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# 1. Introduction

1.1 The purpose of this guidance is primarily to assist Local Health Boards in Wales in handling requests from the public to go to other countries of the European Economic Area (EEA), for treatment to which they are entitled under the NHS. It also provides guidance to help Local Health Boards deal with requests from residents of other EEA countries who wish to come to Wales for treatment.

1.2 It aims to explain the obligations set out in the EU Directive on cross-border healthcare<sup>a</sup>. It is based on the National Health Service (Cross Border Healthcare) Regulations 2013<sup>b</sup> made by the Secretary of State on behalf of England and Wales and associated Directions from Welsh Ministers<sup>c</sup>. These Regulations and accompanying Directions set out the obligations that are placed on Local Health Boards in relation to claims for reimbursement of treatment costs and applications from patients who seek prior authorisation for treatment in another EEA State. This guidance should be read in conjunction with the Regulations and Directions. Implementation date for the Directive by all EU Member States was 25 October 2013.

1.3 The EEA includes the 28 Member States of the European Union (EU) plus Iceland, Liechtenstein and Norway. The Directive does not as yet (at 25<sup>th</sup> October 2013) apply to Iceland, Liechtenstein and Norway pending amendment to the EEA Agreement and therefore in those cases the arrangements put in place by the 2010 Directions (with minor amendment made in 2013) still apply<sup>d</sup>.

1.4 This guidance clarifies individuals' rights to access healthcare in another member state of the EEA and sets out the grounds on which they can claim reimbursement of eligible costs of treatment from their home health system. It refers to the country where the patient is usually resident as the home state and the one abroad where treatment is received as the treatment state.

1.5 This guidance relates to managing applications for treatment between countries within the EEA. Arrangements across borders within the United Kingdom, reciprocal arrangements with other non-EEA countries and, except for passing references, use of the European Health Insurance Card are not within the scope of this guidance.

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<sup>a</sup> 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 No. L88, 4.4. 2011, p.45).

<sup>b</sup> National Health Service (Cross Border Healthcare) Regulations 2013 S I 2013/2269.

<sup>c</sup> National Health Service (Cross-Border Health Care) (Wales) Directions 2013 (2013 No. 26) and the National Health Service (Reimbursement of the Cost of EEA Treatment) (Wales) Directions 2010 (2010 No 40 (W 40)) as amended by The National Health Service (Reimbursement of the Cost of EEA Treatment) (Wales) (Amendment) Directions 2013 (2013 No. 25 ).

<sup>d</sup> National Health Service (Reimbursement of the Cost of EEA Treatment) (Wales) Directions 2010 (2010 No 40 (W 40)) as amended by The National Health Service (Reimbursement of the Cost of EEA Treatment) (Wales) (Amendment) Directions 2013 (2013 No. 25 ).

## 2. The basis for cross-border patient mobility – the Treaty, the Directive and the regulations

2.1 The majority of EU citizens receive healthcare in the Member State where they live, via the health system through which they are covered or insured. However, in some instances, it may benefit the patient to obtain healthcare in another European country.

2.2 EU regulations on the coordination of social security systems (specifically Regulation (EEC) 1408/71, which was replaced by revised provisions in Regulation (EC) No. 883/2004<sup>a</sup> with effect from May 2010) already provide certain levels of reciprocal healthcare cover to EEA citizens. These arrangements apply to tourists requiring necessary care during a temporary stay in another Member State, for example a holiday or business visit (via the European Health Insurance Card – the ‘EHIC’), to people living and working in Europe or, in certain circumstances those who are authorised to travel specifically to receive pre-arranged healthcare. The Regulation also covers state pensioners, as social security provisions (including those for healthcare) are transferable around the EU at state pension age.

2.3 In recent decades the Court of Justice of the European Union (CJEU) has made a number of rulings regarding obtaining healthcare across borders in Europe. Because of the piecemeal nature of these rulings, the development of an EU-wide Directive was seen as necessary to clarify the law and the rights of citizens across the EU. This new Directive reflects existing rights under the Treaty on the Functioning of the European Union and the principles confirmed by established CJEU case law and applies best practice in providing access to these rights. Its main objectives are to:

- clarify and simplify the rules and procedures applicable to patients’ access to cross-border healthcare;
- provide EU citizens with better information on their rights;
- ensure that cross-border healthcare is safe and of high-quality;
- promote cooperation between Member States.

2.4 Pending agreement on the Directive, the CJEU rulings were given effect by the National Health Service (Reimbursement of the Costs of EEA Treatment) Regulations 2010<sup>b</sup> which amended the National Health Service (Wales) Act 2006 to insert sections 6A and 6B setting out the right to reimbursement subject to certain conditions and limitations.

2.5 The Directive sets out the information Member States must provide for patients from other states considering coming to the country to purchase healthcare. It also sets out the arrangements that a Member State must put in place to allow its own citizens to exercise their rights to reimbursement of the costs of cross-border healthcare if they choose to seek such healthcare in another Member State.

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<sup>a</sup> 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 No L 166, 30.4.2004 p.1-123; corrigenda to the Regulation published in OJ No L 200, 7.6.2004 p 1-49 and OJ no L 2044.8.2007, p30. The Regulation applies to the Member States of the EEA and to Switzerland.

<sup>b</sup> S.I.2010/915.

2.6 The home state retains responsibility for deciding what healthcare it will fund on a cross-border basis, so the Directive is not a way for a patient to obtain reimbursement for the costs of a treatment which they obtain in another EU member State if the same or equivalent treatment would not be made available to that patient in their circumstances under their home health service. Member States are required to be clear and transparent as to the entitlements to healthcare patients have within their home system.

### 3. Alternative routes to secure treatment abroad

3.1 There are currently two potential routes for patients to receive planned care in another Member State at the expense of the NHS:

(a) The long-established route under Articles 20 and 27(3) of Regulation (EC) No. 883/2004 which provide reciprocal arrangements that stem from the EU-wide coordination of social security systems, including reciprocal arrangements for access to healthcare and authorisation of pre-planned treatment in another Member State (“the S2 Route”)<sup>a</sup>. Where a patient applies for and is authorised to obtain pre-planned treatment in another Member State, the Secretary of State issues to the patient form S2 as a guarantee of payment;

(b) Directive 2011/24/EU (“the Directive Route”)<sup>b</sup>.

3.2 The key difference between the two routes is that the **S2 route** relates only to state-provided treatment and costs are dealt with directly between Member States, with the S2 acting as a form of payment guarantee. This means that in the majority of cases, the patient is not required to pay anything him – or herself.

3.3 Under the S2 route, Member States retain discretion as to whether to authorise planned treatment in another Member State except in cases where “undue delay” is relevant – i.e. where treatment cannot be provided by the NHS within a time that is medically acceptable, based upon an objective clinical assessment of the patient and his or her individual circumstances. Where this is the case, authorisation must be given. The principles of undue delay are discussed further in section 10 in this guidance. The S2 route does not cover private sector treatment.

3.4 Under the **Directive route**, EU citizens who choose to obtain a healthcare service in another Member State can seek reimbursement of the costs, provided the healthcare service is the same as or equivalent to a service that would have been provided to the patient within the NHS in the circumstances of his or her case. The right to claim reimbursement of costs is limited to the cost to the NHS of the same or equivalent treatment had the patient obtained that treatment from the NHS – or the actual amount paid by the patient where this is lower than the

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<sup>a</sup> The provisions of Regulation (EC) No. 883/2004 apply to the Member States of the EEA and to Switzerland.

<sup>b</sup> In this guidance the term “Directive Route” describes the provisions of the Directive implemented by the National Health Service (Cross-Border Healthcare) Regulations 2013 with effect from 25 October 2013. The “Directive Route” does not apply to Iceland, Norway and Liechtenstein until the Directive applies to those states in accordance with the EEA Agreement.

cost of the equivalent NHS treatment. A patient may receive treatment in the state-provided sector or they may access services in the private sector under the Directive.

3.5 Under the Directive, the principle of reimbursement of costs assumes that patients will pay the overseas provider up front for their treatment and then claim reimbursement. The patient will also bear the financial risk of any additional costs arising. Except where legislation requires the seeking of prior authorisation, a patient may obtain healthcare in another Member State under the Directive without authorisation from his or her Local Health Board, whereas under the S2 route, **all** healthcare must be authorised in advance.

3.6 The table below compares the two routes.

Coverage	S2 Route	Directive Route
EU / EEA	Yes	Yes <sup>a</sup>
Switzerland	Yes	No
Requires prior authorisation	Yes	Specified treatments only
Discretionary (unless undue delay applies)	Yes	Only in the 4 circumstances set out on page 17
Planned healthcare	Yes	Yes
Unplanned (emergency) healthcare	No	Yes
Treatment in state-run / contracted facilities	Yes	Yes
Treatment in private / non-contracted facilities	No	Yes
Must be granted if undue delay applies	Yes	Yes
Requires payment in full up front	No	Yes
Scope restricted to home entitlements only	No	Yes
Retrospective reimbursement (depending on circumstances)	No <sup>b</sup>	Yes

## 4. The Directive – general requirements

4.1 In order to comply with the Directive and with their obligations under direction 2 of the National Health Service (Cross-Border Healthcare) Directions 2013, Local Health Boards must ensure that:

- (a) procedures and criteria for reimbursement must be based on objective and non-discriminatory criteria that are necessary and proportionate;
- (b) information about administrative procedures must be publicly available and easily accessible;
- (c) each application must be dealt with objectively and impartially;
- (d) decisions on applications must be properly reasoned.

<sup>a</sup> For application of the Directive to Iceland, Liechtenstein and Norway, see paragraph 1.3.

<sup>b</sup> Retrospective reimbursement is available where authorisation for treatment under S2 is refused and that refusal is subsequently overturned.

4.2 When considering an application a Local Health Board must take account of the patient's circumstances and specific medical condition and the urgency of the application.

## PART 1: Welsh patients seeking treatment abroad

### 5. The implications for patients

5.1 Under the Directive, patients are entitled to seek reimbursement for health care from state or private providers, within other parts of the EEA if it is the same as or equivalent to a service that would have been available to a patient in their circumstances within their Local Health Board area. Therefore, the Directive does not allow NHS patients to go anywhere within Europe and get any treatment or medicine they may desire and then seek reimbursement from the NHS. In certain, specific circumstances, as set out below in section 8, patients are required to seek prior authorisation for such treatment before it is carried out.

5.2 Treatment is normally available within the NHS only when approved by a competent health professional, and a patient seeking reimbursement will need to demonstrate that that had been provided whether by a competent health professional in the home state or the state of treatment. The Local Health Board and clinicians may have agreed that certain treatments will only be provided if defined clinical criteria are met. Where the patient's circumstances are outside the set criteria, reimbursement may be refused.

5.3 There are some treatments that are provided only in exceptional cases; these are included within Local Health Boards' *Interventions Not Normally Undertaken* (INNU) policies, a copy of which can be obtained from the National Contact Point (NCP) or the Local Health Board.

5.4 There are a range of other issues that patients will need to be aware of when seeking treatment in another European country – for example, there may not be the same standards of care, there may not be the same styles of treatment or of aftercare and there may be language barriers to negotiate. In seeking healthcare in another EEA State, the patient is stepping outside of NHS jurisdiction – consequently, it is the law of the providing country that will apply and it is patients' responsibility to be clear on who in that country is accountable for assuring their safety throughout the course of their treatment.

**5.5 NHS clinicians and organisations cannot be held liable for any failures in treatments organised by the patient and undertaken in another European country under the Directive. Their role is strictly limited to helping facilitate the treatment if that is the patient's expressed wish.**

5.6 As mentioned at paragraph 5.1 above, for certain treatments patients are required to obtain prior authorisation from their Local Health Board before going to another EEA Member State for treatment. Treatments that are subject to prior authorisation are listed at Annex 1. However, all patients wishing to access treatment in another EEA Member State are strongly recommended to contact their Local Health Board in advance of travelling. Contact between the patient and the Local Health Board enables both to clarify whether the patient is entitled to reimbursement for the treatment he or she wishes to receive, whether prior authorisation is required and the level of reimbursement to be expected. It also allows Local Health Boards to ensure patients are aware of all of the possible treatment options within the NHS, which may be more beneficial and convenient for the patient. However, patients cannot be prevented from seeking treatment in Europe simply because alternative services may be available at home.

## 6. What treatment is the patient entitled to?

6.1 As stated, the Directive does not allow a patient to receive reimbursement for any or every treatment (or drug) he or she may obtain elsewhere within the European Union. A patient is only eligible to receive reimbursement for a treatment, product or service where the same or equivalent treatment, product or service would be made available to the patient by the NHS based on their individual clinical circumstances.

6.2 To enable people to exercise their rights under the Directive, the expectation is that there should be easily accessible published information providing appropriate clarity and transparency on NHS entitlements for patients who are considering cross-border healthcare. Patients need this information to understand whether they can access the treatment they require and then expect reimbursement of their costs.

6.3 To help achieve this, the NHS (Cross Border Healthcare) Regulations 2013 and associated Directions<sup>a</sup> place a legal requirement on Local Health Boards to provide patients with the information they need. Each Local Health Board must publish free of charge information that enables patients to find out the range of healthcare services that are generally made available or are generally not made available (as the case may be) to patients for whom the Local Health Board is responsible under the NHS (Wales) Act. The information must:

- include any criteria, clinical thresholds or exceptions that apply to a particular service;
- so far as practicable, describe the services using terms that are easily understood without specialist knowledge.

6.4 The information may be provided by whatever means the Local Health Board thinks appropriate but must be:

- easily accessible;
- available by electronic means;
- made available in a manner that is compatible with the performance by the NCP of its functions under the Cross-Border Healthcare Regulations.

6.5 Cross-border telemedicine services are covered by the Directive, which contains two express references to telemedicine: Article 3(d) which clarifies that 'In the case of telemedicine, healthcare is considered to be provided in the Member State where the healthcare provider is established' and Article 7(7) which makes clear that Local Health Boards impose on someone receiving telemedicine 'the same conditions, criteria of eligibility and regulatory and administrative formalities' as is the case with others seeking healthcare abroad. Therefore, when considering requests for reimbursement for healthcare that has been delivered in another Member State via telemedicine, Local Health Boards must consider whether the actual healthcare or services that the patient received from a healthcare provider established in another Member State was the same as, or equivalent to, treatment that they would have been entitled to on the NHS at home.

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<sup>a</sup> NHS (Cross Border Healthcare) Regulations 2013 (S I 2013/2269) and The National Health Service (Cross-Border Healthcare) (Wales) Directions 2013



6.6 On 14 July 2015, the National Health Service (Cross-Border Healthcare) (Telemedicine) (Wales) Directions 2015 were brought into force. These Directions state that health boards and WAST must have regard to Article 3(d) of the EU Directive.

## 7. What reimbursement is the patient entitled to?

7.1 A patient seeking treatment in another Member State under the Directive would need to pay the healthcare provider directly for their treatment. The patient's home state is required to reimburse the cost of cross-border healthcare, where that is an entitlement and where the costs are eligible for reimbursement. Through setting entitlements as outlined above, Wales can determine what treatment a patient can seek reimbursement for if treated abroad in an EEA country. The level of reimbursement is limited to the cost of equivalent treatment in Wales or the actual cost incurred, whichever is lower.

7.2 The Local Health Board needs to be in a position to give the patient on request a clear estimate of the likely level of reimbursement before the patient goes abroad to assist the patient in deciding whether to travel for treatment. Article 5 of the Directive says that the home state must provide patients on request with information on their rights and entitlements in that Member State relating to receiving cross-border healthcare, in particular as regards the terms and conditions for reimbursement of costs, and there should be a transparent mechanism for calculation of costs of cross-border healthcare that are to be reimbursed to the person involved. This mechanism is to be based on objective, non-discriminatory criteria known in advance and applied at the relevant (local, regional or national) administrative level. Article 9 says that the administrative procedures should be easily accessible and information relating to such a procedure shall be made publicly available at the appropriate level. We are advised that this means that we should be using systems such as the internet to make available such information.

7.3 Once evidence of clinical need has been provided and once the items eligible to be considered for reimbursement have been confirmed from receipts and any supporting documentation, there will be a need to ascertain the cost of the same/equivalent treatment that would have been provided by the NHS and then compare this to the invoices and receipts.

7.4 If the actual amounts paid for treatment in Europe were lower than the NHS costs, then the reimbursable amount is limited to the actual amounts paid (adjusted to take account of any deductible NHS charges in accordance with the rules set out in Section 6BA of the NHS (Wales) Act). If the actual amounts paid were greater than the calculated NHS cost (adjusted to take account of any deductible charges, etc.), then the calculated NHS cost is the maximum amount that may be reimbursed. Any additional cost is borne by the patient.

7.5 The Directive indicates that there should be transparent and objective mechanisms in place for the reimbursement of patient costs and for the criteria for reimbursement to be known in advance. The Directive requires Member State authorities to be able to explain the reimbursement calculation and be able to justify it to applicants. If the reimbursement authority is unable to calculate in a transparent way the equivalent NHS cost, or appropriately decode submitted receipts, then it cannot seek to cap the reimbursement to the NHS cost and may therefore face the prospect of reimbursing the full costs of treatment – including the higher cost where that applies.

7.6 The Directive says that Member States may also restrict reimbursement for overriding reasons of general interest if the demand for cross-border healthcare or certain specific services is undermining the home system. Use of this discretion would require robust evidence that the measure was necessary to ensure sufficient access to a balanced range of healthcare or to control costs and avoid waste of resources. It would be necessary to show that such a restriction was proportionate and not discriminatory. LHBs cannot act on this element of the Directive without securing authority from the Welsh Government. There is also a requirement (article 7(11) of the Directive to notify the Commission of any decisions to limit reimbursement under article 7(9).

## 8. The role of prior authorisation

8.1 The Directive allows Member States to operate a system of prior authorisation for healthcare. To be valid such a system must 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. 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 the wish to control costs and avoid, so far as possible, any waste of financial, technical and human resources and:
  - (i) involves overnight hospital accommodation of the patient in question for at least one night; or
  - (ii) 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 which, on a case-by-case basis, could raise serious and specific concerns relating to the quality or safety of the care with the exception of healthcare which is subject to EU legislation ensuring a minimum level of safety and quality throughout the EU.

8.2 Applying these conditions, it has been agreed that in Wales there will be a system of prior authorisation and the categories that it covers are set out for ease of reference in Annex 1. These have been notified to the European Commission as required. Where a Member State operates a system of prior authorisation, the Directive gives Member States the discretion to refuse authorisation only in four circumstances. These circumstances are set out in full at paragraph 10.14.

8.3 Each Local Health Board must publish free of charge information identifying the services for which prior authorisation is required. The information must, so far as practicable, describe the services using terms that are easily understood without specialist knowledge. The information may be provided by whatever means the Local Health Board thinks is appropriate but must be:

- (a) easily accessible;
- (b) available by electronic means;

(c) made available in a manner that is compatible with the performance by the NCP of its functions under the Cross-Border Healthcare Regulations.

8.4 Patients seeking treatments which do not fall within the scope of the prior authorisation categories in Annex 1 do not need prior authorisation from their Local Health Board before travelling. However, they are still strongly advised to discuss their plans with their Local Health Board for the reasons set out in section 5.

8.5 The process of prior authorisation, where this is applied, is a mechanism by which individual patients can get clarity about a range of matters relating to patient care. This includes confirmation that the treatment is one the NHS offers (i.e. the patient would be entitled to reimbursement and the level of such reimbursement), which elements of the care pathway are being funded, what the patient must do if there is a problem with the treatment they receive, and so on. It also helps ensure patients are aware of all of the possible treatment options within the NHS, which may be more beneficial and convenient for the patient. Patients need to be aware that prior authorisation does not imply clinical approval of a patient's planned healthcare in another Member State, nor does it imply acceptance of any responsibility for that treatment. No duty of care attaches to the authorisation.

8.6 These general principles help highlight the need for Local Health Boards and/or clinical staff to remind anyone wishing to seek medical treatment in another country under the Directive to ensure that they have fully considered all aspects of the arrangements necessary – such as when they will be fit to travel home, whether they need to make any special travel arrangements, to have comprehensive medical insurance for their trip, for example to cover having to stay abroad longer than planned. The cost of insurance and other incidental costs are not reimbursable by the NHS.

8.7 When considering an application for prior authorisation a Local Health Board must:

- i. consider whether the conditions for authorisation under Regulation (EC) No.883/2004 are met; and
- ii. if the conditions are met, the Local Health Board must<sup>a</sup>:
  1. ask the patient if the he or she wishes to be granted authorisation under the Regulation (EC) No. 883/2004; and
  2. unless the patient objects, grant authorisation under Regulation (EC) No. 883/2004.

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<sup>a</sup> Art 8(3) of Directive.

## **9. Roles**

### **The Patient**

9.1 The patient is responsible for:-

- a. ensuring he or she has all relevant information on which to make an informed choice about treatment options;
- b. ensuring that he/she would be entitled to the treatment in question (taking into account the circumstances of his/her case) from his/her home Local Health Board.
- c. seeking prior authorisation from the Local Health Board usually responsible for the person's care for treatment specified on the list at Annex 1.
- d. ensuring he or she is able to pay for their treatment prior to seeking reimbursement on return, unless alternative arrangements have been agreed prior to treatment;
- e. arranging travel insurance to cover any risks.

### **Local Health Boards**

9.2 The NHS (Cross-Border Healthcare)(Wales) Directions 2013 and the NHS (Reimbursement of the Cost of EEA Treatment) (Wales) Directions 2010 (as amended by the NHS (Reimbursement of the Cost of EEA Treatment) (Wales) (Amendment) Directions 2013) set out the duties of Local Health Boards. The Directions which are at annex 2 should be consulted for a comprehensive exposition of LHBs' duties. In summary the Local Health Board must make publicly available the contact details of the person or team at the Local Health Board to whom a resident patient may:

- (a) address a request for information; or
- (b) address a request for advice and assistance

on their rights and entitlements as mentioned above in 9.1 and on receipt of such a request, the Local Health Board must provide such information as it consider appropriate for the purpose of giving effect to the Directive.

9.3 The Local Health Board must supply the information promptly taking into account the patient's specific medical condition, the urgency and the individual circumstances and in any event no later than 10 working days from the day on which the Local Health Board received the patient's request for information.

9.4 The information referred to in paragraph 9.3 may be provided by whatever means the Local Health Board thinks appropriate but it must be:

- (c) easily accessible;
- (d) available by electronic means; and
- (e) made available in a manner that is compatible with the performance by the NCP of its functions under the Cross-Border Healthcare Regulations.

9.5 Following an application for reimbursement, the information that the Local Health Board must provide to an applicant is:

- where authorisation is refused, the reasons in writing for refusal and the information considered by the Local Health Board in reaching that decision;
- a clear statement of the amount of reimbursement;
- if reimbursement is refused or full reimbursement is refused, the reasons in writing for refusal and the information considered in reaching the decision; plus information on the applicant's right to request a review.

9.6 The National Health Service Reimbursement of the Cost of EEA Treatment) (Wales) Directions 2010 as amended <sup>a</sup> requires the Local Health Board to determine applications within 20 working days, unless further information is required in which case the LHB must, within 10 working days of receipt of the information, advise the patient of the further information it needs in order to be able to determine the application. The Local Health Board then has 10 working days from receipt of the additional information to determine the application.

### **The National Contact Point**

9.7 The Directive requires the establishment of what are termed "National Contact Points" (NCPs). These are national or sub-national bodies which can help enquirers secure information about patients' rights and on providers of services available in other Member States. The intention is to establish a network of NCPs around the EU, to facilitate exchange of information and help smooth the path for patients looking to access treatment in a particular Member State. The information given to patients/citizens by NCPs on quality of healthcare, patient safety and procedures to follow will help people make an informed choice on the healthcare they seek.

9.8 The role of the National Contact Point for Wales will be discharged by the Welsh Ambulance Services Trust (NHS Direct).

9.9 As set out in Regulations the National Contact Point (NCP) is responsible for :-

### **Information about treatment in England and Wales**

The NCP must, in so far as it considers it is necessary or desirable for the purposes of enabling visiting patients to exercise their rights in relation to access to healthcare, ensure that information about each of the following is available to or accessible by visiting patients—

- (a) healthcare providers;
- (b) patients' rights;
- (c) complaints procedures and methods of seeking remedies; and
- (d) legal and administrative options available to settle disputes, including in the event of harm arising from the provision of healthcare.

The NCP must also, in so far as it considers it is necessary or desirable for the purposes of enabling visiting patients to exercise their rights in relation to access to healthcare, ensure that information about each of the following is made available to a visiting patient, on request—

- (a) a specific healthcare provider's right to provide services;
- (b) any restrictions on a specific healthcare provider's right to provide services;

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<sup>a</sup> National Health Service (Reimbursement of the Cost of EEA Treatment) (Wales) (Directions 2010 S I 2010 No 40 (W 40); National Health Service (Reimbursement of the Cost of EEA Treatment) (Wales) (amendment) (Directions 2013 S I 2010 No 25 (W 25))

- (c) standards and guidelines on quality and safety;
- (d) provisions on the supervision and assessment of healthcare providers;
- (e) healthcare providers who are subject to the standards mentioned in sub-paragraph (c); and
- (f) accessibility of hospitals for persons with disabilities.

Information provided under this regulation may be provided by whatever means the NCP thinks appropriate but must be—

- (a) easily accessible, and
- (b) available by electronic means.

### **Information about treatment in another member State**

The NCP must, in so far as it considers it is necessary or desirable for the purposes of enabling resident patients to exercise their rights in relation to access to healthcare in other member States, ensure that information about each of the following is available or accessible by resident patients and health professionals—

- (a) the rights and entitlements of resident patients to receive healthcare in another member State;
- (b) the procedures for accessing and determining those rights and entitlements;
- (c) the procedures for appeal and redress if patients consider that their rights have not been respected;
- (d) the terms and conditions for reimbursement of costs; and
- (e) the contact details of national contact points in other member States.

Information provided under this regulation may be provided by whatever means the NCP thinks appropriate but must be—

- (a) easily accessible, and
- (b) available by electronic means.

### **Cross-border co-operation**

In so far as it considers it is appropriate for the purposes of giving effect to the Directive, the NCP must co-operate with—

- (a) the national contact points in other member States;
- (b) the NCP established for England or Wales (as the case may be);
- (c) the national contact points for Northern Ireland and for Scotland established for the purposes of the Directive; and
- (d) the Commission of the European Union.

In particular, that co-operation must include —

- (a) co-operating on standards and guidelines on quality and safety;
- (b) facilitating the exchange of information mentioned in regulation 3(2); and
- (c) co-operating on the clarification of the content of invoices.

## Duty to consult

In so far as it considers it is appropriate for the purposes of giving effect to the Directive (including giving effect to the measures implementing the Directive in these Regulations), the NCP must consult with—

- (a) such organisations representing the interests of patients as it considers appropriate;
- (b) such healthcare providers or organisations representing healthcare providers as it considers appropriate; and
- (c) such persons providing insurance in relation to healthcare or organisations representing such persons as it considers appropriate.

## 10. The Application Process

### Stage 1: Determining eligibility for NHS services

10.1 There are established rules on entitlement to NHS services. For example, entitlement to NHS hospital services is based on whether or not a patient can demonstrate that he or she meets the test of 'ordinary residence' in the United Kingdom (although as mentioned in paragraph 2.4 above there are rights conferred by Regulation 1408/71 (883/2004) on non-United Kingdom residents who meet the relevant requirements).

10.2 Those who are not ordinarily resident are subject to the *NHS (Charges to Overseas Visitors) Regulations 1989*, as amended, are considered overseas visitors when in the United Kingdom and are liable for NHS hospital treatment charges unless an exemption category, listed within these regulations, applies.

10.3 Under Regulation 883/2004, the United Kingdom already reimburses other Member States for the healthcare costs of British pensioners living and registered there. Similar arrangements apply to people working abroad. In normal circumstances, pensioners in this situation are already receiving health care within the system of the other Member State as if they were a citizen of that country and therefore requests for treatment under the Directive in these circumstances should, in the first instance, be addressed to the relevant authority in their Member State of residence.

10.4 Some people may still meet the ordinary residence test for NHS hospital treatment if they spend time out of the United Kingdom. In such cases, Local Health Boards should cross-refer to *The National Health Service (Charges to Overseas Visitors) Regulations 1989<sup>a</sup>*, as amended. Where people retain entitlement for NHS services, they may be eligible for reimbursement under the Directive providing the treatment is the same as or equivalent to one which the NHS would normally fund in that individual's circumstances and they have a clinical need.

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<sup>a</sup> S.I 1989 No. 306.

## **Stage 2: The role of gate-keeping; determining clinical need and NHS entitlements**

10.5 Gate-keeping by healthcare professionals for access to secondary care is an important element of the NHS's way of determining access and entitlements to treatment. It helps direct patients to the appropriate service for diagnosis or treatment

10.6 Under the Directive<sup>a</sup>, the home state may impose on a person seeking reimbursement of the costs of cross-border healthcare, the same conditions, criteria of eligibility and regulatory and administrative formalities 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 NHS, 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, but only so far as the Directive allows.

10.7 Local Health Boards need to be aware also of Directive 2005/36/EC<sup>b</sup> on the recognition of professional qualifications which provides for mutual recognition of professional qualifications of doctors across the EU. Therefore, if an appropriately qualified EU professional indicates that there is a clinical need the Local Health Board cannot question this on the grounds that it is an opinion of a doctor not within its employ. The relevant issue is whether there are criteria of eligibility or other administrative formalities set by LHBs which would restrict access to the treatment in question which have not been appropriately taken into account.

10.8 This needs to be made clear. Patients should not be placed in a position where unwittingly they commit themselves to expenditure that will not be reimbursed.

## **Stage 3: Rules relating to prior authorisation**

10.9 In accordance with the National Health Service (Reimbursement of the Cost of EEA Treatment) (Wales) Directions 2010<sup>c</sup> Local Health Boards are under a duty to establish and publish its procedures for determination of applications for prior authorisation. A patient wishing to go to another EEA Member State to access treatments subject to the prior authorisation arrangements discussed earlier and set out in Annex 1 will need to make an application to the Local Health Board and should provide information on:

- the treatment or service they require;
- evidence of clinical need from either a United Kingdom or overseas health professional.

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<sup>a</sup> Article 7.7.

<sup>b</sup> Directive 2005/36/EC of the European Parliament and of the Council, of 7 September 2005, on the recognition of professional qualifications.

<sup>c</sup> 2010 no. 40 (W.40) as amended by The National Health Service (Reimbursement of the Cost of EEA Treatment) (Wales) (Amendment) Directions 2013 (2013 No. 25 (W.25)).



10.10 When a patient requests prior authorisation for a relevant treatment under the Directive route, the Local Health Board must first of all determine whether or not the patient meets the requirements of the S2 route. If he or she does, authorisation will be granted via that process, unless the patient specifically requests to use the Directive – for example, to access the private/independent sector abroad. This will ensure that appropriate consideration occurs of patients' rights under both sets of legislation and that the relevant case law is applied effectively.

10.11 In turn, the Local Health Board will need to advertise clearly to patients:

- where patients should apply to for prior authorisation;
- how long the process will take;
- what factors will be taken into account in arriving at the decision whether to grant or refuse authorisation;
- what patients can do if they are unhappy with the outcome – i.e. what the appeals/review process is, and what timescales apply.

10.12 The Directions<sup>a</sup> require Local Health Boards to determine applications within 20 working days. If a patient has provided insufficient information the LHB must notify them of that fact within 10 working days of receiving the request. The LHB then has a further 10 working days, from receipt of the further information, to make a determination.

10.13 Local Health Boards will need to consider each application carefully. Generally reimbursement will not be retrospectively authorised where the patient should have applied for prior authorisation but did not do so – unless exceptional reasons apply in a particular case, for example circumstances where it was not possible for the patient to have applied for prior authorisation before receiving the treatment or service in another EEA State. This would be determined on a case by case basis, taking account of the facts of the case. Retrospective authorisation and reimbursement will be given in cases where the initial decision to refuse authorisation or reimbursement is overruled on review or appeal. The Directive gives Member States the discretion to refuse prior authorisation only in the following four circumstances:

- a. where 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; *(e.g. from poor quality care or unproven procedures);*
- b. where the general public will be exposed with reasonable certainty to a substantial safety hazard as a result of the cross-border healthcare in question; *(this might include where a patient who had a highly contagious disease wanted to go to another state for treatment or where a patient with mental health problems and a history of violence requested authorisation);*

- c. where 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; (*this would require evidence from the appropriate regulator or authority*);
- d. where 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 person concerned (i.e. where the NHS can provide the same or equivalent treatment in a medically acceptable period of time based on an objective assessment of the individual patient's condition).

10.14 "Undue delay" cannot be determined simply on the basis of nationally or locally decided general waiting time arrangements for the purpose of managing pre-determined clinical priorities. Whether the waiting time is medically justifiable must be based on an objective medical assessment of the individual patient's condition, including the patient's medical history, the extent of the patient's pain, disability, discomfort or other suffering attributable to the medical condition; whether that pain, disability or discomfort makes it impossible or extremely difficult for the patient to carry out ordinary daily tasks; and the extent to which the service would be likely to alleviate or enable alleviation of the pain, disability, discomfort or suffering.

10.15 Therefore, in a case where the Local Health Board wished to refuse authorisation under criterion (d) above, it would need to be able to set out in full the reasons for refusing the application, and explain the reasons for reaching a decision on the length of time it is reasonable to ask the patient to wait for treatment. The matters to which the Local Health Board must consider in determining whether the length of any (undue) delay is medically justifiable are set out in the National Health Service (Cross-Border Healthcare) Regulations 2013 and include:

- (a) the patient's medical history;
- (b) the extent of any pain, disability, discomfort or other suffering that is attributable to the medical condition to which the healthcare service is to relate;
- (c) whether any such pain, disability, discomfort or suffering makes it impossible or extremely difficult for the patient to carry out ordinary daily tasks, and
- (d) the extent to which the provision of the service would be likely to alleviate, or enable the alleviation of, the pain, disability, discomfort or suffering.

#### **Stage 4: Reimbursing the patient**

10.16 A patient seeking treatment in another Member State under the Directive would need to pay directly for the healthcare. In cases where the treatment is not subject to prior authorisation, and providing it is treatment that the patient would be entitled to receive on the NHS in the circumstances of his or her case, he or she may subsequently request reimbursement from the Local Health Board for some or all of the costs of this treatment.

10.17 In requesting reimbursement for the cost of their treatment, patients will need to complete an application form and provide the Local Health Board with evidence of clinical need, itemised receipts and proof of payment for the treatment or service they have purchased.

10.18 If the patient's receipts and supporting documentation are in a different language, then these will need to be translated. National Contact Points can play a key role in helping to facilitate this with their counterparts in other European countries.

10.19 The maximum level of reimbursement may be limited to the cost of the equivalent NHS service or the actual cost of treatment, where this is lower than the NHS cost. If the treatment for which reimbursement is being requested would normally attract a patient charge under the NHS, the Local Health Board may deduct this from the amount due. Any additional cost is borne by the patient.

10.20 Where the treatment cost has not been previously calculated, a cost will need to be objectively calculated in a transparent way. If Local Health Boards are unable to work out an objective cost, or appropriately decode European Union receipts for healthcare, they may face the prospect of reimbursing the full costs of treatment - including the higher cost where that applies.

10.21 The maximum level of reimbursement may be limited to the cost of the equivalent NHS service or the actual cost of treatment, where this is lower than the NHS cost. Any additional cost is borne by the patient.

10.22 Generally, reimbursement (or the issuing of an S2) will not usually be retrospectively authorised where the patient should have applied for prior authorisation but did not do so - unless exceptional reasons apply in a particular case, for example circumstances where it was not possible for the patient to have applied for prior authorisation before receiving the treatment or service in another EEA State.

10.23 This would be determined on a case-by-case basis, taking account of the facts of the case. Retrospective authorisation and reimbursement will be given in cases where the initial decision to refuse authorisation or reimbursement is overruled on review or appeal.

## 11. Payment of travelling and translation expenses

11.1 Under the Directive<sup>a</sup>, the home state may decide to reimburse other related costs beyond the treatment, such as accommodation and travel costs.

11.2 The effect of current case law is that the costs associated with travel should only be considered where a patient would have been entitled to assistance with such costs if the treatment had been provided in Wales. This would be via the means-tested arrangements set

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<sup>a</sup> Article 7.4.

out in The National Health Service (Travelling Expenses and Remission of Charges) (Wales) Regulations 2007 (WSI 2007 No 1104 ), as amended.

11.3 These Regulations provide for reimbursement of travel costs by the cheapest “reasonable” means of transport only – not accommodation, nor subsistence. Under those arrangements, patients incur the costs and then claim a reimbursement. The “reasonableness” test, according to the guidance, is whether the patient reaches the place of treatment in a reasonable time and without detriment to their condition. Decisions should take into account the distance to be travelled, length of journey, frequency of the journey, availability and accessibility of public transport – as well as the patient's age and medical condition.

11.4 Local Health Boards are advised that they should consider requests for assistance with travel costs from patients who are entitled to such support at home. Reimbursement of such costs should be for the most efficient mode of transport to the destination of treatment and would not normally be expected to extend beyond travel from home to the point of departure from the United Kingdom.

11.5 The Local Health Board will not normally meet the costs of translation of documentation.

## 12. Complaints and Redress

12.1 Patients wishing to access treatment in another EEA country will need to ensure they are fully aware of their rights in respect of complaints procedures and mechanisms for seeking remedies and redress. The National Contact Point and Local Health Board will be able to help with information but as stated earlier the responsibility rests primarily with the patient seeking to travel.

## PART 2: Patients from EEA seeking treatment in Wales

### 13. General considerations

13.1 The inflow of patients from other Member States (“visiting patients”) who wish to access treatment from NHS providers (including those contracted to the NHS in the independent sector) raises particular issues for providers. Whilst there is no specific requirement on the provider to accept any patient, there are a number of factors that need to be considered.

13.2 The Directive does not require providers to accept visiting patients for planned healthcare if this would be to the detriment of ensuring sufficient access for their own patients with similar health needs, nor to prioritise them to the detriment of other patients, for instance by increasing waiting times<sup>a</sup>. However, given that it is possible that providers might be contacted in advance by the prospective patient, his/her clinician or another country’s National Contact Point, providers would need to be able to explain and evidence the lack of capacity and demonstrate that refusal is necessary and show they were not discriminating against nationals of other states on grounds of nationality if rejecting a request for treatment.

13.3 In principle, the strongest grounds for refusing a visiting patient are the lack of service capacity; however, the provider would need to consider whether the patient could be offered the option of joining the waiting list, to be treated alongside “home” patients on the basis of clinical priority. Alternatively, the patient has the option of considering a different provider.

13.4 Healthcare providers in Wales who are providing treatment to visiting patients under the provisions of the Directive must:

- provide patients with relevant information on treatment options and quality and safety;
- provide clear invoices and price information;
- apply fees in a non-discriminatory manner;
- ensure transparent complaints procedures and procedures to obtain redress;
- apply adequate systems of professional liability insurance or similar;
- respect privacy in the processing of personal information;
- supply patients with a copy of the record of their medical treatment.

13.5 It is important to note that pricing must be non-discriminatory. Providers cannot make up a price or seek to charge more simply because the person is a visiting patient seeking treatment under the Directive. Healthcare providers must therefore apply the same scale of fees for healthcare to visiting patients as for domestic patients. If there is no comparable price for domestic patients, the price must be based on objective, non-discriminatory criteria. The NHS (Cross Border Healthcare) Regulations 2013 provide that where a visiting patient receives an NHS service for which a charge can be made, the visiting patient must not be charged more than the amount that would have been charged if that service had been provided to an NHS patient.

13.6 If providers (including providers from the independent sector contracted to deliver NHS services) accept a visiting patient for treatment, they must not assume that such patients wish to be considered as private patients. Providers must ensure that they explain to the visiting patient

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<sup>a</sup> See recital 21 and Article 4(3) of the Directive.

the choice between private care and NHS care. This is because although the patient is independent of the NHS system and is not referred formally by their state health system, they are exercising their rights under the Directive and may themselves receive reimbursement from their state system for eligible costs under the provisions of the Directive (i.e. turning around the reimbursement process outlined in this guidance).

13.7 Similarly, primary care providers should not assume that a visiting patient can, or should be treated as a private patient – at the same time, patients who specify from the outset that they *do* wish to be treated privately may be charged in the same way as at the equivalent cost to private patients resident in Wales.

13.8 In terms of how these requirements are met, for secondary care provided by the NHS, relevant NHS bodies should recover the full cost of the treatment given to a visiting patient under the Directive. Member States must have a transparent mechanism for the calculation of costs for cross-border healthcare and this must be based on objective, non-discriminatory criteria known in advance.

13.9 For GP and GP out of hours services, if a visiting patient is treated as an NHS patient (as they should be unless they specifically request to be treated on a private basis), then that treatment / consultation is currently free of charge, regardless of nationality. If medicines are prescribed on a WP10 NHS prescriptions form and are dispensed by a pharmacy which is contracted to an LHB then those medicines are free of charge.

13.10 Charges for NHS dental services differ, in that they relate to average costs by treatment band for courses of treatment – that is, on the basis of a contract value, which is delivered through an agreed number of units of dental activity.

13.11 Providers will need to ensure systems are in place for dealing with requests for treatment from visiting patients. This includes processes for seeking more information about the patients' condition and diagnoses where this is not initially available, systems for dealing with payment direct from the patient, clear information about the services they provide and the terms of treatment.

13.12 It is possible that the inflow of patients from other EEA States may, over time create a demand exceeding the capacity in the NHS for certain treatments - or there may be a need to control costs relating to the planning or funding of services. The Directive allows Member States to retain the possibility, in exceptional cases, to adopt measures controlling access to treatment where this is necessary and proportionate to ensure sufficient and permanent access to healthcare for domestic citizens.

13.13 Should such a situation arise, this would be a matter for Welsh Ministers in conjunction with the Secretary of State. LHBs cannot decide to adopt such measures. Any decision by Government to exercise this provision in the Directive could not be arbitrary, nor a policy of first resort and would need to be supported by clear evidence on the effects of cross-border healthcare on the home system. If such circumstances arise, Local Health Boards should provide the Welsh Government with any such evidence.

## 14. Roles and responsibilities

### The Patient

14.1 The patient is responsible for :-

- a. ensuring he or she has all relevant information on which to make an informed choice about treatment options;
- b. ensuring that he/she would be entitled to the treatment in question (taking into account the circumstances of his/her case) from his/her home Local Health Board
- c. seeking prior authorisation from the healthcare provider usually responsible for the person's care.
- d. ensuring he or she is able to pay for the treatment prior to seeking reimbursement on return, unless alternative arrangements have been agreed prior to treatment;
- e. arranging travel insurance to cover any risks.

### **The National Contact Point – NHS Direct**

14.2 As set out in Regulations the National Contact Point is responsible for the functions as specified within paragraph 9.9.

### **The Provider – a Local Health Board**

14.3 The NHS (Cross-Border Healthcare)(Wales) Directions 2013 and the NHS (Reimbursement of the Cost of EEA Treatment) (Wales)Directions 2010 (as amended by the NHS (Reimbursement of the Cost of EEA Treatment) (Wales) (Amendment) Directions 2013) set out the duties of Local Health Boards. The Directions which are at annex 2 should be consulted for comprehensive exposition of LHBs' duties. In summary the Local Health Board is responsible for:-

- providing relevant information to help individual patients to make an informed choice on treatment options; availability, quality and safety of the healthcare they provide in Wales;
- providing clear invoices and clear information on prices;
- providing clear information on their authorisation or registration status, insurance cover or other means of personal or collective protection with regard to professional liability.

### **The Provider – a non NHS / Private Provider**

14.4 The non NHS / Private Provider is responsible (as for Welsh patients) for:

- providing relevant information to help individual patients to make an informed choice on treatment options; availability, quality and safety of the healthcare they provide in Wales;
- providing clear invoices and clear information on prices;
- providing clear information on its authorisation or registration status, insurance cover or other means of personal or collective protection with regard to professional liability.

## **15. Complaints and Redress**

15.1 Local Health Boards will need to ensure they can provide information relating to redress and complaints procedures in respect of treatment they have provided.

Annex 1 - Healthcare Requiring Prior Approval



Patients wishing to travel abroad for treatment in the European Economic Area and seek reimbursement from the NHS will require prior approval for treatments in the following list. The rationale for inclusion of treatments in this list is provided in the attachment at the end of this list.

Patients seeking treatments that do not fall within the scope of the list below are still **strongly advised** to discuss their plans with their Health Board in advance to ensure that they are fully aware of their entitlement to reimbursement for the treatment from the NHS in Wales and to ascertain the level of reimbursement they would be entitled to.

Service type	List of treatments and interventions subject to Prior Approval for pre-planned treatments	Reference in the WHSSC specialised services list (see the rationale in the annex)	Reason
Artificial Limb Services	Prosthetics and complex orthotics and cochlear implants.	CP35 – Cochlear Implants	High cost items where the NHS enters into long-term contracts to manage the items over many years.
Bariatric/ Weight Loss Services	All surgery including balloon, banding by-pass, gastric sleeve	Bariatric Surgery CP29	High cost interventions based on planning with an overnight stay
Cancer Services	All inpatient cancer surgery, non-surgical treatments including radiotherapy and stereotactic radiosurgery, chemotherapy, bone marrow transplants, stem cell transplants, brachytherapy, reconstructive post-cancer surgery and drug therapy ( in line with NICE criteria).	CP67 – Radiolabelled Therapy for the treatment of Neuroendocrine Tumours  CP01 - Low Dose Brachytherapy in the Treatment of Localised Prostate Cancer	High cost interventions based on planning with an overnight stay and patient safety considerations in view of the need for long-term follow-up on a consistent basis
Cardiac Services	All cardiac surgery, invasive cardiology including trans-aortic valve replacement, heart failure treatments, implantable defibrillators	CP12 Cardiac resynchronisation	High cost interventions based on planning with an overnight stay and patient safety considerations in view of the need for long-term follow-up on a

			consistent basis
Complex Restorative Dental Services	All surgery including post-trauma, post-cancer and hyperbaric oxygen Therapy		High cost interventions based on planning with an overnight stay
Congenital Surgery Services	All surgery		High cost interventions based on planning with an overnight stay
Diagnostic testing	PET scans, genetic testing	CP04 – Positron Emission Tomography (PET)	High cost interventions based on planning with an overnight stay using highly specialised infrastructure and equipment
Fertility Services	All fertility treatments including IVF, donor eggs and sperm, egg, sperm and embryo storage, surrogacy, sperm retrieval <b>NB:</b> Please see attached fertility policy for treatments and access criteria	CP38 – Fertility Specialist Service	High cost interventions based on planning with an overnight stay
Gender Identity Disorder Services	All treatments, all gender reassignment surgery	CP21 – Specialised Adult Gender Identity Service	High cost interventions based on planning with an overnight stay
General Surgery Services	All in-patient surgery of two day and over, all in-patient upper gastrointestinal surgery		High cost interventions based on planning with an overnight stay
Gynaecology Services	All inpatient surgery		High cost interventions based on planning with an overnight stay
Haematology/	All immune-deficiency services and treatment,		High cost interventions based on planning

bleeding disorder Services	including major blood disorders (including hepatitis B, hepatitis C).		with an overnight stay and patient safety considerations in view of the need for long-term follow-up on a consistent basis
Hepatobiliary/ Pancreatic Services	All hepatobiliary and pancreatic surgery		High cost interventions based on planning with an overnight stay
Immunology Services	All drugs and treatments, including immunotherapy		High cost treatments and patient safety considerations in view of the need for long term follow up on a consistent basis.
Intensive Care/ High Dependency Care	All major surgery or treatment which requires pre-planned high dependency and/or intensive care as part of the treatment		High cost interventions based on planning with an overnight stay and patient safety considerations in view of the urgency of provision
Maternity Services	Foetal medicine and foetal surgery		High cost interventions based on planning with an overnight stay
Maxillo-facial Surgery Services	All major inpatient surgery		High cost interventions based on planning with an overnight stay
Medicine	Long term inpatient rehabilitation		High cost interventions based on planning and patient safety considerations in view of the need for long-term follow-up on a consistent basis
Mental Health Services	Treatments and therapies for children's mental illness including autistic spectrum disorder and serious adult mental illness		High cost interventions based on planning with patient safety considerations in view of the need to protect the patient and wider

	including eating disorders, substance abuse, post-traumatic stress disorder, veterans post traumatic stress disorder		public health concerns
Nationally Designated Services/ Rare Conditions	All rare conditions as listed on the NHS Specialised Services website	<a href="http://www.specialisedservices.nhs.uk/services">www.specialisedservices.nhs.uk/services</a>	High cost interventions based on planning requiring highly specialised and cost-intensive medical involvement
Metabolic Disorder Services	All treatments including enzyme replacement therapy	CP56 – ERT Policy	High cost interventions based on planning with an overnight stay
Nephrology Services	All in-patient renal surgery and treatments. <b>NB:</b> All transplant services are excluded under the Directive		High cost interventions based on planning with an overnight stay
Neurosciences	All neurosurgery, including epilepsy surgery, invasive neuroradiology (stenting), neuro rehabilitation post brain injury and all central neurological conditions	CP22 – Stereotactic Radiotherapy	High cost interventions based on planning with an overnight stay
Ophthalmology Services	All inpatient surgery, inpatient cataract surgery		High cost interventions based on planning with an overnight stay
Orthopaedic Services	All joint replacement surgery. All spinal surgery, non-surgical treatment of scoliosis		High cost interventions based on planning with an overnight stay and patient safety considerations in view of the need for long-term follow-up on a consistent basis requires service planning following

			procedures
Pain Management	Invasive pain management techniques, Cognitive Behavioural Therapy, nerve stimulators		High cost interventions based on planning with an overnight stay using highly specialised infrastructure and equipment
Palliative and End of Life Care	All end of life and palliative care		High cost intervention based on length of treatment and interventions that might be required
Plastic Surgery Services	All corrective/reconstructive surgery, all skin cancer surgery and treatments, laser therapy, hair removal	CP42 – Treatment of benign skin conditions  PP45 – Abdominoplasty / Apronectomy following significant weight loss  CP69 – Breast Surgery  CP43 – Facial Surgery	High cost interventions based on planning with an overnight stay using highly specialised infrastructure and equipment subject to tight criteria on entitlement
Pre-Genetic Diagnosis Services	All genetic testing services	CP57 Genetic Testing for Inherited Cardiac Conditions	Patient safety considerations in view of the need for this service need to be considered as part of a wider patient care pathway.
Thoracic Services	All thoracic surgery, invasive techniques, pulmonary hypertension drugs, cystic fibrosis		High cost interventions based on planning with an overnight stay using highly specialised infrastructure and equipment
Transplant Services	The Directive does not apply to the allocation of and access to organs		

	for the purpose of organ transplant		
Urology Services	All in-patient urological surgery and invasive techniques including erectile dysfunction surgery		High cost interventions based on planning with an overnight stay
Vascular services	All invasive vascular surgery, treatments including diagnostics.		High cost interventions based on planning with an overnight stay using highly specialised infrastructure and equipment

## Attachment: Rationale for inclusion of treatments in the prior authorisation list

The rationale for this prior approval list has been developed in line with Article 8 of the Directive. That article allows a system of prior authorisation, but only insofar as it is necessary and proportionate to the objective to be achieved. It may not constitute a means of arbitrary discrimination or an unjustified obstacle to the free movement of patients.

The introduction to the Directive refers to a number of issues that prior authorisation may consider including<sup>1</sup>:

- planning of services to ensure that there is sufficient and permanent access to a balanced range of high-quality hospital treatment
- a desire to control costs and to prevent, as far as possible, any wastage of financial, technical and human resources
- ensuring the safety of the patient, in a sector well known for information asymmetry,

Article 8 says that 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 overnight hospital accommodation of the patient in question for at least one night; or  
(ii) 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.

The schedule is based upon a review of

- the existing central commissioning arrangements for specialised commissioning for unusual or high cost interventions by the Welsh Health Specialised Services Committee (WHSCC); where items from this list have been assessed as appropriate for prior authorisation the relevant WHSCC policy is referred to in column 3 (note that these references do not necessarily cover all the items in column 2);
- a full assessment of other services in relation to high cost and issues such as use of resources and patient safety.

The reason for inclusion in each case is indicated.

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<sup>i</sup> Recitals 40, 43



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Annex 2 - The National Health Service (Reimbursement of the Cost of EEA Treatment) (Wales) (Amendment) Directions 2013

