrektywy-o-transgranicznej-opiece-zdrowotnej-w-polsce

Part 1: Questionnaire

*__Note 1__: In cases where administrative requirements are set out in the legislative/regulatory framework at decentralised/regional/local level, please complete the template for the data collection twice, once for each of the two most relevant regions/jurisdictions (e.g., in terms population).

__*Note 2__: Setting out a Prior Authorisation (PA) system is optional for Member States. Should your country not have a system of PA in place under Directive 2011/24/EU, Section 1 will not need to be completed.

SECTION 1 PRIOR AUTHORISATION PROCEDURE(S)			
Questions	**Answer**	**Sources**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to PA procedures for a cross-border healthcare under Directive 2011/24/EU?	**Answer:** Prior authorisation is required when a person[573] wishes to provide treatment listed in the List of Benefits Regulation in another EU /EEA Member State. Prior consent for such treatment is issued in the form of an administrative decision approved by the President of the National Health Fund. This decision is made before treatment begins.[574]	**Source(s):** Regulation of the Minister of Health of 18 March 2021 on issuing consent to obtain healthcare services outside the country and covering transport costs (Journal of Laws of 2021, item 644) [575] (referred to as the "**consent regulation**").	N/A

[573] Called also “applicant/patient”.
[574] Official website of the National Health Fund: https://www.nfz.gov.pl/dla-pacjenta/nasze-zdrowie-w-ue/leczenie-planowane-wymagajace-uprzedniej-zgody/zbyt-dlugi-czas-oczekiwania-na-leczenie-w-polsce/zgoda-uprzednia-na-podstawie-dyrektywy-transgranicznej/ [in Polish].
[575] Regulation of the Minister of Health of 18 March 2021 on issuing consent to obtain healthcare services outside the country and covering transport costs (Journal of Laws of 2021, item 644 (Rozporządzenie Ministra Zdrowia w sprawie wydawania zgody na uzyskanie świadczeń opieki zdrowotnej poza granicami kraju oraz pokrycie kosztów transportu z dnia 18 marca 2021 r. (Dz. U. z 2021 r. poz. 644), zwane dalej „rozporządzeniem w sprawie wydawania zgody”), https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU2021000064

	The legislative sources governing PA in Poland are listed in the following column (sources).	Art. 42b sec. 9, art. 42f and article. 20 paragraph 11 of the Act of 27 August 2004 on health care services financed from public funds (Journal of Laws of 2020, item 1398, as amended)[576], (referred to as the "**Act on Benefits**"). Regulation of the Minister of Health of 3 September 2020 on the list of health care services requiring prior consent of the President of the National Health Fund (Journal of Laws of 2020, item 1556)[577] (referred to as the "**Regulation on the list of benefits**"). Ordinance of the Minister of Health of September 26, 2005 on medical criteria to be followed by service providers when placing recipients on waiting lists for healthcare services (Journal of Laws No. 200,	

[576] Act of 27 August 2004 on health care services financed from public funds Journal of Laws of 2020, item 1398, as amended, (Ustawa z dnia 27 sierpnia 2004 r. o świadczeniach opieki zdrowotnej finansowanych ze środków publicznych (Dz. U. z 2020 r. poz. 1398, z późn. zm.), zwana „ustawą o świadczeniach", available at: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20042102135

[577] Regulation of the Minister of Health of 3 September 2020 on the list of health care services requiring prior consent of the President of the National Health Fund (Journal of Laws of 2020, item 1556), (Rozporządzenie Ministra Zdrowia z dnia 3 września 2020 r. w sprawie wykazu świadczeń opieki zdrowotnej wymagających uprzedniej zgody Prezesa Narodowego Funduszu Zdrowia (Dz.U. z 2020 r., poz. 1556), zwane „rozporządzeniem w sprawie wykazu świadczeń), available at: http://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20200001556

		item 1661) [578], (referred to as the "**Ordinance on medical criteria medical**"). Regulation of the Minister of Health of 9 November 2015 on the method and criteria for determining the acceptable waiting time for selected ranges of healthcare services (Journal of Laws of 2015, item 1948) [579] (referred to as the "**Regulation on the acceptable waiting time**"). Regulations of the Minister of Health issued pursuant to Art. 31d of the Act on benefits specifying lists of guaranteed benefits in individual scopes of benefits[580] (hereinafter referred to as	

[578] Ordinance of the Minister of Health of September 26, 2005 on medical criteria to be followed by service providers when placing recipients on waiting lists for healthcare services (Journal of Laws No. 200, item 1661), (Rozporządzenie Ministra Zdrowia z dnia 26 września 2005 r. w sprawie kryteriów medycznych, jakimi powinni kierować się świadczeniodawcy, umieszczając świadczeniobiorców na listach oczekujących na udzielenie świadczenia opieki zdrowotnej, zwane „rozporządzeniem w sprawie kryteriów medycznych", dostępne [w języku polskim] pod adresem: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20052001661

[579] Regulation of the Minister of Health of 9 November 2015 on the method and criteria for determining the acceptable waiting time for selected ranges of healthcare services (Journal of Laws of 2015, item 1948), (Rozporządzenie Ministra Zdrowia z dnia 9 listopada 2015 r. w sprawie sposobu i kryteriów ustalania dopuszczalnego czasu oczekiwania na wybrane zakresy świadczeń opieki zdrowotnej (Dz.U. z 2015 r., poz. 1948), http://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20150001948

[580] Regulations of the Minister of Health issued pursuant to Art. 31d of the Act on benefits specifying lists of guaranteed benefits in individual scopes of benefits, Rozporządzenia Ministra Zdrowia wydane na podstawie art. 31d ustawy o świadczeniach określające wykazy świadczeń gwarantowanych w poszczególnych zakresach świadczeń, zwane dalej „rozporządzeniami w sprawie świadczeń gwarantowanych" , available at: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20200001556

		"**regulations on guaranteed benefits**").	
2. Is this the same procedure as for PA under the Social Security Coordination Regulations?	**Answer:** **Yes ☒ No ☐** The procedure and requirements related to the application for the prior approval of the President of the National Health Fund are identical to the requirements for obtaining the consent of the President of the Fund for obtaining in an EU or EFTA Member State other than the Republic of Poland, healthcare services or its continuation, in the case of benefits provided in accordance with the provisions on coordination (consent provided for in Article 42i of the Act on benefits). However, consent under the coordination provisions applies to any type of service for which the patient intends to travel to another EU / EFTA country (and not, as in the case of prior consent, only of those explicitly defined in the List of Benefits Regulation).		N/A
3. What body is in charge of handling the PA applications? *(e.g., where and to whom PA applications have to be submitted?)*	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations)* The National Health Fund: the decision on prior authorisation is issued in a form of administrative decision by the of the president	**Source(s):** National Health Fund official website;[584] Paragraph 1 (1a) of the Regulation of the Minister of Health of 18 March 2021 on the issuance of consent to obtain healthcare services outside the country and on	N/A

[584] National Health Fund official website available at: https://www.nfz.gov.pl/dla-pacjenta/nasze-zdrowie-w-ue/leczenie-planowane-wymagajace-uprzedniej-zgody/zbyt-dlugi-czas-oczekiwania-na-leczenie-w-polsce/zgoda-uprzednia-na-podstawie-dyrektywy-transgranicznej/

	of the provincial branch of the National Health Fund. The decision of the President of the National Health Fund is final – it is not possible to appeal against it at the level of the National Fund. However, it is possible to issue a complaint against it to the Provincial Administrative Court in Warsaw. The deadline for submitting a complaint against the decision of the President of the National Health Fund is 30 days from the date of delivery of the decision to the complainant.[581] Furthermore, it is worth noting that pursuant to Art. 42 f (2) of the Act on of 27 August 2004 on healthcare services financed from public funds[582] (hereinafter also referred to as: Act on benefits), the president of the provincial branch of the Fund may, by way of an administrative decision, refuse to grant prior consent, if the healthcare provision covered by the application: 1) is **not** a guaranteed service (please see Question 4); 2) requested healthcare treatment may be provided in Poland, by a healthcare provider	costs of transport reimbursement;[585] Art. 42f of Act of 27 August 2004 on healthcare services financed from public funds (Journal of Laws of 2020, item 1398, as amended), known as the "Act on benefits"[586]	

[581]National Health Fund official website – National Contact Point for cross border healthcare, available at: http://www.kpk.nfz.gov.pl/pl/leczenie-w-innym-panstwie/leczenie-planowane-uprzednia-zgoda-na-uzyskanie-leczenia-poza-granicami-kraju.html#informacje-dla-pacjenta

[582] Act of 27 August 2004 on healthcare services financed from public funds (Journal of Laws of 2020, item 1398, as amended), known as the "Act on benefits" (Ustawa z dnia 27 sierpnia 2004 r. o świadczeniach opieki zdrowotnej finansowanych ze środków publicznych (Dz. U. z 2020 r. poz. 1398, z późn. zm.), zwana „ustawą o świadczeniach"), available at [in Polish]: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20042102135

[585] Para.1(1)of the Regulation of the Minister of Health of 18 March 2021 on the issuance of consent to obtain healthcare services outside the country and on costs of transport reimbursement (Rozporządzenie Ministra Zdrowia z dnia 18 marca 2021 r. w sprawie wydawania zgody na uzyskanie świadczeń opieki zdrowotnej poza granicami kraju oraz pokrycie kosztów transport), available at [in Polish]: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20210000644

[586] Act of 27 August 2004 on health care services financed from public funds (Journal of Laws of 2020, item 1398, as amended), known as the "Act on benefits" (Ustawa z dnia 27 sierpnia 2004 r. o świadczeniach opieki zdrowotnej finansowanych ze środków publicznych (Dz. U. z 2020 r. poz. 1398, z późn. zm.), zwana „ustawą o świadczeniach"), available at [in Polish]: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20042102135

	who has an agreement for the provision of healthcare services, within a permitted period not exceeding the patient's allowable waiting time for a given service, on the basis of medical criteria, taking into account the current state of health of the patient, the degree of ailments experienced by him and the nature of his disability , at the time of application, and the history of the disease and its expected development; 3) it poses a significant risk to the health of the patient and such risk outweighs the potential health benefits; 4) poses a significant health risk to the society; 5) is to be provided by an entity providing health services, operating in a Member State of the European Union other than the Republic of Poland, for which there are significant doubts as to compliance with the quality and safety standards established by the state in which it provides health services.[583]		
4. Who is entitled to apply for PA? *(e.g., can the patients apply themselves, or is treating doctor filing/partially filling the request, etc.)*	**Answer:** *If there is a national doctor involved, is there a requirement that this doctor is contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA?* In accordance with the § 2 point 2 of the "Regulation of the Minister of Health of 18 March 2021 on the issuance of consent to obtain healthcare services outside the country and cover the costs of transport", the applicant (patient) shall fill in the following parts of the	**Source(s):** The Regulation of the Minister of Health of 18 March 2021 on the issuance of consent to obtain healthcare services outside the country and on costs of transport reimbursement (Rozporządzenie Ministra Zdrowia z dnia 18 marca	

[583] National Health Fund official website – National Contact Point for cross border healthcare, available at: http://www.kpk.nfz.gov.pl/pl/leczenie-w-innym-panstwie/leczenie-planowane-uprzednia-zgoda-na-uzyskanie-leczenia-poza-granicami-kraju.html#informacje-dla-pacjenta

	form: IB, II and VI. These parts of the form can be also filled in on behalf of the patient by legal representative; spouse; a relative or relative up to the second degree in a straight line; person that lives together with the patient; a person authorised by you - in this case attach a power of attorney to the application.[587] Then the applicant (patient) forwards the application to a health insurance doctor with 2nd degree specialisation or the title of specialist in the field of proper medicine due to the scope of the requested treatment or diagnostic tests, hereinafter referred to as a "specialist doctor".[588] The physician who complies with said criteria shall complete the part III of the form.[589] The applicant (patient) then forwards the form to the National Health Fund with completed parts IB, II, III and VI with required documents attached.[590] Please note that the required documents that need to be attached to the form are further elaborated on under Question 6. The applicant / patient must apply for prior consent only if the treatment he / she is	2021 r. w sprawie wydawania zgody na uzyskanie świadczeń opieki zdrowotnej poza granicami kraju oraz pokrycie kosztów transport).[593]	

[587] National Health Fund official website available at: https://www.nfz.gov.pl/dla-pacjenta/nasze-zdrowie-w-ue/leczenie-planowane-wymagajace-uprzedniej-zgody/ [in Polish].

[588] § 3 point 2 of the Regulation of the Minister of Health of 18 March 2021 on the issuance of consent to obtain healthcare services outside the country and cover the costs of transport (Rozporządzenie Ministra Zdrowia z dnia 18 marca 2021 r. w sprawie wydawania zgody na uzyskanie świadczeń opieki zdrowotnej poza granicami kraju oraz pokrycie kosztów transport), available at [in Polish]: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20210000644

[589] § 3 point 3 of the Regulation of the Minister of Health of 18 March 2021 on the issuance of consent to obtain healthcare services outside the country and cover the costs of transport (Rozporządzenie Ministra Zdrowia z dnia 18 marca 2021 r. w sprawie wydawania zgody na uzyskanie świadczeń opieki zdrowotnej poza granicami kraju oraz pokrycie kosztów transport), available at [in Polish]: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20210000644

[590] § 3 point 4 of the Regulation of the Minister of Health of 18 March 2021 on the issuance of consent to obtain healthcare services outside the country and cover the costs of transport (Rozporządzenie Ministra Zdrowia z dnia 18 marca 2021 r. w sprawie wydawania zgody na uzyskanie świadczeń opieki zdrowotnej poza granicami kraju oraz pokrycie kosztów transport), available at [in Polish]: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20210000644

[593] Regulation of the Minister of Health of 18 March 2021 on the issuance of consent to obtain healthcare services outside the country and on costs of transport reimbursement Rozporządzenie Ministra Zdrowia z dnia 18 marca 2021 r. w sprawie wydawania zgody na uzyskanie świadczeń opieki zdrowotnej poza granicami kraju oraz pokrycie kosztów transportu, dostępnego [w języku polskim] pod adresem: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20210000644

	seeking is covered by the Regulation of the Minister of Health of 3 September 2020 on the list of healthcare services requiring prior consent of the President of the National Health Fund known as the "Regulation on the list of benefits".[591] In other cases, reimbursement of medical expenses under the Directive does not require prior consent and is made on general terms (based on the application for reimbursement submitted after treatment). The Order on the List of Benefits lists healthcare services for which reimbursement is possible with prior consent. The list includes the following benefits: "1) healthcare services which require the patient to stay in the hospital at least until the next day, regardless the type of services provided; 2) treatment under drug programs referred to in the Act of 12 May 2011 on the reimbursement of drugs, foodstuffs for particular nutritional uses and medical devices (Journal of Laws of 2020, item 357, 945 and 1493); 3) isotope therapy; 4) stereotaxic teleradiotherapy; 5) hadron beam proton beam teleradiotherapy; 6) hyperbaric therapy;		

[591] Regulation of the Minister of Health of 3 September 2020 on the list of healthcare services requiring prior consent of the President of the National Health Fund (Rozporządzenie Ministra Zdrowia z dnia 3 września 2020 r. w sprawie wykazu świadczeń opieki zdrowotnej wymagających uprzedniej zgody Prezesa Narodowego Funduszu Zdrowia) (Dz.U. z 2020 r., poz. 1556), zwane „rozporządzeniem w sprawie wykazu świadczeń", dostępne [w języku polskim] pod adresem: http://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20200001556

	7) implantation of a baclofen pump in the treatment of spasticity resistant to pharmacological treatment; 8) genetic research; 9) positron emission tomography; 10) nuclear medicine research."[592]		
5. Is there a specific application form/module which the person seeking PA needs to submit?	**Answer:** *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?*	**Source(s):** § 2 point 1 of the Regulation of the Minister of Health of 18 March 2021 on the issuance of consent to obtain healthcare services outside the country and cover the costs of transport;[597] Art. 42 f (1a) and art. 42 f(4) ustawy Act of 27 August 2004 on health	

[592] List attached to the Regulation of the Minister of Health of 3September 2020 on the list of healthcare services requiring prior approval of the director of the provincial branch of the National Health Fund (Journal of Laws of 2020, item 1556), referred to as the "Regulation on the list of benefits" (Rozporządzenie Ministra Zdrowia z dnia 3 września 2020 r. w sprawie wykazu świadczeń opieki zdrowotnej wymagających uprzedniej zgody dyrektora oddziału wojewódzkiego Narodowego Funduszu Zdrowia (DZ. U. z 2020 r., poz. 1556), zwane „rozporządzeniem w sprawie wykazu świadczeń"), available at [in Polish]: http://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20200001556

[597] § 2 point 1 of the Regulation of the Minister of Health of 18 March 2021 on the issuance of consent to obtain healthcare services outside the country and cover the costs of transport (Rozporządzenie Ministra Zdrowia z dnia 18 marca 2021 r. w sprawie wydawania zgody na uzyskanie świadczeń opieki zdrowotnej poza granicami kraju oraz pokrycie kosztów transport), available at [in Polish]: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20210000644

	§ 3 point 1 of "the Regulation of the Minister of Health of 18 March 2021 on the issuance of consent to obtain healthcare services outside the country and cover the costs of transport" states that the form which the person seeking PA needs to submit is attached in the Annex 1 to the said Regulation.[594] The scope of data included in the application is specified in Art. 42f paragraph. 4 of the Act on benefits. According to the said provision, in the part filled in by the patient (or his legal representative, spouse, relative or affinity up to the second degree in a straight line, a person who lives together or a person authorized by the patient), the following information shall be included: - name and surname and PESEL (personal identification number) of the applicant. In the absence of PESEL number - the number of the document confirming the applicant's identity and date of birth should be included. Further information that are required in the application form are: - the address of the place of residence and the correspondence address of the patient. - In case the application is submitted by a statutory representative, a spouse, relative or relationship up to the second degree in a straight line, a cohabiting person or a person authorized by the recipient, name and surname and PESEL number of one of these persons is required (in the absence of PESEL number - the number of the document	care services financed from public funds [598]	

	confirming the applicant's identity and date of birth should be included). - Address, of the place of residence and the correspondence address of this person, telephone number, email address, is also necessary to be included. - Moreover, in the application there must be an indication of the entity providing health services operating in another EU Member State or the EEA, which is to provide healthcare services to which the application relates, together with a justification and a declaration made under the pain of criminal liability under Art. 233 § 1 and 2 of the Criminal Code that the data contained in the application are consistent with the facts.		

[594] Annex I, Regulation of the Minister of Health of 18 March 2021 on the issuance of consent to obtain healthcare services outside the country and cover the costs of transport (Rozporządzenie Ministra Zdrowia z dnia 18 marca 2021 r. w sprawie wydawania zgody na uzyskanie świadczeń opieki zdrowotnej poza granicami kraju oraz pokrycie kosztów transport), available at [in Polish]: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20210000644

[598] Art. 42 f ust. 1a oraz ust. 4 ustawy z dnia 27 sierpnia 2004 r. o świadczeniach opieki zdrowotnej finansowanych ze środków publicznych (Dz. U. z 2020 r., poz. 1398, z późn. zm.)

	In the part filled by the doctor, the following information are included: - name and surname of the doctor completing the application, - a stamp, an imprint or a sticker containing the license number to practice the profession and the specialization of the doctor filling in the application, - a stamp, an imprint or a sticker containing the name and address of the service provider with whom the filling physician is located. Further, the doctor includes clinical diagnosis of the health problem that is the reason for the application, and concomitant diagnoses, using the International Statistical Classification of Diseases and Problems Healthcare ICD-10, information about the course of the disease to date and the treatment used, prognosis of the likely further course of the disease, indication of the detailed scope of treatment or diagnostic tests to which the application relates, specification of the admissible waiting time of the recipient for the provision of healthcare services to which the application relates, justification of the request. The application with the required attachments should be then submitted in paper to the Headquarters of the National Health Fund in Warsaw.[595] However, the application can be also submitted in the form of an electronic document with a qualified electronic signature, personal signature or a trusted signature. The		

	required attachments can also be submitted with the digital path.[596]		
6. What (other) documentation has to be submitted in order to substantiate a PA request?	*If applicable, please specify:* - *What documents and what particulars are required;* - *Whether there are requirements as to who has to issue the documents (e. g., a doctor contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA or any doctor);* - *Whether the submission of the documentation is optional, mandatory, or recommended.* **Answer:** There are the following documents required as mandatory: - copy of medical records related to the scope of the requested treatment; - if the copy of medical records is written in a foreign language, there must be Polish	**Source(s):** National Health Fund official website[601] Annex 1 of the Regulation of the Minister of Health of 18 March 2021 on the issuance of consent to obtain healthcare services outside the country and cover the costs of transport[602]	

[595] As above.
[596] National Health Fund official website available at: https://www.nfz.gov.pl/dla-pacjenta/nasze-zdrowie-w-ue/leczenie-planowane-wymagajace-uprzedniej-zgody/zbyt-dlugi-czas-oczekiwania-na-leczenie-w-polsce/zgoda-uprzednia-na-podstawie-dyrektywy-transgranicznej/
[601] As above.
[602] Annex 1, Annex 2, Regulation of the Minister of Health of 18 March 2021 on the issuance of consent to obtain healthcare services outside the country and cover the costs of transport (Rozporządzenie Ministra Zdrowia z dnia 18 marca 2021 r. w sprawie wydawania zgody na uzyskanie świadczeń opieki zdrowotnej poza granicami kraju oraz pokrycie kosztów transport), available at [in Polish]: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20210000644

	translation attached (it does not need to be a sworn translation);[599][600] To the application there has to be an applicant's declaration attached that states that the patient is included in waiting list for the provision of benefits and to qualify for a medical category, determined in accordance with the criteria medical services specified in the regulations issued on the basis of art. 20 paragraph 11, and the date of granting the benefit, with an indication the service provider keeping this list and medical documentation. In the case of medical documentation prepared in a foreign language translation of this documentation into Polish; the translation does not have to be a sworn translation.		
7. Are there any costs associated with the handling of the PA request? - *Direct costs (e.g., fixed costs for submitting or filing a PA request).* - *Indirect costs* (*e.g., translations, stamps, etc).*	**Answer:** *Direct costs:* None identified. *Indirect costs:* None identified.	**Source(s):** N/A	

[599] National Health Fund official website available at: https://www.nfz.gov.pl/dla-pacjenta/nasze-zdrowie-w-ue/leczenie-planowane-wymagajace-uprzedniej-zgody/zbyt-dlugi-czas-oczekiwania-na-leczenie-w-polsce/zgoda-uprzednia-na-podstawie-dyrektywy-transgranicznej/

[600] Annex 1, Annex 2, Regulation of the Minister of Health of 18 March 2021 on the issuance of consent to obtain healthcare services outside the country and cover the costs of transport (Rozporządzenie Ministra Zdrowia z dnia 18 marca 2021 r. w sprawie wydawania zgody na uzyskanie świadczeń opieki zdrowotnej poza granicami kraju oraz pokrycie kosztów transport), available at [in Polish]: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20210000644

8. Are there any specific **time requirements** linked to a PA request? (*e.g., time within which a requesting person must submit the PA application and/or time within which the requested body must take a decision on the PA request, etc.*).	**Answer:** *- If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* Pursuant to Art. 42d paragraph. 2 point 5 of the Act on Benefits, if the patient (recipient) does not obtain the prior consent of the President of the National Health Fund before granting him benefits in another EU / EEA Member State, the President of the National Health Fund must issue a decision to refuse the reimbursement of cross-border treatment costs. Simultaneously with art. 42d paragraph. 3 of the Act on benefits, it follows that the provisions of para. 2 paragraph 5 shall not apply if the recipient, after 30 days from the date of submission of a complete application for prior consent, due to the urgent need to undertake treatment necessary to save life or health, resulting from the confirmed clinical condition, undergo such treatment in the territory of another than the Republic of Poland of an EU or EEA Member State. The cited provisions of Art. 42d of the Act on Benefits determines the functional time frame for the patient and the authority relating to the date of submission of the application by the patient and the date of the authority issuing prior consent. However, § 5 sec. 12 of the Regulation of the Minister of Health of March 18, 2021 on the issuance of consent to obtain healthcare services outside the country and coverage of transport costs, the instruction indicates	**Source(s):** Art. 42d sec. 2 point 5 and section 3 of the Act of 27 August 2004 on health care services financed from public funds (Journal of Laws of 2020, item 1398, as amended), hereinafter referred to as the "Act on benefits". § 5 clause 12 of the Regulation of the Minister of Health of 3 September 2020 on the list of health care services requiring prior approval of the President of the National Health Fund (Journal of Laws of 2020, item 1556)	

	the period of 5 days as the date by which the authority is obliged to issue a decision on prior consent, with the commencement of run of the above-mentioned the time limit depends on the completion of the investigation in the case (including obtaining the necessary medical opinions).		
9. Are there **differences in the procedural/administrative requirements for requesting PA** based on, for instance, the type of treatment for which PA is requested, the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* There are no such differences - if the treatment that a patient wishes to receive outside of Poland is included in the list of benefits provided for in the Regulation on the list of benefits, the procedure is the same for any type of treatment, profile of the insured person or any other criterion.	**Source(s):** The Regulation of the Minister of Health of 18 March 2021 on the issuance of consent to obtain healthcare services outside the country and on costs of transport reimbursement.[603] Articles: 42b (9); 42f, Art. 20 (2) point 6 and Art. 20 (11) of the Act of 27 August 2004 on health care services financed from public funds (Journal of Laws of 2020, item 1398, as amended), known as the "Act on benefits".[604] Regulation of the Minister of Health of 3 September 2020 on the list of	

[603] The Regulation of the Minister of Health of 18 March 2021 on the issuance of consent to obtain healthcare services outside the country and on costs of transport reimbursement (Rozporządzenie Ministra Zdrowia z dnia 18 marca 2021 r. w sprawie wydawania zgody na uzyskanie świadczeń opieki zdrowotnej poza granicami kraju oraz pokrycie kosztów transport), available at [in Polish]: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20210000644

[604] Act of 27 August 2004 on health care services financed from public funds (Journal of Laws of 2020, item 1398, as amended), known as the "Act on benefits" (Ustawa z dnia 27 sierpnia 2004 r. o świadczeniach opieki zdrowotnej finansowanych ze środków publicznych (Dz. U. z 2020 r. poz. 1398, z późn. zm.), zwana „ustawą o świadczeniach"), available at [in Polish]: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20042102135

		healthcare services requiring prior approval of the director of the provincial branch of the National Health Fund (Journal of Laws of 2020, item 1556), referred to as the "Regulation on the list of benefits".[605] Regulation of the Minister of Health on medical criteria to be followed by service providers when placing beneficiaries on the waiting lists for the provision of healthcare services of September 26, 2005 (Journal of Laws No. 200, item 1661), referred to as the "Regulation on medical criteria".[606] Regulation of the Minister of Health on the method and criteria for determining the permissible waiting time for selected ranges of healthcare services of November 9, 2015	

[605] Regulation of the Minister of Health of 3 September 2020 on the list of healthcare services requiring prior approval of the director of the provincial branch of the National Health Fund (Journal of Laws of 2020, item 1556), referred to as the "Regulation on the list of benefits" (Rozporządzenie Ministra Zdrowia z dnia 3 września 2020 r. w sprawie wykazu świadczeń opieki zdrowotnej wymagających uprzedniej zgody dyrektora oddziału wojewódzkiego Narodowego Funduszu Zdrowia (DZ. U. z 2020 r., poz. 1556), zwane „rozporządzeniem w sprawie wykazu świadczeń"), available at [in Polish]: http://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20200001556

[606] Regulation of the Minister of Health on medical criteria to be followed by service providers when placing beneficiaries on the waiting lists for the provision of healthcare services of September 26, 2005 (Journal of Laws No. 200, item 1661), referred to as the "Regulation on medical criteria" (Rozporządzenie Ministra Zdrowia z dnia 26 września 2005 r. w sprawie kryteriów medycznych, jakimi powinni kierować się świadczeniodawcy, umieszczając świadczeniobiorców na listach oczekujących na udzielenie świadczenia opieki zdrowotnej zwane „rozporządzeniem w sprawie kryteriów medycznych"), available at [in Polish]: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20052001661

		(Journal of Laws of 2015, item 1948), referred to as the "Regulation on the permissible waiting time".[607] Regulations of the Minister of Health issued pursuant to Art. 31d of the Act on benefits, specifying lists of guaranteed benefits in individual scopes of benefits, hereinafter referred to as "Regulations on guaranteed benefits".[608]	
10. Is there a specific PA form (i.e., form used for issuing/granting PA) and, if the answer is positive, what form?	**Answer:** The decision is taken in the form of administrative decision issued by the president of the provincial branch of the National Health Fund. [609]	**Source(s):** Regulation of the Minister of Health of 3 September 2020 on the list of healthcare services requiring prior approval of the president of the provincial branch of the National Health Fund[610]	

[607] Regulation of the Minister of Health on the method and criteria for determining the permissible waiting time for selected ranges of healthcare services of November 9, 2015 (Journal of Laws of 2015, item 1948), referred to as the "Regulation on the permissible waiting time" (Rozporządzenie Ministra Zdrowia z dnia 9 listopada 2015 r. w sprawie sposobu i kryteriów ustalania dopuszczalnego czasu oczekiwania na wybrane zakresy świadczeń opieki zdrowotnej, zwane „rozporządzeniem w sprawie dopuszczalnego czasu oczekiwania"), available at: http://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20150001948

[608] Regulation of the Minister of Health issued pursuant to Art. 31d of the Act on benefits, specifying lists of guaranteed benefits in individual scopes of benefits, hereinafter referred to as "Regulations on guaranteed benefits"(Journal of Laws 2013 item 1248) (Rozporządzenie Ministra Zdrowia z dnia 24 września 2013 r. w sprawie świadczeń gwarantowanych z zakresu podstawowej opieki zdrowotnej, zwane tez "rozporzadzeniem w sprawie swiadczen gwarantowanych), Dz.U. 2013 poz. 1248, available at [in Polish]: http://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20130001248

[609] Regulation of the Minister of Health of 3 September 2020 on the list of healthcare services requiring prior approval of the director of the provincial branch of the National Health Fund (Journal of Laws of 2020, item 1556), referred to as the "Regulation on the list of benefits" (Rozporządzenie Ministra Zdrowia z dnia 3 września 2020 r. w sprawie wykazu świadczeń opieki zdrowotnej wymagających uprzedniej zgody dyrektora oddziału wojewódzkiego Narodowego Funduszu Zdrowia (DZ. U. z 2020 r., poz. 1556), zwane „rozporządzeniem w sprawie wykazu świadczeń"), available at [in Polish]: http://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20200001556

[610] Regulation of the Minister of Health of 3 September 2020 on the list of healthcare services requiring prior approval of the director of the provincial branch of the National Health Fund (Journal of Laws of 2020, item 1556), referred to as the "Regulation on the list of benefits" (Rozporządzenie Ministra Zdrowia z dnia 3 września 2020 r. w sprawie wykazu świadczeń opieki zdrowotnej wymagających uprzedniej zgody dyrektora

11. Please list any other administrative requirements in your country in relation to the PA procedure for cross-border healthcare.	**Answer:** None identified.	**Source(s):**		
SECTION 2 REIMBURSMENT PROCEDURE(S)				
Questions	**Answer:**	**Sources**	**Does/do the identified requirement(s) also apply domestically? (i.e., is the requirement non-discriminatory?)**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to reimbursement procedures for cross-border healthcare	**Answer:** The reimbursement procedure under the provisions implementing the cross-border Directive is carried out in an administrative manner, taking into account specific provisions, by a decision of the President of the National Health Fund.[611]	**Source(s):** Art. 42b and 42d of the Act of 27 August 2004 on healthcare services financed from public funds.[613]	N/A	N/A

oddziału wojewódzkiego Narodowego Funduszu Zdrowia (DZ. U. z 2020 r., poz. 1556), zwane „rozporządzeniem w sprawie wykazu świadczeń"), available at [in Polish]: http://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20200001556

[611] Art. 42d of the Act of 27 August 2004 on health care services financed from public funds (Journal of Laws of 2020, item 1398, as amended), known as the "Act on health care benefits (Ustawa z dnia 27 sierpnia 2004 r. o świadczeniach opieki zdrowotnej finansowanych ze środków publicznych (Dz. U. z 2020 r. poz. 1398, z późn. zm.), zwana „ustawą o świadczeniach"), available at: https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20042102135/U/D20042135Lj.pdf [in Polish]

[613] Art. 42 b and 42d of the Act of 27 August 2004 on health care services financed from public funds (Journal of Laws of 2020, item 1398, as amended), known as the "Act on health care benefits (Ustawa z dnia 27 sierpnia 2004 r. o świadczeniach opieki zdrowotnej finansowanych ze środków publicznych (Dz. U. z 2020 r. poz. 1398, z późn. zm.), zwana „ustawą o świadczeniach"), available at: https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20042102135/U/D20042135Lj.pdf [in Polish]

under Directive 201/24/EU?	The procedure is initiated at the request of the recipient or his legal representative. The form is set out in the Annex to the Regulation of the Minister of Health of September 3, 2020 on the model application for reimbursement of healthcare services provided outside the country (Journal of Laws of 2020, item 1557).[612]	Regulation of the Minister of Health of 4 March 2021 on the application form for the reimbursement of costs of healthcare services provided outside the country.[614] National Health Fund official website[615]		
2. Is this the same procedure as for reimbursement under the Social Security Coordination Regulations?	**Answer:** **Yes ☐ No ☒** There are some differences in regard to procedures as for reimbursement between the Directive and the Social Security Coordination Regulations (hereinafter also referred to as: SSCR). [616] The most significant differences are presented below: • Firstly, as to the *geographical scope* of the procedures, under the Social Security Coordination Regulations, aside from EU Member States and EEA countries as provided in the Directive, EFTA countries are also included. • Further, under the Directive regulations, *institution responsible* for determining the amount to be reimbursed is the National Health		N/A	N/A

[612] Annex to the Regulation of the Minister of Health of 4 March 2021 on the application form for the reimbursement of costs of healthcare services provided outside the country (Journal of Laws of 2021, item 429), (Rozporządzenie Ministra Zdrowia z dnia 4 marca 2021 r. w sprawie wzoru wniosku o zwrot kosztów świadczeń opieki zdrowotnej udzielonych poza granicami kraju (Dz. U. z 2021 r. poz. 429), available at: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20210000429

[614] Regulation of the Minister of Health of 4 March 2021 on the application form for the reimbursement of costs of healthcare services provided outside the country (Journal of Laws of 2021, item 429), (Rozporządzenie Ministra Zdrowia z dnia 4 marca 2021 r. w sprawie wzoru wniosku o zwrot kosztów świadczeń opieki zdrowotnej udzielonych poza granicami kraju (Dz. U. z 2021 r. poz. 429), available at: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20210000429

[615] National Health Fund official website, available at: https://www.nfz.gov.pl/dla-pacjenta/nasze-zdrowie-w-ue/zwrot-kosztow-leczenia-w-panstwach-ueefta-/

[616] National Health Fund official website – National Contact Point for cross border healthcare, available at: http://www.kpk.nfz.gov.pl/pl/leczenie-w-innym-panstwie/zwrot-kosztow-swiadczen.html#v-por%C3%B3wnanie-procedury-zwrotu-koszt%C3%B3w-za-%C5%9Bwiadczenia-realizowane-w-ramach-przepis%C3%B3w-ustawy-implementuj%C4%85cej-dyrektyw%C4%99-transgraniczn%C4%85-i-przepis%C3%B3w-o-koordynacji-system%C3%B3w-zabezpieczenia-spo%C5%82ecznego

	Fund, whereas under the SSCR it is the institution of the place of stay in the country of treatment. [617] • Moreover, in both cases as a rule the National Health Fund is the institution that reimburses the cost – however, under the SSCR it is also possible that the cost will be reimbursed directly in the state of the treatment, provided that its legislation provides for such a possibility.[618] • As to the method of determining the amount of the reimbursement: under the Directive the amount is determined according to the current rates in the country of insurance, while under the SSCR the amount is determined according to the rates applicable in the country in which the treatment was provided.[619] • There is also a difference in terms of types of treatments for which costs are reimbursed: under the Directive, only the treatments will be reimbursed that are guaranteed in the Member State of affiliation (here: Poland; please see Question 4 under Section 1 for more information on these treatments), while under the SSCR the scope of the reimbursed treatments are in accordance with the legislation of the state where the treatment took place.[620] • Furthermore, there are differences as to the nature of reimbursed treatments. Under the Directive, reimbursed treatments can be the following: planned services requiring prior consent of the National		

[617] National Health Fund official website – National Contact Point for cross border healthcare, available at: http://www.kpk.nfz.gov.pl/pl/leczenie-w-innym-panstwie/zwrot-kosztow-swiadczen.html#v-por%C3%B3wnanie-procedury-zwrotu-koszt%C3%B3w-za-%C5%9Bwiadczenia-realizowane-w-ramach-przepis%C3%B3w-ustawy-implementuj%C4%85cej-dyrektyw%C4%99-transgraniczn%C4%85-i-przepis%C3%B3w-o-koordynacji-system%C3%B3w-zabezpieczenia-spo%C5%82ecznego

[618] National Health Fund official website – National Contact Point for cross border healthcare, available at: http://www.kpk.nfz.gov.pl/pl/leczenie-w-innym-panstwie/zwrot-kosztow-swiadczen.html#v-por%C3%B3wnanie-procedury-zwrotu-koszt%C3%B3w-za-%C5%9Bwiadczenia-realizowane-w-ramach-przepis%C3%B3w-ustawy-implementuj%C4%85cej-dyrektyw%C4%99-transgraniczn%C4%85-i-przepis%C3%B3w-o-koordynacji-system%C3%B3w-zabezpieczenia-spo%C5%82ecznego

[619] National Health Fund official website – National Contact Point for cross border healthcare, available at: http://www.kpk.nfz.gov.pl/pl/leczenie-w-innym-panstwie/zwrot-kosztow-swiadczen.html#v-por%C3%B3wnanie-procedury-zwrotu-koszt%C3%B3w-za-%C5%9Bwiadczenia-realizowane-w-ramach-przepis%C3%B3w-ustawy-implementuj%C4%85cej-dyrektyw%C4%99-transgraniczn%C4%85-i-przepis%C3%B3w-o-koordynacji-system%C3%B3w-zabezpieczenia-spo%C5%82ecznego

[620] National Health Fund official website – National Contact Point for cross border healthcare, available at: http://www.kpk.nfz.gov.pl/pl/leczenie-w-innym-panstwie/zwrot-kosztow-swiadczen.html#v-por%C3%B3wnanie-procedury-zwrotu-koszt%C3%B3w-za-%C5%9Bwiadczenia-realizowane-w-ramach-przepis%C3%B3w-ustawy-implementuj%C4%85cej-dyrektyw%C4%99-transgraniczn%C4%85-i-przepis%C3%B3w-o-koordynacji-system%C3%B3w-zabezpieczenia-spo%C5%82ecznego

	Health Fund; healthcare services covered by the list referred to in art. 42e paragraph. 1 of the Act on healthcare services; planned services that do not require prior consent after meeting the specified conditions in art. 42b of the Act on healthcare services; as well as treatments that are necessary from a medical point of view. [621] • Under the SSCR reimbursed treatments are health services planned only on the basis of the prior authorisation of the National Health Fund; as well as healthcare that was necessary from a medical point of view (including also when a patient did not have European Health Insurance Card – EHIC). [622] • Another difference that is worth noting concerns the time requirements: while under the Directive the patient has 6 months from the date of invoicing of the treatment to apply for the reimbursement; under the SSCR there is no specific deadline provided for the application. [623] • There are different forms provided for these two procedures: (please see Question 4 in Section 2 for the required form under the Directive); form under the SSCR can be found on the Contact Point website, similarly as the form required by the Directive.[624]			
3. What body is/are responsible of handling the reimbursement applications?	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most*	**Source(s):** Art. 42b and 42d of the Act of 27 August 2004 on	N/A	N/A

[621] Form for reimbursement application under the SSCR, available at the National Health Fund website: https://www.nfz.gov.pl/gfx/nfz/userfiles/_public/dla_pacjenta/leczenie_za_granica_ekuz/wniosek_o_zwrot_kosztow_leczenia_0_sprawdzone.doc
[622] Form for reimbursement application under the SSCR, available at the National Health Fund website: https://www.nfz.gov.pl/gfx/nfz/userfiles/_public/dla_pacjenta/leczenie_za_granica_ekuz/wniosek_o_zwrot_kosztow_leczenia_0_sprawdzone.doc
[623] Form for reimbursement application under the SSCR, available at the National Health Fund website: https://www.nfz.gov.pl/gfx/nfz/userfiles/_public/dla_pacjenta/leczenie_za_granica_ekuz/wniosek_o_zwrot_kosztow_leczenia_0_sprawdzone.doc
[624] Form for reimbursement application under the SSCR, available at the National Health Fund website: https://www.nfz.gov.pl/gfx/nfz/userfiles/_public/dla_pacjenta/leczenie_za_granica_ekuz/wniosek_o_zwrot_kosztow_leczenia_0_sprawdzone.doc

(e.g., where and to whom reimbursement applications have to be submitted?)	*important/relevant insurance provider in your country (e.g., based on the number of affiliations).* National Health Fund is the relevant institution responsible of handling the reimbursement applications. As mentioned under Question 1, the reimbursement procedure under the provisions implementing the cross-border Directive is carried out in an administrative manner, taking into account specific provisions, by a decision of the President of the National Health Fund. There is a possibility of appeal from mentioned decision to the Administrative Court. The appeal can be lodged by the patient or his/her legal representative. [625] Pursuant to Art. 42d paragraph. 16 of the Act on health care services, the order of examination of applications for reimbursement is dependent on the order of receipt of applications by the National Fund. [626]	healthcare services financed from public funds.[628] Regulation of the Minister of Health of 4 March 2021 on the application form for the reimbursement of costs of healthcare services provided outside the country.[629] National Health Fund official website[630]		

[625] Art. 42d of the Act of 27 August 2004 on health care services financed from public funds (Journal of Laws of 2020, item 1398, as amended), known as the "Act on health care benefits (Ustawa z dnia 27 sierpnia 2004 r. o świadczeniach opieki zdrowotnej finansowanych ze środków publicznych (Dz. U. z 2020 r. poz. 1398, z późn. zm.), zwana „ustawą o świadczeniach"), available at: https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20042102135/U/D20042135Lj.pdf [in Polish]

[626] National Contact Point for cross border healthcare, available at: http://www.kpk.nfz.gov.pl/pl/leczenie-w-innym-panstwie/zwrot-kosztow-swiadczen.html#v-por%C3%B3wnanie-procedury-zwrotu-koszt%C3%B3w-za-%C5%9Bwiadczenia-realizowane-w-ramach-przepis%C3%B3w-ustawy-implementuj%C4%85cej-dyrektyw%C4%99-transgraniczn%C4%85-i-przepis%C3%B3w-o-koordynacji-system%C3%B3w-zabezpieczenia-spo%C5%82ecznego

[628] Art. 42 b and 42d of the Act of 27 August 2004 on health care services financed from public funds (Journal of Laws of 2020, item 1398, as amended), known as the "Act on health care benefits (Ustawa z dnia 27 sierpnia 2004 r. o świadczeniach opieki zdrowotnej finansowanych ze środków publicznych (Dz. U. z 2020 r. poz. 1398, z późn. zm.), zwana „ustawą o świadczeniach"), available at: https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20042102135/U/D20042135Lj.pdf [in Polish]

[629] Regulation of the Minister of Health of 4 March 2021 on the application form for the reimbursement of costs of healthcare services provided outside the country (Journal of Laws of 2021, item 429), (Rozporządzenie Ministra Zdrowia z dnia 4 marca 2021 r. w sprawie wzoru wniosku o zwrot kosztów świadczeń opieki zdrowotnej udzielonych poza granicami kraju (Dz. U. z 2021 r. poz. 429), available at: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20210000429

[630] National Health Fund official website, available at: https://www.nfz.gov.pl/dla-pacjenta/nasze-zdrowie-w-ue/zwrot-kosztow-leczenia-w-panstwach-ueefta-/

	Reimbursement is done in the way patient indicated in the form – it can be done via bank transfer to the bank account or via post transfer to the address indicated in the application. [627] The application should be submitted to the National Health Fund in paper form or in the form of an electronic document with a qualified electronic signature, personal signature or a trusted signature. Required attachments can be digital.			
4. Is there a specific application form/module which the person seeking reimbursement needs to submit?	**Answer:** *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?* The form is set out in the Annex to the Regulation of the Minister of Health of September 3, 2020 on the model application for reimbursement of healthcare services	**Source(s):** Art. 42b and 42d of the Act of 27 August 2004 on healthcare services financed from public funds.[633] Regulation of the Minister of Health of 4 March 2021 on the application form for the reimbursement of costs of healthcare services provided outside the country.[634]	**Yes** ☐ **No** ☒ Please note that an equivalent procedure for reimbursement does not exist domestically due to the fact that costs are anticipated by the NHF in Poland (i.e., there is no comparable procedure).	

[627] National Contact Point for cross border healthcare, available at: http://www.kpk.nfz.gov.pl/pl/leczenie-w-innym-panstwie/zwrot-kosztow-swiadczen.html#v-por%C3%B3wnanie-procedury-zwrotu-koszt%C3%B3w-za-%C5%9Bwiadczenia-realizowane-w-ramach-przepis%C3%B3w-ustawy-implementuj%C4%85cej-dyrektyw%C4%99-transgraniczn%C4%85-i-przepis%C3%B3w-o-koordynacji-system%C3%B3w-zabezpieczenia-spo%C5%82ecznego

[633] Art. 42 b and 42d of the Act of 27 August 2004 on health care services financed from public funds (Journal of Laws of 2020, item 1398, as amended), known as the "Act on health care benefits (Ustawa z dnia 27 sierpnia 2004 r. o świadczeniach opieki zdrowotnej finansowanych ze środków publicznych (Dz. U. z 2020 r. poz. 1398, z późn. zm.), zwana „ustawą o świadczeniach"), available at: https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20042102135/U/D20042135Lj.pdf [in Polish]

[634] Regulation of the Minister of Health of 4 March 2021 on the application form for the reimbursement of costs of healthcare services provided outside the country (Journal of Laws of 2021, item 429), (Rozporządzenie Ministra Zdrowia z dnia 4 marca 2021 r. w sprawie wzoru wniosku o zwrot kosztów świadczeń opieki zdrowotnej udzielonych poza granicami kraju (Dz. U. z 2021 r. poz. 429), available at: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20210000429

	provided outside the country (Journal of Laws of 2020, item 1557).[631] All the information should be translated into Polish (but sworn translation is not required).[632] The information required are the following: - name and surname and PESEL number of the recipient, and in the case of him missing - number of the document confirming identity and date of birth, the address of the recipient's place of residence and correspondence address. - Name and surname, address and PESEL number of the legal representative of the patient, and in the case of its absence - the document number proving the identity and date of birth. Further, a date and name of the country of the provision of healthcare to which it relates application for reimbursement should be included, the total amount that was paid for the provision of healthcare, which concerns a request for reimbursement, specifying the currency, telephone number or e-mail	National Health Fund official website[635]		

[631] Annex to the Regulation of the Minister of Health of 4 March 2021 on the application form for the reimbursement of costs of healthcare services provided outside the country (Journal of Laws of 2021, item 429), (Rozporządzenie Ministra Zdrowia z dnia 4 marca 2021 r. w sprawie wzoru wniosku o zwrot kosztów świadczeń opieki zdrowotnej udzielonych poza granicami kraju (Dz. U. z 2021 r. poz. 429), available at: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20210000429

[632] National Contact Point for cross border healthcare, available at: http://www.kpk.nfz.gov.pl/pl/leczenie-w-innym-panstwie/zwrot-kosztow-swiadczen.html#v-por%C3%B3wnanie-procedury-zwrotu-koszt%C3%B3w-za-%C5%9Bwiadczenia-realizowane-w-ramach-przepis%C3%B3w-ustawy-implementuj%C4%85cej-dyrektyw%C4%99-transgraniczn%C4%85-i-przepis%C3%B3w-o-koordynacji-system%C3%B3w-zabezpieczenia-spo%C5%82ecznego

[635] National Health Fund official website, available at: https://www.nfz.gov.pl/dla-pacjenta/nasze-zdrowie-w-ue/zwrot-kosztow-leczenia-w-panstwach-ueefta-/

	address of the patient or his statutory representative, if any. The application should contain a bank account number, where the reimbursement is to be made by bank transfer (and in the case of an foreign account - also other necessary data of this account), name and surname and address of the bank account holder (if the account this does not belong to the beneficiary to whom the reimbursement is applied for cost). If the costs are refunded by a post transfer, the address to which the postal transfer is to be forwarded shall be provided. Lastly, a declaration of the person submitting the application, submitted under the pain of pain criminal liability under Art. 233 § 1 and 2 of the Criminal Code that the data contained in the application is true. The application for reimbursement shall be accompanied by: - original invoice issued in other than the Republic of Poland EU or EEA member state by the entity providing the benefits or the original bill issued in a Member State EU or EEA by a pharmacy or a supplier of medical devices, a copy of an invoice issued in a country other than the Republic of Poland member states of the EU or EEA by the entity providing benefits health insurance. In case when			

	the invoice does not clearly state that, the additional document confirming the coverage of the entire cost of the service to which the application for reimbursement relates should be included as well. The application should be submitted to the National Health Fund in paper form or in the form of an electronic document with a qualified electronic signature, personal signature or a trusted signature. Required attachments can be digital.			
5. What (other) documentation has to be submitted in order to substantiate a reimbursement request?	**Answer:** *If applicable, please specify:* - *What documents are required;* - *Whether the submission of the documentation is optional, mandatory, or recommended.* There are the following mandatory documents that need to be attached to the form in order to substantiate a reimbursement request (if they were initially prepared in a foreign language, the translation to Polish is required – however, sworn translation is not required):[636]	**Source(s):** Art. 42b and 42d of the Act of 27 August 2004 on healthcare services financed from public funds.[641] Regulation of the Minister of Health of 4 March 2021 on the application form for the reimbursement of costs of healthcare	**Yes ☐** **No ☒** Cfr. Answer to question 4 above.	

[636] National Contact Point for cross border healthcare, available at: http://www.kpk.nfz.gov.pl/pl/leczenie-w-innym-panstwie/zwrot-kosztow-swiadczen.html#iii-1-wniosek-o-zwrot-koszt%C3%B3w-oraz-wymagane-do-przed%C5%82o%C5%BCenia-przy-wniosku-dokumenty

[641] Art. 42 b and 42d of the Act of 27 August 2004 on health care services financed from public funds (Journal of Laws of 2020, item 1398, as amended), known as the "Act on health care benefits (Ustawa z dnia 27 sierpnia 2004 r. o świadczeniach opieki zdrowotnej finansowanych ze środków publicznych (Dz. U. z 2020 r. poz. 1398, z późn. zm.), zwana „ustawą o świadczeniach"), available at: https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20042102135/U/D20042135Lj.pdf [in Polish]

	1) original invoice containing in particular: • details of the invoice issuer and the date of its issue, • details of the beneficiary to whom the application for reimbursement relates, • information necessary to identify the benefit to which the application for reimbursement relates, in particular information enabling the identification of the codes of the International Classification of Medical Procedures ICD-9 and the International Statistical Classification of Diseases and Health Problems ICD-10 or data on medications dispensed, foodstuffs for particular nutritional uses or medical devices - in the absence of these data on the invoice, they should be included in the documentation attached to the application for reimbursement of costs; [637] 2) confirmation of covering the entire cost of the service, if it does not result from the attached invoice; [638] 3) original or a copy, respectively:	services provided outside the country.[642] National Health Fund official website[643]		

[637] National Contact Point for cross border healthcare, available at: http://www.kpk.nfz.gov.pl/pl/leczenie-w-innym-panstwie/zwrot-kosztow-swiadczen.html#iii-1-wniosek-o-zwrot-koszt%C3%B3w-oraz-wymagane-do-przed%C5%82o%C5%BCenia-przy-wniosku-dokumenty

[638] National Contact Point for cross border healthcare, available at: http://www.kpk.nfz.gov.pl/pl/leczenie-w-innym-panstwie/zwrot-kosztow-swiadczen.html#iii-1-wniosek-o-zwrot-koszt%C3%B3w-oraz-wymagane-do-przed%C5%82o%C5%BCenia-przy-wniosku-dokumenty

[642] Regulation of the Minister of Health of 4 March 2021 on the application form for the reimbursement of costs of healthcare services provided outside the country (Journal of Laws of 2021, item 429), (Rozporządzenie Ministra Zdrowia z dnia 4 marca 2021 r. w sprawie wzoru wniosku o zwrot kosztów świadczeń opieki zdrowotnej udzielonych poza granicami kraju (Dz. U. z 2021 r. poz. 429), available at: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20210000429

[643] National Health Fund official website, available at: https://www.nfz.gov.pl/dla-pacjenta/nasze-zdrowie-w-ue/zwrot-kosztow-leczenia-w-panstwach-ueefta-/

	- referrals, and in the case of referrals referred to in the regulations issued on the basis of art. 59aa paragraph. 2 of the Act on healthcare services, the printout referred to in art. 59b paragraph. 2 point 3 of the above-mentioned the act, or the order referred to in Art. 42b paragraph. 3-5 of the Act on healthcare services (does not apply to benefits for which the recipient has obtained prior consent); - prescription referred to in art. 42b paragraph. 10 of the Act on healthcare services, - orders referred to in art. 42b paragraph. 11 of the Act on healthcare services; 2) in the case of treatments in the field of drug programs (referred to in Article 15 (2) (15) of the Act on health care services), the application for reimbursement is accompanied by a certificate of the service provider confirming qualification to the appropriate drug program (not applicable to benefits for which the recipient has obtained prior authorisation); [639] 3) if the application for reimbursement concerns a medicine, food for special purposes or a medical device purchased on the basis of a			

[639] National Contact Point for cross border healthcare, available at: http://www.kpk.nfz.gov.pl/pl/leczenie-w-innym-panstwie/zwrot-kosztow-swiadczen.html#iii-1-wniosek-o-zwrot-koszt%C3%B3w-oraz-wymagane-do-przed%C5%82o%C5%BCenia-przy-wniosku-dokumenty

	prescription issued in another EU or EEA country (referred to in 42b (10) (1) of the Act on healthcare services), to the application is also accompanied by a copy of the medical documentation which shows the medical legitimacy of issuing a prescription for a drug, foodstuff for special purposes or medical device to which the application relates; [640]			
6. Are there any costs associated with the handling of the reimbursement request? - *Direct costs (e.g., fixed costs for submitting or filing a reimbursement request, proportion deducted from the reimbursable amount).* - *Indirect costs* (*e.g., translations, stamps, etc).*	**Answer:** *Direct costs:* None identified. *Indirect costs:* None identified.	**Source(s):** N/A	**Yes** ☐ **No** ☐	N/A
7. Are there any specific time requirements linked to a	**Answer:**	**Source(s):**	**Yes** ☐ **No** ☒	

[640] National Contact Point for cross border healthcare, available at: http://www.kpk.nfz.gov.pl/pl/leczenie-w-innym-panstwie/zwrot-kosztow-swiadczen.html#iii-1-wniosek-o-zwrot-koszt%C3%B3w-oraz-wymagane-do-przed%C5%82o%C5%BCenia-przy-wniosku-dokumenty

reimbursement request? (*e.g., time within which the reimbursement requests must be submitted and/or time within the requested body must handle the request and/or reimburse the costs, etc.*).	*If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* The application for reimbursement must be submitted within 6 months from the date of invoice for the services covered by the application. [644] Pursuant to Art. 42d paragraph. 16 of the Act on health care services, the order of examination of applications for reimbursement is dependent on the order of receipt of applications by the National Fund. [645] The deadline for considering the application depends on the possible need to conduct an investigation during the process of the reimbursement application.[646] As a rule, the time limit for considering an application without the need to conduct an explanatory procedure is 30 days from the	Art. 42b and 42d of the Act of 27 August 2004 on healthcare services financed from public funds.[653] Regulation of the Minister of Health of 4 March 2021 on the application form for the reimbursement of costs of healthcare services provided outside the country.[654] National Health Fund official website[655]	Cfr. Answer to question 4 above.	

[644] National Contact Point for cross border healthcare, available at: http://www.kpk.nfz.gov.pl/pl/leczenie-w-innym-panstwie/zwrot-kosztow-swiadczen.html#iii-2-terminy-rozpatrzenia-wniosku-o-zwrot
[645] National Contact Point for cross border healthcare, available at: http://www.kpk.nfz.gov.pl/pl/leczenie-w-innym-panstwie/zwrot-kosztow-swiadczen.html#v-por%C3%B3wnanie-procedury-zwrotu-kosztu-%C3%B3w-za-%C5%9Bwiadczenia-realizowane-w-ramach-przepis%C3%B3w-ustawy-implementuj%C4%85cej-dyrektyw%C4%99-transgraniczn%C4%85-i-przepis%C3%B3w-o-koordynacji-system%C3%B3w-zabezpieczenia-spo%C5%82ecznego
[646] National Contact Point for cross border healthcare, available at: http://www.kpk.nfz.gov.pl/pl/leczenie-w-innym-panstwie/zwrot-kosztow-swiadczen.html#iii-2-terminy-rozpatrzenia-wniosku-o-zwrot
[653] Art. 42 b and 42d of the Act of 27 August 2004 on health care services financed from public funds (Journal of Laws of 2020, item 1398, as amended), known as the "Act on health care benefits (Ustawa z dnia 27 sierpnia 2004 r. o świadczeniach opieki zdrowotnej finansowanych ze środków publicznych (Dz. U. z 2020 r. poz. 1398, z późn. zm.), zwana „ustawą o świadczeniach"), available at: https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20042102135/U/D20042135Lj.pdf [in Polish]
[654] Regulation of the Minister of Health of 4 March 2021 on the application form for the reimbursement of costs of healthcare services provided outside the country (Journal of Laws of 2021, item 429), (Rozporządzenie Ministra Zdrowia z dnia 4 marca 2021 r. w sprawie wzoru wniosku o zwrot kosztów świadczeń opieki zdrowotnej udzielonych poza granicami kraju (Dz. U. z 2021 r. poz. 429), available at: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20210000429
[655] National Health Fund official website, available at: https://www.nfz.gov.pl/dla-pacjenta/nasze-zdrowie-w-ue/zwrot-kosztow-leczenia-w-panstwach-ueefta-/

	date of initiating the procedure. Nevertheless, in a situation where the examination of the application for reimbursement requires an explanatory procedure, the time limit for examining the application is 60 days from the date of initiating the procedure. However, the following is not included in the time limit:[647] • the period from the day the recipient is called to complete the application until the date of receipt of this supplement by the National Fund or until the ineffective expiry of the deadline for supplementing the application; [648] • the period from the day the inquiry is sent to the national institution until the Fund receives the answer of that institution; [649] In a situation where the examination of the application for reimbursement requires an explanatory procedure with the participation of the national contact point for cross-border healthcare, operating in a Member State of the European Union or the European Economic Area other than Poland, the time limit for examining the application is 6 months from the date of initiation of the procedure. [650] If no arrangements have been made within the above-mentioned period to clearly determine the amount of reimbursement, the costs will be reimbursed immediately after that date, in the amount corresponding to the amount that			

[647]

[648] National Contact Point for cross border healthcare, available at: http://www.kpk.nfz.gov.pl/pl/leczenie-w-innym-panstwie/zwrot-kosztow-swiadczen.html#iii-2-terminy-rozpatrzenia-wniosku-o-zwrot
[649] National Contact Point for cross border healthcare, available at: http://www.kpk.nfz.gov.pl/pl/leczenie-w-innym-panstwie/zwrot-kosztow-swiadczen.html#iii-2-terminy-rozpatrzenia-wniosku-o-zwrot
[650] National Contact Point for cross border healthcare, available at: http://www.kpk.nfz.gov.pl/pl/leczenie-w-innym-panstwie/zwrot-kosztow-swiadczen.html#iii-2-terminy-rozpatrzenia-wniosku-o-zwrot

	should be considered the most likely basis for reimbursement in a given case. In the proceedings, the doubts are resolved in favor of the recipient. [651] It is worth noting that in each of the above-mentioned cases, the payment of the reimbursement amount due should take place within 7 days from the day the National Fund becomes aware that the decision has become final or by January 31 of the following year in the situation referred to in Art. 42 h of paragraph 1. 1 of the Act on healthcare services. [652]			
8. Are there any non-reimbursable thresholds, deductions *(except the deductions for administrative costs mentioned above) etc.?*	**Answer:** *If yes, please specify the thresholds.* None identified.	**Source(s):** N/A	**Yes** ☐ **No** ☐	N/A
9. In instances where a PA (or prior-notification) has already been issued, is a separate/simplified procedure available for requesting reimbursement?	**Answer:** *If yes, please describe the simplified procedure.* None identified.	**Source(s):** N/A	**Yes** ☐ **No** ☐	N/A

[651] National Contact Point for cross border healthcare, available at: http://www.kpk.nfz.gov.pl/pl/leczenie-w-innym-panstwie/zwrot-kosztow-swiadczen.html#iii-2-terminy-rozpatrzenia-wniosku-o-zwrot
[652] National Contact Point for cross border healthcare, available at: http://www.kpk.nfz.gov.pl/pl/leczenie-w-innym-panstwie/zwrot-kosztow-swiadczen.html#iii-2-terminy-rozpatrzenia-wniosku-o-zwrot

**applicable only if the country has a PA system.*				
10. Are there additional administrative/procedural requirements for reimbursement depending on, for instance, the type of treatment for which reimbursement is requested, or the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* None identified.	**Source(s):** N/A	**Yes** ☐ **No** ☐	N/A
11. Please list any other administrative requirements in your country in relation to the procedures of reimbursement of cross-border healthcare.	**Answer:** None identified.	**Source(s):** N/A	**Yes** ☐ **No** ☐	N/A

Part 2: Checklist for verification with national/regional body

Name of the body: National Health Fund, Head Office
Country/Region: Poland
Date of verification call: 29-06-2021 and 08-07-2021

Template for the Data Collection	**Aspects to be verified** *Tick the boxes if the information in the template for the data collection has been verified and/or complemented by the national body*		**Comments** *Include any additional comments and/or information provided by the contacted body*
Section 1 – Prior Authorisation			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Justification/purpose of the identified requirement(s) (Column 4)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	The feedback received was incorporated in the answers of Part 1 - Section 1.
Section 2 - Reimbursement			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Whether the requirement applies domestically (Discriminatory assessment) (Column 4) ▪ Justification/purpose of the identified requirement(s) (Column 5)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☐ Question 11	The feedback received was incorporated in the answers of Part 1 - Section 2.

PORTUGAL – COUNTRY REPORT

Part 0: Preliminary Assessment

1. **Please indicate whether the rules governing the administrative procedures/requirements for requesting PA and reimbursement under Directive 2011/24/EU in your country are set out at:**

A. National level ☒

B. Decentralised/regional/local level ☐

In case (1.B): Please indicate the two most relevant jurisdictions in your country (i.e., in terms of population):

The Portuguese State is unitary and is constituted by a continental territory in Europe and two autonomous regions, with their own self-government institutions and political and administrative statutes: the Azores and Madeira archipelagos[656].

Cross-border health care is controlled by a national continental contact point (in Lisbon) and 2 national regional contact points (in Azores and Madeira).

NOTE: In case (1.B) the template for the data collection (Part 1) should be complete twice, once for each of the two most relevant regions/jurisdiction indicated above.

2. **Please indicate the national body best suited to verify the accuracy of the information collected in Part 1, and justify your selection.**

Body to be contacted for Task 2:

The national body best suited to verify the accuracy of the information collected is the General Health Department of the Ministry of Health ("Direção Geral de Saúde"), since it is the Ministry of Health's central health policy department (according to article 12 of Decree-Law n.º 124/2011 of 29 December 2011).

(In case 1.B, please indicate two relevant bodies, one respectively for each Region/jurisdiction)

Reasons for Selection:

[656] Article 6 of the Constitution of the Portuguese Republic of 2 April 1976 (http://www.parlamento.pt/legislacao/documents).

Part 1: Questionnaire

*__Note 1__: In cases where administrative requirements are set out in the legislative/regulatory framework at decentralised/regional/local level, please complete the template for the data collection twice, once for each of the two most relevant regions/jurisdictions (e.g., in terms population).

__*Note 2__: Setting out a Prior Authorisation (PA) system is optional for Member States. Should your country not have a system of PA in place under Directive 2011/24/EU, Section 1 will not need to be completed.

SECTION 1 PRIOR AUTHORISATION PROCEDURE(S)			
Questions	**Answer**	**Sources**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to PA procedures for a cross-border	**Answer:** - Law n.º 52/2014 adopted by the National Parliament on 25 August 2014, that provides rules for facilitating the access to cross-border healthcare and promoting cooperation on cross-border healthcare, transposing	**Source(s):** Law n.º 52/2014 adopted by the National Parliament on 25 August 2014[657] Administrative Rule n.º 191/2014[658]	N/A

[657] Lei n.º 52/2014, de 25 de agosto, que estabelece normas de acesso a cuidados de saúde transfronteiriços e promove a cooperação em matéria de cuidados de saúde transfronteiriços, transpondo a Diretiva n.º 2011/24/UE, do Parlamento Europeu e do Conselho, de 9 de março de 2011, e a Diretiva de Execução n.º 2012/52/UE da Comissão, de 20 de dezembro de 2012, available at: https://dre.pt/home/-/dre/56346572/details/maximized, (last accessed 1 July 2021).

[658] Portaria n.º 191/2014, de 25 de setembro, que define os cuidados de saúde transfronteiriços sujeitos a autorização prévia, available at: https://dre.pt/home/-/dre/57462077/details/maximized, (last accessed 1 July 2021).

healthcare under Directive 2011/24/EU?	Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 and Commission Implementing Directive 2012/52/EU of 20 December 2012 of 20 December 2021 - Administrative Rule n.º 191/2014 adopted by the Ministry of Health on 25 September 2014, that determines which cross-border healthcare is subject to prior authorization - Administrative Rule n.º 194/2014 adopted by the Ministry of Health on 30 September 2014, which establishes the concept, the process of identification, approval and recognition of the	Administrative Rule n.º 194/2014[659] Order n.º 11778/2014[660] Order n.º 11779/2014[661] Order n.º 11712/2014[662] Order n.º 11042-F/2014[663] Decree- Law n.º 173/2014[664] Administrative Rule n.º 195/2016[665] Law n.º 95/2019[666] Regional Decree n.º 3/2016/M[667]	

[659] Portaria n.º 194/2014, de 30 de setembro, que estabelece o conceito, o processo de identificação, aprovação e reconhecimento dos Centros de Referencia Nacionais para a prestação de cuidados de saúde, designadamente para o diagnóstico e tratamento de doenças raras, available at: https://dre.pt/pesquisa/-/search/57695124/details/normal, (last accessed 1 July 2021).

[660] Despacho n.º 11778/2014, do Gabinete do Secretário de Estado Adjunto do Ministro da Saúde, de 22 de setembro de 2014, que estabelece as condições de que depende o reconhecimento em Portugal das receitas médicas emitidas noutro Estado-membro, available at: https://dre.pt/web/guest/pesquisa/-/search/57152349/details/normal, (last accessed 1 July 2021).

[661] Despacho n.º 11779/2014 do Secretário de Estado Adjunto do Ministro da Saúde, de 22 de setembro de 2014, que designa os Serviços Partilhados do Ministério da Saúde, E.P.E., como autoridade nacional responsável pela cooperação em matéria de saúde em linha, available at: https://dre.pt/home/-/dre/57152350/details/2/maximized?parte_filter=31, (last accessed 1 July 2021).

[662] Despacho n.º 11712/2014 do Secretário de Estado Adjunto do Ministro da Saúde, de 19 de setembro de 2014, que designa o INFARMED – Autoridade Nacional do Medicamento e Produtos de Saúde, I.P., como autoridade nacional responsável pela avaliação das tecnologias da saúde, available at: https://direitodamedicina.sanchoeassociados.com/arquivo/despacho-n-o-117122014-ministerio-da-saude-designa-o-infarmed-autoridade-nacional-do-medicamento-e-produtos-de-saude-i-p-como-autoridade-nacional-responsavel-pela-avaliacao/, (last accessed on 1 July 2021).

[663] Despacho n.º 11042-F/2014, de 29 de Agosto de 2014, que aprova o modelo de receita médica reconhecido em qualquer Estado-Membro da União Europeia, available at: https://dre.pt/pesquisa/-/search/56384957/details/normal, (last accessed on 1 July 2021).

[664] (Decreto-Lei n.º 173/2014, de 19 de novembro, que procede à terceira alteração ao Decreto-Lei n.º 124/2014, de 29 de dezembro, que aprova a Lei Orgânica do Ministério da Saúde, à primeira alteração ao Decreto-Lei n.º 35/2012, de 15 de fevereiro, que aprova a orgânica da Administração Central do Sistema de Saúde, I.P., e à segunda alteração ao Decreto-Lei n.º 22/2012, de 30 de janeiro, que aprova a orgânica das Administrações Regionais de Saúde, I.P.), available at: https://dre.pt/home/-/dre/58940164/details/maximized, (last accessed 1 July 2021).

[665] Portaria n.º 195/2016, de 19 de julho, que altera os artigos 4.º ("Deveres e obrigações do Centro de Referência) e 12.º ("Centro Afiliado do Centro de Referência") da Portaria n.º 194/2014, available at: https://dre.pt/home/-/dre/74967223/details/maximized, (last accessed 1 July 2021).

[666] (Lei n.º 95/2019, de 4 de setembro, que aprova a Lei de Bases da Saúde e revoga a Lei n.º 48/90, de 24 de agosto, e o Decreto-Lei n.º 185/2002, de 20 de agosto, avialable at: https://dre.pt/home/-/dre/124417108/details/maximized, (last accessed 1 July 2021).

[667] Decreto Legislativo Regional n.º 3/2016/M, de 28 de janeiro, que procede à adaptação ao Sistema Regional de Saúde da Região Autónoma da Madeira da Lei n.º 15/2014, de 21 de março, available at: https://dre.pt/home/-/dre/73318737/details/maximized, (last accessed 1 July 2021).

	National Centres of Reference, namely for the diagnosis and treatment of rare disorders - Order n.º 11778/2014 of the Assistant Secretary of the State to the Ministry of Health, of 22 September 2014, on the recognition of prescriptions issued in another Member State - Order n.º 11779/2014 of the Assistant Secretary of the State to the Ministry of Health, of 22 September 2014, that designates the Shared Services of the Ministry of Health as the national authority responsible for eHealth cooperation -Order n.º 11712/2014 of the Assistant Secretary of the State to the Ministry of Health, of 19 September 2014, that designates INFARMED – National Authority of Medicines and Health Products as the national authority responsible for the health technology assessment -Order n.º 11042-F/2014 of the Assistance Secretary of State to the Ministry of Health, of 29 August 2014 that approves the prescriptions' model recognised in all EU Member States -Decree- Law n.º 173/2014 adopted by the Portuguese Government on 19 November 2014, that alters the structure of the Central Administration of the Health System, so that it can exercise the competencies of national contact point for cross-border healthcare	-	

	- Administrative Rule n.º 195/2016 adopted by the Ministry of Health on 19 July 2016, that amends articles 4 ("Duties and Rights of the Center of Reference") and 12 ("Affiliated Center to the Reference Centre") of Administrative Rule n.º 194/2014 adopted by the Ministry of Health on 30 September 2014 - Law n.º 95/2019 approved by the Portuguese Parliament on 4 September 2019, that approves the Basic Law on Health and revokes Law n.º 48/90 approved by the Portuguese Parliament on 24 August 1990 and Law n.º 185/2002 approved by the Portuguese Government on 20 August 2002 - adopted by the Madeira's Legislative Assembly on 28 January 2016, that adapts the Regional Health System of Madeira to Law n.º 15/2014 of 21 March 2014 **Note**: no Regional Decree adapting the Regional Health System of Azores to Law n. º 15/2014 of 21 March 2014 was found.		
2. Is this the same procedure as for PA under the Social Security Coordination Regulations?	Answer: Yes ☐ No ☒ There are 2 main different procedural requirements for requesting PA: - The requirement done under Law n.º 52/2014 of 25 august, that transposes Directive 2011/24/EU;		N/A

	- The requirement done under Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004, and n.º 987/2009, of the European Parliament and of the Council of 16 September 2009. The claim form is the same, but the administrative process is different in both cases. Portuguese citizens can also have access to state-provided healthcare during a temporary stay in any of the EU countries, Iceland, Liechtenstein, Norway and Switzerland, when they are not travelling for the express purpose of obtaining medical treatment, if they have the European Health Insurance Card.[668]	

[668] Healthcare not subject to prior authorization:
The main rule applicable to cross-border healthcare determines that the Portuguese State will ensure that the direct cost of the cross-border healthcare is reimbursed to the patient that has received it, if the healthcare provided is considered as healthcare that the Portuguese State had the duty to provide him or her within the National Health System or the Regional Health Systems of Azores and Madeira and if the Portuguese State is the Member Sate of affiliation for the purposes of Directive 2011/24/EU of 9 March 2011.
Cross – border healthcare is provided taking into account the principles of universal access, of good quality of the healthcare provided, equity and solidarity and in accordance with:
a) the legislation of the Member State of treatment;
b) standards and guidelines on quality and safety laid down by the Member State of treatment; and
c) EU law on safety standards.
The cross-border healthcare provided has to be adequate to the health condition of the beneficiary, been scientifically proved as efficient, in accordance with the best international evidence.
The types of treatment eligible for reimbursement are the ones foreseen in the National Tariff of NHS or in the Regional Tariffs of the above referred Regional Health Systems, or in the legal framework that determines the State's or the Regional Governments' co-payment in the price of medicinal products.
Health-care providers can not discriminate against patients on the grounds of nationality.
Law n.º 52/2014 of 25 August 2014 does not apply to:
a) Services in the field of long-term care the purpose of which is to support people in need of assistance in carrying out routine, everyday tasks;
b) Allocation of and access to organs for the purpose of organs transplants;
c) National and Regional Public Vaccination Programs.
Exceptionally and with obedience to the principle of proportionality, the Portuguese State may adopt measures regarding restrictions to the access to a certain treatment. These measures have to be justified by overriding reasons of general interest, such as planning requirements relating to the aim of ensuring sufficient and permanent access to a balanced range of high-quality treatment at a national level or at the level of a medical department or hospital.
Healthcare that is subject to prior authorization:
a) Chirurgical cross-border healthcare that involves overnight hospital accommodation of the patient in question for at least one night; or
b) Cross-border healthcare that requires use of highly specialized and cost-intensive medical infrastructure or medical equipment;
c) Cross-border healthcare that involves treatments presenting a particular risk for the patient or the population;
d) Cross-border healthcare provided by a healthcare provider that, on a case by case basis, is considered by the national entity competent to issue the prior authorization, as giving rise to serious and specific concerns relating to the quality or safety of the care.
These categories of healthcare subject to prior authorization were made publicly available by the Portuguese Government in the Annex to Administrative Rule n.º 191/2014 of 25 September 2014:
a) Diagnosis and treatment of disorders for which reference centres officially recognised by the Portuguese Ministry of Health exist in Portugal
b) Chirurgical cross-border healthcare that involves hospital accommodation
c) Hospital accommodation that has a Diagnosis-related Group relative cost equal or higher than 2.0 according to the Portuguese National Health System Price Index
d) Accommodation in intensive care units

3. What body is in charge of handling the PA applications? *(e.g., where and to whom PA applications have to be submitted?)*	Answer: *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations)* The Central Administration of the Health System (Administração Central do Sistema de Saúde, I.P. – ACSS), that ensures at a national level, the management of human	**Source(s):** Article 5 of Law n.º 52/2014 of 25 August 2014 Central Administration of the Health System (Administração Central do Sistema de Saúde, I.P. – ACSS)[669] Regional Health Service of Madeira – SESARAM	N/A

e) Burnt unit care
f) Accommodation in mental health or psychiatric departments, units or hospitals
g) Outpatient surgery that requires the implantation of a Medical device authorized by the National Authority of Medicines and Health Products, INFARMED, with exception of surgical sutures
h) Outpatient surgical procedure that has a Diagnosis-related Group relative cost equal or higher than 2.0 according to the Portuguese National Health System Price Index
i) Plastic and reconstructive surgery
j) Pharmacological treatments or treatments with biological products or agents that are more expensive than 1500 euros per month
k) Oncological treatment
l) Use of immunosuppressants
m) Radiosurgery
n) Transplantation and cellular therapy
o) Renal dialysis
p) Renal Lithotrpsy
q) Incapacity treatment that requires a motorized wheel chair, lower limb prostheses or upper limb prosthesis, with the exception of a hand or foot partial prosthesis, a hearing device or bitutors (orthopaedic devices)
r) Genetic analysis, including pharmacogenetics and pharmacogenomics
s) Medically assisted procreation
t) PET/Positrom Emission Tomography, Gamma Camara, Computed tomography, Gamma Camara – TC/, PET – RM /Positrom emission tomography and Magnetic Resonance Imaging, SPECT/Single Photon Emission Computed Tomography
u) Magnetic resonance imaging
v) Hyperbaric Chamber

[669] Website available at: www.acss.min-saude.pt.
More information available also at: http://diretiva.min-saude.pt/.

	and financial resources of the Ministry of Health and of the National Health System. The 2 national Regional Contact Points are: • in Madeira: Regional Health Service of Madeira – SESARAM "Serviço de Saúde da Região Autónoma da Madeira" • in Azores: Regional Directorate for Health of Azores. The continental National Contact Point and the Regional National Contact Points provide patients and health professionals clear, accurate an easily accessible information on cross-border healthcare, health care provided in Portugal and healthcare providers that legally provide healthcare in the Portuguese territory. This information is available by electronic means (http://www.acss.min-saude.pt and http://www.sns.gov.pt) in format accessible to people with disabilities. Information is also provided to patients on request on: a) Clinical rules in force in the National Health System that are applicable to all healthcare providers that exercise their professional activity; b) Laws applicable to the assessment and supervision of healthcare providers;	"Serviço de Saúde da Região Autónoma da Madeira"[670] Regional Directorate for Health of Azores[671]	

[670] Website available at: http://www.searam.pt.
[671] Website available at: http://portal.azores.gov.pt.

	c) The right of a specific provider to provide services or any existing restrictions to its practice in the national territory; d) Patients' rights relating to receiving cross-border healthcare, in particular as regards the terms and conditions for reimbursement of costs and the rights arising from EU Regulations on the coordination of Social Security Systems; e) Administrative and judicial complaint procedures; f) Access to healthcare providers by people with disabilities; g) Data relating to the National Contact Points of the other EU Member States; h) Data that have to be included in prescriptions issued in a State Member that is not the State where they are going to be dispensed.		
4. Who is entitled to apply for PA? *(e.g., can the patients apply themselves, or is treating doctor filing/partially filling the request, etc.)*	**Answer:** - *If there is a national doctor involved, is there a requirement that this doctor is contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA?* For the purpose of Law n.º 52/2014 of 25 August 2014 "beneficiary" means the beneficiaries of the National Health System and the beneficiaries of the Regional Health Systems of Azores and Madeira, namely: a) Portuguese citizens;	**Source(s):** Article 3 of Law n.º 52/2014 of 25 August 2014 Article 21, paragraph 3 of Law n.º 95/20-19 of 4 September	

	b) Persons, including members of their families and their survivors, who are covered by Chapter I of Title III of Regulation (EC) Nº 883/2004 of the European Parliament and of the Council of 29 April 2004, for whom the Portuguese State is considered competent according to the applicable EU Regulations and Portuguese law; c) Nationals of a third country with residence in Portugal who are covered by Regulation (EC) N.º 859/2003 of the Council of 14 May 2003, or by Regulation (EU) N.º 1231/2010 of the European Parliament and of the Council of 24 November 2010, or by the Portuguese legislation.		
5. Is there a specific application form/module which the person seeking PA needs to submit?	**Answer:** *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?* The request for prior authorization for the categories of healthcare referred in the Annex to Administrative Rule n.º 191/2014 of 25 September 2014 requires a claim form to be electronically submitted through the user portal or handed (if in paper) to hospital unit of beneficiary zone of residence or to the	**Source(s):** Article 12, paragraph 4 of Law n.º 52/2014 of 25 August 2014 Article 3 of Law n.º 52/2014 of 25 August 2014 Order n.º 11042-F/2014 of 29 August 2014	

	competent regional health unity in Azores or Madeira. The request for prior authorization has to include a non-exhaustive mandatory list of elements: a) Identification of the patient (name, citizen's ID n.º, NHS ID n.º, Fiscal ID n.º, Social Security ID n.º, fiscal residence, date of birth, gender) b) Member State of treatment and the health unit of treatment; c) Clinical information with the justification of the need of providing cross-border healthcare; d) Healthcare unit where he/she is receiving treatment (if applicable); e) N.º of inscription in the National Waiting List for Surgery (if applicable). The request claim form ("Requerimento Pedido de Autorização Prévia") was adopted by the National Contact Points and is available on line on https://diretiva.min-saude.pt/autorizacao-previa/req-pedido-de-autorizacao-previa/ For the purpose of Law n. º 52/2014 of 25 August "medical prescription" is understood as a prescription for a medicinal product or for a medical device issued by a member of a regulated health profession within the meaning of Article 3(1)a of Directive 2005/36/EC who is legally entitled to do so in the Member State in which the prescription is issued.		

	The medical prescription requested by the patient of cross-border healthcare has to obey to an official model that has a list of elements that have to be included in those prescriptions. The list of elements that have to appear on the prescriptions of products are: - Identification of the patient (surname, first name (s), date of birth, telephone, beneficiary n.º); - Issue date of the prescription; - Identification of the prescribing health professional (surname, first name(s), professional qualification, details for direct contact (email, telephone or fax), work address and signature; - Identification of the prescribed product, where applicable (common name, brand name if applicable, pharmaceutical formulation, quantity, strength and dosage regimen). The list of elements that have to appear on prescriptions of medical treatments, according to the above referred annex are: - Identification of the patient (full name); - Place of prescription; - Identification of the prescribing health professional (full professional name, professional qualification, details for direct contact); - Identification of the prescribed product, where applicable (generic name/name, package dose, form, package, dosage).		

6. What (other) documentation has to be submitted in order to substantiate a PA request?	**Answer:** *If applicable, please specify:* - *What documents and what particulars are required;* - *Whether there are requirements as to who has to issue the documents (e. g., a doctor contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA or any doctor);* Documents relating to clinical information have also to be provided, according to the request claim form ("Requerimento Pedido de Autorização Prévia"), adopted by the National Contact Points and is available on line on http://diretiva.min-saude.pt/. The clinical information is subject to a hospital clinical evaluation regarding the need for diagnosis or treatment and surgical adequacy. The patient shall therefore firstly request a hospital consultation in order to obtain the Hospital Clinical Assessment Report (ACH) to attach to the PA request.	**Source(s):** Art. 9-10-11 of Law n.º 52/2014 of 25 August 2014 ACSS website.[672]	

[672] Available at: https://diretiva.min-saude.pt/autorizacao-previa/processo-de-autorizacao-previa/.

7. Are there any costs associated with the handling of the PA request? - *Direct costs (e.g., fixed costs for submitting or filing a PA request).* - *Indirect costs* (*e.g., translations, stamps, etc).*	Answer: *Direct costs:* If the PA request is submitted electronically or by e–mail, there are no direct costs. If it is handed or sent mail the costs (photocopies, stamps) are supported by the beneficiary. *Indirect costs:* Translation costs are not covered. It is the patient's responsibility to translate to Portuguese all medical and financial documentation in order for it to be understood. Translators have to be completed by an official translator. Translation costs are not refunded to the patient.	**Source(s):** Article 9, paragraph 3 of Law n.º 52/2014 of 25 August 2014	
8. Are there any specific **time requirements** linked to a PA request? (*e.g., time within which a requesting person must submit the PA application and/or time within which the requested body must take a decision on the PA request, etc.*).	**Answer:** - *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* There are specific time requirements: 1. The insured person makes the request for prior authorization to receive cross-border healthcare electronically submitting or handing the above referred claim form. 2. In 20 days a clinical evaluation is carried out on the necessity of the required diagnosis or treatment or on the adequacy of the surgery	**Source:** Article 13 of Law n.º 52/2014 of 25 August 2014 Article 19 of Law n.º 52/2014 of 25 August 2014	

	required. This time limit may be shorten in cases of clinical urgency. The clinical evaluation must have a proposal of acceptance or refusal to grant prior authorization of the required cross-border healthcare. 3. The claim form and the clinical evaluation report are send by the healthcare unit where the clinical evaluation was done to the National Contact Point (ACSS, I.P.) or to the Regional Contact Points for appreciation. 4. These Contact Points answer the request for prior authorization within 15 working days, starting from the date of the reception of the report with the clinical evaluation. This time limit may be shortened if the patient specific medical condition requires it. 5. In case of doubt, from a clinical perspective, the National Contact Points may require the advice of the General Health Department of the Ministry of Health (Direção Geral de Saúde). The opinion of Direção Geral de Saúde must be issued within 5 working days. 6. The National Contact Points will refuse to grant prior authorization in the following situations: a) if the patient will, according to a clinical evaluation, be exposed with reasonable certainty to a patient-safety risk that cannot be regarded as acceptable, taking into account	-	

	the potential benefit for the patient of the sought cross-border healthcare; b) if the general public will be exposed with reasonable certainty to a substantial safety hazard as a result of the cross-border healthcare in question; c) if the healthcare is to be provided by a healthcare provider that raises serious and specific concerns relating to the respect of standards and guidelines on quality of care and patient safety; if this healthcare can be provided on the Portuguese territory within a time limit which is medically justifiable, taking into account the current state of health and he probable course of the illness of the concerned patient. a) The National Contact Points will inform the patient when his/hers situation is covered by Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004, and n.º 987/2009, of the European Parliament and of the Council of 16 September 2009. Law n. º 52/2014 of 25 August foresees no specific sanctions for behaviors such as missing the deadlines on the part of the requesting person or the requested body. It only determines that ACSS, I.P, Direção Geral de Saúde and the national regional contact points and shall draw up every year a report on the operation of this Law and		

	submit it, respectively, to the Minister of Health and to the members of the Regional Governments of Azores and Madeira. If the deadlines are not respected by the healthcare unit responsible for the clinical evaluation, by ACSSS,I.P. or by the other official referred entities, general administrative, civil or even criminal national law provisions may apply, according to the circumstances of the case. In particular, the beneficiary may complain to the Health Regulatory Authority ("Entidade Reguladora da Saude") that controls the activity of all health units that provide healthcare in Portugal.		
9. Are there **differences in the procedural/administrative requirements for requesting PA** based on, for instance, the type of treatment for which PA is requested, the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* None identified.	**Source(s):**	
10. Is there a specific PA form (i.e., form used for issuing/granting PA) and, if the answer is positive, what form?	**Answer:** As above referred, the request claim form ("Requerimento Pedido de Autorização Prévia") was adopted by the National Contact Points and is available on line on http://diretiva.min-saude.pt/	**Source(s):**	
11. Please list any other administrative requirements in your	**Answer:** See answer to question 8, please.	**Source(s):**	

country in relation to the PA procedure for cross-border healthcare.				
SECTION 2 REIMBURSMENT PROCEDURE(S)				
Questions	Answer:	**Sources**	**Does/do the identified requirement(s) also apply domestically? (i.e., is the requirement non-discriminatory?)**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to reimbursement procedures for cross-border healthcare under Directive 201/24/EU?	**Answer:** The legislation that regulates reimbursement is Article 8 of Law n.º 52/2014 of 25 August 2014. The Portuguese State ensures that the cost of the cross-border healthcare is reimbursed to the patient that has received it only up to the limit that the State would have paid if the healthcare had been provided within the National Health System or the Regional Health Systems, had the healthcare been provided in the national territory (in accordance with the National Tariff of NHS or in the Regional Tariffs of the above referred Regional Health Systems, or in the legal framework that determines the State's or of the Regional Governments' co-payment in	**Source(s):** Article 8 of Law n.º 52/2014 of 25 August 2014	N/A	N/A

	the price of medicinal products. This limit of reimbursement will be reduced if the cost of the cross-border health care is higher than the real cost of the received healthcare. The Portuguese State shall not make the reimbursement of costs of cross-border healthcare in the following cases: b) If the cross-border healthcare provider is not legally considered to be a health professional according to the legislation of the Member State of treatment or does not comply with the health care quality and patient safety standards adopted by this State; c) If the cross-border healthcare was provided to persons who are covered by Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004, and n.º 987/2009, of the European Parliament and of the Council of 16 September 2009; d) If the provided cross-border specific treatment is covered by the above referred exceptional measures regarding restrictions to the access to and further reimbursement of a certain treatment. These measures, adopted in accordance with the principle of proportionality, have to be justified by overriding reasons of general interest, such as planning requirements relating to the aim of ensuring sufficient and permanent access to a balanced range of high-			

	quality treatment at a national level or at the level of a medical department or hospital. They can also be justified by the need to control costs and avoid, as far as possible, any waste of financial, technical and human resources in the NHS or in the Regional Health Systems of Azores and Madeira. The Portuguese State has the duty to notify the Commission of these decisions to limit reimbursement on these grounds.			
2. Is this the same procedure as for reimbursement under the Social Security Coordination Regulations?	**Answer:** **Yes ☐ No ☒**		N/A	N/A
3. What body is/are responsible of handling the reimbursement applications? (e.g., where and to whom reimbursement applications have to be submitted?)	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* The reimbursement request form is electronically submitted or handed to ACSSS, I.P. or to the National Regional Contact Points of Azores and Madeira. It can be submitted by the beneficiary or on his/her behalf.	**Source(s):** Article 9, paragraph 1 of Law n.º 52/2014 of 25 August 2014	N/A	N/A

4. Is there a specific application form/module which the person seeking reimbursement needs to submit?	**Answer:** *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?* The specific application form which the person seeking for reimbursement needs to submit was approved by the national contact point: ACSS and is available online on http://diretiva.min-saude.pt/. It can be submitted electronically or in paper. The reimbursement request has to provide the following mandatory information: a) Acceptable proof of payment documentation, that has reference to the beneficiary's name, the State Member where the healthcare was provided, name of the healthcare provider and the diagnosis and treatment details b) The ID n.º of the citizen, his/her NHS n.º, Fiscal ID n.º, Social Security n.º, address for tax purposes, age, sex, and when applicable, the n.º of his insurance contract and the name of the insurance company; c) The reason why the treatment was provided abroad; d) The clinical evaluation that proves the need of cross-border healthcare,	**Source(s):** Article 9 of Law n.º 52/2014 of 25 August 2014	**Yes** ☐ **No** ☐	

	done by a NHS or a Regional Health Service physician, with specialization in General and Familiar Medicine, or the document that proves that the prior authorization was obtained, when applicable; e) The clinical data on the healthcare provided, with express reference to the medical diagnosis and the treatment plan, in accordance with the International Statistical Classification of Diseases and Related Health Problems or a similar classification adopted by the Member State of treatment, date of admission, date of hospital discharge, and what happened after that day.			
5. What (other) documentation has to be submitted in order to substantiate a reimbursement request?	**Answer:** *If applicable, please specify:* - *What documents are required;* - *Whether the submission of the documentation is optional, mandatory, or recommended.* The documentation, that can be send by e-mail or handed includes: a) The completed application form; b) Medical documents previously scanned or photocopied. The submission of the documentation is mandatory. No proof of electronic payment is required. According to the above mentioned claim for, the only information required to the patient in order to have access to reimbursement is a	**Source(s):** Article 9, paragraph 2 of Law n.º 52/2014 of 25 August 2014 ACSS Informative Order n.º 5/2015/DPS/ACSS of 16 January 2015 (https://acss.min-saude.pt)	**Yes ☐** **No ☐**	

	scan (or in paper) of the receipt with the following data: a) Date of the receipt b) N.º of the receipt c) Amount in currency paid d) Treatment's CID Code (International Statistical Classification of Diseases and Related Health Problems).			
6. Are there any costs associated with the handling of the reimbursement request? - *Direct costs (e.g., fixed costs for submitting or filing a reimbursement request, proportion deducted from the reimbursable amount).* - *Indirect costs* (*e.g., translations, stamps, etc).*	**Answer:** *Direct costs:* If the reimbursement request is submitted electronically or by e–mail, there are no direct costs. If it is handed or sent mail the costs (photocopies, stamps) are supported by the beneficiary. *Indirect costs:* Translation costs are not covered. It is the patient's responsibility to translate to Portuguese all medical and financial documentation in order for it to be understood. Translators have to be completed by an official translator. Translation costs are not refunded to the patient. The patient normally pays the provider for the treatment costs themselves and is reimbursed by the National Health System or the Regional Health Systems. Only treatment costs can be assessed for reimbursement. Travel and accommodation costs will not be reimbursed.	**Source(s):** Article 9, paragraph 3 of Law n.º 52/2014 of 25 August 2014 Article 10 of Law n.º 52/2014 of 25 August 2014	**Yes** ☐ **No** ☐	

	Reimbursement is up to the National Tariff of NHS or in the Regional Tariffs of the above referred Regional Health Systems, or to the price that results from in the legal framework that determines the State's or the Regional Governments' co-payment in the price of medicinal products. From the amount reimbursed is deducted the value that corresponds to user charges (fees that users of the NHS usually pay) and to the payment done by another entity that is responsible from a contractual point of view (v.g. health insurance companies)			
7. Are there any specific time requirements linked to a reimbursement request? (*e.g., time within which the reimbursement requests must be submitted and/or time within the requested body must handle the request and/or reimburse the costs, etc.*).	**Answer:** *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* The requesting person must submit the form or hand it within 30 days from the date of the receipt. It can take up to 90 days to process the application and decide if the beneficiary is eligible for reimbursement. It may take longer if the application is incomplete and the National Contact Points need to request additional information if the information provided is incomplete or inaccurate. In this case the deadline to decide if the beneficiary is eligible for reimbursement is suspended until the requested information is provided and it is possible to assess fully and correctly the application.	**Source(s):** Article 9, paragraphs 4, 5 and 6 of Law n.º 52/2014 of 25 August 2014 Article 19 of Law n.º 52/2014 of 25 August 2014	**Yes** ☐ **No** ☐	

	In case of doubt, from a clinical perspective, the National Contact Points may require the advice of the General Health Department of the Ministry of Health (Direção Geral de Saúde). The opinion of Direção Geral de Saúde must be issued within 5 working days. Law n. º 52/2014 of 25 August foresees no specific sanctions behaviors such as missing the deadlines on the part of the requesting person or of the requested body. It only determines that ACSS, I.P, Direção Geral de Saúde and the national regional contact points and shall draw up every year a report on the operation of this Law and submit it, respectively, to the Minister of Health and to the members of the Regional Governments of Azores and Madeira. If the deadlines are not respected by the requesting person he or she will lose the right to be reimbursed. If they are not respected by ACSSS,I.P. or by the other of the official referred entities, general administrative, civil or even criminal national law provisions may apply, according to the circumstances of the case. In particular, the beneficiary may complain to the Health Regulatory Authority ("Entidade Reguladora da Saude") that controls the activity of all health units that provide healthcare in Portugal.			
8. Are there any non-reimbursable thresholds, deductions *(except the deductions*	**Answer:** *If yes, please specify the thresholds.* As far as we were able to know, no.	**Source(s):**	**Yes** ☐ **No** ☐	

for administrative costs mentioned above) etc.?				
9. In instances where a PA (or prior-notification) has already been issued, is a separate/simplified procedure available for requesting reimbursement? **applicable only if the country has a PA system.*	**Answer:** *If yes, please describe the simplified procedure.* As far as we were able to find out, there is no simplified procedure in these cases.	**Source(s):**	**Yes** ☐ **No** ☒	
10. Are there additional administrative/procedural requirements for reimbursement depending on, for instance, the type of treatment for which reimbursement is requested, or the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* **Not identified**	**Source(s):**	**Yes** ☐ **No** ☒	
11. Please list any other administrative requirements in your country in relation to the procedures of reimbursement of cross-border healthcare.	**Answer:** **Not identified**	**Source(s):**	**Yes** ☐ **No** ☒	

Part 2: Checklist for verification with national/regional body

Name of the body: N/A
Country/Region: N/A
Date of verification call: N/A

Template for the Data Collection	*Tick the boxes if the information in the template for the data collection has been verified and/or complemented by the national body*		*Include any additional comments and/or information provided by the contacted body*
Section 1 – Prior Authorisation			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Justification/purpose of the identified requirement(s) (Column 4)	☐ Question 1 ☐ Question 2 ☐ Question 3 ☐ Question 4 ☐ Question 5	☐ Question 6 ☐ Question 7 ☐ Question 8 ☐ Question 9 ☐ Question 10 ☐ Question 11	
Section 2 - Reimbursement			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Whether the requirement applies domestically (Discriminatory assessment) (Column 4) ▪ Justification/purpose of the identified requirement(s) (Column 5)	☐ Question 1 ☐ Question 2 ☐ Question 3 ☐ Question 4 ☐ Question 5	☐ Question 6 ☐ Question 7 ☐ Question 8 ☐ Question 9 ☐ Question 10 ☐ Question 11	

ROMANIA – COUNTRY REPORT

Part 0: Preliminary Assessment

1. **Please indicate whether the rules governing the administrative procedures/requirements for requesting PA and reimbursement under Directive 2011/24/EU in your country are set out at:**

A. National level ☒

B. Decentralised/regional/local level ☐

In case (1.B): Please indicate the two most relevant jurisdictions in your country (i.e., in terms of population):

Region/jurisdiction: 1: N/A

Region/jurisdiction 2: N/A

NOTE: In case (1.B) the template for the data collection (Part 1) should be completed twice, once for each of the two most relevant regions/jurisdiction indicated above.

2. **Please indicate the national body best suited to verify the accuracy of the information collected in Part 1, and justify your selection.**

Depending on the characteristics of your national healthcare system, the relevant body may be: a) *the national social security body*; or b) *an insurance fund*. In the latter case, please indicate the most representative fund (e.g., the one with the highest number of affiliations).

Body to be contacted for Task 2: The National Health Insurance House (in Romanian: *Casa Națională de Asigurări de Sănătate*)

(In case 1.B, please indicate two relevant bodies, one respectively for each Region/jurisdiction)

Reasons for Selection: The National Health Insurance House is, as per the Romanian legislation implementing the provisions of the Directive 2011/24/EU the main body in charge with coordination and verification of the administrative procedures for Prior Authorisation and Reimbursement of costs for cross-border healthcare. The National Body for Health Insurance is also the National Contact Point.

Part 1: Questionnaire

*__Note 1__: In cases where administrative requirements are set out in the legislative/regulatory framework at decentralised/regional/local level, please complete the template for the data collection twice, once for each of the two most relevant regions/jurisdictions (e.g., in terms population).

__*Note 2__: Setting out a Prior Authorisation (PA) system is optional for Member States. Should your country not have a system of PA in place under Directive 2011/24/EU, Section 1 will not need to be completed.

SECTION 1 PRIOR AUTHORISATION PROCEDURE(S)			
Questions	**Answer**	**Sources**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to PA procedures for a cross-border healthcare under Directive 2011/24/EU?	**Answer:** The Government Decision no. 304/2014 for the approval of the methodological norms regarding cross-border healthcare[673] (hereinafter the "***Government Decision 304/2014***")	**Source(s):** Government Decision 304/2014 NCP website http://www.cnas-pnc.ro/?l=en	N/A
2. Is this the same procedure as for PA under the Social Security Coordination Regulations?	**Answer:** **Yes ☐ No ☒**		N/A

[673] Full title of the measure in Romanian "*Decizia nr. 304 din 16 aprilie 2014 pentru aprobarea Normelor metodologice privind asistenţa medicală transfrontalieră*", available at: http://www.cnas-pnc.ro/legislatie?l=en , last accessed on 01/07/2021

	Note of the National body contacted for the verification of the data collected: the procedures are totally different.		
3. What body is in charge of handling the PA applications? *(e.g., where and to whom PA applications have to be submitted?)*	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* The County Health Insurance Houses – 43 in Romania, coordinated by the National Health Insurance House, which, as per the law, is in charge with the methodological guidance and control of the manner in which the insurance houses apply the legal provisions[674].	**Source(s):** NCP website http://www.cnas-pnc.ro/?l=en	N/A
4. Who is entitled to apply for PA? *(e.g., can the patients apply themselves, or is treating doctor filing/partially filling the request, etc.)*	**Answer:** *If there is a national doctor involved, is there a requirement that this doctor is contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA?* As per Article 2 of the Government Decision 304/2014 the patient, his family members (parent, wife/husband, daughter/son) or a proxy of the patient shall submit a request for prior authorisation with the National Health Insurance House where the patient is registered.	**Source(s):** Articles 1 and 2 of the Government Decision 304/2014; Justifying memo of Government Decision 304/2014[675].	No specific purpose for the administrative formalities was identified. However, the justifying memo of the Government Decision 304/2014 provides that in establishing the types of healthcare that are subject to PA and the criteria that must be fulfilled in order for PA to be obtained, the following provisions of Directive 24/2011 were taken into account: - The PA system, including the criteria and application of such criteria, as well as the individual decisions to refuse granting PA are limited to what is necessary and proportional to the objective to be achieved, and may not constitute a means of arbitrary discrimination or an unjustified obstacle to the free movement of patients.

[674] As per the functions of the National Health Insurance House, available at: http://www.cnas.ro/page/prezentare-generala.html, last accessed on 01/07/2021
[675] Full title of the measure in Romanian "*NOTĂ DE FUNDAMENTARE la Hotărârea Guvernului nr. 304/2014 pentru aprobarea Normelor metodologice privind asistenţa medicală transfrontalieră*", available at: https://www.gov.ro/ro/guvernul/procesul-legislativ/note-de-fundamentare/nota-de-fundamentare-hg-nr-304-16-04-2014&page=45, last accessed on 01/07/2021

			- The healthcare that may be subject to PA is limited to healthcare that is made subject to planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical, and human resources. The justifying memo further explains that, in this context, the types of healthcare subject to PA were established, namely: - PET-CT in ambulatory regime, - hospital healthcare granted in continuous hospitalisation regime – hospital accommodation for more than 24 hours (for the following types of treatment: implant or replacement of a cardiac defibrillator, articular tumoral endoprosthesis, segmentary implant of spinal column, coronary bypass with/without invasive cardiac investigations, birth), - medication in ambulatory treatment, - medicinal devices in ambulatory treatment, for which the following are provided: ○ A high level of prices/tariffs reimbursed in the social health security system in Romania and that, in the condition of applying EU Directive no. 24/2011 would have as consequence a great pressure over the social health security sole national fund; ○ Certain granting conditions in Romania and that, in the conditions of application of the EU Directive no. 24/2011 cannot constitute a means of discrimination or an unjustified obstacle to the free movement of patients.
5. Is there a specific application form/module which	**Answer:** *If yes, please specify:*	**Source(s):**	**Input provided by the National Health Insurance House (14/06/2021)**:

the person seeking PA needs to submit?	*- What information is required;* *- Is the information mandatory, optional, or recommended?* *- Is this application form/modules available online?* *- Does the form have to be submitted in paper or can it be submitted electronically?* There is no specific application form/module applicable at national level. However, the major county insurance houses have a specific application form available on their websites. The following information is required through the application form: - Name of the county health insurance house to which the application form is addressed; - name, national ID number, telephone number of the applicant; - the medical unit where the medical assistance will be provided and the Member State where it is located; - the type of treatment for which PA is requested; - date and signature of the applicant. The information requested is mandatory. An annex to the form contains a detailed list of what documents need to be attached to the request for PA. The detailed list of documents to be attached to the request from is presented in the Question below.	Article 2, Chapter I of the Government Decision 304/2014	It would have been more burdensome for patients to have to fill in a standard application form. Each patient has different justifying documents depending on the country where the documents were issued, and it would have been impossible to include all possible types of justifying documentation in a single form. What is important is for the patient to submit with its application all justifying documents it has in its possession. In some countries the patient is not even provided with the proof of payment of its treatment and such documents are obtained through the NCPs. This is an additional reason why a standard form was not implemented. **Additional input provided by the National Health Insurance House (02/07/2021)**: the county health insurance houses are allowed flexibility in publishing a draft application form/module. However, during discussions it was revealed that the forms published on the websites of the county health insurance houses are not updated as per the today applicable form of Government Decision 304/2014. In what concerns electronic submission of the application form, this is also up to the county health insurance houses. However, considering that some of the documents attached to the application form must be submitted in original, electronic submission would in most cases not be possible. Finally, the National Health Insurance House indicated that the application form and attached documents can be submitted either in person or by registered post or courier to the registry of the county health insurance house where the applicant is registered. The registry will then direct the application and documents to the relevant department within the health insurance house.

	The documents need to be submitted in paper either in person or by registered post or courier. There is no indication of an email address where the documents can be sent and moreover, some documents to be attached to the request need to be submitted in original copy, which makes electronic submission impossible. The application form and attached documents are submitted to the registry of the county health insurance house where the applicant is registered and directed from there to the relevant department within the county health insurance house.		
6. What (other) documentation has to be submitted in order to substantiate a PA request?	**Answer:** *If applicable, please specify:* *- What documents and what particulars are required;* *- Whether there are requirements as to who has to issue the documents (e. g., a doctor contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA or any doctor);* *- Whether the submission of the documentation is optional, mandatory, or recommended* As per the Government Decision 304/2014 the request for PA shall be accompanied by: (i) a copy of the ID card or birth certificate of the patient and (ii) the documents provided by Article 1 of the Government Decision 304/2014. These documents are:	**Source(s):** Articles 1 and 2, Chapter I of the Government Decision 304/2014	N/A

	• For PET-CT healthcare in ambulatory regime, **a doctors' letter (physician referral) accompanied by a decision of approval issued by the expert commission within the National Health Insurance House;** • In case of healthcare provided in continuous hospitalisation regime, **a medical report rafted by a doctor within a clinical hospital or, as the case may be, a county hospital, that has contractual relations with a health insurance house in Romania** (a template model can be found in Annex I to Government Decision 304/2014). • In case of medicines for outpatient treatment for which is required the approval by the experts of the National Health Insurance House,[676] **the copy of the medical prescription accompanied by the document proving the experts' approval.** Additionally, as per the application form made available on the websites of the county health insurance houses, a request for PA (in all the cases above mentioned) must be accompanied by the following documents: a) Written confirmation from the medical assistance provider in the Member State of the European Union where the cross-border healthcare will be granted, regarding its availability to provide the indicated cross border		

[676] Note of the National expert: Please note that PA is not applicable of this type of treatment in the republished version of Government Decision 304/2014. It seems that the application forms identified on the websites of several of the county health insurance houses are not up to date with latest legal provisions.

	medical assistance in the period indicated by the applicant; b) A document issued by the national contact point for cross border healthcare from the Member State where the cross border medical assistance will be provided, showing that the medical assistance provider does not generate serious and specific concerns regarding the observance of the standards and guidelines regarding the quality of medical assistance and safety of patients, including provisions regarding supervision. The submission of the above-mentioned documentation is mandatory. As above mentioned, the documents must be submitted either in person, or by registered post or courier at the registry of the county health insurance house where the applicant is registered. The documents are directed to the relevant department within the county health insurance house. **Note of the National body contacted for the verification of the data collected:** As per the **information provided by the National Health Insurance House**, it is not a requirement that the doctor issuing the medical report required for issuance of PA to have a contract with the national insurance provider in Romania.		

7. **Are there any costs** associated with the handling of the PA request? - *Direct costs (e.g., fixed costs for submitting or filing a PA request).* - *Indirect costs* (*e.g., translations, stamps, etc).*	**Answer:** *Direct costs:* None identified. *Indirect costs*: None identified.	**Source(s):** Government Decision 304/2014, Chapter I	N/A
8. Are there any specific **time requirements** linked to a PA request? (*e.g., time within which a requesting person must submit the PA application and/or time within which the requested body must take a decision on the PA request, etc.*).	**Answer:** *- If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* Yes There is no time limit within which the patient must file its request for PA. However, the county Health Insurance House must communicate in writing to the applicant the rejection of its request for PA within 5 working days as of the registration of the request for PA. The Government Decision 304/2014 also establishes that the maximum validity term of the PA is established as per the provisions of Annex 2 to the Government Decision 304/2014. Annex 2 to the Government Decision 304/2014 provides that the maximum validity term of the PA is the maximum time interval during which the insured person can present himself/herself to the healthcare provider in the member	**Source(s):** Articles 1, 2, Chapter I and Annex 2 to the Government Decision 304/2014.	**Input provided by the National Health Insurance House (14/06/2021)**: a patient requiring PA must calculate its timing so as to ensure that its request for PA is filed with the country Health Insurance House at least 5 days prior to its appointment with the doctor abroad, so as to ensure that it obtains the PA in due time. It is possible for a small country health insurance house to issue the PA in less than 5 days, while it is also possible for a larger health insurance house to require the maximum 5 days to issue the PA.

	state of the European Union in which the cross-border healthcare will be provided.[677] The Government Decision 304/2014 does not provide the consequences of breach of this legal deadline by the National Health Insurance House.		
9. Are there **differences in the procedural/administrative requirements for requesting PA** based on, for instance, the type of treatment for which PA is requested, the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* Yes. There is a difference between the documents that must be attached to the request for PA, depending on the type of medical services for which PA is requested, as follows (outlined also in Question 5): • In case of PET-CT healthcare in ambulatory regime, a doctors' letter accompanied by a decision of approval issued by the expert commission within the National Health Insurance House; • In case of healthcare provided in continuous hospitalization regime, a medical report drafted by a doctor within a clinical hospital or, as the case may be, a county hospital, that has contractual relations with a health insurance house in Romania;	**Source(s):** Article 1 and 2, chapter I of the Government Decision 304/2014	No specific justification/purpose for the different requirement identified in the consulted sources.

[677] In case of PET-CT healthcare the maximum validity term of the PA is the maximum validity term of the decision of approval issued by the expert commission within the National Health Insurance House.

	• In case of medicines for outpatient treatment for which is required the approval by the experts of the National Health Insurance House, the copy of the medical prescription accompanied by the document proving the experts' approval. Please note that there is also a difference between the validity term of the PAs in each case.[678]		
10. Is there a specific PA form (i.e., form used for issuing/granting PA) and, if the answer is positive, what form?	**Answer:** Yes. The PA form is provided as Annex 2 to the Government Decision 304/2014. The PA form shall be issued by the National Health Insurance House, including details regarding the name, ID number of the patient, place of residence, request for PA number and date, type of cross-border healthcare for which PA is granted and validity term of the PA. The PA is signed by the President – general director of the National Health Insurance House issuing the PA.	**Source(s):** Annex 2 to the Government Decision 304/2014s	N/A
11. Please list any other administrative requirements in your country in relation to the PA procedure for cross-border healthcare.	**Answer:** None identified.	**Source(s):** Government Decision 304/2014, Chapter I	**Input provided by the National Health Insurance House (14/06/2021):** such procedures were put in place due to the high costs of the types of treatment that are covered by the Directive and Government Decision 304/2014.

[678] There is no specific provision of the maximum validity term of a PA granted for PET-CT healthcare. This means that the maximum validity is at the discretion of the National Health Insurance House. However, the Government Decision 304/2014 provides that the maximum validity term of the PA in case of healthcare provided in continuous hospitalization regime, provided under Article 1, point 2 of the Government Decision 304/2014 is the same as the maximum validity term of the decision of approval issued by the expert commission within the National Health Insurance House.

SECTION 2 REIMBURSMENT PROCEDURE(S)				
Questions	**Answer:**	**Sources**	**Does/do the identified requirement(s) also apply domestically? (i.e., is the requirement non-discriminatory?)**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to reimbursement procedures for cross-border healthcare under Directive 201/24/EU?	**Answer:** Government Decision 304/2014, Chapter II.	**Source(s):** http://www.cnas-pnc.ro/?l=en	N/A	N/A
2. Is this the same procedure as for reimbursement under the Social Security Coordination Regulations?	**Answer:** **Yes ☐ No ☒** Note of the National body contacted for the verification of the data collected: the procedures are totally different.		N/A	N/A
3. What body is/are responsible of handling the reimbursement applications? (e.g., where and to whom reimbursement	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).*	**Source(s):** Government Decision 304/2014, Chapter II	N/A	N/A

applications have to be submitted?)	The County Health Insurance Houses – 43 in Romania, all coordinated and under the supervision of the National Health Insurance House, who, as per the law, is in charge with the methodological guidance and control of the manner in which the insurance houses apply the legal provisions.[679]			
4. Is there a specific application form/module which the person seeking reimbursement needs to submit?	**Answer:** *If yes, please specify:* *- What information is required;* *- Is the information mandatory, optional, or recommended?* *Is this application form/modules available online?* *- Does the form have to be submitted in paper or can it be submitted electronically?* There is no specific form nationally applicable available. Article 3, para. (1) of Government Decision 304/2014 provides that a request for reimbursement must be made in writing (written request), by the patient, its family members (parent, husband/wife, son/daughter) or a proxy of the applicant and accompanied by justifying documents. The Government Decision 304/2014 does not indicate what information is required, whether it is mandatory, optional or recommended.	**Source(s):** Article 3, Chapter II of Government Decision 304/2014	**Yes ☐** **No ☒** The answer is no due to the fact that for domestic treatments in Romania insured persons do not need to file a reimbursement request, as the costs of the healthcare are anticipated directly by the national health fund. Nonetheless the same calculation method applies, namely the amount to be reimbursed for healthcare abroad is calculated in the same way as they would calculate the amount to be	The justifying memo of Government Decision 304/2014 provides in what concerns the methodology for reimbursement of prices/tariffs representing the costs of the cross-border healthcare: - Reimbursement of the costs of the cross-border healthcare granted on the territory of a member state of the European Union and paid by the insured person is made if the medical services, the medicinal drugs and medical devices are found amongst the services to which the insured person is entitled to in accordance with the legislative framework of social health security and are reimbursed from the social health security unique national fund; - The level at which the reimbursement operation of the costs of the cross-border healthcare is made does not

[679] As per the functions of the National Health Insurance House, available at: http://www.cnas.ro/page/prezentare-generala.html, last accessed on 01/07/2021

	However, the major county health insurance houses have a form published on their websites. The information requested in the form includes: - The name of the county health insurance house to which the request is addressed; - Name and national ID number of the applicant; - Home address; - Telephone number - Bank account number and bank name; - Name of the Member State where the medical assistance was provided; - A short description of the history of the situation; - A list of documents attached to the request; - Date and signature of the applicant. The information required is mandatory. The application form is available on the websites of the county health insurance houses (only the websites of the major health insurance houses were verified). The form request has attached a list of documents that need to be attached to the request. Some of the documents to be attached to the request are requested in original. Consequently, only submission in person or by registered post of the form and attached documents is possible. There is no indication of whether the form can be submitted electronically and, in any event the original documents requested as attachments		anticipated for domestic healthcare.	surpass the level at which such would have been covered if it had been afforded in Romania, but no more than the costs paid by the insured person; - Reimbursement of the costs of the cross-border healthcare afforded on the territory of a member state of the European Union and paid by the insured person is made on the basis of the eligibility criteria established in accordance with the provisions of the Government Decision for the approval of the frame contract regarding the conditions for providing healthcare in the social health security system and in the Government Decision approving the national health programs and the methodological norms for applying such. For this aspect the provisions of the EU Directive no. 24/2011 according to which the Member State of affiliation may impose on an insured person seeking reimbursement of the costs of cross-border healthcare, including healthcare received through means of telemedicine, the same conditions, criteria of eligibility and regulatory and administrative formalities, whether set at a local, regional

	to the request cannot be submitted electronically. The documents are submitted with the registry of the county health insurance house where the applicant is registered and afterwards directed to the relevant department within the county health insurance house. Additionally, the Government Decision indicates the **conditions** that an applicant must fulfil.[680]			or national level, as it would impose if this healthcare were provided in its territory, were taken into account. The explanatory memo also provides that these eligibility criteria cannot be discriminatory and constitute an obstacle to the free movement of patients, services or goods, unless it is objectively justified by planning

[680] To this end, **para. (1) of Article 3** of the Government Decision provides that the health insurance house reimburses the costs of the cross-border healthcare afforded on the territory of a member state of the European Union and paid by the applicant, at the level of the tariffs established in Article 4 of the decision (detailed under question 8 below) if:

a) The medical services, medicinal drugs and medical devices are found amongst the services to which the insured person is entitled to according to the legislation applicable to social health security and covered from the social health security unique national fund, **except** for:
   (i) Treatment of patients that require isolation and mandatory admittance into hospital and treatment of persons deprived of their liberty for which the court of law ordered performance of the penalty in a hospital prison;
   (ii) Home care services and home palliative care;
   (iii) Allocation of organs and access to organs in view of undergoing organ transplant;
   (iv) Except for chapter V of title XVIII of Law no. 95/2006 regarding the reform in the health field, with subsequent amendments and additions, population vaccination programs against infectious diseases, that are meant exclusively to protect the heath of the population and that are the object of specific planification and implementation measures;
   (v) The types of healthcare provided by article 1 afforded in a member state of the European Union for which there is no PA for reimbursement of the costs of the cross-border healthcare;
   (vi) The medicinal drugs that form the object of a special medical prescription, as provided by article 781, para. (2) if Law no. 95/2006, with subsequent amendments and additions.
b) The following **eligibility criteria** are met:
   (i) The hospital medical services were afforded in a member state of the European Union, following a medical examination made by a medical attendant that affords medical services in the social health security system in Romania, finalised with the issuance of a letter of admittance into hospital, with the exception of the situations that fall under the criteria that allow admittance into hospital without a letter of admittance, provided by the frame contract regarding the conditions for providing healthcare in the social health security system;
   (ii) The medicinal drugs in the ambulatory treatment were provided in another member state of the European Union, following a medical examination performed by a medical attendant that provides medical services in the social health security system in Romania, finalized with the issuance of a medical prescription in the conditions provided by the frame contract regarding the conditions for providing healthcare in the social health security system and in the technical norms for performing the national public health programs;
   (iii) The medical devices in ambulatory treatment were afforded in a member state of the European Union, following a medical examination performed by a medical attendant that provides medical services in the social health security system in Romania, finalized with the issuance of a medical prescription and for which the health insurance house issued an approval decision in the conditions provided by the frame contract regarding the conditions for providing healthcare in the social health security system.

				requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources. **Input provided by the National Health Insurance House (14/06/2021)**: it would have been more burdensome for patients to have to fill in a standard application form. Each patient has different justifying documents depending on the country where the documents were issued and it would have been impossible to include all possible types of justifying documentation in a single form. What is important is for the patient to submit with its application all justifying documents it has in its possession. In some countries the patient is not even provided with the proof of payment of its treatment and such documents are obtained through the NCPs. This is an additional reason

				why a standard form was not implemented. **Additional input provided by the National Health Insurance House (02/07/2021)**: the county health insurance houses are allowed flexibility in publishing a draft application form/module. However, during discussions it was revealed that the forms published on the websites of the county health insurance houses are not updated as per the today applicable form of Government Decision 304/2014. In what concerns electronic submission of the application form, this is also up to the county health insurance houses. However, considering that some of the documents attached to the application form must be submitted in original, electronic submission would in most cases not be possible. Finally, the National Health Insurance House indicated that the application form and attached documents can be submitted either in person or by registered post or courier to the registry of the county health insurance house where the applicant is registered. The registry will then direct the

				application and documents to the relevant department within the health insurance house
5. What (other) documentation has to be submitted in order to substantiate a reimbursement request?	**Answer:** *If applicable, please specify:* *- What documents are required;* *- Whether the submission of the documentation is optional, mandatory, or recommended.* Article 1, para. (2) of the Government Decision 304/2014 provides that **"justifying documents"** under para. (1) of Article 3 of the decision means any medical document, including: 1. a letter of admittance into hospital, 2. a medical prescription for medicinal drugs or medical devices – in copy, showing that the insured person benefited from medical services, medicinal drugs and medicinal devices, dated and signed by the medical person that provided such services, 3. as well as payment documents showing that the medical services, the medicinal drugs and the medicinal devices were fully paid by the insured person, a family member (parent, husband/wife, son/daughter) or a proxy, the level of tariffs/prices distinctly for each medical services, medicinal drug, medical device, including the date of their payment.	**Source(s):** Article 3, paras. (1) and (2), Chapter II of the Government Decision 304/2014	**Yes** ☐ **No** ☒ The answer is no due to the fact that for domestic treatments in Romania insured persons do not need to file a reimbursement request, as the costs of the healthcare are anticipated directly by the national health fund. Nonetheless the same calculation method applies, namely the amount to be reimbursed for healthcare abroad is calculated in the same way as they would calculate the amount to be anticipated for domestic healthcare.	N/A

	As per the Government translation of the justifying documents in Romanian by an authorised translator is under the responsibility of the health insurance house. Additionally, the draft request for reimbursement made available on the websites of the major health insurance houses, includes a detailed list of documents that need to be attached to the request, mentioning which documents are requested in copy and which in original. The list attached to the form provides that the request for reimbursement must be accompanied by the following documents: 1. Identity card or birth certificate for children under the age of 14 – in copy; 2. The proof of insured person of the respective county health insurance house – in original; 3. Letter of admittance in the hospital following a medical evaluation (for hospital medical services); the medical prescription for medicinal drugs issued following a medical evaluation (for medication in ambulatory treatment); the decision of approval of the medical devices (for medical devices in ambulatory); [681] 4. Medical documents (discharge report, etc.) showing that the medical services were provided, in the language of the member state – 2 copies – as well as an authorized			

[681] All these documents must be issued prior to the medical services being provided in the Member State.

	translation in Romanian language – one original and one copy[682]; 5. Payment documents (invoices, receipts, coupons, etc.) showing that the medical services were fully paid for, the level of the tariffs/prices distinctly for each medical service and the date when the medical services were paid for. 6. For special medical services in ambulatory, the following are also needed: medical documents showing that the medical services were provided, in the language of the EU Member State – 2 copies - as well as an authorised translation in Romanian language – one original and one copy. The submission of the documents is mandatory.			
6. Are there any costs associated with the handling of the reimbursement request? - *Direct costs (e.g., fixed costs for submitting or filing a reimbursement request, proportion deducted from the reimbursable amount).*	**Answer:** *Direct costs:* None identified. *Indirect costs:* None identified. The Government Decision 304/2014 provides that translation costs are to be borne by the health insurance house handling the request for reimbursement. Therefore, there are no direct or indirect costs associated with handling the reimbursement request.	**Source(s):** Article 3, para. (2), Chapter II of the Government Decision 304/2014.	**Yes** ☒ **No** ☐	N/A

[682] As per the information provided by the National Health Insurance House the requirement for an authorised translation to be provided by the applicant is no longer applicable; the draft request is not updated - the translation of the documents is under the responsibility of the health insurance house, in all cases.

- *Indirect costs* (*e.g., translations, stamps, etc).*				
7. Are there any specific time requirements linked to a reimbursement request? (*e.g., time within which the reimbursement requests must be submitted and/or time within the requested body must handle the request and/or reimburse the costs, etc.*).	**Answer:** *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* There is no deadline provided under which the applicant must submit a request for reimbursement. However, Article 3, para. (8) of the Government Decision 304/2014 provides that if the request for reimbursement is rejected, such decision must be communicated to the applicant within 30 working days as of registration of the request.[683] Article 3, para. (6) of the Government Decision 304/2014 also provides that reimbursement of the cross-border medical services costs is made by the health insurance house within maximum 60 days as of the date the budgetary allocation of the amount is made by the National Health Insurance House (Cfr. Last column for additional information provided by the National Health Insurance House).	**Source(s):** Article 3, paras. (6) and (8), Chapter II of the Government Decision 304/2014	**Yes ☐** **No ☒**	**Input provided by the National Health Insurance House (14/06/2021)**: the Directive does not lay down a mandatory term within which the patient must receive reimbursement of the costs. Similarly, Government Decision 304/2014 also does not lay down such deadline. However, in practice and in all reports sent to the European Commission regarding the implementation of the Directive a medium term was calculated and is frequently reported, namely 69.5 days. In other words, the medium term within which the biggest county Health Insurance Houses ensure reimbursement of the costs of cross-border treatments is 69.5 days.

[683] If within this time, the National Health Insurance House contacted an NCP from the other Member State for clarifying the payment documents, this shall be communicated to the applicant within 3 working days as of the date the NCP was contacted. If, after receiving clarifications from the NCP in Romania, the National Health Insurance House decides to reject the request for reimbursement, the decision is communicated to the applicant within 10 working days as of the date the answer from the NCP in Romania is received.

	The Government Decision 304/2014 does not provide the consequences if the deadlines are missed. However, given that the National Health Insurance House must follow these deadlines, this will affect the validity of its decisions regarding reimbursement, which can be challenged by the applicant with the competent courts of law.[684]			
8. Are there any non-reimbursable thresholds, deductions *(except the deductions for administrative costs mentioned above) etc.?*	**Answer:** No specific non-reimbursable thresholds (besides the general rule set out by Article 3, para (7) of the Government Decision 304/2014 according to which the reimbursement shall not be surpass the value in Romanian currency of the cross-border healthcare paid by the insured person, a family member or its proxy, at the exchange rate of the National Bank of Romania at the date of payment, by comparing the price paid with the level established for reimbursement under Article 4 of the Decision, distinctly for each medical services/medicinal drug or medical device. As mentioned, Article 4, para. (1) of the Government Decision 304/2014 specifies the reimbursable amounts for healthcare	**Source(s):** Article 3, para. (7), Article 4, Chapter II of the Government Decision 304/2014	**Yes** ☐ **No** ☒	The justifying memo of Government Decision 304/2014 provides in what concerns the methodology for reimbursement of prices/tariffs representing the costs of the cross-border healthcare: - Reimbursement of the costs of the cross-border healthcare granted on the territory of a member state of the European Union and paid by the insured person is made is the medical services, the medicinal drugs and medical devices are found amongst the services to which the insured person is entitled to in accordance with the legislative framework of social health security and are reimbursed

[684] Additionally, Moreover, article 913 of Law no. 95/2006 regarding the reform in the health field provides that in the event that the health insurance houses do not approve the insured persons' requests regarding reimbursement of the value of the cross-border healthcare, the institutions are under an obligation to communicate their refusal, in writing, indicating the legal basis, within the deadline provided by the methodological norms approved by government decision. The insured persons can file a challenge against the decision mentioned before or against the level of the costs of the cross-border assistance reimbursed, at the health insurance house where the insured person is registered. Against the answer to the challenge or upon the expiry of the term within which the challenge must be answered, the insured person may file a challenge with the competent court of law.

	treatments, which correspond to the prices in Romania. Article 4, para. (3) of the Government Decision 304/2014 additionally provides that other costs, such as costs for accommodation and travel made by the insured person, as well as additional costs paid by handicapped persons due to one or more handicaps they suffer from, are not covered.			from the social health security unique national fund; - The level at which the reimbursement operation of the costs of the cross-border healthcare is made does not surpass the level at which such would have been covered if it had been afforded in Romania, but no more than the costs paid by the insured person; - Reimbursement of the costs of the cross-border healthcare afforded on the territory of a member state of the European Union and paid by the insured person is made on the basis of the eligibility criteria established in accordance with the provisions of the Government Decision for the approval of the frame contract regarding the conditions for providing healthcare in the social health security system and in the Government Decision approving the national health programs and the methodological norms for applying such. For this aspect the provisions of the EU Directive no. 24/2011 according to which the Member State of affiliation may impose on an insured person seeking reimbursement of the costs of cross-border healthcare,

				including healthcare received through means of telemedicine, the same conditions, criteria of eligibility and regulatory and administrative formalities, whether set at a local, regional or national level, as it would impose if this healthcare were provided in its territory, were taken into account. The explanatory memo also provides that these eligibility criteria cannot be discriminatory and constitute an obstacle to the free movement of patients, services or goods, unless it is objectively justified by planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources.
9. In instances where a PA (or prior-notification) has already been issued, is a separate/simplified procedure available	**Answer:** *If yes, please describe the simplified procedure* No such simplified procedure identified.	**Source(s):** Government Decision 304/2014	**Yes ☐** **No ☐**	N/A

for requesting reimbursement? **applicable only if the country has a PA system.*				
10. Are there additional administrative/procedural requirements for reimbursement depending on, for instance, the type of treatment for which reimbursement is requested, or the profile of the insured person, or any other criterion?	**Answer:** None identified.	**Source(s):** Government Decision 304/2014, Chapter II	**Yes** ☐ **No** ☐	N/A
11. Please list any other administrative requirements in your country in relation to the procedures of reimbursement of cross-border healthcare.	**Answer:** No further administrative requirements were found.[685]	**Source(s):** Government Decision 304/2014, article 8, Chapter III	**Yes** ☐ **No** ☒	The justifying memo of Government Decision no. 304/2014 provides that through the decision, provisions regarding the access of patients to medical files, continuity of treatment in Romania, namely the situations when healthcare providers

[685] Note of the National expert: Article 8, para. (1) of Government Decision 304/2014 provides that in the event that a prescription, for medicines or medical devices available in Romania, is issued in the Member State of treatment, and if the delivery of prescription is requested in Romania, the continuity of the medical treatment shall be ensured. To this end, the medical document issued by the doctor in the Member State of treatment is the document that needs to be then submitted to a doctor in Romania, in order to assess the therapeutical scheme in view of its maintaining or change.

Article 8, para, (2) of Government Decision 304/2014 provides that in case the insured person wishes to continue the treatment in the Romanian social health security system, he/she shall attend a doctor that provides its services at a provider that is in contractual relations with the health insurance house. In this case the first presentation at the doctor is made with the document provided under para. (1), without a doctor's letter sending him/her to other specialties or a letter to admit into hospital being required. The subsequent required medical services are provided in the conditions regulated under the frame-contract regarding the conditions for providing healthcare in the social health security system and the methodological norms for its application, respectively in the Government decision for approval of the national health programs and technical norms for drafting the national health programs, approved by order of the ministry of health and of the president of the National Health Insurance House.

				operating in Romania ensure priority access to healthcare to Romanian patients, were introduced. [686]

[686] Input provided by the National Health Insurance House (14/06/2021): it is important to mention that in Romania there are two fundamentally different reimbursement procedures: (i) one under the Directive, as herein described and (ii) one under art 35 of Regulation 883/2004 and articles 25 and 26 of Regulation 987/2009. One of the differences between the two reimbursement procedures is, for example the reimbursement thresholds: while reimbursement under the Directive is made within national thresholds, reimbursement under the Regulations is integral.

Part 2: Checklist for verification with national/regional body

Name of the body: The National Health Insurance House - the National Contact Point
Country/Region: Romania
Date of verification call: 14 June 2021; additional call on 2 July 2021

Template for the Data Collection	**Aspects to be verified** *Tick the boxes if the information in the template for the data collection has been verified and/or complemented by the national body*		**Comments** *Include any additional comments and/or information provided by the contacted body*
Section 1 – Prior Authorisation			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Justification/purpose of the identified requirement(s) (Column 4)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	The feedback received has been incorporated in the questionnaire (Section 1).
Section 2 - Reimbursement			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Whether the requirement applies domestically (Discriminatory assessment) (Column 4) ▪ Justification/purpose of the identified requirement(s) (Column 5)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	The feedback received has been incorporated in the questionnaire (Section 2).

SLOVAKIA – COUNTRY REPORT

Part 0: Preliminary Assessment

1. **Please indicate whether the rules governing the administrative procedures/requirements for requesting PA and reimbursement under Directive 2011/24/EU in your country are set out at:**

A. National level ☒

B. Decentralised/regional/local level ☐

In case (1.B): Please indicate the two most relevant jurisdictions in your country (i.e., in terms of population):

Region/jurisdiction: 1: N/A

Region/jurisdiction 2: N/A

NOTE: In case (1.B) the template for the data collection (Part 1) should be complete twice, once for each of the two most relevant regions/jurisdiction indicated above.

2. **Please indicate the national body best suited to verify the accuracy of the information collected in Part 1, and justify your selection.**

Depending on the characteristics of your national healthcare system, the relevant body may be: a) *the national social security body*; or b) *an insurance fund*. In the latter case, please indicate the most representative fund (e.g., the one with the highest number of affiliations).

Body to be contacted for Task 2: Všeobecná zdravotná poisťovňa a.s. (General Health Insurance Fund) and Health Care Surveillance Authority (HCSA)

(In case 1.B, please indicate two relevant bodies, one respectively for each Region/jurisdiction)

Reasons for Selection: The Všeobecná zdravotná poisťovňa, a.s.. (General Health Insurance Fund) is the biggest Health Insurance Company in Slovakia. HCSA is the founder of the National Contact Point for Cross-Border Healthcare in Slovak Republic. It is the body supervising the provision of Health Care and Health Insurance. The data collected was verified by the HCSA. The General Health Insurance Fund was also contacted by the national legal expert for the verification of the information in Part 1, but no answer has been yet received.

Part 1: Questionnaire

*__Note 1__: In cases where administrative requirements are set out in the legislative/regulatory framework at decentralised/regional/local level, please complete the template for the data collection twice, once for each of the two most relevant regions/jurisdictions (e.g., in terms population).

__*Note 2__: Setting out a Prior Authorisation (PA) system is optional for Member States. Should your country not have a system of PA in place under Directive 2011/24/EU, Section 1 will not need to be completed.

SECTION 1 PRIOR AUTHORISATION PROCEDURE(S)			
Questions	**Answer**	**Sources**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to PA procedures for a cross-border healthcare under Directive 2011/24/EU?	**Answer:** 1.The Act no. 580/2004 Coll. of 21 October 2004 on Health Insurance and on the amendment of Act no. 95/2002 Coll. on Insurance and on Amendments to Certain Acts.[687] 2.Decree of Ministry of Health of The Slovak Republic no. 232/2014 Coll. of 11 August 2014 regulating the procedure of the healthcare provider, the health insurance company and the	**Source(s):** The Act no. 580/2004 Coll. of 21 October 2004 on Health Insurance and on the amendment of Act no. 95/2002 Coll. on Insurance and on Amendments to Certain Acts Decree of Ministry of Health of The Slovak Republic no. 232/2014 Coll. of 11 August 2014 regulating the procedure of the healthcare provider, the health insurance company and the Healthcare surveillance authority	N/A

[687] Zákon č. 580/2004 Z.z. z 21. októbra 2004 o zdravotnom poistení a o zmene a doplnení zákona č. 95/2002 Z. z. o poisťovníctve a o zmene a doplnení niektorých zákonov (The Act no. 580/2004 Coll. on Health Insurance and on the amendment of Act no. 95/2002 Coll. on Insurance and on Amendments to Certain Acts, 21 October 2004 with later amendments), available at https://www.slov-lex.sk/pravne-predpisy/SK/ZZ/2004/580/20210601, (last accessed on 15 June 2021),

	Healthcare surveillance authority in the provision of cross-border healthcare.[688] 3. Decree of Ministry of Health of The Slovak Republic no. 341/2013 Coll. of 23 October 2013 provides cross-border healthcare which is subject to the prior authorization of the relevant insurance undertaking for the purpose of reimbursement[689]	in the provision of cross-border healthcare Decree of Ministry of Health of The Slovak Republic no. 341/2013 Coll. of 23 October 2013 provides cross-border healthcare which is subject to the prior authorization of the relevant insurance undertaking for the purpose of reimbursement	
2. Is this the same procedure as for PA under the Social Security Coordination Regulations?	**Answer:** **Yes ☒ No ☐**		N/A
3. What body is in charge of handling the PA applications? *(e.g., where and to whom PA applications have to be submitted?)*	**Answer:** *- Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* PA applications have to be submitted to Health Insurance Company. [690]	**Source(s):** The Act no. 580/2004 Coll. of 21 October 2004 on Health Insurance and on the amendment of Act no. 95/2002 Coll. on Insurance and on Amendments to Certain Acts	N/A

[688] Vyhláška Ministerstva zdravotníctva Slovenskej republiky z 11. augusta č. 232/2014 Z. z. ktorou sa upravuje postup poskytovateľa zdravotnej starostlivosti, zdravotnej poisťovne a Úradu pre dohľad nad zdravotnou starostlivosťou pri poskytovaní cezhraničnej zdravotnej starostlivosti (Decree of Ministry of Health of The Slovak Republic no. 232/2014 Coll. regulating the procedure of the healthcare provider, the health insurance company and the Healthcare surveillance authority in the provision of cross-border healthcare, 11 August 2014 with later amendments) available at https://www.slov-lex.sk/pravne-predpisy/SK/ZZ/2014/232/20140901, (last accessed on 15 June 2021).

[689] Vyhláška Ministerstva zdravotníctva Slovenskej republiky z 23. októbra 2013 č. 341/2013 Z.z., ktorou sa ustanovuje cezhraničná zdravotná starostlivosť, ktorá podlieha predchádzajúcemu súhlasu príslušnej zdravotnej poisťovne na účely jej preplatenia (Decree of Ministry of Health of The Slovak Republic no. 341/2013 Coll. provides cross-border healthcare which is subject to the prior authorization of the relevant insurance undertaking for the purpose of reimbursement, 23 October 2013 with later amendments) available at https://www.slov-lex.sk/pravne-predpisy/SK/ZZ/2013/341/20131101, (last accessed on 15 June 2021).

[690] Zákon č. 580/2004 Z.z. z 21. októbra 2004 o zdravotnom poistení a o zmene a doplnení zákona č. 95/2002 Z. z. o poisťovníctve a o zmene a doplnení niektorých zákonov (The Act no. 580/2004 Coll. on Health Insurance and on the amendment of Act no. 95/2002 Coll. on Insurance and on Amendments to Certain Acts, 21 October 2004 with later amendments), available at https://www.slov-lex.sk/pravne-predpisy/SK/ZZ/2004/580/20210601, (last accessed on 15 June 2021), para. 9f and

Vyhláška Ministerstva zdravotníctva Slovenskej republiky z 11. augusta č. 232/2014 Z. z. ktorou sa upravuje postup poskytovateľa zdravotnej starostlivosti, zdravotnej poisťovne a Úradu pre dohľad nad zdravotnou starostlivosťou pri poskytovaní cezhraničnej zdravotnej starostlivosti (Decree of Ministry of Health of The Slovak Republic no. 232/2014 Coll. regulating the procedure of the healthcare

	In Slovakia, there are three health insurance companies (one state-owned and two private) and their systems are regulated by law. Všeobecná zdravotná poisťovňa, a.s. is the biggest Health Insurance Company in Slovakia.	Decree of Ministry of Health of The Slovak Republic no. 232/2014 Coll. of 11 August 2014 regulating the procedure of the healthcare provider, the health insurance company and the Healthcare surveillance authority in the provision of cross-border healthcare	
4. Who is entitled to apply for PA? *(e.g., can the patients apply themselves, or is treating doctor filing/partially filling the request, etc.)*	**Answer:** *- If there is a national doctor involved, is there a requirement that this doctor is contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA?* Patients can apply themselves (but application needs to be signed by the healthcare provider who suggests the scheduled healthcare).[691]	**Source(s):** The Act no. 580/2004 Coll. of 21 October 2004 on Health Insurance and on the amendment of Act no. 95/2002 Coll. on Insurance and on Amendments to Certain Acts Decree of Ministry of Health of The Slovak Republic no. 232/2014 Coll. of 11 August 2014 regulating the procedure of the healthcare provider, the health insurance company and the Healthcare surveillance authority in the provision of cross-border healthcare Information from website of Všeobecná zdravotná poisťovňa, a.s.[692] Explanatory memorandum to the Act no. 220/2013 Coll. which amending Act no. 580/2004 Coll. on health	It follows from the explanatory memorandum to the Act no. 220/2013 Coll. which amending Act no. 580/2004 Coll. on health insurance and on the amendment of Act no. 95/2002 Coll. on Insurance and on Amendments to Certain Acts, as amended, and Amending Certain Acts of 26 June 2013 that a patient submits an application, but the healthcare provider who suggested the scheduled healthcare is obliged to provide assistance to the patient to fill in the PA application.

provider, the health insurance company and the Healthcare surveillance authority in the provision of cross-border healthcare, 11 August 2014 with later amendments) available at https://www.slov-lex.sk/pravne-predpisy/SK/ZZ/2014/232/20140901, (last accessed on 15 June 2021), para. 3 to 5.

[691] para. 9f (1) of The Act no. 580/2004 Coll. on Health Insurance and on the amendment of Act no. 95/2002 Coll. on Insurance and on Amendments to Certain Acts, 21 October 2004 with later amendments.

[692] Available at: https://www.vszp.sk/.

		insurance and on the amendment of Act no. 95/2002 Coll. on Insurance and on Amendments to Certain Acts, as amended, and Amending Certain Acts of 26 June 2013[693]	
5. Is there a specific application form/module which the person seeking PA needs to submit?	**Answer:** *If yes, please specify:* *- What information is required;* *Is the information mandatory, optional, or recommended?* *- Is this application form/modules available online?* *- Does the form have to be submitted in paper or can it be submitted electronically?* Yes, there is specific application form that has to be used by all insurance companies.[694] The application must contain: a) the insured person's name, surname, date of birth and birth ID number, if assigned; b) the address of the insured person's place of residence; c) the insured person's diagnosis; d) justification of the need for planned healthcare by the healthcare provider;	**Source(s):** The Act no. 580/2004 Coll. of 21 October 2004 on Health Insurance and on the amendment of Act no. 95/2002 Coll. on Insurance and on Amendments to Certain Acts Decree of Ministry of Health of The Slovak Republic no. 232/2014 Coll. of 11 August 2014 regulating the procedure of the healthcare provider, the health insurance company and the Healthcare surveillance authority in the provision of cross-border healthcare. The Act no. 71/1967 Coll. on administrative proceedings (administrative procedure).[698] Information from website of Všeobecná zdravotná poisťovňa, a.s.	Mandatory content of application was determined to avoid problems due to insufficient legislation.[700]

[693] Available at: https://zakony.judikaty.info/predpis/zakon-220/2013/audit-dovodove-spravy.

[694] Annex no. 4 of Decree of Ministry of Health of The Slovak Republic no. 232/2014 Coll. regulating the procedure of the healthcare provider, the health insurance company and the Healthcare surveillance authority in the provision of cross-border healthcare, 11 August 2014 with later amendments.

[698] The Act no. 71/1967 Coll. on administrative proceedings (administrative procedure), 29 June 1967 with later amendments https://www.slov-lex.sk/pravne-predpisy/SK/ZZ/1967/71/.

[700] Explanatory memorandum to the Act no. 220/2013 Coll. which amending Act no. 580/2004 Coll. on health insurance and on the amendment of Act no. 95/2002 Coll. on Insurance and on Amendments to Certain Acts, as amended, and Amending Certain Acts of 26 June 2013 available at https://zakony.judikaty.info/predpis/zakon-220/2013/audit-dovodove-spravy.

	e) confirmation of the prescription and justification of the need to provide the proposed treatment by a clinical facility with the relevant specialisation; f) a calculation of expected costs for the planned healthcare abroad prepared by the foreign healthcare provider which will provide healthcare; g) confirmation of possible admission by the foreign healthcare provider after a positive decision of the health insurance company [695] The above Information is mandatory. The application form is available online on website of all of the health insurance companies..[696] Application can be submitted in paper form or in electronic form.[697]	Explanatory memorandum to the Act no. 220/2013 Coll. which amending Act no. 580/2004 Coll. on health insurance and on the amendment of Act no. 95/2002 Coll. on Insurance and on Amendments to Certain Acts, as amended, and Amending Certain Acts of 26 June 2013.[699]	
6. What (other) documentation has to be submitted in order to substantiate a PA request?	**Answer:** *If applicable, please specify:* *- What documents and what particulars are required;*	**Source(s):** Information from website of Všeobecná zdravotná poisťovňa, a.s.	Health Insurance Company require medical documentation and informed consent beyond legislation. These requirements are not regulated by law.

[695] para. 9f (1) of The Act no. 580/2004 Coll. on Health Insurance and on the amendment of Act no. 95/2002 Coll. on Insurance and on Amendments to Certain Acts, 21 October 2004 with later amendments.

[696] https://www.vszp.sk/poistenci/zdravotna-starostlivost-zahranici/planovana-liecba-cudzine.html, https://www.union.sk/liecba-v-zahranici/, https://www.dovera.sk/poistenec/potrebujem-poradit/zdravotna-starostlivost-v-cudzine/ako-dostat-spat-peniaze-za-osetrenie-v-cudzine.

[697] Zákon č. 71/1967 Z.z. z 29.06.1967 o správnom konaní (správny poriadok) (The Act no. 71/1967 Coll. on administrative proceedings (administrative procedure), 29 June 1967 with later amendments), available at https://www.slov-lex.sk/pravne-predpisy/SK/ZZ/1967/71/, paragraph 19 (1).

[699] Available at: https://zakony.judikaty.info/predpis/zakon-220/2013/audit-dovodove-spravy.

	- Whether there are requirements as to who has to issue the documents (e. g., a doctor contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA or any doctor); *- Whether the submission of the documentation is optional, mandatory, or recommended* Mandatory parts of the application required by the Health Insurance Company are: a) medical documentation on the current treatment related to the suggested scheduled health care;[701] b) informed consent on possible financial participation. - In case of special medical procedures (for example transplantation) a mandatory requirement of the application is the decision of the apposite commission of the transplant center allowing the inclusion of the patient on the list for transplantation.		
7. Are there any costs associated with the handling of the PA request? - *Direct costs (e.g., fixed costs for submitting or filing a PA request).* - *Indirect costs* (*e.g., translations, stamps, etc).*	**Answer:** *Direct costs:* None identified *Indirect costs:* If a patient submits a PA request in paper form or sends it through the post, the cost for stamps applies. Documents are accepted in foreign language.	**Source(s):** The Act no. 580/2004 Coll. of 21 October 2004 on Health Insurance and on the amendment of Act no. 95/2002 Coll. on Insurance and on Amendments to Certain Acts Decree of Ministry of Health of The Slovak Republic no. 232/2014 Coll. of 11 August 2014 regulating the procedure of the healthcare provider, the health insurance company and	Direct costs were not identified in legislation and not even on the Health Insurance Company websites. In our opinion this makes it easier for patients to apply and achieve their goal.

[701] Note of the National expert: according to the website of Všeobecná zdravotná poisťovňa, a.s., the health insurance company's medical examiner shall be able to comment the planned treatment, therefore all medical documentations related to that treatment shall be provided.

		the Healthcare surveillance authority in the provision of cross-border healthcare Information from website of Všeobecná zdravotná poisťovňa, a.s.	
8. Are there any specific **time requirements** linked to a PA request? (*e.g., time within which a requesting person must submit the PA application and/or time within which the requested body must take a decision on the PA request, etc.*).	**Answer:** - *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* Insurance providers take a decision within 15 working days. from receipt of complete application. In case of urgent and life-threatening diseases insurance provider take a decision without delay. [702] If the insurance provider makes a decision after the deadline, it may be fined for breach of legal obligations by Health Care Surveillance Authority.[703] If the application is not complete, the insurance provider sends the application back to the patient within 15 working days from acceptance of application. The insurance provider sets a deadline for rectifying the deficiencies. If the	**Source(s):** The Act no. 580/2004 Coll. of 21 October 2004 on Health Insurance and on the amendment of Act no. 95/2002 Coll. on Insurance and on Amendments to Certain Acts Information from website of Všeobecná zdravotná poisťovňa, a.s. The Act no. 71/1967 Coll. on administrative proceedings (administrative procedure), 29 June 1967 with later amendments The Act no. 581/2004 Coll. on Health Insurance Companies, Supervision of Health Care and on Amendments	The prior authorisation procedure is governed by The Act no. 71/1967 Coll. on administrative proceedings (law for general administrative procedures), 29 June 1967 with later amendments. So the PA application procedure rules are regulated. In our opinion it is for patient which can be sure that they will have decision about their application and within what time.

[702] para. 9f (4) of The Act no. 580/2004 Coll. on Health Insurance and on the amendment of Act no. 95/2002 Coll. on Insurance and on Amendments to Certain Acts, 21 October 2004 with later amendments.

[703] Zákon č. 581/2004 Z.z. z 21. októbra 2004 o zdravotných poisťovniach, dohľade nad zdravotnou starostlivosťou a o zmene a doplnení niektorých zákonov (The Act no. 581/2004 Coll. on Health Insurance Companies, Supervision of Health Care and on Amendments to Certain Acts, 21 October 2004 with later amendments) available at https://www.slov-lex.sk/pravne-predpisy/SK/ZZ/2004/581/20210501, (last accessed on 15 June 2021), Paragraph 64 (1).

	patient misses the deadline, the insurance provider suspends the PA proceedings.[704] Patients can appeal against the decision of Health Insurance Company within 20 working days from the date of delivery of the decision.[705]	to Certain Acts, 21 October 2004 with later amendment	
9. Are there **differences in the procedural/administrative requirements for requesting PA** based on, for instance, the type of treatment for which PA is requested, the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* In case of special medical procedures (for example transplantation) a mandatory requirement of the application is the decision of the apposite commission of the transplant center allowing the inclusion of the patient on the list for transplantation. In case of scheduled health care in connection with an accident at work or an occupational disease, the application should contain, in addition to all the information outlined above at Question 5 and 6, the accident record or occupational disease report.[706]	**Source(s):** Decree of Ministry of Health of The Slovak Republic no. 232/2014 Coll. of 11 August 2014 regulating the procedure of the healthcare provider, the health insurance company and the Healthcare surveillance authority in the provision of cross-border healthcare Information from website of Všeobecná zdravotná poisťovňa, a.s.	
10. Is there a specific PA form (i.e., form used for issuing/granting PA) and,	**Answer:**	**Source(s):** Decree of Ministry of Health of The Slovak Republic no. 232/2014 Coll.	

[704] para. 19 (3) of The Act no. 581/2004 Coll. on Health Insurance Companies, Supervision of Health Care and on Amendments to Certain Acts, 21 October 2004 with later amendments.
[705] The relevant health insurance company may decide on the appeal itself if it upholds the appeal in full; if it does not take a decision within 15 working days from the date of receipt of the appeal, it is obliged to submit the appeal within this period together with the results of the supplemented proceedings and with the file material to the Health Care Surveillance Authority. This body makes a decision within 15 working days from the date of receipt of the appeal (para. 9f (4) to (6) of The Act no. 580/2004 Coll. on Health Insurance and on the amendment of Act no. 95/2002 Coll. on Insurance and on Amendments to Certain Acts, 21 October 2004 with later amendments).
[706] para. 4 (2) of Decree of Ministry of Health of The Slovak Republic no. 232/2014 Coll. regulating the procedure of the healthcare provider, the health insurance company and the Healthcare surveillance authority in the provision of cross-border healthcare, 11 August 2014 with later amendments.

if the answer is positive, what form?	If the Health Insurance Company gives its consent, it will issue and send to the patient the following documents: a) S2 with a limited period of validity and a limited scope of planned care[707] b) DA1 with limited period of validity and a limited scope of planned care in case of work accident and occupational disease[708] These documents entitle patient to receive the planned treatment.	of 11 August 2014 regulating the procedure of the healthcare provider, the health insurance company and the Healthcare surveillance authority in the provision of cross-border healthcare		
11. Please list any other administrative requirements in your country in relation to the PA procedure for cross-border healthcare.	**Answer:** No other requirements were identified.	**Source(s):** N/A	N/A	
SECTION 2 REIMBURSMENT PROCEDURE(S)				
Questions	**Answer:**	**Sources**	**Does/do the identified requirement(s) also apply domestically? (i.e., is the requirement non-discriminatory?)**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the	**Answer:**	**Source(s):**	N/A	N/A

[707] Note of the National expert: this form is used to granting PA according to the Regulation and the Directive too.
[708] para. 4 (3) Decree of Ministry of Health of The Slovak Republic no. 232/2014 Coll. regulating the procedure of the healthcare provider, the health insurance company and the Healthcare surveillance authority in the provision of cross-border healthcare, 11 August 2014 with later amendments.

requirements related to reimbursement procedures for cross-border healthcare under Directive 201/24/EU?	1. The Act no. 580/2004 Coll. of 21 October 2004 on Health Insurance and on the amendment of Act no. 95/2002 Coll. on Insurance and on Amendments to Certain Acts 2. Decree of Ministry of Health of The Slovak Republic no. 232/2014 Coll. of 11 August 2014 regulating the procedure of the healthcare provider, the health insurance company and the Healthcare surveillance authority in the provision of cross-border healthcare	The Act no. 580/2004 Coll. of 21 October 2004 on Health Insurance and on the amendment of Act no. 95/2002 Coll. on Insurance and on Amendments to Certain Acts Decree of Ministry of Health of The Slovak Republic no. 232/2014 Coll. of 11 August 2014 regulating the procedure of the healthcare provider, the health insurance company and the Healthcare surveillance authority in the provision of cross-border healthcare		
2. Is this the same procedure as for reimbursement under the Social Security Coordination Regulations?	**Answer:** **Yes ☒ No ☐** The procedure under the Regulation and under the Directive is mainly the same with the exception of time limit for submitting reimbursement request. If the cost of the healthcare is reimbursement under the Regulation, patient must submit request within 1 year of the provision of Cross-Border Healthcare.[709] But under the Directive the patient must submit the request within 6 months of the provision of Cross-Border Healthcare.		N/A	N/A
3. What body is/are responsible of handling the reimbursement applications? (e.g., where and to whom reimbursement applications have to be submitted?)	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* Reimbursement application must be submitted to Health Insurance Company. [710]	**Source(s):** The Act no. 580/2004 Coll. of 21 October 2004 on Health Insurance and on the amendment of Act no. 95/2002 Coll. on Insurance and on Amendments to Certain Acts Decree of Ministry of Health of The Slovak Republic no. 232/2014 Coll. of 11 August 2014 regulating the	N/A	N/A

[709] para. 9b (14) of The Act no. 580/2004 Coll. on Health Insurance and on the amendment of Act no. 95/2002 Coll. on Insurance and on Amendments to Certain Acts, 21 October 2004 with later amendments (last accessed on 15 June 2021),
[710] para. 10 (1) of The Act no. 580/2004 Coll. on Health Insurance and on the amendment of Act no. 95/2002 Coll. on Insurance and on Amendments to Certain Acts, 21 October 2004 with later amendments

	In Slovakia, there are three health insurance companies (one state-owned and two private) and their systems are regulated by law. Všeobecná zdravotná poisťovňa, a.s. is the biggest Health Insurance Company in Slovakia.	procedure of the healthcare provider, the health insurance company and the Healthcare surveillance authority in the provision of cross-border healthcare		
4. Is there a specific application form/module which the person seeking reimbursement needs to submit?	**Answer:** *If yes, please specify:* *- What information is required;* *- Is the information mandatory, optional, or recommended?* *Is this application form/modules available online?* *- Does the form have to be submitted in paper or can it be submitted electronically?* Yes, there is specific form for the reimbursement application.[711] The application must contain: a) the insured person's name, surname, date of birth and birth ID number, if assigned; b) the address of the insured person's place of residence, c) the date of provision of healthcare, d) description of the disease, e) total amount of costs of cross-border healthcare, f) the method of sending the reimbursed amount of costs The above information is mandatory.	**Source(s):** The Act no. 580/2004 Coll. of 21 October 2004 on Health Insurance and on the amendment of Act no. 95/2002 Coll. on Insurance and on Amendments to Certain Acts Information from website of Všeobecná zdravotná poisťovňa, a.s. The Act no. 71/1967 Coll. on administrative proceedings (administrative procedure), 29 June 1967 with later amendments	**Yes** ☐ **No** ☒ *This system of reimbursement does not apply domestically. The national legislation does not regulate the procedures for reimbursement of costs for health care provided in the national territory as in Slovakia the costs related to health are anticipated by the State..*	The purpose and/or justification of the requirements were not identified in sources consulted (lack of literature and case law).

[711] Annex 9 and 10 of Decree of Ministry of Health of The Slovak Republic no. 232/2014 Coll. regulating the procedure of the healthcare provider, the health insurance company and the Healthcare surveillance authority in the provision of cross-border healthcare, 11 August 2014 with later amendments.

	The application form is available online on website of all of the health insurance companies and it can be submitted in paper form or in electronic form.[712]			
5. What (other) documentation has to be submitted in order to substantiate a reimbursement request?	**Answer:** *If applicable, please specify:* *- What documents are required;* *- Whether the submission of the documentation is optional, mandatory, or recommended.* Mandatory documents to be submitted with the reimbursement request are: a) original proof of payment (a document from a cash register, a cash receipt or a document the text of which includes confirmation of receipt of a sum, in the case of a cash payment, or an original counterfoil for a postal order, a copy of an account statement, the original of a debit order from a bank or branch of a foreign bank or the original of confirmation of a debit from a bank account, in the case a cashless payment) b) record of treatment, report on provided health care; c) an original of a document listing provided medical procedures such as an invoice, bill	**Source(s):** The Act no. 580/2004 Coll. of 21 October 2004 on Health Insurance and on the amendment of Act no. 95/2002 Coll. on Insurance and on Amendments to Certain Acts	**Yes** ☐ **No** ☒ *This system of reimbursement does not apply domestically. The national legislation does not regulate the procedures for reimbursement of costs for health care provided in the national territory as in Slovakia the costs related to health are anticipated by the State..*	The purpose and/or justification of the requirements were not identified in the sources consulted (lack of literature and case law).

[712] para. 19 (1) of The Act no. 71/1967 Coll. on administrative proceedings (administrative procedure), 29 June 1967 with later amendments.

	for medical procedures, prescription for medicines or medical devices[713] Foreign language documents are accepted even without an official translation.[714]			
6. Are there any costs associated with the handling of the reimbursement request? - *Direct costs (e.g., fixed costs for submitting or filing a reimbursement request, proportion deducted from the reimbursable amount).* - *Indirect costs* (*e.g., translations, stamps, etc).*	**Answer:** *Direct costs:* None identified. *Indirect costs:* If a patient submits reimbursement request in paper form a send it through the post, there is a cost for stamps.	**Source(s):** The Act no. 580/2004 Coll. of 21 October 2004 on Health Insurance and on the amendment of Act no. 95/2002 Coll. on Insurance and on Amendments to Certain Acts Decree of Ministry of Health of The Slovak Republic no. 232/2014 Coll. of 11 August 2014 regulating the procedure of the healthcare provider, the health insurance company and the Healthcare surveillance authority in the provision of cross-border healthcare Information from website of Všeobecná zdravotná poisťovňa, a.s.	**Yes** ☐ **No** ☒ *This system of reimbursement does not apply domestically. The national legislation does not regulate the procedures for reimbursement of costs for health care provided in the national territory as in Slovakia the costs related to health are anticipated by the State..*	Direct costs were not identified in legislation and not even on Health Insurance Company websites. In the opinion of the national legal expert this makes it easier for patients to apply and achieve their goal.
7. Are there any specific time requirements linked to a reimbursement request? (*e.g., time within which the reimbursement requests must be submitted and/or time within the requested body must handle the*	**Answer:** *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* The reimbursement request must be submitted within 6 months of the provision of Cross-Border	**Source(s):** The Act no. 580/2004 Coll. of 21 October 2004 on Health Insurance and on the amendment of Act no. 95/2002 Coll. on Insurance and on Amendments to Certain Acts	**Yes** ☐ **No** ☒ *This system of reimbursement does not apply domestically. The national legislation*	In the opinion of the national legal expert the time requirements allow the patients to be sure that they a decision about their application will be taken within a specific timeframe.

[713] para. 10 (2) of The Act no. 580/2004 Coll. on Health Insurance and on the amendment of Act no. 95/2002 Coll. on Insurance and on Amendments to Certain Acts, 21 October 2004 with later amendments.
[714] para. 10 (5) of The Act no. 580/2004 Coll. on Health Insurance and on the amendment of Act no. 95/2002 Coll. on Insurance and on Amendments to Certain Acts, 21 October 2004 with later amendments.

request and/or reimburse the costs, etc.).	Healthcare or the patient's right to reimbursement expires.[715] The insurance provider is obliged to reimburse the costs no later than 6 months after the receipt of the request for reimbursement.[716] If the Health Insurance Company makes a decision after the deadline, it may be fined for breach of legal obligations by the Health Care Surveillance Authority.[717]	The Act no. 581/2004 Coll. on Health Insurance Companies, Supervision of Health Care and on Amendments to Certain Acts, 21 October 2004 with later amendment	*does not regulate the procedures for reimbursement of costs for health care provided in the national territory as in Slovakia the costs related to health are anticipated by the State..*	
8. Are there any non-reimbursable thresholds, deductions *(except the deductions for administrative costs mentioned above) etc.?*	**Answer:** *If yes, please specify the thresholds.* No such thresholds identified. However, if the patient is a debtor on health insurance, the Health Insurance Company will reimburse him only for the costs of urgent health care.[718]	**Source(s):** The Act no. 580/2004 Coll. of 21 October 2004 on Health Insurance and on the amendment of Act no. 95/2002 Coll. on Insurance and on Amendments to Certain Acts	**Yes** ☒ **No** ☐ *This applies domestically, too.*	
9. In instances where a PA (or prior-notification) has already been issued, is a separate/simplified procedure available for requesting reimbursement? **applicable only if the country has a PA system.*	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* None identified.	**Source(s):** N/A	**Yes** ☐ **No** ☐	N/A

[715] para. 9d (8) of The Act no. 580/2004 Coll. on Health Insurance and on the amendment of Act no. 95/2002 Coll. on Insurance and on Amendments to Certain Acts, 21 October 2004 with later amendments.
[716] para. 10 (6) of The Act no. 580/2004 Coll. on Health Insurance and on the amendment of Act no. 95/2002 Coll. on Insurance and on Amendments to Certain Acts, 21 October 2004 with later amendments.
[717] County Court of Bratislava, ruling of 5 November 2019, file reference 5S/237/2017, *Všeobecná zdravotná poisťovňa a.s. v Healthcare surveillance authority* available at https://www.beck-online.sk/bo/document-view.seam?documentId=njzwwxzsgaytoxzvonptemzx&rowIndex=0#.
[718] para. 10 (6) of The Act no. 580/2004 Coll. on Health Insurance and on the amendment of Act no. 95/2002 Coll. on Insurance and on Amendments to Certain Acts, 21 October 2004 with later amendments.

10. Are there additional administrative/procedural requirements for reimbursement depending on, for instance, the type of treatment for which reimbursement is requested, or the profile of the insured person, or any other criterion?	**Answer:** None identified.	**Source(s):** N/A	**Yes** ☐ **No** ☐	N/A
11. Please list any other administrative requirements in your country in relation to the procedures of reimbursement of cross-border healthcare.	**Answer:** No other requirements were identified.	**Source(s):** N/A	**Yes** ☐ **No** ☐	N/A

Part 2: Checklist for verification with national/regional body

Name of the body: Health Care Surveillance Authority
Country/Region: Slovak Republic
Date of verification call: 14/06/2021

Template for the Data Collection	**Aspects to be verified** *Tick the boxes if the information in the template for the data collection has been verified and/or complemented by the national body*		**Comments** *Include any additional comments and/or information provided by the contacted body*
Section 1 – Prior Authorisation			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Justification/purpose of the identified requirement(s) (Column 4)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	No additional comments. The feedback provided during the verification call was incorporated in the questionnaire – Section 1.
Section 2 - Reimbursement			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Whether the requirement applies domestically (Discriminatory assessment) (Column 4) ▪ Justification/purpose of the identified requirement(s) (Column 5)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	No additional comments. The feedback provided during the verification call was incorporated in the questionnaire – Section 2.

SLOVENIA – COUNTRY REPORT

Part 0: Preliminary Assessment

1. **Please indicate whether the rules governing the administrative procedures/requirements for requesting PA and reimbursement under Directive 2011/24/EU in your country are set out at:**

A. National level ☒

B. Decentralised/regional/local level ☐

In case (1.B): Please indicate the two most relevant jurisdictions in your country (i.e., in terms of population):

Region/jurisdiction: 1:

Region/jurisdiction 2:

NOTE: In case (1.B) the template for the data collection (Part 1) should be completed twice, once for each of the two most relevant regions/jurisdiction indicated above.

2. **Please indicate the national body best suited to verify the accuracy of the information collected in Part 1, and justify your selection.**

Depending on the characteristics of your national healthcare system, the relevant body may be: a) *the national social security body*; or b) *an insurance fund*. In the latter case, please indicate the most representative fund (e.g., the one with the highest number of affiliations).

Body to be contacted for Task 2: Zavod za zdravstveno zavarovanje Slovenije or short and hereinafter: ZZZS (English: Health Insurance Institute of Slovenia) Address: Miklošičeva cesta 24, 1000 Ljubljana**;** Website: https://www.zzzs.si/

(In case 1.B, please indicate two relevant bodies, one respectively for each Region/jurisdiction)

Reasons for Selection: The ZZZS is a professional institution which exercises its powers in the field of health care. It is carrier and provider of compulsory health insurance in the Republic of Slovenia.

Part 1: Questionnaire

*__Note 1__: In cases where administrative requirements are set out in the legislative/regulatory framework at decentralised/regional/local level, please complete the template for the data collection twice, once for each of the two most relevant regions/jurisdictions (e.g., in terms population).

__*Note 2__: Setting out a Prior Authorisation (PA) system is optional for Member States. Should your country not have a system of PA in place under Directive 2011/24/EU, Section 1 will not need to be completed.

SECTION 1 PRIOR AUTHORISATION PROCEDURE(S)			
Questions	**Answer**	**Sources**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to PA procedures for a cross-border healthcare under Directive 2011/24/EU?	**Answer:** The requirements related to PA procedures for a cross-border healthcare under Directive 2011/24/EU are regulated in Slovene: a) *Health Care and Health Insurance Act* (especially Articles from 44.a to 44.e; Article 77.b); b) *Rules on Compulsory Health Insurance* (especially Article from 133 to 136) c) *Order on the list of health services, for which prior authorisation is required*	**Source(s):** Health Care and Health Insurance Act (Slovene: Zakon o zdravstvenem varstvu in zdravstvenem zavarovanju)[719] Rules on Compulsory Heath Insurance (Slovene: Pravila	N/A

[719] Zakon o zdravstvenem varstvu in zdravstvenem zavarovanju (Slovene official abbreviation: ZZVZZ; English name: Health Care and Health Insurance Act; adopted by National Assembly on 12 February 1992 with later amendments; published: Uradni list RS (Official Journal), št. (No.) 72/06 – uradno prečiščeno besedilo (official consolidated version), 114/06 – ZUTPG, 91/07, 76/08, 62/10 – ZUPJS, 87/11, 40/12 – ZUJF, 21/13 – ZUTD-A, 91/13, 99/13 – ZUPJS-C, 99/13 – ZSVarPre-C, 111/13 – ZMEPIZ-1, 95/14 – ZUJF-C, 47/15 – ZZSDT, 61/17 – ZUPŠ, 64/17 – ZZDej-K, 36/19, 189/20 – ZFRO, 51/21. Available at: http://pisrs.si/Pis.web/pregledPredpisa?id=ZAKO213 (last accessed on 18 June 2021).

	The *Order on the list of health services, for which prior authorisation is required* (see FN. 3) establishes a list of highly specialised and expensive medical infrastructure or medical equipment used for medical services, for which, as of 8 February 2014, prior approval of the ZZZS is mandatory as a condition for claiming the right to reimbursement of costs under Article 44c of the Health Care and Health Insurance Act. The list includes the following: - scintillation camera with or without positron emission coincidence detector, - a positron camera, - positron emission tomography, - computed tomography, - hyperbaric chamber, - a nuclear magnetic resonance imaging device for clinical use, - a nuclear magnetic resonance spectrometry device for clinical use.	obveznega zdravstvenega zavarovanja)[720] Order on the list of health services, for which prior authorisation is required (Slovene: Odredba o seznamu zdravstvenih storitev, za katere se zahteva predhodna odobritev)[721]	
2. Is this the same procedure as for PA under the Social	**Answer:** **Yes ☒ No ☐**		N/A

[720] Pravila obveznega zdravstvenega zavarovanja (Slovene official abbreviation: POZZ; English Name: Rules on Compulsory Health Insurance. Adopted by National Assembly on 24 November 1994 with later amendments. Published: Uradni list RS, št. 79/94, 73/95, 39/96, 70/96, 47/97, 3/98, 3/98, 51/98 – odl. US, 73/98 – odl. US, 90/98, 6/99 – popr., 109/99 – odl. US, 61/00, 64/00 – popr., 91/00 – popr., 59/02, 18/03, 30/03, 35/03 – popr., 78/03, 84/04, 44/05, 86/06, 90/06 – popr., 64/07, 33/08, 7/09, 88/09, 30/11, 49/12, 106/12, 99/13 – ZSVarPre-C, 25/14 – odl. US, 25/14, 85/14, 10/17 – ZČmIS, 64/18, 4/20, 42/21 – odl. US, 61/21. Available at: http://www.pisrs.si/Pis.web/pregledPredpisa?id=PRAV3562 (last accessed on 19 June 2021).

[721] Odredba o seznamu zdravstvenih storitev, za katere se zahteva predhodna odobritev (English name Order on the list of health services, for which prior authorisation is required)**.** Adopted on 30 December 2012 by Minster of Health. Published: Uradni list RS, št. 6/14**.** Available at: http://www.pisrs.si/Pis.web/pregledPredpisa?id=ODRE2260 (last accessed on 18 June 2021).

Security Coordination Regulations?			
3. What body is in charge of handling the PA applications? *(e.g., where and to whom PA applications have to be submitted?)*	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* The insured person submits an application for approval of planned treatment abroad (PA application) to the ZZZS, Regional Unit Ljubljana, Miklošičeva cesta 24, 1507 Ljubljana.	**Source(s):** Health Care and Health Insurance Act - Article 77.b(2-3)	N/A
4. Who is entitled to apply for PA? *(e.g., can the patients apply themselves, or is treating doctor filing/partially filling the request, etc.)*	**Answer:** *If there is a national doctor involved, is there a requirement that this doctor is contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA?* The application for PA must be submitted by the **insured person** to the ZZZS. The doctor is not involved in the application itself. An application for PA may also be submitted by the insured person's **legal representative or proxy** on behalf of the insured person claiming health care abroad (e. g., parents for a child, guardian for a ward).[722]	**Source(s):** Health Care and Health Insurance Act - Articles 44a(1), 44.b(1), 44.c(1) Rules on compulsory health insurance – Articles 135(1), 135.a(1), 135.b(1)	In the compulsory health insurance scheme in Slovenia, insured persons are the insured persons themselves and the family members insured through them. (Article 14 of the Health Care and Health Insurance Act). Therefore, also family members, who are not directly insured, can also apply for PA. Following Article 44.a of the Health Care and Health Insurance Act, the insured person has the right to an examination, investigation or treatment abroad if the possibilities of treatment in the Republic of Slovenia have been exhausted and the examination, investigation or treatment abroad can reasonably be expected to cure or improve the condition of the insured person's health or to prevent further deterioration of his or her health.

[722] To be entitled to treatment abroad based on a referral issued by a doctor in Slovenia, the person must meet the following conditions: must have health insurance in Slovenia (so-called insured person);must have a referral issued by a doctor in Slovenia before going abroad for treatment; must have received medical services abroad that

			No further justification/purpose for the requirement was identified in the sources consulted.
5. Is there a specific application form/module which the person seeking PA needs to submit?	**Answer:** *If yes, please specify:* *a) What information is required;* *b) Is the information mandatory, optional, or recommended?* *c) Is this application form/modules available online?* *Does the form have to be submitted in paper or can it be submitted electronically?* Yes, in Slovenia we have **three** specific application forms, which the person seeking for PA must use:[723] a) an application form for a planned medical treatment abroad due to exhausted treatment options in Slovenia. This application could be used for planned medical treatments in all States (not just EU member states, but also for example USA, Canada). This reimbursement is based on national regulation.	**Source(s):** Health Care and Health Insurance Act– Article 44.a for a) Health Care and Health Insurance Act – Article 44.b for b) Health Care and Health Insurance Act – Article 44.c for c); *Order on the list of health services, for which prior authorisation is required* Rules on compulsory health insurance – Articles 135 to 136 and 238a.	No justification/purpose for the requirement was identified in the sources consulted.

are covered by compulsory insurance Slovenia, receive treatment in another EU country; must have prior authorisation from the ZZZS if he/she is going to receive health services abroad that require an overnight stay in a hospital; must have prior authorisation from the ZZZS, if he/she will receive health services abroad that are on the list for prior authorisation. (Rules on compulsory health insurance – Article 228.a)

[723] Information also available at the NCP portal: http://www.nkt-z.si/wps/portal/nktz/home/abroad/planned/!ut/p/z1/tc5NjsIwDAXgq5gFS2QDFYJlQdDhf4RGqGSDQkkhA01oYmCY05Oy4gIsbX96zygwRWHkTR8ka2vkOcwb0dlGzeE4aS9p3O2NiGJaf_2Mvnst6jdxguId0GIVQDKl9WwYESVRlaB_y1LEKDJrWP0xpubEjf865bL0dboflVOQSQMacm32oE1uXfH6AKQHthAIBxWALEAZ1nxW--rglC52V-dVEbZgc8isZ191ttx8MD-guEg-NqpETD9QdDmJ3eMe154iE2zu/

	b) an application form for a planned medical treatment abroad due to excessive waiting period in Slovenia. This application form could be used for planned medical treatment in an EU member state or EEA member state or Sweiss Confederation. This reimbursement is based on the Regulation 883/2004; **c) an application form for a planned medical treatment abroad on the basis of a medical referral from a doctor in Slovenia. This application could be used just for reimbursement cost if the medical treatment was planned and performed in an EU member state. This reimbursement is based on Directive 2011/24/EU.** **In the light of the above, only the third application form will be considered for the purpose of the present questionnaire.** **What information is required*?*** **Adc)** *I. Information on the applicant(s)*: Name and surname; Date of birth; Address (place, street and house number, postcode and postal address); Supplementary insurance information: name of the insurance company and policy no.; *II. Information on the insured person if he/she is not the applicant (to be completed only if the applicant is not an insured person who has received health services abroad)*: Name and surname; Date of birth; Address:	All application forms are available at https://zavarovanec.zzzs.si/wps/portal/portali/azos/pravice_zdravstvenih_storitev/pravice_zdravljenje_tujina/	

	place, street and house number, postcode and postal address; relationship to the insured person (legal representative, proxy); power of attorney provided (circle as appropriate): YES-NO-NOT REQUIRED *III. Information of a referral*: Type of a referral posting (circle as appropriate): a. inpatient treatment, b. medical services requiring the use of highly specialised and expensive medical infrastructure or medical equipment ('*Order on the list of health services for which prior authorisation is required*'); Country of referral; Provider in another Member State of the European Union; Explanation (Health Care and Health Insurance Act – Article 44.c). **Is the information mandatory, optional, or recommended?** Yes, all information is mandatory (Rules on compulsory health insurance – Article 238a.) **Is this application form/modules available online?** Yes, the application forms are available online (see website of Health Insurance institute of Slovenia: https://zavarovanec.zzzs.si/wps/portal/portali/azos/pravice_zdravstvenih_storitev/pravice_zdravljenje_tujina/). **Does the form have to be submitted in paper or can it be submitted electronically?** The application forms can be submitted:		

	a) by mail to address: ZZZS, Miklošičeva cesta 24, 1000 Ljubljana; b) by email: OELJ@zzzs.si; c) or personally to the following address: Mala ulica 3, 1000 Ljubljana.		
6. What (other) documentation has to be submitted in order to substantiate a PA request?	**Answer:** *If applicable, please specify:* - *What documents and what particulars are required;* - *Whether there are requirements as to who has to issue the documents (e. g., a doctor contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA or any doctor);* - *Whether the submission of the documentation is optional, mandatory, or recommended.* Yes, in all three cases there is a prescribed documentation that has to be submitted in order to substantiate a PA request. In the light of what indicated under Question 5, only the third application form will be considered for the purpose of the present questionnaire. **What documents and what particulars are required?** **a)** an application form for a planned medical treatment abroad on the basis of a medical referral from a doctor in Slovenia:	**Source(s):** Rules on compulsory health insurance – Articles 135a to 135.c and 238a. to 238.c).	The documentation that neeeds to be added to the PA application must be official documentation which must be provided by the doctor who carries out his or her medical activity in Slovenia. This could be a doctor in the public or private sector.

	i) an indication of the treatment the insured person wants to receive in another Member State of the European Union; ii) medical documentation of previous treatment in the Republic of Slovenia; iii) documentation showing that the insured person is entered in a waiting list; iv) documentation showing the date fixed for the treatment in the Republic of Slovenia and with which provider; v) at the request of the ZZZS, other documentation which the ZZZS needs in order to take a decision on the PA of hospital medical services in another Member State of the European Union (Rules on compulsory health insurance – Article 238.c(1) **Whether there are requirements as to who has to issue the documents (e. g., a doctor contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA or any doctor).** An insured person may search for PA based on a previously issued referral from a doctor in the Republic of Slovenia for specialist outpatient medical services, except for specialist outpatient medical services that the insured person may receive without a referral in the public health network the Republic of Slovenia.		

	Whether the submission of the documentation is optional, mandatory, or recommended. The submission of the documentation is **mandatory** (Rules on compulsory health insurance – Articles 135a to 135.c and 238a. to 238.c).		
7. **Are there any costs** associated with the handling of the PA request? - *Direct costs (e.g., fixed costs for submitting or filing a PA request).* - *Indirect costs* (*e.g., translations, stamps, etc).*	**Answer:** ***Direct costs**:* None identified. Applications are administrative fee-free. ***Indirect costs**:* For example: *translations of documentation, costs of copying of medical documentation, stamps, professional support by the lawyer or other expert…)*	**Source(s):** Administrative Fees Act (Slovene: Zakon o upravnih taksah[724]) - Article 28(pt. 12)	No justification/purpose for the requirement was identified in the sources consulted.
8. Are there any specific **time requirements** linked to a PA request? (*e.g., time within which a requesting person must submit the PA application and/or time within which the requested body must take a decision on the PA request, etc.*).	**Answer:** *- If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* Following the Slovene General Administrative Procedure Act, the time limit for issuing and serving a decision is as soon as possible, but no later than two months, starting from the date of submission of a **complete application**.	**Source(s):** Zakon o splošnem upravnem postopku[725] - Article 222(1-2)	*No justification/purpose for the requirement was identified in the sources consulted.*

[724] Zakon o upravnih taksah (hereinafter: ZUT; English: Administrative Fees Act). Adopted by the National Assembly on 26 Januar 2000 with later amendments. Published: Uradni list RS, št. 106/10 – uradno prečiščeno besedilo, 14/15 – ZUUJFO, 84/15 – ZZelP-J, 32/16, 30/18 – ZKZaš, 189/20 – ZFRO. Available at: http://pisrs.si/Pis.web/pregledPredpisa?id=ZAKO2146 (last accessed on 19 June 2021).

[725] Zakon o splošnem upravnem postopku (Slovene official abbrevation: ZUP; English General Administrative Procedure Act). Adopted by the National Assembly on 16 September 1999 with later amendments. Published: Uradni list RS, št. 24/06 – uradno prečiščeno besedilo, 105/06 – ZUS-1, 126/07, 65/08, 8/10, 82/13, 175/20 – ZIUOPDVE. Available at: http://pisrs.si/Pis.web/pregledPredpisa?id=ZAKO1603 (last accessed on 19 June 2021).

	If the ZZZS does not issue an authorisation decision and does not deliver it to the applicant within two months of receipt of his complete application, the applicant has the right to appeal. In this case, it is considered as if his/her application had been rejected.	ZUP – Article 222(4)	
9. Are there **differences in the procedural/administrative requirements for requesting PA** based on, for instance, the type of treatment for which PA is requested, the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* None identified.	**Source(s):** *Order on the list of health services, for which prior authorisation is required* – Article 2	
10. Is there a specific PA form (i.e., form used for issuing/granting PA) and, if the answer is positive, what form?	**Answer:** In accordance with the ZUP, the PA will be issued as an administrative decision. It must be in written form. The written administrative decision on PA shall comprise: an introduction, a title, an operative part (dispositif), a statement of reasons, a statement of the remedy, and, if it is issued in physical form, the signature of the official and the stamp of the authority, or, if it is issued in electronic form, the secure electronic signatures of the official and of the authority, authenticated by a qualified certificate; if the secure electronic signature of the official is authenticated by a qualified certificate which also contains the indication of the authority, the secure electronic signature of the authority shall not be	**Source(s):** ZUP – Article 201(2)	

	required. In cases for which the law or a regulation issued pursuant to the law so provides, the individual parts of the decision shall not be mandatory. If the decision is produced automatically, it may have a facsimile instead of a signature and a stamp ZUP – Article 201(3)).			
11. Please list any other administrative requirements in your country in relation to the PA procedure for cross-border healthcare.	**Answer:** None identified.	**Source(s):** N/A	N/A	
SECTION 2 REIMBURSMENT PROCEDURE(S)				
Questions	**Answer:**	**Sources**	**Does/do the identified requirement(s) also apply domestically? (i.e., is the requirement non-discriminatory?)**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to reimbursement procedures for cross-border healthcare under Directive 201/24/EU?	**Answer:** The requirements related to reimbursement procedures for a cross-border healthcare under Directive 2011/24/EU are regulated in Health Care and Health Insurance Act.	**Source(s):** Zakon o zdravstvenem varstvu in zdravstvenem zavarovanju – Health Care and Health Insurance Act (see Fn. 1) Pravila obveznega zdravstvenega	N/A	N/A

		zavarovanja – Rules on compulsory health insurance (see FN. 2).		
2. Is this the same procedure as for reimbursement under the Social Security Coordination Regulations?	**Answer:** **Yes ☒ No ☐**		N/A	N/A
3. What body is/are responsible of handling the reimbursement applications? (e.g., where and to whom reimbursement applications have to be submitted?)	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* The insured person submits a reimbursement application to any of the regional offices of the ZZZS (the PA application must be forwarded to the ZZZS in Ljubljana).	**Source(s):**	N/A	N/A
4. Is there a specific application form/module which the person seeking reimbursement needs to submit?	**Answer:** *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?*	**Source(s):** Health Care and Health Insurance Act - Article 44.a Health Care and Health Insurance Act – Article 44.a(2) Health Care and Health Insurance Act – Article 44.b(2)	**Yes ☐** **No ☒** *Slovenia has a social health insurance system based on a single public insurer, the Health Insurance Institute of Slovenia, which provides universal compulsory health insurance. Patients don't pay up front and therefore there is no comparable*	

	Yes, in Slovenia there are **three** specific application forms, which the person seeking for reimbursement must use: **a)** an aapplication form for reimbursement of costs of planned medical treatment abroad (and travel costs) due to exhausted treatment options in Slovenia. This application could be used for planned medical treatments in all States (not just EU member states, but also for example USA, Canada). This reimbursement is based on national regulation. **b)** an application form for reimbursement of costs of planned medical treatment abroad (and travel costs) in an EU Member State, EEA Member State or Swiss Confederation due to excessive waiting period in Slovenia. This application form could be used for planned medical treatment in an EU member state or EEA member state or Swiss Confederation. This reimbursement is based on the Regulation 883/2004**;** **c)** an application form for **reimbursement of costs of planned medical treatment in another EU Member State** on the basis of a medical referral from a doctor in Slovenia**. This application could be used just for reimbursement cost if the medical treatment was planned and performed in an EU member state. This reimbursement is based on Directive 2011/24/EU.**	Health Care and Health Insurance Act – Article 44.c Reimbursement form available online: *https://zavarovanec.zzzs.si/wps/portal/portali/azos/pravice_zdravstvenih_storitev/pravice_zdravljenje_tujina/*	*reimbursement procedure for reimbursement.* *According to the national legal expert the requirements for cross-border reimbursement do not appear to be discriminatory nonetheless.*	

	In the light of the above, only the third application form will be considered for the purpose of the present questionnaire. **What information is required*?*** **Adc)** *Information about the basis for the reimbursement* a) a previously issued ZZZS decision for the authorised treatment in another Member State of the European Union (No. and date of a decision), b) *a previously issued referral for specialist outpatient treatment, c) a previously issued ZZZS decision on spa treatment (No. and date of a decision).* *I.Information on the insured person who has received healthcare in the Member State of the European Union:* Name and surname; Date of birth; Address (place, street and house number, postcode and postal address). *II.Information on the insured person if he/she is not the applicant (to be completed only if the applicant is not an insured person who has received health care services in another Member State of the European Union)*: Name and surname; Date of birth; Address: place, street and house number, postcode and postal address; relationship to the insured person (legal representative, proxy); power of attorney provided (circle as appropriate): YES-NO-NOT REQUIRED *III. Information on the country of claim*: Country of claim; Amount of the claim for reimbursement of health services; Type of			

	health service provided in another Member State of the European Union (circle as appropriate): a. examination, b. investigation, c. hospital treatment, d. medical services requiring the use of highly specialised and expensive medical infrastructure or medical equipment, d. specialised outpatient treatment, e. spa treatment; information how and when the applicant contacted a healthcare provider in another EU Member State and the proof of the latter. *IV. Information of the Bank Account to which the reimbursement of health care costs should be paid*: Transaction Account Holder (name and surname); number of the bank account; Name of the bank with which the bank account is opened. (Health Care and Health Insurance Act - Article 44.c) **Is the information mandatory, optional, or recommended?** All the information listed above are mandatory. If they are not included, the application is treated as an incomplete application. **Is this application form/modules available online?** Yes, all three reimbursement forms are available online:			

	https://zavarovanec.zzzs.si/wps/portal/portali/azos/pravice_zdravstvenih_storitev/pravice_zdravljenje_tujina/ **Does the form have to be submitted in paper or can it be submitted electronically?** The reimbursement forms (signed and with all needed documents) have to be submitted to the regional units or branches of the ZZZS: a) by post; b) by e-mail; or c) personally.			
5. What (other) documentation has to be submitted in order to substantiate a reimbursement request?	**Answer:** *If applicable, please specify:* - *What documents are required;* - *Whether the submission of the documentation is optional, mandatory, or recommended.* Yes, also other documentation has to be submitted. ***What documents are required;*** **Application for reimbursement of the costs of planned medical treatment in another Member State of the European Union** - mandatory documentation to the application for the reimbursement: 1. on the basis of a previously issued decision of the Slovene ZZZS authorising	**Source(s):** Health Care and Health Insurance Act – Article 44.c	**Yes** ☐ **No** ☒ Cfr. Question 4 above.	

	treatment in another Member State of the European Union: - original invoice and proof of payment of the invoice, - appropriate documentation of the treatment provided in another Member State of the European Union, - details of the account number and the organisation holding the bank account to which the payment should be made. 2. on the basis of a previously issued referral for specialist outpatient treatment: - proof that the insured person has been referred for specialist outpatient services by a personal or referring doctor from Slovenia, - the original invoice and proof of payment of the invoice, - appropriate documentation of the treatment provided; and - details of the account number and the organisation holding the bank account to which the payment should be made. 3. on the basis of a previously issued decision of the Slovene ZZZS on spa treatment: - original invoice and proof of payment of the invoice, - appropriate documentation of the treatment provided; and - details of the account number and the organisation holding the bank account to which the payment should be made.			

	Whether the submission of the documentation is optional, mandatory, or recommended. The submission of above listed documentation is mandatory. If any of the documentation is not submitted, the reimbursement application is treated as an incomplete application.			
6. Are there any costs associated with the handling of the reimbursement request? - *Direct costs (e.g., fixed costs for submitting or filing a reimbursement request, proportion deducted from the reimbursable amount).* - *Indirect costs* (*e.g., translations, stamps, etc).*	**Answer:** ***Direct costs:*** All three applications are administrative fee-free. ***Indirect costs:*** must be paid by the applicants (e. g. translations of the medical record, copying costs, postal services costs, professional support by the lawyer or other expert……)	**Source(s):** ZUT (see FN. 4) – Article 222(1-2)	**Yes** ☐ **No** ☒ Cfr. Question 4 above.	
7. Are there any specific time requirements linked to a reimbursement request? (*e.g., time within which the reimbursement requests must be submitted and/or time within the requested body must handle the*	**Answer:** *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* In accordance with the Slovene ZUP, the time limit for issuing and serving a decision is as soon as possible, but no later than 2	**Source(s):** ZUP (see FN. 5) - Article 222(1-2)	**Yes** ☐ **No** ☒ Cfr. Question 4 above.	

request and/or reimburse the costs, etc.).	months, starting from the date of submission of a **complete application**. If the ZZZS does not issue a decision on the reimbursement and does not deliver it to the applicant within two months of from the receiving his complete application, the applicant has the right to appeal. In this case, it is considered as if his/her application had been rejected.	ZUP – Article 222(4)		
8. Are there any non-reimbursable thresholds, deductions *(except the deductions for administrative costs mentioned above) etc.?*	**Answer:** *If yes, please specify the thresholds* There are no specific non reimbursable thresholds, besides the general rule by which the average price of healthcare services in the Republic of Slovenia is taken into account for reimbursement purposes. If this is higher, the amount taken into account is the cost of the service in another EU country. The ZZZS reimburses the insured person part of the costs due to him/her under the **compulsory health insurance**, and the difference up to the full value is reimbursed by the insurance company with which the insured person may have ~~has~~ a **supplementary health insurance**.	**Source(s):** Health Care and Health Insurance Act – Article 44.c(3)	**Yes** ☒ **No** ☐ Cfr. Question 4 above.	The insured person is not entitled to reimbursement for listed treatments if they are carried out abroad: - health services in primary health care, - health services in the field of long-term care, including non-acute hospital treatment and treatment and care in social welfare institutions, - health services in the field of procurement and transplantation of human body parts, - health services in the field of screening programmes, - the cohabitation of a parent, foster parent, guardian, spouse or cohabiting partner, when cohabiting with the child of his/her spouse or

				cohabiting partner, in a health care institution or health resort, - medical devices which are the subject of a loan for the purposes of medical treatment, care and rehabilitation at home, - a trained guide dog to which a blind person is entitled, - travel expenses and accompaniment (Health Care and Health Insurance Act – Article 44.c(3).
9. In instances where a PA (or prior-notification) has already been issued, is a separate/simplified procedure available for requesting reimbursement? **applicable only if the country has a PA system.*	**Answer:** *If yes, please describe the simplified procedure.* Yes, the procedure for requesting reimbursement is simplified as the insured person has already provided all the necessary documentation to establish the eligibility for the PA. Therefore, in this case, only the evidence of the procedure needs to be submitted and not the complete documentation. The ZZZS will then decide only about the reimbursement.	**Source(s):**	**Yes** ☐ **No** ☒ Cfr. Question 4 above.	No justification/purpose for the requirement was identified in the sources consulted.
10. Are there additional administrative/proced	**Answer:**	**Source(s):**	**Yes** ☐	No justification/purpose for the requirement was

ural requirements for reimbursement depending on, for instance, the type of treatment for which reimbursement is requested, or the profile of the insured person, or any other criterion?	*If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* None identified under the Directive. [726]	Rules on compulsory health insurance – Article 158	**No** ☒ Cfr. Question 4 above.	identified in the sources consulted.
11. Please list any other administrative requirements in your country in relation to the procedures of reimbursement of cross-border healthcare.	**Answer:** No additional administrative requirements identified.	**Source(s):** N/A	**Yes** ☐ **No** ☐	N/A

[726] The special application for reimbursement of costs of medical services during a temporary stay abroad (for emergency and unplanned medical treatment abroad) is a special application. Additional to general Information on the insured person who has received emergency and unplanned medical treatment abroad (Name and surname; Date of birth; Address (place, street and house number, postcode and postal address), the applicant has to define also the purpose of his/her staying abroad (work, professional training or study, business or private travel, permanent residence,…) and the method of claiming health services abroad (based on the European Health Insurance Card or a certificate temporarily replacing the European Health Insurance Card). This special application procedure appears to relate to reimbursement claims according to the Social Security Coordination Regulations.

Part 2: Checklist for verification with national/regional body

Name of the body: Zavod za zdravstveno zavarovanje Slovenije, Miklošičeva cesta 24, 1507 Ljubljana
Country/Region: Slovenija
Date of verification call: 22/06/2021

Template for the Data Collection	**Aspects to be verified** *Tick the boxes if the information in the template for the data collection has been verified and/or complemented by the national body*		**Comments** *Include any additional comments and/or information provided by the contacted body*
Section 1 – Prior Authorisation			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Justification/purpose of the identified requirement(s) (Column 4)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	Where relevant, feedback received has been incorporated in the answers to the questions of Part 1 - Section 1.
Section 2 - Reimbursement			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Whether the requirement applies domestically (Discriminatory assessment) (Column 4) ▪ Justification/purpose of the identified requirement(s) (Column 5)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	Where relevant, feedback received has been incorporated in the answers to the questions of Part 1 - Section 2.

SPAIN – COUNTRY REPORT

Part 0: Preliminary Assessment

1. **Please indicate whether the rules governing the administrative procedures/requirements for requesting PA and reimbursement under Directive 2011/24/EU in your country are set out at:**

A. National level ☐

B. Decentralised/regional/local level ☒

In case (1.B): Please indicate the two most relevant jurisdictions in your country (i.e., in terms of population)*:

Region/jurisdiction 1: **Catalunya**

Region/jurisdiction 2: **Galicia**

NOTE: In case (1.B) the template for the data collection (Part 1) should be complete twice, once for each of the two most relevant regions/jurisdiction indicated above.

***NOTE BY LEGAL EXPERT:** Directive 2011/24/EU was transposed in Spain by the Royal Decree 81/2014[727] (national level), which gives Autonomous Communities (regional level) competences to regulate the procedures to request PA and reimbursement of costs for cross-border healthcare under Directive 2011/24/EU. However, not all Autonomous Communities exercised the delegated powers to regulate these administrative procedures/requirements. In the two most populated regions (Andalucía and Catalunya), for example, no such regional regulation was enacted. For this reason, for the purpose of this research and for a matter of completeness, the Autonomous Communities of Catalunya and Galicia were selected for the completion of the templates for the data collection (despite Galicia not being the most populated region). This selection was made in consideration of the fact that, on one hand, Catalunya (second most populated region in the country) provides an example of a region which did not regulate the administrative procedures/requirements on a regional level and, therefore, follows the national rules established in the Royal Decree 81/2014; and, on the other hand, Galicia provides an example of an Autonomous

[727] Real Decreto 81/2014, de 7 de febrero, por el que se establecen normas para garantizar la asistencia sanitaria transfronteriza, y por el que se modifica el Real Decreto 1718/2010, de 17 de diciembre, sobre prescripción médica y órdenes de dispensación (Royal Decree 81/2014, of February 7, which establishes rules to guarantee cross-border healthcare, and which modifies Royal Decree 1718/2010, of December 17, on medical prescription and dispensing orders), published in: «BOE» no. 34, of February 8, 2014, pages 10915 to 10948 (34 pages), available at https://www.boe.es/diario_boe/txt.php?id=BOE-A-2014-1331 (last accessed on 10 June 2021).

Community that did regulate on a regional level these aspects. Moreover, it should be noted that given that the most populated region of Andalucía also did not regulate the matters at regional level, it can be concluded that the data collected with respect to Catalunya is applicable in Andalucía as well.

2. **Please indicate the national body best suited to verify the accuracy of the information collected in Part 1, and justify your selection.**
Depending on the characteristics of your national healthcare system, the relevant body may be: a) *the national social security body*; or b) *an insurance fund*. In the latter case, please indicate the most representative fund (e.g., the one with the highest number of affiliations).

Body to be contacted for Task 2:

- For Catalunya: CatSalut: Catalan Health Service

- For Galicia: SX Health planning and insurance **(**Galician Health Department)

(In case 1.B, please indicate two relevant bodies, one respectively for each Region/jurisdiction)

Reasons for Selection: both bodies in each Autonomous Community are in charge of healthcare and, specifically, of cross-border healthcare.

Part 1: Questionnaire

*__Note 1__: In cases where administrative requirements are set out in the legislative/regulatory framework at decentralised/regional/local level, please complete the template for the data collection twice, once for each of the two most relevant regions/jurisdictions (e.g., in terms population).

__*Note 2__: Setting out a Prior Authorisation (PA) system is optional for Member States. Should your country not have a system of PA in place under Directive 2011/24/EU, Section 1 will not need to be completed.

Questionnaire 1. Catalonia

SECTION 1 PRIOR AUTHORISATION PROCEDURE(S)			
Questions	**Answer**	**Sources**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to PA procedures for a cross-border healthcare under Directive 2011/24/EU?	Answer: Royal Decree 81/2014, of February 7, which establishes rules to guarantee cross-border healthcare, and which modifies Royal Decree 1718/2010, of December 17, on medical prescription and dispensing orders (Royal Decree 81/2014).[728] In particular:	Source(s): Royal Decree 81/2014.	N/A

[728] Real Decreto 81/2014, de 7 de febrero, por el que se establecen normas para garantizar la asistencia sanitaria transfronteriza, y por el que se modifica el Real Decreto 1718/2010, de 17 de diciembre, sobre prescripción médica y órdenes de dispensación (Royal Decree 81/2014, of February 7, which establishes rules to guarantee cross-border healthcare, and which modifies Royal Decree 1718/2010, of December 17, on medical prescription and dispensing orders), published in: «BOE» no. 34, of February 8, 2014, pages 10915 to 10948 (34 pages), available at https://www.boe.es/diario_boe/txt.php?id=BOE-A-2014-1331 (last accessed on 10 June 2021).

	Article 16 (Minimum requirements of the prior authorisation procedure) 1. The prior authorisation procedure will be that established by the competent health authorities. The request will be addressed to the body assigned by it, and will conform to the format established for that purpose. 2. The competent health administration must check if the conditions established in article 20 of Regulation (EC) No. 883/2004, of April 29, 2004 are met. If these conditions are met, it will grant prior authorisation in accordance with the provisions of the aforementioned Regulation, unless the patient chooses to apply the provisions of this royal decree. In order to facilitate this choice, the consequences derived from the application of the two options must be reported. 3. Once the instruction of the procedure is finished, a reasoned decision will be issued that will be notified to the interested party, with expression of the claims and proceeding resources, in accordance with the provisions of Law 30/1992, of November 26. 4. The maximum period for notification of the authorisation decision or, where appropriate, denial of prior authorisation will be 45 days, from the date of receipt of the request by the competent health authority. Notwithstanding the foregoing, the competent health authority will take into account the specific condition, urgency and individual circumstances of the patient, when evaluating a request for cross-border healthcare. 5. Once the period has elapsed without an express decision having been given, the request		

	may be deemed accepted by administrative silence, in the terms provided in article 43 of Law 30/1992, of November 26.		
2. Is this the same procedure as for PA under the Social Security Coordination Regulations?	Answer: Yes ☒ No ☐ Formally: NO Substantially: YES The procedures <u>can be considered substantially equivalent</u> considering that, if the request for prior authorisation under the Directive meets the conditions set out in Art. 20 of EC Regulation 883/2004, the authorisation is granted pursuant to this Regulation, unless the patient requests otherwise. Source(s): Royal Decree 81/2014, Article 15(2).		N/A
3. What body is in charge of handling the PA applications? ***(e.g., where and to whom PA applications have to be submitted?)***	Answer: *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* Competent authorities of the Autonomous Community where the insured is domiciled, the National Institute of Health Management or the corresponding mutuality of public workers, where appropriate, are in charge of handling the PA applications (Royal Decree 81/2014, Article 15(1)). These competent health authorities will establish the PA procedure. The request will be addressed	Source(s): Royal Decree 81/2014 Article 15(1) Article 16(1) Article16(2) CatSalut. Catalan Health Service website.[731]	N/A

[731] Available at: https://catsalut.gencat.cat/ca/coneix-catsalut/acces-sistema-salut/assistencia-transfronterera/persones-assegurades-catalunya/com-solicitar/autoritzacio-previa/.

	to the body assigned by them (Royal Decree 81/2014, Article 16(1)). The competent health administration must check if the conditions established in article 20 of Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems (Regulation (EC) 883/2004)[729] are met. If these conditions are met, it will grant prior authorization in accordance with the provisions of the Regulation, unless the patient chooses to apply the provisions of this royal decree. In order to facilitate this choice, the consequences derived from the application of the two options must be reported. (Royal Decree 81/2014, Article 16(2)). To apply for prior authorisation, patients must fill in the specific form available and present it to the citizen care services in the health region. The Catalan Health Service then centralises all the applications. (CatSalut. Catalan Health Service website)[730].		
4. Who is entitled to apply for PA? *(e.g., can the patients apply themselves, or is treating doctor filing/partially filling the request, etc.)*	Answer: *If there is a national doctor involved, is there a requirement that this doctor is contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA?* No such requirement identified.	Source(s): CatSalut. Catalan Health Service website	No specific indication of a particular purpose was identified in the sources consulted.

[729] Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems, OJ L 166 30.4.2004, p. 1, available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02004R0883-20190731 (last accessed on 10 June 2021).
[730] CatSalut. - Servei Català de la Salut. Available at: https://catsalut.gencat.cat/ca/coneix-catsalut/acces-sistema-salut/assistencia-transfronterera/persones-assegurades-catalunya/com-solicitar/autoritzacio-previa/ (last accessed on 10 June 2021).

	Patients can apply for PA themselves (CatSalut. Catalan Health Service website).		
5. Is there a specific application form/module which the person seeking PA needs to submit?	Answer: Yes. To request prior authorisation, patients must fill in the specific form which is available online (CatSalut. Catalan Health Service website). *If yes, please specify:* - *What information is required;* The application must be accompanied by a clinical report with the diagnosis and prescription of a treatment (surgery, specific treatment, etc.), whether carried out from public or private care. 1. Identification data of the patient; 2. Details of the applicant (only if different from the patient); 3. Clinical data of the patient: diagnosis that motivates the health care, consultation, treatment, technique or procedure proposed in the health center of Catalonia, inclusion or not in the waiting list of a health center of Catalonia; 4. Application: diagnosis that motivates the health care, consultation, treatment, technique or procedure requested by the patient, other procedures that could derive from the care received;	Source(s): CatSalut. Catalan Health Service website. Specific PA form.[732]	No specific indication of a particular purpose was identified in the sources consulted.

[732] Available at: https://catsalut.gencat.cat/web/.content/minisite/catsalut/ciutadania/acces_sistema_salut/assistencia_transfronterera/altres_ue/240z564sap_sol_autoritzacio_assistencia_altre_pais.

	5. Center to which the patient will go to for the care abroad. 6. List of the attached documentation. - *Is the information mandatory, optional, or recommended?* The information is mandatory. - *Is this application form/modules available online?* Yes, it is available online. - *Does the form have to be submitted in paper or can it be submitted electronically?* The form can be submitted in person, presenting it to the citizen care services in the patient's health region. It can also be submitted electronically or via email.		
6. What (other) documentation has to be submitted in order to substantiate a PA request?	Answer: *If applicable, please specify:* - *What documents and what particulars are required;* - *Whether there are requirements as to who has to issue the documents (e. g., a doctor contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA or any doctor);* - *Whether the submission of the documentation is optional, mandatory, or recommended.* Besides the clinical report with the diagnosis and prescription of a treatment (surgery, specific treatment, etc.), whether carried out from public or private care (see above), the following document must be attached to the PA request form:	Source(s): Specific PA form.	No specific indication of a particular purpose was identified in the sources consulted.

	- individualised clinical evaluation on the health status of the patient, the possible evolution and the possibility or not of assistance in the autonomous community of the patient, in a justifiable term. This documentation is mandatory. No other requirements (nor any particular indication on who has to issue these documents) were identified in the sources consulted.		
7. Are there any costs associated with the handling of the PA request? - *Direct costs (e.g., fixed costs for submitting or filing a PA request).* - *Indirect costs* (*e.g., translations, stamps, etc).*	Answer: *Direct costs:* None identified. *Indirect costs:* None identified.	Source(s): N/A	No specific indication of a particular purpose was identified in the sources consulted.
8. Are there any specific time requirements linked to a PA request? (*e.g., time within which a requesting person must submit the PA application and/or time within which the requested body must take a decision on the PA request, etc.*).	Answer: - *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* Time within which the requested body must take a decision on the PA request: the maximum period for notification of the concession resolution or, where appropriate, denial of prior authorization will be 45 days, from the date of receipt of the request by the competent health authority (Royal Decree 81/2014 Article 16(4)).	Source(s): Royal Decree 81/2014 Article 16(4) Article 16(5)	No specific indication of a particular purpose was identified in the sources consulted.

	Consequences if deadlines are not respected: Once the period has elapsed without an express resolution having fallen, the request may be deemed approved by administrative silence, in the terms provided in article 43 of the Law 30/1992, of November 26, on the Legal Regime of Public Administrations and Common Administrative Procedure (Law on the Legal Regime of Public Administrations and Common Administrative Procedure).[733] (Royal Decree 81/2014 Article 16(5)).		
9. Are there differences in the procedural/administrative requirements for requesting PA based on, for instance, the type of treatment for which PA is requested, the profile of the insured person, or any other criterion?	Answer:. *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* No such differences identified.	Source(s): N/A	N/A
10. Is there a specific PA form (i.e., form used for issuing/granting PA) and, if the answer is positive, what form?	Answer: There is not a specific form used to grant the PA. Once the instruction of the procedure is finished, a reasoned decision will be issued and notified to the interested party, with expression of the	Source(s): Royal Decree 81/2014 Article 16(3)	No specific indication of a particular purpose was identified in the sources consulted.

[733] Ley 30/1992, de 26 de noviembre, de Régimen Jurídico de las Administraciones Públicas y del Procedimiento Administrativo Común (Law 30/1992, of November 26, on the Legal Regime of Public Administrations and Common Administrative Procedure), published in: «BOE» no. 285 of 11/27/1992, available at https://www.boe.es/buscar/act.php?id=BOE-A-1992-26318 (last accessed on 10 June 2021).

	claims and proceeding resources, in accordance with the provisions of the Law on the Legal Regime of Public Administrations and Common Administrative Procedure (Royal Decree 81/2014, Article 16(3)).		
11. Please list any other administrative requirements in your country in relation to the PA procedure for cross-border healthcare.	Answer: None identified.	Source(s): N/A	N/A

SECTION 2 REIMBURSMENT PROCEDURE(S)				
Questions	**Answer:**	**Sources**	**Does/do the identified requirement(s) also apply domestically? (i.e., is the requirement non-discriminatory?)**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to reimbursement procedures for cross-border healthcare	Answer: Royal Decree 81/2014, of February 7, which establishes rules to guarantee cross-border healthcare, and which modifies Royal Decree 1718/2010, of December 17, on medical prescription and dispensing orders (Royal Decree 81/2014).	Source(s): Royal Decree 81/2014.	N/A	N/A

under Directive 201/24/EU?	In particular: Article 14 (Minimum requirements for the reimbursement procedure). 1. The procedure for the reimbursement of expenses will be established by the competent authorities. 2. The reimbursement request will be addressed to the body assigned for this purpose by the competent health administration, within a maximum period of three months from the date of payment of the assistance received and will follow the format that has been established for that purpose. 3. The reimbursement request shall be accompanied, at least, by the documents included in Annex I, to facilitate the assessment of the origin and amount of the reimbursement of the real cost of the health care provision. 4. Once the required documentation has been received, the competent body will carry out the appropriate checks to determine the right to reimbursement, compliance with the conditions in which the prior authorization was granted, where appropriate, and the corresponding amount, in accordance with the applicable rates in each case. 5. Once the instruction of the procedure has finished, a reasoned resolution will be issued that will be notified to the interested party, with expression of the claims and proceeding resources, in accordance with the provisions of Law 30/1992, of November 26. 6. The maximum period for notification of the resolution of the reimbursement procedure will be three months, from the date of receipt of the			

	request by the competent health authority. 7. Once the period has elapsed without express resolution having fallen, the request may be deemed estimated by administrative silence, in the terms provided in article 43 of Law 30/1992, of November 26.			
2. Is this the same procedure as for reimbursement under the Social Security Coordination Regulations?	Answer: Yes ☒ No ☐ Formally: NO Substantially: YES (see Question 2 above) Reimbursement form under Regulation 987/09		N/A	N/A
3. What body is/are responsible of handling the reimbursement applications? (e.g., where and to whom reimbursement applications have to be submitted?)	Answer: *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* Expenses paid by an insured whose State of affiliation is Spain, who has received cross-border healthcare, will be reimbursed by the corresponding competent healthcare administration, in accordance with article 14, provided that said healthcare is included among the benefits to which the insured have the right according to the common portfolio of services of the National Health System or, where appropriate, the complementary portfolio of the corresponding Autonomous Community, without prejudice to the provisions of Regulation (EC) 883/2004 (Royal Decree 81/2014, Article 10(1)).	Source(s): Royal Decree 81/2014. Article 10(1) Article 14(2) Article 14(4) CatSalut. Catalan Health Service website.	N/A	N/A

	The reimbursement request will be addressed to the body assigned for this purpose by the competent health administration, within a maximum period of three months from the date of payment of the assistance received and will be adjusted to the format that has been established for that purpose (Royal Decree 81/2014, Article 14(2)).[734] Once the required documentation has been received, the competent body will carry out the appropriate checks to determine the right to reimbursement, compliance with the conditions in which the prior authorisation was granted, where appropriate, and the corresponding amount, in accordance with the applicable rates in each case (Royal Decree 81/2014, Article 14(4)). Applications must be submitted to the CatSalut (Catalan healthcare system) health regions using the form provided. CatSalut will reimburse the applicant, at most, for the same amount that he/she would have borne if the assistance received had been provided in Catalonia.			
4. Is there a specific application form/module which the person seeking reimbursement needs to submit?	Answer: Yes. The reimbursement request will be accompanied, at least, by the documents included in Annex I, to facilitate the assessment of the origin and amount of the reimbursement of the real cost of the health care provision (Royal Decree 81/2014, Article 14(3)).	Source(s): Royal Decree 81/2014, Article 14(3) ANNEX I CatSalut. Catalan Health Service website.	Yes ☐ No ☒ In Spain, healthcare is provided by the National Health System or by the	According to Article 14(3) of Royal Decree 81/2014, the purpose of the documents that need to be submitted together with the request (and listed in Annex I of the law is "to facilitate the

[734] Note of the National expert: The reimbursement request will have to follow a specific form, specified below in Question 4.

	If yes, please specify: - *What information is required;* Pursuant to Annex I of Royal Decree 81/2014: Documentation for the refund procedure: 1. Original invoices, from the health care provider or dispensing establishment, in which it must be proven by the vendor that they have been paid. It must include, at least: a) Patient identification: name, surname and DNI or NIE number or passport. b) Identification of the natural or legal person issuing the invoices: name or company name and address. c) Name of the service or clinical unit. d) Identification data of the professional responsible for cross-border healthcare. e) The various healthcare concepts carried out in detail, in the manner specified by the competent health authority, the amount of each one and the date of completion. f) Where appropriate, the name of the medicine, health product or dietary food for special medical purposes dispensed, the number of containers dispensed, the amount paid by the patient and the date of dispensing.	Specific reimbursement form.[735]	insurance provider without a reimbursement system. Costs are normally anticipated and the patient does not have to pay for any treatment of the public system.[736]	assessment of the origin and amount of the reimbursement of the real cost of the health care provision".

[735] Available at:
https://catsalut.gencat.cat/web/.content/minisite/catsalut/ciutadania/acces_sistema_salut/assistencia_transfronterera/altres_ue/240z564sra_sol_reembossament_assistencia_altre_pais

[736] Note of the National expert**:** In principle, the health services of the National Health System are only provided by its qualified personnel, in its centres and services, owned or arranged. However, there are a series of exceptional situations in which it is foreseen that the expenses of that assistance will be reimbursed, once it has been verified that the public services could not be used in a timely manner and that they were not carried out abusively. This is stated in article 9 of Law 16/2003, of May 28, on cohesion and quality of the National Health System (Law on cohesion and quality of the National Health System. In addition, article 4.3 of the Royal Decree 1030/2006 of September 15, which establishes the portfolio of common services of the National Health System and the procedure for its action (Royal Decree 1030/2006) establishes the requirements that must be met for the reimbursement of medical expenses caused by health care cases outside the National Health System.

	2. Copy of the medical prescription or the clinical report of the care provided, which must inexcusably include: a) Clinical reason for providing cross-border healthcare. b) Diagnostic procedures or main and secondary therapeutic procedures carried out for the purpose of cross-border healthcare (indicating whenever possible an approved identification code, such as CIE9-MC or similar). c) Subsequent medical revisions/checks to be carried out and estimated term for them. d) Any other data that is considered appropriate to review, to clarify the health care received or its real cost, provided that it is strictly necessary for the assessment of the origin and amount of the reimbursement. - *Is the information mandatory, optional, or recommended?* The information is mandatory (with the exception of "any other data that is considered appropriate to review, to clarify the health care received or its real cost" which must be attached only if it is "strictly necessary for the assessment of the origin and amount of the reimbursement". - *Is this application form/modules available online?* Yes, the form is available online. - *Does the form have to be submitted in paper or can it be submitted electronically?*			

	Applications can be submitted electronically and in person, presenting it to the CatSalut health regions using the established form provided online.			
5. What (other) documentation has to be submitted in order to substantiate a reimbursement request?	Answer: *If applicable, please specify:* - *What documents are required;* - *Whether the submission of the documentation is optional, mandatory, or recommended.* Although it is not indicated in Annex I of Royal Decree 81/2014, the Catalan Health Department requests the previously granted prior authorisation from CatSalut, if applicable.	Source(s): CatSalut. Catalan Health Service website.	Yes ☐ No ☒	According to Article 14(3) of Royal Decree 81/2014, the purpose of the documents that need to be submitted together with the request (and listed in Annex I of the law is "to facilitate the assessment of the origin and amount of the reimbursement of the real cost of the health care provision".
6. Are there any costs associated with the handling of the reimbursement request? - *Direct costs (e.g., fixed costs for submitting or filing a reimbursement request, proportion deducted from the reimbursable amount).* - *Indirect costs* (*e.g., translations, stamps, etc).*	Answer: *Direct costs:* None identified. *Indirect costs:* None identified.	Source(s): N/A	Yes ☐ No ☐ N/A	There are no indirect costs because documents are accepted in English. In any case, no official translations are required.

7. Are there any specific time requirements linked to a reimbursement request? (*e.g., time within which the reimbursement requests must be submitted and/or time within the requested body must handle the request and/or reimburse the costs, etc.*).	Answer: *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* Time requirements: The reimbursement request will be addressed to the body assigned for this purpose by the competent health administration, within a maximum period of three months from the date of payment of the assistance received and will conform to the form that has been established for that purpose. (Royal Decree 81/2014, Article 14(2)). The maximum period for notification of the resolution of the reimbursement procedure will be three months, from the date of receipt of the request by the competent health authority (Royal Decree 81/2014, Article 14(6)). The Catalan Health Service will check that the information presented is adequate and will issue an express decision motivated by the granting or refusal of the authorization and the interested party will be notified. Appeals and claims may be lodged against this decision. So, if everything is correct, you will receive a notice or notification and the refund in the bank account you indicated in the application. Administrative silence is understood as acceptance of the application. Consequences for not meeting the deadline:	Source(s): Royal Decree 81/2014, Article 14(2) Article 14(6) Article 14(7) CatSalut. Catalan Health Service website.	Yes ☐ No ☒	No specific indication of a particular purpose was identified in the sources consulted.

	Once the period has elapsed without an express decision having been taken, the request may be deemed estimated by administrative silence, in the terms provided in article 43 of Law on the Legal Regime of Public Administrations and Common Administrative Procedure. (Royal Decree 81/2014, Article 14(2)).			
8. Are there any non-reimbursable thresholds, deductions *(except the deductions for administrative costs mentioned above) etc.?*	Answer: *If yes, please specify the thresholds.* None identified.	Source(s): N/A	Yes ☐ No ☐ N/A	N/A
9. In instances where a PA (or prior-notification) has already been issued, is a separate/simplified procedure available for requesting reimbursement? **applicable only if the country has a PA system.*	Answer: *If yes, please describe the simplified procedure.* No such simplified procedure identified.	Source(s): N/A	Yes ☐ No ☐ N/A	N/A
10. Are there additional administrative/procedural requirements for reimbursement depending on, for instance, the type of treatment for which reimbursement is requested, or the profile of the insured	Answer: *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* No such simplified procedure identified.	Source(s): art. 10.2	Yes ☐ No ☐ N/A	N/A

person, or any other criterion?				
11. Please list any other administrative requirements in your country in relation to the procedures of reimbursement of cross-border healthcare.	Answer: None identified.	Source(s): N/A	Yes ☐ No ☐ N/A	N/A

Questionnaire 2. Galicia

SECTION 1 PRIOR AUTHORISATION PROCEDURE(S)			
Questions	**Answer**	**Sources**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to PA procedures for a cross-border healthcare under Directive 2011/24/EU?	Answer: Royal Decree 81/2014, of February 7, which establishes rules to guarantee cross-border healthcare, and which modifies Royal Decree 1718/2010, of December 17, on medical prescription and dispensing orders (Royal Decree 81/2014).[737] Instruction 5/2014 by which the procedures are developed for cross-border healthcare regulated by the Royal Decree 81/2014, of 7 February, establishing rules to guarantee cross-border healthcare (Instruction 5/2014)[738]	Source(s): Royal Decree 81/2014 Instruction 5/2014	N/A

[737] Real Decreto 81/2014, de 7 de febrero, por el que se establecen normas para garantizar la asistencia sanitaria transfronteriza, y por el que se modifica el Real Decreto 1718/2010, de 17 de diciembre, sobre prescripción médica y órdenes de dispensación (Royal Decree 81/2014, of February 7, which establishes rules to guarantee cross-border healthcare, and which modifies Royal Decree 1718/2010, of December 17, on medical prescription and dispensing orders), published in: «BOE» no. 34, of February 8, 2014, pages 10915 to 10948 (34 pages), available at https://www.boe.es/diario_boe/txt.php?id=BOE-A-2014-1331 (last accessed on 10 June 2021).

[738] Instrución pola que se desenvolven os procedementos para a atención sanitaria transfronteiriza regulada polo real decreto 81/2014, do 7 de febreiro, polo que se establecen normas para garantir a asistencia sanitaria transfronteiriza (Instruction 5/2014 by which the procedures are developed for cross-border healthcare regulated by the Royal Decree 81/2014, of 7 February, establishing rules to guarantee cross-border healthcare), published 15 may 2014, available at https://www.sergas.es/Asistencia-sanitaria/Instruci%C3%B3n-514- (last accessed on 10 June 2021).

	Note: Royal Decree 81/2014 provides in article 16(1) the possibility to Autonomous Communities (competent health authorities) to establish the PA procedure. In Galicia, this was done via the Instruction n.5/2014. Therefore, the answers below are completed based on the specific regional law regulating the matter.		
2. Is this the same procedure as for PA under the Social Security Coordination Regulations?	Answer: Yes ☒ No ☐ Formally: NO Substantially: YES The procedures <u>can be considered substantially equivalent</u> considering that, if the request for prior authorisation under the Directive meets the conditions set out in Art. 20 of EC Regulation 883/2004, the authorisation is granted pursuant to this Regulation, unless the patient requests otherwise. Source(s): Royal Decree 81/2014, Article 15(2).		N/A
3. What body is in charge of handling the PA applications? ***(e.g., where and to whom PA applications have to be submitted?)***	Answer: *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* The request for prior authorisation will be addressed to the Integrated Management Organisational Structure (EOXI) to which the patient's health card is assigned and may be presented at EOXI itself or at any of the	Source(s): Instruction 5/2014 Section5(1)(point 2) Section 5(1)(point 4)	N/A

	places established in article 38.4 of Law on the Legal Regime of Public Administrations and Common Administrative Procedure, using for this purpose the application form available on the portal of the Ministry of Health (http://www.sergas.es/) and in the assistance centres of the Organisational Structures of Integrated Management of the Galician Health Service. (Instruction 5/2014, Section 5(1)(point 2)). EOXI will be competent to decide on the application for authorisation of cross-border healthcare, in accordance with Article 5, s) of the Decree 168/2010, of 7 October, which regulates the organisational structure of integrated management of the Galician Health Service (Decree which regulates the organisational structure of integrated management of the Galician Health Service)[739] (Instruction 5/2014, Section 5(1)(point 4)).		
4. Who is entitled to apply for PA? ***(e.g., can the patients apply themselves, or is treating doctor filing/partially filling the request, etc.)***	Answer: *If there is a national doctor involved, is there a requirement that this doctor is contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA?* Patients can apply for PA themselves. Patients with a valid health card from the Galician Health Service, with the right to health care provided by this entity and who	Source(s): Instruction 5/2014 Section 2(2)	No specific indication of a particular purpose was identified in the sources consulted.

[739] Decreto 168/2010, de 7 de outubro, polo que se regula a estrutura organizativa de xestión integrada do Servizo Galego de Saúde (Decree 168/2010, of 7 October, which regulates the organizational structure of integrated management of the Galician Health Service), DOG Num. 199 Friday, October 15, 2010 Pg. 17,203, available at https://www.xunta.gal/dog/Publicados/2010/20101015/Anuncio34C0E_gl.html (last accessed on 10 June 2021).

	have the status of insured or beneficiary recognized by the National Social Security Institute (INSSS) or the Social Marine Institute (ISM) which had been attended to by a healthcare provider from another Member State of the European Union, in the cases provided for in the said Royal Decree. (Instruction 5/2014, Section 2(2))		
5. Is there a specific application form/module which the person seeking PA needs to submit?	Answer: Yes, a specific application module exists and is available online. The requirements and information to be provided are set out in the form as well as in Section 5(1)(point 2) of the Instruction 5/2014. *If yes, please specify:* - *What information is required;* The application will be accompanied by the official health care prescription sheet by a Primary Care physician or other specialist, which states at least: - Identification of the doctor who carries out the prescription. - Patient identification. - Diagnosis or diagnostic suspicion. - Main clinical data of the patient. - Prescribed health services. - Modality of health care (outpatient or with hospital admission).	Source(s): Instruction 5/2014 Section 5(1)(point 2) Specific PA form.[740]	No specific indication of a particular purpose was identified in the sources consulted.

[740] Available at: https://www.sergas.es/Asistencia-sanitaria/Documents/573/Solicitude_autorizaci%C3%B3n_previa.pdf.

	- Priority of attention. - The name, country and address of the healthcare provider where the cross-border care will be provided. - *Is the information mandatory, optional, or recommended?* The information is mandatory. - *Is this application form/modules available online?* Yes, the form is available online. - *Does the form have to be submitted in paper or can it be submitted electronically?* The request for prior authorisation has to be submitted only in person to the Integrated Management Organisational Structure (EOXI) to which the patient's health card is assigned and may be presented at EOXI itself or at any of the places established in article 38.4 of the Law on the Legal Regime of Public Administrations and Common Administrative Procedure.		
6. What (other) documentation has to be submitted in order to substantiate a PA request?	Answer: *If applicable, please specify:* - *What documents and what particulars are required;* - *Whether there are requirements as to who has to issue the documents (e. g., a doctor contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA or any doctor);*	Source(s): Instruction 5/2014 Section 5(1)(point 2) Specific PA form.	No specific indication of a particular purpose was identified in the sources consulted.

	- *Whether the submission of the documentation is optional, mandatory, or recommended.* All the documentation required is specified above in the answer to question n. 5 (the official health care prescription sheet by a Primary Care physician or other specialist is needed, see above).		
7. Are there any costs associated with the handling of the PA request? - ***Direct costs (e.g., fixed costs for submitting or filing a PA request).*** - ***Indirect costs* (*e.g., translations, stamps, etc).***	Answer: *Direct costs:* None identified. *Indirect costs:* None identified.	Source(s): N/A	N/A
8. Are there any specific time requirements linked to a PA request? **(*e.g., time within which a requesting person must submit the PA application and/or time within which the requested body must take a decision on the PA request, etc.*).**	Answer: *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* Time requirements: Yes, there are time requirements related to the PA request. The decision will be dictated and notified to the interested party, in accordance with the provisions of Royal Decree 81/2014, within a maximum period of 45 days from the date of receipt of the application (Section 5(1)(point 6)).	Source(s): Instruction 5/2014 Section 5(1)(point 6) Section 5(1)(point 5)	No specific indication of a particular purpose was identified in the sources consulted.

	Consequences if deadlines are not met: After the elapse of the aforementioned 45 days, the application may be considered approved due to administrative silence, as established in Article 43 of Law on the Legal Regime of Public Administrations and Common Administrative Procedure. Instruction 5/2014 (Section 5(1)(point 6)).		
9. Are there differences in the procedural/administrative requirements for requesting PA based on, for instance, the type of treatment for which PA is requested, the profile of the insured person, or any other criterion?	Answer: *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* No such differences identified.	Source(s): N/A	N/A
10. Is there a specific PA form (i.e., form used for issuing/granting PA) and, if the answer is positive, what form?	Answer: The resolution will be motivated and it will indicate that against it, the interested person may lodge an administrative complaint prior to the social jurisdictional route, in accordance with the provisions of article 71 of the Law regulating social jurisdiction. The Galician Health Department does not have a specific form to grant PA. However, each area management (EOXI) is in charge of issuing the resolution and they can issue their own specific form.	Source(s): Instruction 5/2014 Section 5(1)(point 5)	No specific indication of a particular purpose was identified in the sources consulted.
11. Please list any other administrative requirements in your	Answer: If the application for prior authorisation does not meet the required requirements, the	Source(s): Instruction 5/2014	No specific indication of a particular purpose was identified in the sources consulted.

country in relation to the PA procedure for cross-border healthcare.	person concerned will be required to complete the documentation or correct the errors within 15 working days, indicating that, if she/he fails to do so, he/she will be deemed to have withdrawn his petition. In such case, a resolution will have to be dictated in the terms revised in the article 42 of the Law on the Legal Regime of Public Administrations and Common Administrative Procedure. The expiration of the maximum period for resolving and notifying the procedure will be suspended until the interested party fixes the defects in the application.	Section 5(1)(point 3)		
SECTION 2 **REIMBURSMENT PROCEDURE(S)**				
Questions	**Answer:**	**Sources**	**Does/do the identified requirement(s) also apply domestically? (i.e., is the requirement non-discriminatory?)**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to reimbursement procedures for cross-	Answer: Royal Decree 81/2014, of February 7, which establishes rules to guarantee cross-border healthcare, and which modifies Royal Decree 1718/2010, of December 17, on medical prescription and dispensing orders (Royal Decree 81/2014).[741]	Source(s): Royal Decree 81/2014 Instruction 5/2014	N/A	N/A

[741] Real Decreto 81/2014, de 7 de febrero, por el que se establecen normas para garantizar la asistencia sanitaria transfronteriza, y por el que se modifica el Real Decreto 1718/2010, de 17 de diciembre, sobre prescripción médica y órdenes de dispensación (Royal Decree 81/2014, of February 7, which establishes rules to guarantee cross-border healthcare, and which modifies Royal

border healthcare under Directive 201/24/EU?	Instruction 5/2014 by which the procedures are developed for cross-border healthcare regulated by the Royal Decree 81/2014, of 7 February, establishing rules to guarantee cross-border healthcare (Instruction 5/2014)[742] Note: Royal Decree 81/2014 provides in article 14(1) the possibility to Autonomous Communities (competent health authorities) to establish the reimbursement procedure. In Galicia, this was done via the Instruction n.5/2014 Therefore, the answers below are completed based on the specific regional law regulating the matter.			
2. Is this the same procedure as for reimbursement under the Social Security Coordination Regulations?	Answer: Yes ☒ No ☐ Formally: NO Substantially: YES (see Question 2 above)		N/A	N/A
3. What body is/are responsible of handling the reimbursement applications?	Answer: *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant*	Source(s): Instruction 5/2014 Section 5(3)(point 1) Section 5(4)(point 1)	N/A	N/A

Decree 1718/2010, of December 17, on medical prescription and dispensing orders), published in: «BOE» no. 34, of February 8, 2014, pages 10915 to 10948 (34 pages), available at https://www.boe.es/diario_boe/txt.php?id=BOE-A-2014-1331 (last accessed on 10 June 2021).

[742] Instrución pola que se desenvolven os procedementos para a atención sanitaria transfronteiriza regulada polo real decreto 81/2014, do 7 de febreiro, polo que se establecen normas para garantir a asistencia sanitaria transfronteiriza (Instruction 5/2014 by which the procedures are developed for cross-border healthcare regulated by the Royal Decree 81/2014, of 7 February, establishing rules to guarantee cross-border healthcare), published 15 may 2014, available at https://www.sergas.es/Asistencia-sanitaria/Instruci%C3%B3n-514- (last accessed on 10 June 2021).

(e.g., where and to whom reimbursement applications have to be submitted?)	*insurance provider in your country (e.g., based on the number of affiliations).* Reimbursement of expenses may be requested to the Integrated Management Organizational Structure to which the patient's health card is assigned, which may be submitted to EOXI itself or in any of the places established in article 38.4 of Law on the Legal Regime of Public Administrations and Common Administrative Procedure. (Instruction 5/2014, Section 5(3)(point 1)). The processing and resolution of requests for reimbursement of expenses will correspond, after issuance of the corresponding report-proposal by the corresponding unit of the Competent Integrated Management Organisational Structure, to the following bodies: a) In the case of applications for reimbursement of expenses equal to or less than 30,000 euros, it corresponds to the Organizational Structure of Integrated Management, in accordance with article 5 of the Order of 5 July 2012 on delegation of powers to central and peripheral bodies of the Galician Health Service. b) If the amount is more than 30,000 euros, they will be processed by the integrated management, the resolution corresponding to the Health Care Directorate, in accordance with article 2.1 of the Order of 5 July 2012 on delegation of powers to central and peripheral bodies of the Galician Health Service. (Instruction 5/2014, Section 5(4)(point 1)).			

4. Is there a specific application form/module which the person seeking reimbursement needs to submit?	Answer: Yes, a specific form exists and is available online. *If yes, please specify:* - *What information is required;* According to Section 5(3)(point 2) of the Instruction 5/2014: Requests for reimbursement of cross-border care costs shall be accompanied, where appropriate, by the following documentation:[743] a) Document accrediting the prescription of health care by a Primary Care doctor or another specialist, stating at least: - Identification of the doctor who carries out the prescription. - Patient identification. - Diagnosis or diagnostic suspicion. - Prescribed health services. - Priority of attention.	Source(s): Instruction 5/2014 Section 5(3)(point 2) Section 5(3)(point 1) Specific Reimbursement form.[744]	Yes ☐ No ☒ In Spain, healthcare is provided by the National Health System or by the insurance provider without a reimbursement system. Costs are normally anticipated and the patient does not have to pay for any treatment of the public system.[745]	Art. 14(3) of Royal Decree 81/2014: The reimbursement request will be accompanied, at least, by the documents included in Annex I, to facilitate the assessment of the origin and amount of the reimbursement of the real cost of the health care provision. No further indication of a particular purpose was identified in the sources consulted.

[743] Note of the National body: The request would not be automatically rejected if one of these requirements is missing, given that the main document is the **original invoice** (which is essential) and that not all countries may include all the specifications indicated in this answer.
[744] Available at: https://www.sergas.es/Asistencia-sanitaria/Formulario-para-a-solicitude-de-reembolso.
[745] Note of the National expert**:** In principle, the health services of the National Health System are only provided by its qualified personnel, in its centres and services, owned or arranged. However, there are a series of exceptional situations in which it is foreseen that the expenses of that assistance will be reimbursed, once it has been verified that the public services could not be used in a timely manner and that they were not carried out abusively. This is stated in article 9 of Law 16/2003, of May 28, on cohesion and quality of the National Health System (Law on cohesion and quality of the National Health System. In addition, article 4.3 of the Royal Decree 1030/2006 of September 15, which establishes the portfolio of common services of the National Health System and the procedure for its action (Royal Decree 1030/2006) establishes the requirements that must be met for the reimbursement of medical expenses caused by health care cases outside the National Health System.

	b) Photocopy of the authorisation resolution, in the case of one of the health benefits subject to prior authorisation, specified in Annex I of this instruction. c) Clinical reports and prescription sheets carried out by the cross-border healthcare service provider, stating at least: - Patient identification. - Identification of the doctor responsible for the health care provided, including their health profession and specialty. - Health care provider where the care was provided. - Diagnoses or diagnostic suspicions. - Health services and procedures performed. - Type of care provided (outpatient or inpatient). - Patient prescriptions. - Reviews to be carried out and estimated time for them. - Other data that it is considered appropriate to specify. d) Original invoice from the cross-border healthcare service provider, which clearly reads: - Identification and residence of the patient receiving the health service. - Name or corporate name and address of the natural or legal person issuing the invoices. - Name of the service or clinical unit.			

	- Identification data of the professional responsible for cross-border assistance. - The various health concepts carried out, in detail, specifying the amount of each of them and the date of implementation. - Date of admission and date of hospital discharge, if applicable. - Where applicable, name of the medicine, health product or dietetic food for special uses dispensed, the number of containers dispensed, the amount paid by the patient and the date of dispensation. e) Receipt proving payment by the supplier. - *Is the information mandatory, optional, or recommended?* The information to be provided is mandatory. - *Is this application form/modules available online?* Yes, the form is available online. - *Does the form have to be submitted in paper or can it be submitted electronically?* The form has to be submitted in paper format.			
5. What (other) documentation has to be submitted in order to substantiate a reimbursement request?	Answer: *If applicable, please specify:* - *What documents are required; Whether the submission of the documentation is optional, mandatory, or recommended.*	Source(s): Instruction 5/2014 Section 5(3)(point 2) Section 5(3)(point 1)	Yes ☐ No ☒	No specific indication of a particular purpose was identified in the sources consulted.

	Additional documentation includes the official or professional translations, where applicable.			
6. Are there any costs associated with the handling of the reimbursement request? - ***Direct costs (e.g., fixed costs for submitting or filing a reimbursement request, proportion deducted from the reimbursable amount).*** - ***Indirect costs* (*e.g., translations, stamps, etc).***	Answer: *Direct costs:* None identified. *Indirect costs:* Yes. In the event that the documentation provided is not in Galician or Spanish, an official or professional translation of it will be attached.[746] (Instruction 5/2014 Section 5(3)(point 4))	Source(s): Instruction 5/2014 Section 5(3)(point 4)	Yes ☐ No ☒	No specific indication of a particular purpose was identified in the sources consulted.
7. Are there any specific time requirements linked to a reimbursement request? **(*e.g., time within which the reimbursement requests must be submitted and/or time within the requested body must handle the request and/or reimburse the costs, etc.*).**	Answer: *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* Time requirements: Yes time requirements are in place both for requesting reimbursement as well as for the reimbursement as such. Requesting reimbursement: Reimbursement of expenses may be requested within a maximum period of three months from the date of payment of the care received through an application addressed to the Organisational Structure of Integrated Management to which the patient's health	Source(s): Instruction 5/2014 Section 5(3)(point 1) Section 5(3)(point 3) Section 5(4)(point 2).	Yes ☐ No ☒	No specific indication of a particular purpose was identified in the sources consulted.

[746] Note of the National expert: The translation of the original invoice is also needed.

	card is assigned. (Instruction 5/2014, Section 5(3)(point 1)). If the documentation provided does not meet the required requirements, the interested party will be required to complete or correct the errors within 15 working days, indicating that failure to do so will result in withdrawal of the application. in this case, a resolution which must be dictated in the terms provided for in article 42 of the Law on the Legal Regime of Public Administrations and Common Administrative Procedure. The expiration of the maximum period for resolving and notifying the procedure will be suspended until the interested party fixes the defects in the application. (Instruction 5/2014, Section 5(3)(point 3)). Providing the decision on reimbursement: The decision will be issued in accordance with the provisions of Article 14 of the Royal Decree 81/2014, in a reasoned manner, and must be notified to the interested party within a maximum period of three months from the date of receipt of the application, stating the amount to be reimbursed with a report detailed assessment of the costs requested or, in the event of a refusal, explaining the reasons for that decision (Instructions 5/2014, Section 5(4)(point 2)). Consequences if deadline is not met: If no express decision is notified within 3 months, the application will be deemed to			

	have been approved due to administrative silence, in the terms provided for in article 43 of Law on the Legal Regime of Public Administrations and Common Administrative Procedure (Instructions 5/2014, Section 5(4)(point 2)).			
8. Are there any non-reimbursable thresholds, deductions *(except the deductions for administrative costs mentioned above) etc.?*	Answer: *If yes, please specify the thresholds.* None identified.	Source(s): N/A	Yes ☐ No ☐ N/A	N/A
9. In instances where a PA (or prior-notification) has already been issued, is a separate/simplified procedure available for requesting reimbursement? **applicable only if the country has a PA system.*	Answer: *If yes, please describe the simplified procedure.* No such procedure identified.	Source(s): N/A	Yes ☐ No ☐ N/A	N/A
10. Are there additional administrative/procedural requirements for reimbursement depending on, for instance, the type of treatment for which reimbursement is requested, or the profile of the insured person, or any other criterion?	Answer: *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* None identified.	Source(s): N/A	Yes ☐ No ☐ N/A	N/A

11. Please list any other administrative requirements in your country in relation to the procedures of reimbursement of cross-border healthcare.	Answer: The requirements that patients must meet to apply for reimbursement of cross-border healthcare are as follows: a) Be in possession of a valid health card from the Galician Health Service and have the status of insured persons or beneficiaries recognized by the National Social Security Institute or the Social Marine Institute. b) That the care for which reimbursement is requested: • It is within the benefits included in the common portfolio of services of the National Health System or in the complementary portfolio of services of the Galician Service of Health. • It had been provided by an authorised healthcare provider from another Member State of the European Union. • It had been prescribed by a Primary Care physician or other specialist, as the case may be. c) Have the prior authorisation of the corresponding integrated management, in those cases listed in Annex I of this instruction.	Source(s): Instruction 5/2014 Section 5(1)(point 2)	Yes ☐ No ☐ N/A	No specific indication of a particular purpose was identified in the sources consulted.

Part 2: Checklist for verification with national/regional body

1. Catalonia

Name of the body: Catalan Health Service
Country/Region: Spain- Catalonia
Date of verification call: 18/06/2021

Template for the Data Collection	**Aspects to be verified** *Tick the boxes if the information in the template for the data collection has been verified and/or complemented by the national body*		**Comments** *Include any additional comments and/or information provided by the contacted body*
Section 1 – Prior Authorisation			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Justification/purpose of the identified requirement(s) (Column 4)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	The feedback/comments received have been incorporated in the questionnaire.
Section 2 - Reimbursement			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Whether the requirement applies domestically (Discriminatory assessment) (Column 4) ▪ Justification/purpose of the identified requirement(s) (Column 5)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	The feedback/comments received have been incorporated in the questionnaire.

2. Galicia

Name of the body: SX Health planning and insurance (Galician Health Department)
Country/Region: Spain- Galicia
Date of verification call: 17/06/2021

Template for the Data Collection	**Aspects to be verified** *Tick the boxes if the information in the template for the data collection has been verified and/or complemented by the national body*		**Comments** *Include any additional comments and/or information provided by the contacted body*
Section 1 – Prior Authorisation			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Justification/purpose of the identified requirement(s) (Column 4)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	The Integrated Management Organizational Structure (EOXI), body in charge of handling PA and reimbursement is now called **Area Management**. The feedback/comments received have been incorporated in the questionnaire.
Section 2 - Reimbursement			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Whether the requirement applies domestically (Discriminatory assessment) (Column 4) ▪ Justification/purpose of the identified requirement(s) (Column 5)	☒ Question 1 ☒ Question 2 ☒ Question 3 ☒ Question 4 ☒ Question 5	☒ Question 6 ☒ Question 7 ☒ Question 8 ☒ Question 9 ☒ Question 10 ☒ Question 11	The feedback/comments received have been incorporated in the questionnaire.

SWEDEN – COUNTRY REPORT

Part 0: Preliminary Assessment

1. **Please indicate whether the rules governing the administrative procedures/requirements for requesting PA and reimbursement under Directive 2011/24/EU in your country are set out at:**

A. National level ☒

B. Decentralised/regional/local level ☐

In case (1.B): Please indicate the two most relevant jurisdictions in your country (i.e., in terms of population):

Region/jurisdiction: 1: N/A

Region/jurisdiction 2: N/A

NOTE: In case (1.B) the template for the data collection (Part 1) should be complete twice, once for each of the two most relevant regions/jurisdiction indicated above.

2. **Please indicate the national body best suited to verify the accuracy of the information collected in Part 1, and justify your selection.**
Depending on the characteristics of your national healthcare system, the relevant body may be: a) *the national social security body*; or b) *an insurance fund*. In thelatter case, please indicate the most representative fund (e.g., the one with the highest number of affiliations).

Body to be contacted for Task 2: Swedish Social Insurance Agency (Försäkringskassan)

(In case 1.B, please indicate two relevant bodies, one respectively for each Region/jurisdiction)

Reasons for Selection: As derives from the national law implementing Directive 2011/24/EU, Act (2013: 513) on compensation for costs as a result of care in another country within the European Economic Area (free translation), (*Lag (2013:513) om ersättning för kostnader till följd av vård i ett annat land inom Europeiska ekonomiska samarbetsområdet*), this is the competent authority (see 14 § in the cited act).

Part 1: Questionnaire

*__Note 1__: In cases where administrative requirements are set out in the legislative/regulatory framework at decentralised/regional/local level, please complete the template for the datacollection twice, once for each of the two most relevant regions/jurisdictions (e.g., in terms population).

__*Note 2__: Setting out a Prior Authorisation (PA) system is optional for Member States. Should your country not have a system of PA in place under Directive 2011/24/EU, Section 1 willnot need to be completed.

Note: in Sweden no PA system has been introduced under Directive 2011/24/EU. For this reason, Section 1 of the questionnaire below has not been completed.

SECTION 1 PRIOR AUTHORISATION PROCEDURE(S)			
Questions	**Answer**	**Sources**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to PA procedures for a cross-border healthcare under Directive 2011/24/EU?	**Answer:** As drives form Act 2013:513, and is conformed in travaux preparatoires to this law, Sweden has chosen not to introduce a PA system. There is a possibility to obtain an advance notification/assessment regardingthe right to receive reimbursement (11 §).	**Source(s):** The key legal act in the area is the following act of the Parliament (law) Act (2013: 513) on compensation for costs as a result of carein another country within the European Economic Area[747] (Hereinafter – Act 2013:513). Travaux preparatoires, Government bill	N/A

[747] Act (2013: 513) on compensation for costs as a result of care in another country within the European Economic Area, Lag (2013:513) om ersättning för kostnader till följd av vård i ett annat land inom Europeiska ekonomiska samarbetsområdet. Available at: https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/lag-2013513-om-ersattning-for-kostnader-till_sfs-2013-513

		2012/13:150, p.67-70.[748]	
2. Is this the same procedure as for PA under the Social Security Coordination Regulations?	**Answer:** **Yes ☐ No ☐**		N/A
3. What body is in charge of handling the PA applications? *(e.g., where and to whom PA applications have to besubmitted?)*	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* N/A	**Source(s):**	N/A
4. Who is entitled to apply forPA? *(e.g., can the patients apply themselves, or is treating doctor filing/partially filling therequest, etc.)*	**Answer:** - *If there is a national doctor involved, is there a requirement that this doctor is contracted by the national insurance provider in the EU/EEA EFTA State issuingthe PA?* N/A	**Source(s):**	

[748] Government bill 2012/13:150. Prop 2012/13:150, Patientrörlighet i EU - förslag till ny lagstiftning. Available at [https://www.regeringen.se/49bbd5/contentassets/8e07c6ea6eed404dbfccfa33863cd1ea/patientrorlighet-i-eu---forslag-till-ny-lagstiftning-prop-201213150] (last accessed on 16 June 2021).

5. Is there a specific application form/module which the person seeking PA needs to submit?	**Answer:** *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* N/A	**Source(s):**	
6. What (other) documentation has to be submitted in order to substantiate a PA request?	**Answer:** *If applicable, please specify:* - *What documents and what particulars are required;* - *Whether there are requirements as to who has to issue the documents (e. g., a doctor contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA or any doctor);* - *Whether the submission of the documentation is optional, mandatory, or recommended.* N/A	**Source(s):**	
7. Are there any costs associated with the handling of the PA request? - *Direct costs (e.g., fixed costs for submitting or filing a PA request).* - *Indirect costs* (*e.g., translations, stamps, etc).*	**Answer:** *Direct costs:* *Indirect costs:* N/A	**Source(s):**	

8. Are there any specific **time requirements** linked to a PA request? (*e.g., time within which a requesting person must submit the PA application and/or time within which the requested body must take a decision on the PA request, etc.*).	**Answer:** *- If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or therequested body?* N/A	**Source(s):**	
9. Are there **differences in the procedural/administrative requirements for requestingPA** based on, for instance, the type of treatment for which PA is requested, the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs,time limits, etc.?)* N/A	**Source(s):**	
10. Is there a specific PA form (i.e., form used for issuing/granting PA) and, if the answer is positive, what form?	**Answer:** N/A	**Source(s):**	
11. Please list any other administrative requirements in your country in relation to the PA procedure for cross-border healthcare.	**Answer:** N/A	**Source(s):**	

SECTION 2 REIMBURSMENT PROCEDURE(S)				
Questions	**Answer**	**Source(s)**	**Does/do the identified requirement(s) also apply domestically? (i.e., is the requirement non-discriminatory?)**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to reimbursement procedures for cross-border healthcare under Directive 201/24/EU?	**Answer:** Act (2013: 513) on compensation for costs as a result of care in another country within the European Economic Area[749] (Hereinafter – Act 2013:513).	**Source(s):** Act (2013:513).	N/A	N/A
2. Is this the same procedure as for reimbursement under the Social Security Coordination Regulations?	**Answer:** **Yes ☐ No ☒** It is not the same procedure. Section 2 of the Act 2013:513 provides that the Act does not apply when the right to get reimbursement is based on Regulation 883/2004 (see 2 §). The reimbursement procedure under the Regulation is not regulated in a particular way, but it is based directly on the Regulation.		N/A	

[749] Act (2013: 513) on compensation for costs as a result of care in another country within the European Economic Area, Lag (2013:513) om ersättning för kostnader till följd av vård i ett annat land inom Europeiska ekonomiska samarbetsområdet. Available at: https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/lag-2013513-om-ersattning-for-kostnader-till_sfs-2013-513

	Sources: Act 2013:513. See also Travaux preparatoires, Government bill 2012/13:150, p.39, 112.			
3. What body is/are responsible of handling the reimbursement applications? (e.g., where and to whom reimbursement applications have to be submitted?)	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).* The Swedish Social Insurance Agency is the competent authority.	**Source(s):** Act (2013: 513).	N/A	N/A
4. Is there a specific application form/module which the person seeking reimbursement needs to submit?	**Answer:** *If yes, please specify:* *What information is required;* **Information about the care** (region of insurance, period of care, reason for the care, and a brief description of the care content; uploading of the documentation of care, e.g. medical records, and other documents). **Information about the care provider**	**Source(s):** Swedish Social Insurance Agency.[751] Reimbursement form.[752] Note of the National body: These requirements are not set out in law. They are indicated in the Agency's internal working	**Yes** ☐ **No** ☒ The Swedish health care system is mainly government-funded, universal for all citizens and decentralized (although private health care also exists). Moreover when, within	

[751] Available at: https://www.forsakringskassan.se/login#/.
[752] Available at: Planerad vård utomlands (forsakringskassan.se) (accessed 1 July 2021).

	(title, address). **Other information about the care** (whether the prior notice has been received, whether the person has protection against high care costs or is entitled to get it free, whether the person isregistered regarding high costs for the medicinal products, as well as a choice for the individual to choose whether s/he wants Försäkringskassan to provide information about the drug costs so that they are included in the high-cost protection in the event of compensation). **Information about the costs relating to care** (description in afree text, as well as uploading of the receipts). Finally, personal details (name, personal number, place of residence, signature). *Is the information mandatory, optional, or recommended?* Most of the information is mandatory. Non-mandatory information: address of the care provider (but the country is mandatory). *Is this application form/modules available online?* The paper form is available for download or can be accessed at the Agency's office.[750] There is also an online system that allows to fill out the application for an individual's care or to fill it out for the care received by a minor.	documents.	the established national framework, a patient chooses to obtain healthcare in another region in Sweden (according to the so-called "vårdvalssysstem"), the patient pays only a patient fee, and not the whole cost of the service. Thus, the question of reimbursement is generally not relevant for healthcare provided nationally and the reimbursement procedure for cross-border healthcare is therefore not comparable to a national one. See Chapter 7, Section 3 of the Health and Medical Services Act(2017:30)/ Hälso- och	

[750] Available at: https://www.forsakringskassan.se/wps/wcm/connect/028c7d98-2bbb-4c07-afbd-ea566a4a8558/fk5422-022-f-002.pdf?MOD=AJPERES&CVID=

	It is accessible through logging the personal information on the competent authority's electronic system, Swedish Social Insurance Agency. *Does the form have to be submitted in paper or can it be submitted electronically?* All applications can be made electronically or in paper. Note of the National body: Electronic applications are encouraged.			
5. What (other) documentation has to be submitted in order to substantiate a reimbursement request?	**Answer:** *If applicable, please specify:* - *What documents are required;* - *Whether the submission of the documentation is optional, mandatory, or recommended.* • Documentation of care, e.g. medical records, and other documents. • Receipts. (scanned copies appear to be accepted, as per the information provided on the Agency's website). No other requirements than the ones accounted for above are required.	**Source(s):** Swedish Social Insurance Agency. Reimbursement form. Note of the National body: These requirements are not set out in law. They are indicated in the Agency's internal working documents.	**Yes** ☐ **No** ☒ See comment above.	

6. **Are there any costs associated with the handling of the reimbursement request?** - *Direct costs (e.g., fixed costs for submitting or filing a reimbursement request, proportion deducted from the reimbursable amount).* *Indirect costs (e.g., translations, stamps, etc).*	**Answer:** *Direct costs:* None identified. *Indirect costs:* None identified. Under the general provisions of the Administrative Procedures Act (2017:900) (free translation), Förvaltningslag (2017:900), the Authority has a duty to use an interpreter should a translation be necessary or the person concerned does not speak Swedish and thus cannot exercise the rights, or has an impairment that severely limits the ability to see, hear or speak.	**Source(s):** Act (2013: 513) The Administrative Procedures Act (2017:900), Förvaltningslag (2017:900), § 13.[753]	**Yes** ☐ **No** ☒ See comment above.	The comment on interpreter, applies indistinctly of the nature of the case being handled.
7. Are there any specific time requirements linked to a reimbursement request? (*e.g., time within which the reimbursement requests must be submitted and/or time within the requested body must handle the request and/or reimburse the costs, etc.*).	**Answer:** *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?* No, Act (2013:513) does not specify any time limit for the patient to request a reimbursement. In accordance with 15 § of Act (2013:513), the decision regarding reimbursement shall be made as soon as it is possible, but at the latest, 90 days after a complete request has been submitted. If particular circumstances require so, deviation from the 90-day period	**Source(s):** Act (2013: 513), §15	**Yes** ☐ **No** ☒ See comment above.	

[753] Administrative Procedures Act (2017:900). Förvaltningslag (2017:900), https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/forvaltningslag-2017900_sfs-2017-900 (accessed 1 July 2021).

	is possible.[754] No specific consequences identified.			
8. Are there any non-reimbursable thresholds, deductions *(except the deductions for administrative costs mentioned above) etc.?*	**Answer:** *If yes, please specify the thresholds.* No, there are no reimbursement thresholds. As a general rule, reimbursement shall be provided to a maximum amount which corresponds to the actual cost of care incurred by the patient. Further specifications apply regarding reimbursement of particular care/produces (see below under Question 10)	**Source(s):** Act (2013: 513), 6 § see also 7 § - 10 §.	**Yes** ☐ **No** ☒ See comment above.	

[754] Note of the National body: A 10 year limit for requesting of the reimbursement, as stipulated in Section 2 of Act on limitation (Preskriptionslag (1981:130)) would apply once the Directive 2011/24 have been in place for 10 years. This is a general administrative time limit.

9. In instances where a PA (or prior-notification) has already been issued, is a separate/simplified procedure available for requesting reimbursement? **applicable only if the country has a PA system.*	**Answer:** *If yes, please describe the simplified procedure.* N/A	**Source(s):** Act (2013: 513) 11 §	**Yes** ☐ **No** ☒ See comment above.	
10. Are there additional administrative/procedural requirements for reimbursement depending on, for instance, the type of treatment for which reimbursement is requested, or the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)* No specific differences in the procedures as such. It is however worth noting that some issues concerning the calculation methods for reimbursement according to national fees had been addressed in 2016 by the Supreme Administrative Court in Sweden (Case number HFD 2016 ref. 27)[755]. Specifically, in this case the Court clarified and assessed the transparency of the reimbursement calculation methods for cross-bord healthcare, taking into account the following provisions of the Act (2013: 513):	**Source(s):** Act (2013: 513), 7 § - 10§.	**Yes** ☐ **No** ☒ See comment above.	

[755] Case number HFD 2016 ref. 27 - Fråga om ersättning för kostnader för vård i annat land inom EES. Available at: https://www.domstol.se/globalassets/filer/domstol/hogstaforvaltningsdomstolen/avgoranden-2008-2018/2016/hfd-2016-ref.-27.pdf

	- In accordance with 6 § of the Act (2013: 513), compensation is provided with a maximum amount that **corresponds to the actual costs for the care that have been incurred for the patient.** - In accordance with 7 § of the Act (2013: 513), for health and medical care and for dental care other than that referred to in section 10 (reviewed below), the compensation shall be determined **at an amount corresponding to the care cost that would have arisen if the patient's care had been provided in Sweden**. (the price of Sweden shall then be taken into account). - The same principle also applies to medicines, other goods, aids, consumables and other care products that a patient has received at the time of care. When determining the amount of compensation, a deduction must be made with an amount corresponding to the fees that the patient would have paid for the care in Sweden. - In accordance with 8 §, for aids and consumables that a patient has acquired at any other time than the time of care, the compensation shall be determined in the same way as specified in 7 § (price of Sweden). - In accordance with 9 §, for			

	medicines and other goods that a patient has acquired at a time other than the time of care, and for which there is an at least equivalent product within the pharmaceutical benefits according to the Act (2002: 160) on pharmaceutical benefits etc., the compensation shall be determined at an amount corresponding to cost reduction that the patient would have been entitled to if the drug or product had been included in the drug benefits. In determining this reimbursement, for each medicinal product or product, a cost amount shall be determined that corresponds to the lowest selling price that has been determined for a product that is at least equivalent and that is included in the pharmaceutical benefits. However, if there are medical reasons, a higher selling price may be set. The amount which, in a comparison between the determined cost amount and the actual cost that the patient has had, is the lowest, shall be used as the basis for determining the compensation. - In accordance with 10 §, for dental care that would have been eligible for support under the Act (2008: 145) on state dental care support, if it had been provided in Sweden, the compensation shall be determined at an amount corresponding to what the Swedish Social Insurance Agency would			

	have paid if the dental care had been provided in Sweden. The same applies to medicines and other care products that a patient has received at the time of care.			
11. Please list any other administrative requirements in your country in relation to the procedures of reimbursement of cross-border healthcare.	**Answer:** There is prior notification system, which is non-mandatory and different from the PA mechanism. As derives from 11 § of the Act, the competent authority shall reimburse for the specified care at least the amount that is indicated in the prior notice. Note of the National body: Sometimes the following challenge emerges: a person has not been registered in the social insurance system with the Authority. The registration requirement applies indistinctly and could be an issue when the person has worked abroad for a while and returns to Sweden. Insuch a case, first, the registration issue needs to be resolved.	**Source(s):** Act (2013: 513)	**Yes** ☐ **No** ☐	N/A

Part 2: Checklist for verification with national/regional body

Name of the body: Swedish Social Insurance
Country/Region: Sweden
Date of verification call: 16/06/2021

Template for the Data Collection	**Aspects to be verified** *Tick the boxes if the information in the template for the data collectionhas been verified and/or complemented by the national body*		**Comment** *Include any additional comments and/or information provided by the contacted body*
Section 1 – Prior Authorisation			
For each question verify the accuracy and/orfill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Justification/purpose of the identifiedrequirement(s) (Column 4)	☒Question 1 ☒Question 2 ☒Question 3 ☒Question 4 ☒Question 5	☒Question 6 ☒Question 7 ☒Question 8 ☒Question 9 ☒Question 10 ☒Question 11	No additional comments.
Section 2 - Reimbursement			

For each question verify the accuracy and/orfill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Whether the requirement applies domestically (Discriminatory assessment)(Column 4) ▪ Justification/purpose of the identifiedrequirement(s) (Column 5)	☒Question 1 ☒Question 2 ☒Question 3 ☒Question 4 ☒Question 5	☒Question 6 ☒Question 7 ☒Question 8 ☒Question 9 ☒Question 10 ☒Question 11	**The feedback received has been incorporated in the respective sections of the above questionnaire.** For a matter of clarity, such comments are reported also here below: Q4 As indicated by the Authority in the call, they urge individuals to apply for reimbursement electronically. As emphasised by the Authority, generally, 10 year limit stipulated in Section 2 of Act on limitation (Preskriptionslag (1981:130)) would apply, once the rights based on directive 2011/24 reach 10 years. Q11 In the call, the Authority has informed that sometimes a challenge emerges that a person has not been registered in the social insurance system with the Authority. The registration requirement applies indistinctly and could be an issue when theperson has worked abroad for a while and returns to Sweden. In such a case, first, the registration needs to be resolved.

Annex B - Directive 2011/24/EU and the Regulations on the Coordination of Social Security Systems

Patients prefer healthcare to be available as close to where they live and work as possible. In the vast majority of cases, the health systems of the EU Member States ensure that the healthcare to patients is provided within their own Member State. It is in general considered to be safer and more efficient to be treated within one healthcare system. However, there are situations when cross-border healthcare can be more appropriate, such as:

- for highly specialised care requiring particular resources or expertise that is beyond the capacity of every Member State to provide (e.g., for rare diseases);
- in border regions, where the nearest appropriate healthcare provider may be across the border in another Member State;
- in cases of lack of capacity, where local services are unable to provide the appropriate healthcare and there is capacity available in another Member State.

With this in mind, in March 2011, the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare ("the Directive") was adopted. In particular, the Directive provides a framework for cross-border healthcare, establishing the rights of patients to seek reimbursement for healthcare received in another Member State, and ensuring that these rights can be used in practice. While the organisation and delivery of healthcare is the responsibility of the Member States, EU citizens have the right to travel to another Member State to receive medical care, in line with the principles of free movement of people, services and goods.[756]

Regulations on the Coordination of Social Security Systems
Already before the Directive was adopted, the right to seek healthcare in other Member States has been regulated by the Regulations on the Coordination of Social Security Systems, namely Regulation (EC) No 883/2004[757], and the implementing Regulation (EC) No 987/2009[758] (hereinafter, "the Regulations").

The Regulations lay down common rules to protect social security rights when moving within the EU, ensuring the coordination of different social security systems while respecting the characteristics of national legislations. The Regulations entitle persons for whom a medical treatment becomes necessary during a stay in another Member State to the same benefits as patients insured in the host Member State, using the European Health Insurance Card. Additionally, they provide for patients to be able to seek planned healthcare in another EU country, subject to prior authorisation (hereinafter "PA") from their own healthcare system. The health services covered by the Regulations are limited to those that are delivered by private or public healthcare

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[756] See Recital 10, according to which "the Directive established rules for facilitating access to safe and high-quality cross-border healthcare in the Union and to ensure patient mobility in accordance with the principles established by the Court of Justice, and to promote cooperation on healthcare between Member States, whilst fully respecting the responsibilities of the Member States for the definition of social security benefits relating to health and for the organisation and delivery of healthcare and medical care and social security benefits, in particular for sickness."

[757] Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems. Available at: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:166:0001:0123:en:PDF.

[758] Regulation (EC) No 987/2009 of the European Parliament and of the Council of 16 September 2009 laying down the procedure for implementing Regulation (EC) No 883/2004 on the coordination of social security systems. Available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32009R0987.

facilities or professionals affiliated with the social security system of the country of treatment.

Under the Regulations, the PA system implies that persons travelling to another country for the purpose of receiving a scheduled treatment have to be authorised to do so in advance by the institution of the competent Member State, which shall bear the costs of such treatment[759]. Under the Regulations, PA shall be accorded if the treatment is among the benefits provided for by the legislation in the Member State where the person concerned resides, and where he/she cannot receive it within a *"medically justifiable"* time-limit, taking into account the state of health.[760] If PA is granted, the patient seeking healthcare abroad is covered at the same level as if he/she was insured under the social security system of the country of treatment, the costs in most instances being paid directly by the competent institution which granted PA (i.e., so called "direct contribution" system, by which the patient does not need to anticipate the costs of the medical care abroad for which PA was received). Nevertheless, in the event that the patient may have actually had to bear such costs him/herself, he/she is entitled to claim the reimbursement of such costs from the competent institution.[761]

Directive 2011/24/EU

As of its adoption in 2011, Directive 2011/24/EU complements the framework established by the Regulations. In particular, the Directive clarifies that patients are entitled to seek healthcare abroad, including planned care, and to subsequently be reimbursed for it by the Member State of affiliation.

In principle, the general rule under the Directive (and the main difference with the Regulations) is that patients have the right to be reimbursed by the Member State of affiliation the costs for planned treatments provided in another Member State, without the need of Prior Authorisation (PA), if the treatment in question is among the benefits to which the person is entitled in the Member State of affiliation[762] (i.e., falls within their national "healthcare basket"). This however implies that patients must pay the healthcare up-front, and then receive the reimbursement afterwards (while under the PA system of the Regulations, the costs are normally paid directly by the institution of the competent Member State).

An exception to this general rule is provided by Article 8(2), which introduces the possibility for Member States to make reimbursement of costs for healthcare received in another Member State subject to prior authorisation (PA), within the specific limitations set out in this provision[763]. However, such an option is by no means intended to be overused, as this would be regarded as restriction of the free

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[759] Article 26(1) of Implementing Regulation 987/2009.
[760] Article 20(2) of Regulation 883/2004.
[761] Article 26(7) of Implementing Regulation 987/2009.
[762] Article 7(1) of the Directive.
[763] Pursuant to Article 8(2) of the Directive: "Healthcare that may be subject to prior authorisation shall be limited to healthcare which:
(a) *is made subject to planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources and: i) involves at least one night of hospitalisation; or ii) requires the use of highly specialised and cost-intensive medical infrastructure or equipment;*
(b) *treatments presenting a particular risk for the patient or the population; or*
(c) *is provided by a healthcare provider that, on a case-by-case basis, could give rise to serious and specific concerns relating to the quality or safety of the care, with the exception of healthcare which is subject to Union legislation ensuring a minimum level of safety and quality throughout the Union*".

movement of services[764]. In fact, according to Article 8(1), PA should be restricted to "*what is necessary and proportionate to the objective to be achieved and may not constitute a means of arbitrary discrimination or an unjustified obstacle to the free movement of patients*".

As regards the amount of the healthcare costs that shall be reimbursed in the application of the Directive, this shall be equal to the costs that the Member State of affiliation would have incurred if the treatment had been provided in its territory[765]. For all the costs exceeding this amount, it is up to the Member State to decide whether to grant reimbursement or not. Furthermore, it should be noted that the Directive aims at ensuring reimbursement of costs not only of public but also other healthcare providers.[766]

However, according to the Directive, patients should not be deprived of the more beneficial rights guaranteed by Regulations (e.g., direct contribution), when the relevant conditions of the latter are met.[767] With this in mind, pursuant to Article 8(3) of the Directive, when handling PA requests under the Directive the Member State of affiliation shall ascertain whether the conditions laid down in Regulation (EC) No 883/2004 have been met and, if so, PA shall be granted pursuant to that Regulation, unless the patient requests otherwise.

The Directive in any case is without prejudice of Member States' right to offer patients a voluntary system of so-called "prior notification" whereby the patient may seek and receive written confirmation of the amount to be reimbursed on the basis of an estimate. This estimate shall take into account the patient's clinical case, specifying the medical procedures likely to apply.[768] Though the prior notification system is optional for Member States, it may be considered as a helpful tool for providing patients with clarity and supporting the authorities in complying with their obligations.[769]

Main differences between Directive 2011/24/EU and the Social Security Coordination Regulations

As previously mentioned, the Regulations and the Directive complement each other. In particular, the right to receive reimbursement is regulated in detail by the Directive, "*without prejudice to Regulation (EC) No 883/2004*".[770] In order to provide more clarity, the main differences between the Regulations and Directive 2011/24/EU which are relevant for the tasks to be conducted under WP1.b. of the present Study, can be summarised as follows:

- **Assumption of costs:**
  - **Regulations:** in most instances, direct contribution by the social security system of the competent Member State (i.e., costs paid directly up-front

[764] Recital 38 of the Directive.
[765] Article 7(4) of the Directive.
[766] According to Article 1(2), the Directive applies to the provision of healthcare to patients, regardless of how it is organised, delivered and financed. Moreover, according to the definition contained in Article 3(g) of the Directive, 'healthcare provider' means any natural or legal person or any other entity legally providing healthcare on the territory of a Member State.
[767] Recital 31 of the Directive.
[768] Article 9(5) of the Directive.
[769] Report of the European Committee of Regions of 13 July 2020 on 'Implementation of the Cross-border Healthcare Directive in the European regions'. Available at: https://cor.europa.eu/en/engage/Documents/RegHub/report-consultation-03-cross-border-healthcare.pdf
[770] Article 7(1) of the Directive.

and without anticipation of costs for the patient). The healthcare costs are covered to the same level, as if as though the patient concerned were insured under the legislation of the Member State of treatment;
  - **Directive:** the patient is required to anticipate the cost of the treatment and subsequently is entitled to submit a claim for the reimbursement. Reimbursement is normally equal to the cost that the patient's healthcare system would have incurred if the treatment had been provided in the patient's country, without exceeding the actual costs of healthcare received.

- **Prior Authorisation (PA):**
  - **Regulations:** PA for planned treatment abroad is always required under the Regulations. By contrast, treatments that become necessary on medical grounds during a patient's temporary stay in another Member State do not require PA and are obtained in healthcare facilities affiliated with the social security system of the country of treatment using the European Health Insurance Card;
  - **Directive**: PA should be an exception, and as a general rule the patient is entitled to claim reimbursement for healthcare treatments abroad without asking for PA. Member States have the option to introduce a PA system for certain types of treatment and respecting the conditions of the Directive (specifically, Article 8). Many Member States have done so.

- **Healthcare providers:**
  - **Regulations:** cover health services delivered by public or private healthcare facilities or professionals affiliated with the social security system of the country of treatment;
  - **Directive:** reimbursable services may be provided by public and private healthcare providers, even if not affiliated with the social security system of the country of treatment.

Annex C - Bodies contacted for the verification of the data collected

The table below presents an overview of which bodies have been contacted by national legal experts in each country for the verification of the data collected in the national country reports, and whether the information collected has been verified by such bodies. In particular, in six countries (AT, CY, FR, LI, LU, PT) the verification of the data collected with the relevant national/regional bodies was not possible due to the lack of response or unavailability of the body contacted by the national legal experts. In three countries (BG, DK, ES, NL) the data collected were verified by more than one body in each country.

Table A. 1: Bodies contacted for the verification of the data collected

Country	Bodies contacted for verification of the data collected	Information verified YES/NO
AT	Österreichische Gesundheitskasse (ÖGK) - Austrian Health Insurance Fund[771]	NO
BE	National Institute for Health and Disability Insurance[772]	YES
BG	1) National Health Insurance Fund (NHIF);[773] and 2) Ministry of Heath[774]	YES
CY	Ministry of Health[775]	NO
CZ	Všeobecná zdravotní pojišťovna České Republiky (VZP ČR)[776]	YES
DE	The German National Contact Point[777] Bundesministerium für Gesundheit (Federal Ministry of Health)[778]	YES

[771] Available at: https://www.gesundheitskasse.at/cdscontent/?contentid=10007.813892&portal=oegkportal.
[772] Available at: https://www.inami.fgov.be/fr/Pages/default.aspx. The national country report was also sent to this body, on its own request, by Spark Legal Network for further validation on 30/09/2021, however, no further comments were received.
[773] Available at: https://www.en.nhif.bg/.
[774] Available at: https://www.mh.government.bg/en/.
[775] Available at: https://www.moh.gov.cy/moh/moh.nsf/index_en/index_en.
[776] Available at: https://www.vzp.cz/
[777] Available at: https://www.eu-patienten.de/en/behandlung_ausland/liste_nationaler_kontaktstellen_eu_ausland/nationale_kontaktstellen_eu.jsp. The national country report was also sent to this body, on its own request, by Spark Legal Network for further validation on 30/09/2021. This body provided feedback in writing to Spark Legal Network on 8/10/2021.
[778] Available at: https://www.bundesgesundheitsministerium.de/english-version.html (this body was contacted by the national legal expert for the verification of the data collected, but no feedback was received).

Country	Bodies contacted for verification of the data collected	Information verified YES/NO
DK	1) Regionsrådet, Region Syddanmark (The Regional Council, Region Syddanmark)[779]; and 2) Danish Patient Safety Authority (Coordinating NCP).[780]	YES
EE	The Estonian Health Insurance Fund (EHIF)[781]	YES
EL	National Organisation for the Provision of Health Services (EOPYY-ΕΟΠΥΥ Ενιαίος Οργανισμός Παροχών Υπηρεσιών Υγείας)[782]	YES
ES	1) Catalan Health Service[783]; and 2) SX Health planning and insurance (Galician Health Department)[784]	YES
FI	Kansaneläkelaitos (KELA)[785]	YES
FR	Caisse primaire d'assurance maladie (CPAM) (Primary health insurance fund) (and regional offices)[786]	NO
HR	Croatian Health Insurance Fund (CHIF)[787]	YES
HU	National Health Insurance Fund of Hungary (NEAK)[788]	YES
IE	HSE Cross Border Directive[789]	YES
IS	Icelandic Health Insurance (IHI)[790]	YES
IT	Ministry of Health[791]	YES
LI	Amt für Gesundheit (Office of Public Health)[792]	NO

[779] Available at: https://www.regionsyddanmark.dk/wm436558.
[780] Available at: https://en.stps.dk/en/citizens/national-contact-point-for-cross-border-in-the-eueea/. The national country report was sent to this body, on its own request, by Spark Legal Network for further validation on 30/09/2021.This body provided feedback in writing to Spark Legal Network on 8/10/2021.
[781] Available at: https://haigekassa.ee/en.
[782] Available at: https://www.eopyy.gov.gr/ekpy/view. The national country report was sent to this body, on its own request, by Spark Legal Network for further validation on 30/09/2021.This body provided additional feedback in writing to Spark Legal Network on 8/10/2021.
[783] Available at: https://catsalut.gencat.cat/ca/coneix-catsalut/acces-sistema-salut/assistencia-transfronterera/persones-assegurades-catalunya/com-solicitar/autoritzacio-previa/.
[784] Available at: https://www.sergas.es/.
[785] Available at: https://www.kela.fi/. The national country report was also sent to this body, on its own request, by Spark Legal Network for further validation on 30/09/2021. This body confirmed the accuracy of the data collected on 08/10/2021.
[786] Available at: https://www.annuaire-administration.com/cpam/. The national country report was also sent to this body, on its own request, by Spark Legal Network for further validation on 30/09/2021, however no further comments were received.
[787] Available at: https://hzzo.hr/en. The national country report was sent to this body, on its own request, by Spark Legal Network for further validation on 30/09/2021.This body provided feedback in writing to Spark Legal Network on 30/09/2021.
[788] Available at: http://neak.gov.hu/.
[789] Available at: https://www2.hse.ie/services/cross-border-directive/about-the-cross-border-directive.html.
[790] Available at: https://www.sjukra.is/english/.
[791] Available at: https://www.salute.gov.it/portale/home.html. The national country report was also sent to this body, on its own request, by Spark Legal Network for further validation on 30/09/2021, however no further comments were received.
[792] Available at: https://www.llv.li/inhalt/117345/amtsstellen/patientenmobilitat-im-eu-ewr-raum.

Country	Bodies contacted for verification of the data collected	Information verified YES/NO
LT	National Health Insurance Fund under the Ministry of Health[793]	YES
LV	The National Health Service (Nacionālais veselības dienests)[794]	YES
LU	Caisse nationale de santé - D'Gesondheetskeess (CNS) (National Health Fund)[795]	NO
MT	1) Department of Social Security[796]; 2) Maltese National Contact Point[797]	YES
NL	1) CZ insurance fund;[798] 2) Menzis insurance fund[799]; and 3) CAK (Dutch NCP)[800]	YES
NO	The Norwegian Ministry of Health and Care Services and the Norwegian Directorate of Health[801]	YES
PL	The National Health Fund[802]	YES
PT	Direção Geral de Saúde (General Health Department - Ministry of Health)[803]	NO
RO	The National Health Insurance House[804]	YES
SE	Försäkringskassa (Swedish Social Insurance Agency)[805]	YES
SI	Health Insurance Institute of Slovenia[806]	YES
SK	Health Care Surveillance Authority[807]	YES

[793] Available at: https://ligoniukasa.lrv.lt/lt/paslaugos/paslaugu-aprasymai/tarpvalstybines-sveikatos-prieziuros-islaidu-kompensavimas-paslauga-teikia-teritorines-ligoniu-kasos-1.
[794] Available at: https://www.vmnvd.gov.lv/en/about-us.
[795] Available at: https://cns.public.lu/fr.html.
[796] Available at: https://socialsecurity.gov.mt/en/. Please note that this body did not provide feedback on the data collected.
[797] Available at: https://deputyprimeminister.gov.mt/en/cbhc/Pages/Cross-Border.aspx. The national country report was sent to this body, on its own request, by Spark Legal Network for further validation on 30/09/2021.This body provided feedback in writing to Spark Legal Network on 7/10//2021.
[798] Available at: https://www.cz.nl/en. The national country report was sent to this body, on its own request, by Spark Legal Network for further validation on 30/09/2021. This body provided feedback in writing to Spark Legal Network on 7/10//2021.
[799] Available at: https://www.menzis.nl/englishwebsite.
[800] Available at: https://www.hetcak.nl/zelf-regelen/ncp.
[801] Available at http://www.helsedirektoratet.no/portal/page?_pageid=134,112387&_dad=portal&_schema=PORTAL&language=english.
[802] Available at: https://www.nfz.gov.pl/dla-pacjenta/nasze-zdrowie-w-ue/leczenie-planowane-wymagajace-uprzedniej-zgody/zbyt-dlugi-czas-oczekiwania-na-leczenie-w-polsce/zgoda-uprzednia-na-podstawie-dyrektywy-transgranicznej/.
[803] Available at: SNS – Portal do SNS.
[804] Casa Națională de Asigurări de Sănătate, available at: http://cnas.ro/. The national country report was also sent to this body, on its own request, by Spark Legal Network for further validation on 30/09/2021, however no further comments were received.
[805] Available at: https://www.government.se/government-agencies/social-insurance-agency--forsakringskassan/.
[806] Zavod za zdravstveno zavarovanje Slovenije (ZZZS). Available at: https://www.zzzs.si/.
[807] Available at: https://www.udzs-sk.sk/en/abouth-the-hcsa/.

Annex D - Bodies handling the administrative requests across the countries

The table below presents an overview of the bodies which have been identified in each country as being responsible for handling the PA and reimbursement requests for cross-border healthcare under the Directive.[808] Countries where no PA system was found to be implemented are coloured in grey.

In sixteen countries (BG, CY, EE, EL, FI, HR, HU, IE, IS, LV, LU, MT, NO, PL, PT[809], SE, national-level bodies are in charge of handling the requests for PA (where applicable) and for reimbursement. In Bulgaria, additionally, there are two national bodies, with two different procedures.[810] In five countries (DK, ES, IT, LT, SI), local or regional bodies or local offices of the national healthcare authority are involved in handling the requests.[811] Furthermore, in seven countries (AT, BE, CZ, DE, FR, NL, SK[812]), different insurance providers are in charge of handling the requests. Finally, in almost all countries where a PA system has been implemented, the same body is competent for both procedures (PA and reimbursement), with two exceptions (LU and SI). Particularly, in Luxembourg, PA requests are handled by the *Caisse nationale de santé - D'Gesondheetskeess* (CNS) (National Health Fund), while for reimbursement requests, the body can vary depending on the employment sector of the insured person.[813] In Slovenia, the national body is in charge of PA applications, while the regional body is competent for requests of reimbursement.

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808 For more information, please refer to the national country reports, Part 1, Section 1, question 3 and Section 2, question 3.

809 With the exception of regional bodies in the two autonomous regions of Azores and Madeira.

810 Please note that in Bulgaria, PA and reimbursement requests are handled either by the National Health Insurance Fund (NHIF) or by the Ministry of Health, depending on the respective healthcare service or product. According to the national legislation, the NHIF is entitled to handle requests related to: i) Medical devices applied in the hospital medical care; ii) Medical healthcare provided in the framework of outpatient procedures for nuclear medical computed tomography imaging; iii) Medicinal products included in Annex No 2 of the Positive Pharmaceutical List under Article 262(6), item 2 of the Pharmaceutical Products in Human Medicine Act, intended for treatment of malignant diseases in the hospital medical care; iv) Medical devices, paid according to Ordinance No 2 of 2019 for the medical and other services under Articles 82(1a) and 82(3) of the Health Act. The Ministry of Health is instead entitled to handle requests related to: i) Assisted reproduction activities; ii) Transplantation of organs, tissues and cells. For this reason, the national report has been completed with the information about both procedures.
For more information, please see Part 1, Section 1, Question 1 of the national country report.

811 For example, Italy has a national system for healthcare, but PA and reimbursement requests are handled by the local health units. Spain, instead, has a complete decentralised system, as the Autonomous Communities have competences for regulating PA and reimbursement procedures for cross-border healthcare. Please note that, because of this reason, the national report has been completed with the information gathered in Catalunya and Galicia. Catalunya provides an example of a region which did not exercise its competences in regulating the area (and therefore, the federal legislation is applicable), while Galicia constitutes an example of a Region with its own procedural rules on this matter. In Portugal, even if the jurisdiction is national, there are both a national body and regional bodies, which are competent to deal with the procedures, respectively for the continental territory in Europe and the two autonomous regions of Azores and Madeira. For more information on this, please see Section 1 of Annex E.

812 In Slovakia, there are three health insurance companies, among which the main one is state-owned, while the other two are private. Please note that, even if there are also two private insurance companies, the system is regulated by national law and the procedures apply, therefore, nationally.

813 Please note that the following national funds might be competent: the CNS for private sector workers; the Caisse de maladie des fonctionnaires et employés publics (CMFEP) (Health Insurance Fund for Civil Servants and Public Employees) and Caisse de maladie des fonctionnaires et employés communaux (CMFEC) (Health Insurance Fund for Communal Civil Servants and Employees) for public sector workers; and the Entraide médicale des CFL (EMCFL) (CFL Health Insurance Fund) for the employees of the Luxembourg Rail Company.

Table A.2 Bodies handling the administrative requests

Country	Body for PA	Body for reimbursement	Type/level of body
AT	Competent Health Insurance Institution: • Austrian Health Insurance Fund (Österreichische Gesundheitskasse) • Insurance Institution for Public Employees, Railways and Mining (Versicherungsanstalt öffentlicher Bediensteter, Eisenbahn und Bergbau) • Social Insurance for the Self-Employed (Sozialversicherung der Selbständigen)[814]	*Idem*	Insurance providers
BE	Insurance funds	*Idem*	Insurance providers
BG	• National Health Insurance Fund (NHIF) • Ministry of Health	*Idem*	National body
CY	N/A (no PA)	*Idem*	National body
CZ	N/A (no PA)	Regional offices of the insurance funds.	Insurance providers.
DE	Health insurance providers. The most important/relevant is the "Verband der Ersatzkassen e.V. (vdek)" (Association of Substitute Funds e.V.).	Idem.	Insurance providers.
DK	The Regional Council of each region[815]	*Idem*	Local bodies.
EE	The Estonian Health Insurance Fund (if a PA system is introduced)	*Idem*	National body.
EL	National Organisation for the Provision of Health Services (ΕΟΡΥΥ-ΕΟΠΥΥ Ενιαίος Οργανισμός Παροχών Υπηρεσιών Υγείας)	*Idem*	National body.
ES	• For Catalunya: the Catalan Health Service[816] • For Galicia: Integrated Management Organisational Structure (EOXI)	*Idem.*[817]	Regional bodies.

[814] The data provided have been gathered from the Austrian Health Insurance Fund, which is the largest Austrian federal social insurance institution with the most insured persons.

[815] These are the following: 1) Søg forhåndsgodkendelse i Region Hovedstaden; 2) Søg forhåndsgodkendelse i Region Sjælland; 3) Søg forhåndsgodkendelse i Region Syddanmark; 4)Søg forhåndsgodkendelse i Region Midtjylland; 5) Søg forhåndsgodkendelse i Region Nordjylland.

[816] According to the national legislation, the competent authorities of the Autonomous Community, the National Institute of Health Management or the corresponding mutuality of public workers are in charge of handling PA applications. They establish the procedure and specify a body in charge of receiving the application.

[817] Please note that for Galicia, if the reimbursement request is more than 30,000 euros, the request will be processed by the Health Care Directorate

Country	Body for PA	Body for reimbursement	Type/level of body
FI	N/A (no PA)	Kansaneläkelaitos (KELA) – National social security body	National body.
FR	Local Primary health insurance funds (CPAMs)	*Idem*	Insurance providers.
HR	Croatian Health Insurance Fund (CHIF)	*Idem*	National body
HU	National Health Insurance Fund of Hungary (NEAK)[818]	*Idem*	National body.
IE	Health Service Executive (HSE)[819]	*Idem*	National body.
IS	Icelandic Health Insurance (IHC)[820]	*Idem*	National body.
IT	Local health units (ASL – Azienda Sanitaria Locale)[821]	*Idem*	Regional/local bodies.
LI	N/A (not clear if a PA system is established under the Directive).	N/A (not clear if a reimbursement system is established under the Directive).	N/A (Not clear).
LT	N/A (no PA)	Territorial health insurance funds (5 in total) (e.g., Vilnius Territorial Health Insurance Fund, Kaunas Territorial Health Insurance Fund).	Regional/local bodies.
LV	N/A (no PA)	The National Health Service (Nacionālais veselības dienests)[822]	National body.
LU	Caisse nationale de santé - D'Gesondheetskeess (CNS) (National Health Fund)[823]	Either: 1. CNS - (National Health Fund) for the private sector, which is the main public health fund based on the number of affiliations. 2. Caisse de maladie des fonctionnaires et employés publics (CMFEP) (Health Insurance Fund for Civil Servants and Public Employees) and Caisse de maladie des fonctionnaires et employés communaux (CMFEC) (Health Insurance Fund for Communal Civil Servants and Employees) for the public sector.	National insurance funds

[818] Available at: http://neak.gov.hu/.
[819] Available at: https://www.hse.ie/eng/
[820] Available at: https://www.sjukra.is/heilbrigdisthjonusta/rettindi-milli-landa/laeknismedferd-erlendis/langur-bidtimi-eftir-medferd-a-islandi/heilbrigdisthjonusta-yfir-landamaeri-innan-ees-landa/
[821] There are more than 100 local health units in Italy.
[822] Available at: https://www.vmnvd.gov.lv/en
[823] Available at: https://cns.public.lu/fr.html

Country	Body for PA	Body for reimbursement	Type/level of body
		3. Entraide médicale des CFL (EMCFL) (CFL Health Insurance Fund) for the employees of the Luxembourg Rail Company.	
MT	The Office of the Chief Medical Officer of the Ministry of Health (the NCP)[824]	*Idem.*	National body.
NL	Private insurance providers.[825]	*Idem.*	Insurance providers.
NO	N/A (no PA)	The Norwegian Health Economics Administration in the Directorate of Health (Helfo)[826]	National body.
PL	National Health Fund[827]	*Idem.*	National body.
PT	At national level: • Central Administration of the Health System (Administração Central do Sistema de Saúde, I.P. – ACSS). 2 national Regional Contact Points: • Madeira: Regional Health Service of Madeira – SESARAM "Serviço de Saúde da Região Autónoma da Madeira" • Azores: Regional Directorate for Health of Azores	*Idem.*	National and Regional bodies.
RO	County Health Insurance Houses – 43 in Romania	*Idem.*	Regional/local bodies.
SE	N/A (no PA)	Swedish Social Insurance Agency (Försäkringskassa[828]	National body.
SI	ZZZS, Regional Unit of Ljubljana	ZZZS, Regional offices.	PA: National body. Reimbursement: Regional/local bodies.
SK	3 health insurance companies (one state-owned and two private); "Všeobecná zdravotná poisťovňa, a.s."[829] is the	*Idem*.	National (public/private insurance funds)

[824] Available at: https://deputyprimeminister.gov.mt/en/CMO/Pages/Chief-Medical-Officer.aspx.
[825] National legal research has been conducted in NL with regards to the administrative procedures for cross-border healthcare established by the following two insurance providers: 1) CZ (https://www.cz.nl/en); and 2) Menzis (https://www.menzis.nl/englishwebsite).
[826] Available at: https://www.helfo.no.
[827] National Health Fund official website available at: https://www.nfz.gov.pl/dla-pacjenta/nasze-zdrowie-w-ue/leczenie-planowane-wymagajace-uprzedniej-zgody/zbyt-dlugi-czas-oczekiwania-na-leczenie-w-polsce/zgoda-uprzednia-na-podstawie-dyrektywy-transgranicznej/.
[828] Available at: https://www.government.se/government-agencies/social-insurance-agency--forsakringskassan/.
[829] Available at: https://www.vszp.sk/.

Country	Body for PA	Body for reimbursement	Type/level of body
	biggest Health Insurance Company in Slovakia.		

Annex E - Summarised overview of data collected: PA procedures

1. Application modules to request PA

Table A. 3 Application modules for PA procedures[830]

No PA | Yes | No | Not clear

Country	AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HR	HU	IE	IS	IT	LI	LT	LV	LU	MT	NL		NO	PL	PT	RO	SE	SI	SK
Form for requesting PA		831	832		N/A			N/A			N/A							833	N/A	N/A			**C**	**M**	N/A			834	N/A		
Available online			835	836	N/A		837	N/A	838	839	N/A			840	841	842	843		N/A	N/A	844	845		846	N/A	847	848	849	N/A	850	851

830 For more information, please refer to the national country reports, Part 1, Section 1, question 4.
831 Please note that a standardised file of the extensive medical report needs to be filled in by the specialised doctor, to be submitted together with the application.
832 Applicable for both PA procedures available in Bulgaria (NHIF and Ministry of Health). Please note, however, that for PA procedure for transplantation services (under the Ministry of Health), a PA application form is not available, but its submission is in free form.
833 No information available.
834 There is no standardised application form. However, the minimum information that must be provided in the request is set out in the legislative sources. For the sources and the reasons for not having a standardised form, please refer to the RO country report, Section 1, question 5. Moreover, the national body contacted for verification of the data collected indicated that the county health insurance houses are allowed flexibility in publishing a draft application form/module. However, it appeared that the forms published on the websites of the county health insurance houses are not updated as per the today applicable legislative framework.
835 Applicable for both PA procedures available in Bulgaria (NHIF and Ministry of Health), available at: https://www.en.nhif.bg/.
836 Despite PA not being required in Cyprus for cross-border healthcare under the Directive (i.e., the PA requirement was recently removed and is currently not foreseen by national legislation), nonetheless information on the PA requirement appeared to still be available on the website of the NCP. A link to a specific application module for PA is available at: https://www.moh.gov.cy/Moh/cbh/cbh.nsf/page24_en/page24_en?OpenDocument. It should be noted that the application form seems to be relevant for requesting PA under the Regulations.
837 Available at: https://www.regionh.dk/Sundhed/Patientguiden/i-behandling-paa-hospital/rejse-og-ophold-i-udlandet/Sider/Forhaandsgodkendelse.aspx.
838 Available at: https://eu-healthcare.eopyy.gov.gr/gr/key_docs.aspx.
839 PA application form for Catalunya available at: https://catsalut.gencat.cat/web/.content/minisite/catsalut/ciutadania/acces_sistema_salut/assistencia_transfronterera/altres_ue/240z564sap_sol_autoritzacio_assistencia_altre_pais.pdf. PA application form for Galicia available at: https://www.sergas.es/Asistencia-sanitaria/Documents/573/Solicitude_autorizaci%C3%B3n_previa.pdf.
844 Form for PA request available at: https://cns.public.lu/dam-assets/formulaires/transfert-a-etranger/Demande_Transfert_Etranger_FR_07_2017_.pdf

[841] Available on the HSE's website at: https://www2.hse.ie/file-library/cross-border-directive/cbd-application-for-prior-authorisation.pdf.

[842] Available on the IHI's website: https://www.sjukra.is/heilbrigdisthjonusta/rettindi-milli-landa/laeknismedferd-erlendis/langur-bidtimi-eftir-medferd-a-islandi/heilbrigdisthjonusta-yfir-landamaeri-innan-ees-landa/.

[843] Please note that generally the form is not available online, but a template can be found in Annex A to the Guidelines on Cross-border Healthcare of 2017.

[844] Form for PA request available at: https://cns.public.lu/dam-assets/formulaires/transfert-a-etranger/Demande_Transfert_Etranger_FR_07_2017_.pdf

[845] Please note that at the time of the data collection task, the link to the PA application form on the national authority's website redirected to an incorrect form (i.e., the specific module for the reimbursement request). The specific form for PA application was ultimately not identified during the national research conducted by the national legal expert. However, on 7/10/2021 the Maltese NCP informed Spark Legal Network that the mistaken link on the website has been corrected, and the form is therefore currently available online.

[846] Available at: Vergoeding medische behandeling buitenland (menzis.nl).

[847] The form to be used is included in Annex I to the following legislative measure: Regulation of the Minister of Health of 18 March 2021 on the issuance of consent to obtain healthcare services outside the country and cover the costs of transport (Rozporządzenie Ministra Zdrowia z dnia 18 marca 2021 r. w sprawie wydawania zgody na uzyskanie świadczeń opieki zdrowotnej poza granicami kraju oraz pokrycie kosztów transport), available at [in Polish]: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20210000644

[848] Available at: https://diretiva.min-saude.pt/autorizacao-previa/req-pedido-de-autorizacao-previa/.

[849] The national body contacted for verification of the data collected indicated that the county health insurance houses are allowed flexibility in publishing a draft application form/module. However, it appeared that the forms published on the websites of the county health insurance houses are not updated as per the today applicable legislative framework.

[850] Available at: https://zavarovanec.zzzs.si/wps/portal/portali/azos/pravice_zdravstvenih_storitev/pravice_zdravljenje_tujina/

[851] Specific application form has to be used by all three insurance companies in SK. Annex no. 4 of Decree of Ministry of Health of The Slovak Republic no. 232/2014 Coll. regulating the procedure of the healthcare provider, the health insurance company and the Healthcare surveillance authority in the provision of cross-border healthcare, 11 August 2014 with later amendments. (Vyhláška Ministerstva zdravotníctva Slovenskej republiky z 11. augusta č. 232/2014 Z. z. ktorou sa upravuje postup poskytovateľa zdravotnej starostlivosti, zdravotnej poisťovne a Úradu pre dohľad nad zdravotnou starostlivosťou pri poskytovaní cezhraničnej zdravotnej starostlivosti). Available at https://www.slov-lex.sk/pravne-predpisy/SK/ZZ/2014/232/20140901.

2. Forms used to issue/grant PA

According to the findings of the national data collection, in the majority of countries (AT, BE, DK, EL, ES, IE, IS, MT, PL, SI), no specific form for granting PA was identified.[852] In Bulgaria, no form was identified for the PA procedure within the Ministry of Health, but a form is available for the PA procedure within the National Health Insurance Fund (NHIF). In the Netherlands, a PA form can be used by the health insurance providers, but it is not required, as the decision can also be communicated via letter. In some countries (FR, LU, NL, SK), the PA form used under Directive 2011/24/EU might be the same as the S2 form used under the Social Security Coordination Regulations. In one country (DE) the German NCP indicated that the S2 form is only for granted healthcare under the Regulation 883/2004, not for cases concerning the Directive.[853] Among these, in three countries (LU, NL and SK), the PA form is not the only option, as national authorities can also use other means or form to communicate the decisions. In Italy, the form used is the same as the one used to request the PA, which contains a specific section to be completed by the competent body, which is then returned to the applicant. Finally, in other instances, decisions could be taken by way of a letter (IE, MT, NL) or administrative decisions (ES, PL, SI).

3. Information to be included in the application module/attachments

The following table presents a summarised overview of what information and which documents have been found to be required for the submission of a PA request in each country, as illustrated also in Chapter 3 of the present report.[854] Countries where no PA system was found to be implemented are coloured in grey. It should be noted that in the case of Estonia, though no PA system has been implemented, the requirements identified in national legislation in the event that it is implemented in the future have been incorporated in the table below, for a matter of completeness. Moreover, in Liechtenstein no information on the PA procedural requirements under the Directive was identified.[855]

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[852] For more information, please refer to the national country reports, (Part 1) Section 1, question 10.

[853] Information provided to Spark Legal Network by the German NCP on 1/10/2021.

[854] For more information, please refer to the national country reports, (Part 1) Section 1, questions 5 and 6.

[855] It should be also noted that in nine countries (AT, BE, EL, FR, HR, HU, LU, SI, SK), the procedures for requesting PA under the Directive or the Regulations on the Coordination of Social Security Systems (the 'Regulations') appear to be the same. In Austria, for instance, it was noted that the PA application forms do not seem to make a distinction between whether PA is requested under the Directive or under other legal bases. In five countries (CZ, ES, IS, IT, PL), though being formally different (e.g., in terms of application modules and/or in terms of information to be provided with the application), the procedures are considered as being substantially equivalent, in consideration of the fact that, even when applicants apply for PA according to the formalities required for the procedure under the Directive, nonetheless the bodies handling the procedures must check whether the PA request complies with the requirements of the Regulations and, if so – and unless the patient specifically requests otherwise – the PA shall be granted according to the more favourable rules of the Regulations. In one country (PT) it was found that the same application form may be used, but the applicant must indicate whether PA is requested under the Directive or Regulations and, depending on the choice, the body involved in providing a reasoned decision will differ (however, patients may change their choice whilst the procedure is ongoing). In one country (MT), the Maltese NCP informed Spark Legal Network that "the procedure for PA under the Regulation is similar, in the sense that the Treatment Abroad Committee assesses the application that is done by the clinician and raised to the committee". In two countries (BG, RO), the procedures under the Directive and the Regulations appear to be different, but no further information on such differences was gathered during the data collection tasks. In one country (DK) the Danish Patient Safety Authority informed Spark Legal Network that the procedures are also different. However, it may be inferred that also in the latter countries, the procedures may be considered to be substantially the same, to the extent that the bodies handling the procedures may be required to check whether the PA requests under the Directive meet the more favourable requirements of

Table A.4 Information to be included in the application/request

Country	Information required	Mandatory?	Electronic submission?
AT	**Information in the module/request:** No specific application form for PA exists.	N/A	No.
	Documents to be attached/substantiate the request: Information on: • The type of treatment, • The intended treatment objective, • The time of the treatment, • The health care provider from whom the treatment is to be received, • The documents on the state of health which allow an assessment of the urgency of the treatment.	No[856]	
BE	**Information in the module/request:** No specific application form for PA exists.	N/A	No. Submission via registered letter.[857]
	Documents to be attached/substantiate request: Standardised extensive medical report including the following information: • patient details (name, national security number, address), • referring doctor details, • initiating applicant (referring doctor/at the suggestion of another doctor – name and details/doctor at the request of the patient), • medical problem (medical diagnosis, relevant history, previous treatments and results, attached medical records), • requested healthcare (medical description, details of the healthcare faculty, care modalities – if outpatient or day admission or hospitalization, follow-up care – description, frequency, and if possible in Belgium), • circumstances of application for care abroad (other doctors consulted in Belgium and their written advice), • medical/technical availability of the requested healthcare in Belgium (availability of the requested healthcare in Belgium? If	Yes	

the Regulations and, if so, to grant PA according to the latter regime. In two countries (DE, NL), the answer to the question on whether the procedures under the Directive and the Regulations are the same may vary depending on the different insurance providers (whilst also considering that one of the main factors determining whether PA is required or not, depends on whether or not the healthcare provider is a contracted or non-contracted one). In the case of the Netherlands, it should be noted that the data collected showed that the PA procedures established by two insurance providers – CZ and Menzis – appear to be the same under the Directive and the Regulations. Finally, in one country (LI), it is unclear whether a PA system under the Directive has been implemented.

856 The documentation is not mandatory but recommended in order to provide the eligibility.

857 Or any other way that allows to verify the date of submission.

Country	Information required	Mandatory?	Electronic submission?
	yes: corresponding nomenclature number; if no: alternative treatment in Belgium), • reasons for not using the healthcare available in Belgium (in case of "more favourable medical circumstances", give reasons why did not chose healthcare in Belgium), • date and signature.		
BG	**<u>PA procedure within the NHIF</u>** **Information in the module/request:** • applicant's details (name, family name phone/email), • national identification number of the applicant, • parents' details for minors, • type of the healthcare services or medical device, • name and country of the healthcare establishment where the healthcare service will be provided, • national identification number of the patient, • permanent and current address of the patient, • national ID/passport details, • date, place, signature of the applicant and of the patient.	Yes.	No. Submission on paper, either via post or in person.
	Documents to be attached/substantiate the request: • copy of the ID of the patient, • medical documentation certifying the disease and the diagnosis made, the treatment carried out and the conclusions from medical specialists justifying the need for the treatment, • template declaration regarding the fact that that the person is not insured in another country or that the minor (if relevant) has not received approval for payment under Ordinance No 2 of 2019, • copy of document certifying the parental/guardian/trustee relationship, if applicable, • power of attorney, if applicable, • data protection declaration. Additionally, for medical devices: • copy of document certifying the quality of parent, guardian, custodian or person performing substitute care of the patient, • medical documentation issued not more than 2 months prior to the submission, certifying the diseases, the condition and the diagnosis, the treatment carried out and the treatment plan, including the need to apply for PA,	Yes.	

Country	Information required	Mandatory?	Electronic submission?
	• official document from a medical establishment abroad, indicating type and prices of the medical device, and technical specification (if possible), • information from the medical establishment abroad regarding: (a) the presence or absence of a label on the medical device; and (b) possibility to provide a label of the medical device, • personal data protection declaration, • template declaration of the patient declaring that he/she is not using another instrument for financing with public funds for the same services, • power of attorney.		
	<u>PA procedure within the Ministry of Health</u> **Information in the module/request:** **<u>a) for assisted reproduction activities</u>** • woman's personal details (also phone/email), • national identification number of the applicant, • ID and number of the issuing body, • Permanent address and address for correspondence, • citizenship, • partner's details and national identification number (if relevant) • medical establishment chosen, • information on the means by which the applicant wishes to receive the issued individual administrative act (via email, post etc.), • date, place, signature. **b) for transplantation** No specific application form for PA exists.	Yes.[858]	No. Submission on paper, either via post or in person.
	Documents to be attached/substantiate the request: **<u>a) for assisted reproduction activities</u>** • medical documentation certifying the need for assisted reproduction activities, • interim medical report recommending these activities, • medical documentation certifying the absence of certain circumstances preventing from applying the assisted reproduction method, • copy of ID card, • documentation certifying the lack of blood relationship between the applicant and the partner,	Yes.	

[858] The only non mandatory information is the partner's details.

Country	Information required	Mandatory?	Electronic submission?
	• template informed consent of the applicant and the partner, • template declaring absence of guardianship. **b) for transplantation** • copy of ID, • power of attorney, if relevant, • medical documentation issued not more than 6 months prior to the application, certifying the disease and the diagnosis, the treatment carried out, interim medical report, opinions, conclusions, recommendations of medical specialists.		
CY	***Note: PA not implemented in Cyprus*** *(The module for PA available online required the following information and documents)* **Information in the module/request:** • personal details of the applicant, • requested health services, • declaration (signature, date, full name).	N/A	N/A
	Documents to be attached/substantiate the request: • copy of ID or relevant certificate issued by the Ministry of Health • copy of the medical report which shall include: ○ diagnosis/diseases ○ patient history ○ current state of health ○ reasons for which cross-border healthcare is suggested	N/A	
CZ	N/A (no PA)		
DE	**Information in the module/request:** The application form can vary depending on the health insurance provider.	N/A	N/A
	Documents to be attached/substantiate request: The documentation can vary depending on the health insurance provider.	N/A	
DK	**Information in the module/request:** The information required is that contained in the documentation to be attached to the form.	Yes.	Yes. Submission is possible either electronically or via post.
	Documents to be attached/substantiate request: • copy of the doctor's referral for treatment in a hospital, • patient's written consent for the Region to obtain additional information, • description of the treatment to be received in the foreign hospital, • date of the treatment, • price of the treatment, • copy of the special health card (if not applicable, the yellow health card)	Yes.	
EE	***Note: PA not implemented in Estonia*.**	N/A	Not indicated.

Country	Information required	Mandatory?	Electronic submission?
	Information in the module/request: No specific application form for PA exists		
	Documents to be attached/substantiate the request: If PA were to be implemented, the following documents would be required together with the application: • referral from a general/specialised doctor with a licence to provide the relevant healthcare service in Estonia. Note: an expert evaluation to identify the need for the healthcare sought may be requested by the EHIF.	Yes.	
EL	**Information in the module/request:** • patient's personal details, • identity/passport number, • insurance type, • Social Security Insurance Fund, • number of Medical Booklet, • reference to disabilities (if applicable), • address, email, phone number, • country of treatment, • type of treatment, • details of treatment provider (optional information)	Yes (except where optional)	Yes. Submission either via email or registered post.
	Documents to be attached/substantiate the request: • medical opinion of a specialised doctor (from Clinic or Hospital), • certificate from at least two hospitals in the country confirming that the proposed healthcare cannot be provided in Greece within a medically acceptable period, • disability certification decision (if applicable), • other supporting documentation (optional)	Yes (except where optional)	
ES	**<u>PA procedure in Catalunya</u>** **Information in the module/request:** • patient's personal details; • details of the applicants (if different); • Clinical data of the patient: diagnosis for which the healthcare is required, consultation, treatment proposed in the health centre of Catalunya, inclusion or not in the waiting list of Catalunya. • Request: diagnosis for which the healthcare is required, consultation, treatment proposed in the health centre, other procedures/treatments which could follow. • centre to which the patient will go for the care.	Yes.	Yes. Submission is possible in person, electronically or via email.
	Documents to be attached/substantiate the request:	Yes,	

Country	Information required	Mandatory?	Electronic submission?
	• clinical report with the diagnosis and prescription of the treatment (whether carried out from private or public care), • individualised clinical evaluation of the health status of the patient, the possible evolution and the possibility or not of assistance in the Autonomous Community of the patient in a justifiable term.		
	PA procedure in Galicia **Information in the module/request:** The required information is contained in the documentation to be attached.	Yes.	No. Submission only in person.
	Documents to be attached/substantiate the request: • official healthcare prescription sheet by a Primary Care physician or other specialist, which states at least: ○ details of the doctor carrying out the prescription, ○ patient identification, ○ diagnosis or diagnostic suspicion, ○ main clinical data of the patient, ○ prescribed health services, ○ modality of healthcare (outpatient or hospitalisation), ○ priority of attention, ○ name, country, address of the healthcare provider.	Yes.	
FI	N/A (no PA)		
FR	**Information in the module/request:** No specific application form for PA exists.	N/A	No. Submission via letter.
	Documents to be attached/substantiate the request: • medical consultation issued by general/specialised doctor containing the following: ○ patient's details, ○ the disease and the type of healthcare needed, ○ reasons why the healthcare has to be performed abroad, ○ country of treatment, ○ details of the facility, ○ start and end of the planned healthcare.	Yes.	
HR	**Information in the module/request:** No specific application form for PA exists.	N/A	Yes.[859] on paper
	Documents to be attached/substantiate the request: • medical indication for the solicited treatment,	Yes.	

[859] This was confirmed by the Croatian NCP.

Country	Information required	Mandatory?	Electronic submission?
	• scheduled date for the appointment in the contacted healthcare institution, • Dates available for the appointment with other Member States' healthcare providers.		
HU	**Information in the module/request:** • Personal data of the patient, • Name and affiliation of the treating doctor, • Planned treatment to be carried out abroad, • Data of the chosen health care provider (country, name and address, and details of the treating doctor), • Details of transportation (if requested), • Declaration of the patient/parent/guardian that he/she is aware of the fact that the costs will have to be paid by the patient and that they will be reimbursed up to the cost of the equivalent treatment in Hungary. **Information that should be given by the treating physician:** • Summary of the diagnostic evaluation related to the planned treatment • Main diagnosis, • If the planned treatment is available in Hungary: when the treatment could have been carried out and where, waiting time, waiting list and if the treatment is urgent, • If the planned treatment is not available in Hungary: what is the most standard and financed care available in Hungary for the diagnosis of the patient.	Yes.	No. Submission only on paper.
	Documents to be attached/substantiate the request: The documentation and the information described above, together with: • Relevant documents of the diagnostic evaluation of the treating physician.	Yes.	
IE	**Information in the module/request:** PA is optional but recommended. If PA is requested, the specific application form/module must be completed with the following information: **Module Section A** (to be completed by the patient): • Particulars of the patient/insured person • Particulars of the GP • Reasons for travelling abroad. **Module Section B** (to be completed by the GP): • Details of the healthcare and Healthcare provider abroad (Name of Treating Consultant; Name of Treating Hospital; Proposed Treatment; DRG Code of the proposed provider; Name of accepting	Yes. (PA is optional, however should a PA request be filed, the information in the module is mandatory).	Yes. Submission via post or by email.

Country	Information required	Mandatory?	Electronic submission?
	consultant (outside the State if different from the treating consultant); Name of accepting hospital (outside the State if different from the treating consultant) • Name and date of birth of the patient; Indication of whether the patient is attending the doctor in public or private capacity • Summary of the condition from which the patient suffers • Certification of the specific treatment that the patient requires outside the state; • Answers to the following questions (Yes/NO) *ix. Is this treatment available within the State? (Only treatments that are available within the State qualify for reimbursement under the CBD.)* *x. Is the patient currently receiving this treatment in Ireland?* *xi. Is the treatment medically necessary?* *xii. Will the treatment meet the patient's needs?* *xiii. Is this treatment contrary to the Irish Constitution or any legislation to your knowledge?* *xiv. Is the treatment regarded as a proven form of medical attention and not experimental or test treatment?* *xv. Is the treatment required as a result of injuries received in a road traffic accident or other accidental injury?* *xvi. Does the proposed healthcare pose any public health risks for the patient and/or the public in general?* *(if yes, provision of further details)* • Indication of whether: *iii. The treatment abroad is being provided in a recognised hospital or other institution which is under the control of a Registered Medical Practitioner?* *iv. That hospital is a public hospital available to National Health Agencies for Public Patients in that country.* • Confirmed cost of treatment • Date of Admission (if known) • Probable duration of stay • Probable date(s) of Out-Patient Department visit(s).		
	Documents to be attached/substantiate request: The following documentation is mandatory to substantiate a PA request: ○ A valid referral letter* issued prior to and for the purpose of accessing the healthcare in question OR a copy of waiting list letter for a public hospital in Ireland.	Yes (with the exception of proof of an initial consultation which is not required if a waiting list	

Country	Information required	Mandatory?	Electronic submission?
	○ Evidence of the outpatient consultation with the consultant abroad OR a consultant treating the patient in a public capacity in Ireland at which the recommendation of inpatient care was determined. ○ A fully completed Application Form (Green in colour) ○ Proof of travel abroad (e.g. flight/ferry tickets, accommodation in patients/applicants name, toll/parking charges or a till receipt from a shop in the locality). ➔ Proof of an initial consultation is not required where a person has already attended their public consultant in Ireland and subsequently been placed on an inpatient/day case treatment waiting list and where this waiting list letter is being submitted as part of the path of referral for the treatment abroad.	letter is submitted).	
IS	**Information in the module/request:** **A**. Information to be provided by the patient: • Particulars of the patient/insured person **B.** Information to be filled in by the doctor (and provided to the IHI either directly by the doctor, or by the patient/insured person applying for PA): • Particulars of the doctor (Name of doctor, place of work, work phone, mobile phone, and e-mail address; Doctor's license number). • Short medical history (including the onset of the disease, its stage and the patient's state of health, as well as the probable progression of the disease should be described) • Type of recommended treatment/examination (Name of treatment/examination in both Icelandic and English; Registration number of the treatment according NCSP-IS). • Residence abroad (within the EEA) and planned treatment (Name and location of hospital). • Indication of: - Whether there is an appointment booked for the recommended treatment. - Urgency of the treatment (needed within a few days; Within a few weeks; Within a few months; Other). - Whether there is a comparable treatment available in Iceland.	Yes.	Yes. Submission on paper or electronically.[860]

[860] The electronic application may be done by the applicant through the IHI's web portal or via the doctor's web portal.

Country	Information required	Mandatory?	Electronic submission?
	- The length of the waiting time for comparable treatment in Iceland. - The need for components of treatment and/or if there is a specialised aftercare.		
	Documents to be attached/substantiate the request: • Short medical history (including the onset of the disease, its stage and the patient's state of health, as well as the probable progression of the disease should be described) (followed by the information described above).	Yes.	
IT	• Particulars of the patient; • Indication of the type of service; • The diagnostic or therapeutic indication; • Health service to be used; • Healthcare provider where the patient intends to go, including address; • Urgency indication (yes/no). If yes, motivation for the urgency must be provided; • Indication (tick box) of which documents have been attached.	Yes.	Yes. Submission on paper form or by certified email.[861]
	Documents to be attached/substantiate the request: • Prescription of the doctor (on the prescription pad of the NHS or prescription of the doctor or other professional qualified in another EU State). • Original clinical documentation. (The opinion of an expert working at the National Network for rare disease could be asked in case the patient has a rare disease)	Yes.	
LI	**Information in the module/request:** No information available.		
	Documents to be attached/substantiate the request: No information available.		
LT	N/A (no PA)		
LV	N/A (no PA)		
LU	**Information in the module/request:** *To be completed by a doctor:* • Details of the patient (name, address and affiliation number), Details of the doctor filling the PA application; • Diagnosis; • Information on the healthcare (type of healthcare; dates/expected duration/reasons for which it is needed) • Details of the healthcare provider who will be performing the planned healthcare.	Yes (where applicable).	Yes. Submission possible by email.

[861] Applications via non-certified email are accepted in exceptional cases of urgency or impossibility to physically reach the ASL premises, in order to start the procedure. Nonetheless, the issuance of the PA will still be subject to the paper submission and/or submission via certified email.

Country	Information required		Mandatory?	Electronic submission?
	• *If applicable:* i) the type of highly specialised and cost-intensive hospital equipment that will be used; ii) the reasons why the treatment in Luxembourg is impossible/inadequate/cannot be given within reasonable time limit [..]. • *If the insured person seeks the transport cost to be covered:* the details regarding the type of transport and the reason why this transport is needed.			
	Documents to be attached/substantiate the request: No additional documents required (the form is completed directly by a doctor).		N/A	
MT	**Information in the module/request:** Unclear/not identified. The link to the PA application form[862], redirects to the form required for reimbursement, namely the 'Claim Form for Reimbursement of Treatment / Health Care Service(s) Sought Under Cross-Border Regulations'. Therefore, it is not clear what information is required in the PA application form.		Unclear/not specified.	Unclear/not specified.
	Documents to be attached/substantiate the request: Ticket of referral from the patient's clinician, i.e. a specialist as per Specialist Accreditation Register (indicating the patient's medical condition(s)/diagnosis, time-line of events and the medical need for the treatment prior to it being sought).[863]		Yes.	
NL	**CZ insurance**	**Information in the module/request:** • Personal information: name, address, birth date and relation number; • Estimate or quotation of the costs;	Yes.	No.
		Documents to be attached/substantiate the request: • Referral of the treating doctor; • Medical indication of the treating doctor with a treatment plan; • *If applicable,* depending on the treatment, a request form.	Yes (if applicable)	
	Menzis insurance	**Information in the module/request:** • Name of the patient and policy number, • Birth date and address, • Date of treatment, • Country of treatment,	Yes.	Yes.

[862] Available at the following webpage: https://deputyprimeminister.gov.mt/en/cbhc/Pages/Cross-Border.aspx.
[863] It was unclear from the national desk research whether other documentation may be required to substantiate a PA application request.

Country	Information required		Mandatory?	Electronic submission?
		• Reason for treatment abroad, • Information on the provider abroad.		
		Documents to be attached/substantiate the request: • Referral of a specialist, • Statement of reasons of treatment abroad, • Treatment plan, • Estimate or quotation of costs, • Date of treatment, • In case of treatment non-existent in the Netherlands, scientific proof of standards of the treatment (might be requested for treatments not known domestically)	Yes (except for the scientific proof)	
NO	N/A (no PA)			
PL	**Information in the module/request:** • Applicant's contact details and PESEL (personal identification number) – if PESEL is absent, the number of the document confirming the applicant's identity, • Address of the patient, • Contact details of the statutory representative, spouse, relative or other representative, if relevant, • Address of the representative, • Entity providing healthcare together with the justification • Declaration that the data contained are true. Information of the part to be filled by the doctor: • contact details of the doctor, • stamp, imprint or sticker of the licence number to practice the profession and the specialisation of the doctor, • stamp, imprint or sticker of the name and address of the service provider with whom the doctor is located, • clinical diagnosis of the health problem.	Yes.	Yes. Submission with qualified electronic signature.
	Documents to be attached/substantiate the request: • Copy of medical records related to the scope of the requested treatment; • Declaration that states that the patient is included on waiting list for the provision of benefits (including the indication of the so-called 'medical category' (i.e.,indication of whether the case is 'urgent' or 'stable' according the national classification system). • Translation of the documentation.	Yes.	
PT	**Information in the module/request:**	Yes.	Yes.

Country	Information required	Mandatory?	Electronic submission?
	• Patient's contact details (name, ID, NHS ID number, Fiscal ID number, Social Security ID number, fiscal residence, date of birth, gender), • Member State of treatment, • Clinical information with the justification of the need of treatment abroad (to be provided via Hospital Clinical Assessment Report (ACH)), • Healthcare unit of treatment (if applicable), • Number of registration on the national waiting list for surgery (if applicable) If medical prescriptions are involved, the following information must appear on the prescription: • Patient's contact details, • Issue date of the prescription, • Identification of the prescribing health professional, • Identification of the prescribed product. If medical treatments are involved, the following information have to appear: • Identification of the patient, • Place of prescription, • Identification of the prescribing health professional, • Identification of the prescribed product, where applicable.		Submission either electronically or on paper.
	Documents to be attached/substantiate the request: • The Hospital Clinical Assessment Report (ACH), describing the need for diagnosis or treatment and surgical adequacy.	Yes.	
RO	**Information in the module/request:** • Name of the county health insurance house to which the application form is addressed; • Details of the applicant; • Medical unit where the medical assistance will be provided and the Member State where it is located; • Type of treatment for which PA is requested; • Date and signature of the applicant.	Yes.	No.[864]
	Documents to be attached/substantiate the request: • Copy of the ID card or birth certificate of the patient; and *Depending on the treatment:* • For PET-CT healthcare in ambulatory regime: a doctor's letter (physician referral) accompanied by a decision of approval issued by the expert	Yes.	

[864] Please note that the national body contacted for the verification of the data collected indicated that the county health insurance houses have discretion in what concerns electronic submission of the application form. However, considering that some of the documents attached to the application form must be submitted in original, electronic submission would in most cases not be possible.

Country	Information required	Mandatory?	Electronic submission?
	commission within the National Health Insurance House. • Healthcare provided in continuous hospitalisation regime: medical report drafted by a doctor within a clinical hospital or a county hospital.[865] (a template model is available). • Medicines for outpatient treatment for which the approval by the experts of the National Health Insurance House is required: copy of the medical prescription accompanied by the document proving the experts' approval. **Moreover:**[866] • Written confirmation from the medical assistance provider abroad of its availability to provide the service in the period indicated by the applicant; • Document issued by the foreign NCP, showing that the medical assistance provider does not give rise to serious and specific concerns relating to the observance of the standards and guidelines regarding the quality of medical assistance and safety of patients, including provisions regarding supervision.		
SE	N/A (No PA)		
SI	**Information in the module/request:** • Information on the applicant(s)/insured person • Information of a referral (Type of a referral posting; country of referral; healthcare provider abroad; and an explanation).	Yes.	Yes. Submission possible by email.
	Documents to be attached/substantiate the request: • Medical referral from a doctor in Slovenia including: *i.* Indication of the treatment; *ii.* Medical documentation of previous treatment in Slovenia; *iii.* Documentation showing that the insured person is entered on a waiting list; *iv.* Documentation showing the date fixed for the treatment in the Republic of Slovenia and with which provider. Other documentation may be requested by the body if needed.	Yes.	
SK	**Information in the module/request:** **Information on the insured person** • Diagnosis;	Yes.	Yes.

[865] According to the national legislative framework, the doctor within the county houses would seem to be required to have "contractual relations with a health insurance house in Romania"; However, as per the information provided by the National Health Insurance House contacted for the verification of the data collected, it is not a requirement that the doctor issuing the medical report required for issuance of PA to have a contract with the national insurance provider in Romania.

[866] The following requirements were not identified in the national legislative provisions, but have been identified by the national legal expert on some of the websites of the county houses in Romania.

Country	Information required	Mandatory?	Electronic submission?
	• Justification of the need for the planned healthcare by the healthcare provider; • Confirmation of the prescription and justification of the need to provide the proposed treatment by a clinical facility with the relevant specialisation; • Calculation of expected costs for the planned healthcare abroad prepared by the foreign healthcare provider which will provide healthcare; • Confirmation of possible admission by the foreign healthcare provider after a positive decision of the health insurance company.		
	Documents to be attached/substantiate the request: • Medical documentation on the current treatment related to the suggested scheduled health care; • informed consent on possible financial participation. *In case of special medical procedures (for example transplantation):* • the decision of the apposite commission of the transplant centre allowing the inclusion of the patient on the list for transplantation.	Yes.	

4. Involvement of doctors in the application process and additional steps for patients

The following table presents information on whether across the countries, besides the provision of a referral for treatment, doctors are involved in the application process for PA (e.g., for the completion and/or filing of the application forms or requests) (Column 2). The table also presents a summarised overview of whether, besides a consultation with a practitioner, patients are required to undergo additional steps (e.g., additional consultations with other healthcare providers, registrations on the waiting lists in the Member State of affiliation, etc.) (Column 3). Finally, the table indicates whether the practitioners involved across the countries must be affiliated to the national social security system, or whether they may be practitioners from any EU/EEA country (Column 4).

Table A. 5 Involvement of doctors and additional steps

Country	Doctors involved in the PA application process (besides providing a referral)	Additional steps (besides consultation to obtain a referral)	Specification on doctor's affiliation (national/contracted doctor or EEA/non contracted doctor)
AT	Not required.	Not identified.	Yes, national. It is mentioned that the "national attending doctor/hospital" must

Country	Doctors involved in the PA application process (besides providing a referral)	Additional steps (besides consultation to obtain a referral)	Specification on doctor's affiliation (national/contracted doctor or EEA/non contracted doctor)
			consider the treatment abroad necessary.
BE	A physician specialised in the treatment needed must fill in a medical report. Based on the legislation, it is the responsibility of the patient to send the application together with the extensive medical report to the sickness fund to get PA (though, in practice, the specialised physician may also send the documentation directly to the sickness fund).	The following information *may* be included in the medical report to be submitted with the application: "Name and written advice of other doctors consulted in Belgium from the same field as the one in which the insured party is being referred abroad". The information appears 'optional', as it is stated in the template medical report that 'the health insurer's advising doctor *can* request this before making a decision".	Yes, EU/EEA. The specialised physician required to fill in the medical report must be entitled to practice medicine in any EU/EEA State.
BG	Not required (for both procedures).	For procedures within the NHIF: only for medical devices, the patient needs to submit extra documentation from the medical establishment abroad. In particular: 1. an official document from a medical establishment abroad, indicating the type and price of the medical device, and technical specification; 2. information from the medical establishment abroad regarding: (a) the presence or absence of a label on the medical device; and (b) the possibility to provide a label of the medical device. For procedures under the Ministry of Health: not identified.	Not specified.
CY	N/A	N/A	N/A

Country	Doctors involved in the PA application process (besides providing a referral)	Additional steps (besides consultation to obtain a referral)	Specification on doctor's affiliation (national/contracted doctor or EEA/non contracted doctor)
CZ	N/A	N/A	N/A
DE	Not required by national law (it might depend on the health insurance provider).	Not required by national law (it might depend on the health insurance provider).	Not specified.
DK	Not required.	Among the documents that need to be submitted by the patient there is also information from the foreign hospital of treatment (description, date and price of the treatment). This might imply that patients have to contact foreign providers in advance.	Not specified.
EE	N/A (But if there were a PA system, the doctor would not be involved in the application procedure)	N/A (But if there were a PA system, an expert evaluation might be required in order to identify the need for the healthcare and the time for the provision of the service).	N/A (But if there were a PA system, yes, national: a referral from a national medical specialist would be needed).
EL	Not required.	Among the documents that need to be submitted, the patient must also provide a certificate from at least two hospitals in the country that the healthcare cannot be provided in Greece in a reasonable time.	Not specified.
ES	Not required (neither in Catalunya nor Galicia).	- Catalunya Among the required information, there is also the possibility to indicate whether or not the patient has been included on the waiting list of a health centre of the region. - Galicia Not identified.	- Catalunya Not specified. - Galicia Not specified (though the application needs to be accompanied by the details for the identification of the doctor who refers for a treatment).
FI	N/A	N/A	N/A

Country	Doctors involved in the PA application process (besides providing a referral)	Additional steps (besides consultation to obtain a referral)	Specification on doctor's affiliation (national/contracted doctor or EEA/non contracted doctor)
FR	Not required.	Not identified.	Not specified.
HR	Not required.	Among other, the following information is required: - the scheduled date for the appointment in the contacted healthcare institution or contacted private practice physician or contracted supplier of orthopaedic and other prostheses in Croatia; - the dates available for the appointment or the possible date of admittance to the healthcare provider in another MS. This implies that the patient needs to contact other healthcare providers in Croatia and in other Member States.	Yes, national/contracted. It is specified that the treating doctor issuing the documentation has to be contracted by the national authority.
HU	Optional. Both the patient and the doctor are entitled to fill in the application form. If the doctor proceeds to file the application, the patient's signature is mandatory. In addition, there is certain information that needs to be provided by the doctor.	Not identified. (However, information on the availability of the treatment and the waiting times in Hungary has to be provided).	Yes, national/contracted. It is specified that the treating doctor has to be contracted by the national authority.
IE	Both the patient and the doctor have to fill in the application: the patient has to fill in Section A, while the doctor has to fill in Section B. It is however the patient that files the application.	Alternative options/steps are provided to the applicant. Among the documentation that needs to be submitted with the request there is also: 1. A referral letter OR a copy of waiting list letter confirming that the patient is on a public waiting list for a hospital in Ireland. 2. Evidence of the outpatient consultation	Yes, EU/EEA (Though it depends on the alternative path chosen by the applicant - see previous column). Referrals submitted by a GP in Ireland or abroad are accepted (though it is only a specialist doctor who knows the treatment he/she is going to provide

Country	Doctors involved in the PA application process (besides providing a referral)	Additional steps (besides consultation to obtain a referral)	Specification on doctor's affiliation (national/contracted doctor or EEA/non contracted doctor)
		with the consultant abroad OR a consultant treating the patient in a public capacity in Ireland at which the recommendation of inpatient care was determined. (Note: Proof of an initial consultation is not required where a person has already attended a public consultant in Ireland and subsequently been placed on an inpatient/day case treatment waiting list and where this waiting list letter is being submitted as part of the path of referral for the treatment abroad.)	who can assist the patient with the optional PA).[867]
IS	The doctor is required to (at least) partially fill in the application form. Both the patient and the doctor can proceed with the submission.	Not identified. (Though the applicant does not seem to necessarily have to be included on a waiting list, however, among others, the following information has to be provided: 1. If there is a comparable treatment available in Iceland; 2. the length of the waiting time for comparable treatment in Iceland).	Not specified.
IT	Not required.	Not identified for the applicant. (In case of rare diseases, the national authority may require the opinion of a national expert to be carried out after the submission of the PA application).	Yes, national or EU. The referral for a treatment can be provided either by a national doctor or a doctor qualified in another EU Member State.
LI	N/A	N/A	N/A

[867] Information provided to Spark Legal Network by the Irish NCP on 1/10/2021.

Country	Doctors involved in the PA application process (besides providing a referral)	Additional steps (besides consultation to obtain a referral)	Specification on doctor's affiliation (national/contracted doctor or EEA/non contracted doctor)
LT	N/A	N/A	N/A
LU	The doctor is required to fill in the PA application, but the patient is required to submit it.	Not identified. (However, the doctor filling in the application form has to provide, among other information, indication/reasons why the treatment proves to be impossible or inadequate in Luxemburg or that it cannot be provided within a reasonable time limit).	Not specified.
LV	N/A	N/A	N/A
MT	Not required.	Not identified.	Yes, accredited. It is specified that the referral doctor must be a Specialist accredited on the "Specialist Accreditation Register".
NL	CZ The doctor usually files the application, but also the patient can do so. Menzis The involvement of the doctor is not required for the application.	1. CZ Not identified. 2. Menzis Not identified (However, further documentation on scientific proof of standards of the treatment has to be provided, if the treatment does not exist in the Netherlands).	Not specified.
NO	N/A	N/A	N/A
PL	Both the patient and the doctor have to fill in the application form: the patient has to fill in parts B, II and VI, while the doctor has to fill in Part III. It is however the patient that files the application.	Among the information that has to be submitted with the application form there is also the following: the applicant's declaration that the patient is included on the waiting list for the provision of the benefits and the indication of the so-called 'medical category' (i.e., indication of whether the case is 'urgent' or 'stable' according the	Not specified

Country	Doctors involved in the PA application process (besides providing a referral)	Additional steps (besides consultation to obtain a referral)	Specification on doctor's affiliation (national/contracted doctor or EEA/non contracted doctor)
		national classification system).	
PT	Not required.	Among the information that needs to be provided by the applicant there is also: the number of registration in the National Waiting List for Surgery (if applicable). (Note: the clinical information to be submitted with the PA request must be provided in the form of a 'Hospital Clinical Assessment Report')	Not specified.
RO	Not required.	Among the documentation accompanying the application and depending on the type of healthcare, additional documents are to be submitted that require the involvement of an expert commission within the National Health Insurance House. Additionally, the medical institute providing the treatment and national contact point of the Member State of treatment have also to be contacted. The medical institute needs to provide written confirmation of the availability to provide the requested treatment, while the national contact point in the Member State of treatment needs to issue documentation on the fact that the foreign medical institute does not generate serious and specific concerns regarding the observance of quality standards..	According to the legislation, it seems that at least for healthcare provided in a continuous hospitalisation regime, the doctor issuing the medical report has to be in a contractual relationship with a health insurance house in Romania. According to the information provided by the National Health Insurance House, the doctor involved in the medical report does not need to have a contract with the insurance provider.
SE	N/A	N/A	N/A

Country	Doctors involved in the PA application process (besides providing a referral)	Additional steps (besides consultation to obtain a referral)	Specification on doctor's affiliation (national/contracted doctor or EEA/non contracted doctor)
SI	Not required.	Among the documents that are to be submitted there are: 1. Documentation showing that the person is entered on a waiting list. 2. Documentation showing the date scheduled for the treatment in Slovenia and with which provider.	Yes, national. The referral has to be issued by a doctor in Slovenia.
SK	Not required.	Among the documents that need to be provided, there are also the following: 1. Calculation of expected costs by the foreign healthcare provider. 2. Confirmation of possible admission by the foreign healthcare provider. Only in case of special medical procedures (such as transplants), the decision of a specific commission allowing the procedure is needed.	Not specified.

5. Costs associated with the submitting of PA requests

The following table presents a summarised overview on what costs have been identified across the countries with regard to the submitting of a PA request, as illustrated also in Chapter 3 of the present report[868]. Please note that in Liechtenstein no information on the PA procedural requirements under the Directive was identified. Countries where no PA system was found to be implemented are coloured in grey.

Table A.6 Costs associated with the handling of PA procedures

Country	Direct costs	Indirect costs
AT	None identified.	None identified.
BE	None identified.	Costs for: • Postal costs, if applicable,

[868] For more information, please refer to the national country reports, (Part 1) Section 1, question 7.

Country	Direct costs	Indirect costs
		• Costs of the medical consultation, if needed for the extensive medical report.
BG	None identified.[869]	Translation costs.[870]
CY	N/A (No PA)	N/A (No PA)
CZ	N/A (No PA)	N/A (No PA)
DE	None identified, apart from the affiliation fee to the health insurance provider.[871]	None identified.[872]
DK	None identified.	None identified.
EE	N/A (No PA)	N/A (No PA)
EL	None identified.	None identified.
ES	For Catalunya: None identified. For Galicia: None identified.	• For Catalunya: None identified. • For Galicia: None identified.
FI	N/A (No PA)	N/A (No PA)
FR	None identified.	Costs for: • Postal costs, if applicable, • Costs of the medical consultation, if needed for the extensive medical report.
HR	None identified.	None identified.
HU	None identified.	None identified.
IE	None identified.	Certified translation of the application form (if not competed in English).
IS	None identified.	Potential costs for doctor's appointment/assistance during the PA process.
IT	None identified.	Posting costs, if applicable.
LI	No information available.	No information available.
LT	N/A (no PA)	N/A (no PA)
LV	N/A (no PA)	N/A (no PA)

869 For both PA procedures within the NHIF and within the Ministry of Health.
870 For both PA procedures within the NHIF and within the Ministry of Health.
871 The affiliation fee is compulsory for the health insurance services in Germany.
872 These can vary depending on the different insurance providers.

Country	Direct costs		Indirect costs
LU	None identified.		None identified.
MT	None identified.		Translations to English.[873]
NL	**CZ**	None identified.	Costs for: • Postal costs, if applicable • Translation for any other language than Dutch, English, German, French or Spanish.
	Menzis	None identified	Translation for any other language other than Dutch and English.
NO	N/A (no PA)		N/A (no PA)
PL	None identified.		Translation costs.
PT	None identified.		Costs for: • Postal costs, if applicable, • Official translation costs.
RO	None identified.		None identified.
SE	N/A (no PA)		N/A (no PA)
SI	None identified.		Costs for: • Postal costs, if applicable, • Translations of documentation, • Copying of medical documentation, • Professional support by a lawyer or other expert (if needed).
SK	None identified.		Potential postal costs, if applicable.

6. Time requirements for PA procedures

The following table presents a summarised overview on the time requirements, which have been identified across the countries with regards to PA procedures, as illustrated also in Chapter 3 of the present report[874]. Countries where no PA system was found to be implemented are coloured in grey. In the case of Estonia, though no PA system has been implemented, the requirements identified in national legislation in the event that it was to be implemented in the future have been incorporated in the table below, for a matter of completeness. Moreover, in Liechtenstein no information on the PA procedural requirements under the Directive was identified.

[873] Information provided to Spark Legal Network by the Maltese NCP on 7/10/2021.
[874] For more information, please refer to the national country reports, (Part 1) Section 1, question 8.

Table A.7 Time requirements for PA procedures

Country	Time limits for applicant/patient	Time limits for PA decision	Consequences if deadlines are not met
AT	None identified.	Within 2 weeks.	No direct consequences identified.
BE	None identified.	Within 45 days from the day when the application was received.[875]	Silent consent (the approval is assumed to be granted).
BG	None identified.	For PA procedure with the NHIF: Within 2 months. For PA procedure with the Ministry of Health: Within 6 months.[876]	No direct consequences identified.
CY	N/A (No PA)	N/A (No PA) (Note: according to the sources consulted, the time requirement appeared to be 30 days – however, PA under the Directive is no longer required in Cyprus).	N/A (No PA)
CZ	N/A (No PA)	N/A (No PA)	N/A (No PA)
DE	None identified.	Within 3 weeks or, in case where a decision of the medical service is needed, within 5 weeks.	The health insurance provider shall inform the applicant explaining its reasons. If no reasons are provided, the application shall be considered to be approved.
DK	None identified.	Within 14 days.	No direct consequences identified.
EE	*Note: no PA in Estonia.* None identified.	*Note: no PA in Estonia* Within 60 days from the receipt of the application.[877]	*Note: no PA in Estonia* None identified.

[875] If additional information is needed by the advisory physician, the period is suspended.
[876] For PA procedure for transplantation activities. No indication with regards to the assisted reproduction activities.
[877] If PA was introduced.

Country	Time limits for applicant/patient	Time limits for PA decision	Consequences if deadlines are not met
EL	None identified.	Within 60 days from the submission of the application.[878]	No direct consequences identified (but if the request cannot be processed within the time limit, the authority has to notify the interest party and provide justification/indicate if documents are missing).
ES	• For Catalunya: None identified. • For Galicia: None identified.	• For Catalunya: within 45 days from the date of the receipt of the request. • For Galicia: within 45 days from the date of receipt of the application.	• For Catalunya: silent consent (the approval is assumed to be granted). • For Galicia: silent consent (the approval is assumed to be granted).
FI	N/A (No PA)	N/A (No PA)	N/A (No PA)
FR	At least 14 days before departure.	Within at least 14 days.	Silent consent (the approval is assumed to be granted).
HR	None identified.	Within 60 days.	No direct consequences identified.
HU	None identified.	Within 60 days.	No direct consequences identified.
IE	None identified.	15-20 working days.	No direct consequences identified.
IS	None identified.	No specific time requirements. The following general requirements apply: 1. Decisions should be taken "As quickly as possible". 2. The authority has to prioritise the applications depending on the urgency of the treatment.	No direct consequences identified.
IT	None identified.	30 days (15 days in case of motivated urgency).	No direct consequences identified.[879]

[878] If submission is made to an incompetent authority, this latter has to forward the application to the competent one within 5 days and notify the interested party.

[879] Patients may address the application to the holder of the substitute power. In this case, the deadline for the conclusion of the procedure will be halved compared to what was originally indicated. Judicial remedy for administrative inaction is also possible.

Country	Time limits for applicant/patient	Time limits for PA decision	Consequences if deadlines are not met
LI	No information available.	No information available.	No information available.
LT	N/A (no PA)	N/A (no PA)	N/A (no PA)
LV	N/A (no PA)	N/A (no PA)	N/A (no PA)
LU	None identified.	3 weeks after receiving the PA application (at the latest).[880]	No direct consequences identified
MT	None identified.	6 weeks from receipt of the request.[881]	No direct consequences identified.
NL	• CZ: None identified. • Menzis: None identified (best requested 10 to 15 days before the treatment)	• CZ: within 10 days after the request is made.[882] • Menzis:10-15 working days.	• CZ: None identified. • Menzis: Notification to the patient is needed.
NO	N/A (no PA)	N/A (no PA)	N/A (no PA)
PL	None identified.	5 days as of the completion of the investigation in the case (including obtaining the necessary medical opinions).	If no decision is taken by the body within 30 days, the patient does not lose the right to be reimbursed if he/she received treatment abroad without PA for matters of urgency.
PT	None identified.	• 20 days for the clinical evaluation required (which can be shorten in case of urgency); • 15 working days for handling the PA request. In case of doubt, the advice of the General Health Department of the Ministry of Health might be required: the opinion shall be issued in 5 days.	No direct consequences identified.

[880] If the CNS is not able to take a decision within the 3 weeks period, it notifies to the insured person the reason for the delay.

[881] Moreover, according to the information provided to Spark Legal Network by the Maltese NCP on 7/10/2021, there appears to be a general commitment requirement for the Ministry of Health to address any queries and requests for information within the shortest possible time and not more than seven working days. If a case is urgent, a decision could be taken within 24-48 hours.

[882] It is a target, not a guarantee.

Country	Time limits for applicant/patient	Time limits for PA decision	Consequences if deadlines are not met
RO	None identified.	5 working days as of the registration of the request.	No direct consequences identified.
SE	N/A (no PA)	N/A (no PA)	N/A (no PA)
SI	None identified.	2 months from the submission.	No direct consequences identified. Application considered rejected (with right of appeal).
SK	None identified.[883]	15 days (and in case of urgent and life-threatening diseases: "without delay").	No direct consequences identified.

[883] However, if the application is not complete, the insurance provider sends the application back to the patient within 15 working days from acceptance of application. The insurance provider sets a deadline for rectifying the deficiencies. If the patient misses the deadline, the insurance provider suspends the PA proceedings.

Annex F - Summarised overview of data collected: reimbursement procedures

1. Application modules for reimbursement procedures

Yes | No | Not clear | Other

Country	AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HR	HU	IE	IS	IT	LI	LT	LV	LU	MT	NL		NO	PL	PT	RO	SI
Form for requesting reimbursement	884	885	886																				C	M				887	
Available online		888	889	890	891		892	893	894	895	896	897			898	899	900		901	902		903	904	905	906	907	908	909	91

884 Please note that each health insurance institution provides forms which are specific for each service. These forms are, however, supporting, but not mandatory.
885 Please note that a standardised file of the extensive medical report needs to be filled in by the specialised doctor, to be submitted together with the application.
886 Applicable for both reimbursement procedures available in Bulgaria (NHIF and Ministry of Health).
887 There is no standardised application form. However, the minimum information that must be provided in the request is set out in the legislative sources. For the sources and the reasons for not having a standardised form, please refer to the RO country report, Section 2, questions 4 and 5. Moreover, the national body contacted for verification of the data collected indicated that the county health insurance houses are allowed flexibility in publishing a draft application form/module. However, it appeared that the forms published on the websites of the county health insurance houses are not updated as per the today applicable legislative framework.
888 Some insurance funds make the form available online.
889 Please note that a reimbursement request form is available for requests handled by the NHIF, while it is not available for requests handled by the Ministry of Health.
890 Available at: https://www.moh.gov.cy/Moh/cbh/cbh.nsf/page24_en/page24_en?OpenDocument.
891 Available at: https://media.vzpstatic.cz/media/Default/formulare/application-for-reimbursement-of-costs-of-health-en.pdf.
894 Available at: https://eu-healthcare.eopyy.gov.gr/gr/key_docs.aspx.
895 Reimbursement request form for Catalunya available at: https://catsalut.gencat.cat/web/.content/minisite/catsalut/ciutadania/acces_sistema_salut/assistencia_transfronterera/altres_ue/240z564sra_sol_reembossament_assistencia_altre_pais.pdf.
Reimbursement request form for Galicia available at: https://www.sergas.es/Asistencia-sanitaria/Formulario-para-a-solicitude-de-reembolso.
896 Available at: https://www.kela.fi/sairaanhoito-kansainvalisissa-tilanteissa-hoitoon-hakeutuminen-ulkomaille.
897 Available at: https://www.ameli.fr/sites/default/files/formualires/221/s3125.pdf.
898 A Pro-Forma invoice is available online. However, the submission of this form is optional. See: Health Service Executive Cross-Border Healthcare Directive: Pro-Forma Invoice', available at: https://www2.hse.ie/file-library/cross-border-directive/cross-border-directive-pro-forma-invoice.pdf.
899 The form is available online on the IHI website, accessible at: https://www.sjukra.is/media/althjodadeild/Application-for-reimbursement-of-medical-cost-abroad.docx.
900 Please note that generally the form is not available online, but a template can be found in Annex B to the Guidelines on Cross-border Healthcare of 2017.

[899] The form is available online on the IHI website, accessible at: https://www.sjukra.is/media/althjodadeild/Application-for-reimbursement-of-medical-cost-abroad.docx.

[900] Please note that generally the form is not available online, but a template can be found in Annex B to the Guidelines on Cross-border Healthcare of 2017.

[901] Available at: https://ligoniukasa.lrv.lt/lt/paslaugos/paslaugu-aprasymai/tarpvalstybines-sveikatos-prieziuros-islaidu-kompensavimas-paslauga-teikia-teritorines-ligoniu-kasos-1.

[902] Available at: https://www.vmnvd.gov.lv/lv/pakalpojumi/iesniegumu-veidlapas.

[903] Claim Form for Reimbursement of Treatment / Health Care Service(s) Sought Under Cross-Border Regulations (referred to as 'Prior Authorisation Form' on the Health.gov.mt website). Available at: https://deputyprimeminister.gov.mt/en/cbhc/Pages/Cross-Border.aspx.

[904] CZ form available at: 476.808.001.001.2007_Declaratieformulier_Buitenland CZ_V2.indd.

[905] Menzis form available at: Declaratieformulier-ziektekosten-buitenland-menzis.pdf.

[906] Aavailable in English at: https://www.helfo.no/skjema/Søknad%20om%20refusjon%20for%20helsetjenester%20mottatt%20i%20et%20annet%20EØS-land%20Sveits-05-24a.10-engelsk.pdf/ (Helfo. Søknad om refusjon for helsetjenester mottatt i et annet EØS-land/Sveits. In Norwegian, available at: https://www.helfo.no/skjema/Søknad%20om%20refusjon%20for%20helsetjenester%20mottatt%20i%20et%20annet%20EØS-land%20Sveits-05-24a.10-bokmål.pdf/).

[907] The form is available in Annex to the following legislative measure: Regulation of the Minister of Health of 4 March 2021 on the application form for the reimbursement of costs of healthcare services provided outside the country (Journal of Laws of 2021, item 429), (Rozporządzenie Ministra Zdrowia z dnia 4 marca 2021 r. w sprawie wzoru wniosku o zwrot kosztów świadczeń opieki zdrowotnej udzielonych poza granicami kraju (Dz. U. z 2021 r. poz. 429), available at: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20210000429.

[908] Available at: http://diretiva.min-saude.pt/.

[909] The national body contacted for verification of the data collected indicated that the county health insurance houses are allowed flexibility in publishing a draft application form/module. However, it appeared that the forms published on the websites of the county health insurance houses are not updated as per the today applicable legislative framework.

[910] Available at: https://www.forsakringskassan.se/wps/wcm/connect/028c7d98-2bbb-4c07-afbd-ea566a4a8558/fk5422-022-f-002.pdf?MOD=AJPERES&CVID=

[911] Available at: https://zavarovanec.zzzs.si/wps/portal/portali/azos/pravice_zdravstvenih_storitev/pravice_zdravljenje_tujina/.

[912] Specific application form has to be used by all three insurance companies in SK. Annex no. 9 and 10 of Decree of Ministry of Health of The Slovak Republic no. 232/2014 Coll. regulating the procedure of the healthcare provider, the health insurance company and the Healthcare surveillance authority in the provision of cross-border healthcare, 11 August 2014 with later amendments. (Vyhláška Ministerstva zdravotníctva Slovenskej republiky z 11. augusta č. 232/2014 Z. z. ktorou sa upravuje postup poskytovateľa zdravotnej starostlivosti, zdravotnej poisťovne a Úradu pre dohľad nad zdravotnou starostlivosťou pri poskytovaní cezhraničnej zdravotnej starostlivosti). Available at https://www.slov-lex.sk/pravne-predpisy/SK/ZZ/2014/232/20140901.

2. Information to be included in the application module/attachments

The following table presents a summarised overview of what information and which documents have been found to be required for the submission of a reimbursement request in each country, as illustrated also in Chapter 3 of the present report[913]. Please note that in Liechtenstein no information on the procedural requirements for reimbursement under the Directive was identified.[914]

Table A. 8 Information to be included in the application/request

Country	Information required	Mandatory?	Electronic submission?
AT	**Information required in the modules/request:** The information is to be requested by the competent health insurance institution, but the following information should be indicated: the treatment, invoice and proof of payment. There are separate specific forms depending on the services.	No[915]	Yes
	Document to substantiate/attach: The required documentation has to be requested by the health insurance institution of affiliation.	Yes	
BE	**Information required in the modules/request:** The specific form has to be requested by the insurance fund of affiliation. In those cases where the form is available online, the following information are requested:	The data indicated with an 'M' are mandatory.	No.

[913] For more information, please refer to the national country reports, (Part 1) Section 2, questions 4 and 5.

[914] It should also be noted that in seventeen countries (AT, BE, CY, CZ, DK, EE, FI, FR, HU, IT, IS, LT, LU, LV, NO, SI, SK), the procedures for requesting reimbursement under the Directive or the Regulations on the Coordination of Social Security Systems (the Regulations) appear to be the same (though different methods of calculating the amounts to be reimbursed are used depending on the applicable regime). In Austria, for instance, it was noted that the reimbursement application forms do not seem to make a distinction between whether reimbursement is requested under the Directive or under other legal bases. In eleven countries (BG, DK, EL, ES, HR, IE, MT, PL, PT, RO, SE), the procedures to request reimbursement seem to differ (e.g., in some instances different modules appear to be available respectively for reimbursement requests under the Directive or the Regulations). In two countries (DE, NL), not only the reimbursement procedures may differ from one insurance provider to another, but it should also be noted that one of the main factors determining the applicable reimbursement regime is whether or not the healthcare provider is a contracted or non-contracted one (rather than whether reimbursement is sought under the Directive or the Regulations). However, in the case of the Netherlands, it should be noted that the data collected showed that the reimbursement procedures established by two insurance providers – CZ and Menzis – appear to be the same under the Directive and the Regulations. Finally, in one country (LI), it was unclear what procedural steps applicants must follow in order to request reimbursement for cross-border healthcare under the Directive.

[915] The form is supporting, but not mandatory.

Country	Information required	Mandatory?	Electronic submission?
	• patients' details (name, nationality, address, also telephone end email), (M) • national security number (M) • country in which the healthcare services were provided, (M) • period of visit, (M) • reason of visit, (M) • description of the circumstances of the treatment, (M) • name of medical advisor, (M) • amount paid, • weather you have a private insurance and if so which, (M) • proof of healthcare services, • date of the completion of the documentation • signature (M)		
	Document to substantiate/attach: No clear indication on which further documentation is needed. The insurance funds are required to inform patients on the documents needed.	N/A	
BG	**<u>Reimbursement procedure with the NHIF</u>** **Information required in the modules/request:** • patient's personal details (with postal address and telephone number, national identification number, contacts of the parent, guardian, trustee, if applicable, bank account), • information of the received cross-border healthcare (country, city, period of stay, diagnosis, type of medical care, treatment and diagnostic procedures, period in which the medical care was received, details of the institution of treatment, information on the medical documentation attached to the application – interim medical report/laboratory test/imaging tests, information on whether the medical treatment was received under the procedures for local insured persons or not), • information on the expenses (invoices, information on the medical institution-issuer of the documents, amount of the expenses and currency, date, type of medical care received, declaration of truthfulness, signature).	Yes	No. Submission either via post or in person.
	Document to substantiate/attach: • copy of ID of the patient,	Yes	

Country	Information required	Mandatory?	Electronic submission?
	• originals of the expense-related and payment documents, • copy of the confirmation of the bank account by the bank, • copy of a document certifying for the capacity of the parent/guardian/trustee, if relevant, • power of attorney, if relevant, • certificate of heirs (if applicable). Additionally, for highly specialised healthcare for which a referral is required in Bulgaria: • original of the medical referral, • medical documentation related to the results of the performance of the health service in the other Member State. Additionally, for medicinal products, dietary foods for special medical purposes and medical devices: • copy of the prescription form		
	<u>Reimbursement procedure with the Ministry of Health</u> No form for reimbursement available. The request shall be made in free form. No further details according to the legislation, but the information required are contained in the documents attached to the application.	N/A	
	Document to substantiate/attach: • copy of ID of the patient, • copy of a document certifying the quality of a parent/guardian/trustee relationship, if relevant, • power of attorney, if relevant, • medical documentation for conducted examination, with type and scope of the examination, • medical documentation certifying the performed examinations/the diagnosis/monitoring/diseases and prescription form (all, where applicable), • financial-reporting document, • copy of confirmation of the bank account by the bank.	Yes	
CY	**Information required in the modules/request:** • patient's details, • healthcare service provided, • declaration (signature, date, full name)	Yes.	Yes. Submission via email or in person.
	Document to substantiate/attach: • copy of PA (if applicable)	Yes.	

Country	Information required	Mandatory?	Electronic submission?
	• original invoice/payment receipt/certified copy of the medical prescription and payment from the pharmacy • copy of the medical report from the center of the responsible healthcare provided in case of PA • complete and signed authorisation form from Payments by FISMA[916] and confirmation of the IBAN from the Bank • copy of medical ID or relevant certificate issued by the Ministry of Health		
CZ	**Information required in the modules/request:** • patients' contact details, • details on the state where services were received, • amount requested to be reimbursed.	Yes.	Yes. Submission is possible either electronically or on paper (via post or in person).
	Document to substantiate/attach: • original copy of the payment receipt, • copy of the medical reports issued abroad, • Czech translation, • birth certificate/other documents proving family relationship for the legal representative (if needed), • power of attorney for the authorised representative (if needed).	Yes.	
DE	**Information required in the modules/request:** The application form can vary depending on the health insurance provider. An example (AOK request) can be provided: • insured personal details, • insurance affiliation number, • permanent address, • phone number, • bank account, • information regarding the visit abroad for receiving healthcare services, • information regarding the health insurance, • information regarding the healthcare service, • all proof of payment, medical prescriptions, doctor or hospital reports (original invoice), • additional payments or co-payments customary in the country (reimbursable only under certain conditions),	N/A	N/A

[916] Integrated Financial Management System of Cyprus.

Country	Information required	Mandatory?	Electronic submission?
	• medicines or remedies and aids (reimbursable only if prescribed by a doctor).		
	Document to substantiate/attach: The documentation can vary depending on the health insurance provider.	N/A	
DK	**Information required in the modules/request:** The information required are those contained in the documentation that needs to be submitted.[917]	Yes.	Yes. Submission either electronically or via post.
	Document to substantiate/attach: • original invoice and receipt, • description of the treatment (where and when it was provided) • copy of the referral from a doctor or the prescription (if relevant) • The patient's statement as to whether full or partial public reimbursement has already been granted. • A description of the goods and services received Additionally, for non-residents: • copy of the yellow health insurance card, • bank account. For the certain categories of pensioners or their family members: • a copy of the applicant's EU health insurance card. For the family members listed of a frontier worker: • a copy of the frontier worker's special health card and a copy of the applicant's EU health insurance card. Moreover, f**or applications of reimbursement of hospital treatment which required PA, but for which PA was not obtained,** the following should also be submitted: • a copy of the referral for hospital treatment from a doctor/GP, • patient's permission for the regional authorities to seek further information about patient's health,	Yes.	

[917] Please note that in Denmark the conditions for reimbursement are the same for healthcare received in Denmark and for healthcare received abroad.

Country	Information required	Mandatory?	Electronic submission?
	• description of the treatment received abroad, • price of the treatment, • date of the treatment. • the price offer from the foreign hospital		
EE	**Information required in the modules/request:** • patient's contact details, • bank account, • date of application, • signature • description of the disease/trauma • information on whether the need for treatment arose during a temporary stay, • date of the treatment, • country, city, place of treatment, • whether it concerns private or public healthcare provider, • clear indication of whether the patient wants to be reimbursed on the basis of the Directive or the Regulation.	Yes.	No. Submission is possible only in person or via post.

	Document to substantiate/attach:
	• original receipts and proof of payment for medical treatments, or
	• copies of the prescriptions and proof of payment for medication, or
	• original receipts from purchases and proof of payment for medical devices.
	Additionally:
	• referral from a general or specialised medical care (mandatory only if appliable),[918]
	• copy of health records from the service provider who provided the treatment abroad, which shall include the following info:
	  ○ personal data of the patient,
	  ○ period of care and of hospitalisation,
	  ○ facility of the treatment,
	  ○ diagnosis,
	  ○ state of health of the patient,
	  ○ description of the treatment,
	  ○ tests, analyses and operations performed,
	  ○ medicinal product administered or prescribed.
		Yes.	

EL	**Information required in the modules/request:** • patient's personal details,	Yes.	Yes.

[918] Except in specific cases, see below.

Country	Information required	Mandatory?	Electronic submission?
	• identity/passport number, • insurance type, • Social Security Insurance Fund, • number of Medical Booklet, • reference to disabilities (if applicable), • address, email, phone number, • country of treatment, • type of treatment, • details of treatment provider (optional information)		Submission either electronically or by registered post.
	Document to substantiate/attach: • medical certificate/diagnosis of the treating doctor for the medical operations performed, • certificate from a treating doctor regarding the legal status of the institution of treatment, • original payment receipts, • original proof of payment of medication, • original payment receipts for supply of additional care items. All the documents must be legally issued, original and must indicate number, date of issue and analysis of all relevant medical procedures, drugs, items. Additionally, they must be certified by the respective Greek Consulate, officially translated. The competent authority may request additional supporting documents as well as request the completion of special forms.	Yes.	
ES	**<u>Reimbursement procedure in Catalunya:</u>** **Information required in the modules/request:** The required information is contained in the documentation that shall accompany the application.	Yes.	Yes. Submission is possible electronically and in person.

	Document to substantiate/attach:
	• original invoices from the health care provider, which shall include at least:
	  ○ patient's contact details (name surname and DNI or INE number or passport),
	  ○ identification of the natural/legal person issuing the invoices,
	  ○ name of the service or clinical unit,
	  ○ identification data of the professional responsible for cross-border healthcare,
		Yes (except "any other data").	

Country	Information required	Mandatory?	Electronic submission?
	○ healthcare procedures carried out in detail, specified by the competent health authority, indicating the amount of each and the date; • copy of the medical prescription of the clinical result of the care provided which must include: ○ clinical reason for providing cross-border healthcare, ○ diagnostic procedures/therapeutic procedures carried out for the purpose of the cross-border healthcare, ○ subsequent medical revision checks, ○ any other data considered as appropriate to clarify the healthcare received. If applicable, the previously granted PA.		
	<u>Reimbursement procedure in Galicia:</u> **Information required in the modules/request:** The required information is contained in the documentation that shall accompany the application.	Yes.	No. Submission on paper only.
	Document to substantiate/attach: • document accrediting the prescription of healthcare by a Primary Care doctor or another specialist, stating at least: ○ identification of the doctor who carries out the prescription, ○ patient identification, ○ diagnosis or diagnostic suspicion, ○ prescribed health services, ○ priority of attention. • photocopy of the PA, • clinical reports and prescription sheets carried out by the cross-border healthcare service provider, indicating at least: ○ patient identification, ○ identification of the doctor responsible for the healthcare provided, ○ healthcare provider, ○ diagnoses, ○ health services and procedures performed, ○ type of care provided (outpatient or hospitalisation), ○ patient prescriptions,	Yes.	

Country	Information required	Mandatory?	Electronic submission?
	○ reviews to be carried out and estimated time for them, ○ any other data (if relevant) • original invoice from the healthcare service provider which indicates: ○ identification and residence of the patient receiving the health service, ○ name of the legal person issuing the invoice, ○ name of the service or clinical unit, ○ identification data of the professional responsible for cross-border assistance, ○ various health procedures carried out, with the amount of each and the date of implementation, ○ name of medicine/health products, the number of containers dispensed and the amount paid, if applicable, ○ receipt proving payment by the supplier.		
FI	**Information required in the modules/request:** • patient's personal data, • account number, • details on the context in which the treatment was received (if unplanned treatment in a Nordic country, EU/EEA country, non-EEA country or Switzerland, planned healthcare), • reason for which the costs were born, • if the patient obtained any reimbursement from elsewhere than KELA, • why the treatment abroad was needed, • country, place and type of doctor of the treatment, • purchased medications, • other costs: travel, accommodation or other, • date and signature.	Not specified.	No. Submission via post.
	Document to substantiate/attach: • copies of receipts, medical prescriptions and reports, • all other additional information the patient wishes to provide.	Not specified.	
FR	**Information required in the modules/request:** • patients' details, • details of the stay abroad,	Yes.	No.

Country	Information required	Mandatory?	Electronic submission?
	• details of the healthcare performed abroad, • indication on whether the patient wants to be reimbursed under the French regime or the country of treatment's one, • amount already reimbursed by the country where the healthcare has been provided, if any.		Submission is possible only by post or in person.
	Document to substantiate/attach: • original copies of the invoices and payments receipts, • additional documents could be requested if the CPAM deems this necessary.	Yes.	
HR	**Information required in the modules/request:** There is no specific request form for reimbursement.	N/A	Yes.[919]on paper
	Document to substantiate/attach: • original medical documentation declaring the medical services obtained, • original medical receipt issued to the insured person, • form that explicitly provides which medical services were provided, • form that explicitly mentions that the receipt has been fully paid.		
HU	**Information in the module/request:** A specific form is not available, but together with the request for reimbursement, the evaluation of the Hungarian treating physician is also required. **Information in the evaluation by the treating physician:** • Data of the patient; • Data of the treatment provided abroad; • Opinion of the treating physician on the issue if the treatment provided was the same as the treatment authorised; • Evaluation of the treating physician on the effectiveness of the treatment; • Further treatment to be carried out; • Name of the health care provider carrying out the further treatment of the patient.	Yes.	No. Submission on paper.

[919] This was confirmed by the Croatian NCP.

Country	Information required	Mandatory?	Electronic submission?
	Documents to be attached/substantiate request: Besides the evaluation of the Hungarian physician (described above), the patient has to also submit all the medical documents received abroad (preferably the discharge summary), together with the invoice and the financial document providing that he/she paid.	Yes.	
IE	**Information in the module/request:** Pro-forma invoice (optional): • Section A: to be completed by the patient • Section B: to be completed by the doctor: same information required in the PA application form.	No.	Yes. Submission via post or via email.
	Documents to be attached/substantiate the request: ○ A valid path of referral i.e. a referral letter* OR a copy of a waiting list letter for a public hospital in Ireland if same has not already been provided at prior authorisation stage. ○ A fully completed Pro Forma Invoice form (Pink in colour) in English only **(optional)** ○ The original invoice from the healthcare provider abroad. ○ The original receipt of payment from the healthcare provider abroad. ○ Proof of your payment of your healthcare costs e.g. Bank transfer, Credit Card Payment (statement) ○ Proof of travel abroad e.g., flight/ferry tickets, accommodation receipts in patients/applicants name, toll/parking charges or a till receipt from a shop in the locality. ○ Evidence of initial outpatient consultation with treating clinician abroad on a date prior to admission (i.e., an invoice & receipt from initial consultation OR a medical report which includes the date of nitial consultation). → Proof of an initial consultation is not required where a person has already been assessed by their public consultant in Ireland and subsequently been placed on an inpatient treatment waiting list and where this waiting list letter is being submitted as the path of referral for your treatment abroad. The initial	Yes (with the exception of the Pro Forma Invoice)	

Country	Information required	Mandatory?	Electronic submission?
	consultation or outpatient consultation must pre-date any inpatient or day case treatment. ○ Photocopy of the medical card.		
IS	**Information in the module/request[920]:** • Particulars of the patient/insured person (Name, ID number (kennitala), Residence in Iceland, Postal code, Phone number, Residence abroad, and ID number abroad). • Country of stay; • Travel period; • Reasons of stay (option to tick the box 'Getting medical treatment abroad'). • Further description of the medical treatment abroad • Indication of whether the patient has applied for reimbursement at a private insurance company (and if yes, with whom).	Yes.	Yes. Submission both on paper or electronically[921]
	Documents to be attached/substantiate the request: **Always required:** • Invoice breakdown. • Payment confirmation. • Medical certificate. • Flight tickets – back and forth confirming temporary stay. **Required depending on the healthcare service:** • If health insurance participation to the cost of domestic healthcare is conditional upon other requirements (e.g., that a doctor's referral is required) the same conditions shall apply to reimbursement for services applied for in another EEA state (i.e., not further specified, variable from case to case according to domestic requirements). • Translations of the documents may be required.	Yes.	
IT	**Documents to be attached/substantiate the request:**	Yes.	Yes.

[920] Based on the Application for reimbursement of domestic medical cost, the exact same information is required for treatments abroad compared to domestic treatment, with the except of the following information: Residence abroad; ID number abroad; Country of stay; Travel period; Reasons of stay; further explanation of medical treatment abroad; If the patient has applied for reimbursement at a private insurance company – if yes, with whom".

[921] The electronic application may be done by the applicant through the IHI's web portal or via the doctor's web portal.

Country	Information required	Mandatory?	Electronic submission?
	• Particulars of the patient, • Amounts of the costs sustained (in EUR), • Declaration of reasons for which the applicant could not benefit of the 'direct contribution', • Bank account details, • Date and signature.		Either on paper form or by certified Email.
	• Prescription from a doctor or from a licensed professional in the country of origin (unless already submitted for PA); • Original certification of the care provider, certifying the treatment provided with discharge diagnosis or the report of the diagnostic examination carried out, • Receipted invoices, • Translation into Italian of the health and expense documentation.	Yes.	
LI	**Information in the module/request:** No information available.		
	Documents to be attached/substantiate the request: No information available.		
LT	**Information in the module/request:** • Particulars of the insured person (or his/her representative) (name, address, contact details etc.) • Bank details of the insured (or his/her representative)	Yes.	No. Submission on paper form.
	Documents to be attached/substantiate the request: • ID; • Referral of an affiliated doctor - If the insured person was provided with specialised outpatient or inpatient personal health care services in the country of treatment (except for primary personal health care services);[922] • Original financial documents (invoices, cashier's checks, cash receipts, etc.);	Yes.	
LV	**Information in the module/request:** • Particulars of the person seeking reimbursement; • Information on the rights to receive health care services (whether the person was / was not considered to be insured	Yes.	Yes. Through the single State and local government

[922] Other documents may be required for the reimbursement of medicines, medical aids, medical devices. For more information, please see LT country report, Section 2, question 5.

Country	Information required	Mandatory?	Electronic submission?
	under another social security system at the time of receiving the health care service); • Country where the health care services were received; • Reason for receiving the health care service abroad; • Personal current account details;		services portal (https://latvija.lv/) It may also be submitted on paper or electronically with a secure electronic signature and time stamp, or on paper form by post, or submitted in person to the competent authority.
	Documents to be attached/substantiate the request: • A document certifying the payment, in which the information identifying the recipients of the service is indicated. • A document of the health care service provider which contains the following information: i) health care services provided to a person; ii) the period of provision of health care services; iii) the price of health care services provided to a person for each service separately; iv) confirmation of payment for the provided health care services; v) the diagnosis on the basis of which the health care service has been provided to the person. • Prescription or referral from a family doctor or specialist for the relevant healthcare service (only if required domestically).	Yes.	
LU	**Information in the module/request:** The request must contain: • Details of the insured person (name, address, 13-digit identification number). • Bank account statement to receive the payment (only if is the first reimbursement request).	Yes.	No.
	Documents to be attached/substantiate request: • Original copies of the invoices and payment receipts.	Yes.	
MT	**Information in the module/request:** • Patient details • Health care service(s) (diagnosed medical condition for which the patient has received treatment abroad; whether prior authorisation was sought; details of	Yes.	Yes.[923]

[923] Information provided to Spark Legal Network on 7/10/2021 by the Maltese NCP. Specifically, the NCP noted that thought there is a specific form, in practice it is not always used. If the form is not used, patients are asked to send in electronic format all necessary documentation (e.g., invoices, medical reports, and payment receipts) and the reimbursement is normally accepted when all the documents are sent.

Country	Information required		Mandatory?	Electronic submission?
	the health care service(s) / treatment(s) received abroad). • Details of Health Care Provider(s) where patient received treatment: (particulars of the provider; details of the pharmacy that dispensed drugs (if any); whether the patient was satisfied with the service and quality of the health care service(s) received). • Details of the expenditure for which reimbursement is being claimed (date of receipt, establishment paid, treatment covered, and receipt amount paid).			
	Documents to be attached/substantiate the request: • Ticket of referral from the patient's clinician (must be a specialist if PA is sought) (indicating medical condition(s)/diagnosis, timeline of events and the medical need for the treatment prior to it being sought). • Medical Summary: a letter/report from the health care facility where the treatment was received (include a description of the treatment(s) received, date(s) the treatment(s) was/were received, any diagnostic tests performed and any medication/drug(s) used as part of the treatment). • Copy of Schedule V form (yellow card) (if applicable)[924]. • Original itemised receipts.		Yes.	
NL	**CZ insurance**	**Information in the module/request:** • Patient's details and relation number, • Date of bill, name of doctor or institute, currency and amount, • Country, • Reasons for being abroad, • Period of stay, • Type of care received, • Whether and, if so, how long the hospitalisation lasted, • Whether there was a referral, • Whether or not the patient has notified the CZ of the travel insurance provider,	Yes.	Yes. Submission also possible through an app or via email.

[924] Any patient suffering from a chronic condition which is listed under the second part of the Fifth Schedule of the Social Security Act is entitled to free medication for that specific disease and entitlement is based solely upon the presence of disease irrespective of means, income or age. See health.gov.mt, 'Schedule V', available at: https://deputyprimeminister.gov.mt/en/poyc/Pages/Schedule-V.aspx.

Country	Information required	Mandatory?	Electronic submission?
	• Whether the patient gave to the healthcare provider a S2 or a treaty form 111, • Whether the patient has a travel insurance with medical coverage and, if so, with which provider and policy number.		
	Documents to be attached/substantiate the request: • If request is made through the app or online: a digital photo of the bills or a scan of the bills, • If applicable, the treatment plan, • If applicable, the referral (mandatory in case of planned care in hospital or with a specialist).	Yes.	
	Menzis insurance	**Information in the module/request:** • Patient's policy number, birth date, name, address, email and phone, • Name of the doctor or institute, date of treatment, amount, country, currency, whether the amount has been paid by the patient or not, whether it concerns an accident or not, • Period of stay abroad, • Reason for being abroad, • Whether the care could be deferred until the return to the Netherlands, • Description of what happened and care received, • Type of healthcare provider, • Whether there was hospitalisation or not, • Whether the patient showed the EHIC, • Whether or not the patient notified a helpline, • Whether the complaints were already known in the Netherlands and, if so, the treating doctor/institute,	Yes.	Yes. Submission via email.

Country	Information required	Mandatory?	Electronic submission?
	• Whether the patient had travel insurance and, if so, which provider and policy number.		
	Documents to be attached/substantiate request: • Original bills, • Translations of bills (for languages other than Dutch, English, German), • Copy of the travel insurance, if applicable, • Treatment report of the specialist of the treatment in the Netherlands and the referral, if applicable.	Yes.	
NO	**Information in the module/request:**[925] • Particulars of the patient. • Healthcare received. • Indication of the patient's connection to the country of treatment (e.g., weeks a year spent in the country). • Other patient's information (family, social security status, benefits, employment, etc). • Whether the treatment was planned and, if not, what institution was contacted first for medical care. • Whether the patient had a referral from a healthcare professional (and if yes, from which country). • Details of the healthcare provider. • Details of the treatment, including date and amount paid in local currency. • Whether prior notification had been received. • Any other information.	Yes.	Yes.
	Documents to be attached/substantiate the request: • Referral letter (not required for emergency medical care, for a general practitioner, for manual therapy or chiropractic therapy). • Copy of the treatment provider's licence to practice or specialist authorisation from the country of treatment (only for non-hospital treatment). • Relevant summary patient care record/discharge summary from specialist	Partially (some documents are only required if relevant).	

[925] The same form is used also for reimbursement under the Social Security Regulations (therefore, some of the questions asked in the form are aimed at collecting information which would be relevant for reimbursement under the more favourable scheme of the aforementioned Regulations).

Country	Information required	Mandatory?	Electronic submission?
	healthcare provider (only for treatment at a hospital or from a specialist). • For expenses on medication: prescription, pharmacy receipt and packaging or copy of the packaging stating the active ingredient(s). • For laboratory tests: requisition and documentation of the types of tests done. • For scans/X-rays: requisition. • Original itemised bills/itemised receipt or other proof of payment such as a bank statement. **The following documentation must be enclosed if relevant for the application:** • For treatment at a hospital or from a specialist: If the individual has been assessed by the Norwegian specialist health service for the medical condition, a copy of the assessment should be enclosed. • The letter confirming entitlement to treatment within the specialist healthcare or the letter advising on the date of the appointment. • If the treatment is for an occupational injury: NAV (the Norwegian Labour and Welfare Administration) decision confirming the occupational injury/illness. • Other documentation the individual believes to be relevant for the application.		
PL	**Information in the module/request:** • Applicant's contact details and PESEL (personal identification number) – if PESEL is absent, the number of the document confirming the applicant's identity, • Address of the patient, • Contact details of the statutory representative, spouse, relative or other representative, if relevant, • Country of treatment and date, • Total amount paid, specifying the currency, telephone number or email of the patient/representative, • Bank account number, • Address for the postal transfer, if needed, • Declaration that the data contained are true.	Yes.	Yes. Submission on paper or electronically.
	Documents to be attached/substantiate the request: • Original invoice (containing in particular: details of the invoice issuer and the date of	Yes.	

Country	Information required	Mandatory?	Electronic submission?
	its issue; details of the beneficiary to whom the application for reimbursement relates; information necessary to identify the benefit to which the application for reimbursement relates, in particular information enabling the identification of the codes of the International Classification of Medical Procedures ICD-9 and the International Statistical Classification of Diseases and Health Problems ICD-10 or data on medications dispensed, foodstuffs for particular nutritional uses or medical devices - in the absence of these data on the invoice, they should be included in the documentation attached to the application for reimbursement of costs) or confirmation of covering the entire cost of the service, if it does not result from the attached invoice. • Original or a copy of (where applicable according to the applicable legislation):[926] - Referrals - Prescriptions - Orders - Certificate of the service provider confirming qualification to the appropriate drug program - Copy of the medical documentation which shows the medical legitimacy of issuing a prescription for a drug, foodstuff for special purposes or medical device.		
PT	**Information in the module/request:** • ID number of the patient, NHS number, Fiscal ID number, Social Security number, address for tax purposes, age, sex and number of the insurance contract and name of the provider, if applicable, • Reasons why the treatment was provided abroad, • Clinical evaluation (by a NHS or a Regional Health Service physician) that proves the need for cross-border healthcare, with specialisation in General and Familiar Medicine, or the document that proves that the prior authorisation was obtained, when applicable; • Clinical data on the healthcare provided with reference to the medical diagnosis and the treatment plan in accordance with the International Statistical Classification of Diseases	Yes.	Yes. Submission electronically or on paper.

[926] For more details on the applicable legislation see PL country report, Section 2, question 5.

Country	Information required	Mandatory?	Electronic submission?
	and Related Health Problems or a similar classification adopted by the Member State of treatment, date of admission, date of hospital discharge, and what happened after that day.		
	Documents to be attached/substantiate the request: • Copy of medical documentation, • Acceptable proof of payment documentation, with reference to the beneficiary's name, country where the healthcare was provided, name of the healthcare provider, diagnosis and treatment details, • Certified translation, if applicable.	Yes.	
RO	**Information in the module/request:** Not specified in the legislative sources.[927]	N/A	No.[928]
	Documents to be attached/substantiate the request: • Letter of admittance into hospital, • Medical prescription for medicinal drugs or medical devices – in copy, showing that the insured person benefited from medical services, medicinal drugs and medicinal devices, dated and signed by the medical person that provided such services, • Payment documents showing that the medical services, the medicinal drugs and the medicinal devices were fully paid by the insured person, a family member (parent, husband/wife, son/daughter) or a proxy, the level of tariffs/prices distinctly for each medical services, medicinal drug, medical device, including the date of their payment. (*Note: a Government translation of the justifying documents in Romanian by an authorised translator is under the responsibility of the health insurance house, i.e. not a requirement for the applicant*).	Yes.	

[927] Some of the major county health insurance houses have a form published on their websites. The information requested in the form includes details of the patient, indication of a bank account number; Member State where the medical assistance was provided; short description of the history of the situation; the list of documents to be attached to the request, date and signature of the applicant. However, the national body contacted for the verification of the data collected indicated that these forms might not be up-to-date. Moreover, the county houses have flexibility in deciding whether to publish a form or not, but this is not required by the national legislative and regulatory framework.

[928] Please note that the national body contacted for the verification of the data collected indicated that the county health insurance houses have discretion in what concerns electronic submission of the application form. However, considering that some of the documents attached to the application form must be submitted in original, electronic submission would in most cases not be possible.

Country	Information required	Mandatory?	Electronic submission?
	NOTE: application forms available on some of the websites of the county insurance houses require additional documents. However, the national body contacted for the verification of the data collected indicated that such forms might appear to not be up-to-date with the current legislative framework requirements.		
SE	**Information in the module/request:** • Personal details (name, personal number, place of residence, signature). • Information about the care (region of insurance, period of care, reason for the care, brief description of the care content). • Information about the care provider (title, address). • Other information about the care (whether the prior notification had been submitted, whether the person has protection against high care costs or is entitled to get it free, etc.). • Information about the costs relating to care (description in a free text, as well as uploading of the receipts).	Yes.	Yes.
	Documents to be attached/substantiate the request: • Documentation of care (e.g. medical records). • Receipts.	Yes.	
SI	**Information in the module/request:** • Information about the basis for the reimbursement (PA decision if previously issued; or previously issued referral for specialist outpatient treatment; or a previously issued ZZZS decision on spa treatment (No. and date of a decision); • Information on the insured person/applicant; • Country of claim; • Amount of the claim; • Type of health service provided; • Information how and when the applicant contacted a healthcare provider in another EU Member State and the proof of the latter; • Bank Account details.	Yes.	Yes. Submission by email.
	Documents to be attached/substantiate the request: If reimbursement is requested on the basis of a previously issued referral for specialist outpatient treatment:	Yes.	

Country	Information required	Mandatory?	Electronic submission?
	• Proof of referral for specialist outpatient services by a personal or referring doctor from Slovenia; • Original invoice and proof of payment of the invoice, • Appropriate documentation of the treatment provided in another Member State of the European Union. (For reimbursement requests based on a previously issued PA or previously issued decision of the Slovene ZZZS on spa treatment, the proof or referral is not needed).		
SK	**Information in the module/request:** • Information on the insured person/applicant; • Date of provision of healthcare; • Description of the disease; • Total amount of costs of cross-border healthcare; • Method of sending/receiving the reimbursed amount of costs.	Yes.	Yes.
	Documents to be attached/substantiate the request: • Original proof of payment; • Record of treatment, report on provided health care; • Original of a document listing the provided medical procedures (e.g., invoice).	Yes.	

3. Costs associated with the handling of reimbursement procedures

The following table presents a summarised overview on what costs have been identified across the countries with regards to the handling of a reimbursement request, as illustrated also in Chapter 3 of the present report[929]. Please note that in Liechtenstein no information on the procedural requirements for reimbursement under the Directive was identified.

Table A.9 Costs associated to the handling of reimbursement procedures

Country	Direct costs	Indirect costs
AT	None identified.	Translation costs (in theory, but in practice translation is not being asked).[930]
BE	None identified.	Potential postal costs, if applicable.

[929] For more information, please refer to the national country reports, (Part 1) Section 2, question 6.
[930] This was confirmed by the competent National body.

Country	Direct costs	Indirect costs
BG	None identified.	Translation costs.
CY	None identified.	Potential postal costs, if applicable.
CZ	None identified.	Costs for: • Translations (unless documentation is in Czech or in Slovak), • Postal costs, if applicable.
DE	None identified, but this can vary depending on the health insurance provider.	Costs for: • Translations. • Postal costs, if applicable. Additionally, there can be administrative costs and co-payments.[931]
DK	None identified.	None identified.
EE	None identified.	Costs for: • Postal costs, if applicable. • Translation costs.
EL	None identified.	Costs for: • certification by the respective Greek Consulate, • the official translation.
ES	• For Catalunya: None identified • For Galicia: None identified.	• For Catalunya: None identified. • For Galicia: Costs for official or professional translations.
FI	None identified.	Postal costs, if applicable.
FR	None identified.	Postal costs, if applicable.
HR	None identified.	None identified.
HU	None identified.	None identified.
IE	None identified.	Translation costs (if the optional pro-forma invoice is not completed in English). There may also be additional costs if the documents submitted are not comprehensive (e.g., need to post original documents).
IS	None identified.	Potential costs for translation (if applicable).

[931] In case of patient with private health insurance, there are administrative non reimbursable fees explicitly provided. In case of patient with a statutory health insurance, it is specified that the health insurance provider shall provide for sufficient deductions from the reimbursed amount for administrative costs and the lack for a value-for-money audit and that co-payments shall be deducted too.

Country	Direct costs	Indirect costs
IT	None identified.	Costs for: • Postal costs, if applicable • Translation into Italian (if requested on a case-by case basis)
LI	No information available.	No information available.
LT	None identified.	None identified.
LV	None identified.	Certified translation (potentially requested) as a legal requirement under national administrative law.[932]
LU	None identified.	None identified.
MT	None identified.	None identified.
NL	• CZ: None identified. • Menzis: None identified.	• CZ: Postal costs (if applicable) and translation costs for languages other than Dutch, English, German, French or Spanish. • Menzis: Postal costs (if applicable) and translation costs for languages other than Dutch, English, German.
NO	None identified.	Potential costs for State-authorised translation (if applicable).[933]
PL	None identified.	Translation costs.
PT	None identified.	Costs for: • Stamps and postal costs (if applicable) • Official translations.
RO	None identified.	None identified.
SE	None identified.	None identified.
SI	None identified.	Costs for:

[932] The requirement of certified translation is a legal requirement incorporated in the national legislative framework. However, the competent authority (the National Health Service) contacted for the verification of the data collected at national level for LV has indicated that in practice (currently) there seem however to be no indirect costs for the person requesting reimbursement, as translation of documents is not requested in practice. In the authority's view, the translation shall be provided or the costs thereof shall be borne by the competent authority. No other potential indirect costs have been identified by the competent authority (the National Health Service). Therefore, though the law requires the translation, there appear to be room to disapply the provisions based on discretion.

[933] All documentation must be in Norwegian, Danish, Swedish or English. If the documents are in another language, Helfo may ask the individual to provide a state-authorised translation. In this assessment, emphasis shall be placed on the size of the claim amount. If it entails unreasonable costs for the user to translate the claim based on the amount to be reimbursed, Helfo shall assess whether there is a need for translation, or whether the documentation can still be understood by Helfo. In such cases, Helfo cannot demand that the user have the documents translated by a state-authorised translator.

Country	Direct costs	Indirect costs
		• Stamps and postal costs (if applicable) • Translations of documentation, • Copying of medical documentation, • Professional support by a lawyer or other expert (if applicable).
SK	None identified.	Potential postal costs.

4. Time requirements for reimbursement procedures

The following table presents a summarised overview of the time requirements which have been identified across the countries with regards to reimbursement procedures, as illustrated also in Chapter 3 of the present report[934]. Please note that in Liechtenstein no information on the procedural requirements for reimbursement under the Directive was identified.

Table A. 10 Time requirements for reimbursement procedures

Country	Time limits for applicant/patient	Time limits for reimbursement decision	Consequences if the deadlines are not met
AT	Generic administrative rule for reimbursement: 42 months after the treatment.	None identified.	No direct consequences identified.
BE	Generic administrative rule for reimbursement: 2 years after the treatment.	None identified.	No direct consequences identified.
BG	For PA procedure with the NHIF: Within 5 years from the treatment. For PA procedure with the Ministry of Health: Within 6 months from the treatment.	No further specification.	No direct consequences identified.
CY	None identified.	Within 90 days.	No specific direct identified.
CZ	None identified.	Within 30 days. In exceptionally	The applicant can file a complaint to the Ministry of Health.

[934] For more information, please refer to the national country reports, (Part 1) Section 2, question 7.

Country	Time limits for applicant/patient	Time limits for reimbursement decision	Consequences if the deadlines are not met
		complicated case, there are 30 days more.	
DE	None identified.	Within 3 weeks or, in case a decision of the medical service is needed, 5 weeks.	The health insurance provider shall inform the applicant explaining its reasons. If no reasons are provided, the request shall be considered approved.
DK	3 years after the treatment.	None identified.	None identified.
EE	None identified.	Within 3 months, with an extension up to 6 months if this is necessary to establish relevant facts. Deadline for the bank transfer: within 15 days from the decision.	No specific direct consequences identified.
EL	6 months after the invoice was issued.	Within 60 days.[935]	None identified, but if the request cannot be processed within the time limit, the authority has to notify the interested party and provide justification/indicate if documents are missing.
ES	• For Catalunya: 3 months from the payment of the service. • For Galicia: 3 months from the payment of the service. If some documents are missing, the patient will have 15 working days to complete the request.	• For Catalunya: within 3 months. • For Galicia: within 3 months.	• For Catalunya: silence-consent (if deadline elapses without an expressed decision, the request is considered as accepted). • For Galicia: silence-consent (if deadline elapses without an expressed decision, the request is considered as accepted).
FI	6 months after the treatment.	No specific identified requirements – "without undue delay".	No direct consequences identified.

[935] If the request is made to an incompetent authority, this latter has to forward the application to the competent one within 5 days and notify the interested party.

Country	Time limits for applicant/patient	Time limits for reimbursement decision	Consequences if the deadlines are not met
FR	Within 2 years.[936]	None identified.	No direct consequences identified.
HR	3 years after the treatment.	Within 30 working days.	No direct consequences identified.
HU	Within 30 days.	None identified.	If the patient does not meet the deadline and no reasonable justification is provided, the reimbursement is not granted.
IE	None identified.	Targeted timeframe of 30 working days.	No direct consequences identified.
IS	None identified.	No specific time requirements identified. The following general time requirements apply: 1. Applications should be handled "As quickly as possible". 2. The four-year general limitation period for claims applies also to reimbursement procedures.[937]	No direct consequences identified.
IT	60 days from the provision of the service.	60 days from the receipt of the request.	No direct consequences identified.
LI	No information available.	No information available.	No information available.
LT	1 year from the provision of the services.	20 working days from the date of receipt of the application (the payment should be	For the insured person: loss of reimbursement entitlement. For the body: No direct consequences identified.

[936] Further specifications:
For medical expenses for diseases: the 2 years period starts from the first day of the civil quarter which follows the quarter when the healthcare was provided.
For maternity costs: the 2 years period starts from the date of the first medical confirmation of the pregnancy.

[937] Administrative Procedures Act no. 37/1993. Available in English at: https://www.legislationline.org/download/id/4753/file/Iceland_Administrative_Procedures_Act_1993_en.pdf.

Country	Time limits for applicant/patient	Time limits for reimbursement decision	Consequences if the deadlines are not met
		made within 30 days of this decision).[938]	
LV	1 year from the provision of the services.	None identified.	For the insured person: reimbursement request not considered if submitted by the insured person after one year.
LU	2 years following the payment of the invoice.	None identified.	For the insured person: loss of reimbursement entitlement.
MT	None identified.	6 to 12 months.[939]	For the body: No direct consequences identified.
NL	• CZ: within 36 months. • Menzis: within 3 years after receiving the invoice.	• CZ: 10 days[940] • Menzis: within 2 weeks if the declaration of costs was made as soon as possible.	• CZ: the costs will not be reimbursed. • Menzis: the costs will not be reimbursed.
NO	6 months from the day of the treatment (3 years if it was not possible to claim the benefit before).	12 weeks.	For the insured person: loss of reimbursement entitlement. For the body: No direct consequences identified.
PL	6 months from the day of the invoice.	30 days from the date of initiating the procedure (standard procedure); 60 days: where the examination of the application for reimbursement requires an explanatory procedure; 6 months: where the examination of the application for reimbursement requires an explanatory procedure with the participation of a foreign NCP.	For the insured person: loss of reimbursement entitlement. For the body: if no arrangement is made, the costs will be reimbursed immediately after that expiry of the deadline.

938 The shorter timeframe (10 working days from the date of the decision) is only established for transfer of the reimbursable amount for the purchase of orthopedic technical devices and joint endoprostheses in the country of treatment.

939 Information provided to Spark Legal Network by the Maltese NCP on 7/10/2021. The NCP also indicated that the timeframes will be made available on the website, which is currently being updated.

940 It is a target, not a guarantee.

Country	Time limits for applicant/patient	Time limits for reimbursement decision	Consequences if the deadlines are not met
PT	Within 30 days from the date of the receipt.	90 days (extendable if the application is incomplete); 5 days in case the opinion of the General Health Department of the Ministry of health is needed.	The patient may complain to the Health Regulatory Authority.
RO	None identified.	30 days to communicate rejection (as of the registration of the request) 60 days for payment (as of the date the budgetary allocation of the amount is made by the National Health Insurance House)	No direct consequences identified.
SE	None identified.[941]	90 days after a complete request has been submitted	No direct consequences identified.
SI	None identified.	2 months from submission.	Applicant has the right of appeal (as if the application was rejected).
SK	6 months from the provisions of the healthcare.	6 months after the receipt of the request.	For the insured person: loss of reimbursement entitlement. For the body: No direct consequences identified.

5. Non reimbursable thresholds

The following table presents a summarised overview of the requirements which have been identified across the countries with regards to non-reimbursable thresholds for cross-border healthcare under the Directive, as illustrated also in Chapter 3 of the present report[942]. Please note that in the case Liechtenstein no information on the procedural requirements for reimbursement under the Directive was identified.

[941] A 10-year limit for requesting of the reimbursement, as stipulated in Section 2 of Act on limitation (Preskriptionslag (1981:130)) would apply once the Directive 2011/24 have been in place for 10 years. This is a general administrative time limit.
[942] For more information, please refer to the national country reports, (Part 1) Section 2, question 8.

Table A. 11 Non reimbursable thresholds

Country	Non-reimbursable thresholds
AT	For cross-border healthcare without prior authorisation, patients will receive only a care cost allowance or a reimbursement of the 80% of the tariff which would be reimbursed domestically for contracted care. This threshold also applies domestically when patients address themselves to non-contracted healthcare providers.
BE	None identified.
BG	No specific non reimbursable thresholds applicable for cross-border healthcare. Reimbursement available only up to the national tariff.
CY	Non reimbursable services: • refractive surgery • cosmetic surgery • consumables (shoes, wheelchairs etc.) The list of reimbursable amounts for the specific procedures is available on the NCP portal.[943]
CZ	No specific non reimbursable thresholds applicable for cross-border healthcare. Reimbursement available only up to the national tariff.
DE	Deductions for administrative costs can be made.
DK	No specific non reimbursable thresholds applicable for cross-border healthcare.
EE	No specific non reimbursable thresholds applicable for cross-border healthcare. Reimbursement available only up to the national tariff.
EL	No specific non reimbursable thresholds applicable for cross-border healthcare. Reimbursement is available only up to national tariff.
ES	• For Catalunya: None identified; • For Galicia: None identified.
FI	Reimbursement up to the amount that would be reimbursed domestically should the treatment be provided in a private establishment. Additional thresholds exist in relation to the reimbursement of: - medicines (initial deductible of 50 euros), - dental expenses (reimbursed only when the treatment is necessary to cure an illness other than dental illness, and reimbursement is not available for dental prosthetic procedures or dental technology expenses), - travel costs: reimbursed as if the trip would have been made to the closest healthcare establishment available for the treatment.

[943] Available at the following: http://www.cylaw.org/KDP/data/2013_1_143.pdf.

Country	Non-reimbursable thresholds
FR	No specific non reimbursable thresholds applicable for cross-border healthcare. Reimbursement available up to the national tariff.
HR	No specific non reimbursable thresholds applicable for cross-border healthcare. Reimbursement available up to the national tariff.
HU	No specific non reimbursable thresholds applicable for cross-border healthcare. Reimbursement available up to the national tariff.
IE	○ For outpatient healthcare claims (not involving an overnight stay), the maximum reimbursement for an outpatient consultation in a hospital abroad is €168 (as of March 2021). ○ Inpatient care abroad, the HSE will deduct €80 per night, to a maximum of €800, from the amount to be repaid (however, a person will not have to pay the €80 per night if they either have a medical card or have already paid €800 for overnight stays in hospitals abroad or in Ireland in the last 12 months). ○ Orthodontic treatments: If a patient is currently on an Orthodontic Assessment Waiting list in Ireland but has not yet been assessed, they can choose to have this assessment carried out abroad and claim up to €100.00 towards the cost of the assessment.[944]
IS	None identified.
IT	None identified.
LI	No information available.
LT	None identified.
LV	None identified.
LU	None identified.
MT	No specific non reimbursable thresholds applicable for cross-border healthcare.[945]
NL	No specific non reimbursable thresholds applicable for cross-border healthcare. Generally, different calculation methods seem to be applied by insurance providers, depending on whether the healthcare for which a patient seeks reimbursement is provided by a contracted or non-contracted provider. • CZ: there is a contractual determined amount to be paid by the patient, after that threshold, the insurance company covers the rest. • Menzis: there is a contractual determined amount to be paid by the patient, after that threshold, the insurance company covers the rest.
NO	None identified.
PL	None identified.

[944] The assessment abroad must be carried out in line with the HSE Orthodontic Assessment Tool.
[945] Information provided to Spark Legal Network by the Maltese NCP on 7/10/2021.

Country	Non-reimbursable thresholds
PT	None identified.
RO	None identified.
SE	None identified.
SI	None identified.
SK	None identified.

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