

## **ALL WALES PROCEDURE**

# PROCEDURE FOR WELSH PATIENTS ACCESSING TREATMENT IN COUNTRIES OF THE EUROPEAN ECONOMIC AREA

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Produced By	An all Wales working group comprising representatives from each health board in Wales and from the Welsh Health Specialised Services Committee (WHSSC)
Linked Documents	<ul> <li>Guidance for the NHS on Cross Border (EEA) Healthcare and Patient Mobility</li> <li>Patient Leaflet concerning EEA Treatments</li> </ul>
Review Date	Any change in guidance or legislation will trigger an immediate review.

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#### **SECTION 1**

#### 1. INTRODUCTION

#### **Purpose of this Procedure**

1.1 A comprehensive range of NHS healthcare services are routinely made available by local health boards in Wales. In addition, the Welsh Health Specialised Services Committee (WHSSC), working on behalf of all the health boards in Wales, commissions a number of more specialised services at a national level. The use of the term 'health board' or 'local health board' in this procedure also includes WHSSC unless specified otherwise.

Under certain circumstances, EEA residents are entitled to secure funding for healthcare treatment in other European Economic Area (EEA) countries. A full list of EEA Member States (countries) is attached at *Appendix A*.

This procedure clarifies Welsh residents 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 local health board.

1.2 Patients are legally entitled to request treatment in another EEA country if they would be entitled to that same treatment from the NHS in Wales, with the exception of those exclusions outlined within this procedure under Section 2.1. In certain, specific circumstances, patients are able either to seek prior approval for such treatment before it is carried out and then claim reimbursement of its costs, or to make a retrospective claim for reimbursement. Reimbursements will be made in line with the cost of treatment had it been provided or commissioned within the home health system or the invoiced cost of the treatment in the EEA, whichever is the lower. Reimbursement will be considered in line with a cost assessment based on the normal modality of delivery in the patient's home system.

The patient is required to meet any difference between the cost that would have been met by the home healthcare system and the cost of being treated by their choice of provider and treatment modality within the European Economic Area should that be higher.

The Welsh Government document 'Cross Border Healthcare and Patient Mobility 2013' provides guidance to health boards in Wales on the handling of requests from patients for treatment in countries of the European Economic Area (EEA) and requests from patients from the EEA requesting treatment in Wales.

This procedure has been written in accordance with the 'Directive 2011/24/EU of the European Parliament and of the Council of 9<sup>th</sup> March 2011' on the application of patients rights in cross-border healthcare.

1.3 Health boards in Wales have developed this procedure to support a clear and open process for making decisions on requests under the Directive to ensure that it is fair, lawful, open and transparent. It enables those responsible for decision-making to demonstrate that they have followed due process, given full consideration to the entitlements of patients as set out in the Regulations and been both rigorous and fair in arriving at their decisions. It also provides a clear process for challenge and appeal.

1.4 A patient leaflet is available which explains the entitlements of patients and how to make a request for treatment in another EEA country. It also outlines how these costs are reimbursed in line with the costs of treatments available on the NHS in Wales. Help and support should a patient wish to speak with someone is also available from the local health board. The contact details are:

EEA Co-ordinator Cardiff and Vale IPFR Commissioning Team Public Health Division 1<sup>st</sup> Floor Global Link Dunleavy Drive CARDIFF CF11 0SN

Tel: 02921832101

Email: CAV.Irt@wales.nhs.uk

http://www.cardiffandvaleuhb.wales.nhs.uk/home

#### **SECTION 2**

#### 2. PATIENT ENTITLEMENT TO TREATMENT AND REIMBURSEMENT

#### 2.1 Entitlements

Patients are entitled to seek health care service 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 within their local health board area, with the exception of:-

- Treatments that require prior approval for funding (outlined in Section 4).
- Treatments which are included within the health board's Interventions Not Normally Undertaken (INNU) policy, a copy of which can be obtained from the National Contact Point (NCP) or your local health board.
- Drugs which are not routinely prescribed in the NHS in Wales, including drugs that;
  - a) are not licensed for their intended use;
  - have not been approved by the National Institute of Clinical Excellence (NICE) or the All Wales Medicine Strategy Group (AWMSG)
  - c) are not on the British National Formulary (BNF)
- Treatments whereby the patient does not meet the clinical access criteria.
- Treatments which are clearly excluded within the Directive as per point 3 of Chapter 1 which outlines that:

This Directive shall not apply to;

a) services in the field of long-term care the purpose of which is to support people in need of assistance in carrying out routine, everyday tasks;

- b) allocation of and access to organs for the purpose of organ transplants;
- c) with the exception of Chapter IV, public vaccination programmes against infectious diseases which are exclusively aimed at protecting the health of the population on the territory of a Member State and which are subject to specific planning and implementation measures.

#### 2.2 Applications must demonstrate that:-

- The patient has a clinical need for the proposed treatment and that this can be supported by appropriate, written clinical opinion and supporting evidence.
- The patient meets the clinical access criteria that would be applied had they sought the treatment in their home healthcare system.
- The treatment is one that would normally have been available to the patient in their home healthcare system.

This supports the NHS Wales policy in terms of fairness, equity and access to services.

The services provided by the NHS in Wales are supported by a range of clinical, cost effectiveness and safety guidelines. This ensures that health services provided are fully accredited, approved by the appropriate licensing and regulatory agencies, and supported by good evidence of health benefit.

2.3 Healthcare provision, including the differing clinical thresholds at which patients within NHS Wales become entitled to access treatments, can be difficult to understand. To help patients a list of the types of treatments that might be available on the NHS, providing the criteria above have been met, is available on the following website: PbR National Tariff 2014/15 price index.

This list is provided as guidance only and is liable to change. We would urge caution in using this list for the reasons explained above. <u>Patients are therefore encouraged to contact their health board to seek advice on their entitlement to reimbursement under the Directive that takes account of their own personal clinical circumstances.</u>

If all the relevant information has been provided by the patient, health boards should respond to enquiries within 10 working days.

#### 2.4 Reimbursement

The maximum level of reimbursement a patient may be entitled to would depend on the expected treatment plan according to their clinical need and the cost of providing the treatment had the patient received it in their local health board.

Health boards in Wales do not maintain a common treatment tariff. In the absence of an NHS Wales tariff, health boards in Wales have agreed to utilise the Payment by Results (PBR) tariff operating in the English NHS as the general basis of reimbursement for equivalent treatments provided in the EEA. This is based on the desire by Welsh health boards to demonstrate a reimbursement tariff that is equitable, consistent, up to date, proven in practice and based on wide ranging UK reference costs. It is felt that this provides a sound proxy of the average costs incurred within NHS Wales in the delivery of health care.

The attached web address links to the current PBR tariff. Please refer to Annex 5A – National Prices. PbR National Tariff 2014/15 price index.

Inclusion of a treatment within the tariff does not necessarily entitle a patient to reimbursement for the same treatment provided within the EEA. Equally the tariff reflects a wide range of healthcare conditions and treatments which can prove confusing. The tariff represents the maximum level of reimbursement that could potentially be claimed for treatment; where actual treatment costs incurred are lower than the tariff level, reimbursement can only be claimed for the lower value.

For these reasons patients are encouraged to make contact with their local health board so that the appropriate information to help patients make an informed decision can be provided. It is possible that patients may commit to a treatment in the EEA and subsequently discover that they were not entitled to reimbursement, or that the level of reimbursement does not cover the level of cost they have incurred in the EEA.

To aid this process, patients are advised to read section 6 of this procedure which provides information on how to claim for reimbursement of the treatment costs incurred and the basis on which the reimbursement level is assessed.

If a patient wishes to speak with a health board representative concerning entitlement or reimbursement they can contact;

EEA Co-ordinator
Cardiff and Vale IPFR
Commissioning Team
Public Health Division
1st Floor
Global Link
Dunleavy Drive
CARDIFF
CF11 0SN

Tel: 02921832101

Email: CAV.Irt@wales.nhs.uk

http://www.cardiffandvaleuhb.wales.nhs.uk/home

#### 2.5 **Residency**

To be eligible to seek reimbursement of treatment costs incurred within the EEA patients must be ordinarily resident in the local health board area and the treatment is one that is normally provided or commissioned by the local health board for its residents. Patients may also be asked to provide evidence to the health board of their permanent residency within the local health board area.

2.6 If a patient requires any medical treatment that becomes necessary during a trip within the EEA, for example during illness or following an accident, the patient's European Health Insurance Card (EHIC) should be used. This allows the patient access to emergency treatment in state provided healthcare services in the EEA at the same cost incurred by residents of the respective EEA state.

Further details of the EHIC systems can be accessed at the following website: <a href="http://www.nhs.uk/NHSEngland/Healthcareabroad/EHIC/Pages/about-the-ehic.aspx">http://www.nhs.uk/NHSEngland/Healthcareabroad/EHIC/Pages/about-the-ehic.aspx</a>

The EHIC is not an alternative to health insurance and does not, for example, cover the costs of repatriation from EEA countries back to the United Kingdom. It is therefore important that patients hold both a valid EHIC card and carry current private travel insurance before travelling to EEA countries.

#### 2.7 State Provided Care (S2)

Some patients may be entitled to apply under S2 rules whereby the health board may consider commissioning a treatment on behalf of a patient. The S2 route only relates to state provided treatment and does not cover private sector treatments. For further information on S2 commissioned health care, patients should contact their local health board representative.

#### 2.8 Timescale for information

Once all the necessary information is received, the local health board will aim to confirm the details of entitlement and likely reimbursement within 10 working days.

#### **SECTION 3**

#### 3. SEEKING ADVICE FOR HEALTHCARE TREATMENT IN THE EEA

- 3.1 In line with section 2 above, whereby patients are encouraged to seek confirmation of their entitlements, local health boards also recommend that patients consider the following points which underline the benefit of contacting the local health board before travelling for treatment to confirm:-
  - That the patient is entitled to NHS care from the local health board to which they are applying:
  - That the patient is entitled to the specific treatment requested;
  - That the patient is entitled to NHS aftercare and whether it will be available;
  - Whether Prior Approval is required;
  - The likely level of cost reimbursement that will apply.

It is advisable that this should happen before the patient accesses treatment in another EEA country as it will allow health boards to provide patients with knowledge of the possible treatment options within the NHS as well as entitlement and reimbursement information to inform any decision to progress with treatment in the EEA.

For hospital care, a health board may request that the patient is reviewed by a local NHS Consultant to verify their clinical need and confirm that they meet the clinical access threshold criteria that applies in the home healthcare system.

3.2 To help health boards provide relevant entitlement advice to patients on request, including whether prior approval will be required, patients are advised that the following information will be required by the health board:-

- Details of the clinical condition which is being treated and information on the procedure / treatment which needs to be carried out;
- Copies of any clinical letters supporting the clinical need for this treatment;
- Details on the cost of the treatment abroad.
- 3.3 Following confirmation of their entitlement, a patient may be required to seek prior approval if the treatment required falls under certain criteria. This is covered in Section 4 of this procedure.
- 3.4 It is the patient's responsibility to;
  - Be clear on who in the EEA country in which they wish to be treated is accountable for assuring their safety throughout the course of their treatment;
  - Understand that health boards cannot vouch for the quality of providers that the UK
    does not regulate health boards are not liable for the clinical negligence of
    practitioners or clinicians in the country undertaking the treatment any liability of
    the provider would have to be established in accordance with the legislation of the
    host state;
  - Make their own enquiry about the level and adequacy of insurance cover carried by the proposed provider in the EEA;
  - Understand their responsibility to make arrangement for adequate personal insurance;
  - Understand that they will be required to pay for the treatment they have received directly to the provider, prior to making a claim for reimbursement from their local health board;
  - Note that the maximum level of reimbursement will be limited to the lower of the
    cost of the equivalent local NHS service in their local health board or the cost of the
    treatment provided in the EEA. This means that in some cases the level of
    reimbursement may be lower than the cost of the treatment in the EEA.
  - Ensure that appropriate aftercare arrangements are in place after they have returned home including linkage with local NHS services and aftercare, if required
  - Ensure that they are able to provide all of the relevant information required to make a prior approval request, when needed, and a claim for reimbursement.
  - Ensure all medical documentation and invoices are translated into English or Welsh.

Note that reimbursement will only be made in respect of invoices directly addressed to the patient by the healthcare provider with accompanying proof of payment. Reimbursement will not be made to third party brokers acting on behalf of the patient in the pursuit of business.

If a patient is unclear about advice they have received or their entitlements, they are advised to follow the prior approval process outlined below in Section 4.

#### **SECTION 4**

4. CIRCUMSTANCES WHEN PRIOR APPROVAL FROM THE LOCAL HEALTH BOARD IS REQUIRED

- 4.1 In line with the Directive, health boards will require patients to seek prior approval for certain treatments. The services / treatments which require prior approval are set out in *Appendix B*.
- 4.2 Each health board in Wales also has a separate policy called 'Interventions not Normally Undertaken' (INNU). This policy sets out a list of healthcare treatments that are not normally available on the NHS in Wales and is subject to patients meeting clinical eligibility criteria. This is because;
  - there is currently insufficient evidence of clinical and/or cost effectiveness; and/or
  - the intervention has not been reviewed by the National Institute for Healthcare and Clinical Effectiveness (NICE) or the All Wales Medicines Strategy Group (AWMSG); and/or
  - the intervention is considered to be of relatively low priority for NHS resources.

A copy of your Local Health Board INNU policy is available on request from EEA Coordinator, Cardiff and Vale IPFR, Commissioning Team, Public Health Division, 1<sup>st</sup> Floor, Global Link, Dunleavy Drive, CARDIFF, CF11 0SN, Tel: 02921832101.

A patient seeking any treatment listed in the health board's INNU policy will be required to seek prior approval from the health board to demonstrate that they meet the exclusion criteria that entitles them to the requested treatment within their local health service.

- 4.3 Patients seeking treatments that do not fall within the scope of the prior approval list and local INNU policy are still encouraged to discuss their plans with their local health board in advance, in line with section 2 and 3 above, to ensure that patients are fully aware of their entitlement to the required treatment in the home healthcare system.
- 4.4 Patients may under certain circumstances make retrospective claims for treatments, which ordinarily the health board would have required application for prior approval. This relates to treatments where there would have existed 'undue delay' in waiting for the treatment in the home healthcare system.

The European Court has stressed that judgement with regard to "undue delay" must be based on a clinical assessment of what is a medically acceptable period for the individual clinical circumstances of the patient, and that this assessment needs to be kept under review while the patient is waiting for treatment. Offering treatment within a national waiting time target does not necessarily avoid 'undue delay'.

- 4.5 When assessing undue delay, section 6B(6) of the National Health Service (Wales) Act 2006 requires a health board to have regard to:
  - the patient's medical history;
  - the extent of any pain, disability, discomfort or other suffering that is attributable to the medical condition to which the service is to relate:
  - whether any such pain, disability, discomfort or suffering makes it impossible or extremely difficult for the patient to carry out ordinary daily tasks; and
  - 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

#### 4.6 Refusal Criteria

Where prior approval is required, health boards have the discretion to refuse reimbursement in the following circumstances;

- a) Where the patient will, according to 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 approval.
- 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 of supervision, whether these standards are 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 line 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 there is no 'undue delay' in providing treatment on the NHS).
- 4.7 Those seeking prior approval will be required to complete an application form. A copy of the application form can be found at *Appendix C*. This is also available on the health board website or from the EEA Lead in the local health board. The application form sets out the information that will be required before a decision can be made.

#### This includes:

- Evidence to demonstrate that the patient is a resident of the local health board area:
- Full details of the proposed treatment and the EEA country in which it will be provided. This should be detailed by procedure or drugs treatment.
- The patient's diagnosis for which treatment is being sought.
- The reason why the treatment is being requested outside of the UK;
- Summary of the current medical symptoms and quality of life;
- Any clinical supporting information from the patient's home GP and/or Hospital Consultant;
- Summary of any previous treatment/s received relevant to the condition for which treatment is being sought;
- Confirmation that the patient would be entitled to the same treatment in their local health board area.
- Details of the EEA healthcare provider including the lead clinician overseeing treatment. Supporting documentation from the EEA provider should include written confirmation of the proposed treatment, and associated costs, prepared on the provider's business paper, including the full address, phone number, email and web address contact details as appropriate.
- Confirmation on whether or not the requested treatment is a continuation of current treatment funded via another route:
- Details on whether or not the intervention is considered to be experimental, part of a clinical trial or clinical research;

- Confirmation on whether or not any of the requested treatment has been organised by a third party;
- Confirmation on whether or not any previous prior approval has been granted in relation to this intervention.

Additional information may be required by the local health board if the information provided is not sufficient for it to complete a reasonable assessment of clinical need, patient entitlement and undue delay where this applies.

4.8 Following receipt of the Prior Approval application (Appendix C) and supporting information, local health boards will aim to process applications within 20 working days, unless further information is required from the patient (in which case this target will not apply whilst the required information is provided by the patient).

The outcome of all applications will be notified to the patient in writing within 5 working days of a decision being made. The notification letter will also provide the reasons for reaching the decision made. If an application is refused, details on how to seek a review of the decision will also be provided.

- 4.9 In considering the application, the local health board will also take into account the following factors;
  - Whether the treatment falls under the services for which Prior Approval is required (Appendix B)
  - Whether the service / treatment would be provided by the NHS in Wales and there is a patient entitlement to the proposed treatment;
  - Whether the treatment is experimental;
  - There is a proven or well-evidenced clinical risk to the patient or to wider public health if the patient travels abroad;
  - If there is adequate aftercare or follow-up arrangements in place for the treatment in question;
  - Any evidence that the intended provider and / or clinician have previous negligent or fraudulent actions (this criterion is expected to be used only in very rare cases where accurate and substantiated information/evidence is available).

Prior approval by the local health board will remain valid for a period of 6 months from the date of the letter of notification. If treatments are not completed within 6 months of the date of notification of prior approval the patient must contact the EEA coordinator to discuss whether a new application for prior approval is required.

Subsequent application for reimbursement of costs must be submitted to the local health board within 3 months of the date of treatment. These timescales reflect that:

- A key consideration by the local health board in its original decision to grant
  prior approval may have been undue delay. If the treatment is not undertaken
  within 6 months of the decision to grant prior approval it may be the case that
  the local health board could have provided the treatment required on its
  territory within a time line which is medically justifiable.
- A six month delay in receiving the approved treatment may lead to a patient's condition changing requiring a revised set of considerations for the patient and the local health board in determining a new prior approval
- The local health board is responsible for the stewardship of its limited resources and requires confirmation of financial liabilities incurred within appropriate timescales for accounting and planning purposes.

If, for any reason, treatment and reimbursement application timescales cannot be complied with, or the treatment is deferred or suspended, the patient should contact the EEA co-ordinator in the local health board. To proceed with the proposed treatment the patient may be required to submit a new application.

A change in proposed treatment or provider will necessitate a new Prior Approval application where prior approval remains a requirement according to the schedule of treatments and services listed in Appendix B of this procedure.

#### **SECTION 5**

#### 5. HOW TO REQUEST A REVIEW OF THE DECISION

5.1 If a request for treatment in another EEA country is declined, or a request for reimbursement is not granted in full, a patient has the right to ask for this decision to be reviewed in line with the following:

#### 5.2 The 'review period'

There will be a period of **20 working days** from the day the health board decision is received by the originator of the request during which they may request a review by the Review Panel ('the review period"). The letter from the health board that accompanies the original decision will state the deadline for any review request. In calculating the deadline, Saturdays, Sundays and public holidays in Wales will not be counted.

The review process in each health board will follow the same process used for their Individual Patient Funding Request (IPFR) Panel decisions

#### 5.3 Who can request a review?

A review can be requested by the patient (or their official advocate)

#### 5.4 What is the scope of a review?

It does not constitute a review of the merits of the original decision. It has the restricted role of hearing review requests that fall into one or more of three strictly limited grounds. A review request on any other ground will not be considered.

The 3 grounds are:

**Ground One**: The health board has failed to act fairly and in accordance with the Directive and Procedure on Making Decisions on Requests for Treatment in another EEA Country

The health board is committed to following a fair and equitable procedure throughout the process. A patient who believes they have not been treated fairly by the health board may request a review on this ground. This ground relates to the procedure followed and not directly to the decision and it should be noted that the decision with which the patient does not agree is not necessarily unfair.

**Ground Two**: The health board has made a decision which is irrational in the light of the evidence submitted

The Review Panel will not normally entertain a review request against the merits of the decision reached by the health board. However, a patient may request a review where the decision is considered to be irrational or so unreasonable that no reasonable health board could have reached that conclusion. A claim that a decision is irrational contends that those making the decision considered irrelevant factors, excluded relevant ones or gave unreasonable weight to particular factors.

Ground Three: The health board has exceeded its powers

The health board is a public body that carries out its duties in accordance with the Statutory Instruments under which it was established. A patient may request a review on the grounds that the health board has acted outside its remit or has acted unlawfully in any other way.

Reviews which may require a significantly disproportionate resource relative to the health needs of the local population may be rejected at Chief Executive's discretion.

#### 5.5 How is a review request lodged?

A patient who wishes to request a review should lodge their request with the IPFR Co-ordinator of the health board, within the review period. The documents lodged must include the following information:

- The aspect(s) of the decision under challenge and
- The detailed ground(s) of the review request.

If the review request does not contain the necessary information or if the review does not appear to the local health board officer to fall under any one or more grounds of review, they will contact the patient to request further information or clarification.

The Chair of the Review Panel may refuse to progress a review that does not include all of the above information.

#### 5.6 What is the timescale for a review to be heard?

The Review Panel will aim to hear a review within **20 working days** of the request being lodged with the health board. The date for hearing any review will be confirmed to the patient, and where applicable their advocate, and clinician in a letter.

This review process allows for clinically urgent cases, as deemed by the referring/supporting clinician, to be considered outside of the panel process by the health board's Chair together with a Clinical Member of the Review Panel. Any such decisions will be made in line with the principles of this policy.

#### 5.7 Who will sit on the Review Panel?

The health board will appoint members of the Review Panel in accordance with their IPFR Review Panel procedure.

The health board will intend to inform the patient and their clinician of the membership of the Review Panel as soon as possible after a review request has been lodged. None of the members of the Review Panel will have had any prior involvement in the original submission.

In appointing the members of the Review Panel, the health board will endeavour to ensure that no member has any interest that may give rise to a real danger of bias. Once appointed, the Review Panel will act impartially and independently.

#### 5.8 Initial scrutiny by the Health Board Officer

The review documents lodged will be scrutinised by an officer of the local health board who will look to see that they contain the necessary information. The review documents must contain the following information:

- The aspect(s) of the decision under challenge and
- The detailed ground(s) of the review request.

If the review request does not contain the necessary information or if the review does not appear to the scrutiny officer to fall under any one or more grounds of review, they will contact the referrer (patient or their clinician) to request further information or clarification.

A review will only be referred to the Review Panel if, after giving the patient and their clinician an opportunity to elaborate or clarify the grounds of the review the Chair of the Review Panel is satisfied that it falls under one or more of the grounds upon which the Review Panel can hear the review.

#### 5.9 Can new data be submitted to the Review Panel?

No, because should new or additional data become available then the application should be considered again by the original panel in order to maintain a patient's right to review at a later stage.

#### 5.10 Can patients attend Review Panel Hearings?

Patients and/or their unpaid representative may attend Review Panel Hearings as observers but will not be able to participate. This is because the purpose of a review hearing is to consider the process that has been followed and not to hear new or different evidence.

If new or different evidence becomes available, the case will automatically be scheduled for reconsideration by the Panel. Patients and/or their unpaid representatives are able to make their written representations to the new Panel in order for their views to be taken into account.

It is important for all parties to recognise that review panel hearings may have to discuss complex, difficult and sensitive information in detail and this may be distressing for some or all of those present. Patients and/or their unpaid representatives should be aware that they will be asked to retire at the end of the Review Panel discussion in order for the Panel to make their decision. The Chairman

of the Panel will then immediately inform the patient and/or their advocate of the decision and the reason for making it. They will not enter into any further discussion.

#### 5.11 The Decision of the Review Hearing

The Review Panel can either;

- Uphold the grounds of the review and ask the original Panel to reconsider the request; or
- Not uphold the grounds of the review and allow the decision of the original Panel to stand.

In exceptional circumstances, the Review Panel may also make a recommendation for action to the Board. The action can only be progressed following its ratification by the Board (or by the Chief Executive in urgent matters).

Should a patient be dissatisfied with the decision of the Review Panel, they are able to make a complaint. Please refer to Section 10 for information on this.

#### 5.12 After the review hearing

The Chair of the Review Panel will notify patients and their clinicians of the Review Panel's decision in writing. This letter will be sent **within 5 working days** of the Panel. The Review Panel will aim to send its decisions to the Board for information within **20 days** of the hearing, but there may be some instances in which a longer interval is necessary. The Board will then make the full text of the decision available to the patient and their clinician.

#### 5.13 How will WHSSC undertake a review?

As the WHSSC is a collaborative committee arrangement to support all health boards in Wales, it will not be able to constitute a review panel. WHSSC will therefore refer any requests it receives for a review of its decisions to the health board in which the patient lives. A WHSSC representative who was not involved in the original panel will become a member of the review panel on these occasions.

A senior health board officer will be present at review hearings to give advice on proceedings as per their governance role. The WHSSC Senior IPFR Officer will clerk the hearing.

#### **SECTION 6**

#### 6. REIMBURSEMENT OF TREATMENT COSTS

- 6.1 A patient is only entitled to reimbursement of treatment costs;
  - Where the patient has demonstrated their entitlement as per Section 2

And either:

- Prior approval was not required
- An entitlement for which prior approval is required and has been granted; or

- An entitlement for which prior approval is required but was not sought or granted and the health board concludes that "undue delay" applies. Undue delay has to be determined on the basis of the individual's clinical needs, history and prognosis: It cannot be determined on the basis of local or national waiting times, or targets for waiting times. 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.
- 6.2 Providing the reimbursement claim relates to a treatment that the patient would be entitled to receive in their home NHS healthcare system, they may subsequently request reimbursement from their local health board for some or all of the costs of the treatment. Costs reimbursed will be restricted to the lower of:
  - The cost of the treatment in the home system, or
  - The actual invoiced cost of the treatment provided by the EEA provider.

This cost assessment excludes any travel or accommodation costs that may have been incurred by individuals to attend their treatment (see Section 7).

To receive reimbursement, patients will need to provide documentary proof detailing:-

- The treatment received
- The date of treatment
- That full payment has been made to the healthcare provider within the EEA
- The value of the payment made to the healthcare provider within the EEA
- The currency used in transacting payment to the healthcare provider within the EEA.

This information must be supported by a bona fide invoice from the healthcare provider to the patient and a verified receipt of payment. The invoice should detail each and all components of healthcare provided.

Invoices from third party brokers acting on behalf of the patient in the pursuit of business will not be accepted.

The form for completion of treatment and payment is at *Appendix D*.

A claim for reimbursement must be received by the health board within 3 months of the date of completion of a treatment.

If prior approval was required, and confirmed, the treatment must be completed, within 6 months of the date of notification of approval by the health board. Failure to comply with these timescale will require a new application for prior approval.

These timescale requirements support local health boards in maintaining knowledge of their liabilities and to ensure compliance with their duty to steward financial resources effectively.

6.3 Following the European Union Directive, the maximum level of reimbursement will be limited to the cost of the equivalent NHS service or the actual cost of the treatment in the EEA, whichever is lower. This will be a fully absorbed cost.

Local health boards will base their assessment of the cost of treatment in the home system on the 'Payment By Results' (PBR) tariff system working in the English NHS.

#### This:

- Promotes equity and consistency across health boards in Wales
- Publishes an indicative reimbursement rate in advance of enquiry
- Allows the reimbursement system to be updated annually
- Bases reimbursement consideration on widely utilised, proven and credible cost criteria.

Local health boards will provide a link to the current PBR tariff on their EEA Treatment website page.

The PBR tariff provides a comprehensive list of treatments generally provided by the NHS. Due to the number of treatments and their clinical terminology there is the potential for patients to be confused when using the PBR tariff to consider their entitlement to treatment and the potential maximum cost reimbursement level. For this reason patients are encouraged to contact their local health board in advance of committing to a treatment in the EEA. The local health board will provide assistance in identifying the relevant treatment and its cost reimbursement value in the home health system.

6.4 When prior approval by the health board was required, retrospective funding applications may be considered by the health board where undue delay in the home system can be demonstrated. What potentially constitutes undue delay is explained in more detail in Section 4 and 6.1 of this procedure.

If undue delay is demonstrated, a patient's application is still required to demonstrate that the clinical threshold for treatment has been met, as outlined in this procedure. Patients are still encouraged to contact their local health board for clarification of entitlement and likely costs reimbursement prior to any commitment to a treatment in the EEA, even if the patient considers that undue delay may be a factor in their decision.

Retrospective applications where undue delay applies have to comply with the timescales for application, i.e. claims must still be received by the health board within three months of the date of treatment.

- 6.5 If the treatment for which reimbursement is being considered would normally attract a patient charge under the NHS, health boards will deduct this from the amount due.
- 6.6 The person who applies for reimbursement of costs incurred does not have to be the patient it may be another person such as a close relative or friend who has paid for the medical treatment. This must be indicated clearly by the applicant in the claims process.

Irrespective of who has paid the healthcare provider, all documentation (invoices and receipts) made available by the healthcare provider (and submitted in support of a reimbursement application) must be issued in the name of the patient who has received treatment and clearly detail the cost of all treatment components provided in an itemised manner.

Local health boards will not reimburse third parties which have incurred costs on behalf of the patient in the pursuit of business. Services are sometimes provided by persons/organisations, on a profit or 'not for profit' basis, to assist patients to access treatment in the EEA. These arrangements are a private matter between the patient and the third party. The local health board will not consider reimbursement in respect of any of these services.

Local health boards will not reimburse costs when the there is evidence that the cost of treatment has been applied for or has already been met by existing medical insurance. The claim form asks the patient to declare whether this is the case.

6.7 Some claims may require a foreign currency translation when it is the actual cost of treatment in the EEA that will be reimbursed and this has been invoiced in a foreign currency.

When this occurs, the reimbursement calculation will be based on the spot exchange rate applicable on the document date of the transaction (i.e. the date on the receipt or invoice). The health board will use a reputable historical financial record to access the relevant spot rate such as the Bank of England 'Statistical Interactive Database - daily spot exchange rates against Sterling':

http://www.bankofengland.co.uk/boeapps/iadb/Rates.asp

#### **SECTION 7**

#### 7. FURTHER CONSIDERATIONS

#### 7.1 Payment of Travel Expenses

Patients will only be entitled to reimbursement of travel expenses if they were entitled to such reimbursement within NHS Wales. The level of reimbursement will only be the same as the travel costs between home and your local health provider. This is set out within 'The National Health Service (Travelling Expenses and Remission of Charges) (Wales) Regulations 2007 (WSI 2007 No 1104), as amended.'

#### 7.2 Insurance Cover

Anyone seeking medical treatment in another country is reminded to ensure that they have comprehensive medical insurance for their trip. Regular travel insurance does not routinely cover people going abroad expressly for medical treatment, just as many policies will automatically exclude cover for any pre-existing health condition.

The cost of such insurance is not reimbursable by the NHS.

#### 7.3 Repatriation

It is the patient's responsibility to ensure that adequate repatriation arrangements are in place following the events of any unforeseen circumstances. This would include;

- Repatriation arrangements to the UK for onward treatment following any clinical complication whereby alternative travel arrangements are required;
- Repatriation following death

Patients are therefore advised that adequate medical insurance as outlined in Section 7.2 should be in place and should also cover repatriation costs.

#### 7.4 **Document Translation**

In order to assist the health board in reaching a decision with regards to a patient's entitlement to treatment abroad, any documentation presented in support of a claim should be translated into English or Welsh prior to being sent to the health board.

#### 7.5 Aftercare Arrangements

When considering travelling abroad for treatment, patients are strongly advised to contact their health board or GP to discuss any aftercare arrangement that may be required following their return to the United Kingdom.

#### 7.6 **Accommodation Costs**

Patients are not entitled to claim for accommodation costs prior to and following discharge from hospital. It is the patient's responsibility to ensure that adequate financial arrangements are in place to cover any accommodation costs.

The cost of the hospital stay, if applicable, will be seen as an integral component of the cost of the treatment being claimed for.

Patients who require escorts or assistance to travel will need to ensure that financial arrangements are in place to cover these costs. These costs will not be covered by the health board

#### **SECTION 8**

#### 8. RAISING A CONCERN

8.1 Making a request for treatment in another EEA country does not conflict with a patient's ability to raise a concern with their local health board.

The health board can only respond to concerns raised in respect of healthcare either provided or directly commissioned by it, or in respect of how it has handled a patient's claim for reimbursement.

The health board cannot consider concerns raised in respect of the healthcare services provided by providers in other EEA countries.

You can choose to raise any concern in writing by completing our 'Raising a Concern' form, or you can write direct to the relevant health board representative. The contact details are:

The Patient Experience Team at Cardiff and Vale UHB, Concerns Department, 7<sup>th</sup> Floor Brecknock House, University Hospital Wales, Cardiff CF14 4XW.

You can also email your concern to: concerns@wales.nhs.uk

Or, if you would prefer to talk to someone about you concern you can telephone the Team on 02920 742 202.

8.2 If a patient holds a concern regarding their treatment by the EEA provider this must be raised with the provider in accordance with the provider's governance arrangements and the regularity arrangements in place in the provider's respective EEA state.

#### **SECTION 9**

#### 9 REVIEW OF THIS PROCEDURE

9.1 This procedure will be reviewed in accordance with changes to European and English and Welsh law and in response to procedural matters arising through its operation.

Any change in guidance or legislation will trigger an immediate review.

#### **SECTION 10**

#### 10. PATIENTS FROM EEA SEEKING TREATMENT IN WALES

#### **General considerations**

- 10.1 The inflow of patients from other EEA 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.
- 10.2 The Directive does not require providers to accept patients for planned healthcare if this would be to the detriment of their own patients with similar health needs. However, given that it is possible that local health boards may be contacted in advance by either the prospective patient, his/her clinician or potentially another countries National Contact Point, local health boards would need to demonstrate that

they were not simply discriminating against EEA nationals on grounds of nationality if rejecting a request for treatment.

In principle, the strongest grounds for refusing a visiting patient are the lack of service capacity; however in reality they would be offered the option of joining the relevant waiting list, to be treated alongside "home" patients on the basis of, they have the option of considering a different provider.

- 10.3 Where healthcare is provided for a patient from another EEA country in Wales, that healthcare provider will:
  - 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 and redress procedures;
  - 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.

#### Charging

10.4 In line with the Directive, Welsh healthcare providers will not operate a discriminatory pricing structure. Visiting patients from other EEA countries will be charged on the same basis as reimbursement is made to Welsh patients applying for treatment in the EEA.

This will generally be in line with the PBR tariff.

Where there is no comparable price for domestic patients, the price will 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 cost had that service been provided to an NHS patient.

10.5 Where a visiting patient is accepted for treatment, it will not automatically be assumed that they want to be treated as a private patient. 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 fundamental right as an EEA citizen and may themselves receive reimbursement from their state system for eligible costs under the provision of the Directive. However, patients who specify from the outset that they do wish to be treated privately may be charged at the equivalent cost to private patients in Wales.

It should be noted that only those services which are a standard part of the normal treatment arrangements for Welsh patients would be considered and would be subject to the national waiting times targets that are in place.

10.6 For GP and GP out of hour's services, if a visiting patient is treated as an NHS patient, then the treatment/consultation is currently free of charge, regardless of nationality. Charges are, however levied for medication dispensed via community pharmacies.

- 10.7 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.
- 10.8 Welsh healthcare providers need to ensure systems are in place for dealing with requests for treatment for visiting patients. This would include processes for seeking more information about the patient's condition, diagnoses where this is not initially available, systems for dealing with the payment direct from the patient and clear information about the services and terms of the treatment they provide.

#### **SECTION 11**

#### 11. EMERGENCY BRAKE PROVISION

- 11.1 It is possible that the inflow of visiting patients and/or the outflow of home patients seeking treatments in the EEA may, over time, place pressure on the resources of the local health board, creating a demand that exceeds the capacity existing in the NHS for certain treatments or there may be a need to control costs relating to the planning or funding of services. Therefore, the Directive allows the NHS in Wales 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.
- 11.2 Should such a situation arise, this would be a matter for Welsh Ministers. Any decision 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 such evidence.

#### **SECTION 12**

#### 12 EQUALITY IMPACT ASSESSMENT

- 12.1 This policy has been subject to a summary equality impact assessment following the inception of the EEA Directive on 25th October 2013.
- 12.2 The Health Board is committed to ensuring that, as far as is reasonably practicable, the way it provides services to the public and the way it treats staff, patients and others reflects their individual needs and that we will not does not discriminate, harass or victimise individuals or groups unfairly on the basis of sex, pregnancy and maternity, gender reassignment, disability, race, age, sexual orientation, disfigurement, religion and belief, family circumstances including marriage and civil partnership. These principles run throughout our work and are reflected in the core values, staff employment policies, service delivery standards and Strategic Equality Plan and Equality Objectives. The Health Board believes that all staff should have fair and equal access to training as highlighted in both the Equality Act 2010 and the 1998 Human Rights Act. The responsibility for implementing the Plan falls to all employees and UHB Board members, volunteers, agents or contractors delivering services or undertaking work on behalf of the UHB.
- 12.3 The responsibility to identify, assess and mitigate inequality impacts exist in current services provided and commissioned by the Health Board within its home system. In creating improved access to EEA healthcare services the Health Board considers that the equality principles and responsibilities it observes in the home system also apply to the system it operates to support resident's rights to access treatment in the EEA. By supporting its residents' consideration of alternative treatments in the EEA, the Health Board does not consider that it's procedure creates or worsens any inequalities that didn't previously exist as indicated by the Equality Impact Assessment supporting this procedure.

#### **APPENDIX A**

List of EEA Member States (Countries) Covered under this Policy

#### **EU Member States**

Austria

Belgium

Bulgaria

Croatia

Cyprus

Czech Republic

Denmark

Estonia

Finland

France

Germany

Greece

Hungary

Ireland

Italy

Latvia

Lithuania

Luxembourg

Malta

Netherlands

Poland

Portugal

Romania

Slovakia

Slovenia

Spain

Sweden

United Kingdom

#### Non EU Member States

Norway

Iceland

Liechtenstein

Switzerland (S2 (PREVIOUSLY E112) route only)

#### **APPENDIX B**

#### **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 annex to the list. In addition, there are services which are excluded from this policy and these are also provided in the annex to the 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.

The following list is in addition to any treatments listed in the health board's schedule of 'Interventions Not Normally Undertaken' (the 'INNU' list) which can be accessed from the health board's website or directly on request from the contact points in this procedure. All INNU treatments are subject to prior approval by the health board.

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, aids and Appliances Services	Prosthetics and complex orthotics, highly specialised equipment, highly specialised wheelchairs and cochlear implants.	CP59 - All Wales Posture & Mobility Service 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

Service type	List of treatments and interventions subject to Prior Approval for preplanned treatments	Reference in the WHSSC specialised services list (see the rationale in the annex)	Reason
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	<u>CP04 - Positron Emission</u> <u>Tomography (PET)</u>	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 as outlined in the WHSSC 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	<u>CP21 - Specialised Adult</u> <u>Gender Identity Service</u>	High cost interventions based on planning with an overnight stay
General Surgery Services	All in-patient surgery of two nights or more, including all in-patient upper gastro-intestinal surgery		High cost interventions based on planning with an overnight stay

Service type	List of treatments and interventions subject to Prior Approval for preplanned treatments	Reference in the WHSSC specialised services list (see the rationale in the annex)	Reason
Gynaecology Services	All inpatient surgery		High cost interventions based on planning with an overnight stay
Haematology/ bleeding disorder Services	All immune deficiency services and treatment, including major blood disorders (including hepatitis B, hepatitis C); enzyme replacement therapy		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
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	All Maternity Services, including Foetal medicine and foetal surgery		High cost interventions based on planning with an overnight stay and patient safety considerations in terms of continuity of care.
Maxillo-facial Surgery Services	All major inpatient surgery		High cost interventions based on planning with an overnight stay

Service type	List of treatments and interventions subject to Prior Approval for preplanned treatments	Reference in the WHSSC specialised services list (see the rationale in the annex)	Reason
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	All Mental Health treatments and therapies including eating disorders, substance abuse, post-traumatic stress disorder, veterans post traumatic stress disorder		High cost interventions based on planning with patient safety considerations in view of the need to protect the patient and wider public health concerns and the need for long term follow up and care on a consistent basis.
Nationally Designated Services/ Rare Conditions	All rare conditions as listed on the NHS Specialised Services website	http://www.specialisedservices.n hs.uk/services	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 - Sterotactic Radiotherapy	High cost interventions based on planning with an overnight stay

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
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 including both surgical and 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.
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 Palliative care including end of life 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 CP44 - Body Contouring 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 to be considered as part of a wider patient care pathway.

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
Telemedicine Consultations	All consultations via the medium of electronic interface		To avoid health boards incurring multiple financial liabilities without prior knowledge and consideration which potentially undermines local planning.  To ensure that the nature of the consultation relates to accepted clinical aims in line consultations delivered in the home system
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

#### Annex B (Cont.): Rationale for inclusion of treatments in the prior approval 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 approval, 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 approval may consider including<sup>i</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 approval 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 approval the relevant WHSSC 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.

#### **Policy Exclusions**

The EU Directive specifically specifies some services are excluded from this policy, these include:

- services in the field of long-term care the purpose of which is to support people in need of assistance in carrying out routine, everyday tasks;
- allocation of and access to organs for the purpose of organ transplants;
- with the exception of Chapter IV, public vaccination programmes against infectious diseases which are exclusively aimed at protecting
  the health of the population on the territory of a Member State and which are subject to specific planning and implementation measures.
  All standard aids and appliances including standard wheelchairs, which are not routinely purchased for patients but 'lent' to patients for
  their period of need via a community pooled resource.



### ALL WALES PRIOR APPROVAL REQUEST (PAR) APPLICATION FORM

#### In respect of Welsh Patient's Accessing Treatment in Countries of the European Economic Area

1. Details of Resident/Patient in	naking request		
Forename/ Given Name:		Surname/ Family Name:	
Address: (including postcode)			Postcode:
Have you lived in the UK for more than one year?	□ Yes □ No	0	i ostode.
National Insurance (NI No)			
It may be necessary to contact othersidency. Please state your cons		□ Yes	□ No
Contact Telephone No:		NHS Number:	
Date of Birth: (dd/mm/yyyy)		Male or Female:	
Registered GP or Dentist Name and Practice Address:			
2. Details of European organis	ation providing treatmen	t/surgery received	
2. Details of European organis Company/treatment centre name:	sation providing treatmen	t/surgery received	
Company/treatment centre	sation providing treatmen	t/surgery received	
Company/treatment centre name:  Company/treatment centre	sation providing treatmen	t/surgery received	
Company/treatment centre name:  Company/treatment centre address:	sation providing treatment	Fax No:	□ Private healthcare facility
Company/treatment centre name:  Company/treatment centre address:  Telephone No:  Is the healthcare provided by:  Name of lead clinician responsible for your care:		Fax No:	
Company/treatment centre name:  Company/treatment centre address:  Telephone No:  Is the healthcare provided by:  Name of lead clinician responsible for your care:  Company/treatment centre contact name in case of queries:		Fax No:	
Company/treatment centre name:  Company/treatment centre address:  Telephone No:  Is the healthcare provided by:  Name of lead clinician responsible for your care:  Company/treatment centre		Fax No:	

• •	porting request (must be a GP/ Consultant who is currently providing care for the patient)
Name:	
Job Title:	
NHS Health Board, Trust or GP Practice:	
Correspondence address:	
Telephone No:	
Email:	
Secretary's Name:	Telephone
	No:
4. Prior Approval Request	
What intervention are you seeking:	<ul><li>□ Drug</li><li>□ Medical Device</li><li>□ Surgical procedure</li><li>□ Therapy</li></ul>
3	☐ Assessment/Opinion and ☐ Other – please specify further management
Cost of the Intervention requested.	
Diagnosis:	
Summary of the condition and	
the treatment being sought abroad (Please provide	
supporting evidence eg clinic letters, scan reports etc)	
Are you currently being treated for this condition in the UK?	□ Yes □ No
If yes, who is currently managing	
your care and where?	
If not, please explain why.	
Are you currently on an NHS	
waiting list for this treatment/ surgery? If so, where?	
What plans are in place to ensure that any aftercare	

required is available when	
arrive back in Wales followi	ing
the treatment/ surgery	
requested? Please evidend	ce this
is in place.	
Is the treatment/surgery a	
continuation of current trea	
funded via another route?	If yes,
please provide details	
In seeking healthcare in an	other EEA State, you are stepping outside of NHS jurisdiction. Consequently, it is
	atment that will apply and therefore it is your responsibility to be clear on who in
	nent is accountable for assuring your safety throughout the course of your treatment.
	ssioners cannot be held liable for any failures in treatments undertaken in another
	e Directive. Their role is strictly limited to helping facilitate this if that is the patient's
	onfirm you understand this statement and its implication:   Yes  No
5 Additional Inform	ation or any other relevant Information: please include any supporting evidence
	need, evidence of follow up care arrangements.
moraumy, omnou	Tiood, oridonos or follow up sais arrangomentes
6. Patient consent to	request further clinical and non clinical information to support application
I confirm that I consent to	Cardiff & Vale University Health Board requesting additional clinical information on my
	ation. By giving my consent I agree for those processing my application for approval to
	records and waiting list information.
Resident/Patient's	<u> </u>
Signature:	
ga.a	
7. Patient Declaratio	n
I confirm that I have comple	eted this application form to the best of my knowledge.
. commit and mave comple	side and application form to the boot of my knowledge.
Resident/Patient's	
Signature & Date:	
orgreature of action	

#### Depending on your place of residency, please return the request to:

Health Board	Post	Email, Fax & Telephone
ABMU HB	PAR Team, Abertawe Bro Morgannwg	ABM.IPFR@wales.nhs.uk
	University Health Board, 1 Talbot Gateway,	Fax: 01639 687675
	Baglan Energy Park, Port Talbot, SA12 7BR	Tel: 01639 683389
Aneurin Bevan	PAR Team, Aneurin Bevan Health Board	IPFR.ABB@wales.nhs.uk
	Llanfrechfa Grange Rm 43, Llanfrechfa	Fax: 01633 623817
	Grange House Cwmbran, NP44 8YN	Tel: 01633 623432
Betsi Cadwaladr	IPFR Team, Planning Dept, Glan Clwyd	IPFR.BCUHB@wales.nhs.uk
	Hospital, Sarn Lane, Bodelwyddan LL18 5UJ	Fax: 01745 448211
		Tel: 01745 448788 x7930
Cardiff & Vale	Cardiff and Vale IPFR, Commissioning	CAV.Irt@wales.nhs.uk
	Team, Public Health Division, 1 <sup>st</sup> Floor,	Fax: 02912 832117
	Global Link, Dunleavy Drive, Cardiff,	Tel: 02921832101
	CF11 0SN	
Cwm Taf	PAR Team, Cwm Taf Health Board,	Cwmtaf.IPFR@wales.nhs.uk
	Ynysmeurig House, Navigation Park,	Fax: 01443 744889
	Abercynon, CF45 4SN	Tel: 01443 744821
Hywel Dda	PAR Team, Hywel Dda Health Board,	karen.thomas20@wales.nhs.uk
	Headquarters, Merlins Court, Winch Lane,	Fax: 01437 771272
	Haverfordwest, Pembrokeshire. SA61 1SB	Tel: 01437 771237
Powys	PAR Team, Powys Teaching Health Board,	alison.howells4@wales.nhs.uk
	Monnow Ward, Bronllys Hospital, Bronllys,	Fax: 01874 712685
	Brecon, Powys. LD3 0HG	Tel: 01874 712681
Welsh Health Specialised	PAR Team, Welsh Health Specialised	WHSSC.IPC@wales.nhs.uk
Services Committee	Services Committee (WHSSC), Unit 3a,	Fax: 02920 869534
(WHSSC)	Caerphilly Business Park. CF83 3ED	Tel: 01443 443 443 ext 8123
(**11330)		

#### **Application Form Guidance Notes**

Please note that if your application is approved you will need to have your treatment and submit a claim for reimbursement within six months of the date of approval. If you do not submit your claim for reimbursement before this deadline a new application may have to be submitted.

Please ensure that you have filled in the form clearly and as fully as possible; not every question needs to be answered for every case but please put 'not applicable' rather than leaving a section blank.

You need to ensure that you have comprehensive medical insurance in place (the cost of such insurance is not reimbursable by the NHS); regular travel insurance does not cover you going abroad for planned medical treatment.

**Section 1** – This section is to assist the Health Board in establishing the entitlement of the patient using their residency and to provide the patients contact details.

**Section 2** – Provides details of the organisation where the patient is seeking treatment/surgery.

**Section 3** – This section provides the clinical contact information where the Health Board can obtain further information to support Section 4 and understand local clinical thresholds for treatment.

**Section 4** – This sets out the detail of the treatment/surgery being sought.

**Section 5 -** Gives the patient the opportunity to provide any additional/supporting information to support their application.

**Section 6** – There is some information we may need to confirm and without your approval we will be unable to request it under confidentiality regulations and this could cause a delay in your application. **Section 7** – Patient signature and date on completion of form.

We understand that the rules and regulations surrounding treatment in another EEA country are complicated and can sometimes be difficult to understand. If you would like our help to complete this form please contact the EEA Co-ordinator in your local health board.

#### **APPENDIX D**

## ALL WALES REIMBURSEMENT FORM In respect of Welsh Patient's Accessing Treatment in Countries of the European Economic Area



1. Details of Resident/Patient ma	aking Request	
Forename/ Given Name:		Surname/ Family Name:
Address: (including postcode)		Postcode:
Have you lived in the UK for more than one year?	☐ Yes ☐ No	rosicode.
National Insurance (NI No)		
It may be necessary to contact oth residency. Please state your cons		□ Yes □ No
Contact Telephone No:		NHS Number:
Date of Birth: (dd/mm/yyyy)		Male or Female:
Registered GP or Dentist Name and Practice Address:		
2. Confirmation of Treatment for (*please delete as applicable)	or which Prior Approval wa	as Provided/Not Provided
(*please delete as applicable) Please provide the Unique Prior Approval Number if applicable as provided in the approval letter	Unique Prior Approval Num	nber:
(*please delete as applicable) Please provide the Unique Prior Approval Number if applicable as		Surgical procedure  Therapy
(*please delete as applicable) Please provide the Unique Prior Approval Number if applicable as provided in the approval letter What intervention did you	Unique Prior Approval Num  Drug Medical Device Assessment/Opinion a	Surgical procedure  Therapy
(*please delete as applicable) Please provide the Unique Prior Approval Number if applicable as provided in the approval letter What intervention did you receive:	Unique Prior Approval Num  Drug Medical Device Assessment/Opinion a	Surgical procedure  Therapy
(*please delete as applicable) Please provide the Unique Prior Approval Number if applicable as provided in the approval letter What intervention did you receive:  Cost of the Intervention.	Unique Prior Approval Num  Drug Medical Device Assessment/Opinion a	Surgical procedure  Therapy
(*please delete as applicable) Please provide the Unique Prior Approval Number if applicable as provided in the approval letter What intervention did you receive:  Cost of the Intervention.  Diagnosis:  Summary of the condition and the treatment received (Please provide supporting evidence eg	Unique Prior Approval Num  Drug Medical Device Assessment/Opinion a	Surgical procedure Therapy Other – please specify

and where?	
If not, please explain why.	
Were you on an NHS waiting list for this treatment/ surgery? If so, where?	
What aftercare are you receiving back in Wales following the treatment/surgery received?	
Was the treatment/surgery a continuation of current treatment funded via another route? If yes, please provide details	
the law of the country of treatment the Member State of treatment is a NHS clinicians and commissioners European country under the Direct	ther EEA State, you stepped outside of NHS jurisdiction. Consequently, it is that will apply and therefore it is the your responsibility to be clear on who in accountable for assuring your safety following your treatment. It is cannot be held liable for any failures in treatments undertaken in another tive. Their role is strictly limited to helping facilitate this if that is the patient's you understand this statement and its implication:
3. Details of Clinician supporting	ng request (must be a GP/ Consultant who is currently providing care for the patient)
Name:	
Job Title:	
NHS Health Board, Trust or GP Practice:	
Correspondence address:	
Telephone No:	
Email:	
Secretary's Name:	Telephone No:

4. Details of European organisa	ation providing treatment/surgery received	
Date of Admission: (dd/mm/yyyy)	Date of Discharge: (dd/mm/yyyy)	
Company/treatment centre name:		
Company/treatment centre address:		
Telephone No:	Fax No:	
Was the healthcare provided by:		rivate healthcare facility
Name of lead clinician	Cate provided nearineare facility	Trate realiticals facility
responsible for your care:		
Company/treatment centre contact name in case of queries:		
Telephone No:		
Email address:		
Treatment/Surgery Received	Details	Cost
Diagnostic tests (eg blood tests, scans etc)		
Surgery/medical		
Devices (eg hip/knee prosthetics etc)		
Pharmacy costs (eg drugs charged for over and above the surgery costs)		
Length of stay (eg how many days were you in a hospital bed if not included in surgery/medical costs)		
Sundries (any other costs incurred)		
TOTAL COSTS INCURRED		
	her relevant information (please include any support	 ing evidence including
evidence of follow up care received		g oviderioo moldumg

result in your reimbur b. Reimbursement will b	ation  th and submit copies of all invoices and submit copies and	nt to NHS care and you	will not be reimbursed in
		Total Invoice Value:	
Invoice no:		Invoice currency:	
Amount paid by resident/pa	atient or representative:		
Total paid:			
reimbursement will be per Section 7 of the "A European Economic A Insurance and repat Patients Accessing To accessing Treatment d. Accommodation cosper Section 7 of the "A European Economic A European Econo	triation costs are not reimburse reatment in Countries of the Eur ill not be reimbursed as per Sect in Countries of the European Edits incurred prior to and followin All Wales Procedure for Welsh Farea".  The althcare provider must be made afty brokers in the pursuit of busing the procedure of the pursuit of busing the made and the pursuit of busing the pursuit of busing the pursuit of the pursuit of busing the pursuit of	Patients Accessing Treated per Section 7 of the "A opean Economic Area"; tion 7 of the "All Wales Proconomic Area"; g discharge from hospital Patients Accessing Treated out directly to the patients	rour local health provider as ment in Countries of the all Wales Procedure for Welsh rocedure for Welsh Patients all will not be reimbursed as ment in Countries of the ent receiving treatment.
TOTAL COSTS INCURRED	Description		Cost
Total costs claimed			
			Cost
TOTAL AMOUNT CLAIMED	FOR REIMBURSEMENT		000.
TOTAL ANICONT CLAIMED FOR REINIDURSEINENT			

#### 6. Resident/Patient declaration

- a. I confirm that the information provided above is accurate, complete and in accordance with the entitlements under the "All Wales Procedure for Welsh Patients Accessing Treatment in Countries of the European Economic Area".
- I, the patient, give full permission to the Health Board to contact the Overseas Treatment Centre and/or my GP/Dentist directly to verify any information provided on this form.
- c. I confirm that no costs being claimed for treatment, as stated above, were incurred for commercial gain by business intermediaries acting as third party brokers.
- d. I confirm that I have not received or applied for funding from private healthcare insurance for this treatment or that the insurance company has not reimbursed the Treatment Centre directly for this care.

Resident/Patient's Signatur	re:			
Please print name in BLOCK CAPITAL LETTERS:			Date:	
If reimbursement is being the details below:	g claimed	by someone other than the patient of	eg parent/gua	rdian, please complete
Relationship to the Resident/Patient:				
Signature of representative	<b>)</b> :			
Please print name in BLOCK CAPITAL LETTERS:			Date:	
Address of representative:				
Contact telephone no of representative:				

Depending on your place of residency, please return the request to:

Health Board	Post	Email, Fax & Telephone
ABMU HB	PAR Team, Abertawe Bro Morgannwg	ABM.IPFR@wales.nhs.uk
	University Health Board, 1 Talbot Gateway,	Fax: 01639 687675
	Baglan Energy Park, Port Talbot, SA12 7BR	Tel: 01639 683389
Aneurin Bevan	PAR Team, Aneurin Bevan Health Board	IPFR.ABB@wales.nhs.uk
	Llanfrechfa Grange Rm 43, Llanfrechfa	Fax: 01633 623817
	Grange House Cwmbran, NP44 8YN	Tel: 01633 623432
Betsi Cadwaladr	IPFR Team, Planning Dept, Glan Clwyd	IPFR.BCUHB@wales.nhs.uk
	Hospital, Sarn Lane, Bodelwyddan LL18 5UJ	Fax: 01745 448211
		Tel: 01745 448788 x7930
Cardiff & Vale	Cardiff and Vale IPFR, Commissioning	CAV.Irt@wales.nhs.uk
	Team, Public Health Division, 1 <sup>st</sup> Floor,	Fax: 02912 832117
	Global Link, Dunleavy Drive, Cardiff,	Tel: 02921832101
	CF11 0SN	
Cwm Taf	PAR Team, Cwm Taf Health Board,	Cwmtaf.IPFR@wales.nhs.uk
	Ynysmeurig House, Navigation Park,	Fax: 01443 744889
	Abercynon, CF45 4SN	Tel: 01443 744821
Hywel Dda	PAR Team, Hywel Dda Health Board,	karen.thomas20@wales.nhs.uk
	Headquarters, Merlins Court, Winch Lane,	Fax: 01437 771272
	Haverfordwest, Pembrokeshire. SA61 1SB	Tel: 01437 771237
Powys	PAR Team, Powys Teaching Health Board,	alison.howells4@wales.nhs.uk
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	Brecon, Powys. LD3 0HG	Tel: 01874 712681
Welsh Health Specialised	PAR Team, Welsh Health Specialised	WHSSC.IPC@wales.nhs.uk
Services Committee	Services Committee (WHSSC), Unit 3a,	Fax: 02920 869534
(WHSSC)	Caerphilly Business Park. CF83 3ED	Tel: 01443 443 443 ext 8123

#### **Reimbursement Form Guidance Notes**

This form is to claim reimbursement of:

- \* **Approved prior approval applications** once treatment is completed. This needs to be done within six months of the date of approval of treatment. If you do not submit your claim for reimbursement before this deadline a new application may have to be submitted;
- \* **Retrospective claims** where prior approval was not required to be sought and the patient meets the entitlement criteria. This needs to be done within three months of treatment completion/discharge.

Please note that the Health Board will only reimburse according to the modality that normally would have been applied in the host system (please see Section 6 of the "All Wales Procedure for Welsh Patients Accessing Treatment in Countries of the European Economic Area").

Please ensure that you have filled in the form clearly and as fully as possible; not every question needs to be answered for every case but please put 'not applicable' rather than leaving a section blank.

**Section 1** – This section is to assist the Health Board in establishing the entitlement of the patient using their residency and to provide the patients contact details.

**Section 2** – Provides confirmation of the treatment received in respect of an approved prior approval application (to validate what was approved against what is actually being received) and in the case of retrospective reimbursement to provide detail of the treatment/surgery received.

**Section 3** – This section provides the clinical contact information where the Health Board can obtain further information to understand local clinical thresholds for treatment.

**Section 4** – This sets out the detail of where the treatment/surgery was provided and a breakdown of the costs incurred.

**Section 5** – This section requires a breakdown of the costs incurred for treatment and any other costs for which you may be entitled to be reimbursement.

**Section 6** – Patient declaration for reimbursement, signature and date on completion of form.

If you would like our help to complete this form please contact the PAR Team on: 02921 832101.