



Individual Funding Requests (IFR)

**Commissioning Policy v2
April 2011**

Although Primary Care Trusts (PCTs) and East Midlands Specialised Commissioning Group (EMSCG) were abolished at the end of March 2013 with the formation of 5 Nottinghamshire County wide clinical Commissioning Groups (CCGs) policies that were in place prior to 1 April 2013 remain in place to ensure a consistent approach.

The NHS Mansfield and Ashfield Clinical Commissioning Group have adopted this policy, in its existing form, at a meeting of its Governing Body on 23 March 2013.

This policy sets the overall parameters within which care will be delivered.

**Commissioning Policy NHS Nottinghamshire County
Individual Funding Requests**

i. Version Control Sheet

Version	Section/Para/ Appendix	Version/Description of Amendments	Date	Author/ Amended by
1	Whole document	N/A	N/A	TD
2	<p>5.1 Exceptionality</p> <p>Appendix D: Guidance notes for clinicians. Section 4.</p> <p>4.3 Treatments covered by PCT commissioning policies.</p> <p>Glossary</p> <p>4.10 Treatment in another country.</p>	<p>Inclusion of the word 'education' in relation to social factors not usually considered in an IFR application.</p> <p>Wording included to emphasise that is the referring clinician's responsibility to ensure the IFR treatment request form is completed comprehensively and accurately, along with any relevant research papers, to avoid undue delays in decision making.</p> <p>Wording amended to 'East Midlands Specialised Commissioning Group (EMSCG) policies agreed at the EMSCG Board shall be binding upon all 9 PCTs in the East Midlands; however PCTs reserve the right not to adopt a collaborative/PCT policy proposed by the EMSCG Board'.</p> <p>Glossary of terms has been added to the document.</p> <p>Wording amended to 'Requests for treatment in another country will be considered in accordance with arrangements set out by the Department of Health (S2 form and Article 56); and set out under the East Midlands Framework document 'Patients seeking treatment in the EU, EEU and Switzerland'.</p>	April 2010-Dec 2010.	AF/PCT IFR leads

<p>Appendix C. IFR Treatment Request Form.</p>	<p>3. Diagnosis section added.</p> <p>4. Details of requester to include secure e mail/correspondence and clinical director/DTC/MDT/ethics support. Also section added to include details of the MDT approval/meeting following first ICDF review meeting 11/01/2011 at SHA.</p> <p>5. Consent section added.</p> <p>Wording added to emphasise clinician's responsibility for providing a complete form.</p> <p>7. Definition of exceptionality added to section.</p> <p>8. Definition of Incidence and Prevalence added.</p> <p>9.b Question added regarding the potential for the application to set a precedent for other patients.</p>		
<p>Timescales.</p>	<p>Acknowledgement to referrer amended from 3 to 5 working days.</p> <p>IFR manager to advise referrer within 5 working days of date of acknowledgment letter if request covered by existing contracts etc. Changed to 10 working days.</p> <p>Acknowledgement to referrer of treatment request form changed from 3 to 5 working days.</p> <p>Review panel changed from being convened within 10 working days of receipt of request if grounds for review are accepted, to 20 working days.</p>		
<p>4.9 Second opinions</p>	<p>Second opinions section expanded and clarified (taken from Nottingham City PCT wording).</p> <p>Based upon the CPAG</p>		

<p>6.6 Triaging of a Treatment Request Form (TRF)</p>	<p>recommendation on 29/10/2010 the following wording has been added: “However, if a requesting clinician believes they have significant new clinical evidence that they did not provide in their first submission which they feel may have made a difference to the decision made, then the clinician can submit a new IFR application with this new evidence.”</p>		
<p>6.7 Identifying urgent cases/ 6.9 Membership of the IFR panel/ Appendix F (section 5 Quorum).</p>	<p>Wording added to advise minimum membership to be quorate for urgent cases, and that quoracy for clinically urgent meetings is different to the usual IFR panel membership due to the need for an urgent decision to be made.</p>		
<p>6.8 Organisation of an IFR meeting.</p>	<p>It was confirmed at the CPAG meeting 29/10/10, patients could be involved by providing written correspondence. Sentence has been added to advise if patients wish to provide written evidence they can be directed to where they can seek help to do this e.g. PALS.</p>		
<p>Whole document</p>	<p>Reference to correspondence as ‘written correspondence’ throughout.</p>		
	<p>Typo’s/spelling and grammatical errors corrected.</p>		
	<p>Statements amended if document is referring to the patient’s clinician and not the patient. E.g. ‘the patient must demonstrate exceptional clinical circumstances’, amended to ‘the clinician must demonstrate that the patient has exceptional clinical circumstances’.</p>		
	<p>Reference to ‘Clinical team’ removed</p>		

	Throughout document.	from document, and replaced with 'referring clinician'. Amendments made following legal advice.	26/04/11	
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ii. EQUALITY STATEMENT

NHS Nottinghamshire County is committed to ensuring equality of access and non-discrimination.

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1. INTRODUCTION

The NHS exists to serve the needs of all of its patients but also has a statutory duty financially to break even (National Health Service Act 2006). Primary Care Trusts (PCTs) have a responsibility to provide health benefit for the whole of their population, whilst commissioning appropriate care to meet the clinical needs of individual patients. NHS Nottinghamshire County is a PCT and receives a fixed budget from Central Government with which to commission the healthcare required by its population. Commissioned services include those provided through primary, secondary and tertiary care NHS providers, the independent sector, voluntary agencies and independent NHS contractors and in house service providers.

The mechanism through which investment and disinvestment decisions are taken is the Local Operational Plan (LOP) process. PCTs do not expect to make significant decisions outside this process and in particular do not expect to commit significant new resources in year to the introduction of new healthcare technologies (including drugs, surgical procedures, public health programmes) since to do so risks ad hoc decision making and can destabilise previously identified priorities.

The LOP process, by its very nature, focuses on cohorts of patients with the more common clinical conditions. It cannot meet every healthcare need of all patients in any one clinical group or address the specific needs of patients with less common clinical conditions. The fact that the PCT is not meeting a healthcare need due to resource constraints is an inevitable fact of life in the NHS and does not indicate that the PCT is breaching its statutory obligations.

The PCT is required to have a process for considering funding for individuals who seek NHS commissioned services outside established commissioning policies. There are in general two types of requests that come before an Individual Funding Request (IFR) Panel, namely:

1. Requests for funding treatments for medical conditions where the PCT has no established commissioning policy (as shown by PCT policy or the treatments which are approved for routine funding in service agreements).
2. Requests for funding treatments for medical conditions where the PCT does have an established commissioning policy for that condition but where the requested individual treatment is not in the PCT policy or does not meet the criteria set out in the policy.

This policy requires requests in the first category to be considered against the tests of clinical effectiveness, cost effectiveness and affordability provided the requesting clinician is able to demonstrate that the patient represents an Individual Patient (as defined in this policy who does not have exceptional clinical circumstances). For patients in the second category the policy requires, as a threshold condition, the requesting clinician to demonstrate that the patient has exceptional clinical circumstances. If the clinician demonstrates that the patient has exceptional clinical circumstances (as defined in this policy) the request will be considered against the tests of clinical effectiveness, cost effectiveness and affordability.

This approach ensures that decisions relating to resource allocation are made transparently and consistently in relation to treatment for those patients with rare conditions, those patients for whom treatments of uncertain or unproven medical benefit are sought, or where treatment costs requested may be out of proportion with the benefit to the patient.

Each PCT is responsible for the management of Individual Funding Requests. This policy must be used to consider:

- requests for any form of medical treatment or care which is not included within existing service agreements;
- requests for any form of medical treatment or care which, for this particular patient, are outside the parameters set by existing service agreements;
- requests for any form of medical treatment or care where the treatment or care proposed could not be considered to be 'mainstream'.

NHS Nottinghamshire County has established an IFR process to consider such applications. This may include consideration by an Individual Funding Requests Panel. In considering an individual case the Panel will apply the PCT Commissioning Principles for decision making set out in Section 3 and the underpinning policies of the PCT.

2. PURPOSE

The IFR process set out in this policy will be used to consider individual requests for funding where a service, intervention or treatment falls outside existing service agreements.

This process will ensure that each request for individual funding is considered in a

fair and transparent way, with decisions based on the best available evidence and in accordance with the PCT commissioning principles.

3. PCT COMMISSIONING PRINCIPLES THAT UNDERPIN IFR DECISION MAKING

It is important that a PCT ensures a consistent approach is used to guide the allocation of its resources in both population based and individual commissioning decisions.

A principle¹ based decision making process supports the strategic planning and the effective use of resources within a PCT. All PCT commissioning decisions need to be made in accordance with these principles.

The Principles that the PCT seeks to support are:

- the PCT requires clear evidence of clinical effectiveness before NHS resources are invested in the treatment
- the PCT requires clear evidence of cost effectiveness before NHS resources are invested in the treatment
- the cost of the treatment for this patient and others within any anticipated cohort is a relevant factor.
- the PCT will consider the extent to which the individual or patient group will gain a benefit from the treatment
- the PCT will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
- The PCT will consider all relevant national standards and take into account all proper and authoritative guidance
- Where a treatment is approved, the PCT will respect patient choice as to where a treatment is delivered.

When considering an IFR, a PCT will also ensure that decisions:

- comply with relevant national policies or local policies and priorities that have been adopted by the PCT concerning specific conditions or treatments
- are based on the available evidence concerning the clinical and cost effectiveness of the proposed treatment, including any NICE publications and;

¹ principle: *a basic truth or a general law or doctrine that is used as a basis of reasoning or a guide to action or behaviour*

- are taken without undue delay; a pragmatic approach may need to be taken when dealing with urgent requests i.e. where a delay in reaching a decision to fund adversely affects the clinical outcome.

The PCT considers all lives of all patients to be of equal value and in making decisions about funding treatments will seek not to discriminate on the grounds of age, sex, sexuality, race, religion, lifestyle, occupation, family and caring responsibilities, social position, financial status, family status (including responsibility for dependents), intellectual/cognitive functioning or physical functioning save where a difference in the treatment options made available to patients is directly related to the patient's clinical condition or is related to the anticipated clinical benefits for this individual to be derived from a proposed form of treatment.

4. POLICY GUIDANCE

In considering individual cases, the PCT will apply the Commissioning Principles, the underpinning policies of the PCT and the following guidance which expands upon them.

4.1 Introduction of New Drugs and Technologies

The PCT will not introduce new drugs/technologies in an ad hoc basis through the mechanism of individual case funding. To do so risks inequity, since the treatment will not be offered openly and equally to all with equal need. There is also the risk that diversion of resources in this way will de-stabilise other areas of health care which have been identified as priorities by the PCT. The PCT expects consideration of new drugs/technologies to take place within the established planning frameworks of the NHS (for example the Local Operational Plan). This will enable clear prioritisation against other calls for funding and the development of implementation plans which will allow access for all patients with equal need.

4.2 NICE New Technology Appraisals (TAs).

Drugs and technologies that are approved as the result of a NICE Technology Appraisal (TA) need to be implemented within 3 months of the appraisal being published. The PCT will, within resource constraints, seek to ensure implementation of NICE TAs without delay but recognises that the PCT may take the full period of 3

months before a new commissioning policy can be brought into place where significant service change and/or development are required as part of the implementation. NICE also produces clinical guidelines which are a valuable source of good practice which the PCT will take into account in developing policy but the PCT retains discretion and is not mandated by Directions to implement such Guidance within a fixed time period or at all.

4.3 Treatments Covered by PCT Commissioning Policies

The PCT policy is that treatments not currently included in established care pathways (as identified for example in the Schedules to the service agreements with acute care providers) or identified for funding through the LOP process are not routinely funded. For a number of these interventions the PCT has published specific policy statements setting out restrictions on access based on evidence of effectiveness or relative priority for funding.

Policy development is an ongoing process and future policy on further treatments, in response to NICE Guidance/Guidelines, health technology assessments etc will be produced and published.

East Midlands Specialised Commissioning Group (EMSCG) policies agreed at the EMSCG Board shall be binding upon all 9 PCTs in the East Midlands; however PCTs reserve the right not to adopt a collaborative/PCT policy proposed by the EMSCG Board.

4.4 Treatments Not Covered by PCT Commissioning Policies

Specific groups of patients may not be covered by PCT Commissioning Policy including:

- Patients with conditions for which the PCT does not have an agreed policy, including patients with rare conditions and whose proposed treatment is outside agreed service agreements
- Patients with conditions for which the PCT does have an agreed policy but who may have exceptional clinical circumstances which lead to their clinician seeking a treatment that is not routinely available.

In such circumstances the PCT will not have given approval in advance to fund the treatment and approval will therefore be required under this policy. The treating

clinician should consider, before making the application, whether the requested treatment is an appropriate request judged against the PCT Commissioning Principles.

The role of IFR Panel is to make decisions on individual cases. It cannot be used as a means of 'creeping implementation' for new technologies. Consideration therefore needs to be given as to the likelihood of other patients having the same clinical need who could also benefit from the proposed treatment. If there are or are likely to be other patients then, properly considered, the request is for a service development and not an individual application. Where a decision may affect other patients, the application should be considered as a service development and not through the IFR process.

Patients with rare conditions should neither be advantaged nor disadvantaged simply because their condition is uncommon. This means that the same approach will be taken in applying the principles of clinical effectiveness and cost effectiveness to patients with rare conditions as should be applied to all other patients.

4.5 Requests to Continue Funding for Patients Coming Off Drugs Trials

The PCT does not expect to provide funding for patients to continue medication/treatment commenced as part of a clinical trial. In line with the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Declaration of Helsinki, the responsibility lies with those conducting the trial to ensure a clear exit strategy from a trial AND that those benefiting from treatments provided within the trial setting will have ongoing access to those treatments. The initiators of the trial (provider trusts and drug companies) have a moral obligation to continue funding patients benefiting from treatment until such time as the PCT agrees to fund through the LOP process. Where the treatment is not prioritised through the LOP, the responsibility remains with the trial initiators. The Research Ethics Committee should require this assurance as part of the approval for the trial.

4.6 Requests to Continue Funding for Treatments Commenced 'at risk' by Providers or by others (Including Patients)

On occasions, a request is received where a provider trust has commenced an unfunded treatment prior to asking for or receiving confirmation that the Primary Care Trust will approve funding. Evidence that the patient is responding to the treatment is

then presented as part of the case for PCT funding.

The provider trust's decision to commence treatment in advance of any decision by the PCT to fund is a clear risk taken by the trust and/or patient. The PCT accepts no responsibility for the decision taken by the provider trust in these circumstances.

In considering a request for funding the PCT will apply the criteria set out in this policy as it would for any other request, and accords no special privileges because the unfunded drug was given by a provider trust.

The PCT policy is that, unless a decision has been taken to approve routine funding for a treatment, the treatment will only be commissioned for an individual patient if the clinician is able to demonstrate that the patient has exceptional clinical circumstances. The fact that a patient has responded to a drug or other treatment in a manner which was anticipated for a proportion of patients who are commenced on the treatment is unlikely to be sufficient to demonstrate exceptional clinical circumstances.

Where such an application is approved on the basis of the clinician demonstrating that the patient has exceptional clinical circumstances (as defined in this policy), the PCT will not accept responsibility for the costs of any treatment provided by the provider trust prior to authorisation being given by the PCT.

A similar approach will be adopted if a treatment has been funded initially by a pharmaceutical company or other third party.

There are occasions where the initial stages of an unfunded treatment have been funded privately by the patient. The PCT will consider any information submitted on behalf of a patient in support of their case that the patient has exceptional clinical circumstances. This may include evidence derived from treatment that has been purchased privately and used by the patient. However, this potentially opens the way for a limited group of patients who can afford to fund a treatment that the PCT does not usually fund to be able to demonstrate benefit by virtue of access to private care and then submit this as a reason to justify NHS funding for the treatment in their particular case. This is a potentially inequitable approach and, in order to ensure that the PCT does not act in an inequitable manner, the issue of exceptional clinical circumstances will therefore continue to be the criteria applied by the IFR process. Accordingly, the PCT adopts no presumption in favour of continuing treatment which

has been previously paid for privately by the patient. As stated above, evidence that a treatment works as anticipated for a proportion of patients in the patient's clinical circumstances is unlikely, in itself, to provide evidence of exceptionality.

4.7 Requests to Continue Funding of Care Commenced privately e.g. reverting to NHS care

Patients who are having private treatment have a right to revert to NHS funded treatment at any point during their care. However, if they wish to exercise this right, the PCT will expect their care to be transferred to local pathways. Funding for the individual to continue care in a private facility, or to transfer to an NHS provider with which a clinical consultant privately has a contract of employment will not routinely be authorised unless they form part of local pathways. Where personal clinical circumstances may make such funding appropriate the case will require consideration by the IFR process.

4.8 Decisions Inherited from Other Primary Care Trusts e.g. patients who move

Occasionally patients move into the area and become the responsibility of the PCT (by registering with an **NHS Nottinghamshire County** GP) when a package of care or treatment option has already been approved by the PCT that was previously responsible for the patient's care. The PCT's policy is that, subject to resource constraints, it will normally agree to continue the treatment providing the care pathway has been initiated by a responsible NHS consultant and the requested treatment remains clinically appropriate.

4.9 Second opinions

A patient has no legal right to a second consultant opinion under current NHS guidance. However, they are entitled to request one and this should normally be approved if:

1. the request is supported by the patient's GP or consultant (the 'first consultant opinion')

AND

2. the second opinion is available from a clinical specialist who practices within a

relevant mainstream NHS commissioned specialist service. This opinion needs to provide a balanced view of the benefits and risks and for care which is not routinely commissioned it should be from a specialist who is:

- independent of the first 'consultant opinion' provider
- independent of the specific service, service provider or provider of the intervention that is being requested (unless no other specialist is available who could provide that balanced opinion).

AND

3. the patient is seeking to establish access to care on the grounds of clinical ability to benefit and not social factors (that are not taken into account under Individual Funding Request processes).

Third or fourth opinions for the same clinical condition will not normally be supported unless there are extenuating circumstances.

4.10 Treatment in another country

Requests for treatment in another country will be considered in accordance with arrangements set out by the Department of Health (S2 form and Article 56); and set out under the East Midlands Framework document 'Patients seeking treatment in the EU, EEU and Switzerland'.

5. DEFINING EXCEPTIONALITY AND AN INDIVIDUAL PATIENT

5.1 Exceptionality

The words "exceptional", "exceptionality" and "exceptional clinical circumstances" bear their natural meanings as defined in Oxford English Dictionary. However the PCT recognises that the meaning of these words has given rise to considerable difficulty in the past and offers the following guidance to assist the IFR Panel and clinicians as to how to approach the meaning of the words.

There is a difference between "individual" and "exceptional". Every patient has features of his or her condition which are specific to that individual and are not likely to be repeated in other patients with the same clinical condition at the same stage of progression of the condition. Exceptionality is not the same as individuality.

In order to be able to consider whether a patient has exceptional clinical circumstances the IFR Panel may find it helpful to focus on the following issues:

1. Are there any clinical features of the patient's case which make the patient significantly different to the general population of patients with the condition in question at the same stage of progression of the condition?
2. Would the patient be likely to gain significantly more clinical benefit from the requested intervention than might be normally expected for the general population of patients with the condition at the same stage of the progression of the condition?

The implications of this approach are that if a patient can be seen to be part of a group of patients for whom a treatment is not made available by the PCT under the PCT's existing policies then exceptionality for this individual patient is unlikely to be demonstrable. In this case the appropriate process for obtaining funding for the requested treatment will be for the PCT to change its policy. Such a change must happen through the LOP process (which will require the development of a business case and for the treatment to be prioritised against other developments) or through the PCT agreeing to make a change to its policy outside the LOP process. Once the change is made it will apply to all similar patients. However the IFR Process is not the procedure for the PCT to make such policy changes.

The PCT is required to achieve financial balance each year and therefore has a default policy of not funding a treatment where no specific policy exists to approve funding for the treatment. If the PCT has not previously been asked to fund an intervention that has the potential to affect a number of patients, the application should be made by clinicians for the PCT to consider the intervention through its general commissioning policy and not by way of an IFR application.

The PCT policy is that the IFR committee should consider requests for treatments that are not routinely available based on the patient's clinical circumstances. This means that social and personal factors such as age, gender, education, caring responsibilities and family circumstances can only be taken into account where they are relevant to the patient's clinical outcome. Whilst a patient's professional, economic or social standing or their family responsibilities are important to individuals, the PCT policy is that they are not relevant in assessing whether a patient has exceptional clinical circumstances.

5.2 An Individual Patient

For the purposes of this policy, an Individual Patient is determined by reviewing the incidence and prevalence of the requested intervention for a particular condition at the same stage of progression of that condition. If the PCT has no policy for the intervention being requested for a particular condition, then the IFR Panel can only consider the request if both the incidence and prevalence criteria that are set out below are met **or the patient has exceptional clinical circumstances compared to the cohort of patients (however small) with the presenting condition.** In some cases, PCTs may have adopted policies for small numbers of patients which have often been developed regionally. If the request is covered by such a policy then it should be viewed as a request to change the policy and therefore will not be considered by the IFR policy, even if the incidence and prevalence criteria are met.

An IFR request **for an individual patient** will be considered by the IFR Panel on its individual merits with the decision on whether to fund a requested intervention based on the evidence of clinical and cost effectiveness and affordability. If both the prevalence and incidence criteria are not met then the PCT will not consider that the request represents an individual patient. In these circumstances, funding can only be provided if a decision is made by the PCT to develop a policy for the requested intervention for a group of patients, including the requesting patient; **unless the patient has exceptional clinical circumstances compared to the cohort of patients (however small) with the presenting condition.** Such a change must happen through the LOP process (which will require the development of a business case and for the treatment to be prioritised against other developments) or through the PCT agreeing to develop a policy outside the LOP process. Once the policy is developed it will apply to all similar patients. However the IFR Process is not the procedure for the PCT to develop such policy.

Incidence e.g. the number of new cases of a disease in a defined population within a specified period of time

The intervention for a particular condition at the same stage of progression of that condition is expected to be initiated for two or fewer patients per million population per year (10 patients across the East Midlands SHA PCTs population per year).

Prevalence e.g. the number of cases of a disease in a defined population at a point in time

The total number of patients on the intervention for a particular condition at the same

stage of progression of that condition is less than 10 patients per million population at any one time (40 patients across the East Midlands SHA PCT population)

6. THE PROCESS FOR MANAGING INDIVIDUAL FUNDING REQUEST (IFR)

6.1 Who can submit an IFR

This policy will apply to any patient for whom the PCT is the responsible commissioner. A doctor, or other health care professional directly involved in the care of a patient, can make a request for an intervention not routinely funded (as defined in Section 2.). It is the referring clinician's responsibility to ensure the treatment request form is completed as accurately and comprehensively as possible to avoid possible delays in considering the request. A patient, or a non-clinical representative, may not submit an IFR as a clinical sponsor is required. On receipt of a submission the following IFR process should be followed. The IFR process is described in the table in Appendix A. and diagrammatically in the flowchart in Appendix B.

6.2 Administration and Reporting

Requests will be date stamped, processed and logged onto the PCT IFR database by the responsible IFR Officer (normally a Commissioning Manager). Acknowledgement will be sent to the referrer within 5 working days, with a copy to the patient/carer or guardian. It will be the responsibility of the IFR Officer to manage all requests received and correspondence with the referrer and patient/carer or guardian. The IFR Officer will normally be a member of the PCT Commissioning Team.

For each request received, a unique numbered case file will be generated with all paperwork pertinent to the case kept in chronological order. All decisions will be fully documented and all communication will be in writing whenever possible. When telephone conversations take place, a file note will be added as a record of the conversation. Both the evidence considered and the decision made will be recorded in writing. All national and local NHS policies regarding confidentiality, retention and destruction of records will be adhered to. The case files will be regularly reviewed by the IFR Panel and an annual report of cases considered by the IFR Panel and Review Panel will be submitted to the PCT Board.

6.3 Timescale for Managing an IFR

Requests will be managed within a maximum period of 40 working days from the date of the receipt of a Treatment Request Form to the date of the letter from the PCT informing the requesting clinician of the decision of the IFR Panel. Within this time period, a number of recommended maximum time periods for stages of the IFR process are set out in Appendix A, but these are advisory, rather than mandatory, providing the overall process is completed within the 40 day period.

6.4 Initial Handling of an IFR

Cases are initially dealt with, and screened, by the IFR Officer who will advise the referrer whether the existing portfolio of contracts, SLAs or current commissioning policies would cover the request. If a policy exists, and where appropriate, the IFR Officer will check whether the criteria within the policy can be applied. Where clinical advice is required, the IFR Officer will seek advice from the Public Health Directorate. Clinically urgent requests will be determined by a senior Public Health professional, nominated by the Director of Public Health, and will be managed under 6.7 'Identifying Urgent Cases'.

If an individual meets the criteria within a policy, and a decision to agree funding can be made at this point by the IFR Officer, then a response will normally be sent to the referrer within 10 working days of the date of acknowledgement of the initial request by the PCT. The IFR Officer is unable to authorise referrals outside existing contractual arrangements.

If the IFR Officer has reason to consider that simple application of SLAs and/or current commissioning policies would be inappropriate for a case, then the IFR Officer should advise the referrer, and the patient/guardian or carer, normally within 10 working days, that an Individual Funding Request must be submitted to the IFR Officer at the PCT using the IFR Treatment Request Form (Appendix C). A copy of the Guidance Notes for submission of a Treatment Request Form should be included (Appendix D) and the Patient Information Leaflet explaining the process (produced by the PCT). If a clinician wishes to discuss whether submission of a Treatment Request Form is appropriate, or would like help with completing the Treatment Request Form, then they should contact the IFR Team in the Public Health Directorate.

6.5 Submission of a Treatment Request Form (TRF)

Only a clinician directly involved in the clinical care of the patient (usually their Consultant or GP) can submit a Treatment Request Form. On receipt of a Treatment Request Form, the PCT IFR Officer will acknowledge receipt within 5 working days using a standard letter outlining the PCT IFR process. The patient's GP will be sent a copy of all correspondence regarding the case if they are not the requesting clinician.

6.6 Triage of a Treatment Request Form

The Treatment Request Form will be triaged by the IFR Officer and a senior Public Health professional, nominated by the Director of Public Health (the Screening Pair).

The skills and expertise required of the screening pair are the ability to:

- Determine whether an existing policy or SLA adequately covers the treatment request
- Interpret the PCT definitions of exceptionality and an individual patient in the context of the clinical information that is presented

The pair will be able to consider three options;

- Approve the request if covered by an existing SLA/ commissioning policy
- Refuse the request without reference to the IFR Panel
- Refer to the IFR Panel

The criteria that are used to triage a Treatment Request Form is whether there is an arguable case, based on the evidence presented in the application, that the IFR Panel could consider approving funding for the requested treatment under this policy.

The application will be refused at the triaging stage if:

1. the requested treatment arises in relation to a medical condition where there is PCT policy and (a) the requested treatment is not a treatment that is approved under the policy, and (b) there is no arguable case on the evidence presented that the patient can show exceptional clinical circumstances.
2. The requested treatment arises in relation to a medical condition where there is no PCT policy and (a) on the evidence presented the requested intervention for that particular condition may affect other patients in the PCT population as defined in this policy under 5.2. and (b) is no arguable case on

the evidence presented that the patient can show exceptional clinical circumstances (which will normally be determined by comparing this patient to the cohort of patients (however small) with the presenting condition) so that the request should be properly treated as a request to change the PCT policy.

Where there is uncertainty, the case should be referred to the IFR Panel. All decisions made by the Screening Pair will be recorded and reported to the IFR Panel on a quarterly basis.

A routine request will normally be triaged within 10 working days of the date of receipt of the Treatment Request Form by the PCT unless additional information is required when an additional 10 working days will be granted. The requesting clinician will be contacted by letter and asked to comment on whether any additional information should be included in the Treatment Request Form.

If a request is refused a letter will be sent to the clinician and the patient explaining the reasons for the decision and outlining the options that are available, including using the NHS Complaints Procedure.

If a request is refused at the triaging stage this policy does not provide a right of appeal to the IFR Committee and does not provide a right to request that the decision should be reviewed by the Review Committee. However the patient has a right to make a complaint under the NHS Complaints Procedure. One outcome of such a complaint could be to require the triaging process to be reconsidered or for the case to be referred to the IFR Panel for consideration. However, if a requesting clinician believes they have significant new clinical evidence that they did not provide in their first submission which they feel may have made a difference to the decision made, then the clinician can submit a new IFR application with this new evidence.

If a request is referred for consideration by the IFR panel a meeting will normally be convened within 20 working days of the date of the triage meeting

6.7 Identifying Urgent Cases

A senior Public Health professional, nominated by the Director of Public Health, can determine that a case is clinically urgent at any point in the IFR process after consultation with the patient's clinicians. The timing of an urgent IFR Panel will be based on the individual clinical circumstances and the risks of an adverse clinical

outcome if a funding decision on treatment is delayed. An 'extraordinary' IFR meeting can be convened of a senior Public Health professional, nominated by the Director of Public Health, and a Clinical Member of the Professional Executive Committee, or equivalent. This is the minimum membership required to be quorate, with other panel members attending, if available, in order to reach an immediate decision.

Ideally all urgent cases will be considered by a face-to-face meeting, but exceptionally, where the clinical need makes this impossible, communication via phone or e-mail will be deemed appropriate. Decisions that are made urgently outside of a formal IFR Panel meeting will be taken for ratification to the next meeting of the IFR Panel.

Where an urgent request is required to be considered, the IFR Panel shall continue to follow the procedure set out in this policy. In particular if a request, even if urgent, may affect other patients with the condition in question at the same stage of progression of the condition, and thus is inappropriate for an IFR request, it shall be refused. Where, in order for the PCT to be able lawfully to commission the requested treatment, the PCT is required to change its commissioning policy, this can only happen if the clinician and/or the patient request the PCT to make an in-year change to its commissioning policy. Such an application must be made outside the IFR policy.

6.8 Organisation of an IFR Meeting

The IFR Officer will arrange the date of the meeting and contact the requesting clinician to ask if they wish to submit any further information.

The IFR Officer will provide written correspondence to the patient/carer or guardian to inform them of the date set for consideration by the Panel, to list the items of information that will be presented to the Panel, and to ask them if they wish to provide written information to the Panel. However, the IFR Officer should remind the patient that decisions can only be made on the grounds of the patient's clinical circumstances and not on the basis of the patient's social or personal circumstances. If a patient wishes to provide written information, they should be directed to where they can seek assistance with this e.g. to the Patient Advisory Liaison Service (PALS).

The patient/carer or guardian, or their clinical or non-clinical representative, are not entitled to attend the panel in person.

The IFR Officer may also write to other health professionals with clinical involvement in the patient's care (for example consultant, therapist etc), or to others with specialist knowledge with regard to the condition/intervention, for clarification of the patient's needs, evidence base etc, if appropriate.

The IFR Officer, with support from Public Health and Medicines Management, will produce a summary of the case using the Decision Framework Document (Appendix F) which will be considered by the IFR Panel. All the documentation that has been received regarding the request will also be made available to the panel but in an anonymised form to protect confidentiality.

6.9 Membership of the IFR Panel

NHS Nottinghamshire County will have an Individual Funding Request (IFR) Panel (Terms of Reference Appendix G). The IFR Panel will consider all cases referred to it by the Screening Tier.

Members of the IFR panel should together have the skills and expertise necessary to make effective, fair and rational decisions by considering the evidence in the Decision Framework Document. The key competencies and experience required within a Panel are:

- Ability to understand and interpret the clinical information regarding the individual case and place it in the context of a wider clinical population
- Ability to understand and interpret clinical and cost effectiveness data (critical appraisal skills)
- A lay/societal perspective
- Ability to understand and advise on the broader commissioning policy implications for the PCT including consideration of the intervention in the LOP process

The core panel will consist of:

- Director of Public Health or nominated deputy
- Executive Director or nominated deputy

- Clinical Member of the Professional Executive Committee (PEC)/ Clinical Cabinet or equivalent
- Non-Executive Director/ PCT lay representative

Other individuals with specific expertise and skills may also be included on the panel e.g. pharmacist, commissioning manager in order to ensure effective and robust decision making.

The panel members will determine who is to chair the panel. The panel will only be quorate if three of the core members are present, including the Director of Public Health (or nominated deputy) and the Clinical Member of the Professional Executive Committee (PEC)/ Clinical Cabinet (or equivalent). Membership for quoracy of urgent panels is different (please see section 6.7).

The IFR Officer will present the case to the members of the panel. Decisions will be reached by consensus where possible, but if a consensus cannot be achieved, will be decided by a vote of the panel members. If the panel is equally split then the chair will have a casting vote. Clinical members of the PEC who have had any clinical involvement with an individual case cannot be part of the panel hearing for that request.

6.10 Decision making framework of the IFR Panel

The IFR Panel is a sub-committee of the PCT Board and has delegated authority to make decisions in respect of funding for individual cases. It is not the role of the IFR Panel to make commissioning policy on behalf of the PCT. Consideration by the IFR Panel will always start from the overall policy position (whether or not the intervention has been prioritised through the LOP) and will seek to determine exceptionality on that basis using the definition in Section 5.

The IFR Panel shall only be entitled to approve requests for funding of treatment for individual funding requests where each of the following conditions are met:

- a) Either (1) the clinician makes an individual request for funding for treatment in connection with a patient's presenting medical condition for which the PCT has no policy and where the clinician has demonstrated that the patient represents an Individual Patient (as defined in paragraph 5.2 above) or (2) the clinician makes an exceptionality request for funding for treatment in connection with a patient's medical condition for which the PCT has a policy

and where the clinician has demonstrated that the patient has exceptional clinical circumstances (as defined in paragraph 5.1 above) **or**

(3) the clinician makes an exceptionality request for funding for treatment in connection with a medical condition for which the PCT has no policy and where the patient has demonstrated exceptional clinical circumstances (as defined in paragraph 5.1 above). This option would arise if the patient was not an Individual Patient (as defined in paragraph 5.2 above).

- b) There is sufficient evidence to show that, for the individual patient, the proposed treatment is likely to be clinically effective.
- c) Applying the approach that the PCT takes to the assessments of costs for other treatments outside this policy, the cost to the PCT of providing funding to support the requested treatment is justified in light of the benefits likely to be delivered for the individual patient by the requested treatment.

6.11 Demonstrating exceptional circumstances.

- a) The requesting clinician is required to present a full report to the IFR Panel using the Treatment Request Form which sets out a comprehensive and balanced clinical picture of the history and present state of the patient's medical condition, the nature of the treatment requested and the anticipated benefits of the treatment.
- b) 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.
- c) In determining whether a clinician is able to demonstrate that a patient has exceptional circumstances the IFR Panel shall compare the patient to other patients with the same presenting medical condition at the same stage of progression.

- d) The IFR Panel shall take care to avoid adopting the approach described in the “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 same presenting medical condition at this stage are, to a greater or lesser extent, refractory to existing treatments is unlikely, of itself, to be sufficient to demonstrate exceptional circumstances.

6.12 The likely clinical outcomes of the proposed treatment.

The referring clinician shall:

- a) describe the anticipated clinical outcomes for the individual patient of the proposed treatment and the degree of confidence of the referring clinician that the outcomes will be delivered for this particular patient;
- b) 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.

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

The IFR Panel is not required to accept the views expressed by the referring clinician concerning the likely clinical outcomes for the individual patient of the proposed treatment but is entitled to reach its own views on:

- a) The likely clinical outcomes for the individual patient of the proposed treatment; and
- b) The quality of the evidence to support that decision and/or the degree of confidence that the IFR Panel has about the likelihood of the

proposed treatment delivering the proposed clinical outcomes for the individual patient.

6.13 The costs of the proposed treatment.

The referring clinician shall set out the full attributable costs of and connected to the treatment. The IFR Panel shall be entitled but not obliged to commission its own reports from any duly qualified or experienced clinician or other duly qualified person concerning the full attributable costs of and connected to the treatment.

The IFR Panel shall, so far as it is able to do so on the information before it, apply the principles set out in the PCT policy on cost effectiveness when reaching a view as to whether the requested treatment is likely to be cost effective.

In making the decision as to whether the costs of a requested treatment are justified, the IFR Panel shall refer itself to the approach concerning Quality Adjusted Life Years (QALYs) and Incremental Cost Effectiveness Ratio's (ICERs) that the PCT has adopted for other treatments and is required to bear in mind that the resources requested to support the individual patient will reduce the availability of resources for other investments. The IFR Panel shall have a broad discretion to determine whether the proposed treatment is a justifiable expenditure of the PCT's resources.

6.14 Similar Patients

The IFR Panel shall consider whether the request is a request for a policy variation. If the IFR Panel determines that the case does not refer to an Individual Patient, as defined in this policy, then it shall not be entitled to make a decision on the request (unless the patient demonstrates exceptional clinical circumstances in which case the matter shall be considered as an exceptionality request). In the event that the case does not refer to an Individual Patient the IFR Panel shall refer the request to be considered by the PCT Service Development process.

This step is required because the IFR process is not designed to create precedents which may result in the PCT providing or being obliged to provide the same or similar treatment to other patients. Accordingly if the IFR Panel considers this is not a request about an individual patient then funding can only be provided for the requested treatment if a decision is made by the PCT to amend its policies to provide the treatment for a group of patients, including the requesting patient.

6.15 Recording the decision

The IFR Officer will record the decision of the IFR Panel against each of the above questions on the Decision Framework Document. The completed Decision Making Framework, together with the record of attendance, will form the minutes of the meeting. The minutes will be approved by the Chair of the Panel.

6.16 Outcome of the IFR Panel

The IFR Officer will provide written correspondence on behalf of the Chair of the IFR Panel to the referring clinician, and the patient/guardian or carer, within 5 working days to inform them of the outcome of the IFR Panel meeting with the reasons for the panel decision.

If funding was agreed, the IFR Officer will ensure that the clinician is able to deliver the treatment in a timely manner and that a mechanism is in place to monitor the clinical outcome in order to determine whether the treatment has resulted in benefit to the patient.

If funding was not agreed, the IFR Officer will inform the referring clinician, and the patient/guardian or carer, outlining the further options that are available - either reconsideration or review.

6.17 Reconsideration

If the referring clinician and/or the patient/guardian or carer believes that there is further relevant information that was not considered by the Panel they may ask the PCT to reconsider the case specifically in the light of this information. The additional information must be submitted to the IFR Officer within 10 working days of the date of the letter from the PCT setting out the panel decision. The PCT Screening Pair will determine, normally within 10 working days, whether the additional information significantly alters the nature and strength of the evidence that was submitted to the initial panel meeting.

If the new information is considered to be significant, a further panel meeting will be convened within the timescales set out for the first panel. If the new information is not considered to be significant, the referring clinician and the patient/guardian or carer will be informed by letter with reasons for the decision not to refer the request back to the IFR Panel.

7. REVIEW OF IFR PANEL DECISIONS

7.1 Grounds for requesting a review of the IFR Panel Decision

The referring clinician and/or the patient/guardian or carer can make a request to the PCT for a review of the IFR panel decision. The request should be made in writing to the Chief Executive of the PCT and must be lodged within 20 working days of the date of the letter from the PCT setting out the IFR Panel decision. The Chief Executive may exercise discretion in accepting requests outside this time limit if there are good reasons for the delay.

The request for review must set the grounds on which the IFR panel decision is being challenged. A review can be requested on two grounds. It is believed that:

- The IFR Panel failed to follow due process and, as a result, the decision reached by the panel was different to the one that would be reached if due process had been followed.
- The IFR Panel did not take into account, or weigh appropriately, all relevant evidence when applying the PCT Decision Making Framework.

7.2 Initial Consideration of a Request for a Review of the IFR Panel Decision

The request for a review will be initially considered by an officer designated by the PCT to consider these requests. This officer will not have been involved in the original IFR decision. If the officer considers that there is an arguable case to support the review, then a formal Review Panel meeting will normally be convened within 20 working days of the PCT accepting the need for Review. If the PCT does not accept the grounds put forward for a review, a letter will be sent on behalf of the Chief Executive of the PCT to the referring clinician and/or the patient/guardian or carer explaining the reasons for the decision not to review the IFR panel decision.

7.3 Membership of the Review Panel

NHS Nottinghamshire County will have a Review Panel (Terms of Reference Appendix H).

The Review Panel will consist of:

- Chairman or nominated Non-Executive Director (Chair)

- Chief Executive or nominated Executive Director
- Director of Public Health or Clinical Member of Professional Executive Committee / Clinical Cabinet

None of these members should have been involved in the case prior to the Review Panel. The panel will only be quorate if all three members are in attendance and decisions will be reached by consensus.

7.4 Purpose of the Review Panel

The Review Panel will determine whether the original decision is valid in terms of process followed, the evidence/factors considered and the criteria applied. In deciding the outcome of a review, the Review Panel will consider whether:

- The process followed by the IFR Panel was consistent with that detailed in the IFR Policy
- The decision reached by the IFR Panel:
 - i. was consistent with the PCT Commissioning Principles
 - ii. had taken into account and weighed all the relevant evidence
 - iii. had not taken into account irrelevant factors
 - iv. indicates that members of the panel acted in good faith
 - v. was a decision which a reasonable IFR panel was entitled to reach.

The Review Panel will only consider the following written documentation:

- a) the original Treatment Request Form submitted to the PCT
- b) the IFR process records in handling the request
- c) the IFR Panel records, including the Decision Framework Document and any additional supporting information considered by the IFR Panel
- d) the grounds submitted by the referring clinician and/or the patient/guardian or carer in their request for review.

There will be no other representation at the Review Panel from the IFR Panel or the referring clinician and/or the patient/guardian or carer. The Review Panel will not consider new information or receive oral representations. If there is significant new information, not previously considered by the IFR panel, it will be considered as set out in 6.17 Reconsideration above.

The Review Panel will be able to reach one of two decisions:

- To uphold the decision reached by the IFR Panel.
- To refer the case back to the IFR panel with detailed points for reconsideration.

In the event that the Review Panel consider that either

- the decision may not have been consistent with the PCT Commissioning Principles; or
- the IFR Panel may not have taken into account and weighed all the relevant evidence; or
- the IFR Panel may have taken into account irrelevant factors; or
- the IFR Panel may have reached a decision which a reasonable IFR panel was not entitled to reach,

then the Review Panel shall refer the matter to the IFR Panel if they consider that there is an arguable case that the requested treatment will be approved by the IFR Panel when it reconsiders the case.

If the Review Panel considers that, notwithstanding their decision on the procedure adopted by the IFR Panel, there is no arguable case that the decision would have been different; the Review Panel shall uphold the decision of the IFR Panel.

7.5 Outcome from the Review Panel

The outcome of the Review Panel will be either to uphold the decision of the IFR Panel or to refer the case back to the IFR Panel for reconsideration.

The Review Panel chair will write to the referring clinician, the patient/guardian or carer, and the IFR Panel Chair within 5 working days to inform them of the outcome of the Review Panel meeting with the reasons for the panel decision. Reasons given should only refer to the IFR policy as this is the basis on which the original decision is made.

If the original IFR Panel decision is upheld, the IFR Officer will inform the referring clinician, and the patient/guardian or carer, of their remaining options - either to pursue a complaint through the PCT Complaints Procedure or to take their case to the Healthcare Ombudsman. The PCT Complaints Policy may be used to review the decision making process for an individual case and may result in the matter being reconsidered by the IFR Panel.

If the Review Panel determines that the IFR panel needs to reconsider the case, the IFR Panel should reconvene within 10 working days of the date of decision letter from the Chair of the Review Panel. The IFR Panel will reconsider its decision and in doing so will formally address the detailed points raised by the Review Panel. The IFR panel is not bound to change its decision as a result of the case being referred for reconsideration, but if it confirms its original decision, then clear reasons must be given for not agreeing to fund the treatment request.

8. TRAINING

Members of an IFR Panel (and Review Panel) should together have the skills and expertise necessary to enable them to make effective decisions. Members will need ongoing training to undertake this role, in particular to enable them to comprehend and interpret complex data, and also in the legal and ethical aspects of the panel's work. It is also important to establish a 'core' group of individuals who are regularly involved in IFR decision making to gain the necessary breadth of experience from handling a wide range of clinical cases.

All members of an IFR Panel (and Review Panel) will undergo mandatory induction training organised by the Public Health Directorate of the PCT. This will cover both the legal and ethical framework for IFR decision making, the PCT commissioning processes and structures, and technical aspects of the interpretation of clinical evidence and research. This training will be regularly refreshed to ensure that all panel members maintain the appropriate skills and expertise to function effectively.

9. MONITORING

The IFR process will be monitored and reviewed, both to ensure that decision-making is fair and consistent, and to make sure that the panel are considering the appropriate cases e.g. that both the triage of requests and the panel work effectively. The IFR panel will hold a quarterly meeting to review the IFR database with the IFR Officer to evaluate the process, including the consistency of decision making, and to consider any improvements that could be made.

The PCT will also put in place a mechanism to receive feedback by patients and requesting clinicians as part of the evaluation of the IFR policy and to contribute to ongoing process improvement.

Regional leads for this policy	Dr Tim Daniel Consultant in Public Health East Midlands Specialised Commissioning Team
	Malcolm Qualie Head of Public Health Policy East Midlands Specialised Commissioning Team E mail: Malcolm.Qualie@emscg.nhs.uk Tel: 0116 295 0862
Version	Version 2 Draft 1 (V2D1)
Date agreed by EMSCG Board	28/01/2011
Policy effective from	April 2011
Date of next review	Every three years, or earlier if required.
Acknowledgements	West Midlands SCG East Midlands PCT Individual Funding Request (IFR) leads.

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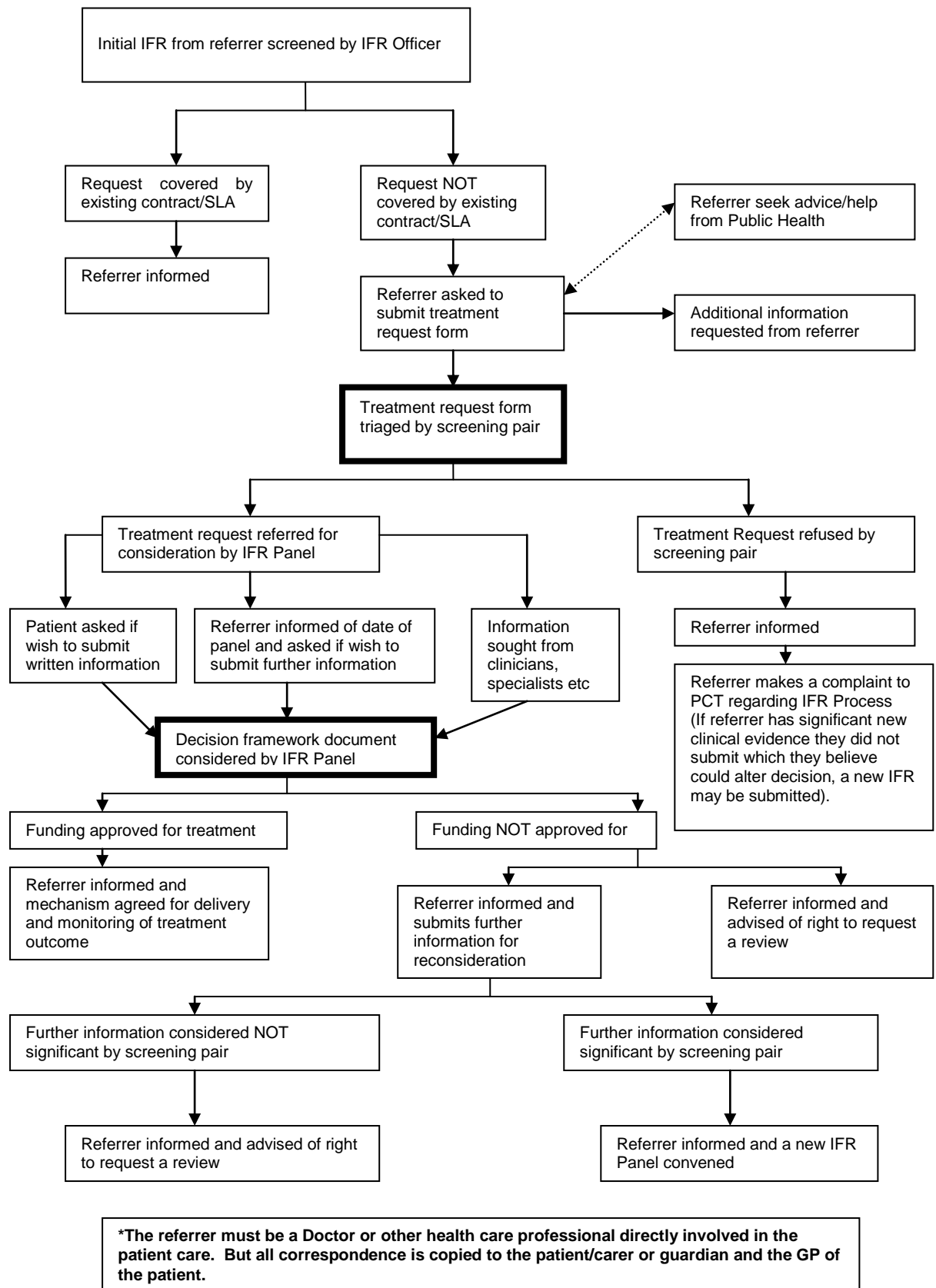
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Appendix A: Stages/Suggested timelines of the IFR process for routine requests

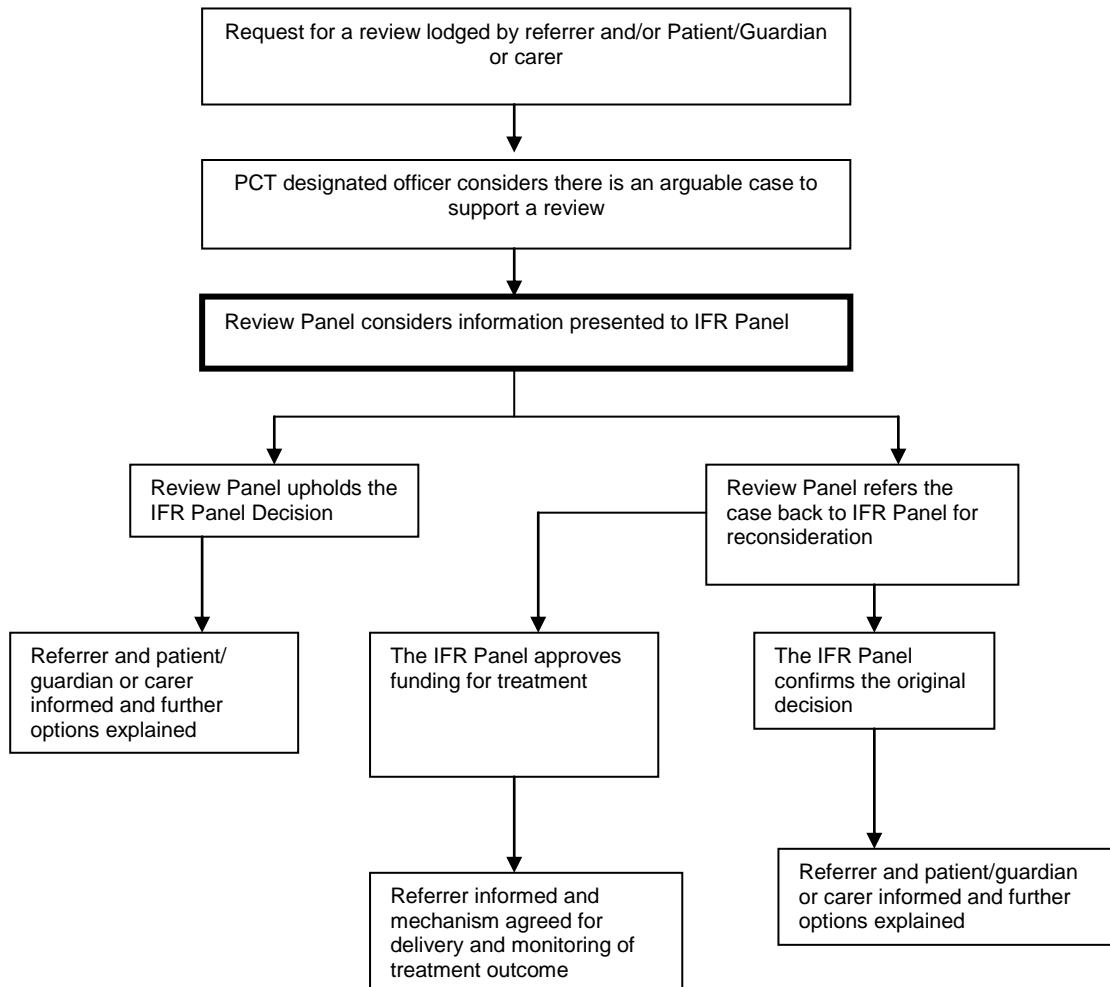
	Responsible Officer	Decision Making Body	Action and Timescales
Initial Receipt of IFR Request	IFR Officer	None	IFR request date stamped and logged on IFR database. Acknowledgement to referrer* within 5 working days.
Screening of IFR request to determine whether covered by existing contracts, SLAs etc.	IFR Officer	IFR Officer	IFR Officer to advise referrer within 10 working days of date of acknowledgement letter if request covered by existing contracts OR need to submit Treatment Request form.
Referrer wishes to discuss request/help to complete Treatment Request form	Public Health Directorate	None	All communication recorded in writing.
Referrer submits Treatment Request form	IFR Officer	None	Acknowledgement to referrer of Treatment Request form within 5 working days.
Triage of Treatment Request form	IFR Officer	IFR Officer and DPH or nominated deputy (Screening Pair)	Request either approved if covered by existing policy OR referred to IFR Panel OR rejected within 10 working days, unless additional information requested from referrer, when a further 10 working days is granted.
IFR Panel	Chair of the IFR Panel	Members of the panel	Panel to be convened within 20 working days of triage meeting. Panel decision to referrer from Chair of IFR Panel within 5 working days.
Reconsideration	IFR Officer	IFR Officer and DPH or nominated deputy (Screening Pair)	Further information from referrer considered within 10 working days and if significant a new IFR Panel convened within 20 working days.
Review Panel	Chair of the Review Panel	Members of the Panel	Request for a Review must be lodged within 20 working days (with discretion). Review Panel to be convened within 20 working days of PCT accepting the need for review. Review Panel decision to appellant from Chair of Panel within 5 working days.

* All correspondence is copied to the patient/carer or guardian and the GP of the patient

Appendix B1: Flowchart of IFR process for routine cases



Appendix B2: Flowchart of review process for routine cases



Appendix C: Individual Funding Treatment Request form

1. PATIENT PERSONAL DETAILS

Patient Name:

Date of Birth:

NHS Number:

GP Name & Practice Details:

Please note that all personal information will be removed prior to the consideration by the Individual Funding Request process.

2. TREATMENT REQUESTED

3. DIAGNOSIS

4. DETAILS OF REQUESTER (include referring clinician. Contact details in the event of query or need for clarification)

Name:

Designation:

Trust/Surgery:

Contact 'phone number:

Secure email or postal address for correspondence:

Provider Trust Clinical Director Support:

(signature of Clinical Director)

Provider Trust approval (please indicate as appropriate).

DTC.....	YES	NO
Ethics.....	YES	NO
MDT.....	YES	NO

Date to DTC / MDT/Ethics:

If discussed and supported by an appropriate MDT, please provide notes here:

5. CONSENT

I confirm that this Individual Funding Request has been discussed in full with the patient and it would / would not be appropriate (please delete as necessary) for the patient to be copied into all correspondence*.

The patient is aware that they are consenting for the Individual Funding Request Team to access confidential clinical information held by clinical staff involved with their care about them as a patient to enable full consideration of this funding request

Signature of Requester:

Date:

* Please note, the PCT is under obligation to let the patient know the outcome of all IFR applications. Where the patient has requested the IFR submission, it is good practice to ask the patient if they wish to be copied into other correspondence between the clinician and the PCT. Where the patient has not made the request, the patient should be copied into other correspondence between the clinician and the PCT unless it is clinically inappropriate to do so.

The onus lies with the requesting clinician to present a full submission to the IFR Team which sets out a comprehensive and balanced clinical picture of the history and present state of the patient's medical condition, the nature of the treatment requested and the anticipated benefits of the treatment. All necessary information including research papers must be submitted with this form.

Requests can only be considered based on the information provided. Incomplete forms providing insufficient information will be returned.

6. CLINICAL BACKGROUND

Outline the clinical situation. Please include:

- Previous therapies tried and current treatment including intolerance and response
- Current performance status/symptoms
- Anticipated prognosis if treatment requested is not funded (include what treatment will be given to the patient)

A. BALANCING THE INDIVIDUAL NEED FOR CARE WITH THE NEEDS OF THE COMMUNITY

7. EXCEPTIONALITY

To meet the definition of 'exceptional clinical circumstances' your patient must demonstrate that they are both:

- Significantly different clinically to the group of patients with the condition in question and at the same stage of progression of the condition

AND

- Likely to gain significantly more clinical benefit than others in the group of patients with the condition in question and at the same stage of progression of the condition

Do you consider this patient to have exceptional clinical circumstances? (Please refer to the PCT definition of what constitutes an exceptional case.) If so please give your reasons.

8. INCIDENCE & PREVALENCE

Incidence is expected to be initiated for two or fewer patients per million population per year (10 patients across the East Midlands SHA PCTs population per year).

Prevalence is less than 10 patients per million population at any one time (40 patients across the East Midlands SHA PCT population)

References are to be provided for stated incidence & prevalence.

What is the anticipated need for this treatment per 1000 head of population i.e. how often would you expect to request this treatment for this condition at this stage of progression of the condition for a given size of population? (Please refer to the PCT definition of what constitutes an individual case.)

9a. Is this a service development that has been discussed with commissioners? Do you plan to submit a future business case for funding of this treatment (rather than submit individual requests for single patients)?

9b. If this treatment were to be funded for this patient on an individual basis, would the decision set a precedent for other requests?

B. EVIDENCE OF CLINICAL AND COST EFFECTIVENESS/ SAFETY

10. If drug therapy is requested, is the drug licensed for the intended use?

11. What is the evidence base for the clinical and cost effectiveness/safety of this procedure/treatment? Has it been subjected to NICE appraisal or other scrutiny? Please include copies of all relevant clinical research.

Is the procedure/treatment part of a current or planned national or international clinical trial or audit?

12. What previous therapies have been tried and what was the response?

13. What are the anticipated clinical benefits in this individual case of the particular treatment requested over other available options?

14. Why are standard treatments (those available to other patients with this condition/stage of the disease) not appropriate for this patient?

15. How will the benefits of the procedure/treatment be measured? What are the intended outcomes and how will these be determined? What 'stopping' criteria will be in place to decide when the treatment is ineffective? (The PCT will require regular feedback on the outcome if the treatment is approved).

16. How frequently has your unit undertaken this treatment/procedure and what were your results? Is this treatment/procedure subject to Trust audit? Please include any available data on the use of this treatment/procedure by your unit.

C. AFFORDABILITY

17. What is the cost of the treatment/procedure and how does this compare with the cost of the standard therapy it replaces? Please ensure you include all attributable costs that are connected to providing the treatment/procedure e.g. drug/staff/follow up/diagnostics etc.

D. ACCESS TO TREATMENT

18. How will the treatment/procedure be given to the patient (e.g. oral/iv etc) and where will the treatment take place?

19. Is this a single treatment/procedure or part of a course? If part of a treatment course, what is the number of doses that will be given and at what intervals? What is the total length of time of the proposed course of treatment?

E. OTHER

20. Clinicians are required to disclose all material facts to the PCT as part of this process. Are there any other comments/considerations that are appropriate to bring to the attention of the IFR Team.

Please complete and return this form to:

The Individual Funding Request Team
NHS Nottinghamshire County
Hawthorn House
Southwell Road West
Rainworth
Mansfield
Nottinghamshire NG21 0HJ

Safe Haven Fax: 01623 673352

NHS Net Acc.: nc-pct.icrteam-nottscounty@nhs.net

Appendix D: Guidance notes for Clinicians

1. How should I decide whether to make an Individual Funding Request?

The criteria on who is eligible to be considered as an Individual Funding Request have been clarified by the new regional policy and will now be applied consistently across all nine East Midlands PCTs. The key consideration is whether the treatment that you wish to request for your individual patient will meet the definition for 'exceptional clinical circumstances' that is set out in the policy.

2. What is meant by 'exceptional clinical circumstances'?

The PCT can not fund requests that should be fairly applied to other patients who have similar clinical circumstances and who should rightly also be offered the treatment if your patient was to be approved. This would require the PCT to agree a new commissioning policy (or amend an existing one) setting out that the treatment was now available for a new group of patients and setting out how this group had been identified. Therefore, to meet the definition of 'exceptional clinical circumstances' you must demonstrate that your patient is both:

- Significantly different clinically to the group of patients with the condition in question and at the same stage of progression of the condition e.g. metastatic bowel cancer not just bowel cancer

AND

- Likely to gain significantly more clinical benefit than others in the group of patients with the condition in question and at the same stage of progression of the condition

In other words, you must show that your patient is very different from others in group of patients with the same condition/stage of the disease and has clinical features that mean that they will derive much more benefit from the treatment you are requesting.

3. Why are only clinical features taken into account?

The PCT must make decisions fairly about funding treatments and not on the basis of age, sex, sexuality, race, religion, lifestyle, occupation, family status (including responsibility for caring for others) social position, financial status etc. unless these directly affect the expected clinical benefit that an individual will derive from a treatment e.g. the effect of the increasing age of a woman on fertility.

4. How do I make an Individual Funding Request (IFR)?

All requests must be made on a standard treatment request form which can be

obtained electronically from the IFR Team at the PCT. It is the responsibility of the referring clinician to ensure that the form is completed accurately by seeking specialist information from other clinicians as required.

The form aims to ensure that all the necessary information is obtained so it is important that it is completed comprehensively and accurately, along with any relevant research papers, by the referring clinician to avoid delays in reaching a decision. The form can either be returned electronically or by post.

5. How can I get advice on what to include when completing a treatment request form?

You can phone or e-mail the IFR Team at the PCT for advice on whether to submit a treatment request form and what to include.

6. Who will make the decision on whether the Individual Funding Request (IFR) is approved?

All new Individual Funding Requests are 'screened' by a Public Health Specialist and a Commissioning Manager to decide whether "exceptional clinical circumstances" have been demonstrated. If there is no evidence of exceptional circumstances (often because the patient is clearly part of a definable cohort) then the request is declined at this stage. If evidence of exceptionality is presented, or if the screeners are uncertain whether the case is exceptional or not, then the case will be forwarded to the PCT IFR Panel. The panel will include a Non-Executive Director, Executive Director, Public Health Specialist and a Clinical Member of the PEC. They will determine whether there is a case for exceptionality and whether the intervention is safe and clinically and cost-effective.

7. How will I be informed of the PCT decision?

You will receive a letter informing you of the decision of the screening of your request within 20 working days of receipt of your treatment request form. If your request is being taken to the PCT Panel will be informed of the date of the panel, usually within a further 20 working days, and will receive a letter outlining the decision of the panel within 5 working days after the panel meeting.

8. How will my patient be informed of whether the request has been approved?

All correspondence will be copied to the patient and to their GP if they are not making

the request.

9. Can either the patient, or a clinician involved in their care, attend the panel?

No. The panel will only consider the written evidence that has been submitted so it is very important that all the evidence is presented in your treatment request form.

10. Can I or my patient appeal, against the PCT decision?

There is no right to appeal against the decision at the 'screening' stage although it is possible to complain under the PCT Complaints Policy. However, this will not overturn the decision of the screening stage but will examine whether the policy was properly followed. If the PCT panel does not approve your request you, or your patient, are entitled to ask for a review of the process that was undertaken by the PCT. The Review Panel will decide if the PCT followed the correct procedures and the PCT Panel reached a decision that was rational and based on all the evidence that was presented.

11. What can I do if my patent is not exceptional e.g. represents a group of patients in similar clinical circumstances

If you disagree with an existing policy then you can try to change it but this can not be achieved through the IFR process. If the treatment or services is covered by Specialised Commissioning, it will need the support of all the relevant clinicians in the region either through a clinical network, if one exists, or by a direct approach to East Midlands Specialised Commissioning Group. Please seek advice from malcolm.qualie@emscg.nhs.uk or visit www.emscg.nhs.uk. For all other services and treatments you should contact your local PCT.

Please note that it would be unusual to introduce a new development in year as each year resources are already committed through an annual round of prioritisation. Hence new developments will usually require reallocation of resources from existing services.

Appendix E: Decision framework document for Individual Funding Request panel

IN STRICTEST CONFIDENCE IFR DECISION FRAMEWORK DOCUMENT

PANEL _____ MEETING _____
DATE _____ PATIENTNo: _____

NHS Nottinghamshire County

DECISION FRAMEWORK DOCUMENT FOR INDIVIDUAL FUNDING REQUEST PANEL

STRICTLY PRIVATE & CONFIDENTIAL – NOT FOR RELEASE OUTSIDE THE PANEL

Notes of Guidance:

1. A copy of this form is to be provided to each panel member for each person in respect of whom an application is being considered
2. The copies will, at the end of the meeting, be collected and retained by the Individual Funding Request Officer
3. The Framework will be used to inform the letter to be written by the Chair of the IFR Panel

Panel Members:

Intervention Requested

Documents pertaining to the case:

Brief background to intervention requested

No	Points for consideration	Discussion notes	Decision
	Individual Need for Care		Yes/No
1	<p>Does the PCT have a policy to cover the treatment which is made available to patients with the medical condition of the patient?</p> <p>Did the panel reach the view that the patient had demonstrated exceptional clinical circumstances in this individual case?</p>		<p>NB: If the PCT has a policy for the condition in question and the patient has not demonstrated exceptional clinical circumstances, the IFR Panel are required to turn down the application.</p>
	Evidence of effectiveness: Clinical / Cost		
2	Does the panel consider that there is robust evidence of the clinical effectiveness of this drug/intervention?		
3	Is there robust evidence that this drug/intervention has been or will be effective in this individual case <u>and</u> that they will gain significantly greater clinical benefit than other patients with the same clinical condition and stage of disease.		

4	Does the panel consider that there is enough evidence to make a decision regarding the cost effectiveness of this drug/intervention? (NICE, Appraisals) and does that evidence indicate the treatment requested will be cost-effective in this individual case?		
No	Affordability	Discussion notes	Decision
5	What are the absolute costs involved in funding this treatment, in relation to the overall resources of the PCT for health care?		
Equity/ Needs of the Community			
6	What will the anticipated impact be on the rest of the patient population should this treatment be funded?		

7	Will it be equitable to the wider population to fund this treatment after consideration of the clinical needs of this patient?		
Other factors			
	Are there any other factors which were considered relevant by the Panel?		

SUMMARY		
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	Funding Approved:	Any conditions / review mechanisms required. Outcome measures to be monitored and date of review.	
	Funding Denied	Reasons	

RETURN THIS FORM TO THE PANEL ADMINISTRATOR AFTER THE MEETING

Appendix F: Terms of reference of the Individual Funding Request Panel

1. Membership

The Individual Funding Request (IFR) panel will have a core membership of:

- Director of Public Health or nominated deputy
- Executive Director or nominated deputy
- Clinical Member of the Professional Executive Committee (PEC)/ Clinical Cabinet or equivalent
- Non-Executive Director/ PCT lay representative

In attendance:

- IFR Officer to record the decision of the IFR Panel against each of the questions in the Decision Framework Document

Other individuals with specific expertise and skills may also be included on the panel e.g. pharmacist, commissioning manager in order to ensure effective and robust decision making. The panel members will determine who is to chair the panel. The IFR Officer will present the case to the other members of the panel. Clinical members of the PEC who have had any clinical involvement with an individual case can not be part of the panel hearing for that request.

2. Purpose

The purpose of the IFR panel is to consider individual requests for NHS commissioned and funded treatment. Each individual funding request will be handled by following the PCT IFR process (see PCT IFR Policy) which will ensure the request is considered in a fair and transparent way, with decisions based on the best available evidence and the PCT commissioning principles.

3. Frequency of meetings

The IFR Panel will normally be held monthly. A case may need to be considered urgently between meetings on the advice of the Director of Public Health, or nominated deputy, after consultation with the patient's clinicians. The timing of the urgent IFR Panel will be based on the individual clinical circumstances and the risk of an adverse clinical outcome if a funding decision on treatment is delayed.

An 'extraordinary' IFR meeting can be convened of a senior Public Health professional, nominated by the Director of Public Health, and a Clinical Member of the Professional Executive Committee, or equivalent, as a minimum membership, with other panel members attending if available in order to reach an immediate decision.

Ideally, all urgent cases will be considered by a face-to-face meeting, but, exceptionally, where the clinical urgency makes this impossible, communication by phone or e-mail will be deemed appropriate

4. Voting Rights

IFR Panel members will seek to reach decisions by consensus where possible, but if a consensus cannot be achieved, decisions will be taken by a majority vote with each panel member present having an equal vote. If the panel is equally split then the chair of the panel will have the casting vote.

5. Quorum

The panel will be quorate if three of the core members are present, including the Director of

Public Health (or nominated deputy) and the Clinical Member of Professional Executive Committee (PEC)/ Clinical Cabinet (or equivalent).

For urgent cases requiring an 'extraordinary' IFR meeting, the meeting will be quorate if the membership consists of a senior Public Health professional, nominated by the Director of Public Health, and a clinical member of the Professional Executive Committee (PEC), or equivalent. Other panel members can attend, if available.

6. Documentation

Individual Funding Requests will be date stamped and logged onto the PCT IFR database by the IFR Officer. It is the responsibility of the IFR Officer to manage all requests received and correspondence relating to each case.

All cases will be anonymised before consideration by the IFR panel. The IFR Officer will produce a summary of the key information using the Decision Framework Document which will be considered by the IFR Panel. All other documentation that has been received regarding the case will also be available to the panel.

Patients will be encouraged to set out their views in writing to the Panel. Save to the extent that is required to ensure anonymity is preserved, the IFR Officer shall not be entitled to redact any written material provided by the patient. However the IFR Officer shall be entitled to put any observations in writing before the IFR Panel that the IFR Officer may have concerning material submitted by a patient including:

- Observations on any areas where issues are raised which do not appear to be supported by the clinical evidence
- Advice to the panel concerning any social, caring or other personal factors raised by the patient which the IFR Panel are not entitled to consider under the terms of the PCT Policy.

The patient shall be entitled on request to a copy of any observations by the IFR Officer. Patients will not be permitted to attend panel meetings in person or be represented by any person at the meeting.

7. Authority

The IFR Panel is a sub-committee of the PCT Board and has delegated authority to make decisions in respect of funding of individual cases. It is not the role of the IFR Panel to make commissioning policy on behalf of the PCT.

8. Accountability

The minutes of the IFR Panel will be approved by the Chair of the Panel. The IFR Panel is accountable to the PCT Board.

9. Reporting and Monitoring

The IFR Officer will record the decision of the IFR Panel against each of the questions in the Decision Framework Document. The completed Decision Making Document, together with the record of attendance, will form the minutes of an individual case. Decisions that are made urgently outside a formal IFR Panel meeting will be taken to the next routine meeting of the IFR Panel.

The IFR Panel will meet on a quarterly basis to review the IFR database with the IFR Officer in order to evaluate the process, including the consistency of panel decision making, and to

consider any improvements that could be made. The IFR Officer will produce an annual report which will be considered by the PCT Board. The Terms of Reference of the IFR Panel will be reviewed annually by the PCT Board.

10. Training

All members of the IFR Panel must undergo mandatory induction training organised by the Public Health Directorate of the PCT. This will cover both the legal and ethical framework for IFR decision making, the PCT commissioning processes and structures, and the technical aspects of interpretation of clinical evidence and research. This training will be regularly refreshed to ensure that all panel members maintain the appropriate skills and expertise to function effectively.

Appendix G: Terms of reference of the Review Panel

1. Membership

The Review Panel will consist of:

- Chairman or nominated Non-Executive Director (Chair)
- Chief Executive or nominated Executive Director
- Director of Public Health or Clinician Member of Professional Executive Committee/
Clinical Cabinet

None of the panel members should have been involved in the case prior to the Review Panel. The Review Panel will not consider either new information that was not available to the IFR Panel or receive oral representations.

2. Purpose

The Review Panel will determine whether the original decision is valid in terms of process followed, the evidence/factors considered and the criteria applied. In deciding the outcome of a review, the Review Panel will consider whether:

- The process followed by the IFR Panel was consistent with that detailed in the IFR Policy
- The decision reached by the IFR Panel:
 - vi. was consistent with the PCT Commissioning Principles
 - vii. had taken into account and weighed all the relevant evidence
 - viii. had not taken into account irrelevant factors
 - ix. indicates that members of the panel acted in good faith
 - x. was a decision which a reasonable IFR panel was entitled to reach.

The Review Panel will be able to reach one of two decisions:

- To uphold the decision reached by the IFR Panel.
- To refer the case back to the IFR panel with detailed points for reconsideration.

Where the Review Panel consider that the decision may not have been consistent with the PCT Commissioning Principles, the IFR Panel may not have taken into account and weighed all the relevant evidence, have taken into account irrelevant factors or reached a decision which a reasonable IFR panel was entitled to reach the Review Panel shall refer the matter to the IFR Panel if they consider that there is an arguable case that requested treatment will be approved.

If the Review Panel considers that, notwithstanding their decision on the procedure adopted by the IFR Panel, there is no arguable case that the decision would have been different, the Review Panel shall uphold the decision of the IFR Panel.

3. Frequency of meetings

The Review Panel will be scheduled monthly. A case may need to be considered urgently on the advice of a senior Public Health professional, nominated by the Director of Public Health, after consultation with the patient's clinicians. The timing of the urgent Review Panel will be based on the individual clinical circumstances and the risk of an adverse clinical outcome if a funding decision on treatment is delayed. Ideally, all urgent cases will be considered by face-to-face meeting, but where the clinical urgency makes this impossible, communication by phone or e-mail will be deemed appropriate.

4. Voting Rights

The Review Panel members will seek to reach a decision by consensus. If this is not possible a decision will be made by a vote with each member having one vote.

5. Quorum

All three panel members must be present for the Review Panel to be quorate.

6. Documentation

The Review Panel will only consider the following written documentation:

- e) the original Treatment Request Form submitted to the PCT
- f) the IFR process records in handling the request
- g) the IFR Panel records, including the Decision Framework Document and any additional supporting information considered by the IFR Panel
- h) the grounds submitted by the referring clinician and/or the patient/guardian or carer in their request for review.

There will be no other representation at the Review Panel from the IFR Panel or the referring clinician and/or the patient/guardian or carer. The Review Panel will not consider new information or receive oral representations. If there is significant new information, not previously considered by the IFR panel, it will be considered as set out in 6.11 Reconsideration above. All information will be anonymised before consideration by the Review Panel.

7. Authority

The Review Panel is a sub-committee of the PCT Board and has delegated authority to undertake a review of IFR Panel decisions in respect of funding of individual cases as defined in 2.Purpose. It is not the role of the Review Panel to reach a decision on funding of an Individual Funding Request nor does the Panel make commissioning policy on behalf of the PCT.

8. Accountability

The Review Panel is accountable to the PCT Board.

9. Reporting and Monitoring

The IFR Officer will produce an annual report which will be considered by the PCT Board. The Terms of Reference of the Review Panel will be reviewed annually by the PCT Board. The IFR Panel will meet on a quarterly basis to review the IFR database with the IFR Officer in order to evaluate the Review process and to consider any improvements that could be made.

10. Training

All members of the Review Panel must undergo mandatory induction training organised by the Public Health Directorate of the PCT. This will cover both the legal and ethical framework for IFR decision making, the PCT commissioning processes and structures and the technical aspects of interpretation of clinical evidence and research. This training will be regularly refreshed to ensure that all panel members maintain the appropriate skills and expertise to function effectively.

Appendix H: Glossary

Word/Abbreviation	Meaning
Affordability	To have enough money to pay for something, without going over budget.
Anonymous	Personal information is not included
Clinical effectiveness	How well a specific test or treatment works when used in the 'real world' (for example, when used by a doctor with a patient at home), rather than in a carefully <i>controlled clinical trial</i> . Trials that assess clinical effectiveness are sometimes called management trials. Clinical effectiveness is not the same as <i>efficacy</i> . (NICE)
Cohort	A group used as part of a research study. The group is made up of people sharing a common characteristic (for example, pupils in the same school year). (nice)
Collaborative	To work with another on a project (Collins English Dictionary, 1994).
Commissioning	The <i>process</i> used by health services and local authorities to: identify the need for local services; assess this need against the services and resources available from public, private and voluntary organisations; decide priorities; and set up contracts and service agreements to buy services. As part of the commissioning process, services are regularly evaluated.(NICE)
Consensus	A statement based on the collective views of a body of experts.(NICE)
Cost effective	Value for money. A test or treatment is said to be 'cost-effective' if it leads to better health than would otherwise be achieved by using the resources in other ways. (nice)
Criteria	Standard of judgement (Collins, 1994).
East Midlands Specialised Commissioning Group (EMSCG)	Specialised Commissioning is the means by which Primary Care Trusts (PCTs) work together to plan, buy and manage services which treat patients with rare conditions. (Taken from www.emscg.nhs.uk) For the East Midlands this is the East Midlands Specialised Commissioning Group.
Exceptional	As defined in section 5.1 of the policy
Health technology appraisal	A health technology appraisal, as undertaken by NICE, is the process of determining the clinical and cost effectiveness of a health technology. NICE health technology appraisals are designed to provide patients, health professionals and managers with an authoritative source of advice on new and existing health technologies. (nice)
Incremental Cost Effectiveness Ratio (ICER)	This is a measure of the additional cost per additional unit of health gain produced by one intervention in comparison to another. (NICE)
Incidence	The number of new cases of a disease divided by the total <i>population</i> at risk during a certain period. It is often expressed as numbers per million. See also <i>prevalence</i> . (NICE)
Individual patient	As defined in 5.2 of the policy

Word/Abbreviation	Meaning
Inequity	A health inequity is an unnecessary, avoidable, unfair and unjust difference between the health or healthcare of one person, and that of another. (NICE)
Local Operating Plan (LOP)	This contains an NHS organisations proposed priorities for investment to ensure delivery of local and national requirements.
Mandated	Official commend/authorisation (Collins, 1994).
National Institute for Health and Clinical Excellence (NICE)	NICE is an independent organisation responsible for providing national guidance on promoting good health and preventing and treating ill health. (NICE).
Primary Care Trust (PCT)	A primary care trust is responsible for buying and overseeing many of the health services for the area it covers. In the East Midlands there are 9 PCT's in total, these being Northamptonshire PCT, Bassetlaw PCT, Derby City PCT, Derby County PCT, Lincolnshire PCT, Nottingham City PCT, Nottinghamshire County PCT and Leicestershire County and Rutland PCT. They can now also be called NHS (organisational name), instead of (organisational name) PCT.
Pragmatic	Concerned with practical consequences rather than theory (Collins, 1994)
Prevalence	Used to describe the proportion of people in a <i>population</i> who have a particular habit, a particular disease or another characteristic. For example, smoking prevalence relates to the proportion of people who smoke in a given population. Prevalence may be expressed in relation to a range of factors including age, sex, socioeconomic and ethnic group. See also <i>incidence</i> . (NICE)
Quality Adjusted Life Years (QALY)	A measure of the state of health of a person or group in which the benefits, in terms of length of life, are adjusted to reflect the quality of life. One QALY is equal to 1 year of life in perfect health. QALYS are calculated by estimating the years of life remaining for a patient following a particular treatment or <i>intervention</i> and weighting each year with a quality of life score (on a zero to one scale). It is often measured in terms of the person's ability to perform the activities of daily life, freedom from pain and mental disturbance.(NICE)
Quorate	Minimum people required to be present at a meeting before any transactions can take place (Collins, 1994).
Rare	Uncommon (Collins, 1994)
Ratification	Approve
Refractory	Unresponsive or resistant to treatment (Blacks Medical Dictionary, 42 nd ed).
Service Level Agreement (SLA)	A service level agreement (SLA) is essentially a communication document that makes clear what the supplier will deliver and what the trust will ensure. It is based on the conditions of contract and specification and does not in any way replace them. (www.pasa.nhs.uk).
Statutory	Required or authorised by law (Collins, 1994).