ALL WALES POLICY

MAKING DECISIONS ON INDIVIDUAL PATIENT FUNDING REQUESTS (IPFR)

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1.0 INTRODUCTION

Purpose of this Policy

1.1 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 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 services at a national level. The use of the term 'health board' throughout this policy includes WHSSC unless specified otherwise. 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).*

1.3 Each health board in Wales has a separate policy 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 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.

The policy, called 'Interventions not Normally Undertaken' (INNU) should be read together with this policy on making decisions.

1.4 The challenge for all health boards is to strike the right balance between providing services that meet the needs of the majority of the population whilst still being able 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 has decided to fund to meet local need within the resource available. To manage this aspect of the health board'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 will have to make.

1.5 To ensure that we follow an open, transparent, fair, clearly understood and easily accessible process, the NHS in Wales has introduced this policy on decision making. 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.

1.6 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. This equality impact assessment is published alongside the policy.

1.7 IPFR should not be confused with requests for packages of care for patients with complex healthcare needs – these are covered by separate Continuing Healthcare arrangements and you should contact the health board's Nursing Department.

1.8 IPFR should also not be confused with treatments that have already been provided or administered. Requests under this policy cannot usually be considered on a retrospective basis.

1.9 IPFR are defined as requests to an individual health board or WHSSC to fund NHS healthcare for individual patients who fall outside the range of services and treatments that a health board has agreed to routinely provide. 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 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 for use in that particular condition);

- a patient 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);

- 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).

1.10 The three categories of treatment will only potentially be funded in exceptional circumstances. It is important to note that the NHS in Wales does not operate a blanket ban for any element of NHS healthcare. We will consider each IPFR on its individual merits and we will determine if the patient should receive funding, either because they meet agreed policy criteria (where it is available) or on the grounds of exceptionality.

1.11 Exceptional is defined in the Oxford Dictionary as being *"of the nature of or forming an exception: out of the ordinary course, unusual, special".* We understand that it can never be possible to anticipate all unusual or unexpected circumstances and so this policy sets out a clear guide to making decisions on IPFR to determine whether evidence of exceptionality has been presented.

2.0 THE LEGAL CONTEXT OF THIS POLICY

2.1 In accordance with their legal obligations, Local Health Boards must:

(a) act within the terms of the statutory functions delegated to them by the Welsh Ministers under NHS legislation and in particular the NHS (Wales) Act 2006;
(b) make their decisions within the exercise of their statutory duties and powers;
(c) be accountable to the Welsh Government for the decisions they make;

(d) act in accordance with the discretionary powers contained in the NHS (Wales) Act 2006 by providing such comprehensive services which it considers are appropriate to meet the reasonable health needs of all those within its geographical area for which it is responsible and for which there is no charge, save where the legislation and/or regulations specifically permit charges;
(e) provide these comprehensive services within the resources delegated by the Welsh Government;
(f) operate within the governance structure created by the Welsh Government;
(g) act in accordance with the requirement to implement guidance published by the National Institute for Clinical Excellence (NICE) and All Wales Medicines Strategy Group (AWMSG) within three months of the publication date; and
(h) act in accordance with the requirements of the Human Rights Act 1998 and the Equality Act 2010.

2.2 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 and that those decisions are rational, logical and lawful.

This is particularly important:
- when life or death decisions are involved;
- when limiting access to specific services or treatments;
- when setting priorities;
- when evidence is not clear or conclusive;
- when the issue is controversial and may not have the support of NICE or AWMSG;
- when other health boards may have used their discretion to make a different decision on a specific topic.

2.3 It is lawful for the health board to have policies about which treatments will, and which will not, be routinely funded. It is lawful for the health board to adopt an IPFR Policy for the exercise of its discretion and to allow for exceptions to it in exceptional circumstances. [R v North West Lancashire Health Authority Ex Parte A(2000)1WLR 977CA].

2.4 Decisions made by health boards may be subject to legal challenges as to the manner in which their discretion has been exercised. Greater consistency in policy and approach, together with greater clarity over clinical criteria for treatment and a consistent approach to dealing with exceptionality (if working well) 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.

2.5 The increasing trend to challenge decisions may have significant financial consequences (and limit the benefit of any priority decisions taken), may undermine the confidence of the patient in his/her health board and may also cause media criticism.

3.0 UNDERSTANDING LEGAL CHALLENGE

3.1 Patients may choose to claim there has been interference in their rights in accordance with the Articles of the Human Rights Convention set out in the Human Rights Act 1998. The Act means that the Human Rights Convention is directly applied to the UK Courts and the Courts have to take account of the Convention and the decisions of the European Court in the interpretation of any legislation.

3.2 Individuals have the right to bring an action alleging interference with their rights where decisions made by health boards may be shown to have contravened the individual Articles of the Human Rights Convention. When life and death decisions are involved, the courts will submit the decision making processes of the health board to rigorous scrutiny. The more substantial the potential interference with human rights, the more the court will require by way of justification before it is satisfied that the decision is reasonable *[R the application of Colin Ross v West Sussex Primary Care Trust 2008 EWHC 2252 (admin)]*

3.3 Judicial Review is a process within administrative law which enables any individual to challenge the decision made by a public body. Greater levels of dissatisfaction may force some patients (who may be supported by a Registered Charity or Pressure Group) to seek redress for their complaints by way of Judicial Review.

3.4 The process of Judicial Review allows the Court to review decisions on the grounds that they are unlawful, procedurally unfair or unreasonable. The Courts will consider whether there has been an:

- error of law;
- excess of powers;
- irrelevancy;
- irrationality;
- an unlawful limitation of discretion or fettering;
- improper delegation of decision making;
- procedural impropriety contrary to the rules of natural justice; and
- bias.

Reviews have included decisions which unfairly discriminate between patients, blanket policies not to treat particular conditions and decisions not to provide promised services.

3.5 The Court will want to consider whether the decision is beyond the range of responses open to a reasonable decision maker. They will examine the powers of the decision-maker, the requirements of the legislation and the manner in which the decision was reached to determine if the decision-maker acted unreasonably or outside its powers.

3.6 A public body is required to give reasons for its decisions. Since it is the decision making process which the courts will scrutinise, it is imperative that the process for health board decisions is transparent, that the patient is able to access and understand the process and to be aware of the reasons for any decision which has been made.

3.7 In addition, the health board should take into account that, in the light of the Human Rights Act, the concept of “proportionality” may come into play. The concept of proportionality means striking a balance between the demands of the wider community and the need to protect an individual’s fundamental rights. Challenge may occur where the health board has balanced various interests and an individual alleges that the balancing was disproportionate to their rights. In this scenario, the health board would be called upon to explain why it considered the challenged action was necessary and suitable to reach the desired end and why the decision did not impose an excessive burden on the applicant.

3.8 In recent years, we have witnessed an increasing tendency for the Courts to use their powers to scrutinise the lawfulness of the decision making process of public bodies, including Health Boards. Previous examples include the Child B Case, challenges by transsexuals for the performance of cosmetic operations and a series of challenges by patients for funding for treatment with high cost cancer drugs not approved by NICE.

Whilst the Courts will not "second guess" decisions on expenditure/use of resources and substitute their own judgement for that of the health board, they will scrutinise the way the decision has been reached to determine whether it is lawful. In a situation where the Courts consider that there has been a flaw in the decision making process, the Courts can order a health board to think again.

4.0 PRINICIPLES UNDERPINNING THIS POLICY

4.1 The principles underpinning this policy and the decision making of the health board and WHSSC are divided into five areas - the NHS core values, the health board core values, evidence-based considerations, ethical considerations and economic considerations.

4.2 **NHS Core Values** are set out by the Welsh Government (WG) 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;
- 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.

4.3 **Health Board Core Values** match the WG Citizen-Centred Principles for Wales:

- **Putting the Citizen First** Putting the citizen at the heart of everything and focusing on their needs and experiences; making the organisation's purpose the delivery of a high quality service.
- **Living Public Service Values** Being a value-driven organisation, rooted in the principles and high standards of public life and behaviour, including openness, customer service standards, diversity and engaged leadership.
- **Engaging with Others** Working well together to deliver the best services possible.
- **Knowing Who Does What and Why** Making sure that everyone involved in the delivery chain understands each others' roles and responsibilities and how together they can deliver the best possible service.
- **Fostering Innovative Delivery** Being creative and innovative in the delivery of public services – working from evidence and taking managed risks to achieve better services.

- **Being a Learning Organisation** Always learning and improving service delivery.
- **Achieving Value for Money** Looking after taxpayers' resources properly and using them carefully to deliver high quality, efficient services.

4.4 Evidence Based Considerations

4.4.1 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.

4.4.2 The purpose of taking an evidence-based approach is to ensure that the best possible care is available and to provide interventions that are effective at reasonable cost and to move away from interventions which are not. The National Institute for Health and Clinical Excellence (NICE) issue Technology Appraisals and the All Wales Medicines Strategy Group issue guidance which Health Boards are required to follow.

4.4.3 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. 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.

4.5 Ethical Considerations

4.5.1 Health Boards 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.

4.5.2 Welsh Health Circular (2007) 076 sets out 6 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.

4.6 Economic Considerations

4.6.1 It is a matter for the health board 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. The health board has to prioritise the services that can be provided and aim to offer quality, cost effective, best value services that provide the best care possible for the local population. The opportunity cost associated with each decision has also to be acknowledged i.e. the alternative uses to which resources could be put.

5.0 MAKING DECISIONS ON IPFR

5.1 Welsh Health Circular (2007) 076 also sets 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 ensures that the health board has a clear and open mechanism for making decisions that is 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 that they have been both rigorous and fair in arriving at their decisions. It also provides a clear process for challenge and appeal.

5.2 In accordance with Welsh Health Circular (2007) 076, NICE definitions and the criteria set out this policy, the health board will make decisions on IPFR based on the following;

Evidence of exceptionality - consideration of the evidence presented of a patient's individual clinical circumstances and taking into reasonable account the following factors:

- **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.

Social factors (such as employment status) will not be considered when making decisions on IPFR. This is consistent with the recent decision of the Court of Appeal *R (on the application of Alexander Thomas Condliff) and North Staffordshire Primary Care Trust.*

5.3 The following guide will be used by all health boards when making IPFR decisions.

Decision Factor	Points to Consider
EXCEPTIONALITY	Have you considered the specific clinical circumstances of this individual request? Have you explored whether grounds for exceptionality are present?
EVIDENCE BASED CONSIDERATIONS	**Clinical and Cost Effectiveness** What scientific (evidence base) is available? – what does NICE or the AWMSG advise? – what does Public Health Wales advise? – are there peer reviewed clinical journal publications? – is there evidence from clinical practice or local clinical consensus? **Service and Policy Implications** Will your decision result in the need to consider policy or service change? If so, refer this issue to the Individual Patient Screening Group for discussion.
ECONOMIC CONSIDERATIONS	**Resources** What is the cost and have you considered whether the health board can afford this request?
ETHICAL CONSIDERATIONS	**Population & Individual Impact** Have you considered the concept of proportionality? Striking a balance between the demands of the wider community against the need to respect an individual's human rights. Have you considered what the decision will mean for the applicant and the wider community? **Values and Principles** Have you considered the values and principles set out in the policy? - putting quality and safety above all else: providing high value evidence based care - eliminating harm, waste and variation - focusing on prevention, health improvement and inequality as key to sustainable development, wellness and wellbeing for future generations - working in true partnerships - investing in staff through training and development - putting the citizen first - living public service values - engaging with others - knowing who does what and why - fostering innovative delivery - being a learning organisation - achieving value for money Is the decision a compromise based on a balance between the scientific (evidence-based) input and a value judgement? Reaching a reasonable answer on this basis is acceptable. **Ethical Issues** Have you considered the ethical framework set out in WHC 2007 076? – this is: - treating populations and people with respect - minimising the harm that an illness or health condition could cause - fairness - working together - keeping things in proportion - flexibility Have you considered the individual in their own right?

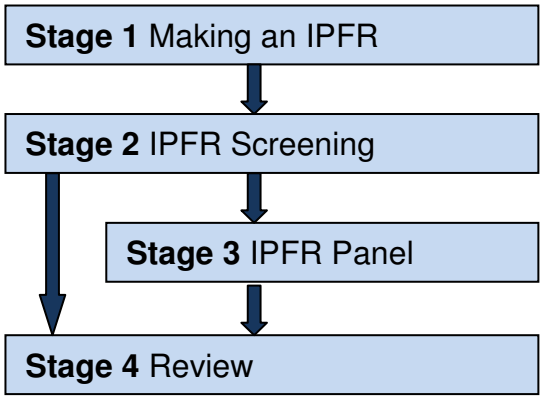
6.0 HOW TO MAKE AN IPFR

6.1 Information on how to make an IPFR

A patient leaflet and a separate leaflet for clinicians explain how an IPFR can be made. These are available for download on the website www.whssc.wales.nhs.uk and also from local libraries and GP surgeries. Further information can be obtained from the IPFR Co-ordinator .

Copies of this policy and the IPFR forms are also available for download from the website, the clinical portal (for clinicians) or by contacting the IPFR Co-ordinator.

6.2 Summary of the IPFR Process



6.3 **Stage 1** Making an IPFR

The patient and their NHS clinician (GP or local hospital consultant or out-of-area hospital consultant) agree together that a request should be made. The standard IPFR form is completed, either by the clinician on the patient's behalf or by the patient with their clinician's support. Patients are able to access advocacy support at any stage during this process to help them make an application.

This form is sent to the IPFR Co-ordinator in hard copy (post or fax) 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 and it is followed up in hard copy.

6.4 **Stage 2** Screening of the IPFR

The IPFR Senior Officer (Manager) will consider the request and determine what can be screened out because:
(a) the request meets pre-agreed criteria and can be automatically funded;
(b) the request matches previous exceptions and precedent has been set;
(c) an alternative and satisfactory solution is found;
(d) the request can be dealt with under existing agreements;
(e) the request represents a service development which needs to be passed to the Individual Patient Screening Group;
(f) the request raises a policy issue where more detailed work is required.

The IPFR Senior Officer (Manager) will then communicate the outcome of the screening stage to the patient and the referring/supporting clinician using a standard

letter, within **10 working days** of the receipt of the request. This letter will also include information on how to request a review of the outcome.

6.5 **Stage 3** Consideration 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 make a decision and will ensure that it is anonymised before each meeting.

This Panel will normally meet at least once per month but may meet more often if required.

The Panel will consider each IPFR on its own merits, using the decision making criteria set out in this policy. The IPFR Co-ordinator or Senior Officer(Manager) will complete a record of the Panel's discussion on each IPFR, including the decision and a detailed explanation for the reason for the decision. They will also prepare standard decision letters to communicate the decisions of the Panel to the patient and referring/supporting clinician. This letter will be sent **within 5 working days** of the Panel and will also include information on how to request a review of the outcome.

6.6 Who will sit on the IPFR Panel?

The health board will appoint core members of the IPFR Panel which will comprise;

- Public Health Director (or deputy – Public Health Consultant with a medical background)
- Medical Director (or deputy - Associate/Assistant Medical Director)
- Director of Therapies & Clinical Science (or deputy - Assistant Director of Therapies)
- Lay Representative nominated by the Community Health Council (or deputy lay representative)

The Chair of the Panel will usually be the Director who holds the executive lead for IPFR in each organisation. This will be either the Public Health Director or the Medical Director.

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, a Senior Pharmacist or Primary Care Director.

Please refer to the Terms of Reference for details of the WHSSC IPFR Panel.

6.7 What about clinically urgent cases?

This process allows for clinically urgent cases, as deemed by the referring/supporting clinician, to be considered outside of the screening and panel process by the Chair of the IPFR Panel. Any such decisions will be made in line with the principles of this policy.

6.8 Can patients and clinicians attend the IPFR Panel?

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. Patients and clinicians are able to supply any written statements they feel should be considered by the Panel. Community Health Councils 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 any issue or request independent expert clinical advice for consideration by the Panel at a further date.

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

6.9 **Stage 4** Request for a Review

A patient can request a review of the IPFR screening outcome and/or the IPFR Panel decision.

If the patient and their referring/supporting clinician agree together that a review request should be made then the standard IPFR Review Form is completed, either by the clinician on the patient's behalf or by the patient with their clinician's support. Patients are able to access advocacy support at any stage during this process to help them make a review application.

This form is sent to the IPFR Co-ordinator in hard copy (post or fax) 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 and it is followed up in hard copy.

The IPFR Co-ordinator will make the arrangements for a Review Hearing to be held and will inform the patient and their referring/supporting clinician of the date of the hearing and the membership of the Review Panel.

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. This letter will also include information on how to make a complaint to the Public Services Ombudsman for Wales.

Section 7 of this Policy explains in detail how the IPFR Review process works.

6.10 Holding IPFR Information

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

Health boards and WHSSC will also log all decisions on a shared database/system to allow the NHS in Wales to identify trends in requests for specific healthcare interventions. This will inform service planning and will not include any patient identifiable information.

7.0 HOW TO REQUEST A REVIEW OF THE DECISION

If an IPFR is declined at the screening stage or by the panel, a patient has the right to ask for this decision to be reviewed in line with the following:

7.1 The 'review period'

There will be a period of **25 working days** from the day the health board or WHSSC's 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.

7.2 Who can request a review?

A review can be requested either (a) by the clinician on the patient's behalf or (b) by the patient with their clinician's support. 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 that review requests are clinically supported.

7.3 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 has failed to act fairly and in accordance with the Policy on Making Decisions on Individual Patient Funding Requests*

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 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. 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 discretion.

7.4 How is a review request lodged?

A review request should be lodged 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 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.

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

7.5 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.

7.6 Who will sit on the Review Panel?

The health board will appoint members of the Review Panel. The Panel will comprise;

- Health Board Independent Board Member – Lay (Chair of the Review Panel)
- Health Board Independent Board Member (with a clinical background)
- Health Board Executive Director (with a clinical background)
- Health Board Chairman
- Chief Officer of the Community Health Council
- Chairman of the Local Medical Committee
- WHSSC Representative (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.

7.7 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. 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.

7.8 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.

7.9 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 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 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.

7.10 The decision of the review hearing

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.

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 way in which the Review Panel carried out its functions, they are able to make a complaint to the Public Services Ombudsman for Wales.

7.11 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 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 **25 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.

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

The health board's IPFR Senior Officer will be present at these review hearings to advise on proceedings as per their governance role. The WHSSC Senior IPFR Officer (Manager) will clerk the hearing.

8.0 REVIEW OF THIS POLICY

8.1 This policy will be reviewed on an annual basis or as required to reflect changes in legislation or guidance.

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

- an exemption to a treatment policy criteria has been agreed;
- new scientific evidence of effectiveness is published for all patients or sub-groups;
- old scientific evidence has been reanalysed 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.

9.0 MAKING A COMPLAINT

9.1 Making an IPFR does not conflict with a patient's ability to make a complaint to the Public Services Ombudsman for Wales. Further information is available on the Ombudsman's website www.ombudsman-wales.org.uk

APPENDIX ONE

TERMS OF REFERENCE IPFR PANEL (Health Board)

PURPOSE

To act as a Committee of the Health Board and hold 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 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.

The 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

The IPFR Panel has delegated authority from the Board to consider requests and make decisions, limited to the purpose set out above.

The IPFR Panel cannot make policy decisions for the health board. Any policy proposals arising from their considerations and decisions will ultimately be reported to the health board Quality and Safety Committee for ratification.

Financial authorisation is as follows:

- the Panel's authorisation limit is set at £125,000
- any decisions resulting in a financial cost in excess of £125,000 must be reported to the Health Board Chief Executive for budget authorisation.

MEMBERSHIP AND ATTENDANCE

- Executive Public Health Director (Chair/ Vice-Chair) or deputy
- Executive Medical Director (Chair / Vice-Chair) or deputy
- Executive Director of Therapies and Clinical Science or deputy
- Lay Representative nominated by the CHC or their deputy

A further two panel members may be appointed at the discretion of the Chair of the Panel, for example a member of the Ethics Committee, a Senior Pharmacist or Primary Care Director.

In Attendance:

- IPFR Senior Officer
- IPFR Co-ordinator
- Finance Advisor

PROCEDURAL ARRANGEMENTS

Quorum: 1 Executive Director (chair or vice-chair) and 2 other panel members.

Meetings: At least once a month with additional meetings held as required and agreed with the Panel Chair.

Urgent Cases: It is recognised that provision must be made for occasions where decisions may need to be made urgently. In these circumstances, the 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 clerk the meetings to ensure proper record sheets of the panel discussions and decisions are made. An electronic database of decisions will also be maintained.

APPENDIX TWO

TERMS OF REFERENCE IPFR PANEL (WHSSC)

PURPOSE

To act as a Sub Committee of the Welsh Health Specialised Services Committee (the Joint Committee) and hold 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 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 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.

The 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**
The IPFR Panel has delegated authority from the Joint Committee to consider requests and make decisions, limited to the purpose set out above. The IPFR Panel cannot make policy decisions for the health board. Any policy proposals arising from their considerations and decisions will be reported to the WHSSC Quality and Safety Committee and or the Joint Committee for ratification. Financial authorisation is as follows: - the Panel's authorisation limit is set at £300,000 for one-off packages and £1million for lifetime packages - any decisions resulting in a financial cost in excess of these limits must be reported to the Director of Specialised and Tertiary Services and the relevant health board for authorisation.	• Independent Chair (who will be from existing members of NHS Organisations Boards) • Lay Representative nominated by the CHC • Nomination at Director level from each of the LHBs A named representative from each of the seven Health Boards who should be a Director or Deputy/Assistant Director. There will be named deputies of appropriate seniority and experience who can operate in the capacity of the primary representative. The intention will be to secure an appropriate balance of professional disciplines to secure an informed multi-disciplinary decision. A further two panel members may be appointed at the discretion of the Chair of the Panel, for example a member of the Ethics Committee or a Senior Pharmacist. These members should come from outside the 7 Health Boards and one of which would be nominated as the vice chair. The Chair of the Panel will review the membership as necessary. **In Attendance from WHSSC** • Medical Director or Deputy • Lead Nurse or Deputy • IPFR Co-ordinator • Finance Advisor • Other WHSSC staff as and when required.

PROCEDURAL ARRANGEMENTS

Quorum: The Chair or Vice-Chair and representation from five of the seven health boards, three of which must be clinical representatives.

Meetings: At least once a month with additional meetings held as required and agreed with the Panel Chair. Video conferencing facilities will be available for all meetings.

WHSSC will be responsible for organising the WHSSC Panel and will provide members with all relevant documentation.

Urgent Cases: It is recognised that provision must 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, then the Director of Specialised and Tertiary Services together with the WHSSC Medical Director or Lead Nurse and the Chair of the WHSSC Panel (or 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.

WHSSC will provide an update of any urgent decisions to the subsequent meeting of the Panel.

Recording: The WHSSC IPFR Co-ordinator will clerk the meetings to ensure proper records of the panel discussions and decisions are made. An electronic database of decisions will also be maintained.

APPENDIX THREE

TERMS OF REFERENCE REVIEW PANEL

PURPOSE

To act as a Committee of the Health Board and hold 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 new information. The Panel may, at its discretion, request the attendance of any clinician to provide clarification on any issue or request independent expert clinical advice to provide clarification on any issue.

SCHEME OF DELEGATION REPORTING	MEMBERSHIP AND ATTENDANCE
The Review Panel has delegated authority from the Board to undertake reviews, limited to the purpose set out above. The full text of the review decision will usually be made available to the Board within 25 days of the review hearing. In exceptional circumstances, the Review Panel may also wish to make a recommendation for action to the Board. The action can only be progressed following its ratification by the Board (or by its Chief Executive in urgent matters).	• Independent Board Member – Lay (Chair of the Review Panel) • Independent Board Member (usually with a clinical background) • Executive Director (with a clinical background) • Health Board Chair • Chief Officer, Community Health Council • Chairman, Local Medical Committee • WHSSC Representative (as required) In Attendance: • 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). It is not appropriate for review panel duties to be deputised.

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. An electronic database of decisions will also be maintained.