

# Individual Funding Requests (IFRs) Policy and Operational Procedures

## VERSION CONTROL

<b>Version:</b>	3.0
<b>Ratified by:</b>	Governing Body
<b>Date ratified:</b>	11 May 2016
<b>Name of originator/author:</b>	IFR Lead
<b>Name of responsible committee:</b>	Clinical Quality & Governance
<b>Date issued:</b>	May 2016
<b>Review date:</b>	May 2018

## VERSION HISTORY

<b>Date</b>	<b>Version</b>	<b>Comment / Update</b>
6 June 2013	1.0	Supported by Clinical Quality & Governance Committee
9 March 2016	2.0	Supported by Clinical Quality & Governance Committee
11 May 2016	3.0	Supported by Clinical Quality & Governance Committee

## Contents

1. Introduction.....	4
2. Individual Funding Requests Process for the Consideration of Cases .....	4
3. Urgent Decisions .....	7
Appendix 1 – General Guidance .....	8
Appendix 2 – Request for funding form.....	16
Appendix 3 - Individual Funding Requests Panel Terms of Reference.....	18
Appendix 4 - Individual Funding Requests Review Panel Terms of Reference .....	19
Appendix 5 - Framework for identifying Individual Funding Requests that are exceptions .....	20

## 1. Introduction

- 1.1. Individual Funding Requests may be received by the Clinical Commissioning Group (CCG) at any time but need to be considered within the overall commissioning framework in order not to distort pre-existing priorities.
- 1.2. An Individual Funding Request (“IFR”) is a request received from a clinician which seeks funding for a single identified patient for a specific treatment on the basis that the patient has exceptional clinical circumstances. Individual Funding Requests will only be accepted from a clinician on behalf of a patient.
- 1.3. The patient must be suffering from a medical condition for which the CCG has commissioning responsibility<sup>1</sup> and either the CCG has no commissioning policy in respect of the treatment for which funding is sought, the patient does not fulfill the criteria for eligibility for treatment set out in the policy or the CCG has a policy stating that it will not routinely fund the drug or intervention for any patient.
- 1.4. The CCG will only consider allocating funding for the treatment for the specific patient, on whose behalf the IFR is submitted, if it can be demonstrated that the patient’s clinical circumstances are exceptional when compared to other patients with the same presenting medical condition at the same stage of progression (“the cohort patients”). Specifically, the IFR Panel may consider, based upon the evidence provided to it, whether or not it has been demonstrated that the patient would, in all likelihood, benefit significantly more from the treatment than the cohort patients.
- 1.5. The IFR should not constitute a request for a service development. Where a clinician feels that a treatment would benefit a group of patients who all share similar clinical circumstances, s/he should contact his/her own trust’s management team with a view to submitting a business case for consideration by the CCG. Likewise, the CCG does not expect the IFR process to be utilised to provide funding for patients to continue to receive treatment commenced as part of a clinical trial. In accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Declaration of Helsinki, responsibility lies with those conducting the trial to ensure a clear exit strategy.
- 1.6. When an IFR is received where a provider trust has commenced an unfunded treatment prior to asking for or receiving confirmation that the CCG will approve funding, that decision is a clear risk taken by the trust. In considering the request for funding, the CCG will apply the criteria set out in this policy just as it would for any other request, with no presumption in favour of the patient continuing the treatment at the CCG’s expense. If a clinician decides to provide a treatment/drug at risk and retrospectively completes an IFR proforma then the IFR must be submitted within three months of the procedure/administration of the drug taking place.
- 1.7. Where patients in receipt of a package of care or treatment option approved by another CCG move into the CCG’s area and become the responsibility of the CCG, the CCG’s policy is that, subject to resource constraints, the CCG will continue to fund the treatment, provided that the care pathway has been initiated by a responsible NHS consultant and the requested treatment remains clinically appropriate.

---

<sup>1</sup> Certain more rare conditions are commissioned centrally by NHS England.

## 2. Individual Funding Requests Process for the Consideration of Cases

2.1. With effect from 1st April 2013 the IFR process is managed on behalf of the CCG by the Commissioning Support Unit (CSU). Legal accountability will remain the responsibility of the CCG.

2.2. There are three tiers to the ordinary Individual Funding Requests process:

### **Tier 1: Initial Submission**

Where a clinician wishes to make a referral or apply for funding for a treatment or therapy which may fall within the remit of the IFR policy, the following process should be followed:

#### **Initial Discussion with Commissioning Support Unit (CSU) IFR Lead/IFR Team**

- I. If the clinician is in any doubt, the IFR Lead/IFR Team will be able to advise, with the support of the relevant commissioning/contract managers, if required, whether the proposed referral/treatment would be covered by our existing portfolio of Service Level Agreements or current commissioning policies. If it would not be, the IFR Lead /Team may be able to suggest an alternative that will meet the patient's clinical needs. The IFR Lead, the IFR team or any other employee of the CSU has not the authority to approve referrals outside existing pathways, whatever the individual patient's personal circumstances. In such cases an IFR should be submitted.

#### **Submission of IFR Pro-forma**

- I. All IFRs must be submitted on the CCG approved IFR pro-forma (see **Appendix 1**) in type-written/word processed format (i.e. not handwritten). It is the responsibility of the requesting clinician through the requesting organisation's management team to ensure that all information relevant to the evaluation of the request is submitted. The pro-forma should be referred to for further detailed instructions on completing it. The CSU IFR Team will write to the requesting organisation/clinician to confirm receipt of the pro-forma. For requests received where the IFR pro-forma has not been used, the CSU IFR team will ask the requesting organisation/clinician to complete the pro-forma and return it within 6 weeks.  
If the pro-forma is not returned within 6 weeks, the request will be treated as withdrawn. Incomplete pro-formas or pro-formas requiring clarification will be returned to the requesting organisation/clinician for proper completion, clarification or the provision of additional information. If information is required from third parties, written consent shall be obtained from the patient before such information is sought.

#### **Triage of IFR Pro-forma**

- I. The CSU IFR Team will review all IFR pro-formas and advise the requesting organisation/clinician in cases where the patient clearly falls within the criteria set out in the commissioning policy and whose treatment will therefore be routinely funded.
- II. In relation to requests where there is no commissioning policy or where the patient clearly falls outside the funding criteria set out in the commissioning policy, the request may be considered as a potential service development, in which case it should be considered against competing priorities in the annual commissioning round, or the request can potentially be considered on grounds of exceptionality. In both these cases submission will need to be made to the CCG's IFR Panel.
- III. 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. A request for treatment will be classified as a request for a service development if there are likely to be a

cohort of similar patients:

- who are in the same or similar clinical circumstances as the patient on whose behalf the request is made;
- whose clinical condition means that they could make a like request (regardless as to whether or not such a request has in fact been made); and who could reasonably be expected to benefit from the requested treatment to the same or a similar degree.

Service developments include, but are not limited to:

New services;

New treatments, including medicines, surgical procedures and medical devices;

New diagnostic tests and investigations;

Quality improvements; and

Requests to vary an existing policy, for example, to add an indication for treatment, expand access to a particular patient sub-group or lower the threshold for treatment.

- IV. If a request, once considered by the IFR panel, is considered to be a service development, a response will be made to the requesting organisation/clinician, who may be invited to develop a business case for consideration by the CCG, if appropriate.

### **Tier Two: Individual Funding Requests Panel**

#### **Preparing a case for the Individual Funding Requests Panel**

- I. Once a fully completed IFR pro-forma is received from the clinician, the CSU IFR Team will write to the patient to advise him/her of the date of the IFR Panel, the operation of the IFR process and to give him/her the opportunity to provide any written evidence which s/he would wish the Panel to take into consideration in reaching its decision as to whether or not s/he has exceptional clinical circumstances. This might include the patient's understanding of the evidence base and how this might apply to him/her and information from clinicians or patient support groups, etc. Non-clinical social factors will not be taken into account.
- II. The CSU IFR Team may also write to other health professionals with clinical involvement in the patient's care (for example consultant, GP, therapist etc) for clarification of the patient's needs, evidence base etc, if appropriate and subject to the patient's consent being obtained.
- III. The CSU IFR Team, with support from Public Health and Medicines Management, where appropriate, will produce a summary of the case for the information of the Panel (see Appendix 2). Additional information may be required and will be requested from parties involved in the case, as appropriate. This summary will act as the front sheet to the documentation received from the referring clinician, patient, etc.
- IV. The IFR Panel will determine all matters within its Terms of Reference (ToR) (see Appendix 3).

### **Tier Three: Individual Funding Requests Review Panel**

- I. Where the IFR Panel decision does not support funding for the treatment or therapy, a request to the IFR Review Panel can be made by the individual patient affected by the decision or by a carer, a parent/guardian or a clinician on behalf of that individual. Such a request may only be made on the ground that due process was not followed by the IFR Panel in reaching its original decision.
- II. The IFR Review Panel will review the process that the IFR Panel followed rather than the decision that was reached. If the IFR Review Panel believes that the correct process was not followed then it will instruct the IFR panel to consider the case again.

- III. A request for a review should be made in writing to the CCG's Accountable Officer within three months of the original IFR Panel decision. This time limit may be extended, in appropriate circumstances, at the discretion of the Accountable Officer.
- IV. The CSU IFR team will support the process and ensure that reviews are presented to the CCG's IFR Review Panel for consideration as expeditiously as possible.
- V. The IFR Review Panel will determine all matters within its ToR (see Appendix 4).

### **3. Urgent Decisions**

- 3.1. There may be occasions when an urgent decision needs to be made before the IFR Panel can be convened. An IFR will be handled as urgent where, considering the nature and severity of the patient's clinical condition, a patient faces a substantial risk of significant harm if a decision is not made before the next scheduled IFR Panel meeting. It is expected that only a small minority of IFRs will be urgent and these will usually involve life-threatening conditions.
- 3.2. Urgency cannot arise as a result of a failure by a clinician to expeditiously submit an IFR pro-forma in the usual way.
- 3.3. Where an urgent IFR request is received from a clinician, the CSU IFR Team will assess the request to ensure that sufficient information is available for the IFR Panel to make a decision without compromising any of the principles upon which decisions should be made.
- 3.4. The CSU IFR Lead will be responsible for distributing the information/evidence received from the requesting clinician electronically to IFR Panel members. S/he will also be responsible for communicating the Panel's decision back to the requesting clinician.
- 3.5. The urgent decision will be made by virtual discussion via email or phone between the IFR Panel members.
- 3.6. The IFR Panel shall be entitled to reach the view that the decision is not of sufficient urgency or of sufficient importance that a decision needs to be made outside of the usual process

## Appendix 1 – General Guidance

### Individual Funding Request Pro-forma

#### GENERAL GUIDANCE

**PLEASE DO NOT HESITATE TO CONTACT THE IFR DEPARTMENT IF YOU WISH TO HAVE AN INITIAL DISCUSSION BEFORE MAKING A SUBMISSION OR BEFORE COMPLETING THE PROFORMA**

**Applications need to include the following information and be completed as follows:**

1. This pro-forma is to be completed by clinicians acting on behalf of their patient to request funding from a Commissioner within the Commissioning Support Unit for individual funding of drugs or other interventions not routinely commissioned by CCGs.

The following should be provided:

- A comprehensive and balanced clinical picture of the history and present state of the patient's medical condition should be provided
- The nature of the treatment requested and the anticipated benefits of the treatment
- The degree of confidence of the Clinical Team that the outcomes will be delivered for this particular patient.
- Previous treatments/interventions this patient has received for this condition and the outcome of these for the patient
- Details of standard NHS treatment that this requested treatment will replace if any
- Expected benefits and risks of treatment
- Any additional material considered to be relevant.
- The Clinical Team should refer to, and preferably include, copies of any clinical research material which supports, questions or undermines the case that is being made that the treatment is likely to be clinically effective in the case of the individual patient. **Please note: it is the responsibility of the requester to supply evidence in support of this request, not the CCG/commissioner**

2. This form should **NOT** be used to request funding for:
  - a. NICE Technical Appraisal Guidance approved interventions for specific indications if patients meets all criteria
  - b. Treatment requiring prior authorisation
  - c. Consideration of potential service developments where there is likely to be a group of patients with similar clinical circumstances who might also be candidates for this intervention
  - d. Approved indications where funding is already sanctioned under an existing commissioning policy and where the patient meets the treatment criteria.
3. 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.
4. To minimise delays in the application process please ensure **ALL** fields are completed comprehensively and in a word processed format, font 11 and style Arial or similar. Incomplete forms or forms with insufficient levels of information will be returned to the requesting clinician and may result in a delay in the request being considered.

5. Personal confidential data should be entered in sections 1-5 **ONLY** repeated use of personal confidential data is not acceptable
6. If reference is made to associated documentation, please indicate clearly which parts of this relate to each specific section
7. If you have received this pro-forma from the CCG please return a completed version within 6 weeks
8. If a pro-forma is faxed in cases of urgency, please ensure that a signed copy is also sent within 2 working days
9. Cut off for submission to the non-urgent Panel is two weeks before the Panel sits. Please contact the IFR Department if you require the Panel date(s).
10. Clinicians should ensure that their organisation has agreed to submission of the request and the Trust Medical Director has countersigned the declaration below.

The directly relevant commissioning policies are:

- The Framework for Commissioning
- The Individual Funding Request Policy and process
- NICE IPG guidance where this exists.

### DECLARATION

1. I confirm that it is not known or likely that there are any other patients within the responsible commissioner's population who are 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 similar degree.
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 and payment relating to the treatment with NHS commissioner IFR management panels, officers of the Commissioning Support Unit, managers of the Clinical Commissioning Group and the public health department to enable the case to be fully researched and considered.
3. To the best of my knowledge I have given the most accurate and up to date information regarding this patient's clinical condition.

Signature of requesting clinician .....Date .....

Signature of Trust Medical Director .....Date .....

Organisation: .....

Telephone: ..... NHS.net Email: .....

Correspondence Address:  
.....

**For Office Use Only**

**Unique Identifier:**

**Date received:**

<b>Application for:</b>			
<b>1 Intervention requested:</b> (Name & type)			
<i>('Intervention' refers to the requested treatment, therapy or investigative procedure – e.g. drug, surgical operation, medical device, and course of therapy. Further details of the intervention should be given in sections 16-18 below.)</i>			
<b>Proposed provider</b> Please provide full name of the proposed provider, postal address, contact telephone number and nhs.net email address			
<b>Patient Details:</b>			
<b>1. Patient name:</b>	<b>2. Date of birth:</b>	<b>3. Age:</b>	<b>4. NHS No:</b>
<b>5. Address:</b>		<b>6. GP &amp; Practice:</b>	
<b>7. Height</b>	<b>8. Weight</b>	<b>9. BMI</b>	<b>10. Smoker Yes/No</b>
<b>Contact Details:</b>			
<b>11. Requesting Clinician</b> Please provide full name and contact details of clinician requesting funding including postal address, contact telephone number and nhs.net email address			
<b>12.</b> Please provide name of any other clinicians who you have discussed this case with and whether they agree that the request is appropriate.			
<b>13.</b> Are you happy for us to contact the patient about the Individual Funding Request Process and copy all correspondence to them?	<b>Yes / No</b> (If no, please confirm that you are taking full responsibility for informing the patient.)		
<b>Case summary:</b>			
<b>14.</b>	<b><i>Diagnosis (i.e. Indication for which the intervention is requested)</i></b>		
	Medical Condition:		
	Relevant Past Medical History:		
<b>15.</b>	<b><i>Please outline the case history</i></b>		
	The duration of the problem		
	Clinical severity (using standard scoring if appropriate)		
	Other relevant diagnoses/co morbidities (including mental health)		
	Prognosis		

16.	<b>Summary of Previous Interventions for this condition</b>	<b>Dates</b>	<b>Nature of Intervention</b>	<b>Reason for stopping*/ response achieved</b>
	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/poorly tolerated			
17.	What would be the „standard“ intervention or clinical pathway for a patient with this condition at this stage?			
18.	What other alternative interventions (other than the requested intervention) are available?			
<b>Details of exceptional circumstances:</b>				
19.	<b>a.</b> An intervention that is covered by a relevant NICE Technology Appraisal or a local commissioning policy, but an exception to the policy.	<i>(Please tick one box)</i> <input type="checkbox"/>	<i>Please explain the exceptional circumstances in section 20 demonstrating:</i> <i>1. The patient differs significantly from other patients who would not be offered this intervention under current policy; and</i> <i>2. There is evidence to suggest that this patient will achieve greater benefit from the intervention than other patients with the same condition.</i>	
	<p style="text-align: center;"><b>OR</b></p> <b>b.</b> An intervention that is not currently routinely funded by the CCG, and for which no relevant national or local commissioning policy exist. <i>(This covers any intervention not included within current local pathways and not agreed through NICE Technology Appraisals, the Local Delivery Plan, or specific local policy.)</i>	<input type="checkbox"/>	<i>Please explain in section 20 why you are seeking funding as an individual patient rather than a policy decision; and provide relevant evidence in section 32.</i> <i>If your justification for the request is that the clinical condition is rare, please give further incidence/prevalence information to support this.</i>	
	<p style="text-align: center;"><b>OR</b></p> <b>c.</b> A referral to a provider with which the CCG does not have a service level agreement for an intervention that could be provided within local pathways	<input type="checkbox"/>	<i>Please explain the exceptional circumstances below in section 20.</i>	
20.	Explanation of exceptional circumstances:  <i>(Please explain why the standard intervention and existing care pathways are inappropriate for this patient, or why an alternative option is being requested in this case.)</i>			
21.	Are you aware of any other similar patients who would benefit from this intervention?		Yes/ No	

	<i>Would you expect to see other patients with the same condition or presentation as this patient within the next 12 months?</i>	
Details of intervention requested:		
22.	<b>Please give details of the proposed intervention, including (where relevant);</b>	
	For devices/ prostheses please specify; what the device is and manufacturer	
	Would this be a discrete episode of care or ongoing care	
	Planned duration of intervention	
	When and how the patient will return to standard/local pathways of care	
23.	<b>Estimated costs</b>	
	Anticipated costs (inc VAT)	£ <i>(Please indicate if cost is per year/cycle/course etc)</i>
	Are there any offset costs?	
	Describe the type & value of offset costs	
	Funding difference being applied for	
24.	Are there any additional associated costs? <i>(e.g. extra costs for delivery of intervention, additional patient monitoring, maintenance and replacement costs for medical devices)</i>	
25.	If this treatment is not approved, what other alternative treatment(s) will be offered to the patient?	
26.	How will you monitor the clinical effectiveness of this intervention?	
27.	Detail the current status of the patient prior to requested intervention.	

28.	<p>What is the minimum time frame/course of treatment at which a clinical response can be assessed? (e.g. after a single course of treatment) Please outline any anticipated or likely adverse effects of the requested treatment for this patient.</p>	
29.	<p>What are the intended outcomes of this treatment? Please outline the expected outcomes (including the anticipated benefit over other available options) of the requested treatment in this patient</p>	
30.	<p>Is the requested intervention a continuation of existing treatment funded via another route?</p>	<p>No / Yes – give details of existing funding arrangement and why ceased</p>
31.	<p><b>Please complete question 31 for Drug applications.</b> <b>(If the requested intervention is non-drug please move to section 32)</b></p>	
	<p>Is requested intervention part of a clinical trial?</p>	<p>Yes / No .If Yes, give details (e.g. name of trial, is it an MRC / National trial?)</p>
	<p>Is the drug funded through a clinical trial?</p>	<p>Yes/No</p>
	<p>Full name of drug</p>	
	<p>Name of manufacturer</p>	
	<p>Planned dose and frequency</p>	
	<p>Planned duration of intervention</p>	
	<p>Route of administration</p>	
	<p>Optimal start date</p>	
	<p>Does the patient have allergies?</p>	
	<p>If the intervention forms part of a regimen, please document in full</p>	<p>(e.g. Drug X as part of regimen Y (consisting of drug V, drug W, drug X and drug Z).</p>
	<p>Drug licensed for requested indication in the</p>	<p>Delete as appropriate: <b>Yes / No</b> (refer to pharmacy if required)</p>

	UK?	
	Has the Trust Drugs and Therapeutics Committee or equivalent Committee approved the requested intervention for use? (if drug or medical device)	Delete as appropriate: <b>Yes / No</b>  If <b>No</b> , Committee Chair or Chief Pharmacist approved: <b>Yes / No</b>
	<i>Application reviewed by Chief Pharmacist or nominated deputy (in the case of a drug intervention)</i>	<b>Name:</b>  <b>Email:</b>
	What is the anticipated toxicity of the intervention for this patient?	
Evidence		
32.	Please outline any relevant supporting evidence (including references).  <i>This should include any evidence supporting the likely clinical or cost effectiveness of this intervention in this patient. Supporting evidence should be as specific as possible to the intervention requested and the indications/exceptional circumstances in this individual case.</i>	
33.	If you are citing clinical evidence in support of this request, please indicate the level of this as follows:	<i>(Please tick one box)</i>
	(i). Evidence from: meta-analysis of RCTs or at least two good quality RCTs	
	(ii). Evidence from one good quality RCT and supporting non-randomised (phase II) trials	
	(iii). Evidence from lower quality RCT(s) and/or more than one phase II study and/or good quality observational studies	
	(iv). Evidence from single phase II study, case studies etc.	
	(v). Expert opinion	

Before sending this to the IFR Department please ensure **ALL** sections have been completed, that **ALL** responses are legible and the form has been signed as requested.

**Please note that cases will only be tabled to the Individual Funding Request Panel when we have received full information as requested above.**

**Failure to do so will result in a delay of your funding request.**

Please return the completed form electronically to:

AGCSU.IFRCW@nhs.net

By post to:

**Individual Funding Request Coventry & Warwickshire Team  
Arden & GEM Commissioning Support Unit  
Westgate House  
Market Street  
Warwick  
CV34 4DE**

## Appendix 2 – Request for funding form

**CCG : Individual Case Patient No.  
Request for funding for xxxxxxxxxxxxxx**

### 1. Background

### 2. Evidence Summary

Intervention:

Indications:

Intended outcomes:

Size of patient population:

Alternative treatments:

Evidence base:

Costs:

### 3. Policy background

Local:

National:

### 4. Issues for the Panel

Attached papers:

References:

## Appendix 3 - Individual Funding Requests Panel Terms of Reference

- 1) The IFR Panel is a formal sub-committee of the CCG's governing body under the scheme of delegation and, as such, has delegated authority from the CCG's governing body to make decisions in respect of funding for individual cases.
- 2) The IFR Panel will consider the evidence submitted in respect of a particular patient and reach a decision as to whether exceptional clinical circumstances have been demonstrated so as to justify a decision to allocate funding for this patient for the treatment sought, when the treatment is not routinely provided to the group of patients of which this patient is otherwise representative, or at all.  
Membership:
  - a. 1 Clinical Member (GP)
  - b. 1 Lead Officer/Contract manager
  - c. 1 Lay Representative
  - d. 1 Public Health representative  
who is employed by the CCG or holds an honorary contract with the CCG
- 3) The IFR Panel will require the attendance of any 3 members to be quorate, one of whom must be the Clinical Member (GP).
- 4) Other parties may be invited to attend the IFR Panel meeting to present cases. Commissioning Support Unit IFR team members will attend to make a record of the proceedings and to provide general administrative support.
- 5) The CCG will be responsible for ensuring attendance of the delegated members and will advise the Commissioning Support Unit on a monthly basis of members attending the IFR Panel. These members will also be available throughout the month to make decisions in respect of any urgent cases.
- 6) The IFR Panel will meet as required but generally monthly. Cases will be considered at the next available IFR Panel meeting. If further information is required to prepare the case for consideration, this may delay presentation to the IFR Panel until the next or subsequent month.
- 7) In cases where urgent consideration is required, an extraordinary IFR Panel meeting may be convened or another method of rapid discussion, e.g. via email, considered. Such decisions will be tabled at the next monthly IFR Panel and recorded in the minutes.
- 8) Cases will be anonymised before consideration by the IFR Panel. No individual who has currently, or has had, clinical involvement with a particular patient will be permitted to sit as an IFR Panel member for that case. The requesting clinician may attend to provide clarification of the evidence submitted. Clinicians attending for this purpose will be excluded from the subsequent IFR Panel discussion of the case. Patients will not be invited to attend the IFR Panel hearing.
- 9) If there is not a unanimous decision in a particular case, the Clinical Member will have the casting vote.
- 10) The Commissioning Support Unit, on behalf of the CCG, will produce letters for signature by the chair, within five working days of the Panel meeting, to the patient (where this is not contra-indicated by the clinician on the initial pro-forma because direct communication is felt not to be in the patient's best interests) and to the referring clinician, setting out the Panel's decision and the reasons for it.
- 11) Patients or clinicians who remain unhappy with an IFR Panel decision may request a review of the process by which the decision was reached
- 12) Anonymised minutes of each meeting will be provided to the private session of the CCG Board on a bi-monthly basis. In addition the Commissioning Support Unit will provide a summary of decisions on an annual basis to the Board and will highlight any individual decisions which may have implications for wider CCG commissioning policy.

## Appendix 4 - Individual Funding Requests Review Panel Terms of Reference

- 1) The IFR Review Panel is a formal sub-committee of the CCG governing body and part of the corporate governance process of the CCG. Its role is to decide whether the IFR Panel has properly followed its own procedures, has properly considered the evidence presented to it and has come to a reasonable decision based upon that evidence.

### Membership:

CCG Accountable Officer  
CCG Chair  
Clinical member of CCG

- 2) All three members must be present for the Review Panel to be quorate. The Chair will be agreed by the panel members.
- 3) The IFR Review Panel cannot include a member of the IFR Panel which initially considered the case under appeal, although they can be in attendance to answer any questions the IFR Review Panel may have about how the request was handled by the IFR Panel. Patients and clinicians will not be invited to attend the IFR Review Panel meetings.
- 4) Frequency of Meetings  
The IFR Review Panel will meet as and when required, when a request for review is lodged against a decision made by the IFR Panel.
- 5) Delegated Powers  
The IFR Review Panel is the final arbiter of the decision. The IFR Review Panel's decision will be reported to the CCG governing body.
- 6) Reporting Procedures  
The CSU, on behalf of the IFR Review Panel will produce letters for signature by the Chair, to the patient/carer/parent/guardian and referring clinician giving details of the Panel's decision within five working days of the Panel meeting.
- 7) The Accountable Officer will be responsible for reporting the decision in confidential session to the governing body.

## Appendix 5 - Framework for identifying Individual Funding Requests that are exceptions

- 1) This policy recognises that there needs to be a distinction between cases where the patient's clinical circumstances are genuinely exceptional and those where the presenting clinical circumstances are representative of a group – even a small group – of other patients.
- 2) Where the presenting clinical circumstances are representative of a group of other patients, the policy of the CCG is that a decision to fund, or not to fund, is a policy decision and should not be taken in the form of a decision for an individual patient. This ensures that the outcome of the decision is applied equally to all the other patients who have the same presenting clinical circumstances and that the principle of prioritisation is upheld.
- 3) The CCG and its constituent committees will at all times make decisions in accordance with the CCG's ethical framework, including the requirement to be mindful not to discriminate on grounds of gender, age, ethnicity, sexual orientation, educational attainment, employment, social or marital status, or religion, save where a difference in treatment is based on objectively justifiable factors and is a justified and proportionate response to the needs of different groups of patients.
- 4) Exceptionality  
There can be no exhaustive definition of the facets of a condition which are likely to bring a particular case within the bracket of "exceptional". The word "exceptional" refers to something to which the general rule is not applicable.
- 5) Whilst everyone's individual circumstances are, by definition, unique, very few patients have clinical circumstances which are exceptional, so as to justify funding for treatment for that patient which is not available to other patients. The following points constitute general guidance. However, the overriding question which an IFR Panel will need to ask itself is: has it been demonstrated that this patient's clinical circumstances are exceptional?

If a patient has a condition for which there is an established care pathway, the IFR Panel may find it helpful to ask itself whether the clinical circumstances of the patient are such that they are exceptional as compared with the relevant subset of patients with that medical condition.

The fact that a patient failed to respond to, or is unable to be provided with, one or more treatments usually provided to a patient with his or her medical condition (either because of another medical condition or because the patient cannot tolerate the side effects of the usual treatment) may be a basis upon which an IFR Panel could find that a patient is exceptional.

- 6) However, the IFR Panel would normally need to be satisfied that the patient's inability to respond to, or be provided with, the usual treatment was a genuinely exceptional circumstance. For example:

If the usual treatment is only effective for a proportion of patients (even if a high proportion), this leaves a proportion of patients for whom the usual treatment is not available or is not clinically effective. If there is likely to be a significant number of patients for whom the usual treatment is not clinically effective or not otherwise appropriate (for any reason), the fact that this particular patient falls into that group is unlikely to be a proper ground on which to base a claim that the patient is exceptional.

If the usual treatment cannot be given because of a pre-existing co-morbidity which could not itself be described as exceptional in this patient group, the fact that the co-morbidity is present in this patient and its impact on treatment options for the requesting patient is unlikely to make the patient exceptional.

7) The most appropriate response in each of the above 2 situations, is to consider whether there is sufficient justification (including consideration of factors such as clinical effectiveness, value for money, priority and affordability) to make a change to the policy adopted by the CCG for funding that patient pathway, so that a change can be made to that policy to benefit a subgroup of patients (of which this particular is potentially one such person). This change needs to be considered as a service development).

8) Non-clinical factors

It is common for an application for individual funding to be put, at least in part, on the grounds that a patient's personal circumstances are exceptional. This assertion can include details about the extent to which other persons rely on the patient, or the degree to which the patient has contributed or is continuing to contribute to society. The CCG understands that everyone's life is different and that such factors may seem to be of vital importance to patients in justifying investment for them in their individual case. However, including non-clinical social factors in any decision-making raises at least three significant problems for the CCG:

Across the population of patients who make such applications, the CCG is unable to make an objective assessment of material put before it relating to non-clinical factors. This makes it very difficult for the IFR Panel to be confident of dealing in a fair and even handed manner in comparable cases.

The essence of an individual funding application is that the CCG is making funding available on a one-off basis to a patient where other patients with similar conditions would not get such funding. If non-clinical factors are included in the IFR decision making process, the CCG does not know whether it is being fair to other patients who are denied such treatment and whose social factors are entirely unknown.

The CCG is committed to a policy of non-discrimination in the provision of medical treatment. If for example, treatment were to be provided on the grounds that it would enable an individual to stay in paid work, then this would potentially discriminate in favour of those working, compared to those not working. To offer a treatment to one patient and not another on the basis that the funded patient was working and the patient denied funding was out of work would breach a principle on which the National Health Service was founded and still currently operates. The CCG has not been mandated to distribute resources based on these divisions within society. Such a decision would also set a precedent for the CCG always to favour those in work over those not currently in work. The same can be said of many other social factors such as having children / not having children, being a carer / not being a carer and so on. Granting requests to fund treatment for adolescents on the grounds that they wish to go to university (and therefore not funding treatment would inhibit the individual from fulfilling their true potential) or because of a person's role in society (e.g. professional) would also be discriminatory and would contribute to social inequality.

9) Generally, the NHS does not take into account social factors in deciding what treatment to provide, unless a service is specifically designed to address health inequality or a prevailing inequity of access to normally provided care or treatment. It does not generally seek to deny treatment to those who may be thought to have caused or contributed to their own illnesses in some way, e.g. it does not deny treatment to those injured participating in sports in which they had voluntarily engaged.

10) In general, the NHS treats the presenting medical condition and does not inquire into the background factors which led to that condition as the basis on which to decide whether to make treatment available or not. The policy of the CCG is that it should continue to apply these principles in individual applications for funding approval. The CCG will therefore seek to commission treatment based on the presenting clinical condition of the patient and not based on the patient's non-clinical social circumstances.

- 11) In reaching a decision as to whether a patient's circumstances are exceptional, the IFR Panel is required to follow the principles that non-clinical social factors, including social value judgments about the underlying medical condition or the patient's circumstances, are not relevant.
- 12) Clinicians will be asked to bear this in mind and not refer to social or non-clinical factors to seek to support the application for an IFR.
- 13) Proving the case that the patient's circumstances are exceptional  
The onus is on the requesting clinician to set out the grounds clearly for the IFR Panel on which it is said that this patient is exceptional. The grounds will usually arise out of an exceptional clinical manifestation of the patient's medical condition, as compared to the general population of patients with that medical condition.
- 14) These grounds must be set out on the pro-forma provided by the CCG and should clearly set out any factors which the clinician invites the IFR Panel to consider as constituting exceptional clinical circumstances. If, for example, it is said that the patient cannot tolerate the usual treatment because of the side effects of another treatment, the referring clinician must explain how usual it is for the patient with this condition not to be able to be provided with the usual treatment.
- 15) If a clear case as to why the patient's clinical circumstances are said to be exceptional is not made out, then the IFR Panel is obliged to refuse the application. The IFR Panel recognises that the patient's referring clinician and the patient together are usually in the best position to provide information about the patient's clinical condition as compared to a subset of patients with that condition. The referring clinician is advised to set out the evidence in detail because the IFR Panel will contain a range of individuals with a variety of skills and experiences but may well not contain clinicians of that specialty. The CCG therefore requires the referring clinician, as part of their duty of care to the patient, to explain why the patient's clinical circumstances are said to be exceptional.
- 16) There is no requirement for the IFR Panel to carry out its own investigations about the patient's circumstances in order to try to find a ground upon which the patient may be considered neither to be exceptional nor to make assumptions in favour of the patient if one or more matters are not made clear within the application. Therefore, if a clear case of exceptionality is not made out on the paperwork placed before the IFR Panel, the Panel will be entitled to turn down the application.
- 17) Multiple claimed grounds of exceptionality  
There may be cases where clinicians seek to rely on multiple grounds to show their case is exceptional. In such cases the IFR Panel should look at each factor individually to determine (a) whether the factor is, hypothetically, capable of making the case exceptional and (b) whether it does, in fact, make the patient's case exceptional. The IFR Panel may conclude, for example, that a factor was incapable of supporting a case of exceptionality and should therefore be ignored. That is a judgment within the discretion of the IFR Panel.
- 18) If the IFR Panel is of the view that none of the individual factors on its own makes the patient's clinical circumstance exceptional, the IFR Panel should then look at the combined effect of those factors which are, in the IFR Panel's judgment, capable of supporting a possible finding of exceptionality. The IFR Panel should consider whether, in the round, these combined factors demonstrate that the patient's clinical circumstances are exceptional. In reaching that decision, the IFR Panel should remind itself of the difference between individual distinct circumstances and exceptional clinical circumstances.

19) The rule of rescue

The IFR Panel will not adopt the approach known 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 of progression are, to a greater or lesser extent, refractory to existing treatments, is unlikely to be sufficient, without more, to demonstrate exceptional circumstances.

20) IFR in the broader context of prioritisation

The IFR Panel shall have a broad discretion to determine whether the proposed treatment is a justifiable expenditure of the CCG’s resources. The IFR Panel is required to bear in mind that the resources requested to support the individual patient will reduce the availability of resources for other investments.

21) Individual Patient Requests for Funding for Treatments for Rare Conditions

The IFR Panel also has delegated authority from the CCG Board to consider requests for funding for interventions for rare conditions. Because there will not be a cohort of similar patients by comparison with whom the Individual Patient might be exceptional, as set out in the previous section of this policy, the IFR Panel will not, in Individual Patient cases, be considering whether or not the patient is exceptional. If incidence and prevalence criteria are both satisfied, as set out below, the IFR Panel will go on to consider the evidence for clinical and cost effectiveness and affordability.

22) For the purposes of this policy, an Individual Patient is defined by the incidence and prevalence of the requested intervention for a particular condition at the same stage of progression.

23) Incidence is the number of new cases of a disease in a defined population within a specified period of time.

24) In order to satisfy the incidence criterion, the intervention for a particular condition at the same stage of progression as that of the Individual Patient is expected to be initiated for not more than three patients per million population per year (i.e. 3 patients across the CCGs’ population per year).

25) Prevalence is the number of cases of a disease in a defined population at a particular point in time.

26) In order to satisfy the prevalence criterion, the total number of patients in receipt of the intervention for a particular condition at the same stage of progression as that of the Individual Patient should not be more than ten patients per million population at any one time (i.e. 10 patients across the CCGs’ population).

27) A request for funding for an Individual Patient should be submitted in exactly the same way as for an IFR. The CCG expects the pro-forma submission to be supported by evidence of incidence and prevalence, as well as evidence of clinical effectiveness and cost effectiveness.

28) Cases will be prepared for and submitted to IFR Panel consideration as set out under the IFR policy. A Review process will likewise be available for patients who believe that the CCG did not follow its own procedures, failed to consider the evidence presented or came to an unreasonable decision upon that evidence.

29) Timescales will apply as set out for the respective stages of the IFR policy.