



Guiding principles for information provision on prior authorisation systems across Member States



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

Guiding principles for information provision on prior
authorisation systems across Member States

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Glossary

Cross-border healthcare: Cross-border healthcare refers to medical treatment outside the patient's country of residence, whether or not under the social security legislation of another Member State. The treatment is considered to be cross-border when received in any another EU/EEA Member State or (but only in case of the application of the Regulations) in Switzerland.

Directive: 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.

EEA: European Economic Area consisting of the Member States of the European Union and three countries of the European Free Trade Association: Iceland, Liechtenstein and Norway.

EHIC: European Health Insurance Card: Free card, issued by the national health insurance institution, that allows the patient access to medically necessary, state-provided healthcare during a temporary stay in another EU/EEA country or Switzerland, under the same conditions and at the same cost (free of charge in some countries) as people insured in that country.

EU: European Union

Member State of affiliation: Member State which under the Regulations is competent to grant to the insured person a prior authorisation to receive appropriate treatment outside the Member State of residence and issue the S2 form. This will normally be the country under whose social security system the patient is insured.

Member State of treatment: Member State on whose territory the cross-border treatment is actually provided or in the case of telemedicine the Member State where the healthcare provider is established.

NCP: National Contact Point. Under Directive 2011/24/EU, all EU/EEA Member States are obliged to designate one or more National Contact Points which provide patients with information on all aspects of cross-border healthcare.

Planned/scheduled healthcare: healthcare provided during a temporary stay abroad of which the explicit purpose was to receive it there.

Prior authorisation: Authorisation that patients need to receive from their national health insurance institution in advance of their travel abroad in order to be guaranteed reimbursement for cross-border healthcare.

Regulations: Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems and 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.

Reimbursement: Repayment to the patient by the national health insurance institution, on certain conditions, of the costs incurred for cross-border healthcare services.

S2 form: Authorisation from the patient's national health insurance institution to obtain planned health treatment in another EU/EEA country, according to the Regulations, i.e. under the same conditions and at the same cost (free of charge in some countries) as people insured in that country.

Necessary (unplanned) healthcare: Healthcare received by a patient in an EU/EEA country or Switzerland, which becomes necessary on medical grounds during the temporary stay in that State for work, study or leisure (i.e. without the initial purpose of the patient's travel being to receive treatment there) and that, taking into account the length of the stay, cannot wait until the patient gets home. This includes treatments provided in conjunction with chronic or existing illnesses¹.

¹ See explanatory note from the European Commission:
<https://ec.europa.eu/social/BlobServlet?docId=6481&langId=en>.

Guiding Principles for information provision on prior authorisation systems

Purpose

In line with Directive 2011/24/EU on the application of patients' rights in cross-border healthcare (hereafter: the Directive) and complementary to the "Guiding Principles and Indicators for the practice of National Contact Points (NCPs) under the Cross-border Healthcare Directive 2011/24/EU"², these Guiding Principles provide recommendations to improve information provided to citizens on prior authorisation systems under the Directive. The purpose of these Guiding Principles is to set out key principles to help NCPs provide more transparent, accessible and understandable patient-oriented information on prior authorisation. The Guiding Principles cover the following main areas:

1. Transparency of prior authorisation systems;
2. Clarity and consistency of prior authorisation procedures;
3. Understandable information on prior authorisation.

Addressees

These Guiding Principles are for:

- **National Contact Points and competent authorities:** to help provide information on prior authorisation systems, so that patients can easily find information on what treatments require prior authorisation from their health insurance institution and how to obtain this prior authorisation for their treatment abroad;
- **Patients and healthcare providers:** to enhance the transparency of the prior authorisation systems and the legal rights of patients to information on how to access cross-border healthcare.

The principles are intended both for countries with and without a prior authorisation system, yet primarily focus on countries in which patients are required to request prior authorisation from the Member State of affiliation (where the patient is insured) before seeking healthcare under the Directive in another EU country. The Guiding Principles leave room for the existing organisational differences between EU countries (including countries with a single prior authorization procedure pursuant to the Directive and the Regulations).

Methodology

These Guiding Principles were developed based on the existing legal obligations and standards as set out in the Directive. In addition, the Guiding Principles draw on the findings of the Study on *Enhancing implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU*. Within the context of this study, Ecorys Nederland BV and Spark Legal Network collected data on prior authorisation systems in place in EU/EEA countries during the period January - August 2021.

During a workshop on 29 September 2021, the Guiding Principles were discussed with the NCPs and the European Patient's Forum (EPF). The Cross-Border Healthcare expert group validated the Guiding Principles in November 2021.

Reading guide

This document starts with a section on cross-border healthcare that clarifies the two legal routes to access healthcare in other EU countries. Subsequently, the three areas of information provision to patients on prior authorisation (transparency of the system, clarity and consistency of procedure and making information understandable) are elaborated in Chapters 1 to 3. A number of Guiding Principles are described for each area, based on the existing legal obligations and standards as set out in the Directive. Furthermore, related to the Guiding Principles, indicators are developed for NCP websites, which are provided in Annex 2.

About Cross-border Healthcare

There are two legal routes for EU/EEA citizens to access healthcare in another EU country: under the Social Security Regulations (EC) No 883/2004 and (EC) No 987/2009 (hereafter: the Regulations) and under Directive 2011/24/EU (hereafter: the Directive). For patients, these two systems should be coherent; either the Regulations apply or the Directive applies when they seek reimbursement for the medical costs of healthcare in another EU country.

The general principle under the Regulations is that patients have the right to access health services abroad as though they were insured under the social security system of that country. Under the Regulations, as an EU citizen, if you require medical care during a temporary stay in another EU country - whether on holiday, a business trip or studying abroad - you are entitled to any treatment that cannot wait until you get home. You have the **same rights to health care as people insured in the country you are in**, using the European Health Insurance Card (EHIC). When citizens want to access planned healthcare under the Regulations, they must request a prior authorisation, the so-called S2 form, which is issued by the competent authority of the EU country where the patient is insured.

The Directive complements the Regulations. It establishes rules for facilitating access to safe and high-quality cross-border healthcare in the EU and ensures patient mobility in accordance with the principles established by the Court of Justice of the EU. The Directive aims to reduce red tape for the patient, as in principle no prior authorisation should be required when seeking cross-border healthcare under the Directive. However, under certain conditions, EU/EEA countries can opt for a prior authorisation system and many of them have done so.

What is prior authorisation for cross-border healthcare?

Prior authorisation is a formal permission from the Member State of affiliation (where the patient is insured) for the assumption of **planned** cross-border healthcare costs.

Under the Directive, **each Member State assesses whether there is a need for a prior authorisation system**, and if so, identifies which healthcare abroad requires prior authorisation. Conversely, prior authorisation is **always** necessary for planned healthcare abroad under the Regulations.

Unplanned healthcare that might become necessary on medical grounds during a temporary stay in another EU/EEA country **does not require prior authorisation** and is received from public healthcare providers by using the European Health Insurance Card.

1 Transparency of the prior authorisation system

Transparency with regard to prior authorisation systems is essential so that patients can make a well-considered decision regarding the use of cross-border healthcare. For that purpose, the Guiding Principles provide recommendations on 1) information that clarifies the difference between the Regulations and the Directive and patients' rights under those two frameworks of EU legislation, 2) an explanation of whether a prior authorisation is required before utilising healthcare under the Directive in another EU country, and 3) if so for which treatments prior authorisation as defined by the Directive is in place, as well as the level of detail of the prior authorisation list; and 4) the reasons for which prior authorisation may be refused, the consequences of seeking healthcare abroad without prior authorisation when required and the rights of patients when they are unable to await the decision on their prior authorisation request.

1. NCPs websites provide patients with information on the existence of two parallel routes for cross-border healthcare, making a clear distinction on the use of the Regulations versus the Directive and respective consequences for patients. This information should explain:
 - a. The difference between the necessary healthcare that is received using the EHIC and planned healthcare;
 - b. That when the conditions to grant prior authorisation under Regulation (EC) No 883/2004 are met, the health insurance institution will grant prior authorisation in accordance with that Regulation, unless the patient requests otherwise;
 - c. Whether the health insurance institution informs patients about their rights under the Directive, and assesses if a prior authorisation can be issued under the Directive in cases where a request for prior authorisation under the Regulation is refused;
 - d. In which situations the Regulations, the Directive or both apply, whether or not these require prior authorisation in the EU country and a comparison of consequences for the patient under the Regulation and the Directive.

See the table in Annex 1 including information on the difference between the Directive and the Regulations. NCPs are recommended to provide such a table on their website and/or a similar table that includes information adapted specifically for the Member State at issue, e.g. following the Estonian example which is also provided in the Annex.

2. NCPs clearly indicate on their websites whether prior authorisation needs to be requested before utilising healthcare under the Directive in another EU country. NCPs in EU countries with no prior authorisation system under the Directive make explicit that no prior authorisation is required. A prior authorisation is always necessary for planned healthcare under the Regulation.
3. In case a prior authorisation system is implemented under the Directive, NCPs websites provide patients with comprehensive information on healthcare for which prior authorisation is required. In particular, this includes:
 - a. a sufficiently defined list of treatments and/or medical equipment that require prior authorisation, including for those treatments that require overnight stay in hospital. This list should be exhaustive, provided on a

detailed level of treatments and/or medical equipment rather than overarching categories;

- b. reference to underlying (overall) criteria based on which the treatment and/or medical equipment has been made subject to prior authorisation in line with Article 8.2 of the Directive (see box below).

Categories of healthcare that may be made subject to prior authorisation under the Directive³

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: 1) involves overnight hospital accommodation of the patient in question for at least one night; or 2) requires use of highly specialised and cost-intensive medical infrastructure or medical equipment;
- b) involves 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.

4. NCPs websites provide patients with information indicating:

- a. the reasons for which prior authorisation may be refused (see box below);
- b. that prior authorisation may not be refused when the healthcare treatment cannot be provided domestically within a time limit that is medically justifiable, taking into account the patient's current state of health and the probable cause of the illness;⁴
- c. how the health insurance institution assesses whether or not the healthcare can be provided in the Member State within a time limit that is medically justifiable.

General principles for reimbursement of costs⁵

Without prejudice to Regulation (EC) No 883/2004 and subject to the provisions of Articles 8 and 9, the Member State of affiliation shall ensure the costs incurred by an insured person who receives cross-border healthcare are reimbursed, if the healthcare in question is among the benefits to which the insured person is entitled in the Member State of affiliation.

Reasons on which prior authorisation may be refused⁶

The Member State of affiliation may refuse to grant prior authorisation 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;

³ Article 8.2 of the Directive.

⁴ Without prejudice to points (a) to (c) of Article 8.6 of the Directive.

⁵ Article 7.1 of the Directive.

⁶ Article 8.6 of the Directive.

- 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 on its territory 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.

5. NCPs websites provide patients with information on the financial consequences of seeking cross-border healthcare without prior authorisation when prior authorisation is required (e.g., no or partial reimbursement).

NB! NCPs should ensure that their websites clearly note that the costs will be reimbursed up to the level that would have been assumed in the Member State of affiliation without exceeding the actual costs of healthcare received. Thus, the patient might not get full reimbursement under the Directive.

6. NCPs websites explain the rights of patients when they are not able to await the decision on the prior authorisation request, for reasons relating to their state of health and/or to the need to receive urgent treatment (see box below).

"[...] national legislation which excludes the reimbursement, by the competent institution, of the costs relating to hospital or major non-hospital care received in another Member State, without prior authorisation, including in specific circumstances where the insured person was prevented from applying for such authorisation or was not able to wait for the decision of the competent institution on the application for authorisation submitted, for reasons relating to his or her state of health or to the need to receive urgent treatment, even though all other conditions for such costs to be assumed are met, does not satisfy the requirement of proportionality [...]"⁷

⁷ Judgment of the Court of Justice of 23 September 2020, *WO*, C-777/18, EU:C:2020:745, paragraph 85.

2 Clear and consistent information on prior authorisation procedures

One of the advantages of the Directive is that there is less red tape for patients and the procedure for requesting prior authorisation under the Directive should be clear to patients to ensure patient mobility in accordance with the principles established by the Court of Justice of the European Union. Clear information on the prior authorisation procedure means that it is important that information on the procedure of prior authorisation is consistent between NCPs and competent national and regional authorities that grant prior authorisation (health insurance institutions). In addition, information provided by other parties, such as healthcare providers and patient organisations, should be in line with information provided by the NCPs and health insurance institutions. Against this background, guidelines are provided on: 1) procedural steps that need to be taken for requesting prior authorisation; 2) procedural steps that are taken to process the request of prior authorisation; 3) maximum processing times related to prior authorisation; 4) coordination on provision of information regarding prior authorisation between national and regional competent authorities, NCPs, healthcare providers and patient organisations.

1. NCP website:

- a. Clearly states which health insurance institution is competent to grant prior authorisation both under the Directive and the Regulations;
- b. The applicable forms for a prior authorisation request are available on the NCP website via a direct link, or a clear description is available on where the application forms can be found. In case there are no request forms or the forms do not specify, the NCP website clearly lists which documents have to be attached to a prior authorisation request;

NB! If there are different forms to request prior authorisation under the Directive and under the Regulations, it should be clear which prior authorisation form to use for which legal route.

- c. Indicates the means of submission of prior- authorisation requests, in particular, whether it is possible to submit them electronically.

In EU countries where electronic submission of prior authorisation requests is possible, the administrative procedures appear less burdensome for patients (e.g., in terms of time, costs, etc.), compared to countries not providing digital means of submission of such requests. Electronic submission is in line with the digital transition in healthcare that aims to facilitate greater access to cross-border healthcare⁸.

- d. Rather than referring to 'a referral from a doctor' or a 'consultation with a doctor', makes it explicitly clear each time which type of doctor referral is required and whether the relevant documents should be provided by a national/contracted doctor, or can be provided by a doctor of other EU/EEA countries (see box below);

⁸ https://ec.europa.eu/health/ehealth/home_en.

In addition to the prior authorisation requirement, national competent authorities may impose the same conditions, criteria for eligibility, regulatory and administrative formalities for healthcare abroad, as it would impose, if this healthcare were provided in its territory (e.g., the requirement to consult a general practitioner before consulting a specialist or before receiving hospital care). However, no conditions, criteria of eligibility and regulatory and administrative formalities [...] may be discriminatory or constitute an obstacle to the free movement of patients, services or goods, unless it is objectively justified [...] ⁹.

- e. Provides information on the procedures for appeal and redress against the decision of the health insurance institution, if patients consider that their rights have not been respected (e.g., the relevant institution, its contact information, time-limits to lodge the appeal, and, if applicable, a link to an online form for appeal and redress etc.);
 - f. Indicates the processing time for prior authorisation requests, including in individual urgent situations;
 - g. Clarifies legal consequences if a decision is not taken within the set time-limit (e.g. whether a positive decision is considered to be taken, if no reply within the set time-limit).
2. NCPs consult with patient organisations, health insurance institutions and healthcare providers to ensure that they provide the same information to patients on prior authorisation.

⁹ Article 7.7 of the Directive.

3 Understandable information on prior authorisation

In addition to transparent and consistent, information provided on prior authorisation should be understandable for patients. Presenting clear information will mitigate the risk of patients being excluded or deter patients from seeking cross-border healthcare. The information should be understandable and inclusive for patients and not discriminate between patients, for example, from different socioeconomic backgrounds, due to language barriers or disabilities. Therefore, in the context of information provision on prior authorisation, the Guiding Principles provide recommendations on 1) accessibility of information; 2) and information that is easy to understand and comprehend.

1. NCPs have an accessible website that is easy to find, informative and contains clear, structured and understandable information on prior authorisation.
2. In order to facilitate patients accessing the information on the prior authorisation system, NCPs are recommended to provide the information on their websites:
 - a. in laymen terms that are easy to understand, including visuals to complement the text;
 - b. in the national official language(s) of the Member State of affiliation, as well as in English. Minority languages should also be considered;
 - c. in alternative formats that enhance accessibility for disabled persons and people with decreased sensory functioning such as screen readers, Easy-to-Read information and key information in sign language.

Table 3.1. Useful links on the Regulations and the Directive that could be provided on the NCP website

Topic	Link
Legal acts	- Directive 2011/24/EU - Regulation No 883/2004 - Regulation No 987/2009
Toolbox for cross-border healthcare	- A manual for patients - Glossary - Checklist - FAQ for incoming patients - FAQ for outgoing patients - Decision tree for patients - Leaflet for Patients: The top ten Mistakes Patients make in Cross-border healthcare - [Placeholder for the links from NCPs websites where lists of healthcare subject to prior authorisation could be found]
Websites of the EC providing information medical treatment abroad	- Health - Your Europe (europa.eu) - European Health Insurance Card - Employment, Social Affairs & Inclusion - European Commission (europa.eu) - How to use the card - Employment, Social Affairs & Inclusion - European Commission (europa.eu) - Planned medical treatment - Information points: planned medical treatment abroad

Annex 1 Information on the difference between the Directive and Regulations

The tables below are examples that NCPs may use for their websites to provide information on healthcare under the Directive and the Regulations. The first table provides an overview of information as set out in the Directive and the Regulations. The second table provides an example following the Estonian NCP website.

Table A.1 Information on healthcare under the Directive and the Regulations

	Directive	Regulations
Type of healthcare provider	The Directive gives you the right to treatment by both public and private healthcare providers.	The Regulations give you the right to treatment by public healthcare providers only.
Payment for cross-border healthcare services	Under the Directive, you have to pay upfront for the healthcare services you use and you will be fully or partially reimbursed afterwards.	Under the Regulations, you are entitled to healthcare abroad as if you were insured under the social security system of the EU/EEA country where you receive treatment. That means that you are entitled to benefits in kind and do not usually have to pay for healthcare upfront where the social security system of the EU/EEA country where you are treated provides such benefits to their own insured persons.
Reimbursement of costs for cross-border healthcare	You can claim the costs you had for healthcare services in another EU/EEA country from your health insurance institution. It will reimburse the costs up to the level that would have been paid in your country of residence (without exceeding the actual costs of healthcare received).	Your health insurance institution at home will take care of paying for the benefits in kind that you received in another EU/EEA country. However, if the EU/EEA country where you are treated does not provide benefits in kind to their own insured persons, you will have to pay the costs upfront and be subsequently reimbursed by your health insurer.
Price for healthcare	Private healthcare providers and, in certain cases, public healthcare providers are allowed to set their own prices or apply "private" prices for your healthcare as for a domestic patient. However, they cannot	The prices charged are the same as for persons covered by the social security system of the EU/EEA country where you received your treatment.

	Directive	Regulations
	discriminate against patients from other EU/EEA countries.	
Prior authorisation	The general rule is that you do not need prior authorisation for cross-border healthcare. Your country of insurance may require prior authorisation for certain healthcare treatments and equipment. Many EU countries do, so it is important to check before going if your treatment is among treatments for which prior authorisation is necessary.	Prior authorisation is always required for reimbursement of planned healthcare. Prior authorisation is granted by the health insurance company, issuing the S2 form for planned healthcare.

Table A.2 Information provided on the Directive and the Regulations on the Estonian NCP-website

	Patients' Rights Directive 2011/24/EL	Regulation (EC) No. 883/2004 Article 20	Regulation (EC) No. 883/2004	Health Insurance Act (\$271)
Type of treatment	Planned and necessary medical care in the EU member states, EFTA member states and Switzerland (excluding planned treatment)	Only planned treatment in the EU member states, EFTA member states and Switzerland	Only necessary medical care in the EU member states, EFTA member states and Switzerland	Only planned treatment outside Estonia.
Which health care services is a person entitled to and what will be reimbursed?	Only the health care services that are listed in the EHIF's list of health care services and the services covered by EHIF in Estonia are reimbursed.	Only the health care services that are listed in the EHIF's list of health care services and the services covered by EHIF in Estonia but which cannot be provided during a medically justifiable period of time.	The reimbursement applies to health care services that belong to reimbursable services in that country Persons are entitled to receive health care services that are listed in the social insurance reimbursements of that country.	The reimbursement applies to health care services that are not provided in Estonia but are prescribed for persons, proven to be medically effective, and the probability of achieving the aim is at least 50 per cent.

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	Patients' Rights Directive 2011/24/EL	Regulation (EC) No. 883/2004 Article 20	Regulation (EC) No. 883/2004		Health Insurance Act (§271)
Which medical institutions can I turn to?	Public and private medical institutions	Public medical institutions only	Public medical institutions only		Public and private medical institutions
Is prior authorisation from EHIF required?	NO. Pursuant to the Estonian Health Insurance Act, a referral from a family physician or private doctor is required.	YES. If authorisation is granted, form E112/S2 is issued	NO	NO. The European Health Insurance Card or its replacement certificate is required.	YES If authorisation is granted, a letter of guarantee or form E112/S2 is issued, or a contract is signed with persons.
Who is reimbursed and how?	Persons are reimbursed directly, after they have received the health care service.	Invoicing will take place between competent national authorities (health insurance funds), i.e. no monetary reimbursement is made to persons.	Persons are reimbursed directly, after they have received the health care service.	Invoicing will take place between competent national authorities (health insurance funds), i.e. no monetary reimbursement is made to persons.	Directly to the medical institution of the foreign country or between national competent authorities, in special cases, also directly to persons after healthcare services have been provided the health care service.
What does a person have to pay for when receiving treatment abroad?	Persons will pay all invoices on site and will be reimbursed retrospectively.	Only co-payments according to local rates of the country that provided the health care service. Deductibles may apply.	Persons will pay all invoices on site and will be reimbursed retrospectively.	Only co-payment according to local rates of the country that provided the health care service.	Only co-payments according to local rates of the country that provided the health care service. Deductibles may apply.
Under which price list are the reimbursements/ payments made?	Persons are made in accordance with the Estonian price list (co-payments, etc. are not reimbursed)	Persons are not reimbursed directly, are made in accordance to the price list of the foreign country.	Reimbursement is made according to local rates of the country that provided the health care service.	Persons are not reimbursed directly, but invoicing is made according to the	According to the price list of the foreign country. (co-payments, etc. are not reimbursed)

	Patients' Rights Directive 2011/24/EL	Regulation (EC) No. 883/2004 Article 20	Regulation (EC) No. 883/2004	Health Insurance Act (§271)
			price list of the foreign country.	
Where can I find more information?	Reimbursement of treatment costs in the EU	Planned medical treatment abroad	Reimbursement of treatment costs in the EU	European Health Insurance Card Planned treatment abroad

Annex 2 Indicators for NCP websites

Table A.3 Legal context and indicators for the guiding principles on transparency

Guiding Principle	Legal context ¹⁰	Indicators for NCPs websites	MSs with prior authorisation ¹¹	MSs without prior authorisation
1. NCPs websites provide patients with information on the existence of two parallel routes for cross-border healthcare, making a clear distinction on the use of the Regulations versus the Directive and respective consequences for patients.	Article 5.b	Explains the difference between the necessary healthcare that is received using the EHIC and planned healthcare.	✓	✓
	Article 8.3	Indicates that when the conditions to grant prior authorisation under Regulation (EC) No 883/2004 are met, the health insurance institution will grant prior authorisation in accordance to that Regulation, unless the patient requests otherwise.	✓	-
	Article 5.b Recital 30	Explains whether the health insurance institution informs patients about their rights under the Directive in cases where a request for prior authorisation is refused under the Regulation.	✓	✓
	Recital 30	Explains whether the health insurance institution assesses if a prior authorisation can be issued under the Directive in cases where a request for prior authorisation is refused under the Regulation.	✓	-
	Article 5.b Recital 30	Explains, in which situations the Regulations, the Directive or both apply, whether these do or do not require prior authorisation in the EU country and provides a comparison of consequences for the patient under the Regulations and the Directive ¹² .	✓	✓
2. NCP website clearly indicates whether prior authorisation needs to be requested before utilising healthcare in another EU country.	Article 5.b (Article 20 of Regulation 883/2004)	Provides the statement that prior authorisation is always necessary for planned healthcare under the Regulations.	✓	✓

¹⁰ Relevant articles of the Cross-border Healthcare Directive <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:en:PDF> and other EU law provisions.

¹¹ Here and further, prior authorisation under the Directive.

¹² E.g. using as an example the above-table "Information on healthcare under the Directive and the Regulations".

Guiding Principle	Legal context ¹⁰	Indicators for NCPs websites	MSs with prior authorisation ¹¹	MSs without prior authorisation
	Article 5.b Article 6(3) Article 8	Clearly states that prior authorisation needs to be requested before utilising healthcare under the Directive in another country.	✓	-
	Article 5.b Article 6(3) Article 8	Makes explicit that no prior authorisation is required for planned healthcare under the Directive.	-	✓
3. In case a prior authorisation system is implemented under the Directive, NCPs websites provide patients with comprehensive information on healthcare for which prior authorisation is required.	Article 8.7 Article 8.2	Publishes a sufficiently defined list of treatments and/or medical equipment that require prior authorisation. This list should be exhaustive, provided on a detailed level of treatments and/or medical equipment rather than overarching categories.	✓	-
	Article 8.7 Article 8.2	Refers to underlying (overall) criteria based on which the treatment and/or medical equipment can be made subject to prior authorisation under Article 8.2 of the Directive.	✓	-
4. NCP website provides patients with information on the reasons on which prior authorisation may and may not be refused.	Article 8.7 Article 8.6 Article 7.1 (Article 20 SSCR)	Provides information on the reasons for which prior authorisation may be refused (both under the Directive and the Regulations).	✓	✓ (as regards the Regulations)
	Article 8.7 Article 8.5 (Article 20 SSCR)	Provides information that prior authorisation may not be refused when the healthcare treatment cannot be provided domestically within a time limit that is medically justifiable.	✓	✓ (idem)
	Article 8.7	Provides information how the health insurance institution assesses whether the healthcare can or cannot be provided in the Member State within a time limit that is medically justifiable.	✓	✓ (idem)
5-6. NCP website provides patients with information on the (financial) consequences of seeking cross-border healthcare	Article 8.7 Article 8.1 (Article 20 of	Provides information on the (financial) consequences of seeking cross-border healthcare without prior authorisation when prior authorisation is required (e.g. no or partial reimbursement).	✓	✓ (idem)

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Guiding principles for information provision on prior authorisation systems across Member States

Guiding Principle	Legal context ¹⁰	Indicators for NCPs websites	MSs with prior authorisation ¹¹	MSs without prior authorisation
without prior authorisation when prior authorisation is required and explains the rights of patients when they are not able to await the decision on the prior authorisation request.	Regulation 883/2004) Article 8.7 Article 8.1 (Article 20 of Regulation 883/2004)	Explains the rights of patients when they are not able to await the decision on the prior authorisation request, for reasons relating to their state of health and/or to the need to receive urgent treatment.	✓	✓ (idem)

Table A.4 Legal context and indicators for the guiding principles on clear and consistent information on prior authorisation procedures

Guiding Principle	Legal context ¹³	Indicators for NCPs websites	MSs with PA	MSs without PA
1. NCP website provides patients with clear and consistent information on prior authorisation procedures.	Article 8.7 Article 9.2	Clearly states which health insurance institution is competent to grant prior authorisation both under the Directive and the Regulations.	✓	✓ (as regards the Regulations)
	Article 8.7 Article 9.2	Provides a direct link to the applicable forms for a prior authorisation request or a good description where the application forms can be found.	✓ (where applicable)	✓ (idem)
	Article 8.7 Article 9.2	In case there are no request forms, clearly indicates that a prior authorisation request could be submitted in a free form.	✓ (where applicable)	✓ (idem)
	Article 8.7 Article 9.2	In case there are no request forms or the forms do not specify, clearly lists what documents have to be attached to a prior authorisation request.	✓ (where applicable)	✓ (idem)
	Article 8.7 Article 9.2	Indicates the means of submission of prior authorisation requests, e.g. whether it is possible to submit them electronically.	✓	✓ (idem)
	Article 8.7 Article 9.2 Article 7.7	Rather than referring to 'a referral from a doctor' or a 'consultation with a doctor', makes it explicitly clear each time from what type of doctor referral is required and	✓ (where applicable)	✓ (idem)

¹³ Relevant articles of the Cross-border Healthcare Directive <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:en:PDF> and other EU law provisions.

Guiding Principle	Legal context ¹³	Indicators for NCPs websites	MSs with PA	MSs without PA
		whether the relevant documents should be provided by a national/contracted doctor, or can be provided by a doctor of other EU/EEA countries.		
	Article 8.7 Article 9.2 Article 9.4	Provides information on the procedures for appeal and redress against the decision of the health insurance institution, if patients consider that their rights have not been respected (e.g., the relevant institution, its contact information, time-limits to lodge the appeal etc.).	✓	✓ (idem)
	Article 8.7 Article 9.2 Article 9.3	Indicates the processing time for prior authorisation requests, including in individual urgent situations.	✓	✓ (idem)
	Article 8.7 Article 9.2	Clarifies legal consequences if a decision is not taken within the set time-limit (e.g. whether a positive decision is considered to be taken, if no reply within the set time-limit).	✓	✓ (idem)
2. NCPs consult with patient organisations, health insurance institutions and healthcare providers to ensure that they provide the same information to patients on prior authorisation.	Article 6.1	NCPs consult and assess information provided to patients with patient organisations.	✓	✓ (idem)
		NCPs consult and assess information provided to patients with health insurance institutions.	✓	✓ (idem)
		NCPs consult and assess information provided to patients with healthcare providers.	✓	✓ (idem)

Table A.5 Legal context and indicators for the guiding principles on understandable information on prior authorisation

Guiding Principle	Legal context ¹⁴	Indicators for NCPs websites	MSs with PA	MSs without PA
1. NCP has an accessible website that is easy to find, informative and contains clear, structured and understandable information on prior authorisation.	Article 6.5	A separate heading, sub-heading or paragraph on prior authorisation.	✓	✓ (as regards the Regulations)
		A separate section of Frequently Asked Questions (FAQ) on prior authorisation.	✓	✓ (idem)

¹⁴ Relevant articles of the Cross-border Healthcare Directive <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:en:PDF>.

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Guiding Principle	Legal context ¹⁴	Indicators for NCPs websites	MSs with PA	MSs without PA
		Contact details for further questions on cross-border healthcare including prior authorisation.	✓	✓ (idem)
		A flow chart for the prior authorisation procedure.	✓	✓ (idem)
2a. NCP website provides patients with information on prior authorisation in laymen terms that are easy to understand	Article 6.5	Additional information on the Regulations and the Directive is provided in a separate document/adding useful links.	✓	✓ (idem)
		NCP requests and assesses feedback from patients and their organisations on the information provision on prior authorisation and improves the website accordingly if needed.	✓	✓ (idem)
		NCP refers to the Toolbox for Cross-Border Healthcare (Manual for Patients) ¹⁵ to provide information that is understandable to patients.	✓	✓ (idem)
2b. NCP website provides patients with information on prior authorisation in the national official language(s) of the country of the NCP, as well as in English.	Article 4.5 Recital 48	Texts provided in national official language(s) (including minority languages) and in English	✓	✓ (idem)
		Prior authorisation list provided in national official language(s) and in English	✓	-
		Information on application form(s) provided in national official language(s) and in English	✓	✓ (idem)
		All other documentation on prior authorisation provided in national official language(s) and in English	✓	✓ (idem)
2c. NCP website provides patients with information on prior authorisation in alternative formats that enhance accessibility for disabled persons and people with decreased sensory functioning.	Article 6.5	Information provided with the option "read-out-loud"	✓	✓ (idem)
		Information provided with the option "increased text size"	✓	✓ (idem)
		Information provided with the option "different colour mode"	✓	✓ (idem)
		Information provided with the option "sign-language"	✓	✓ (idem)

¹⁵ https://ec.europa.eu/health/sites/default/files/cross_border_care/docs/2019_ncptoolbox_ncp_manualncp_en.pdf.

