

Orphan Drug Development Guidebook

Building Block E132

This document defines the content of the Building Block created for each identified tool, incentives, initiative or practice introduced by public bodies or used by developers to expedite drug development in Rare Diseases (RDs).

ITEM	DESCRIPTION
Building Block (BB) Title	EU planned cross-border treatment
References	https://ec.europa.eu/health/cross_border_care/publications_en
Description	<p>People insured in one of the EU countries, who wish to go to another EU Country to be cured for PLANNED TREATMENTS, may access the health care structures and professionals of the foreign EU Country National Health System (NHS). Patients have two different ways to get funding from their Health system, according to the provisions of two EU legislations:</p> <p style="padding-left: 40px;">1) Social Security Regulations: <i>Direct Assistance</i> pursuant to Reg. 883/04 and 987/09</p> <p>The health services provided by healthcare structures or by health professionals, both public or private contracted with the NHS, are paid directly by the patient's Health system (direct assistance). The patient always needs a prior authorization by the patient's Health Institutions and, if permission is granted, patients do not anticipate any cost. Under the Social Security Regulations, prior authorization is always required - both for inpatient and outpatient treatments.</p> <p style="padding-left: 40px;">2) Directive 2011/24/EU on patients' rights in cross-border healthcare: <i>Indirect assistance</i></p> <p>There is a more recent introduced system that does not provide for a direct payment from the patient's Health Institutions, therefore, in general, the patient will have to pay</p>

	<p>directly for treatments and then request a refund. For some types of care it could be necessary to acquire a prior authorization in order to receive a refund.</p> <p>The two ways may call for different procedures and criteria for coverage of costs. It is opportune therefore to get careful information, by contacting the patient’s Health Institutions or the National Contact Point in the patient’s Country of origin, since these 2 EU regulatory provisions may have specific applications in the State where the patient is insured and they can be supplemented by specific national rules.</p> <p>In EU it may facilitate timely access to highly specialized and costly therapies not available in the Country where the patient is insured, but available in another EU Country.</p> <p>Pre-authorized request for scheduled treatments pursuant to Regs 883/04 and 987/09 (i.e., S2 Form certification – Direct Assistance) and according to Directive 2011/24/EU (Indirect Assistance): few weeks for request/approval through the National Contact Point if conditions applies.</p> <p>The pre-authorization request is free of charge, however the patient may have to anticipate all the costs if Directive applies; no costs if Social Security Regulations apply, except co-payment if foreseen.</p>
Category	Regulatory Building Block
Geographical scope	European Union
Availability	<p>Patients with rare diseases may be offered the possibility under the Social Security Regulations (EC) 883/2004 and 987/2009 to seek treatment in another EU/EEA Member State or Switzerland even for diagnosis and treatment which are not available in the patient’s home country. As long as the treatment concerned is covered in the country of treatment, prior authorisation may be granted.</p> <p>It should be noted that patients have merely the right to request prior authorisation in this situation. It remains within the discretion of the NHS/ health insurance provider to grant prior authorisation or not.</p>
Scope of use	<p>Enabling patient timely access to innovative and specialized treatment not available in the EU country where the patient is insured, but available in another EU country.</p> <p>To access timely highly-specialized, costly and innovative therapies not available in the EU country where the patient is insured.</p>

Stakeholders	<ul style="list-style-type: none"> - National Contact Point for the cross-border health-care. - NHS/health insurance provides. - The patient and his/her referring physician.
Enablers / Requirements	Pre-authorisation provided by NHS/Insurer for planned treatments not available in the EU country of residence but available in another EU member state,
Output	<ul style="list-style-type: none"> - S2 Form – portable document (former Form E122) is the proof of pre-authorisation pursuant to EU Regs. 883/04 and 987/09. This form has to be taken by the patient to the treating hospital (reimbursement among the Institutions - the patient has not to anticipate the cost). Tariffs: The reimbursement tariffs of the country of treatment apply (including co-payment if foreseen). - Pre-authorisation pursuant to Directive 2011/24/EU: Under the Directive the pre-authorisation is not always required, unless for specific cases like hospital treatment or highly specialized and expensive treatments, etc. The patient has to anticipate the costs and may file for reimbursement retrospectively upon return home. Tariffs: Same reimbursement tariffs as for treatment provided in the patient home country apply.
Best time to apply and time window	Apply for Pre-authorisation as soon as agreed with the treating center abroad.
Expert tips	<ul style="list-style-type: none"> - If Directive applies, the patient has to keep all the receipts to file for reimbursement upon return home (not needed if used “S2 form” route apply) - Ensure the S2 Form Certificate covers the whole period of the treatment abroad (eventually, request for extension) - Travel and lodging costs are not covered by neither the Regulation nor the Directive and has to be discussed locally with the health insurance/national healthcare provider. - Patients should cover the costs of translation of their medical records before travelling.

PROs:

Under Social Security Regulations (Form S2):

- The patient will be treated as a patient with public health insurance
- The financial risk that the level of costs abroad exceeds the level of costs of the treatment at home is borne by your NHS/ health insurance provider
- The treatment will be free and the patient will only have to pay possible co-payment (by application of the Vanbraekel supplement the patient may be entitled to refund of all or part of the costs of co-payment)

Under the Directive 2001/24/EU:

- For a wide range of treatment there is no obligation to obtain prior-authorization
- When prior authorization is required, the NHS/ health insurance provider may only decline the request based on limited grounds of refusal
- The patient is free to consult private healthcare providers or go to private hospitals
- In case of higher rates of reimbursement in the home country, the patient may enjoy treatment at a lower cost
- In case no prior authorisation is required, the patient may be able to access medical treatment more quickly

CONs:

Under Social Security Regulations:

- Prior authorisation (S2 form) from the NHS/ health insurance provider is required for all types of cross-border healthcare
- The Regs generally do not apply to private hospitals and private healthcare providers, unless they are contracted/ affiliated with the statutory health system.

Under the Directive 2001/24/EU:

- Patients have to pay all costs upfront and claim for reimbursement afterwards
- Patients are only be entitled to reimbursement when the treatment is covered in his/her home country
- The medical costs may exceed the amount assumed by his/her own NHS/ health

	insurance provider
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