



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

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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. The recommendations made can be found at appendix 4.

1.2 Purpose of this Policy

1.2.1 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.

1.2.2 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).

- 1.2.3** 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 Health and Care Excellence (NICE) or the All Wales Medicines Strategy Group (AWMSG); and/or
 - The intervention is considered to be of relatively low priority for NHS resources.
- 1.2.4** The policy, called 'Interventions Not Normally Undertaken' (INNU) should be read together with this policy on making decisions.
- 1.2.5** 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 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 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.
- 1.2.6** 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 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.
- 1.2.7** 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** 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. Further information can be obtained from the Health Board's Nursing Department.
- 1.3.2** IPFR should also not be confused with treatments that have already been provided or administered. Requests **will not** be considered for retrospective funding.

- 1.3.3** 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 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.

- 1.3.4** IPFR 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 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).

- 1.3.5** The three categories of treatment 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. 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 IPFR to determine whether 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 section 6 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** 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, in particular the NHS (Wales) Act 2006 and the secondary legislation that flows from that statute;
 - (b) be accountable to the Welsh Government for the decisions they make;
 - (c) meet the health needs of an individual free of charge, except where the legislation and/or regulations specifically permit charges;
 - (d) provide these comprehensive services within the resources delegated by the Welsh Government;
 - (e) operate within the governance structure created by the Welsh Government;
 - (f) act in accordance with the requirement to implement guidance published by the National Institute for Health and Care Excellence (NICE) and All Wales Medicines Strategy Group (AWMSG) within two months of the final guidance published.

- (g) act in accordance with the requirements of the principles of Administrative Law and all legislation that may be enacted from time to time and which is relevant to the activities of the Health Board; and
- (h) Comply with policies issued by Welsh Government such as Welsh Health Circulars.

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, 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 or AWMSG;
- when life or death decisions are involved;
- when limiting access to specific services or treatments;
- when setting priorities;
- 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 specific clinical circumstances.

2.4 Decisions made by Health Boards may be subject to legal challenge in the High Court. 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 UNDERSTANDING LEGAL CHALLENGE

3.1 One of the grounds which a patient might include in any application they make to the court is the allegation that 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 A public body is required to give reasons for its decisions. Since it is the decision making process which the courts may 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.

3.3 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 even if a particular policy or action which interferes with a Convention right is aimed at pursuing a legitimate aim (for example the prevention of crime) this will not justify the interference if the means used to achieve the aim are excessive in the circumstances. This involves striking a balance between the demands of the wider community and the need to protect an individual’s fundamental rights. Any interference with a Convention right should be carefully designed to meet the objective in question and must not be arbitrary or unfair. 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. If an HB is not sure whether a particular approach would be proportionate, it should seek specialist legal advice before reaching a final decision.

3.4 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. Particularly, 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.

3.5 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.

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

- error of law;
- excess exercise of powers/abuse of power;
- 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;
- Failure to follow its own policy.

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

3.7 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 unlawfully.

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 transgender 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.

3.9 The Courts have shown an increased willingness to “second guess” decisions on expenditure/use of resources and substitute their own judgement for that of a public body, and even if the court does not go that far, it 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 declare the original decision was invalid and order a Health Board to make the decision again.

4 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.

4.1 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 patient’s 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.

4.2 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.

4.3 Evidence-Based Considerations

- 4.3.1** 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.
- 4.3.2** 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 issue guidance which Health Boards are required to follow.
- 4.3.3** Additionally, a central repository for evidence based appraisals will be available which will provide support for clinicians making an application. This will be located on the shared database. Users will be able to upload and access the information available which will develop over time as evidence /new reports are produced.
- 4.3.4** 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.

4.4 Ethical Considerations

- 4.4.1** 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.
- 4.4.2** Resources available for healthcare interventions are finite, so there is a limit to what LHB's 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.

4.4.3 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

4.5 Economic Considerations

4.5.1 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 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.

5 MAKING DECISIONS ON IPFR

5.1 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 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.

5.2 In accordance with Welsh Government communications, NICE definitions, and the criteria set out in this policy, the Health Board 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 Government's 'healthcare costs'](#) website.

5.3 The following guide will be used by all Health Board IPFR Panels when making IPFR decisions.

It is the responsibility of the requesting clinician to demonstrate the clinical case for the individual patient, and of the IPFR panel to consider the wider implications for the NHS, such that the criteria in **either (a) or (b)** below are satisfied:

(a) If guidelines (e.g. from NICE or AWMSG) recommend not to use the intervention/drug;

- I. The clinician must demonstrate that the patient's clinical circumstances are significantly different to the general population of patients for whom the recommendation is not to use the intervention, such that
- 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);

- 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.

6 DECISION MAKING GUIDE

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? • Are 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 a 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 costs for the treatment requested are there 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?

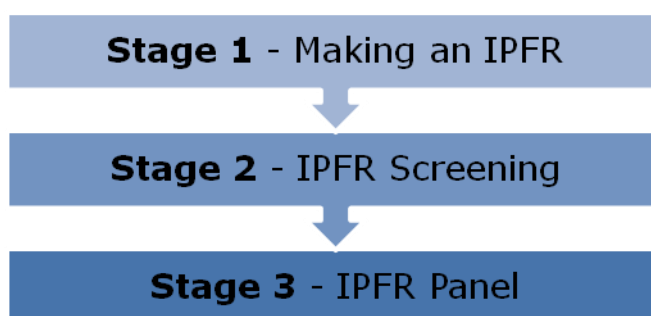
7 HOW TO MAKE A REQUEST FOR FUNDING UNDER THIS POLICY

7.1 Information on how to make an IPFR

A patient leaflet is available explaining how an individual patient funding request (IPFR) can be made. These are available from the hospital consultant, GP surgery or via the Health Board 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.

7.2 Summary of the IPFR Process



7.3 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 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 in hard copy or electronically so that the authorised consent of the clinician is recorded.

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

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.

7.4 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) the request matches previous exceptions and precedent has been set
- (c) an alternative and satisfactory clinical solution is found
- (d) the request represents a service development which needs to be passed to the relevant Division or Director for their action.
- (e) the request raises a policy issue where more detailed work is required

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.

7.5 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 make a decision and will ensure that it 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. 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. 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.

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.

7.6 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 2).

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 1 and 2 for details of the Health Board and WHSSC IPFR Panel.

7.7 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 as per the application form.

7.8 Can patients and clinicians attend the IPFR Panel?

Patients are not permitted to attend IPFR Panels. The reason is 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, such as age and gender. The IPFR Panel will normally reach its decision on the basis of all of the written evidence which is 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.** 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 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.

7.9 Holding IPFR Information

The IPFR Co-ordinator will maintain a confidential electronic record 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.

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.

8 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:

8.1 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 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.

8.2 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.

8.3 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 All Wales Policy on Making Decisions on Individual Patient Funding Requests (IPFR).*

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 not exercised its powers correctly.*

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 the Chief Executive's discretion.

8.4 How is a review request lodged?

A review request form should be completed and logged with the IPFR Co-ordinator of the Health Board 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.

8.5 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.

8.6 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.

8.7 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 6 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.

8.8 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.

8.9 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 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.

8.10 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.

8.11 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.

8.12 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.

8.13 Nothing in this section shall limit or preclude an individual patient's right to bring Judicial Review proceedings if they are unhappy with a decision of the IPFR Panel.

9 REVIEW OF THIS POLICY

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

9.2 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 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.

10 MAKING A COMPLAINT

- 10.1** 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.

11 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	MEMBERSHIP AND ATTENDANCE
<p>The IPFR Panel cannot make policy decisions for the Health Board. Any policy proposals arising from their considerations and decision will ultimately be reported to the Health Board Quality & 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 Senior Officer • 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: 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 of the panel discussions and decisions are made. An electronic database of decisions will also be maintained.

12 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
<p>The IPFR Panel has delegated authority from the Joint Committee to consider requests and make decisions, limited to the purpose set out above.</p> <p>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 Management Group and/or Joint Committee for ratification.</p> <p>Financial authorisation is as follows:</p> <ul style="list-style-type: none"> - 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 	<ul style="list-style-type: none"> • Independent Chair (who will be from existing members of the NHS organisations Boards) • Two Lay representatives • Nomination at Director level from each of the LHBs <p>A named representative from each of the seven Health Boards who should be a Director or Deputy/Assistant Director, or 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.</p> <p>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.</p> <p>In attendance from WHSSC</p> <ul style="list-style-type: none"> • Medical Director or Deputy • Director of Nursing or Deputy • IPFR Co-ordinator • Finance Advisor (if required) • 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 Director of Nursing 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.

13 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 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. An electronic database of decisions will also be maintained.

See detail under section 8.12 of the policy on how WHSSC will undertake a review.

INDEPENDENT REVIEW OF THE IPFR PROCESS IN WALES, January 2017 – LIST OF RECOMMENDATIONS

Recommendation 1

The 2007 ethical framework for commissioning healthcare in Wales should be updated in light of best practice, so that it is useful in making (and explaining) commissioning decisions.

Recommendation 2

Good commissioning practice should be shared between LHBs and WHSSC. A database of commissioning policies should be established, covering all interventions and used by WHSSC and LHBs to record their commissioning policies.

Recommendation 3

LHBs together with WHSSC should set up commissioning liaison meetings to coordinate their “out of area” and “out of county” services.

Recommendation 4

Ways to access interventions – commissioning and other pathways including IPFR – need to be explained more clearly to clinicians and patients. A guidebook should be developed that explains the entire process clearly and simply.

Recommendation 5

A clear and consistent national process for dealing with requests to access services outside LHBs local arrangements (including those of WHSSC) should be developed and communicated. The forms to request services that are routinely commissioned should be short and simple and consistent nationally.

Recommendation 6

The IPFR process should not be used to request services that are routinely commissioned. Different types of requests for interventions should be clearly and consistently differentiated. Information should be provided that helps clinicians to understand the distinction and the different criteria that apply.

Recommendation 7

It should be clearer to patients why they are not routinely allowed to choose their place of treatment and in which circumstances interventions are commissioned outside patients own LHB.

Recommendation 8

The services commissioned by WHSSC should be set out more clearly and accessibly. WHSSC should also explain what services it decides not to commission and why. It needs to be clear whether WHSSC is making an explicit decision that the service should not be provided or whether the LHBs have chosen not to delegate commissioning responsibility to WHSSC.

Recommendation 9

WHSSC and LHB’s should review all their policies that refer to IPFRs and ensure that the policies taken together are up to date, consistent and coherent.

Recommendation 10

LHBs should set up a consistent national policy on the use of inexpensive interventions and introduce a consistent framework within which such decisions should be made, for example, either by making them available on request by clinicians or after suitable LHB approval (e.g. by a Multi-Disciplinary Team (MDT) or head of department).

Recommendation 11

The existing decision-making criteria based on “exceptionality” should be replaced substantially and in line with the proposed decision making criteria and the explanatory notes set out in this report.

Recommendation 12

So that the best evidence is available for future decisions, where possible, clinical outcomes from the IPFR decisions should continue to be tracked and recorded so that the effectiveness of decisions can be assessed over time.

Recommendation 13

The public should be reassured that affordability is not part of the decision criteria for individual patients.

Recommendation 14

Availability of interventions should not generally be part of the decision criteria for individual patients.

Recommendation 15

IPFR panel should record in their decisions a descriptor of their broad estimate of the likely incremental clinical benefit and the broad estimate of the likely incremental cost so their judgements on value for money are clear and transparent.

Recommendation 16

We recommend that non-clinical factors continue not to be taken into account in making intervention decisions.

Recommendation 17

IPFR panels should document the reasons for their decision clearly and in sufficient detail to enable the applying clinician to understand the reasoning and to check that the panel took into account all the relevant factors.

Recommendation 18

IPFR panel should continue to consider actively whether the panel has adequate advice and expertise on which to base its decision for each patient. When considering IPFR applications for specialist conditions, IPFR panels should ensure that they have the best available evidence on which to base their decision. Where necessary, panels should seek the advice of specialists, specialist groups or networks.

Recommendation 19

A national IPFR quality function should be established to support the IPFR panels to ensure quality and consistency. This quality function will provide quality assurance around the decision-making of panels and will promote consistency across Wales. It will include facilitation, advice, training and auditing of the IPFR process, and will have an obligation to report on the quality of the processes and to highlight any concerns through the existing quality and clinical governance processes in NHS Wales.

Recommendation 20

The current configuration of panels should continue.

Recommendation 21

It is vital that all pharmaceutical companies submit their medicines to AWMSG (if they are not already on the NICE work programme) as soon as possible after licensing to obtain a timely, fair and transparent appraisal of the medicines benefit to patients for the particular indication and to reduce the need for IPFR requests for individual patients.

Recommendation 22

Where AWMSG has issued a 'Statement of Advice' notice not endorsing the use of a medicine in NHS Wales, IPFR panels should approve requests for use of that medicine only if they are confident that there is clear evidence of likely clinical benefit to the particular patient which is sufficient to justify the cost of the medicine and associated treatment.

Recommendation 23

The IPFR quality function should create new or improved training materials (including a manual) for clinicians and separately for patients explaining in detail the IPFR process, how it is used, and what to expect.

Recommendation 24

Clinicians should enable patients to make informed decisions. Clinicians should enable their patients to understand all their treatment options and alternatives, the risks and benefits of those options and the likelihood of those risks and benefits, before seeking an IPFR on their behalf.

Recommendation 25

Clinicians should not make an IPFR application for interventions that have little or no realistic chance of clinical benefit solely in response to a patient request.

Recommendation 26

Clinicians should be supported (by training and advice) to understand the assessment process that the panel will follow for a specific request, so that the clinician can better assess the likelihood of an application's success before it is submitted.

Recommendation 27

The IPFR quality function, working with the IPFR coordinator network, should review the design of the forms in light of this report and make further improvements to streamline and simplify the process and to make it easier and quicker for clinicians to apply.