Individual Funding Requests Policy
(and Operating Procedures)
Version History

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<th>Version</th>
<th>Date</th>
<th>Author</th>
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<tr>
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Next review date

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1. Introduction

Clinical commissioning groups, West Suffolk CCG and Ipswich and East Suffolk CCG, commission local NHS health services. NHS England commissions highly specialised health services. Each organisation use national and local policies to prioritise treatments based on available resources and competing demands.

We recognise that there will always need to be a process for considering making additional NHS funding available for the atypical or uncommon patient. The Clinical Commissioning Groups have an Individual Funding Request Panel to perform this function.

Where a commissioning policy exists, the Individual Funding Request Panel considers whether there are sufficient grounds to agree funding for a treatment contrary to our commissioning decision not to fund the treatment for the population in general. The process for consideration in these circumstances is whether ‘exceptionality’ has been demonstrated by the evidence presented.

When the patient is suffering from a presenting medical condition for which the CCG has no policy these will be considered as “individual request” or rarity request.

The CCGs will be able to demonstrate that their decisions are based on sound principles and have been made after careful consideration of all the relevant factors, with reference to local conditions, and with a conscious intent to avoid discrimination.

2. Purpose

The purpose of this document is to ensure that there is a clear process to consider requests for the provision of treatments which are not normally commissioned, or not normally funded.

That requests are considered fairly, rationally and consistently and the process will operate in accordance with the requirements of current national guidance.

3. Roles and Responsibilities

3.1. The IFR Panel

The IFR Panel is responsible for recommending to the CCGs whether Individual Funding Requests should be funded or not, subject to exceptionality being demonstrated. The IFR Panel will sit monthly. Members of the IFR Panel will be drawn from a pool of suitably qualified and trained members which includes:

- GPs;
- Consultants in Public Health;
- Appropriate CCG representatives
- Pharmacists; and
- Lay members.

A legal indemnity will be provided by the CCG, to all legal liabilities of members of the IFR Panel who act in good faith;
Members must have attended induction training, and ensure that they are fully familiar with the IFR Policy before sitting on a Panel.

Members should attend a training session at least once every year, and sit on Panels at least twice a year, in order to retain their eligibility to serve.

The quorum for an IFR Panel is four members, which must include at least one lay person, and at least one clinically-qualified person. It is legitimate for one individual (other than the lay person) to “wear two hats”. As far as practical, the combination of members should be selected to provide a good range of perspectives and relevant skills.

The IFR Panel may be chaired by any of the members provided that s/he has sat as an IFR Panel member at least four times. The Chair must be identified in advance of the meeting, and must be available to approve the minutes and fulfill any other obligations within the specified time frame.

The IFR Panel may call for specialist clinical, legal, financial, or other advice as appropriate.

3.2. Conflicts of interest

Conflict of interest means any activity, commitment, or interest that may adversely affect, compromise, or be incompatible with the obligations of a Panel member. It includes but is not limited to situations where a significant financial or other interest could affect a Panel member’s judgment. Personal knowledge outside of the NHS of any IFR applicant shall usually amount to a conflict of interest.

Members will be required to declare their interests before joining the Panel pool. The IFR Lead Support Officer will be in a position to bear these in mind when organising Panels. As an additional safeguard, at the beginning of every meeting, the Chair should require any member to declare any relevant interests.

Anyone declaring any interest may, depending on the nature of the interest be required by the Chair not to take any part in any discussion or outcome of the relevant case or vote.

3.3. Training for IFR Panel Members

Training will cover the following areas:

- IFR policy and process, including IFR Reviews;
- Legal aspects of the work of IFR Panels;
- Healthcare ethics and applying the Healthcare Ethical Framework to decision-making;
- Consensus decision-making;
- Commissioning practice and CCG funding decisions;
- Critical appraisal skills;
- Methods of assessment of clinical and cost effectiveness;
- Confidentiality, data security, Caldicott principles and the requirements of the Data Protection Act and the Freedom of Information Act; and
- CCG complaints process.

3.4. IFR Triage Group

The IFR Triage Group is a working sub-group of the IFR Panel.

All submissions to the IFR process will be triaged. The purpose of the triage is to ensure that:

- all appropriate information with each request has been submitted.
- sufficient information has been submitted to allow a decision regarding clinical exceptionality.
• identify service development requirements, a request for a treatment should be classified as a request for a service development if there is likely to be a cohort of similar patients who are:
  • in the same or similar clinical circumstances as the requesting patient whose clinical circumstances mean that they could make a likewise request.
  and
  • who could reasonably be expected to benefit from the requested treatment to the same or similar degree.
• redirecting inappropriate submissions as required for example, contacting the contracts team or requesting further information.
• sufficient information has been provided on the available clinical and cost effectiveness information on the requested intervention to allow decision making.

If the IFR Triage Group decides that the funding application is requesting a health care intervention for a medical condition (or sub-group thereof) for which the CCG does not have a policy, the IFR Triage Group shall determine whether, in their judgment, there are likely to be one or more other patients within CCG who are, or are likely to be, in the same or similar clinical circumstances as the requesting patient in the same financial year, and who could reasonably be expected to benefit to the same or a similar degree from the requested treatment (‘Similar Patients’). This will be escalated to the Clinical Oversight Group (COG).

3.5 IFR Equipment Group
The IFR Equipment Group is a working sub-group of the IFR Panel. The purpose of the IFR Equipment Group is to consider individual funding requests for equipment. All requests are subject to all other principles of the IFR Funding Policy. All recommendations from the IFR Equipment Group are reported at the IFR Panel. Membership of the Equipment Group consists of:
• Deputy Chief Nursing Officer (or representative)
• Clinical Assurance & Professional Lead – NHS continuing Healthcare (or representative)
• Lead Community Contracts Manager (or representative)
• Head of Commissioning Finance (or representative)
• Clinical Effectiveness Manager (or representative)

3.6 Role of the Clinical Effectiveness Manager
The Clinical Effectiveness Manager will decide whether or not an IFR should be dealt with under the fast track procedure, and whether the application can be met within commissioned services, and whether the application is not an IFR.

3.7 Role of the IFR Lead Support Officer
Key elements of the IFR Lead Support Officer role will be:
• Managing the work of the Administration Team;
• Establishing the protocols for communicating and liaising with patients and clinicians;
• With the Triage Group, triaging submissions to the IFR process, identifying service development requirements, and redirecting inappropriate submissions as required;
• Contribute to the decision on whether submissions should be fast-tracked;
• Determining the additional information, specialist advice and reviews of evidence necessary to inform the Panel’s recommendation;
• Contributing to the recruitment and training of Panel members;
• Contributing to the continuing development of the IFR process.

3.8 Responsibilities of the Administration Team

The Administration Team will be responsible for:

• Administering the paperwork, ensuring the efficient handling and documentation of submissions, from first receipt through to archiving;
• Maintaining patient confidentiality and data security in accordance with information Governance and Caldicott Guidelines;
• Organising the IFR Panel meetings, and acting as Administrator to the meetings;
• Correspondence; and Progress chasing.

4. Submissions

4.1. Who can make a submission?

IFRs may be submitted by the following NHS personnel: consultant, GP or an equivalent autonomous NHS practitioner provided s/he will be responsible for administering the treatment. The person making the request is referred to in this policy as “the requesting clinician”. Patients may not make applications directly.

4.2. Application form

An application form ensures that relevant information is provided by every clinician for every IFR, regardless of the nature of intervention / treatment requested or the patients’ condition.

Using an application form makes a significant contribution to consistency of decision-making by presenting comparable information in a structured format to the IFR Panel.

The application forms are available at http://www.ipswichandeastsuffolkccg.nhs.uk or http://www.westsuffolkccg.nhs.uk.

Personal and confidential information about the patient and the clinician will not be shared with the IFR Panel. However, depending upon the individual clinical circumstances it may be necessary to re-introduce information on the patient’s age and/or sex for consideration by the IFR Panel. From time to time it may also be necessary to edit the text provided by clinicians to remove information which could compromise the patient’s anonymity. Personal information will only be shared with the panel if it is required for decision making and the patient’s best interests will always be given priority.

Whilst maintaining the confidentiality of patients is of paramount importance, there are also benefits to assuring the anonymity of requesting clinicians.

4.3. Responsibilities of the requesting clinician

The requesting clinician is required to affirm that s/he has discussed the proposed treatment with the patient (or has offered such a discussion) and obtained consent before the application is made for funding on his/her behalf.

The requesting clinician must make the patient aware of the implications of embarking on this process, particularly that it may take some time before the request can be decided and, if the patient is considering privately funding the requested treatment while the IFR is being considered that no retrospective funding is available even if the IFR is approved.

It is the responsibility of the requesting clinician to ensure that all the required information is submitted on the approved IFR request form, including the rationale, clinical evidence, cost
effectiveness information and evidence to support the case for exceptionality where appropriate.
The requesting clinician is required to have consulted appropriate partially excluded policies and
threshold policies for guidance and to ensure the appropriate clinical information is submitted.
When an IFR is submitted by a GP it is expected that s/he will have fully considered whether this is
the correct process to use.
When an IFR is submitted by an NHS consultant or equivalent practitioner, national guidance
requires the submission to be approved by the designated representative of the provider Trust. In
the case of an IFR for a drug this is likely to be the Chief Pharmacist. For other treatments it may
the business manager of the department where the treatment will be provided.

4.4. **IFRs can be withdrawn**

An IFR can be withdrawn at any time by written notice from the requesting clinician, advising the
IFR Team on the reason for withdrawal. For example, it may be necessary to withdraw if the
patient opts for an alternative course of treatment, to fund the treatment privately, or if the patient
dies.

5. **The Process**

5.1. **Receipt of a IFR application**

Only applications set out on the IFR form, and providing all the required information, will enter into
the IFR process.

5.2. **Check for completeness**

The date of receipt will be recorded for all applications received. Within three working days of
receipt of the form, the Administration Team will check the application form and ensure:

- Commissioning of the health care intervention requested is the responsibility of CCGs;
- The CCG is the Responsible Commissioner for the patient;
- All contact details, including instructions for communicating with the patient, have been
  provided;
- Appropriate parts of the form have been fully completed including consent;
- All supplementary documentation referred to is attached; and
- The application has been approved by a suitable representative of the Organisation
  providing the treatment (as appropriate).

The Administration Team will decide when the application is sufficiently complete to proceed to
consideration by the IFR Triage Group.

If the application is not sufficiently complete the Administration Team will contact the requesting
clinician/referrer requesting further information is submitted within 30 days.

5.3. **Triage Group**

The applications will be reviewed by the IFR Triage Group monthly (2 weeks prior to the IFR panel
meeting.

The role of the IFR Triage Group is to filter out funding applications which are not appropriate to be
put before the IFR Panel because the application should be determined through another process
or there is insufficient evidence to support a prima facie case on the grounds of exceptionality or
rarity.

The IFR Triage Group will determine whether the requested health care intervention is for a
medical condition (or conditions) for which there is already a policy.
If the IFR Triage Group decides that the funding application is requesting a health care intervention for a medical condition for which the CCG has a policy, it will next determine:

- If the requested treatment comes within the categories of treatment which the CCG has agreed to fund for a patient in the applicant’s clinical condition under the relevant Commissioning Policy, then an IFR application is not required and funding for the treatment should be approved without reference to the IFR process.
- If the requested treatment (either expressly or by necessary implication) comes within the categories of treatment which the CCG has agreed not to routinely fund for a patient in the applicant’s clinical condition under an existing CCG commissioning policy; or
- The requested treatment falls outside the categories of treatment that the CCG has agreed routinely to fund or not to fund for a patient in the applicant’s clinical condition under the relevant CCG commissioning policy. In such a case the IFR Triage Group shall, after reviewing all the matters set out in the application, decide whether the application demonstrates sufficient evidence of exceptional clinical circumstances that the IFR Panel could properly approve the application.

The Triage Group can make decisions to defer and redirect, and can make recommendations to approve or not approve an application to the IFR Panel.

Recommendations of the Triage Group are documented, and submitted to the IFR Panel for ratification and consideration as appropriate.

5.4. Determining clinical exceptionality

In making a case for clinical exceptionality it needs to be demonstrated that:

*The patient is significantly different to the general population of patients with the condition in question at that stage of the condition’s development; and the patient is likely to gain significantly more clinical benefit from the intervention than might be normally expected for patients with that condition at that stage of the condition’s development.*

*The fact that a treatment is likely to be efficacious for a patient is not, in itself, a basis for exceptionality*

5.5. Redirection and deferred applications

Where the Triage Group does not refer an application to the IFR Panel for ratification or consideration, the Triage Group shall record the reason. The Administration Team will take the appropriate action to either redirect to commissioned services (redirection), or request additional clinical information (deferred).

5.6 Fast-tracking urgent IFRs

IFRs should only be fast-tracked where there is a clear clinical reason to do so. This will usually be that the patient’s health will be significantly compromised by waiting until the next scheduled IFR Panel meeting. It is expected that only a small minority of IFRs will be dealt with in this way, and these will usually involve life-threatening conditions. IFRs will not be fast-tracked on the basis that waiting until the next IFR Panel is inconvenient or problematic for the patient or requesting clinician.

Any administrative delay on the part of the Provider will not be considered as urgent and the application will be processed through the normal channels.

The Clinical Effectiveness Manager will decide whether or not an IFR should be dealt with under the fast-track procedure.

Before assigning IFRs to the fast-track procedure, the Clinical Effectiveness Manager should consider carefully whether sufficient information of acceptable quality is available to make the recommendation without compromising any of the principles upon which recommendations should...
be made.
An extraordinary IFR panel may be convened or virtual panel (via telephone or email) with at least 2 clinically trained voting members of the IFR Panel.
The CCG has no obligation to fund treatment that has commenced before approval. Under no circumstances retrospective funding requests will be supported.
The outcome will be submitted to the IFR Panel during its next scheduled meeting for ratification.
The outcomes available to a fast-track Panel are:
- The request will be approved without conditions;
- The request will be approved with conditions attached;
- The request will not be approved; or
- The outcome will be deferred, whilst further information is obtained.

6. **The IFR Panel Meeting**

6.1. **Agenda and supporting papers**
The Administration Team is responsible for all the logistical arrangements for Panel meetings.
The Administration Team will prepare the agenda and supporting papers for each Panel meeting, in consultation with the IFR Clinical Effectiveness Manager, IFR Lead Support Officer and the Chair as necessary. The agenda should list general business, recommendations from the Triage Group and the Equipment Group, tracked referrals, new submissions, submissions requiring reconsideration, submissions withdrawn, reports, statistical and financial data and any other business.

For each application requiring a decision, the agenda should set out:
- the unique identifier;
- status (i.e. new submission, request for consideration of deferred submission, interim report on patient condition following conditional approval);

Members should receive the agenda and supporting papers no less than 3 working days in advance of each Panel meeting.

If a member requests further information or raises a question about the papers in advance of the meeting, both the request/question and the response should be circulated to all members as soon as possible.

6.2. **Management of the Meeting**
The Chair is responsible for the conduct of the meeting, determining whether the meeting is quorate, and ensuring that the agenda is completed. Panel meetings will be held in private. Requesting clinicians or patients will not be invited to make representations in person. The Panel may request specialists to attend the meeting and advise members during their deliberations, should they deem this to be necessary.

During the meeting the members of the Panel will consider the agenda and supporting papers.

6.3. **Principles to be applied by the IFR Panel**
Each IFR application will be considered on its own merits. Recommendations will be made using the agreed consensus decision-making process (if required) and Panel members should have received training in this method.

In keeping with the principles of the CCG’s Ethical Framework, the IFR Panel will need to take an objective view of the submission, and maintain an open mind about the information and factors to
be considered.

The IFR Panel shall be entitled to recommend approving requests for funding for treatment for a patient where all four of the following conditions are met:

- Either (a) the clinician makes a rarity request for funding for treatment for a patient in connection with a presenting medical condition for which the CCG has no policy or (b) the clinician makes an exceptionality request for funding for treatment for a patient in connection with a medical condition for which the CCG has a policy and the application demonstrates sufficient evidence of exceptional clinical circumstances;

- There is sufficient evidence to show that, for the patient, the proposed treatment is likely to be clinically effective and cost effective;

- Applying the approach that the CCG takes to the assessments of costs for other treatments outside this policy, the cost to the CCG of providing funding to support the requested treatment is justified in the light of the benefits likely to be delivered for the named patient by the requested treatment; and

- The request for this patient is not a request for a policy development.

The IFR Panel shall determine, based upon the evidence provided to the Panel, whether the patient has demonstrated exceptional clinical circumstances. The evidence to show that, for the individual patient, the proposed treatment is likely to be clinically effective may be part of the case that the patient’s clinical circumstances are asserted to be exceptional. However, this is not, in itself, a basis for exceptionality.

In determining whether a patient is able to demonstrate exceptional clinical circumstances the IFR Panel shall compare the patient to other patients with the same presenting medical condition at the same stage of progression.

Whether a clinician can demonstrate that the patient has “exceptional clinical circumstances” depends on the precise clinical facts of each individual case and whether those can genuinely be described as exceptional. However, an IFR Panel may consider that a named patient who has clinical circumstances which, taken as a whole, are outside the range of clinical circumstances presented by other patients with the same medical condition at the same stage of progression as the named patient could show that their clinical circumstances were sufficiently unusual that they could properly be described as being exceptional.

A key factor for consideration is whether the IFR Panel could reasonably envisage a “similar patient” with a similar set of clinical circumstances, which would tend to show that the patient was not exceptional. Examples of this may be where there are multiple subgroups / divisions of related medical conditions which could fall under a broader main condition (e.g. “neurological condition”) and from which many patients may benefit from the requested treatment.

The IFR Panel should take care to avoid adopting:

- The approach described as “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 the same stage are, to a greater or lesser extent, refractory to existing treatments is unlikely, of itself, to be sufficient to demonstrate exceptional circumstances; and

- “Treat and monitor for a short defined period” to see if the patient responds when there is minimal clinical evidence of efficacy available. There are risks with this approach for example in possible unknown adverse effects. Such requests may be more appropriately directed through a research/case study approach.
- The IFR panel may receive written briefings from the CCG Commissioning pharmacist and or colleagues from Public Health Suffolk on the submissions.

6.3. Decisions available to the Panel

When considering an IFR application, the Panel decision will be as follows:

- Approved
- Approved with conditions
- Not approved
- Deferred (more evidence/information is required)
- Redirected (see above definition)

Approved with conditions. IFRs may be approved for funding subject to conditions. In some cases, the Panel may require to be advised of the patient’s status at an interim point in order that they can approve a second phase of treatment.

For example, a clinician may request 6 cycles of a treatment but advise that a response may be observed within 3 cycles. The IFR Panel may agree to fund 3 cycles, but recommend that funding for a further 3 cycles will be conditional upon the patient’s response. The Panel would require a report detailing the response observed after the first 3 cycles.

6.4. Record of Panel meetings and confidentiality

All discussion during a meeting of the IFR Panel will be confidential.

At the end of the meeting the Administrator will ensure that one complete set of original records, including a signed copy of the minutes will be retained for 6 years.

Notes of an IFR Panel meeting will be taken by the Administrator at the meeting, and written up as formal minutes within the specific timescales.

The wording used to describe the Panel’s decisions, conditions and rationales in the minutes will be translated exactly into the outcome letters. Any error or ambiguity in this wording is the responsibility of the Chair.

When preparing minutes, both the Administrator and the Chair should use appropriate language to describe all discussions bearing in mind that these are documents which could become subject to a Freedom of Information Act, Data Protection Act or may be disclosed to a court. The decisions of the IFR Panel are attributable to the Panel as a whole. The minuting of discussion about specific concerns raised by individual submissions should avoid personalities.

The items of general business in the minutes should include:

- The date, time and place the meeting was held;
- The name of all members present, including a note of any member arriving late or leaving early and the items for which they were present;
- Any declarations of interest;
- The name of the Chair;
- The name of the Administrator;
- The name of any member submitting apologies for non-attendance; and
- The name of any observer/clinician/expert adviser who attended and the items for which they were present.
- For each individual IFR application considered by the Panel the minutes should record:
• The unique reference number of the IFR application;
• The status of the application (i.e. new submission, re-consideration referred submission, interim report on patient condition following conditional approval);
• The name of any member who declared an interest in or association with the application, and the nature of the declaration (the Chair to determine whether they should leave the meeting during discussion of that item);
• All the relevant items of information considered with regard to the application;
• Note of the written comments on the application made by any IFR Panel member not present;
• Note of any written statement submitted by the patient, their advocate or clinician;
• A summary of the opinion given by any special advisors attending the meeting
• Specific concerns raised by this submission and the Panel’s response to them;
• The outcome reached and the degree of consensus (if consensus tool used) (shown as X out of Y, where Y is the maximum, depending on the number of Panel members);
• Any conditions attaching to the recommendation (exact wording to be advised by the Chair) including if and when a follow-up report is required;
• The rationale for the recommendation (exact wording to be advised by the Chair);
• The form of words to be used in communicating a negative outcome and rationale to the patient (exact wording to be advised by the Chair); and
• Further information required and/or actions by the IFR Administration Team in the case of a deferred outcome.

The minutes of a Panel meeting will be written up by the Administrator to the meeting and submitted to the Chair of the Panel within 3 working days of the meeting. The Chair of the Panel to approve the minutes within 5 working days of receipt of the minutes by the Administrator.

Copies of the minutes will be distributed to Panel members for their final approval with the agenda for the next meeting. Copies of minutes will not be placed in the public domain. This is in the interests of preserving patient confidentiality. Although patients’ names will have been removed, the IFR process is by definition dealing with singular conditions. The singularity of these may be enough to identify an individual.

6.5. Communicating the Panel’s outcome

The Panel’s outcome will always be communicated in writing by a secure means. The letters communicating the Panel’s outcome may be signed by or on behalf of the Chair within 3 working days of the Chair’s approval of the minutes, the Administration Team will:

• Write to the requesting clinician to convey the Panel’s outcome, any conditions attached to an approval, and whether the conditions require any interim report on the patient’s status;
• Write to the patient (or his/her representative) to convey the Panel’s outcome, provided the patient has indicated they wish to receive such letters, using appropriate language;
• Notify the Panel’s outcome to the appropriate CCG budget holder;
• Update the IFR database.
Patients and their requesting clinician will be able to request a copy of the minutes of the Panel meeting, however only text relating to their case will be disclosed in order to preserve the confidentiality of other cases heard at that meeting.

7. **Reporting, Quality Assurance Checks and Archiving**

The IFR Team will report outcomes to relevant CCG Governing Body or Committees quarterly unless agreed otherwise.

The Administration Team is responsible for the final task of ensuring that:

- All documentation relating to each submission is properly identified, controlled and filed;
- Quality assurance checks are completed;
- Files are updated, closed and securely stored;
- Electronic data is properly documented, secured and stored; and
- Information likely to be required for audit is available in suitable format.

In keeping with the requirement of Records Management: Code of Practice (DH, 2006), IFR files should be kept in archive for a **minimum** of 6 years as determined by the individual ie Children up to their 25th birthday.

8. **Time Periods for Stages of the IFR**

The following table sets out a time frame for each element of the process:

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<tr>
<td>Acknowledgement of receipt of IFR application form</td>
<td>Within 3 working days</td>
</tr>
<tr>
<td>Determine urgency – assign to fast-track if necessary</td>
<td></td>
</tr>
<tr>
<td>Redirect application form if not IFR, and inform the referrer</td>
<td>Within 3 working days</td>
</tr>
<tr>
<td>Check submission is complete, and request additional information as appropriate</td>
<td>Within 5 working days</td>
</tr>
<tr>
<td>Prepare Triage Group papers and distribute in advance of scheduled meeting</td>
<td>At least 2 working days prior to scheduled meeting</td>
</tr>
<tr>
<td>Prepare IFR Panel papers including recommendations made at Triage Group for ratification or consideration.</td>
<td>At least 3 working days prior to scheduled meeting</td>
</tr>
<tr>
<td>Minutes to be written up by the Administrator and submitted to the IFR Panel Chair for approval</td>
<td>Within 3 days of the meeting</td>
</tr>
<tr>
<td>Minutes approved by the IFR Panel Chair</td>
<td>Within 5 working days of receipt of the minutes from the Administrator</td>
</tr>
</tbody>
</table>
9. **Dissatisfaction with the IFR Panel Decision**

The patient or clinician shall be entitled to express dissatisfaction of the decision of the IFR Panel.

- If new evidence becomes available after a decision not to fund has been made by an IFR Panel, then the correct procedure is to request a **Reconsideration** supported by the new evidence.
- If there is no further relevant information to be submitted but there is a query on the process, then there may be grounds for a **Review**.

9.1. **Grounds for Review**

The grounds for a review could be:

- **Illegality**: The refusal of the request was not an option that could lawfully have been taken by the IFR Panel;
- **Procedural impropriety**: The IFR Panel failed to follow due process and, as a result, the decision reached by the Panel was different from the one that would have been reached if due process had been followed;
- **Irrationality**: The IFR Panel did not take into account, or weigh appropriately, all the relevant evidence when making its decision.

9.2. **Requesting a Review**

An intention to request a review should be lodged in writing within one calendar month of the date of the letter notifying the decision of the IFR Panel demonstrating (with evidence) breach of one of the three principles above. The request can be lodged by:

- The clinician who submitted the IFR;
- The patient;
- A person with parental responsibility where the patient is a child under 18 years of age;
- A person appointed with lasting power of attorney if the patient lacks the mental capacity to lodge a request themselves; or

A third party (e.g. friend or relative) with the documented consent of the patient. The request for a review must be acknowledged within 3 working days by the IFR Lead Support Officer.

The person requesting the review has 20 working days in which to provide information in support of their request.

The number of reviews may be difficult to predict and arrangements for Review Panel meetings may need to be flexible in response to demand. However, the Review Panel should meet within 30 days of the date of the letter requesting a review.
If the clinician lodges the request s/he is required to affirm that s/he has discussed the process fully with the patient and is acting with his/her consent. If the patient or his/her representative requests the review they should have the support of the clinician who requested the IFR.

The person lodging the request should write to the IFR Team stating that they wish to ask for a Review of the Panel’s decision and note the grounds for the Review as identified in 9.1, confirming that they have the consent of the other party, and providing as much information/evidence as possible in support.

The IFR Lead Support Officer will write to the patient or his/her representative, and the clinician, acknowledging that a request has been lodged, within three working days of receipt.

10. Remit of the IFR Review Panel

The IFR Review Panel will review all the documents relating to the Review, the original IFR application and the IFR Panel’s decision. The Review Panel will consider whether:

- The IFR Panel acted in accordance with CCGs’ approved procedures;
- The decision was consistent with the Healthcare Ethical Framework for decision-making and the principles set out in the IFR Policy;
- The IFR Panel properly considered the scope and nature of evidence; and
- In reaching its recommendation the IFR Panel took into account and weighed all relevant factors;
- That the members of the IFR Panel acted in good faith;
- If the IFR Review Panel decides that the person requesting the review has made out one or more grounds of the as set out above, it shall send the case back for re-consideration by the IFR Panel;
- The IFR Review Panel shall not have the right to approve funding for the requested treatment but can require that any reconsideration of the decision shall be fast-tracked.

The IFR Review Panel will meet in private and consist of a minimum of 3 members:

- CCG Governing Body Lay member – (Chair)
- Director of Public Health or nominee
- Chief Nurse or nominee
- Lead GP

It is important that the review is independent, and is seen to be independent of the IFR process. For this reason, it is recommended that the IFR Review Panel should be made up of designated individuals (or roles) rather than drawn from a pool. For each designation, a deputy should be nominated. During their membership of the IFR Review Panel these individuals may not also sit as members of IFR Panels.

The IFR Review Panel should comprise a minimum of three members to include: Senior Officer of the CCG, a clinically-qualified person, and a lay member. All members should have experience with the work of the IFR Panel. They should be fully familiar with IFR policy and process, and have received appropriate training.

Members of the IFR Panel whose decision is being challenged should have no contact with the work of the IFR Review Panel unless called to give clarification.

Members of an IFR Review Panel serve as individuals not as representatives of any particular organisation or interest group. A legal indemnity will be provided to all members of the IFR Review Panel who act in good faith.
The IFR Review Panel may call for specialist legal or other advice as appropriate.

10.1. Administration of the Review Process

In order to maintain separation between the IFR process and the Review process, the IFR Administration Team involved with IFR Panel should not be involved in the administration of a IFR Review Panel.

A Review Manager should be appointed to handle contacts with the person requesting the review and manage the paperwork. This Review Manager would not be involved with the work of the IFR Panels, and would not have prior knowledge of the patient. The patient information leaflet outlining the IFR Panel and IFR Review process should make clear that the distinction between the IFR Review process and the IFR Panel process.

10.2. Information provided by the clinician or patient

The patient and his/her clinician will be invited to submit appropriate material, in advance, and in support of the review request. Information may be provided by the clinician and the patient, and on behalf of the patient by guardians, representatives, family members/carers and so on. Only clinical/medical information may be submitted – personal/social/emotional circumstances will not be taken into account by the Review Panel.

Information provided by the clinician should be in English and in writing or a conventional clinical medium such as x-ray or scan results provided these are accompanied by a report on their interpretation from the appropriate consultant.

Information provided by the patient, or on the patient’s behalf by non-clinicians, may be in other languages, or other media, including video recording, audio recording or Braille. If necessary translation services will be accessed by the CCG.

10.3. Actions in advance of the meeting

As soon as the date of the Review Panel meeting is confirmed the patient and or the requesting clinician should be informed, and an invitation for the patient and/or a representative of their choice to submit a written statement for consideration by the Review Panel will be made.

The Review Manager will prepare the agenda and papers for the Review Panel meeting, in consultation with the Chair.

Members will receive the agenda and all papers no less than 3 working days in advance of each meeting.

For each review the members will receive copies of:

- All papers seen by the IFR Panel, including the application form, supplementary information and evidence review;
- The minutes of the IFR meeting(s) at which the submission was considered and a recommendation produced;
- A written statement summarising any advice given verbally by specialists attending the meeting;
- The IFR Panel decision letter;
- The letter stating the intention to request a review;
- All further information provided by the patient, his/her representative, and the clinician in support of the review.

If a member of the IFR Review Panel requests further information or raises a question about the Panel papers, both the request/question and the response will be circulated to all members as soon as possible.
The IFR Review Panel may ask the IFR Lead Support Officer and/or a member of the original IFR Panel to give information in support of the reports produced for the original meeting or to clarify any technical details, and/or to present the case, as necessary.

The Review Panel may also, in appropriate cases, seek external advice including legal advice.

10.4 Review Panel meeting and decision
All discussion during the Review Panel meeting will be confidential. Decisions may be taken using the consensus decision-making process, if deemed necessary by the Chair. The principles of the Ethical Framework will be considered throughout.

The Review Panel may uphold or overturn the decision of the IFR Panel. Reasons for the Review Panel decision must be clear. A decision to overturn does not mean that the request will be funded: it means that the request should be considered again by the IFR Panel, taking into account any specific issues highlighted to them by the Review Panel.

The Review Panel may not defer its decision.

Notes of a Review Panel meeting will be taken by the Review manager, and written up as formal minutes. The minutes will record, as directed by the Chair:

- the decisions taken;
- the reasons for the Panel’s decision; and
- the consensus achieved (if the Consensus Tool is used).

10.5 Minutes
The minutes will be written up and verified and approved by the Chair within three working days of the meeting. The text of the minutes will be used in communicating the Review Panel’s decision.

Copies of the minutes will not be distributed to Review Panel members for their retention and will not be placed in the public domain. This is in the interests of preserving patient confidentiality.

10.6 Communicating the decision
The decision of the Review Panel will be notified in writing and sent by secure means to the patient and the clinician within 5 working days of the meeting.

10.7 Next steps
If the Review Panel upheld the IFR Panel’s decision, the patient and his/her clinician will be advised that no further considerations can be made. Their next recourse must be to the NHS Complaints process.

If the Review Panel overturned the IFR Panel’s decision on procedural grounds then the patient and his/her clinician will be advised that their IFR application will be reconsidered by the IFR Panel, which will take account of any additional evidence which has become available in the meantime.

In this situation the IFR Lead Support Officer will ensure that the reconsideration IFR submission is dealt with in the shortest possible time.

10.8 Filing and archiving
The Review Manager will be responsible for collating all the documentation relating to the review. At the end of the process s/he will hand over all documentation to the IFR Team for closure, quality assurance, archiving and secure storage.

11. Proposed time periods for stages of the Review Process
### Stage | Time period
--- | ---
Patient/clinician notifies the IFR Team that they are dissatisfied with the Decision in writing, stating the grounds that they are requesting a review. | Within one calendar month of date of letter communicating IFR Panel decision
Letter sent acknowledging the request | Within 3 working days of receipt of the letter
All information to be received from person requesting the review and invitation to submit written statement letters sent | Within 20 working days of acknowledgement letter
Panel papers circulated | No less than 3 working days before date of Review Panel Meeting.
Review Panel decision | Not more than 30 working days after the date of the acknowledgement letter
Minutes approved by the Chair of the Review Panel | Within 3 working days of the date of the meeting
Decision communicated to patient and/or Clinician | Within 5 working days of the date of the meeting
Retention of documents relating to IFR Reviews | At least 6 years

### 12. Monitoring Compliance
Monitoring compliance with this Policy will be carried out by:
- quarterly performance reports submitted to the Executive Team which will identify the activity of the IFR team
- Types of requests received
- Panel decisions
- Number of Reviews and outcomes

Quality checks on the data base (blueteq) will ensure:
- Timely handling of requests
- Accuracy of status for each request.

### 13. Definitions and Glossary of Terms
Throughout this policy the term:
- **‘health care intervention’** includes use of a medicine or medical device, diagnostic technique, surgical procedure and other therapeutic intervention.
- **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.
- **The IFR Panel** is the committee of the Clinical Commissioning Group that has
been authorised by the Primary Care Trust’s Board to take decisions on its behalf on individual funding requests.

**Case by case decision making**

in the context of priority setting, occurs when a decision maker decides to allocate NHS resources for a specified treatment for one or more specified patients as a substitute for policy making. This is generally regarded as poor practice because it avoids making an explicit policy.

**Responsible Clinical Commissioning Group**

means the Clinical Commissioning Group which discharges the Secretary of State’s functions under the National Health Service Act 2006 for an individual patient.

**An advocate**

of an individual patient’s choice can be any person chosen by the individual patient, for whom informal consent has been given by the patient (with the exception of a legal representative or pharmaceutical representative) to represent them.

**An Individual Funding Request**

is a request received from an NHS responsible clinician, which seeks funding for a single identified patient for a specific treatment.

**Clinical circumstances**

means the clinical features of the named patient’s medical condition or the progression of the named patient’s condition as opposed to the named patient’s social or personal circumstances, which cannot be taken into account, as this may place the patient in an advantageous position over and above that of another patient.

**Exceptional clinical circumstances**

means that the patient is significantly different to the general population of patients with the condition in question at that stage of the condition’s development; and the patient is likely to gain significantly more benefit from the intervention than might be normally expected for patients with that condition at that stage of the condition’s development. The fact that a treatment is likely to be efficacious for a patient is not, in itself, a basis for exceptionality.

**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; and

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.

The *IFR Panel* is the committee authorised by the CCGs’ Governing Bodies to make recommendations on its behalf on *individual funding requests*.

*A lay member* is a person recruited from the general population of either Ipswich and East or West Suffolk (e.g. from local health network groups), has undergone Criminal Records checks and has received appropriate training, in accordance with the Policy.

The *Requesting clinician* in this policy refers to the person making the request.

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

*A service development* is any aspect of healthcare which the CCG has not historically agreed to fund and which will require additional and predictable recurrent funding. 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*.

*A Similar Patient* refers to the existence of a patient within the patient population who is likely to be in the same or similar clinical circumstances as the requesting patient and who could reasonably be expected to benefit from the requested treatment to the same or a similar degree. The existence of one or more similar patients indicates that a policy position is required of the CCG.

**Treatment** means any form of healthcare intervention which has been proposed by a clinician and is proposed to be administered as
14. References

NHS Commissioning Board, Interim Commissioning Policy: Individual funding requests, April 2013, Reference NHSCB/CP/03


The National Institute for Health and Clinical Excellence, Guide to the Methods of Technology Appraisal


The National Institute for Health and Clinical Excellence, Appraising life-extending, end of life treatments

http://www.nice.org.uk/media/88A/F2/SupplementaryAdviceTACEoL.pdf

Department of Health, The NHS Constitution for England, July 2009,

The National Institute for Health and Clinical Excellence, Guide to the Methods of Technology Appraisal


The National Institute for Health and Clinical Excellence, Appraising life-extending, end of life treatments http://www.nice.org.uk/media/88A/F2/SupplementaryAdviceTACEoL.pdf


http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Actsandbills/DH_064103

Department of Health, World Class Commissioning Competencies, December 2007,

Records Management: Code of Practice (DH, 2006),
Appendix A

Dissatisfaction with the Decision of the IFR Panel

Patient and / or clinician do not accept decision of the panel

- Letter must be submitted stating dissatisfaction of the IFR Panel Decision and stating the reasons. To be received by CCG within 1 calendar month.

  - If
  - Further relevant information is disclosed that demonstrates exceptionality
  - Then
  - IFR Team submit for RECONSIDERATION by IFR Panel within 20 working days.

- If
  - There is a request for a Review identifying the grounds for that challenge (as identified in section per 9.1)
  - Responsible officer writes to the person requesting the Review acknowledging the request within 3 working days of receipt of the letter. Advises that they have 20 working days to provide information and names to the Review Manager

Review Manager will: -
  - * convene a Review Panel within 30 days of receipt of request for a Review
  - *Prepare papers and distribute to panel members at least 3 working days prior to the Review
  - *Notify the person requesting a review of the date the Review will take place
  - *Identify Review Panel Chair

Review Panel meets to consider:-
  - *If the IFR Panel acted in accordance with specified operating procedures
  - *Its decision was consistent with the Ethical Framework for Decision Making and the principles set out in the IFR Policy
  - *The scope and nature of evidence considered was appropriate
  - *In reaching its decision the IFR Panel had taken into account and weighted up all relevant factors

IFR Process correctly followed and Decision Upheld

IFR Team put on notice to deal with resubmission in shortest possible time

Minutes of meeting written up and approved by Chair within 3 working days of Review Panel Meeting

Decision notified to the person requesting the review within 5 working days of Review Panel Meeting

End of Process

OR

If procedural issues have been identified, then the IFR Panel will be instructed to reconsider the decision

NHS complaints procedure to be Followed

Patient or Clinician Still not satisfied
Appendix B:

Equality Impact Assessment

POLICY AND OPERATING PROCEDURES FOR INDIVIDUAL FUNDING REQUESTS (IFRs)

Stage 1 – initial screening

The first stage of conducting an EIA is to screen the policy to determine its relevance to the various equalities issues. This will indicate whether or not a full impact assessment is required and which issues should be considered in it. The equalities issues that you should consider in completing this screening are:

- Race
- Gender
- Gender identity
- Disability
- Religion or Belief
- Sexual orientation
- Age (including younger and older patients)
- Human Rights
- Socio-economic

Aims

To ensure that:

- There is a clear process to consider requests for the provision of treatments which are not normally commissioned, or not normally funded, by CCGs;
- Requests are considered fairly, rationally and consistently, in line with the CCG ethical framework.

The IFR Policy and Operating Procedure reflects national guidance and legislation, specifically the NHS Constitution (2010).

The following statutory rights set out in the NHS Constitution are relevant CCG IFR Policy:

Patients have the right to expect local decisions on funding of other drugs and treatments to be made rationally following proper consideration of the evidence. Further, if the NHS decides not to fund a drug or treatment that a patient and their doctor feel would be right for the patient, then the NHS has to explain their decision to the patient.

Patients have the right to drugs and treatments that have been recommended in NICE Technology Appraisals for use in the NHS, if the patient’s doctor says they are clinically appropriate for them.

In addition, the NHS Constitution makes the following commitment (pledge): to share with

- the patient any letters sent between clinicians about the patient’s care.
- Furthermore, Equity and Excellence: Liberating the NHS (July 2010) states:
- no decision about me without me.

With this in mind, the CGG’s policy offers patients and / or an advocate of their choice to provide a written submission in support of their case.
Effects

What effects will the policy have on staff, patients or other stakeholders?

Are there any barriers (communication, physical access, location, sensitivity etc.) which could inhibit access to the benefits of the policy?

The policy treats all individuals the same. Recommendations are made on the basis of clinical need and likelihood of benefit to the patient and value for money. Each individual request is considered in light of the policy, ethical and evidence based frameworks. The Panel process itself may have a differential impact upon different groups within society such as those with a learning disability, physical disability, or mental health problem, or those from areas of deprivation or whose first language is not English, which may impairs their ability to prepare a written statement for consideration at a Panel hearing if they wish to do so. Such accessibility issues are managed in three ways:

- All patients choosing to submit a written statement to Panel hearings can access a professional advocacy and support service to assist them in preparing documentation, understanding the process and presenting their point of view in the form of a prepared statement to be considered by the IFR panel;
- The option for a telephone discussion with an IFR Team member is available.
- Interpreting and translation is also readily available to those who require it.

Evidence

Is there any existing evidence of this policy area being relevant to any equalities issue?

Identify existing sources of information about the operation and outcomes of the policy, such as operational feedback (including monitoring and impact assessments)/Inspectorate and other relevant reports/complaints and litigation/relevant research publications etc. Does any of this evidence point towards relevance to any of the equalities issues?

No systematic analysis of patients utilising IFR has been conducted as personal data associated with all the diversity themes are not routinely collected.

Currently, audit of the IFR process does not include an assessment of the equality of access to treatments not normally funded, but it is likely that the same inequalities exist within the local demographics known about through Public Health and commissioning initiatives.

Stakeholders and feedback

Describe the target group for the policy and list any other interested parties.

Patients and the public served by the CCGs

Other interested parties include condition-specific /age specific /sexual orientation specific groups such as Cancer UK, MS Society, Parkinson’s Disease Society, Age Concern, Stone Wall, Trans-gender Groups.

Impact

Could the policy have a differential impact on staff, patients, or other stakeholders on the basis of any of the equalities issues:

The policy ensures that the CCGs make recommendations on IFRs in a fair, reasonable, transparent and consistent manner in accordance with principles of governance and probity, having regard to the need to strike the correct balance between commissioning services that meet the needs of the majority of the population and accommodating the differing needs of
individual patients.

The policy makes an explicit link between the IFR process and the corresponding mechanisms for commissioning decisions. Information gained from the IFR process will be used to inform the commissioner of any potential gaps in commissioned services or unintended consequences of other commissioning policies.