



NHS WALES POLICY MAKING DECISIONS ON INDIVIDUAL PATIENT FUNDING REQUESTS (IPFR)

Reference Number	Policy Reference (as per individual Health Board)	Version Number	V9 FINAL November 2023
Linked Documents	Health Board Policies on Interventions Not Normally Undertaken (INNU)		

Classification of Document: Clinical Policy

Area for Circulation: Health Boards and Primary Care providers across Wales

Welsh Health Specialised Services Committee (WHSSC)
Public Health Wales (PHW)
Public Domain via Internet Sites

Policy Development: All Wales IPFR Policy Implementation Group

Consultation: Legal Advice from TBC
NHS Wales Medical Directors
Stakeholder groups

Approved: 17 April 2024

Date of Publication: 01 June 2024

Date of Next Review 01 June 2026

Lead Health Board Contact: Contact details as per individual Health Board

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1 INTRODUCTION

1.1 Background

In 2010, the Director General, Health and Social Services, Chief Executive, NHS Wales requested that Health Boards would work together with the Welsh Health Specialised Services Committee (WHSSC) and Public Health Wales (PHW) to develop an All-Wales policy and standard documentation for dealing with individual patient funding requests (IPFR) for treatment. This policy has been in place since September 2011.

1.1.1 In October 2013, The Minister for Health and Social Services announced a review of the IPFR process in Wales. An independent review group was established to explore how the current process could be strengthened.

1.1.2 In April 2014, the "Review of the IPFR process" report was published. The report concluded that the IPFR process in Wales is comprehensive and supports rational, evidence-based decision making for medicine and non-medicine technologies which are not routinely available in Wales. The review group also made a number of recommendations to strengthen the IPFR process.

1.1.3 In September 2016, following the 2014 review and implementation of its recommendations, the Cabinet Secretary for Health, Well-being, and Sport agreed the time was right for a new, independent review of the IPFR process. The panel would be independent of the Welsh Government and encompass a range of expertise and knowledge.

The "Independent Review of the Individual Patient Funding Requests Process in Wales" report was published in January 2017.

1.1.4 Following a Judicial Review in December 2021, the Welsh Government in July 2022 agreed that a specific and limited review would be undertaken to put beyond doubt how the policy should be interpreted.

1.2 Purpose of this Policy

1.2.1 To ensure an open, transparent, fair, clearly understood and easily accessible process is followed, the NHS in Wales has introduced this Policy on decision making for IPFR's. It describes both the principles underpinning how decisions are made to approve or decline individual patient requests for funding and the process for making them.

1.2.2 Continuing advances in technology, changing populations, better information and increasing public and professional expectations all mean that NHS Health Boards have to agree their service priorities for the application of their financial and human resources. Agreeing these priorities is a complex activity based on sound research evidence where available, sometimes coupled with value judgments. It is therefore important to be open and clear about the availability of healthcare treatments on the NHS and how decisions on what should be funded by the NHS are made.

1.2.3 A comprehensive range of NHS healthcare services are routinely provided locally by primary care services and hospitals across 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 specialist and highly specialist services at a national level. However, each year, requests are received for healthcare that falls outside this agreed range of services. We refer to these as Individual Patient Funding Requests (IPFR).

1.2.4 Each Health Board in Wales has a separate Policy called 'Interventions Not Normally Undertaken' (INNU) setting out a list of healthcare treatments that are not normally available on the NHS in Wales. This is because:

- There is currently insufficient evidence of clinical and/or cost effectiveness; and/or
- The intervention has not been reviewed for the indication under consideration by the National Institute for Health and Care Excellence (NICE) or the All-Wales Medicines Strategy Group (AWMSG); and/or One Wales Medicines process or Health Technology Wales.
- The intervention is considered to be of relatively low priority for NHS resources.

1.2.5 The INNU policy should be read together with this policy on making decisions.

1.2.6 The challenge for all Health Boards and WHSSC is to strike the right balance between providing services that meet the needs of the majority of the population in the geographical area for which it is then given responsibility, whilst having in place arrangements that enable it to accommodate people's individual needs. Key to this is having in place a comprehensive range of policies and schedule of services that the Health Board and/or WHSSC has decided to fund to meet local need within the resource available. To manage this aspect of the Health Board and WHSSC's responsibilities, there will always need to be in place a robust process for considering requests for individual patient funding within the overall priority setting framework. Demand for NHS services is always likely to exceed the resources available and, as a result, making decisions on IPFR are some of the most difficult a Health Board or WHSSC will have to make.

1.2.7 In line with the requirements of the Equality Act 2010 and the Welsh Government guidance 'Inclusive Policy Making' issued in May 2010, a detailed equality impact assessment has been completed to assess the relationship between this policy and the duties of the Act.

1.3 Explaining Individual Patient Funding Requests (IPFR)

1.3.1 IPFRs are defined as requests to a Health Board or WHSSC to fund NHS healthcare for individual patients who fall outside the range of services and treatments that a Health Board or WHSSC has arranged to routinely provide, or commission. This can include a request for any type of healthcare including a specific service, treatment, medicine, device or piece of equipment.

Such a request will normally be within one of the three following categories;

- a patient and NHS clinician have agreed together that they would like a treatment that is either new, novel, developing or unproven and is not within the Health Board's routine schedule of services and treatments (for example, a request to use a cancer drug that has yet to be approved by the Health Board for use in that particular condition);
- a patient and NHS clinician have agreed together that they would like a treatment that is provided by the Health Board in certain clinical circumstances but is not eligible in accordance with the clinical policy criteria for that treatment (for example, a request for treatment for varicose veins for cosmetic reasons alone);
- a patient has a rare or specialist condition that falls within the service remit of the WHSSC but is not eligible in accordance with the clinical policy criteria for treatment (for example, a request for plastic surgery where the indication is personal preference rather than medical need).

1.3.2 IPFRs should not be confused with requests for packages of care for patients with complex continuing healthcare needs – these are covered by separate Continuing Healthcare arrangements. Further information can be obtained from the Health Board's Nursing Department.

1.3.3 IPFRs should also not be confused with treatments that have already been provided or administered. Requests **will not** be considered for retrospective funding.

1.3.4 If the clinical circumstances for the specific individual patient have changed, an IPFR application form describing / explaining / justifying:

- i. why the patient is likely to gain a significant clinical benefit from the proposed intervention; and
- ii. demonstrating that the value for money of the intervention for that particular patient is likely to be reasonable,

then a case may be submitted to the Health Board or WHSSC for consideration for further prospective funding. For example, if a patient funds a treatment themselves and their clinician believes they can demonstrate that the patient has gained significantly more clinical benefit from the intervention than would normally be expected for that treatment, an IPFR can be submitted for consideration.

1.3.5 The three categories of treatment described in 1.3.1 will only potentially be funded in specific clinical circumstances. It is important to note that the NHS in Wales does not operate a blanket ban for any element of NHS healthcare but equally the granting of funding in one case does not mean that funding will be provided for the same treatment for other patients. We will consider each IPFR on its individual merits and in accordance with the arrangements set out in this policy. We will determine if the patient should receive funding based on the significant clinical benefit expected from the treatment and whether the cost of the treatment is in balance with the expected clinical benefits.

1.3.6 In this policy, the words "significantly different to the general population of

patients” means that the patient’s condition does not have substantially the same characteristics as other members of that population. For a patient to be significantly different, their particular clinical presentation is unlikely to have been considered as being part of the population for which the policy was made.

- 1.3.7** In practice, it is not always practical to determine the “benefit” of an intervention in numerical terms in the same way, for example as NICE or the AWMSG. In these situations, a description of the benefit should be used to enable IPFR panels to compare the description of the incremental clinical benefit likely to be obtained. In general, the clinician should compare the benefits of the intervention being requested with what he or she considers to be the next best alternative, which may in some cases be best supportive care.
- 1.3.8** Whether an intervention provides “value for money” is assessed conceptually in terms of the incremental cost per incremental quality-adjusted life year (QALY) of benefit. Whilst “reasonable” value for money is to be interpreted in the same way that “cost-effective” is used in the Health Technology Appraisal (HTA) process operated by NICE and AWMSG.
- 1.3.9** Recognising that it can never be possible to anticipate all unusual or unexpected circumstances this policy aims to establish a clear guide to making decisions on IPFRs to determine whether the evidence that the patient is likely to gain a significant clinical benefit, and the value for money of the intervention for that particular patient is likely to be reasonable, has been presented.

Please refer to the decision-making guidance in Appendix 1 to see how panel members determine the significant clinical benefit expected by the treatment, and whether the cost of the treatment is in balance with the expected benefits.

2 THE LEGAL CONTEXT OF THIS POLICY

- 2.1** Health Boards exercise functions delegated to them by the Welsh Ministers under various statutes and in particular under the National Health Service (Wales) Act 2006 and under secondary legislation made under that Act.
- 2.2** In addition to specific statutory obligations, Health Boards are public bodies, which are required to comply with their legal obligations to act in accordance with the rights of individuals under the European Convention of Human Rights as defined in the Human Rights Act 1998 and under common law.
- 2.3** Health Boards must therefore be able to demonstrate that their decisions are within their powers and comply with their legal obligations. In terms of the exercise of their powers, they must show that they have taken into account all relevant issues in the decision-making process, giving them appropriate weight and that those decisions are rational, logical, lawful and proportionate.

Careful consideration needs to be given in relation to all decisions; particular care may need to be given in the following circumstances:

- when evidence is not clear or conclusive;
- when the issue is controversial and may not have the support of NICE, AWMSG, One Wales or HTW;
- when life or death decisions are involved;
- when limiting access to specific services or treatments;
- when setting priorities;
- When other Health Boards or WHSSC may have used their discretion to make a different decision on a specific topic.

2.4 It is lawful for WHSSC and Health Boards to adopt policies about which treatments will, and which will not, be routinely funded. It is also lawful for WHSCC and Health Boards to adopt this Policy to define the circumstances in which a decision can be made to fund an intervention for a patient where other patients are lawfully denied funding for the same intervention as a result of policies or as a result of an absence of a policy approving funding for that intervention.

2.5 Consistency in policy and approach, together with clarity about clinical criteria for treatment and a consistent approach to dealing with IPFR requests should reduce the need for patients to have to go through a review or appeal process at any level. This should be the desirable outcome as far as it is possible.

3 PRINCIPLES UNDERPINNING THIS POLICY

The principles underpinning this policy and the decision making of the Health Board are divided into five areas - the NHS Core Values, the Prudent Healthcare Principles, Evidence-based Considerations, Ethical Considerations and Economic Considerations.

3.1 NHS Core Values are set out by the Welsh Government as;

- Putting quality and safety above all else: providing high value evidence-based care for our patients at all times;
- Integrating improvement into everyday working and eliminating harm, variation and waste;
- Focusing on prevention, health improvement and inequality as key to sustainable development, wellness and wellbeing for future generations of the people of Wales;
- Working in true partnerships with partner organisations and with our staff; and
- Investing in our staff through training and development, enabling them to influence decisions and providing them with the tools, systems, and environment to work safely and effectively.

3.2 Prudent Healthcare Principles

- Achieve health and wellbeing with the public, patients and professionals as equal partners through co-production;
- Care for those with the greatest needs first, making the most effective use of all skills and resources;
- Do only what is needed, no more, no less; and do not harm;
- Reduce inappropriate variation using evidence-based practices consistently and transparently.

3.3 Evidence-Based Considerations

- 3.3.1** Evidence-based practice is about making decisions using quality information, where possible, and recognising areas where evidence is weak. It involves a systematic approach to searching for and critically appraising that evidence.
- 3.3.2** The purpose of taking an evidence-based approach is to ensure that the best possible care is available to provide interventions that are sufficiently clinically effective to justify their cost and to reduce inappropriate variation using evidence-based practices consistently and transparently. NICE issue Technology Appraisals and the All-Wales Medicines Strategy Group, One Wales and Health Technology Wales issue guidance which Health Boards and WHSSC are required to follow.
- 3.3.3** Additionally, a central repository for evidence-based appraisals is available which provides support for clinicians making an application. This is located on the shared database. Users are able to upload and access the information available which will continue to be developed over time as evidence /new reports are produced.
- 3.3.4** It is also important to acknowledge that in decision making there is not always an automatic "right" answer that can be scientifically reached. A "reasonable" answer or decision therefore has to be reached, though there may be a range of potentially reasonable decisions. This decision is a compromise based on a balance between different value judgements and scientific (evidence-based) input. Those vested with executive authority have to be able to justify, defend and corporately "live with" such decisions.

3.4 Ethical Considerations

- 3.4.1** Health Boards and WHSSC are faced with the ethical challenge of meeting the needs of individuals within the resources available and meeting their responsibility to ensure justice in the allocation of these resources ('distributive justice'). They are expected to respect each individual as a person in his or her own right.
- 3.4.2** Resources available for healthcare interventions are finite, so there is a limit to what Health Boards and WHSSC can routinely fund. That limitation is reasonable providing it is fair, and not arbitrary. It must be based on the evidence both about the effectiveness of those interventions and their cost. A cost-effective intervention is one that confers a great enough benefit to justify its cost. That means policies must be based on research, but research is carried out in populations of patients, rather than individual patients. That leaves open the possibility that what is true for patients in general is not true about a specific individual patient. Fairness therefore also requires that there must be a mechanism for recognising when an individual patient will benefit from a particular intervention more than the general population of patients would. Identifying such patients is the purpose of the IPFR process.

- 3.4.3** Welsh Government communications set out six ethical principles for NHS organisations and these underpin this policy. They are:
- treating populations and particular people with respect;
 - minimising the harm that an illness or health condition could cause;
 - fairness;
 - working together;
 - keeping things in proportion; and
 - flexibility

3.5 Economic Considerations

- 3.5.1** It is a matter for Health Boards and WHSSC to use its discretion to decide how it should best allocate its resources. Such resources are finite and difficult balancing decisions have to be made. Health Boards and WHSSC must prioritise the services that can be provided whilst delivering high-quality, cost-effective services that actively avoid ineffective, harmful, or wasteful care that is of limited benefit. The opportunity cost associated with each decision has also to be acknowledged i.e., the alternative uses to which resources could be put.

4 MAKING DECISIONS ON IPFR

- 4.1** In line with the principles set out earlier in this document, Welsh Government communications set out the key factors for 'good decision making'. These are:
- openness and transparency.
 - inclusiveness.
 - accountability.
 - reasonableness.
 - effectiveness and efficiency.
 - exercising duty of care.
 - lawful decision making; and
 - the right to challenge and appeal

This policy aims to ensure that the Health Board and WHSSC has a clear and open mechanism for making decisions that are fair, open, and transparent. It enables those responsible for decision making to demonstrate that they have followed due process, given full consideration to the above factors, and has been both rigorous and fair in arriving at their decisions. It also provides a clear process for challenge and appeal.

- 4.2** In accordance with Welsh Government communications, NICE definitions, and the criteria set out in this policy, Health Boards and WHSSC should make decisions on IPFRs based on; the evidence presented to demonstrate the expected significant clinical benefit, and the evidence presented outlining the patient's individual clinical circumstances. Decisions should be undertaken whilst taking into reasonable account the evidence base, and the economic and ethical factors below:
- **evidence-based considerations** – clinical and cost effectiveness; service and policy implications.
 - **economic considerations** – opportunity cost; resources available; and
 - **ethical considerations** – population and individual impact; values and principles; ethical issues.

Non-clinical factors (such as employment status) will not be considered when making decisions on IPFR.

This Policy does not cover healthcare travel costs. Information on patient eligibility for healthcare travel costs to receive NHS treatment under the care of a consultant can be found on the Welsh Governments 'healthcare costs' website.

- 4.3** The following criteria must be used by all Health Board and WHSSC IPFR Panels when making IPFR decisions. It is the responsibility of the referring clinician to ensure that sufficient information is placed before the panel to allow the panel to be able to determine whether the criteria are satisfied.

A patient will only be entitled to NHS funding for the requested intervention or drug if the panel conclude that the criteria under **either (a) or (b)** below are satisfied:

(a) If guidelines (e.g. from NICE or AWMSG) recommend NOT to use the intervention/drug, or the clinical access criteria of an applicable policy are not met:

- I. The clinician must demonstrate that the patient's clinical circumstances are significantly different to other patients for whom the recommendation is not to use the intervention;
- II. The clinician can demonstrate that the patient is likely to gain significantly more clinical benefit from the intervention than would normally be expected from patients for whom the recommendation is not to use the intervention, and
- III. The IPFR panel must be satisfied that the value for money of the intervention for that particular patient is likely to be reasonable.

(b) If the intervention has NOT been appraised (e.g. in the case of medicines, by AWMSG or NICE), and there is no applicable policy in place:

- I. The clinician can demonstrate that the patient is likely to gain significant clinical benefit, and
- II. The IPFR panel must be satisfied that the value for money of the intervention for that particular patient is likely to be reasonable.

- 4.4** An IPFR panel is required to decide whether the application fulfils Part A or Part B and then consider the application against the relevant criteria. A panel may only approve applications which meet all of the applicable criteria above. It is however the responsibility of the requesting clinician to demonstrate the clinical case for the patient in respect of the criteria outlined.

4.5 Considerations under Part A

4.5.1 Where a recommendation has been made not to use an intervention, the panel is required to consider whether the patients' clinical circumstances are significantly different to other patients for whom the recommendation is made not to use the intervention'. That process will usually require a comparison between the patient for whom treatment is being requested, and other patients with the same medical condition who could have been offered the requested intervention if the relevant guidance and/or applicable policy allowed.

4.5.2 The panel next need to consider whether there is a significant difference between the clinical circumstances of the patient for whom funding is being requested, and the comparator group, and whether the patient is likely to gain significantly more clinical benefit from the intervention than would normally be expected for patients for whom the recommendation has been made not to use the intervention. If, but only if, both of these criteria are met on the facts of an individual Part A case, the panel will then consider whether the intervention is deemed value for money as described at paragraph 4.7 below.

4.6 Considerations under Part B

4.6.1 In the absence of any appraisal or applicable policy, the panel need to consider whether the referring clinician has provided sufficient evidence to conclude that the patient is likely to gain significant clinical benefit from the intervention requested. If, but only if, both of these criteria are met on the facts of an individual Part B case, the panel will then consider whether the intervention is deemed value for money as described below.

4.7 Value for money

4.7.1 The assessment as to whether the intervention provides "value for money" is a matter of judgement for the panel. The panel should reach a decision exercising its broad discretion to decide whether the value for money of an intervention for a particular patient is likely to be reasonable.

4.7.2 The panel should consider the likely overall costs to the NHS of the requested intervention compared with the next best alternative treatment that is routinely funded on the NHS. The panel should in a similar way consider the overall benefit (effectiveness) of the intervention compared with the next best alternative treatment that is routinely funded on the NHS. If the requested intervention is estimated to be more effective and less costly (than the alternative treatment) then it is likely to represent value for money. If the treatment is less effective and more expensive, then it is unlikely to be deemed value for money. If the treatment is more effective and more costly or less effective and less costly then the panel will need to make a judgement as to whether the treatment is likely to represent value for money. For any scenario, other factors may affect treatment choice, and these should be documented as part of the discussion.

4.7.3 Where presented as part of the evidence, an incremental cost effectiveness ratio (“ICER”) and quality- adjusted life year (QALY) may be considered by the panel provided this is relevant to the individual case and there is appropriate expertise by the group to do so. When assessing this evidence, the panel should consider relevant thresholds in relation to NICE and AWMSG when considering if the intervention is a cost-effective option.

4.8 When making decisions, the panel are entitled to have regard to the factors set out at Appendix 1 to this policy, if the panel consider that addressing those issues may assist the panel in coming to decisions on the criteria set out at paragraph 4.3 above. The panel are not obliged to consider all the factors set out Appendix 1 to this policy and may consider that some of the factors are not relevant on the facts of an individual case or do not assist the panel in coming to its decision on those criteria.

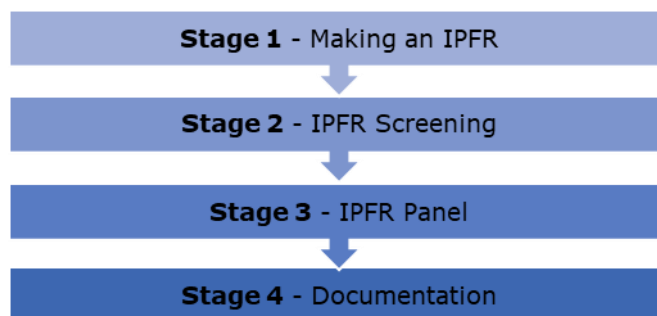
5 HOW TO MAKE A REQUEST FOR FUNDING UNDER THIS POLICY

5.1 Information on how to make an IPFR

A patient leaflet is available explaining how an individual patient funding request (IPFR) can be made. These can be downloaded from the Health Board, WHSSC or AWTTTC website. Further information can be obtained from the IPFR Co-ordinator.

Copies of this policy and the IPFR application forms can also be obtained via the website, or by contacting the IPFR Co-ordinator.

5.2 Summary of the IPFR Process



5.3 Stage 1 Making an IPFR

The patient and their NHS clinician (agree together that a request should be made). The IPFR application form is completed by the clinician on the patient’s behalf. This will ensure that adequate clinical information is provided to aid the decision-making process.

The requesting clinician must sign the application form to indicate that the patient is aware and agrees with the submission of the request. In doing so, the clinician is providing confirmation that the patient is fully informed of the treatment request and all its associated implications.

Ideally, applications for specialised and tertiary services should be completed by the patient's secondary care clinician, unless extenuating circumstances dictate otherwise. This is to ensure that all pertinent information is included in the form thereby avoiding the delay that will arise from the need to request further information before the application can be processed. All IPFR applications should demonstrate support from the relevant clinical lead, head of department or multi-disciplinary team (MDT). Where relevant, advice may also be sought from the internal clinical team.

It is necessary for clinicians to provide their contact details as there may be times when additional clinical information is required during a panel meeting to aid a decision.

The application form is sent to the IPFR Co-ordinator electronically or in hard copy so that the authorised consent of the clinician is recorded.

The IPFR application form must be completed in full to enable the IPFR Panel to reach a fully informed decision.

Should the IPFR Co-ordinator receive an application form which has not been completed sufficiently enough to determine whether or not the request can be screened out or taken to the IPFR Panel, or the incorrect form is completed, the form should be returned to the requesting clinician **within three working days**.

The requesting clinician is responsible for completing and re-submitting the application form **within ten working days**. Should this time elapse, a chaser letter will be sent providing a **further ten working days** to make a submission.

Where the information has still not been provided in the time set, the case shall be closed, and the requesting clinician notified accordingly.

5.4 Stage 2 Screening of the IPFR

The IPFR application will be considered by the IPFR Senior Officer to determine whether the application needs to be screened out because:

- (a) the request meets pre-agreed criteria for a service already commissioned/provided and can be automatically funded
- (b) an alternative and satisfactory clinical solution is found
- (c) the request represents a service development which needs to be passed to the relevant Division or Director for their action.

The IPFR Senior Officer should then communicate the outcome of the screening stage to the requesting clinician using a standard letter, **within five working days** of the decision being made. This letter will also include reasons for the decision and information on any further courses of action required.

5.5 Stage 3 Considerations by the IPFR Panel

Requests that are not screened out will be considered at a meeting of the IPFR Panel. The IPFR Co-ordinator will ensure that the panel has all of the information needed to reach a decision and will ensure that each case is anonymised before each meeting.

Panels will convene at least once per month in order to ensure that applications are dealt with in a timely manner. The volume and urgency of applications may require panels to meet more frequently as and when required.

The panel will consider each IPFR on its own merits, using the decision-making criteria set out in this policy (see appendix 1). Where possible, they should set out their assessment of the likely incremental clinical benefit and their broad estimate of the likely incremental cost so that their judgements on value for money are clear and transparent. The IPFR Co-ordinator or Senior Officer will complete a record of the panel's discussion on each IPFR, including the decision and a detailed explanation for the reason for that decision.

A standard decision letter should be prepared to communicate the decision to the requesting clinician. Correspondence will also be sent to the patient to inform them that a decision has been made and their clinician will contact them within 5 working days to discuss. If this has not happened, patients are encouraged to contact their clinician.

These letters will be sent **within five working days** of the panel's decision and will also include information on how to request a review of the process where a decision has been made to decline the request.

5.6 Who will sit on the IPFR Panel?

The Health Board will appoint core members of the IPFR Panel which will comprise:

- Executive Public Health Director (or deputy – Public Health Consultant)
- Executive Medical Director (or deputy - Associate/Assistant Medical Director)
- Executive Director of Nursing (or deputy – Assistant Director of Nursing)
- Director of Therapies & Clinical Science (or deputy - Assistant Director of Therapies)
- Director of Pharmacy and / or Chief Pharmacist or deputy; and
- Two lay representatives.

The Chair of the Panel will be selected from the group of core members and must have a clinical background (with the exception of WHSSC – see Terms of Reference at Appendix 3).

Each organisation may also wish to appoint up to a further two Panel members at the discretion of the Chair of the Panel, for example a member of the Ethics Committee, Primary Care Director, or Director of Planning.

Please refer to the Terms of Reference at Appendix 2 and 3 for details of the Health Board and WHSSC IPFR Panel.

5.7 What about clinically urgent cases?

The IPFR Policy and process allows for clinically urgent cases, as deemed by the requesting clinician, to be considered outside of the normal screening and panel processes. In these circumstances, the Chair or Vice Chair of the IPFR panel is authorised to make a decision outside of a full meeting of the panel, within their delegated financial limits. Any such decisions will be made in line with the principles of this policy, taking into account the clinical urgency of the request outlined in the application form by the clinician. Those marked urgent will be considered within 24-48 hours (working days only) as per the application form.

5.8 Can patients and clinicians attend the IPFR Panel?

Patients are not permitted to attend IPFR Panels. The reasons are that it would make the process less fair because it would draw to the attention of panel members characteristics of the individual patient that should not influence their decision-making. The IPFR process is anonymous therefore allowing patients to attend would jeopardise this level of scrutiny. The IPFR Panel will normally reach its decision on the basis of all of the written evidence provided, including the IPFR application form and other documentary evidence which is provided in support. Patients and clinicians are able to supply any written statements they feel should be considered by the Panel. **Any information provided which relates to non-clinical factors will not be considered.** Local Llais teams are able to support patients in making such statements if required.

The IPFR Panel may, at its discretion, request the attendance of any clinician to provide clarification on specific issues and/or request independent expert clinical advice for consideration by the panel at a future date. The Chair of the IPFR Panel, may also contact the referring clinician to get more clarification in respect of an individual referral.

The provision of appropriate evidence to the IPFR Panel will be entirely at the Chair of the IPFR Panels discretion.

5.9 Documentation

The IPFR Co-ordinator will maintain a confidential electronic record of all requests. A separate, confidential hard copy file may also be maintained. This information will be held securely in compliance with Data Protection requirements and with Caldicott Guidance.

The IPFR Administration Team retains a record of the IPFR application and subsequent decision and any outcome data that is provided by the clinician. Data will be retained to help inform future planning requirements by identifying patient cohorts both at a local and national level. Data will also be used for the production of an annual report on IPFR's every year as required

by the Welsh Government. This will not include any identifiable data and will use aggregated data.

In addition, a central repository for clinical evidence will be available and will develop over time as and when new evidence reports are produced / become available.

Any information will be held in line with the NHS Information Governance Retention Policy

6 HOW TO REQUEST A REVIEW OF THE PROCESS

If an IPFR is declined by the panel, a patient and/or their NHS clinician has the right to request information about how the decision was reached. If the patient and their NHS clinician feel the process has not been followed in accordance with this policy, a review hearing can be requested in line with the following:

6.1 The 'review period'

There will be a period of **25 working days** from the date of the decision letter during which they may request a review by the review panel ('the review period'). The letter from the Health Board or WHSSC 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.

6.2 Who can request a review?

A review can be requested either (a) by the original requesting clinician on the patient's behalf or (b) by the patient with the original requesting clinician's support. **The review request form must be completed by the clinician.** Both the patient and their clinician must keep each other informed of progress. This ensures the patient is kept informed at all times, that the clinician/patient relationship is maintained, and review requests are clinically supported. Patients are able to access advocacy support at any stage during this process.

6.3 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 or WHSSC has failed to act fairly and in accordance with the All Wales Policy on Making Decisions on Individual Patient Funding Requests (IPFR).*

Health Boards and WHSSC are 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 or WHSSC 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 or WHSSC has prepared 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 or WHSSC. However, a patient may request a review where the decision is considered to be irrational or so unreasonable that no reasonable Health Board or WHSSC 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 or WHSSC has not exercised its powers correctly.*

Health Boards and WHSSC are public bodies which carry 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 or WHSSC has acted outside its remit or has acted unlawfully in any other way.

6.4 How is a review request lodged?

A review request form should be completed and logged with the IPFR Co-ordinator of the Health Board or WHSSC within the review period. The review request form must include the following information:

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

The review request form should be sent to the IPFR Co-ordinator so that the signatures of both the patient and their clinician are recorded. A scanned version sent electronically will also be acceptable as long as signatures are present.

If the patient signature cannot be obtained in a timely manner or at all, the requesting clinician can sign to indicate that the patient is aware and agrees with the submission of the request. In doing so, the clinician is providing confirmation that the patient is fully informed of the treatment request and all its associated implications.

6.5 Initial scrutiny by the IPFR Senior Officer

The review documents lodged will be scrutinised by the IPFR Senior Officer who will look to see that they contain the necessary information. If the review request does not contain the necessary information or if the review does not appear to the IPFR Senior 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.

The Chair of the review panel may refuse to consider a review that does not include all of the above information.

6.6 What is the timescale for a review to be heard?

The review panel will endeavour to hear a review **within 25 working days** of the request being lodged with the Health Board. The date for hearing any review will be confirmed to the patient and their 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.

6.7 Who will sit on the Review Panel?

The Health Board will appoint members of the review panel. The panel will comprise (see Terms of Reference at Appendix 4 for full details);

- Health Board Independent Board Member – Lay (Chair of the Review Panel)
- Health Board Independent Board Member (with a clinical background)
- Health Board Executive Director, or deputy (with a clinical background)
- Chief Officer of the Community Health Council, or deputy
- Chair of the Local Medical Committee, or deputy
- WHSSC Representative at Director level (where applicable)

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.

6.8 Can new data be submitted to the review panel?

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

6.9 Can patients attend review panel hearings?

At the discretion of the panel, 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 IPFR Panel. Patients and/or their unpaid representatives are able to make their written representations to this IPFR Panel in order for their views to be considered.

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.

6.10 The decision of the review panel hearing

The IPFR Senior Officer will complete a record of the review panel's discussion including the decision and a detailed explanation for the reason for the decision. They will also prepare a standard decision letter to communicate the decisions of the panel to the patient and referring/supporting clinician.

The review panel can either;

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

There is no right to a further review unless new and relevant circumstances emerge. Should a patient be dissatisfied with the way in which the review panel carried out its functions, they are able to make a complaint to the Public Services Ombudsman for Wales.

6.11 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 should be sent **within five working days** of the panel and will also include information on how to make a complaint to the Public Services Ombudsman for Wales www.ombudsman-wales.org.uk.

6.12 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 resides. A WHSSC representative who was not involved in the original panel will become a member of the review panel on these occasions.

The Health Boards IPFR Senior Officer will be present at these review hearings to advise on proceedings as per their governance role. In the interests of transparency, and not to confuse the applicant, the WHSSC Senior IPFR Officer will be responsible for circulating the review documentation to review panel members, clerking the hearing, and preparing the standard decision letter to communicate the decision of the review panel to the patient and clinician.

7 QUALITY ASSURANCE

The IPFR Quality Assurance Advisory Group was established in 2017 to monitor and support all IPFR panels to promote quality in decision making and consistency across Wales. The Group meets quarterly to assess anonymised random sample IPFR reports in relation to their completeness, timeliness, and efficiency of communication in line with the NHS Wales IPFR policy process.

8 REVIEW OF THIS POLICY

8.1 This Policy should be reviewed every 3 years or as required to reflect changes in legislation or guidance. The review will be undertaken by the All-Wales IPFR Policy Implementation Group. Any changes made will be undertaken in line with the groups Terms of Reference (see appendix 5) and authorised by the responsible Health Board and WHSSC Committee. Any delay in conducting a review will not prevent WHSCC or a Health Board from being able to rely on this policy.

8.2 Any of the following circumstances will trigger an immediate review of the linked INNU Policy:

- an exemption to a treatment policy criterion has been agreed.
- new scientific evidence of effectiveness is published for all patients or sub-groups.
- old scientific evidence has been re-analysed and published suggesting previous opinion on effectiveness is incorrect.
- evidence of increased cost effectiveness is produced.
- NHS treatment would be provided in all (or almost all) other parts of the UK.
- A National Service Framework recommends care.

9 MAKING A COMPLAINT

9.1 Making an IPFR does not conflict with a patient's ability to make a complaint through the Health Boards or WHSSC's Putting Things Right process, details of which can be found on their website.

9.2 If it is not possible to resolve a concern through local resolution the person raising the concern can refer the matter to the Public Services Ombudsman for

Wales (PSOW). Further information is available on the Ombudsman’s website www.ombudsman-wales.org.uk.

Patients are able to access advocacy support at any stage during this process.

APPENDIX 1: DECISION MAKING GUIDE

This Guide cannot change the meaning of the criteria under paragraph 4.3 of the Policy and may not be relevant to each individual case.

IPFR Panel Decision-Making Factors	IPFR Panel Evidence for Consideration in Decision-Making
SIGNIFICANT CLINICAL BENEFIT	
<p>Is the clinical presentation of the patient’s condition significantly different in characteristics to other members of that population? And Does this presentation mean that the patient will derive a greater clinical benefit from the treatment than other patients with the same condition at the same stage?</p>	<p>Consider the evidence supplied in the application that describes the specific clinical circumstances of the IPFR:</p> <ul style="list-style-type: none"> • What is the clinical presentation of this patient? • Is evidence supplied to explain why the clinical presentation of this patient is significantly different to that expected for this disease and this stage of the disease? • Is evidence supplied to explain why the clinical presentation means that the patient will gain a significantly greater clinical benefit from the treatment than another patient with the same disease at the same stage?
EVIDENCE BASED CONSIDERATIONS	
<p>Does the treatment work? What is the evidence base for clinical and cost effectiveness?</p>	<p>Consider the evidence supplied in the application, and supplementary evidence (where applicable) supplied by professional advisors to the Panel:</p> <ul style="list-style-type: none"> • What does NICE recommend or advise? • What does the AWMSG recommend or advise? • What does the Scottish Medicines Consortium recommend or advise? • What does Public Health Wales advise? • Is there advice available from the One Wales Medicines process or Health Technology Wales? • Is there peer reviewed clinical journal publications available? • What information does the locally produced evidence summary provide? • Is there evidence from clinical practice or local clinical consensus? • Has the rarity of the disease been considered in terms of the ability for there to be comprehensive evidence base available? • Does the decision indicate a need to consider policy or service change? If so, refer to service change processes.
ECONOMIC CONSIDERATIONS	
<p>Is it a reasonable cost? What is the cost of the treatment and is the cost of the treatment likely to be reasonable? i.e. Is the cost of the treatment in balance with the expected clinical benefits?</p>	<p>Consider the evidence supplied in the application, and supplementary evidence (where applicable) supplied by professional advisors to the Panel:</p> <ul style="list-style-type: none"> • What is the specific cost of the treatment for this patient? • What is the cost of this treatment when compared to the alternative treatment they will receive if the IPFR is declined? • Has the concept of proportionality been considered? (Striking a balance between the rights of the individual and the impact on the wider community), in line with Prudent Healthcare Principles. • Is the treatment reasonable value for money?
ETHICAL CONSIDERATIONS	

<p>How has the decision been reached? Is the decision a compromise based on a balance between the evidence-based input and a value judgement?</p>	<p>Having considered the evidence base and the cost of the treatment requested, are there any ethical considerations that have not been raised in the discussions?</p> <ul style="list-style-type: none"> • Is the evidence base sufficient to support a decision? • Is the evidence and analysis of the cost sufficient to support a decision? • Will the decision be made on the basis of limited evidence and a value judgement? If so, have you considered the values and principles and the ethical framework set out in the policy? • Have non-clinical factors been excluded from the decision? • Has a reasonable answer been reached based on the evidence and a value judgement after considering the values and principles that underpin NHS care?
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APPENDIX 2

TERMS OF REFERENCE – INDIVIDUAL PATIENT FUNDING REQUEST PANEL (Health Board)

PURPOSE

The Health Boards IPFR Panel is constituted to act as a Committee of the Health Board and holds delegated Health Board authority to consider and make decisions on requests to fund NHS healthcare for patients who fall outside the range of services and treatments that a Health Board has agreed to routinely provide.

The IPFR Panel will normally reach its decision on the basis of all of the written evidence which is provided to it, including the request form itself and any other documentary evidence which is provided in support of the application.

The IPFR Panel may, at its discretion, request the attendance of any clinician to provide clarification on any issue or request independent expert clinical advice for consideration by the Panel at a further date. The provision of appropriate evidence to the Panel will be entirely at the Panel Chair's discretion.

SCHEME OF DELEGATION REPORTING	MEMBERSHIP AND ATTENDANCE
<p>The IPFR Panel cannot make policy/commissioning decisions for the Health Board. Any policy proposals arising from the panels considerations and decision will ultimately be reported to the Health Board's Quality & Patient Safety Committee for ratification.</p> <p>Financial authorisation is as follows:</p> <ul style="list-style-type: none">- The Panel's authorisation limit will be set at the delegated financial limit as per the individual Health Board structure.- Any decisions resulting in a financial cost in excess of this must be reported to the Health Board Chief Executive for budget authorisation.	<ul style="list-style-type: none">• Executive Public Health Director or deputy• Executive Medical Director or deputy• Executive Director of Therapies and Health Science or deputy• Director of Pharmacy and/or Chief Pharmacist or deputy• Executive Director of Nursing or deputy• Two Lay Representatives <p>A further two panel members may be appointed at the discretion of the panel Chair, for example a member of the Ethics Committee, Primary Care Director, or Director of Planning.</p> <p>In Attendance:</p> <ul style="list-style-type: none">• IPFR Co-ordinator• Finance Advisor (if required)• Senior Pharmacist (if required)

PROCEDURAL ARRANGEMENTS

Quorum: Chair or Vice Chair plus 2 panel members with a clinical background.

Meetings: The IPFR Panel will normally be at least once per month, either virtually, face to face or a combination of both.

Urgent Cases: Provision will be made for occasions where decisions may need to be made urgently. In these circumstances, the Chair or Vice Chair

of the IPFR Panel is authorised to make a decision outside of a full meeting of the Panel, within their delegated financial limits.

Recording: The IPFR Co-ordinator will document the meetings to ensure panel discussions and decisions are appropriately recorded.

Training: All Panel members will receive a local induction.

Panel members should have the opportunity to attend a separate annual refresher session to ensure all members maintain the appropriate skills and expertise to function effectively.

Panel Interest: At the start of the meeting members must declare any personal or prejudicial interests relating to the discussions of the panel.

Consensus: IPFR panel members will seek to achieve decisions by consensus where possible. If the panel is equally split the Chair of the Panel will make the final decision

APPENDIX 3

TERMS OF REFERENCE – INDIVIDUAL PATIENT FUNDING REQUEST PANEL (WHSSC)

PURPOSE

The Welsh Health Specialised Services Committee’s IPFR Panel is constituted to act as a Sub Committee of the Welsh Health Specialised Services Committee (the “Joint Committee”) and holds delegated Joint Committee authority to consider and make decisions on requests to fund NHS healthcare for patients who fall outside the range of services and treatments that a Health Board has agreed to routinely provide.

The IPFR Panel will act at all times in accordance with the All-Wales IPFR Policy taking into account the appropriate funding policies agreed by WHSSC.

The IPFR Panel will normally reach its decision on the basis of all of the written evidence which is provided to it, including the request form itself and any other documentary evidence which is provided in support of the application.

The IPFR Panel may, at its discretion, request the attendance of any clinician to provide clarification on any issue or request independent expert clinical advice for consideration by the Panel at a further date. The provision of appropriate evidence to the Panel will be entirely at the Panel Chair’s discretion.

SCHEME OF DELEGATION REPORTING	MEMBERSHIP AND ATTENDANCE
<p>The IPFR Panel cannot make policy/commissioning decisions for the Health Boards. Any policy proposals arising from the Panel’s considerations and decisions will be reported to the WHSSC Management Group and/or Joint Committee for ratification.</p> <p>Financial authorisation is as follows:</p> <p>Individual Patient Packages</p> <p>The WHSSC scheme of delegation states that financial approval is required for individual NHS patient treatment charges outside of LTS’s and SLA’s concerning one off treatment costs exceeding £750,000. Therefore, any approved IPFR treatment exceeding £750,000 needs to be reported to the Joint Committee.</p> <p>Lifetime costs</p> <p>The WHSSC scheme of delegation states that financial approval is</p>	<ul style="list-style-type: none"> • Independent Chair (from open recruitment) • 2 Lay representatives** • Health Board IPFR Panel Chairs from each Health Board or nominated clinical deputy. • 2 Vice Chairs (appointed from within the panel membership) • WHSSC Medical Director or nominated deputy. • WHSSC Director of Nursing or nominated deputy. <p>A further two panel members from the NHS in Wales may be appointed at the discretion of the Chair of the Panel in conjunction with the WHSSC Medical and/or Director of Nursing, for example a member of an ethics committee.</p> <p>In attendance from WHSSC</p> <ul style="list-style-type: none"> • IPFR Co-ordinator • Finance Advisor (if required) • Governance Advisor • Other WHSSC staff as and when required to clarify on policy/commissioning arrangements/evidence evaluation <p>For particularly complex cases the IPFR Panel may invite other individuals with clinical, pharmacy or commissioning expertise and skills, unconnected with the requesting provider to support decision making.</p>

<p>required for individual NHS patient treatment charges outside of LTS's and SLA's for lifetime costs exceeding £100,000,000. Therefore, any approved IPFR exceeding £1,000,000 needs to be reported to the Joint Committee.</p> <p>Any decisions resulting in a financial cost in excess of these limits must be reported to the Managing Director of Specialised and Tertiary Services for authorisation and the relevant Health Board for information and if over £1 million to the Joint Committee for approval or ratification (if a chairs action was undertaken).</p>	
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**** Definition: Not registered as a healthcare professional, either lay (not currently healthcare worker) or lay plus (no healthcare experience ever) (Health Research Authority 2014) will be eligible.**

PROCEDURAL ARRANGEMENTS

Quorum: The Panel will be quorate with 4 of the 7 Health Boards representatives, 3 of which must be clinical, 1 WHSSC Clinical Director or deputy and the Chair or Vice Chair.

Meetings: The IPFR panel will normally be held as a minimum once per month, either virtually, face to face or a combination of both.

Urgent Cases: Provision will be made for occasions where decisions may need to be made urgently.

Where possible, a virtual panel will be held to consider urgent cases. If this is not possible due to the urgency of the request, or availability of panel members, then the Managing Director of Specialised and Tertiary Services with either the Medical Director or Director of Nursing and Quality and the Chair of the WHSSC Panel (or a vice chair) are authorised to make a decision outside of a full meeting of the Panel, within their delegated financial limits, on behalf of the Panel.

Urgent cases will be reported at the next scheduled IPFR panel. An electronic National IPFR database of all cases will be maintained by AWTTTC.

Recording:

The IPFR Co-ordinator will document the meetings to ensure panel discussions and decisions are appropriately recorded.

Training:

All Panel members will receive a local induction programme.

Panel members should have the opportunity to attend a separate annual refresher session to ensure all members maintain the appropriate skills and expertise to function effectively.

Members Interest:

At the start of the meeting members must declare any personal or prejudicial interests relating to the discussions of the panel.

Consensus:

IPFR Panel members will seek to achieve decisions by consensus where possible. If the panel is equally split the Chair of the Panel will make the final decision.

Review of the TOR:

The Terms of Reference of the WHSSC Panel will be reviewed in line with the All Wales IPFR Policy.

APPENDIX 4

TERMS OF REFERENCE – REVIEW PANEL

PURPOSE

The IPFR Review Panel are constituted to act as a Committee of the Health Board and holds delegated Health Board authority to review (in line with the review process outlined in this policy) the decision-making processes of the Individual Patient Funding Request (IPFR) Panel.

The Review Panel may uphold the decision of the IPFR Panel or, if it identifies an issue with the decision-making process, it will refer the issue back to the IPFR Panel for reconsideration.

The Review Panel will normally reach its decision on the basis of all of the written evidence which is provided to it and will not receive any new information.

SCHEME OF DELEGATION REPORTING	MEMBERSHIP AND ATTENDANCE
<p>The Review Panel has delegated authority from the Board to undertake reviews, limited to the purpose set out above.</p> <p>In exceptional circumstances, the Review Panel may also wish to make a recommendation for action to the Board.</p> <p>The action can only be progressed following its ratification by the Board (or by its Chief Executive in urgent matters).</p>	<ul style="list-style-type: none">• Independent Board Member – Lay (Chair of the Review Panel)• Independent Board Member (usually with a clinical background)• Executive Director or deputy (with a clinical background)• Chief Officer, Community Health Council, or deputy• Chairman, Local Medical Committee, or deputy• WHSSC representative at Director level (as required) <p>In Attendance:</p> <ul style="list-style-type: none">• IPFR Senior Officer (governance advisor)• WHSSC IPFR Senior Officer (as required)

PROCEDURAL ARRANGEMENTS

Quorum: As a minimum, the Review Panel must comprise 3 members (one of whom must have a clinical background, one must be an Independent Board Member and one must be a Health Board Officer).

Meetings: As required.

Urgent Cases: It is recognised that provision must be made for occasions where reviews need to be heard urgently and before a full panel can be constituted. In these circumstances, the Health Board's Chair can undertake the review together with a clinical member of the Review

Panel. This ensures both proper accountability of decision making and clinical input.

Recording: The IPFR Senior Officer will clerk the meetings to ensure a proper record of the review discussion and outcome is made.

See detail under section 6.12 on how WHSSC will undertake a review.