NHS
Herefordshire and Worcestershire
Clinical Commissioning Group

Standard Operational Framework For Individual Funding Requests

July 2021

Commissioning Summary

This operating framework for individual funding requests (IFR) applies to any patient for whom the NHS Commissioner in Herefordshire and Worcestershire, to be referred to hereafter as "the Commissioners", is the "Responsible Commissioner".

The Commissioners consider all lives of all patients whom it serves to be of equal value and, in making decisions about funding treatment for patients, will seek not to discriminate on the grounds of sex, age, sexual orientation, race, educational level, employment status, marital status, religion or beliefs, pregnancy, gender reassignment or disability, save where a difference in the treatment options made available to patients is directly related to the patient's clinical condition or is related to the anticipated benefits to be derived from a proposed form of treatment.

A Glossary to terminology used in this policy can be found in Appendix 1

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Circulated to the following individuals/groups for comments:

Name	Date	Version Reviewed
Policy Alignment Task & Finish Group, which includes	14th August 2019, 22nd October 2019	Version 1.0
Herefordshire & Worcestershire Clinical Commissioning Groups - Joint Commissioning Committee	November 2019	Version 1.0
Herefordshire & Worcestershire CCG Clinical Commissioning Policy Collaborative	October 2020	Version 2.0

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1. Introduction and Background

1.1 Clinical Commissioning Groups (CCGs) were created by the Health & Social Care Act 2012 and established in accordance with the rules set out in the National Health Service Act 2006, as the statutory bodies charged with the function of commissioning healthcare for patients for whom they are statutorily responsible.

1.2 The CCG receives a fixed budget from NHS England to enable it to fulfil this duty. It has a statutory responsibility to maintain financial balance[1] and, as part of discharging this obligation, has to decide how and where finite local resources are allocated.

1.3 The need for health care is always greater than the resources available to a society to meet the demand. Therefore, it is evident that it will not be possible for the CCG to commission all the health care that is needed or wanted by the population it serves and, as a result, it will need to prioritise its commissioning intentions based on the needs of the local population.

1.4 In carrying out these functions, the CCG will act with a view to securing health services that are provided in a way which promotes the NHS Constitution among patients, staff and members of the public. Patients have a right to expect that the CCG will assess and prioritise the health requirements of the local community and commission the services to meet those needs as considered necessary. In discharging its obligations under this policy, in particular, the CCG acknowledges that patients also have a right to expect that local decisions on the funding of treatments which have not been considered by the National Institute for Health and Care Excellence (NICE) in its technology appraisal programme will be made rationally following the proper consideration of evidence.

1.5 Those with the responsibility for health care budgets have to make decisions about priorities at three levels: when developing strategic plans (the main priorities), when deciding year on year which investment and disinvestments to make, and at the individual patient level.

1.6 The CCG has developed a series of Clinical Commissioning Policies to provide guidance to patients and clinicians on a range of interventions or treatments that require a CCG decision before NHS funded treatment can be provided. All policies and related Standard Operating Procedure documents are published on the CCG website: www.herefordshireandworcestershireccg.nhs.uk

1.7 The CCG process for Clinical Commissioning Policy development ensures that they reflect mandated technology appraisal guidance issued by the National Institute for Care and Health Excellence, and either reflect or are more comprehensive than, the NHS England Evidence Based Interventions recommendations.

1.8 There are two categories to support CCG decision making:

- treatments that are not routinely commissioned; which require the submission of, and CCG agreement to, an Individual Funding Request. This document provides guidance on this process.
- treatments that are funded as part of a specific pathway for patients who meet the clinical eligibility criteria for that treatment/intervention; which require the submission of, and CCG agreement to, a Prior Approval request. For more information about this process, please review the CCG Prior Approval Standard Operating Document.

[1] Section 223H National Health Service Act 2006@ Financial duties of clinical commissioning groups: expenditure

1.9 The individual funding request process is used by the CCG to take into account and prioritise requests for individuals with unusual (exceptional) clinical circumstances, which cannot be accommodated through its other commissioning processes. Being part of the CCG's priority setting processes, the decisions taken by the IFR Panel must be guided by the same principles as priority setting in the rest of the organisation. These are set out in the CCG's Ethical Framework for Priority Setting and Resource Allocation document. These principles include taking affordability and relative priority vis-à-vis other needs into account.

Contained within the Ethical Framework are the principles which underpin this Operating Framework, these are listed in **Appendix 2**.

1.10 This document should be read in conjunction with Commissioning Policy WM09 – Individual Funding Requests – February 2012 and the CCG Prior Approval Standard Operating Procedure document, both of which are available on the CCG website at the following address: www.herefordshireandworcestershireccg.nhs.uk

Commissioning Policy WM09 defines what is meant by an individual funding request, what the considerations of a request should be and how a request should be managed. This Operational Framework defines the local arrangements for how these considerations are managed.

1.11 Other Clinical Commissioning Policies may also be relevant to this document and they can be found at the CCG website.

2. Individual Funding Requests (IFR)

2.1 This policy is part of a suite of locally endorsed Commissioning Policies. Copies of these Commissioning Policies are available on the following website address: www.herefordshireandworcestershireccg.nhs.uk

2.2 This policy applies to all patients for whom the CCG has responsibility including:

- People provided with primary medical services by GP practices which are members of any one of the CCGs and
- People usually resident in any of the areas covered by the CCG's and not provided with primary medical services by any CCG.

2.3 In this document, any reference to "treatment" is a reference to a health care intervention provided or proposed to be provided by a clinician of any discipline.

2.4 An Individual Funding Request is a request for a treatment that is not routinely funded by the Commissioners or covered by an existing Commissioning Policy

2.5 Clinicians, on behalf of an individual patient, are entitled to make an Individual Funding Request (IFR) to the Commissioner for treatment that is not normally commissioned by the Commissioner under defined conditions:

The request does not constitute a request for a service development

And

The patient is suffering from a medical condition for which the Commissioner has commissioning responsibility and a commissioning policy[2] and the patient's particular clinical circumstances falls outside the criteria set out in an existing commissioning policy for funding the requested treatment;

Or

The patient is suitable to enter a clinical trial which requires the Commissioner to fund the treatment costs of the trial, or give prior approval to the patient entering the trial to fund the continuation of funding of treatment after the trial has been completed[3][4];

Or

The patient has a rare clinical circumstance, thus rendering it impossible to carry out clinical trials, and for whom the clinician wishes to use an existing treatment on an experimental basis.

2.6 The IFR Process is not designed to create policy or to sanction funding requests which may result in precedent being set to provide the same or similar treatment to an identifiable group of patients. Therefore, where a request is identified as not being individual and there is an identifiable group of patients who may all benefit from the proposed treatment, the requesting clinician should be advised that the request cannot be considered through the IFR process and that an outline business case for a service development must be submitted to one of the following groups for further consideration:

- The relevant Care Planning Programme Group

[2] The CCG's Policy: In Year Service Developments and the Clinical Commissioning Group's approach to treatments not yet assessed and prioritised sets out that the default commissioning policy for a treatment that the CCG has not yet had time to put through normal priority setting processes for service developments is a policy not to fund that particular treatment.
[3] Note that the CCG will not generally fund continuation of treatment without this prior approval.
[4] Consideration of requests to the CCG to support the treatment costs either during or after a clinical trial (which may be a trial sponsors precondition for allowing a patient to enter a clinical trial) has been delegated to those responsible for IFR decision making because it is a decision to fund a treatment not normally funded as the patient level and it will commit additional, often substantial, resource of the CCG. The decision therefore has to be subject to normal priority setting processes at the level of the individual.

- The Medicines and Prescribing Committee
- The Clinical Commissioning Policy Collaborative

Services or treatment pathways that are commissioned by NHS England, have a separate IFR process that local commissioners (CCGs) are not a part of.

Clinicians should use the NHS England IFR form to make an application for funding. If an IFR for NHS England commissioned services is sent to the CCG, it will be sent back to the requesting clinician with advice on accessing the correct process. NHS England will only accept an IFR request from the treating clinician, normally a specialist.

https://www.england.nhs.uk/publication/specialised-services-individual-funding-requests/

3. Making an IFR

3.1. All IFRs will be considered in accordance with this policy. The following paragraphs provide further details on how they will be managed.

3.2. An IFR is made through completion of **IFR PROFORMA (Appendix 4** within this document), available through the CCG website.

3.3. It is expected that the majority of IFRs will be submitted by secondary/tertiary care clinicians rather than primary care clinicians. The requirement for a GP to make an IFR is expected to be relatively rare given the grounds for clinical exceptionality and the complexity of such requests. However, if a GP feels that an IFR is appropriate, expert advice should be sought as appropriate.

3.4. Forms completed by patients or other sources e.g. Members of Parliament will be acknowledged but will not be accepted.

3.5. For secondary care clinicians, completed forms should be submitted to the CCG via Blueteq. For GPs, completed forms should be submitted to the email address noted at the bottom of the form.

3.6. Alternatively, if email access is not available, the GP can send the completed IFR Form by post to this address:

Individual Funding Request Team
NHS Herefordshire & Worcestershire CCG
Coach House
John Comyn Drive
Perdiswell
Worcestershire
WR3 7NS
Tel: 01905 681999 (switchboard)

3.7. Any IFR request received not using the correct form, or not adequately completed will be returned to the requesting clinician, who will be asked to resubmit the request using the appropriate proforma or completing any missing information.

4. Local Consideration of IFRs

4.1 The process for consideration of requests is summarised in **Appendix 3**.

4.2 Requests for services and treatments that are not the responsibility of Herefordshire and Worcestershire Clinical Commissioning Group will be forwarded to the appropriate organisation.

4.3 On receipt of an appropriately completed request for a patient that is the responsibility of the Herefordshire and Worcestershire Commissioners, the details will be entered on the IFR register.

4.4 **Screening of Request**

4.4.1 The IFR manager will undertake an initial "screening" of the request.

If a submitted IFR request indicates that the patient fully complies with an existing policy, the relevant policy decision will be applied to the request, this will normally be redirected to the CCG Prior Approval process. This process is described in the CCG Prior Approval Standard Operating Procedure.

4.4.2 If a request is incomplete or relates to services/treatment pathways that are not the commissioning responsibility of CCGs it will be returned to the requester with appropriate information to that effect.

4.4.3 If a request is made by a patient or Member of Parliament with no evidence of the appropriate clinician making an IFR application, the request will be acknowledged, and the requester redirected to garner the required clinical support.

4.4.4 Remaining requests will be referred to a Level 1 panel for further review and verification.

4.4.5 A **Level 1 IFR Screening tool** should be completed (**Appendix 5**) by the IFR team and as much relevant information as possible (within the timescale) gathered for review.

4.4.6 **Level 1 Terms of Reference** are detailed in **Appendix 6**. The Terms of Reference include details regarding the principles that will be applied and considered during the assessment process.

4.4.7 Level 1 panel reviews are scheduled every two weeks – the CCG will acknowledge an IFR application within 5 working days of receipt, a Panel decision will be communicated to interested parties within 10 working days of the date of the Panel.

4.5 **Level 1 Assessment and Verification**

4.5.1 The level 1 panel will review all completed proformas and supporting information supplied.

4.5.2 The panel will initially verify that any assumptions around service developments and existing policies were accurately made at screening. If the panel determines that the request is a service development or that the request complies with an existing policy then the request will be reconsidered and declined/accepted as appropriate.

4.5.3 The panel will seek to determine whether there is initial evidence of clinical exceptionality. If there is not, the request will be declined.

4.5.4 The panel may determine that further specific information is required and ask that this be reconsidered at a future Level 1 meeting.

4.5.5 Remaining requests will be referred to a Level 2 panel.

4.5.5.1. **A Level 2 IFR Panel Consideration Proforma** (**Appendix 7a**) should be completed by a delegated member of the IFR Level 1 panel.

4.5.5.2. **Level 2 Terms of Reference** are detailed in **Appendix 8**. The Terms of Reference include details regarding the principles that will be applied and considered during the decision-making process.

4.5.5.3. Level 2 panel reviews are scheduled monthly and will usually be undertaken within **20 working days** from referral.

4.6 Level 2 Consideration

4.6.1 The Level 2 panel will review the completed level 2 proforma and additional supporting information.

4.6.2 The request will be considered taking into account all relevant commissioning policies.

4.6.3 The panel will seek to complete the **Level 2 IFR Summary proforma** (**Appendix 9**) for the individual case being considered, giving particular consideration to:

- Clinical Exceptionality
- Clinical Effectiveness
- Cost Effectiveness

Further details on the nature of the considerations is provided in the **Level 2 Terms of Reference** (**Appendix 8**)

An **External Assessment Tool (Appendix 10)** will be completed for each case considered at a level 2 meeting to ensure that the case has been considered in accordance with this policy and that due process has been followed.

4.6.4 Very occasionally an IFR presents a new issue which needs a substantial piece of work before the Commissioner can reach a conclusion upon its position. This may include wide consultation. Where this occurs the IFR panel may adjourn a decision on an individual case until that work has been completed.

4.6.5 The Level 2 panel will approve or decline the request; approvals may be made subject to specified conditions. The decision will be documented on the register and the clinician notified of the outcome by letter (patients will also receive a copy of this letter unless the clinician has requested otherwise). The Panel decision will be communicated to interested parties within 10 working days of the date of the Panel.

On occasions the Level 2 panel may defer a decision and request additional information. Upon receipt of the information, the Level 2 IFR Panel – Additional Information Request form (Appendix 7b) will be completed and the new information considered at the next available level 2 panel meeting or within 20 working days.

4.7 Request for Review (Level 3)

4.7.1 Where a decision making panel has declined to support funding for a requested treatment or has approved the treatment subject to conditions, patients and/or clinicians are entitled to ask that the decision of the IFR panel be reviewed.

4.7.2 Requests for review must be received within 3 months of the date of the meeting when the original decision was made; after this date, requests will be considered as new requests in line with the Operation Policy.

4.7.3 All requests for review must be supported by the senior treating clinician who must explain their reasons for considering that the decision taken by the IFR panel was either:

- not based on all relevant clinical evidence and/or
- misunderstood submitted clinical evidence and/or
- a decision which no reasonable IFR panel could have reached and/or
- procedurally improper

4.7.4 The additional information or request for review will be acknowledged within 5 working days of receipt.

4.7.5 The request will be considered by the level 1 panel in the first instance. This panel will determine whether there is clinical information which was not previously considered or which was misunderstood at the original panel.

4.7.5.1 If there is new clinical information or the evidence was misunderstood, then an appropriate panel will be scheduled to review the information (within 20 working days).

4.7.5.1.1 Requests will be considered in accordance with the panel level at which the case was originally considered.

4.7.5.1.2 For Level 2 panels, the Level 2 IFR Panel – Additional Information Request form (Appendix 7b) should be completed.

4.7.5.1.3 The Panel decision will be communicated to interested parties within 10 working days of the date of the Panel.

4.7.5.2 If there is a suggestion that due process has not been followed or that an unreasonable decision was reached, then a level 3 review panel will be scheduled.

4.7.5.2.1. **Review Panel (Level 3) Terms of Reference** are detailed in **Appendix 11**. The Terms of Reference include details regarding the principles that will be applied and considered during the review process.

4.7.5.2.2. A level 3 panel review will be scheduled within 20 working days where possible. The Panel decision will be communicated to interested parties within 10 working days of the date of the Panel.

4.7.5.3 Where more than one reason for a review has been given, relevant new evidence and misunderstandings will be considered at an appropriate decision making panel level in advance of any process review at Level 3.

4.7.5.4 Where the level 1 panel considers that there is neither any new clinical evidence nor any concern regarding the process, the panel will write to the review requester explaining why a review is not considered appropriate. This will include clarification of both the process undertaken and the evidence considered at the original review panel to substantiate the decision. The Panel decision will be communicated to interested parties within 10 working days of the date of the Panel.

4.7.6 The level 3 panel will consider all the original evidence together with the review information submitted. The panel will determine whether:

- the process followed by the original IFR panel was consistent with the operational policy and/or
- Whether the panel reached an unreasonable decision.

4.7.7 A reasonable decision is one which:

- Was taken following a process consistent with the policies of the organisation
- Took into account and weighed all the relevant evidence
- Did not take into account irrelevant factors
- Indicated that the members of the panel acted in good faith
- Was a decision which a reasonable IFR panel was entitled to reach.

4.7.8 Depending on the conclusions of the review panel following consideration of the original evidence, process and decision made, the review panel may:

- Uphold the original decision not withstanding any procedural error

OR

- Request that the original decision making panel reconsiders its decision

Further detail regarding how these decisions are made is given in **Appendix 11**.

4.7.9 Further Panels will usually be scheduled to meet within 20 working days.

4.7.10 Decisions will be documented on the register and the clinician notified of the outcome by letter (patients will also receive a copy of this letter unless the

clinician has requested otherwise). The Panel decision will be communicated to interested parties within 10 working days of the date of the Panel.

5. Other Issues

5.1 Urgent Individual Funding Requests

The Commissioner recognises that there may be situations where an urgent decision against a request is required before a panel can be convened. The following provisions apply to such a situation:

5.1.1 An urgent request is one which requires an urgent consideration and a decision because the patient faces significant harm if a decision is not made before the next scheduled meeting of the necessary IFR panel, or to facilitate timely palliative care arrangements when necessary.

5.1.2 A matter will not be treated as an urgent request where the apparent urgency arises solely because of:

- a failure by the clinical team to apply for funding through the appropriate route in a timely manner; or
- the patient's expectations being improperly raised by a commitment being given by the Clinician to provide a specific treatment to the patient.

In such circumstances the CCG will expect the treatment to be provided and funded by the Provider

5.1.3 In situations of clinical urgency, the decision will be made by staff authorised to make such a decision as set out in **Appendix 12 "Requirement for Urgent Decision Making".**

5.1.3.1 The panel convened in accordance with **Appendix 12** will as far as possible within the constraints of the situation, follow the general principles and processes of the operational policy for individual funding requests.

5.1.3.2 As much information as is feasible should be provided and considered within the constraints of the timescale.

5.1.3.3 The panel convened to make the urgent decision should be entitled to determine that the decision is not of sufficient urgency or importance to warrant consideration outside of the usual process.

5.1.3.4 The panel convened are entitled to reach the view that in consideration of all the information available, the request represents a service development and so should be refused and/or appropriately referred for policy consideration.

5.2 Patient Communication/Involvement

5.2.1 In order to protect patient confidentiality, IFRs will not be discussed in detail over the telephone. Patients will, however, be copied into all correspondence, unless the clinician has indicated otherwise, to ensure they are kept informed of the progress in relation to their case and when appropriate the outcome of the decision-making process.

Note: Due to changes to working practices, the IFR Team does not have the capability to produce printed letters. Therefore, any communication of Panel decisions, including requests for additional information, will be sent to the requesting clinician. The requesting clinician will be responsible for ensuring the patient is kept updated with the progress of any funding request made on their behalf.

5.2.2 Patients are not invited to attend panel or committee meetings but will be offered the opportunity to submit relevant information in support of their case.

5.3 Clinician Involvement

5.3.1 Whilst patients are not able to attend meetings, every effort will be made to ensure the requesting clinician (or, if more appropriate, a clinician with specialist knowledge in the treatment) is able to attend level 2 meetings. This will ensure a full and comprehensive clinical case is presented to the Panel members and provide an opportunity for the Panel members to raise any questions in relation to the treatment proposed.

5.3.2 In the event of the clinician being unable to attend the level 2 meeting, other options such as teleconferencing will be fully considered to ensure appropriate clinical representation at the meeting at which the IFR is being discussed. Where it is not possible to have clinical representation at the meeting, full consideration will be given to the written clinical information submitted by the clinician in relation to the request.

5.4 The Role of the CCG Complaints Team (CCT)

5.4.1 The CCT service is there to provide patients and/or their advocates with advice and support, to help resolve problems, to provide information on NHS services and to listen to any concerns, suggestions or queries patients may have. The CCT cannot provide information about the status or otherwise of IFR applications.

5.4.2 If further advice and guidance is required on the content of this document or the IFR process, the CCT can be contacted via: hw.complaints@nhs.net

6. Documents which have informed this Operating Procedure

- NHS England: Ethical Framework for Priority Setting Resource Allocation
- NHS England: Individual Funding Requests
- NHS Herefordshire & Worcestershire: Prioritisation Framework for the Commissioning of Healthcare Services
- WM01 – Ethical Framework
- WM02 – Orphan Drugs
- WM03 – Patients Leaving Industry Sponsored Trials
- WM05 – NICE Guidance
- WM07 – Choice
- WM08 – In Year Service Developments
- WM09 – Individual Funding Requests (to be read with local process document)
- WM10 – Patients Leaving Non Commercially Funded Trials
- WM11 – Patients Leaving a CCG Funded Trial
- WM12 – Patients Changing Responsible Commissioner
- WM13 – NHS Private Interface
- WM14 – Experimental Treatments
- WM15 – Trial of Treatment
- NHS Constitution, updated 27th July 2015
- The National Health Service Act 2006, The National Health Service (Wales) Act 2006 and The National Health Service (Consequential Provisions) Act 2006 : Department of Health – Publications
- Department of Health, World Class Commissioning Competencies, December 2007: https://bulger.co.uk/dacorumhealth/daccom/PDF%20Documents/WCC%20competencies.pdf
- Department of Health, The NHS Constitution for England, Updated October 2015: https://www.gov.uk/government/publications/the-nhs-constitution-for-england/the-nhs-constitution-for-england
- The National Prescribing Centre, Supporting rational local decision-making about medicines (and treatments), February 2009.
- NHS Confederation Priority Setting Series, 2008.

- Ethical Framework to support priority setting and resource allocation April 2013 https://www.england.nhs.uk/wp-content/uploads/2013/04/cp-01.pdf

7. Appendices

Appendix 1 - Glossary of Terms

Term	Definition
Annual Commissioning Plan	The *Annual Commissioning Plan* is a document prepared by the Commissioner which defines the healthcare interventions that will be commissioned for defined categories of patients in each financial year. Locally, this is known as the *Commissioning Intentions*.
Annual commissioning round	*The annual commissioning round* is the process by which major funding decisions are taken, including the allocation of new money coming into the NHS. This involves a complex process of prioritisation which involves a series of decisions. This process occurs during the months of October to March for the following financial year.
Clinical effectiveness	C*linical effectiveness* is a measure of how well a healthcare intervention achieves the pre-defined clinical outcomes of interest in a real life population under real life conditions.
Clinical trial	*A clinical trial* is a research study in human volunteers to answer specific health questions. Clinical trials are conducted according to a plan called a protocol. The protocol describes what types of patients may enter the study, schedules of tests and procedures, drugs, dosages, and length of study, as well as the outcomes that will be measured. Each person participating in the study must agree to the rules set out by the protocol. The ethical framework for conducting trials is set out in the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended). It includes, but does not refer exclusively to, randomised control trials.
Cost effectiveness	*Cost effectiveness* is an assessment as to whether a healthcare intervention provides value for money.
Efficacious	A treatment is *efficacious* where it has been shown to have an effect in a carefully controlled and optimal environment. However, it is not always possible to have confidence that data from trials which suggest that treatments will be efficacious will translate into clinically meaningful health gain and more specifically the health gain of interest. This is the difference between disease oriented outcomes and patient oriented outcomes. For example a treatment might have demonstrated a change in some physiological factor which is used as a proxy measure for increased life expectancy, but this relationship might not be borne out in reality.
Exceptional	*Exceptional* means out of the ordinary, unusual or special.
Exceptional clinical circumstances	*Exceptional clinical circumstances* are clinical circumstances pertaining to a particular patient which can properly be described as rare or exceptional. This will usually involve a comparison with other patients with the same clinical condition and at the same stage of development of that clinical condition and refer to features of the particular patient which make that patient out of the ordinary, unusual or special compared to other patients in that cohort. It can also refer to a clinical condition which is so rare that the clinical condition can, in itself, be considered exceptional. That will only usually be the case if the NHS commissioning body has no policy which provides for the treatment to be provided to patients with that rare medical condition.
Experimental and unproven treatments	*Experimental and unproven treatments* are medical treatments or proposed treatments where there is no established body of evidence to show that the treatments are clinically effective. The reasons may include the following: • The treatment is still undergoing clinical trials for the indication in question. • The evidence is not available for public scrutiny. • The treatment does not have approval from the relevant government body. • The treatment does not conform to an established clinical practice in the view of the majority of medical practitioners in the relevant field. • The treatment is being used in a way other than that previously studied or for which it has been granted approval by the relevant government body. • The treatment is rarely used, novel, or unknown and there is a lack of evidence of safety and efficacy.

Term	Definition
	• There is some evidence to support a case for clinical effectiveness but the overall quantity and quality of that evidence is such that the commissioner does not have confidence in the evidence base and/or there is too great a measure of uncertainty over whether the claims made for a treatment can be justified.
Healthcare intervention	A *healthcare intervention* means any form of healthcare treatment which is applied to meet a healthcare need.
In-year service development	An *in-year service development* is any aspect of healthcare, other than one which is the subject of a successful individual funding request, which the Commissioner agrees to fund outside of the annual commissioning round. Unplanned investment decisions should only be made in exceptional circumstances because, unless they can be funded through disinvestment, they will have to be funded as a result of either delaying or aborting other planned developments.
NHS commissioned care	*NHS commissioned care* is healthcare which is routinely funded by the patient's responsible commissioner. The Commissioner has policies which define the elements of healthcare it is and is not prepared to commission for defined groups of patients.
Prior Approval	*Prior Approval* is a process in which treating clinicians demonstrate how a patient meets set threshold criteria prior to listing for surgery for procedures which the commissioner routinely commission in line with agreed clinical eligibility criteria and which are noted within agreed contracts.
Priority setting	*Priority setting* is the task of determining the priority to be assigned to a service, a service development, a policy variation or an individual patient at a given point in time. Prioritisation is needed because the need and demands for healthcare are greater than the resources available.
Rule of rescue	*Rule of rescue* is the observation that human beings, in situations where an individual's life is at risk, have the proclivity to take action to rescue the individual regardless of the cost and the chances of success. Action taken, therefore, is in part about meeting the emotional needs of the decision maker. In the healthcare setting the term has been used in a number of ways. In the West Midlands the term refers to agreeing funding for treatments for patients whose prognosis is grave on the basis that their prognosis is grave and without regard to cost or ability to benefit.
Service Development	A *Service Development* is an application to the Commissioner to amend a commissioning policy to outline/state that a particular healthcare intervention should be routinely funded for a defined group of patients. The term refers to all new developments including new services, new treatments (including medicines), changes to treatment thresholds, and quality improvements. It also encompasses other types of investment that existing services might need, such as pump-priming to establish new models of care, training to meet anticipated manpower shortages and implementing legal reforms. Equitable priority setting dictates that potential service developments should be assessed and prioritised against each other within the annual commissioning round. However, where investment is made outside of the annual commissioning round, such investment is referred to as an *in-year service development*.
Strategic planning	*Strategic planning* is the process by which an organisation determines its vision, mission, and goals and then maps out measurable objectives to accomplish the identified goals. The outcome is a *strategic plan* which sets out what needs to be done and in what time scale. Strategic planning focuses on what should be achieved in the long term (3, 5, 7, or 10 year time span) while operational planning focuses on results to be achieved within one year or less. Strategic plans should be updated through an annual process, with major re-assessments occurring at the end of the planning cycle. Strategic planning directs how resources are allocated.
Treatment	*Treatment* means any form of healthcare intervention which has been proposed by a clinician and is proposed to be administered as part of NHS commissioned and funded healthcare.

Term	Definition
Value for money	*Value for money* in general terms is the utility derived from every purchase or every sum spent.

Appendix 2 – Core Principles from Ethical Framework

Principle 1
The values and principles driving priority setting at all levels of decision making should be consistent.

Principle 2
The Commissioner has a legal responsibility to commission healthcare within the areas allocated to it by the Secretary of State in a manner which is consistent with its legal duty not to overspend its allocated budget.

Principle 3
The Commissioner has a responsibility to make rational decisions in determining the way it allocates resources to the services it directly commissions and to act fairly in balancing competing claims on resources between different patient groups and individuals.

Principle 4
Competing needs of patients and services within the areas of responsibility of the Commissioner should have a fair chance of being considered, subject to the capacity of the Commissioner to conduct the necessary healthcare needs and services assessments. As far as is practicable, all potential calls on new and existing funds should be considered as part of a priority setting process. Services and individual patients should not be allowed to bypass normal priority setting processes.

Principle 5
Access to services should be governed, as far as practicable, by the principle of equal access for equal clinical need. Individual patients or groups should not be unjustifiably advantaged or disadvantaged on the basis of age, gender, disability, sex, sexual orientation, gender reassignment, race (including travelling communities), religion, lifestyle, occupation, social position, financial status, carers, care leavers, homelessness, family status (including responsibility for dependants), pregnancy and maternity, marriage and civil partnerships, intellectual / cognitive function or physical functions.

There are proven links between social inequalities and inequalities in health, health needs and access to healthcare. In making commissioning decisions, priority may be given to health services targeting health needs in sub-groups of the population who currently have poorer than average health outcomes (including morbidity and mortality) or poorer access to services.

Principle 6
The Commissioner should only invest in treatments which are of proven cost-effectiveness unless it does so in the context of well-designed and properly conducted clinical trials that will enable the NHS to assess the effectiveness and/or value for money of a treatment or other healthcare intervention.

Principle 7
New treatments should be assessed for funding on a similar basis to decisions to continue to fund existing treatments, namely according to the principles of clinical effectiveness, safety, cost-effectiveness / value for money and then prioritised in a way which supports consistent and affordable decision making.

Principle 8

The Commissioner must ensure that the decisions it takes demonstrate value for money and an appropriate use of NHS funding based on the needs of the population it serves.

Principle 9
All NHS commissioned care should be provided as a result of a decision by the Commissioner. No other body or individual, other than those authorised to take decisions under the policies of the Commissioner, has a mandate to commit the Commissioner to fund any healthcare intervention unless directed to do so by the Secretary of State for Health.

Principle 10
The Commissioner should strive, as far as practicable, to provide equal treatment to individuals in the same clinical circumstance. The Commissioner should therefore not agree to fund treatment for one patient which cannot be afforded for, and openly offered to, all patients with similar clinical circumstances and needs.

Principle 11
Interventions of proven effectiveness and cost-effectiveness should be prioritised above funding research and evaluation unless there are sound reasons for not doing so.

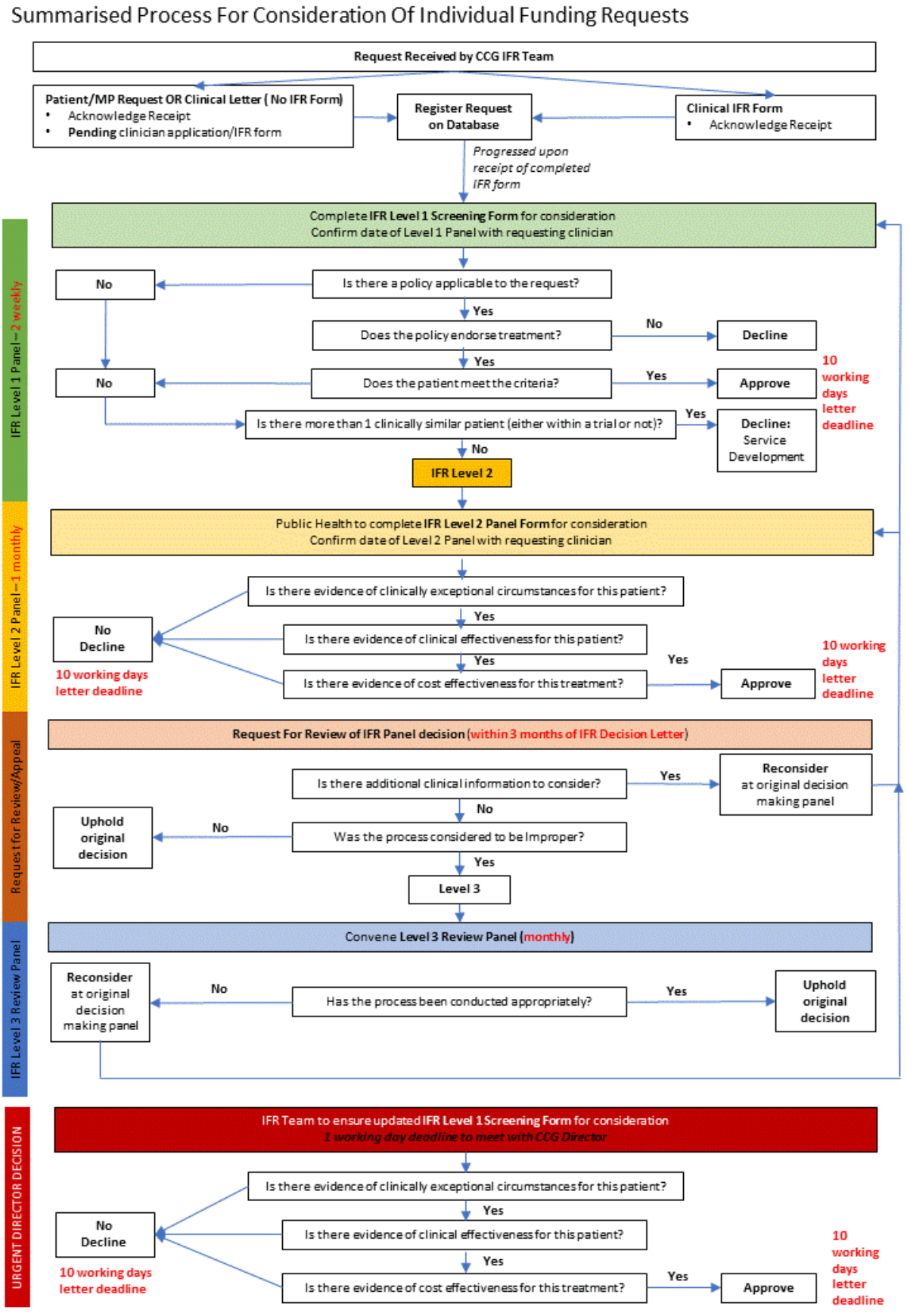
Principle 12
Because the capacity of the NHS to fund research is limited, requests for funding to support research must be subject to normal prioritisation processes. The funding of excess treatment costs for a clinical trial is now considered by NHS England and not within the remit of local Commissioners.

Principle 13
If a treatment is provided within the NHS which has not been commissioned in advance by the Commissioner, the responsibility for ensuring ongoing access to that treatment lies with the organisation that initiated treatment.

Principle 14
Patients participating in clinical trials are entitled to be informed about the outcome of the trial and to share any benefits resulting from having been in the trial. The responsibility for this lies with the party initiating and funding the trial and not the Commissioner unless the Commissioner has either itself funded the trial or agreed in advance to fund aftercare for patients entering the trial.

Principle 15
Unless the requested treatment is approved under existing policies of the Commissioner, the Commissioner will not, save in exceptional clinical circumstances, commission a continuation of privately funded treatment even if that treatment has been shown to have clinical benefit for the individual patient.

Appendix 3 – Summarised Process For Consideration Of Individual Funding Requests



Appendix 4 – Individual Funding Request Application Form

The following application form is available via Blueteq for secondary care clinicians to complete and submit. A Word version of this form is also available on the CCG website for GPs and other Health Care Professionals to use if this is appropriate.

Individual Funding Request Application Form			
Treatment being Requested			
Condition being Treated			
Nature of Intervention	☐ ***Drug*** ☐ ***Surgical Procedure*** ☐ ***Medical Device*** ☐ ***Therapy*** ☐ ***Other (give details)……..***		
On what basis is this request being made?	☐ ***Exceptional Clinical Circumstances*** ***OR*** ☐ ***Rarity of condition or presentation (individuality)*** ***OR*** ☐ ***Participation in an endorsed rial***		
Date of Request		***Date Re by Cc***	

NOTES FOR

1. This proforma is to be completed b ng on behalf of their patient to request funding from a Commis refordshire & Worcestershire for individual funding of **drugs o nterventions not routinely commissioned**.

2. If this request relate eatment, requests should only be submitted to the NHS England's nd, which can be accessed through the following link: **http://www.e ourwork/pe/cdf/**

3. To min ne application process please ensure **ALL** fields are completed comp ncomplete forms or forms with insufficient levels of information will be retu e requesting clinician and may result in a delay in the request being considere

4. This form should **not** be used to request funding for
   a. NICE TAG approved treatments and/or technologies for specific indications
   b. Treatment requiring prior authorisation
   c. Consideration of potential service developments
   d. Approved indications where funding is already sanctioned under an existing commissioning policy and where the patient meets the treatment criteria.

5. This form should **not** be used if there are likely to be other patients with similar clinical circumstances within the commissioning area who may also benefit from the treatment being requested. Where there are likely to be other similar patients funding should be sought through the submission of a business case. This is because the case represents a service development for a predictable population. You should discuss

with your contract team how you submit a business case for consideration through the annual prioritisation round.

6. Clinicians should ensure that their organisation has agreed to submission of the request.

7. Further guidance on completion of this proforma and the nature of the request is detailed in Appendix 1.

DECLARATION

1. **I confirm that it is not expected that there will be more than one patient from within the responsible commissioner's population who is (or is likely to be) in the same (or similar) clinical circumstances as the requesting patient within a 12 month period and who could not reasonably be expected to benefit to the same or a similar degree from the requested treatment unless similar patients are expected to be from the same family group.**
2. **I affirm that I have discussed this individual funding request with my patient. This request is being made with his/her consent for treatment and consent for the sharing of information regarding the case with NHS commissioner IFR management panels.**
3. **To the best of my knowledge I have given the most accurate and up to date information regarding this patient's clinical condition.**

Signed: …… **Print Name: ……**

Designation: …… **Organisation: ……**

Telephone: …… **Email: ……**

Correspondence Address: …… **……**

1. Patient Details

Name:			
Address (including postcode):			
Date of Birth:		***M or F***	
NHS Number:			
GP Name:			
GP Prac Name:			
Decision Treat Date	***DD/MM/YYYY***		

2. Requesting Provider Details

Name of Requesting Provider Trust:			
Type of Organisation	☐ ***NHS Trust*** ☐ ***Other***	☐ ***GP/Dental Practice***	☐ ***Private Sector***

Has approval of request been sought from the organisations contract team?	***☐ Yes ☐ No ☐ Not necessary/relevant***	
From whom was agreement sought?	***Name***	
	Contact telephone number	
If this funding request is approved, the NHS provider will be notified. Please give details of the person who should be notified:		
Name		
Designation		
Contact Details		
Email Address		

3. Diagnosis and Patient's Current Condition

Diagnosis (for which the intervention is requested)		
Has a second consultant opinion or MDT view on the requested intervention been obtained?	***If YES, please give de***	
Current status of the patient	***What is the disease (eg. p… …se)***	
	W… the his…ry of the disease including duration?	
	For cancer, how advanced is the stage?	
	Describe any disease manifestations or metastases	

	What is the patient's clinical severity? (where possible use standard scoring systems eg. WHO, PASI, DAS, walk test, cardiac index)	
	What are the ongoing symptoms and how does this affect the patient's well-being?	

Summary of Previous Interventions for this condition ***Please outline any treatment received to date (non-pharmacological, pharmacological, non-surgical/surgical), the dates of each treatment and the outcome in chronological order.*** ****Reasons for stopping may include:*** • ***Course completed*** • ***No or poor response*** • ***Disease progression*** • ***Adverse effects/r tolera***	***Dates***	***Nature of Intervention***	***Reason for stopping*/ response achieved***

Any other relevant information	

4. About the Intervention Requested

Name of Intervention	
Is the intervention PbR excluded	***☐ No ☐ Yes***
Planned dose, frequency and route ***If the intervention forms part of a regime please document in full.***	
Planned duration of intervention	
Where will the intervention be provided	***☐ Inpatient ☐ Daycase ☐ Outpatient ☐ Other (please specify)*** ***……***
Is the requested intervention a continuation of an existing treatment funded via another route?	***☐ No ☐ Yes – give details of existing funding and why ceased*** ***……***
Is the intervention experimental, part of a trial or research?	***☐ No ☐ Yes – give detail…***
What are the alternative management options for this patient	***What other intervention m…nt receive and why is it not suitable?***
	What interver… patient receive if this request is declined?
	Wh…plications of not providing this intervention (to …d carer)?
What is the evidenc… support t… requested intervention? Please provide additional research information to support this application, include references or copies of clinical research papers which support or	

contribute to this request.		
National and International Guidance Is there any guidance of relevance to this application?		
Local Guidance Has your host commissioner developed a local policy regarding this intervention?		
Estimated costs	***Anticipated costs (inc VAT)***	***Total Cost £ (Please indicate if cost is per y cle, course etc)***
	Are there any offset costs?	***Total Cost***
	Describe the type & value of offset costs	
	Funding difference being applied for	
What is the expected outcome for the intervention being requested for this patient?		
How does this compare with th expected outco from the alternativ (standard) management option for this patient?		
How will effectiveness of the intervention be monitored? Include timeframe and type of investigation to determine effectiveness.		

Are you aware of any other similar patients who would benefit from this intervention? ***If yes, please give details***	***YES / NO***
5. Nature of Request	
For <u>all requests</u>, please describe why this patient's condition or clinical presentation is different to others with the same condition, such that they would benefit more from this treatment/therapy than any other patient.	
For clinical trial funding requests please ensure that a copy of the trial protocol is included and outline the importance of the trial, the robustness of the trial and the benefits of this trial to the patient.	
Potential patie... ple, the number per 100,000 population. numbers: What is ... incidence ... condition?	
Additional Views/Comments made by requesting clinician in support of application:	
Processing this request can take up to 4 weeks from the date that the fully completed application is received. If the case is more urgent than this, please state why: ***Please email with supporting information to:*** ***<u>HW.ifr@nhs.net</u>***	

Appendix 1 ***Guidance for Requesting Clinicians***	
Individual Requests	Almost all of these requests will relate to experimental treatments: either a request to access an experimental treatment, enter a patient into a trial or to use a treatment off-label for a rare clinical condition or situation. **Trial Requests:** For requests to enter patients into a trial (whether to fund to enter the trial or pick up post trial funding) a copy of the trial protocol will need to be forwarded with your application – the key questions are: 1. whether or not the trial is strategically important for the programme area 2. whether or not all the trial data will be in the public domain 3. whether or not the trial protocol is robust (e[illegible]n assess improvements in important clinical outc[illegible] **Off label use** for rare clinical circumstan[illegible]stions are: • Is there evidence of cost effe[illegible]is treatment? It is biologically plausible that [illegible]ill work in this clinical situation? Where the treatment is [illegible]ndicate its UK license status.
Exceptionality Requests	An exceptionality re[illegible]evant where there is an existing general or treatm[illegible]cy and where the responsible commissioner [illegible]en the decision not to fund either the treatment o[illegible]es of patients or NICE have already taken the decision [illegible] either the treatment or some categories of patie[illegible]est you are making [illegible]ion that has to be addressed under these circumstances is [illegible]ical grounds can the CCG justify funding this patient when [illegible]tients with the same condition will not? [illegible] making a case therefore the clinician must specify how this patient is clinical different from others currently excluded from treatment – either in reference to the clinical picture or the expected benefit or both. *Please note that if there are similar patients the request essentially represents a request for a policy variation to be made – i.e. expand access to a subgroup of patients and as such should be treated as a service development and the IFR process not used.*
General Guidance	Applications need to include the following additional information: 1. A comprehensive and balanced clinical picture of the history and present state of the patient's medical condition, 2. The nature of the treatment requested and the anticipated benefits of the treatment. 3. The degree of confidence of the Clinical Team that the outcomes will be delivered for this particular patient. 4. Previous treatments/interventions this patient has received for this condition and the outcome of these for the patient. 5. Details of standard NHS treatment that this requested treatment will replace if any.

6. Expected benefits and risks of treatment.
7. Any additional material considered to b[illegible]levant.

The Clinical Team should refer to, and p[illegible]de, copies of any clinical research material which supp[illegible]or undermines the case that is being made that the tr[illegible].y to be clinically effective in the case of the indi[illegible]

In all cases affordability a[illegible]rity compared to other unfunded developments remain [illegible]ions.

The directly rele[illegible]oning policies are:

- **H[illegible] Worcestershire's Individual Funding [illegible]erating Procedure**
- **[illegible]and's 'Ethical Framework to underpin priority [illegible] and resource allocation within collaborative [illegible]missioning arrangements'**
- **[illegible]HS England's 'Individual funding requests'**
- **NHS England's 'Experimental and proven treatments'**
- **NICE IPG guidance where this exists.**

Please access this link for these and other policies:
http://www.herefordshireandworcestershire.nhs.uk

Appendix 5 – Level 1 IFR Screening Tool

Checklist for IFR Screening

IFR Case No: _____
Initials & Date of Birth: _____
Treatment Request: _____
Date of Panel Meeting: _____

The Panel is required to consider requests for NHS funding against the following areas:

1) Can published local, regional or national guidance be applied to this request;
AND/OR

2) Is there sufficient evidence provided to confirm that the patient is experiencing Clinically Exceptional circumstances to those patients covered by the guidance?
OR

3) The request is for a patient to enter a clinical trial which requires explicit funding?
OR

4) There is no local, regional or national guidance and the patient has a rare clinical circumstance which means that clinical trials cannot be carried out and the request is for the use of an existing treatment on an experimental basis

1	**Summary of Progression of Request to Date**
2	**Background - Diagnosis and History:**
3	**Background - Treatment and Outcome:**
4	**About the Requested Treatment:**
5	**Additional Comments made by the Clinician:**
6	**Usual Management Options:**
7	**Alternative Management Options:**
8	**Potential Patient Numbers:**
9	**Estimated Cost of Treatment:**
10	**Local Guidance/Evidence:**
11	**Notes of Decision Made:** **IFR Level 1 consideration DD/MM/Y** Discussion: Decision: Action:

Decision	[update]
Funding Committed	[update]
Source of Funding	[update]
IFR Level 1 Panel Member Name	**Designation**

Appendix 6 – Level 1 Terms of Reference

LEVEL 1 IFR ASSESSMENT AND VERIFICATION PANEL

1. Membership & Quoracy
Quorate Membership:

IFR, Prior Approval & Contracts Manager

Consultant in Public Health
Medicines Management Representative

Additional Members: Contract Support Manager
Foundation Year 2/GP trainee or Specialist Registrar Public Health

In the event of any of the Panel members being unable to attend the meeting, it is the responsibility of that individual to arrange for another representative with the necessary skills/training to attend in their place.

2. Frequency of Meetings
IFR Assessment and Verification Panels will be held **EVERY TWO WEEKS** (usually Wednesdays).

3. Information considered by the IFR Assessment and Verification Panel
The following information will be considered by the Panel:

- Individual Funding Request Proforma (**Appendix 4**);
- Any other relevant information received from the requesting clinician in relation to the case ie. clinical letters, trial papers, trial abstracts; and/or
- Relevant national guidance ie. NICE and literature reviews ie. Additional trial papers, other national guidance from Scotland and Wales.

The request will initially be assessed by the IFR Assessment and Verification Panel using the **IFR Screening Tool (Appendix 5)** and the discussion and decision documented on the checklist. All information considered by the Panel will be fully anonymised.

4. Main Responsibilities of the IFR Assessment and Verification Panel
The IFR Assessment and Verification Panel is responsible for considering requests for treatments not routinely commissioned. Note: There are separate processes for consideration of requests in relation to services which are the responsibility of other organisations eg. NHS England, Children's Services, Mental Health Services, Learning Difficulties and Continuing Healthcare Placements.

The panel will:

- Assess the information presented on the **IFR Proforma (Appendix 4)** in terms of completeness and detail, requesting further information or completion of the pro-forma as required;
- Complete the Checklist for **IFR Screening (Appendix 5)**;
- Determine whether the request meets the criteria for consideration at IFR Level 2 Panel;
- Action the decision reached by the IFR Assessment and Verification Panel.

If required, the Panel will request that a CCG GP undertake a clinical review of the application to provide a clear clinical opinion on the information provided and the intervention/treatment being requested.

In the event of there being insufficient information on the **IFR Proforma (Appendix 4)** to enable the Panel to determine the nature of the request, the clinician will be asked to submit further information to allow a full assessment of the request to be made.

Policy Status	IFR Presentation	IFR Decision Made
POLICY IN PLACE	IFR patient falls **within the criteria** identified within the policy	**Request approved/rejected** in line with policy guidance
	IFR patient falls **outside of the criteria** within the policy but is identified as '**clinically exceptiona**l' ie. no similar patients identified	Request to be considered on grounds of clinical exceptionality by **Level 2 IFR Panel**
	IFR patient falls **outside of the criteria** identified within the policy and a **group of patients** has been identified as being potentially eligible for the service/treatment	**Request rejected**; needs to be considered as a potential service development
NO POLICY IN PLACE	IFR identified as being potentially **'clinically exceptional within population**' – i.e. no other similar patients identified	Request to be considered on grounds of exceptionality by **Level 2 IFR Panel**
	IFR patient identified as one of a **group of patients** who would potentially be eligible for the service/treatment	**Request rejected**; needs to be considered as a potential service development

The IFR Assessment and Verification Panel is also responsible for initially reviewing any requests received for a review of a previous decision made through the IFR Process. All requests for review must be supported by the senior treating clinician who originated the request, who must explain their reasons for considering that the decision taken by the IFR panel was either:

- not based on all relevant evidence and/or
- misunderstood submitted evidence and/or
- a decision which no reasonable IFR panel could have reached and/or
- procedurally improper

This level 1 IFR Assessment and Verification Panel will determine whether there is information which was not previously considered or which was misunderstood at the original level 2 panel.

- If there is new information or the evidence was misunderstood, then an appropriate level panel will be scheduled to review the information (within 20 working days).
- If there is a suggestion that due process has not been followed or that an unreasonable decision was reached, then a level 3 review panel will be scheduled.
- Where more than one reason for a review has been given, relevant new evidence and misunderstandings will be considered at an appropriate level panel in advance of any process review at Level 3.
- Where it is considered that there is neither any new evidence nor any concern regarding the process, the panel will write to the review requester explaining why a review is not considered appropriate. This will include clarification of both the process undertaken and the evidence considered at the original review panel in order to substantiate the decision.

5. Record Keeping

Notes of the meeting will be made on the Screening Tool (Appendix 5), which will clearly document the rationale for the decision.

6. Communication of decisions

The outcome of the considerations made by the Panel will be communicated in writing within **10 working days** of the date of the IFR Panel at which the case was discussed. Unless the requesting clinician has indicated otherwise, patients will be sent a copy of the correspondence along with a covering letter advising them to discuss the decision with the relevant clinician, if possible.

Note: Due to changes to working practices, the IFR Team does not have the capability to produce printed letters. Therefore, any communication of Panel decisions, including requests for additional information, will be sent to the requesting clinician. The requesting clinician will be responsible for ensuring the patient is kept updated with the progress of any funding request made on their behalf.

7. Timescales

Where there has been insufficient information to enable a decision to be made, the clinician will be given the opportunity to submit further or additional information to the request. This will, however, be time limited and if no further/additional information is received within 30 working days, the request will be closed.

The relevant Commissioning Manager is responsible for following up all outstanding requests and will undertake the following actions:

1. Request for **further information** letter (**within 10 working days** of request being reviewed);
2. **Reminder** letter (**within 20 working days** of request being received).
3. **Closure** letter if no information received (**within 20 working days** of reminder letter being sent).

Appendix 7a – Level 2 IFR Proforma

Level 2 IFR Panel Consideration Proforma

Patient Identifier: [*enter the complex case register number unique to this case*]
Request for: [*enter the treatment/therapy/intervention for consideration*]
Received from: [*enter the clinician initiating this request e.g. GP or Specialist Clinician and where they work e.g. the Hospital or Practice Name*]
Patient GP: *[enter the GP details if different from "received from"]*

The Panel is required to consider requests for NHS funding against the following areas:

1) Clinical **Exceptionality** (against published local, regional or national guidance if the recommendation of that guidance is contrary to the request for this patient).

OR

2) Clinical **Exceptionality** of the patient's clinical condition within the local population if there is no published local, regional or national guidance to be used.

AND

3) Clinical **Effectiveness** of the requested treatment for this patient.
4) Cost **Effectiveness** of the requested treatment.

1) **Background:**

1.1 *Enter main details about the patient and the request.*

1.2 Previous treatment:

1.3 Current treatment:

2) Potential patient numbers:

2.1 *Enter the incidence levels, per 100,0[illegible]r this condition and the potential number of similar patients predicte[illegible]stershire.*

3) About the Condition:

3.1 Include a brief summary abou[illegible]ndition that the treatment is being requested for.

4) Usual management of this condition:

4.1 Enter the recognised NHS treatment pathway for this condition.

5) Proposed Treatment:

5.1 Enter the information provided about the requested treatment for this patient, including duration, dose (for a drug), monitoring.

6) Evidence to support requested treatment:

6.1 Carry out an evidence search for the requested treatment and provide a summary of the evidence found, including evidence provided by the requesting clinician.

7) National and International Guidance:

7.1 *Enter any policies or guidance that has been published regarding the proposed treatment, for example, NICE, regional policies, etc.*

8) Local guidance:

8.1 *Enter any local policies or guidance that have been published regarding the proposed treatment, for example, commissioning, Area Prescribing Committee etc.*

9) Alternative Management Options for this Patient:

9.1 *Enter any details that have been provided about treatment op' .ient if the requested treatment is declined.*

10) Previous IFR Cases Considered:

10.1 *Enter a table of any IFR cases already c this condition/treatment, including the decision made.*

11) Treatment costs:

11.1 *Enter any treatment costs as .ne requested treatment. NB that drug treatment costs will need ' cost of administration and monitoring (i.e. daycase and outpatient*

12) Summary:

12.1 *Summarise the .at is it for etc.*

13) References:

Enter any references used in the consideration of this case.

Appendix 7b – Level 2 IFR Panel - Additional Information Request

Patient Identifier:

Request for:

Received from:

Patient GP:

Summary Of Previous Case Discussion

This case was previously presented on the [ENTER DATE] and .
The details of the panel decision are detailed below.

Clinical Exceptionality:

Clinical Effectiveness:

Cost Effectiveness:

Or provide summary of decision if not documented in this way (for example request for additional information).

Additional Information Request

A letter to the clinician requesting additional information was sent on the

A response from the clinician was received on .

1. Clinician Response to Correspondence

Comment:

2. Summary of Additional Information (where relevant)

Comment:

3. Any Other Relevant Information

Comment:

4. Expert Opinion (if appropriate)

Comment:

Conclusion

Summarise what this new information means.

The IFR panel need to determine whether the new information presented is sufficient with which to support the original request for funding of [ENTER TREATMENT] .

The Level 2 panel is entitled to approve requests for funding for treatment for individual patients where all the following conditions are met:

- The panel is satisfied that there is no cohort of similar patients.
- One of the following conditions is met:
    - The patient is suffering from a medical condition for which the Commissioner has commissioning responsibility and a commissioning position and the patient's particular clinical circumstances falls outside the criteria set out in an existing commissioning policy for funding the requested treatment;

  Or
    - The patient is suitable to enter a clinical trial which requires explicit funding by the Commissioner;

  Or
    - The patient has a rare clinical circumstance, thus rendering it impossible to carry out clinical trials, and for whom the clinician wishes to use an existing treatment on an experimental basis.
- There is sufficient evidence to show that, for the individual patient, the proposed treatment is likely to be clinically and cost-effective or that the clinical trial has sufficient merit to warrant NHS funding.
- Exceptional circumstances apply.
- The Commissioner can afford the treatment.

References:

Appendix 8 – Level 2 Terms of Reference

LEVEL 2 IFR CONSIDERATION PANEL

1. Membership & Quoracy

Quorate Membership (4 voting members):

- A Lay Member (**chair and casting vote**)
- A CCG Associate Director (**Voting**)
- A Consultant in Public Health representing the population in which the patient resides [5] (**Voting**)
- A CCG General Practitioner (**Voting**)
- A Patient & Public Interest (PPI) Representative (**non-Voting**)

Additional Attendees:

- An IFR, Prior Approval & Contracts Manager
- A Medicines Management Representative (when required to present a case)
- A Foundation Year 2/GP trainee or Specialist Registrar Public Health(when required to present a case)

The requesting clinician will be invited to attend the IFR Panel in support of their individual patient's case.

Voting Panel Members are required to have undertaken CCG approved IFR Training.

2. Frequency of Meetings

IFR Panels will be held on **ONCE a month** (extra-ordinary meetings may be convened at short notice if it is determined that an IFR requires consideration before the next scheduled meeting).

3. Patient/Clinician Involvement

Patients will be informed of the action being taken in relation to their case. A Patient Information Leaflet (PIL) will be included in this correspondence. Unless the requesting clinician has indicated otherwise, patients will be copied in to all correspondence, which will include the invitation letter to the requesting clinician that states the date of the IFR Panel at which their case will be considered. The patient may also submit any other relevant information in relation to their case - please see **Section 6.2** of the Operational Framework for further information. It is not permissible for patients or their advocates to attend the IFR Panel meeting but the requesting clinician will be offered the opportunity to attend the meeting on their patient's behalf - see **Section 6.3** of the Operational Framework for further information.

4. Information presented to the IFR Panel

An information pack of the IFR will be prepared for the IFR Panel and will include:

- An **IFR Panel Consideration Proforma (Appendix 7a)** including details of the condition to be treated, incidence and its usual management, evidence of clinical benefit, relevant national guidance and local policies, alternative/conventional treatment if available and full costs of the requested treatment (including ongoing costs);
  And
- Copies of the **IFR Proforma (Appendix 4)** and **Checklist for IFR Screening (Appendix 5)**; **And**

[5] Public Health Consultant for Herefordshire or Public Health Consultant for Worcestershire; if the panel has a case from each population, both Public Health Consultant representatives must attend.

- Copies of any additional information submitted by the requesting clinician in support of the request such as trial papers or trial abstracts on the treatment being proposed;
  And
- Copies of any other relevant correspondence submitted by other relevant parties in support of the request ie. GP, patient;
  And
- Other relevant papers.

Copies of the above papers will be completely anonymised and circulated to all IFR Panel members at least **5 working days** before the date of the meeting.

5. Main Responsibilities of the IFR Panel

a. The Level 2 panel is entitled to approve requests for funding for treatment for individual patients where all the following conditions are met:
   - The panel is satisfied that there is no cohort of similar patients.
   - One of the following conditions is met:
     - The patient is suffering from a medical condition for which the Commissioner has commissioning responsibility and a commissioning position and the patient's particular clinical circumstances falls outside the criteria set out in an existing commissioning policy for funding the requested treatment;

     Or
     - The patient is suitable to enter a clinical trial which requires explicit funding by the Commissioner;

     Or
     - The patient has a rare clinical circumstance, thus rendering it impossible to carry out clinical trials, and for whom the clinician wishes to use an existing treatment on an experimental basis.
   - There is sufficient evidence to show that, for the individual patient, the proposed treatment is likely to be clinically and cost-effective or that the clinical trial has sufficient merit to warrant NHS funding.
   - Exceptional circumstances apply.
   - The Commissioner can afford the treatment.

b. The panel is not required to accept the views expressed by the patient or the Clinical Team concerning the likely clinical outcomes for the individual patient of the proposed treatment but is entitled to reach its own views on:
   - The likely clinical outcomes for the individual patient of the proposed treatment;
     And
   - The quality of the evidence to support that decision and/or the degree of confidence that the IFR panel has about the likelihood of the proposed treatment delivering the proposed clinical outcomes for the individual patient.

c. The Panel is entitled, but not obliged to, commission its own reports from any duly qualified or experienced clinician, medical scientist or other person having relevant skills concerning the case that is being made that the treatment is likely to be clinically effective in the case of the individual patient.

d. Very occasionally an IFR presents a new issue which needs a substantial piece of work before the Commissioner can reach a conclusion upon its position. This may include wide consultation. Where this occurs the IFR panel may place a decision on hold until that work has been completed.

e. The IFR Panel shall take care to avoid adopting the approach described in the "Rule of Rescue". The fact that a patient has exhausted all NHS treatment options available for a particular condition is unlikely, of itself, to be sufficient to demonstrate exceptional circumstances. Equally, the fact that the patient is refractory to existing treatments

where a recognised proportion of patients with the same presenting medical condition at this stage are, to a greater or lesser extent, refractory to existing treatments is unlikely, of itself, to be sufficient to demonstrate exceptional circumstances.

f. Where a Panel approves a request, they may make the approval contingent on such conditions as it considers fit.

g. Where a Panel requests additional information, upon receipt of the information, the Level 2 IFR Panel – Additional Information Request form (Appendix 7b) will be completed and the new information considered at the next available level 2 panel meeting or within 20 working days.

The key purpose of the **PPI representative** is to oversee and provide external scrutiny to the process for managing individual patient requests during the IFR Panel level of the decision-making process.

The **Chair** will be responsible for summarising the discussions and approving the information documented on the **Level 2 IFR Summary Sheet (Appendix 9)**. All discussions and the final decision will be formally minuted and signed off by the Chair of the IFR Panel.

More than one case may be considered at each Level 2 meeting, but each case will be considered individually without reference to another. Paperwork will be individualised and the necessary forms (**Appendix 9 and 10**) will be completed for each case considered.

6. Voting

A consensus decision will be made by all voting members present with the final decision for each case considered carried by a majority vote. If there is a split decision, the Chair will have the casting vote.

Once the decision is made for an individual case, this needs to be ratified by the CCG member with delegated authority for decision making on behalf of their CCG. This member must be from the CCG responsible for the case being considered (on the basis of where the patient is registered).

7. Record Keeping

Notes of the meeting will be made and the rationale for the decision clearly documented using the **Level 2 IFR Summary Sheet (Appendix 9)**. The **External Assessment Tool (Appendix 10)** will be completed as follows:

- The PPI representative will be expected to complete the first section of the Level 2 IFR External Assessment Tool (Appendix 10) to ensure appropriate procedure is undertaken.
- The relevant Commissioning Manager is responsible for ensuring the second part of the form is completed once all relevant action has been taken.

8. Communication of decisions

Decisions will be communicated in writing **within 10 working days** of the date of the meeting. The Chair is responsible for approving the content of the letter; the CCG's Chief Officer will sign the final letter. Unless the requesting clinician has indicated otherwise, patients will be copied into the final correspondence. Given the technical nature of some of the discussions, a covering letter to the patient will also be sent summarising the discussions and final decision.

Note: Due to changes to working practices, the IFR Team does not have the capability to produce printed letters. Therefore, any communication of Panel decisions, including requests for additional information, will be sent to the requesting clinician. The requesting clinician will be responsible for ensuring the patient is kept updated with the progress of any funding request made on their behalf.

Given the individualised nature of the IFRs being considered at Level 2 of the IFR Process, the final correspondence will be tailored according to the Panel's discussions in relation to the individual case. However, standard clauses in the final correspondence letter will include:

- Date of the IFR Panel at which the case was discussed;
  And
- Confirmation of the case being discussed in line with the IFR Process;
  And
- Summary of the discussion and confirmation of the decision made by the IFR Panel, including the rationale on which the decision was made;
  And
- If the request is declined, details of the Review Process including the grounds on which a review can be requested.

Appendix 9 – Level 2 IFR Summary Outcome

In summarising the case, Panel Members use this internal form to consider the following:

Criteria	Comments
Clinical exceptionality: a) Treatment has been requested for which there is no policy and the condition in question is sufficiently rare that it is appropriate to consider funding on an individual case basis (usually <one patient annually) OR b) Treatment has been requested which is not normally funded under current policy and where a request has been made to consider clinical exceptionality	
Clinical effectiveness: Is there sufficiently robust evidence that the treatment is clinically effective, and that the patient in question might reasonably be expected to derive significantly greater benefit than typical patients on whom any policy is based?	
Cost effectiveness Is there sufficiently robust evidence that the treatment is cost effective?	
Other	

Appendix 10 – Level 2 & 3 Assessment Tool

External Assessment Tool for use at Level 2 IFR Panel and Level 3 IFR Review Committee

To be completed by the **PPI representative** during the Level 2 and 3 meetings to assess compliance with the process for managing individual funding requests

		Yes/No	Comments
1	Is the meeting quorate in its membership?		
2	Was the Panel presented with a full briefing pack on the case to be discussed including: • IFR Proforma submitted by the clinician • IFR Complex case for consideration proforma • Copies of all information submitted in support of the request • Copies of other support papers including trial papers		
3	Was the information submitted fully anonymised?		
4	Were all members of the Panel given the opportunity to contribute to the discussion?		
5	Did all voting members give their final decision and provide a rationale on the basis of their decision?		
6	In the event of there being a split decision, were the Panel Members asked to vote and did the Chair have the casting vote?		
7	Was the final decision fully summarised by the Chair and the criteria considered in reaching a decision? *(only applicable to Level 2 decisions)*		

For completion by a member of the IFR Team following the meeting:

		Yes/No	Comments
1	Has the patient been informed of the date of the meeting?		
2	Has the patient been given the opportunity to review the information to be presented and to contribute additional information in support of their case?		
3	Has the patient been informed of the process through which their case is being considered and referred to the NHSW website for further information?		
4	Was the final decision ratified by the CCG representative with delegated authority?		
5	Was the final correspondence ratified by the Chief Officer of the CCG?		
6	Was the decision communicated to the relevant clinician within 5 working days of the meeting date? If no, what was the reason for the delay in the correspondence being sent out?		
7	Was the patient copied into the final correspondence? If not, please state the reason.		
8	If the request was declined at Level 2 of the IFR process, was the appeals process explained in the final correspondence?		
9	Has the IFR register been updated with the outcome of the meeting?		

Appendix 11 – Level 3 Terms of Reference

LEVEL 3 IFR REVIEW COMMITTEE

1. Membership & Quoracy

The IFR Review Committee will consist of the following members of staff who will have had **NO prior involvement** in the case being considered:

Quorate Membership (4 voting members):

- A Lay Member (**chair and casting vote**)
- A CCG Associate Director (**Voting**)
- A Consultant in Public Health representing the population in which the patient resides [6] (**Voting**)
- A CCG General Practitioner (**Voting**)
- A Patient & Public Interest (PPI) Representative (**non-Voting**)

Additional Attendees:

- An IFR, Prior Approval & Contracts Manager
- A Medicines Management Representative (when required to present a case)
- A Foundation Year 2/GP trainee or Specialist Registrar Public Health (when required to present a case)

The requesting clinician will be invited to attend the IFR Panel in support of their individual patient's case.

Voting Panel Members are required to have undertaken CCG approved IFR Training.

2. Frequency of Meetings

Meetings will be convened **when required**. Full consideration will be given to the urgency of the case to ensure the review is considered in a timely manner.

3. Patient Involvement

Patients are not able to attend the IFR Review Committee although they can request to meet with a member of the IFR Review Committee and a Patient Relations Team Officer prior to the date of the Review Committee to clarify any points relating to the case.

4. Information presented to the IFR Review Committee

An information pack will be prepared for the Review Committee and circulated prior to the meeting, which includes:

- The paperwork presented to the original IFR Panel; and
- Copies of paperwork documenting the discussions and decisions made throughout the process of consideration of the request; and
- Copies of the correspondence received outlining the request for a review.

All papers will be completely anonymised prior to being circulated to the Review Committee members and only one copy of the papers retained on secure file.

5. Main Responsibilities of the IFR Review Committee

a. The level 3 panel will consider all the original evidence together with the review information submitted. The panel will determine whether
   - the process followed by the original IFR panel was consistent with the operational policy and/or

[6] Public Health Consultant for Herefordshire or Public Health Consultant for Worcestershire; if the panel has a case from each population, both Public Health Consultant representatives must attend.

- whether the panel reached an unreasonable decision.

A reasonable decision is one which:

- Was taken following a process consistent with the policies of the organisation
- Took into account and weighed all the relevant evidence
- Did not take into account irrelevant factors
- Indicated that the members of the panel acted in good faith
- Was a decision which a reasonable IFR panel was entitled to reach.

b. In the event that the IFR review panel consider that there was a procedural error in the decision of the IFR panel, the review panel shall next consider whether there was any reasonable prospect that the decision making panel may have come to a different decision if the procedural error had not been made.

c. If the IFR Review panel consider that there was no reasonable prospect of the IFR panel coming to a different decision, then the review panel should uphold the decision notwithstanding the procedural error.

d. However, if the IFR Review Panel considers that there was a reasonable prospect that the original decision making panel may have come to a different decision if the panel had not made the procedural error, the IFR Review Panel will require that panel to reconsider the decision.

e. The IFR Review Panel has no powers to authorise funding for the requested treatment but has the right to make recommendations to the IFR panel and/or to request one of the Officers authorised to take urgent decisions to consider exercising that power.

The key purpose of the **PPI representative** is to oversee and provide external scrutiny to the process for managing individual patient requests during the IFR Panel level of the decision-making process.

All discussions and the final decision will be formally minuted and signed off by the Chair of the IFR Panel.

6. Voting

A consensus decision will be made by all voting members present with the final decision for each case considered carried by a majority vote. If there is a split decision, the Chair will have the casting vote.

Once the decision is made, this needs to be ratified by the CCG member with delegated authority for decision making on behalf of their CCG. This member must be from the CCG responsible for the case being considered (on the basis of where the patient is registered).

7. Record Keeping

Notes of the meeting will be made and the rationale for the decision clearly documented.

The **External Assessment Tool (Appendix 10)** will be completed as follows:

- The PPI representative will be expected to complete the first section of the IFR External Assessment Tool (Appendix 10) to ensure appropriate procedure is undertaken.
- The relevant Commissioning Manager is responsible for ensuring the second part of the form is completed once all relevant action has been taken.

8. Communication of Decisions

Decisions will be communicated in writing to the individual requesting the review within **10 working days** of the date of the meeting. The referring clinician, the patients GP and patient will be copied into the final correspondence, unless the requesting clinician has indicated otherwise. Where a request for review has been made on the patient's behalf, the patient will be copied into the final correspondence with a covering letter advising them to discuss the outcome of the review with the relevant clinician.

Note: Due to changes to working practices, the IFR Team does not have the capability to produce printed letters. Therefore, any communication of Panel decisions, including requests for additional information, will be sent to the requesting clinician. The requesting clinician will be responsible for ensuring the patient is kept updated with the progress of any funding request made on their behalf.

Given the individual nature of the IFR's being considered at Level 3 of the IFR Process, the final correspondence will be tailored to the individual case and the Panel's discussions. However, standard clauses in the final correspondence letter will include:

- Date of the IFR Review Committee at which the case was discussed; and
- Confirmation of the case being discussed in line with the IFR Process; and
- Summary of the discussion and confirmation of the decision made by the IFR Review Committee, including the rationale on which the decision was made; and
- If the decision of the IFR decision making Panel is overturned on review, the actions being taken ie. request to be reconsidered by the IFR Panel. If the IFR decision making panel decision is upheld on review, details of the complaints procedure and NHS Ombudsman.

Appendix 12 – Requirement for Urgent Decision Making

URGENT DECISION MAKING PANEL

The Commissioner recognises that there may be situations where an urgent decision against an Individual Funding Request is required, before a level 2 panel can be convened. The following provisions apply to such a situation:

1. **Definition of an Urgent Case**
   An urgent request is one which requires an urgent consideration and a decision because the patient faces a substantial risk of death or significant harm if a decision is not made before the next scheduled meeting of the necessary IFR panel.

   The term "urgency" under this policy does not apply to situations where requesting providers have failed to make the request in a timely manner or where requesting providers have inappropriately raised the patients' expectations; in these situations provider trusts are responsible for proceeding with and funding treatment.

2. **Authorised Staff**
   The following staff may be convened at short notice to constitute a Panel responsible for making an urgent decision:
   - CCG Chief Officer, Managing Director or Chief Finance Officer (**Essential – Decision Making**)
   - Associate Director of Contracting & Procurement and/or IFR, Prior Approval & Contracts Manager and Medicines Management Representative if required (**at least 1 is essential for decision making**)

3. **Frequency**
   Staff will meet as soon as is practical giving consideration to the urgency of the situation, where possible within 1 working day of the urgent request being received.

4. **Main Responsibilities**
   a. The panel convened will as far as possible within the constraints of the situation, follow the general principles and processes of the operational framework for individual funding requests; giving particular attention to the considerations made by the Level 2 panel (see Appendix 8 – Level 2 Terms of Reference).
   b. As much information as is feasible should be provided and considered within the constraints of the timescale.
   c. The panel convened to make the urgent decision should be entitled to determine that the decision is not of sufficient urgency or importance to warrant consideration outside of the usual process.
   d. The panel convened are entitled to reach the view that in consideration of all the information available, the request represents a service development and so should be refused and/or appropriately referred for policy consideration.

5. **Voting/Decision Making**
   The CCG Executive Board Member is responsible for making the decision.

6. **Record Keeping**
   A summary of the key points and considerations of the Panel will be made and the rationale for the decision clearly documented using the **Level 2 IFR Summary Sheet (Appendix 9)**.

7. **Communication of Decision**
   For cases considered to be Urgent, decisions will be communicated by telephone on the day that the decision is made.

A written follow up to this decision will be communicated **within 5 working days** of the date of the meeting. The CCG Board Member is responsible for approving the content of the final letter; the Chief Officer will sign the final letter. Unless the requesting clinician has indicated otherwise, patients will **NOT** be copied into the final correspondence.

Given the individualised nature and limited work-up of urgent IFR cases being considered, the final correspondence will be limited but will include:

- Date of the IFR Panel at which the case was discussed; and
- Confirmation of the case being discussed in line with the IFR Process and basis on which the case was considered Urgent; and
- Summary of the discussion and confirmation of the decision made by the IFR Panel, including the rationale on which the decision was made; and
- If the request is declined, details of the Review Process including the grounds on which a review can be requested.