Interim Standard Operating Procedures: The Management of Individual Funding Requests

April 2013
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# Interim SOP – Individual Funding Requests

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Standard Operating Procedures Statement

This document sets out how the process for managing individual funding requests (IFRs) for NHS CB Prescribed Services will operate. This document should be read in conjunction with the following commissioning policies of the NHS Commissioning Board (NHS CB):

- Ethical framework (NHSCB/CP/O1)
- In-year service developments (NHSCB/CP/O2)
- Individual funding requests (NHSCB/CP/O3)
- Experimental treatments policy (NHSCB/CP/05)

This interim policy will be implemented from 1 April 2013 and subject to further review in 2013/2014.

Equality Statement

The NHS CB has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012. The NHS CB is committed to ensuring equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation. In carrying out its functions, the NHS CB will have due regard to the different needs of protected equality groups in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which they are responsible, including policy development, review and implementation.
1. INTRODUCTION

This document sets out how the process for managing individual funding requests (IFRs) for specialised services will operate. This document should be read in conjunction with the following commissioning policies of the NHS CB:

- Ethical framework (NHSCB/CP/O1)
- In-year service developments (NHSCB/CP/O2)
- Individual funding requests (NHSCB/CP/O3)
- Experimental treatments policy (NHSCB/CP/05)

From April 2013 the NHS CB will be the statutory body responsible for the consideration of IFRs for Prescribed Services. These include specialised services (SS) and services for Military and Offender Health (M&OH). The policies listed above describe the underpinning policy framework for the management of Prescribed Services (PS) IFRs.

There will be a single process for the operational management of all Prescribed Services IFRs which is outlined in this document. For SS this process will be under the remit of 4 of the 10 NHS CB Area Teams with responsibility for specialised services. M&OH IFRs\(^1\) for non-specialised services will be managed by one identified Area Team with this responsibility in each NHS CB region. Specialised services IFRs for the military and for prisoners will be referred to the appropriate SS Area Team.

Each Area Team will manage IFRS on behalf of their region, with regional IFR and IFR review panels making decisions on behalf of the NHS CB. These teams will work closely together to promote transparency, consistency and equity of decision-making across England. The IFR process reflects best practice as outlined in the NPC Handbook of Good Practice Guidance.\(^2\)

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1 The NHS CB will be responsible for all NHS service for M&OH. If the IFR is for a specialised service it will be referred to the Area Teams responsible for SS.

The teams responsible for managing NHS CB IFRs are based in the following NHS CB Area Teams Offices:

North of England: SS: NHS CB Area Team Cumbria, Northumberland Tyne & Wear  
email: nhscb.ifrnorth@nhs.net  
M&OH: NHS CB Area Team

Midlands & East: SS: NHS CB Area Team Leicestershire and Lincolnshire  
email: nhscb.ifrme@nhs.net  
M&OH: NHS CB Area Team

South of England: SS: NHS CB Area Team: Wessex  
email: nhscb.ifrsouth@nhs.net  
M&OH: NHS CB Area Team

London: SS: NHS CB Area Team London  
email: lonhscb.ifr@nhs.net  
M&OH: NHS CB Area Team London

During 2013/14 the responsible Area Teams will collaborate on the procurement of an information technology (IT) solution for the management of IFRs, to be used by all teams. In the interim, each Area Team will establish suitable arrangements to enable consistent management and reporting of IFR activity across England. IT solutions will be expected to align with the processes for the management of IFRs outlined in this document.

The IFR process is described in the table in Appendix A and diagrammatically in the flowchart in Appendix B.
2. MANAGING AN INDIVIDUAL FUNDING REQUEST: THE IFR PROCESS

2.1 Interventions that can be considered for the IFR process

The following criteria should be used to guide a clinician decision to apply for funding of a SS IFR (managed by the NHS CB), rather than that for non-specialised services (managed by Clinical Commissioning Groups (CCGs)). If the following applies then a SS IFR would be deemed appropriate:

- The treatment for which funding is requested is associated with a service described in 'The Manual' for prescribed specialised services and / or the associated 'Identification Rules' Documents.3
- The treatment for which funding is requested is not routinely commissioned by the NHS CB

SS can be expensive to provide and are usually described as high cost/low volume services. Further advice can be obtained from the Chair of the relevant SS Clinical Reference group (CRG) for the intervention, or from one of the 4 SS IFR teams in England, as appropriate.

Requests which do not meet the criteria outlined above will need to be addressed to the primary care Clinical Commissioning Groups (CCGs), the commissioning organisations responsible for non-specialised services. Close working relationships should be maintained between NHS CB IFR Area Teams and the CCG IFR Teams in their region to ensure that requests for Prescribed Services are directed appropriately.

Requests for patients in the military or for prisoners should be addressed to the relevant Area Team managing the healthcare of these groups in the population of England.

Prescribed services are commissioned on a provider basis by the NHS CB. Each Area Team responsible for managing IFRs will take requests from the providers in their region, irrespective of where the patient is registered with the NHS. This is different to the arrangements for primary care Clinical Commissioning Groups (CCGs) where services are commissioned for the population.

2.2 **Who can submit an IFR**

A doctor, or other health care professional directly involved in the care of a patient, can make a request for funding to support a healthcare intervention which has not been agreed to be funded by the NHS CB under its approved policies or via a National Institute for Health and Care Excellence Technology Appraisal (a NICE TA).

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 because the process is to enable an NHS Clinician to apply for funding to support the provision of NHS treatment by that clinician to the patient. They will be familiar with the incidence and prevalence of the condition and have an understanding of their patient’s needs in relation to others with the same condition at the same stage of the disease.

2.3 **Administration and Reporting**

On receipt of a submission the following IFR processes should be completed:

- The date of receipt should be recorded (along with other key information about the patient, the requester and the treatment requested) in the NHS CB IFR database by the responsible IFR Officer. It will be the responsibility of the IFR Officer to manage all requests received and correspondence with the referrer and patient/carer or guardian and GP and with the IFR panel and IFR Review panel.

- Acknowledgement of receipt of the request will be sent to the referrer, usually within 5 working days. If pre-screening (as described in 2.4) has been completed within this timeframe, the acknowledgement will include the outcome of the pre-screening stage. If funding is confirmed the patient/guardian or carer and GP will be copied into the response, unless the clinician making the referral has indicated that it is not clinically appropriate to do so.

- For each request received, a unique numbered case file will be generated. All decisions will be fully documented and all communication from the NHS CB will be confirmed in writing. Emails and letters should be securely archived and when telephone conversations with clinicians and / or patients take place, a file note will be added as a record of the conversation. Area Team staff should be prepared for the sensitive and sometimes contentious nature of such telephone conversations: patients may be anxious or distressed and occasionally angry. Area Team staff will deal with issues of process and refer queries about clinical issues to a screening or panel member. Both the evidence considered for the IFR and the decision made will be recorded in writing. All NHS policies regarding confidentiality, retention and destruction of records will be adhered to.
• The treatments presented for consideration of funding as IFRs will be regularly reported to and reviewed by the IFR Panel and a quarterly report of cases considered by the IFR Panel and Review Panel will be submitted to the NHS CB Medical Directorate Clinical Effectiveness Team. This will identify potential cohorts of patients requiring specific treatments and inform the need for national clinical policy development.

2.4 Timescale for Managing an IFR

• The standard for response times for IFRs will be a maximum period of 40 working days from the date of the receipt of a completed Treatment Request Form to the date of the letter from the NHS CB informing the requesting clinician of the decision of the IFR Panel. This will exclude any working days where the IFR team are awaiting information sought from the requester. Within this time period, a number of recommended maximum time periods for stages of the IFR process are set out in Appendix A. These are advisory, rather than mandatory, providing the overall process is completed within the 40 day period.

• Where an application is made for reimbursement for treatment given to a patient in another EEA country (under section 6A and/or 6B of the National Health Service Act 2006, amended by the National Health Service (Reimbursement of the Costs of EEA Treatment). (England) Directions 2010 and the revised advice 20104), the time periods for consideration of the application for reimbursement under the Directions shall commence on the date that the IFR Panel made a decision on the IFR application. There is a dedicated NHS CB team who will manage such requests once an IFR decision has been made.

2.5 Pre-screening an IFR

• All funding requests are initially dealt with by the IFR Officer who will consider whether the existing portfolio of contracts for directly commissioned services, service level agreement (SLA) or current commissioning policies would cover the request. If a clinical policy exists and is appropriate, the IFR Officer will check whether the criteria within the policy are met. Where clinical advice is required on the treatment requested or the urgency of the case, the IFR Officer will seek

advice from the Public Health Clinicians / Specialists and / or the lead pharmacists assigned to the Area Teams in their region, as appropriate.

- There are four possible responses to a request:
  
  o If an individual meets the criteria for funding within a NHS CB clinical policy or commissioned service, and a decision to agree funding can be made at this point by the IFR Officer, then funding can be confirmed. Some clinical commissioning policies require prior approval before treatment can commence. In other instances, clinicians may be unsure of the commissioning arrangements and are seeking advice. The IFR Officer should not authorise funding outside policy or existing contractual arrangements.

  o If the IFR Officer has reason to consider that the funding request falls outside of the care that is normally commissioned, and the requester has already completed the standard IFR Treatment Request form (Appendix C), the clinician will be informed that the request will be processed as a formal IFR.

  o If not already submitted on the standard form, the IFR Officer will advise the clinician that in order to pursue the request as a formal IFR they should submit the request using the IFR Treatment Request Form (Appendix C). A copy of the Guidance Notes for clinicians should be provided (Appendix D), along with reference to any relevant commissioning policies and the Information for Patients document (Appendix E) explaining the process.

  o If a request is highlighted as urgent by the requester, the IFR Officer should seek clinical advice from the Public Health Clinicians / Specialists and / or the lead pharmacists assigned to the Area Teams in their region, as appropriate. A response to clinically urgent requests will be determined by one of the senior health professionals authorised to make urgent decisions as specified under 2.8 ‘Managing Urgent Cases’.

- A response in line with one of the above options will be sent to the referring clinician within 10 working days of the date of receipt of the initial request.
2.6 Submission of a Treatment Request Form (TRF)

Only a clinician directly involved in the clinical care of the patient (usually their consultant) can submit a Treatment Request Form. It is expected that for Prescribed Service funding requests, the requests will usually be submitted by the clinician who is the intended provider of the treatment.

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 Officer at the appropriate Area Team.

2.7 Screening of a Treatment Request Form: The Screening panel

All completed Treatment Request Forms will be screened by the IFR Officer and authorised senior health professional (the Screening panel) as set out in the Commissioning Policy for Individual Funding Requests (NHSCB/CP/03).

The screening pair will have three options available to them:

- Approve the request if covered by an existing contract with the provider or a commissioning policy and the patient meets the relevant criteria. If funding is confirmed the patient/guardian or carer and GP will be copied into the response, unless the clinician making the referral has indicated that it is not clinically appropriate to do so.

- Refuse the request without referring the case to the IFR Panel, on the grounds that it does not meet the criteria for consideration as an IFR (as outlined in the IFR policy NHSCB/CP/03). A letter will be sent to the clinician and the patient, parent / guardian and GP explaining the reasons for the decision and outlining the options that are available, including using the NHS Complaints Procedure.

- Refer the case to the IFR Panel. The requesting clinician will be contacted and asked to comment on whether any additional information should be included in the Treatment Request Form.

Where there is uncertainty or doubt about the application of the IFR policy, the case will be referred to the IFR Panel.
All decisions made by the Screening Pair will be recorded in the request record and reported to the IFR Panel on a quarterly basis.

A routine request will normally be screened and the outcome communicated within 15 working days of the date of receipt of a Treatment Request Form by the NHS CB. If further information is required from the requester, the timeline for the request is suspended until this is received. The IFR timeline allows for flexibility in the process: if additional research is needed by the screening panel to aid decision making this can be allowed for, but the requester will be notified of the reason for the delay in the screening outcome.

If a request is declined at the screening stage the IFR policy does not provide a right of appeal to the IFR Panel and does not provide a right to request that the decision should be reviewed by the IFR Review Panel. 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 screening 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 screening decision.

2.8 Managing Urgent Cases

Requesting clinicians are responsible for communicating the clinical urgency of a request. An authorised senior health professional (e.g. public health or pharmacy lead) can make a decision that a case is clinically urgent at any point in the IFR process after consultation with the patient's clinician.

The timing will be based on the individual clinical circumstances and the risks of an adverse clinical outcome if a funding decision concerning funding for the requested treatment is delayed.
An ‘extraordinary’ IFR Panel and meeting can be convened comprising an authorised senior health professional and a clinical member of the Area Team IFR Panel. 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 is appropriate. Decisions that are made urgently outside of a formal IFR Panel meeting will be noted at the next meeting of the IFR Panel. The IFR Panel, at that point, may express a view as to whether the IFR request has the support of the panel, which should be recorded in the minutes.

If any urgent treatment request involves both the commencement of a requested treatment and on-going provision of requested treatment, where an urgent IFR decision is taken to commence treatment, any decision about continuing the treatment shall be taken by the next IFR Panel. The decision of the IFR Panel in such circumstances shall be an entirely fresh decision. There shall be no presumption that the treatment shall continue to be funded on the sole ground that an urgent decision was made to commence the treatment.

Where an urgent request is required to be considered, the extraordinary IFR Panel shall continue to follow the procedure set out in this document. 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 the patient represents a cohort and the request is inappropriate for an IFR request, it will be declined.

Where, in order for the NHS CB to be able lawfully to commission the requested treatment, the NHS CB is required to change its commissioning policy, this can only happen if the clinician, by submitting a request on behalf of their patient, seeks an in-year change to the NHS CB commissioning policy. Such a change must be considered outside the IFR process and it will not be funded as an IFR.

2.9 The role of the IFR Officer

The IFR Officer is responsible for coordinating, managing and developing the IFR process, and the work of the IFR panels.
The IFR Officer’s will:

- Establish the protocols for communicating and liaising with patients (including their parent/guardians if appropriate), their GPs and the clinicians responsible for their care who are requesting funding on their behalf. The IFR Officer will be responsible for ensuring there is a single point of contact for patients and clinicians involved in the IFR and IFR Review process and that queries from patients and referring clinicians are directed to the appropriate IFR panel members as necessary.

- Maintain patient confidentiality and data security in accordance with the standards set by the requirements of Information Governance in the NHS and Records Management Code of Practice

- Pre-Screen submissions to the IFR process to ensure appropriate information to be able to consider a request is provided. Redirect inappropriate submissions as required.

- Decide which submissions should be fast-tracked, taking public health and/or pharmacy lead clinical advice as required.

- Formally screen IFRs jointly with the clinical support to the team (public health and/or pharmacy lead) to determine whether the request is appropriate for the IFR panel. The screening panel will also identify whether additional information, specialist advice and reviews of evidence are necessary to inform the IFR panel decision.

- Oversee the scheduling of IFR panel meetings and membership in a rolling programme at least 6 months in advance. Oversee the preparation of the agenda and papers for consideration by the IFR and IFR Review panels.

- Attend IFR Panel meetings in the role of an advisor e.g. on the IFR process itself and/or previous similar requests across all NHS CB regions. The IFR Officer will not sit as a voting member of the IFR Panel. The IFR Officer will present the case to the members of the panel.

- Ensure that all decisions at any point in the IFR process are accurately recorded; the IFR Officer will ensure that the reasons for the decisions are explicit.
• Contribute to the training of panel members, specifically on the process itself and / or managing the administrative arrangements.

• Contribute to the continuing development of the NHS CB IFR process nationally through close working relationships with other Area Teams. This will support consistency in process and the sharing of information.

• Liaise with the NHS CB Clinical Effectiveness Team, responsible for priority-setting and policy development. Highlight where there is a lack of existing policy.

• To oversee the work of the administration team in the registration, administration and monitoring of funding request, including costs and validation of invoices

• To report on the financial impact of IFR committed and actual spend on a monthly basis to the Area Team.

2.10 The role of the Administration team

The Administration team will:

• Administer the paperwork and the databases associated with the IFR process; ensuring the efficient handling and documentation of submissions, from first receipt through to archiving.

• Maintain patient confidentiality and data security in accordance with the standards set by the requirements of Information Governance in the NHS and Records Management Code of Practice.

• Organise the IFR Panel meetings, and act as secretary to the meetings.

• Send out correspondence and track responses.

• Submit returns to the NHS CB Medical Directorate Clinical Effectiveness Team.
Monitor the financial information provided in support of funding requests, to assess accuracy and ensure recording of this data for each request.

To validate invoices against funding request decisions and estimated costs.

2.11 Membership of the IFR Panel

NHS CB Area Teams will plan Individual Funding Request (IFR) Panel meetings sufficient to consider all cases referred by the Screening panel within one month. The Terms of Reference for the IFR Panels are in Appendix G

A panel will consist of the following core membership:

- NHS CB Area Team Medical Director or nominated deputy
- NHS CB Area Team Nursing Director or nominated deputy
- NHS CB Area Team Public Health Consultant / Specialist
- NHS CB Area Team Pharmacy lead for prescribed services
- NHS CB Area Team Service Lead or Supplier Manager
- NHS CB Regional SS Programme of Care Leads (1 of 5 in rotation) (or equivalent for other prescribed services for M&OH e.g. representatives from the Ministry of Defence or Department of Justice)
- Lay representative

For particularly complex cases, other individuals with clinical expertise and skills may also be included on the panel e.g. Clinical Members of appropriate SS Clinical Reference Groups or other specialist clinicians unconnected with the requesting provider.

Public Health trainees can also contribute to the work of the IFR process as part of their training. They can attend panels as non-voting members.

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5 From April 2013 the number of requests for Prescribed Services IFRs following the NHS re-organisation is uncertain. More than one panel meeting may be required per month and panel membership responsibility is shared by all Area Teams in any one region.
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 NHS CB Medical Director (or nominated deputy) and one other clinical Member of NHS CB Area Team.

However, an IFR Panel meeting with only three members present should be the exception. It is expected that this will only happen in unavoidable circumstances and in less than 1 meeting per three year period. This will be part of the audit of the IFR process. The quoracy of urgent panels is different (please see section 2.8).

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 IFR Panel who have had any clinical involvement with an individual case cannot be part of the panel hearing for that request.

2.12 Organisation of an IFR Meeting

IFR Panel meetings and membership will be scheduled in a rolling programme at least 6 months in advance. The IFR Officer will book an IFR case onto the next meeting date 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 and GP 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 about the functional impairment that is produced by their condition. 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. their consultant, GP or practice nurse.

The patient/carer or guardian, or their clinical or non-clinical representative, are not entitled to attend the panel in person. Awaiting the outcome of a funding request can be a highly emotive time for patients and their representatives. It would be inappropriate for them to be placed in a position that could lead them to conclude that the approval or otherwise of their request relied in some part on their ‘performance’ on the day. Equally, the distress of a patient or their representatives
can have an effect on the decision makers where identification with an individual’s circumstances may influence their decision in a way that would not happen for similar cases where the patient is not present.

Following a discussion with a health professional involved in the IFR process, 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 will provide a summary of the case using the Decision Framework Document (Appendix F) which will be considered by the IFR Panel. A clinical member of the screening panel (public health consultant / specialist or pharmacy lead as appropriate to the case) will present the clinical background to the case, including relevant syntheses of the evidence. Recognised published sources of evidence should be used where available. 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.

2.13 Decision making framework of the IFR Panel

The IFR Panel is a sub-committee of the NHS CB 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 NHS CB.

The IFR Panel will take into account the NHS CB policies underpinning decision-making e.g. the NHS CB Ethical Framework, commissioning policy on Individual Funding Requests and any other relevant commissioning policy.

2.14 Recording the decision

The IFR Officer will record the decision of the IFR Panel against each of the questions on the Decision Framework Document (appendix F). The panel will be clear about the rationale for the decision at each stage and this will be written in the decision framework document. A summary statement will be agreed by the panel and this will be used when communicating the decision.
The completed Decision Making Framework, together with the record of attendance, will form the minutes of the meeting. The minutes will be signed off by the Chair of the Panel.

2.15 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 and GP within 5 working days of the panel meeting to inform them of the outcome of the IFR Panel meeting, explaining the reasons for the panel decision. The clinician, the patient, their parent/guardian or carer and their GP will be invited to provide feedback on their experience of the IFR process, in order to inform future reviews of the process.

If funding is agreed, the IFR Officer will confirm with the clinician when treatment is likely to be delivered and that this is in a timely manner. There will be a mechanism in place to monitor the clinical outcome of treatment in order to determine whether it has resulted in benefit to the patient. An appropriate review date will be determined by the panel and recorded. The IFR system will flag when review dates are due. The IFR Officer will ensure that feedback on outcomes is requested and reported back to the panel. This feedback should be a standing agenda item for panel meetings. Provider trusts and their clinicians are expected to comply with such requests for information on the outcome of treatment for their patients. If this information is not available on request it may affect future funding decisions for the continuation of treatment which may then become the responsibility of the trust.

If funding is not agreed, the IFR Officer will inform the referring clinician, and the patient/guardian or carer and GP, outlining fully the reasons for the decision (as agreed by the panel and summarised in the decision framework document). Information on the further options that are available (either reconsideration or review) will be provided.

2.16 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 NHS CB Area Team to reconsider the case specifically in the light of this information.
In order to be assessed as a reconsideration of the previous decision (rather than as a new request), the additional information must be submitted to the IFR Officer within 10 working days of the date of the letter setting out the panel decision.

The NHS CB Area Team Screening panel 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. The outcome of the panel reconsideration will be communicated as described for the first IFR panel meeting.

If the new information is not considered to be significant by the screening panel, the referring clinician and the patient/guardian or carer and GP will be informed by letter with reasons for the decision not to refer the request back to the IFR Panel.

3. REVIEW OF IFR PANEL DECISIONS

3.1 Grounds for requesting a review of the IFR Panel Decision

The referring clinician or the patient or, if the patient is a minor, any person with parental responsibility for the patient, or any person holding a lasting power of attorney for the patient or and/or any close family member or carer for the patient (whether formal or informal) can make a request to the NHS CB Area Team for a review of the IFR Panel decision. The request should be made in writing to the Chief Operating Officer of the NHS CB Area Team and must be lodged within 20 working days of the date of the letter from the NHS CB setting out the IFR Panel decision. The Chief Operating Officer may exercise discretion in accepting requests outside this time limit if there are good reasons for the delay or it appears to the Chief Operating Officer that there is any other good reason to permit a review to be undertaken.

The request for review must set the grounds on which the IFR Panel decision is being challenged. A review can only be requested on the grounds set out in the IFR Policy.
3.2 Initial Consideration of Request for Review of IFR Panel Decision

The request for a review will be initially considered by a public health consultant / specialist from one of the Area Teams not involved in the original IFR application. If the consultant / specialist considers there is an arguable case that a review may conclude in favour of the patient, then a formal Review Panel meeting will be convened. The Panel will normally be convened within 20 working days of the NHS CB Area Team accepting the case for a Review. If the public health consultant / specialist reviewing the case does not accept the grounds put forward for a review, they will report to the regional Medical Director and a letter will be sent on behalf of the regional Medical Director to the referring clinician and/or the patient/guardian or carer explaining the reasons for the decision not to review the IFR Panel decision.

3.3 Membership of the Review Panel

The NHS CB IFR Review Panel will consider requests for review of IFR panel decisions. Terms of Reference are in Appendix H.

The Review Panel will consist of:

- NHS CB Regional Medical Director or nominated deputy
- NHS CB SS National Programme of Care Lead for the clinical area (or equivalent for other prescribed services for M&OH)
- NHS CB Area Team Public Health Consultant / Specialist

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

3.4 Purpose of the Review Panel

The Review Panel will examine all of the papers considered by the IFR Panel, the decision framework document of the IFR Panel meeting, the decision letter and the grounds of appeal. The panel will examine the process followed by the IFR Panel and the decision made by the IFR Panel. The Review Panel will examine the issues raised in the Grounds and the tests set out for a Review in the IFR Policy.
There will be no other representation at the Review Panel meeting 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 2.15 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 NHS CB 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

If any of the above apply, the Review Panel shall refer the matter to the IFR Panel if they consider that there is a reasonable prospect 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 reasonable prospect that the decision would have been different; the Review Panel shall uphold the decision of the IFR Panel.
3.5 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 outcome should be copied to the IFR Officer.

The Review Panel chair will write to the referring clinician, the patient/guardian or carer and GP, 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 Review Panel decision. Reasons given should only refer to the IFR policy as this is the basis on which the original decision is made. The clinician, the patient, their parent/guardian or carer and their GP will be invited to provide feedback on their experience of the IFR Review process.

If the original IFR Panel decision is upheld, the IFR Officer will inform the referring clinician, the patient/guardian or carer and GP, of their remaining options - either to pursue a complaint through the NHS CB Complaints Procedure or to take their case to the Healthcare Ombudsman. The NHS CB 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.

4. MONITORING

The IFR process will be monitored and reviewed at a regional and at a national level.

Regionally the IFR Officer will present to their panel a quarterly review of IFRs considered. The purpose of this is to assess whether intra-panel decision-making has been fair and consistent, and to make sure that the panels are considering appropriate cases e.g. that both the screening of requests and the panel work effectively. This review will include feedback from patients and requesting clinicians.
as part of the evaluation of the IFR policy and clinical feedback on the outcome for individual patients, where known.

These regional reports will be collated and evaluated by the 4 CDF/IFR Leads to assess inter-panel fairness and consistency. A quarterly joint report to the national Clinical Effectiveness Team will identify and recommend treatments with potential cohorts of patients, suitable for national clinical commissioning policy development.

This report will also make recommendations on improvements to the IFR process, informed by responses from requesting clinicians and patients, their parents / guardians or carers and their GPs.

All 4 Area Team IFR teams, including IFR Panel and IFR Review Panel members, will be required to participate in an annual meeting to include:

- Update training for IFR Panel and Review Panel members
- An annual review of requests considered, decision-making processes and decisions made across England
- An opportunity to identify inconsistencies and share good practice.

The responsible Area Team will collect and report quarterly to the Screening, IFR and IFR Review Panels; their cluster-wide Area Teams Heads of Prescribed Services, finance, supplier manager and service leads; their regional Medical Director and the NHS CB Clinical Effectiveness Team:

- Request to decision response times, in line with the standards in this document:
  - Acknowledge of a request for funding should be confirmed to the requester within 5 working days in 95% of cases
  - Pre-screening review outcomes should be communicated within 10 working days of the date of receipt of the request in 95% of cases
  - Screening panel decisions should be communicated within 15 working days of submission of a completed IFR request form (which provides sufficient detail for the request to be considered under the IFR process) in 95% of cases
  - The time period from receipt of request to IFR panel decision (excluding the number of working days awaiting information requested from the referring clinician) should not exceed 40 working days in 95% of cases
  - The outcome of a request for a reconsideration of the IFR Panel decision (on grounds of new information) should be communicated within 10 working days of receipt of the request for reconsideration in 95% of cases
The outcome of a request for a review of an IFR Panel decision (on grounds of process) should be communicated within 25 working days of receipt of the request for review in 95% of cases.

- Outcomes of requests at each stage of the process: pre-screening, screening, Panel decisions and Review panel decisions.
- Numbers of requests approved / declined by the screening panel, the IFR Panel or the Review Panel.
- Feedback from requesters and patients on their experience of the IFR process.
- Clinical outcomes for patients funded via the IFR process, where available.
- Interventions where a clinical commissioning policy may be appropriate i.e. a potential cohort of 20 or more\(^6\) patients have been identified from the data collected across England.

The responsible Area Team will collect and report to their cluster-wide Area Teams Heads of Prescribed Services, finance, supplier manager and service leads:

- Monthly summaries of committed spend outside commissioned services otherwise reported.

5. DOCUMENTS WHICH HAVE INFORMED THIS SOP


- Improving Access to medicines for NHS patients. A report for the Secretary of State for Health by Professor Mike Richards CBE. (November 2008). Available from:

\(^6\) This means an incidence of a new variant of the patient subgroup of about 1 per 2.5 million i.e. a rare manifestation of probably an already rare disease.


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

<table>
<thead>
<tr>
<th>Stage</th>
<th>Responsible Officer</th>
<th>Decision Making Body</th>
<th>Action and Timescales</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Receipt of IFR Request</td>
<td>IFR Officer</td>
<td>None</td>
<td>Funding request date stamped and logged on IFR database. Acknowledgement to referrer within 5 working days of receipt.</td>
</tr>
<tr>
<td>Pre-screening of IFR request to determine whether covered by existing contracts, clinical commissioning policies etc.</td>
<td>IFR Officer</td>
<td>IFR Officer</td>
<td>IFR Officer to advise referrer within 10 working days of date of request whether it is covered by existing contracts OR need to submit Treatment Request form.</td>
</tr>
<tr>
<td>Referrer wishes to discuss request / help to complete Treatment Request form</td>
<td>IFR Officer or Clinical team (PH or pharmacy lead)</td>
<td>None</td>
<td>All communication recorded in writing.</td>
</tr>
<tr>
<td>Referrer submits Treatment Request form</td>
<td>IFR Officer</td>
<td>None</td>
<td>Acknowledgement to referrer of Treatment Request form within 5 working days.</td>
</tr>
<tr>
<td>Screening of completed Treatment Request form</td>
<td>IFR Officer</td>
<td>Screening panel IFR Officer and nominated Clinical team (PH and / or pharmacy lead)</td>
<td>Request either approved if covered by existing policy OR rejected OR referred to IFR Panel within 15 working days*. If additional information requested from referrer, timeline of request is suspended until received. The IFR timeline allows for flexibility in the process: if additional research is needed by the screening panel to aid decision making this can be allowed for, but the requester will be notified of the reason for the delay in the screening outcome.</td>
</tr>
<tr>
<td>IFR Panel</td>
<td>Chair of the IFR Panel</td>
<td>Members of the IFR Panel</td>
<td>Panel to be convened within 20 working days Screening Panel decision. IFR Panel decision to</td>
</tr>
</tbody>
</table>
Interim SOP – Individual Funding Requests

Reconsideration
- IFR Officer
- Screening panel
- IFR Officer and nominated Clinical team (PH and/or pharmacy lead)

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 IFR Review Panel

Request for a Review must be lodged within 20 working days (with discretion). Review Panel to be convened within 20 working days of NHS CB 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/guardian or carer and the GP unless indicated by the requesting clinician as not clinically appropriate.
Appendix B1: Flowchart of IFR process for routine cases

Initial IFR from referrer screened by IFR Officer

Request covered by existing contract / commissioning policy

Referrer informed*

Request NOT covered by existing contract / commissioning policy

Referrer asked to submit treatment request form

Additional information requested from referrer

Treatment request form triaged by screening panel

Treatment request referred for consideration by IFR Panel

Patient asked if wish to submit written information

Referrer informed of date of panel and asked if wish to submit further information

Information sought from clinicians, specialists etc

Decision framework document considered by IFR Panel

Funding approved for treatment

Referrer informed* and mechanism agreed for delivery and monitoring of treatment outcome

Further information considered NOT significant by screening pair

Referrer informed* and advised of right to request a review

Further information considered significant by screening pair

Referrer informed* and a new IFR Panel convened

Funding NOT approved

Referrer informed* and submits further information for reconsideration

Referrer informed* and advised of right to request a review

The referrer must be a Doctor or other health care professional directly involved in the patient care. * All correspondence is copied to the patient/carer or guardian and the GP of the patient.
Appendix B2: Flowchart of review process for routine cases

1. Request for a review lodged by referrer and/or patient/guardian or carer
   - NHS CB designated officer considers there is an arguable case to support a review
   - Review Panel considers information presented to IFR Panel
     - Review Panel upholds the IFR Panel Decision
       - Referrer and patient/guardian or carer informed and further options explained
     - Review Panel refers the case back to IFR Panel for reconsideration
       - The IFR Panel approves funding for treatment
         - Referrer informed and mechanism agreed for delivery and monitoring of treatment outcome
       - The IFR Panel confirms the original decision
         - Referrer and patient/guardian or carer informed and further options explained
**Appendix C: Individual Funding Request (IFR) form**

<table>
<thead>
<tr>
<th><strong>1. PATIENT PERSONAL DETAILS</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Name:</td>
</tr>
<tr>
<td>Date of Birth:</td>
</tr>
<tr>
<td>Address:</td>
</tr>
<tr>
<td>NHS Number:</td>
</tr>
<tr>
<td>GP Name &amp; Practice Details (including GP post code):</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>2. DETAILS OF REQUESTER</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Name:</td>
</tr>
<tr>
<td>Designation:</td>
</tr>
<tr>
<td>Provider trust:</td>
</tr>
<tr>
<td>Contact ‘phone number:</td>
</tr>
<tr>
<td>Secure email or postal address for correspondence:</td>
</tr>
<tr>
<td>Must be <strong>NHS.net email</strong>.</td>
</tr>
<tr>
<td>Only NHS.net can be used for correspondence re IFR requests.</td>
</tr>
<tr>
<td>Provider Trust Clinical Director Support:</td>
</tr>
<tr>
<td>(signature of Clinical Director)</td>
</tr>
</tbody>
</table>
Provider Trust approval (please indicate as appropriate).

Drugs and Therapeutics Committee (DTC) or equivalent ……………………

Multidisciplinary Team (MDT)……………………

Date to DTC / MDT:

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

3. CONSENT

I confirm that this Individual Funding Request (IFR) has been discussed in full with the patient. 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

YES / NO

[Please indicate]

Please note. The NHS CB Area Team is under obligation to let the patient know the outcome of all IFR applications. The patient and parent / guardian or carer and their GP will therefore be copied into correspondence between the clinician and the NHS CB Area Team unless it is clinically not appropriate to do so. Please indicate as follows:

I confirm that it is clinically appropriate for the patient to be copied into all correspondence

YES / NO

[Please indicate]

Signature of Requester:                                                             Date:
Please note that all personal information will be removed prior to the consideration by the Individual Funding Request (IFR) Panel. Do not use patient or clinician / trust identifiers in the remainder of the form.

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 full text copies of 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.

4. Treatment requested

Please indicate which NHS CB Prescribed Service and / or Clinical Reference Group this requests relates to:

5. DIAGNOSIS
SUPPORTING INFORMATION

Please provide all the information requested to avoid delays in processing this request.

6. CLINICAL BACKGROUND

Outline the clinical situation. Wherever possible please refer to the outcome of objective scoring tools for severity / functional impact / stage of the condition. Please include:

- Previous therapies tried, the response and intolerance
- Current treatment, response and intolerance
- Current performance status and symptoms
- Anticipated prognosis if treatment requested is not funded (include what alternative treatment will be given)
7. INCIDENCE & PREVALENCE

Please provide an estimate of the incidence and prevalence of this condition: 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

**Incidence:** …………………………………
(The number of patients expected to have this condition per million population per year)

**Prevalence:** …………………………………
(The number of patients expected to have this condition per million population at any one time)

Please provide references for the stated incidence & prevalence here and attach full text articles and published source with the request form.
8. EXCEPTIONALITY

To meet the definition of ‘exceptional clinical circumstances’ there must be an NHS CB policy in place that describes the availability of the requested intervention and 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?
If so please give your reasons.

*For guidance on how the NHS CB defines an exceptional case see Appendix D of this document: Guidance Notes for clinicians.
9a. Is this a service development that has been discussed with the relevant NHS CB Clinical Reference group?

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 was to be funded for this patient on an individual basis, do you think that this would the decision set a precedent for other requests?

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 full text copies copies of all relevant clinical research. If a request does not include the full text of research papers that are submitted as evidence, these papers cannot be considered by the panel.
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 is the timescale in which a successful outcome will become evident?

What ‘stopping’ criteria will be in place to decide when the treatment is ineffective?

(The NHS CB 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.
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.

THIS SECTION MUST BE COMPLETED TO AVOID DELAYS IN DECISION MAKING

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 this is 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?
20. Clinicians are required to disclose all material facts to the NHS CB 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 NHS CB relevant Area Team as per contact details.
Appendix D: Guidance notes for Clinicians

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

An IFR application is appropriate if you:

- Consider patient to be clinically exceptional compared to other patients excluded from funding as set out in a particular policy
- You wish to use a treatment experimentally for a rare clinical circumstance
- You wish to enter a single patient into a trial and the application is for excess treatment costs

The criteria for eligibility for consideration as an Individual Funding Request have been clarified in the NHS CB Commissioning Policy for Individual Funding Requests (NHSCB/CP/03) and will now be applied consistently for all funding requests where the NHS CB is the responsible commissioner.

2. What is meant by ‘exceptional clinical circumstances’?

The NHS CB has policies which describe how the available resources are shared between the treatments of a range of conditions. In many cases these policies describe the group of patients in whom the treatment will be routinely available and, by definition, other groups of patients would not ordinarily be able to have the treatment. An exceptional case may arise when a clinician finds a patient who would not normally be eligible for treatment under an NHS CB policy but whom the clinician believes has factors about their case that mean that they warrant special consideration.

Such cases are given particular scrutiny because not only does a decision to fund the requested care requires the NHS CB to find the necessary resources from other areas of care but if your patient were to have their treatment funded, the NHS CB would have to make the treatment available to other patients who have similar clinical circumstances to your patient.

This would require the NHS CB 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 for whom the treatment is not routinely available e.g. metastatic bowel cancer not just bowel cancer

AND

• Likely to gain significantly more clinical benefit than others in that 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 a 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 NHS CB 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. What if I want to enter a patient into a trial?

The NHS CB has a mechanism for prioritising and funding clinical trials. Decisions on which trials are funded are taken at a policy level. However there may be instances, for example, with international clinical trials where recruitment in England will be small when the decision is appropriate on a case by case basis. In these instances it is essential to provide the trial protocol, details of the sponsors of the trial, which UK body has supported the trial and patient details.

5. What if I want to use a treatment experimentally for a rare clinical circumstance?

Most decisions about treatments for rare disorders are taken at the policy level to ensure equity of access.
Occasionally there will be very rare conditions, complications of common or rare conditions or other highly unusual clinical circumstances for which a clinician wishes to use an experimental treatment because there is no established or studied treatment and for which trials are impossible. Here the NHS CB will not only be looking for evidence that the clinical circumstances are rare or exceptional but also the review will need to include an assessment of biological plausibility for using a treatment in a setting not previously tested. In this instance you must also forward an explanation of why this drug or treatment is expected to work (namely what are the common pathological processes for the diseases in which the drug has been studied and for those under consideration).

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

From 1 April 2013 the NHS CB will commission Prescribed Services on a provider rather than a population basis. IFR requests for all patients at your trust will be dealt with by the responsible NHS CB Area Team in your region. All requests must be made on a standard treatment request form which is in this document (Appendix D) or can be obtained from your Area Team. The request should be typewritten using this form to ensure that all information is legible. **Please note**: only nhs.net email addresses will be accepted for correspondence about IFRs to preserve patient confidentiality.

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. You should highlight how the patient compares to the research population in whom evidence of a beneficial effect has been demonstrated. These measures will avoid delays in reaching a decision. The form can either be returned electronically or by post.

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

You can e-mail your NHS CB Area Team for advice on whether to submit a treatment request form and what to include. You should ensure that all parts of the IFR request form are completed to avoid delay in the IFR process. The 40 day response timeline for IFR requests is suspended whilst the IFR team is waiting for your response to any queries relating to the request. It is therefore in the interest of a timely response for your patient that you provide accurate contact details and that requests for further information are addressed as soon as possible.
8. Who will make the decision on whether the Individual Funding Request (IFR) is approved?

All new IFRs are ‘screened’ by a senior health specialist (e.g. Public Health consultant and/or pharmacy lead) and the IFR Officer within the NHS CB to decide whether the request meets the criteria for consideration of an IFR. As outlined in the commissioning policy associated with this process (NHSCB/CP/03) there are two characteristics of a request that could make it eligible:

- There is an existing clinical commissioning policy or mandatory National Institute for Health and Clinical Excellence (NICE) technology appraisal guidance but the patient does not meet the criteria for funding. The request is on the basis that ‘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 NHS CB Area Team IFR Panel. They will determine whether there is a case for exceptionality and whether the intervention is safe and clinically cost-effective.

  The panel will include:
  - NHS CB Area Team Medical Director or nominated deputy
  - NHS CB Area Team Nursing Director or nominated deputy
  - NHS CB Area Team Public Health Consultant / Specialist
  - NHS CB Area Team Pharmacy lead for specialised services
  - NHS CB Area Team Service Lead or Supplier Manager
  - NHS CB Regional SS Programme of Care Leads (1 of 5 in rotation)  
    (or equivalent for other prescribed services for M&OH e.g. representatives from the Ministry of Defence or Department of Justice)
  - Lay representative

- The request is for an intervention where there is no existing clinical commissioning policy or guidance. This will usually be because the indication is rare or the intervention is new and no policy or guidance has yet been developed. In the case of a rare indication, the screening panel will assess the incidence and prevalence. This assessment will be made using published epidemiological research and also taking into account other similar requests received by the NHS CB ATs across England. If the incidence and prevalence is below a threshold figure the case will be forwarded to the NHS CB Area Team IFR Panel. If the threshold test is not met, the request will be declined on the grounds that funding an individual case would be inequitable for the defined cohort. If the intervention is new, and the threshold test is not met...
(i.e. the patient represents a cohort) the IFR process is not appropriate and you will be directed to the process for requesting a service development.

9. How will I be informed of the NHS CB decision?

You will receive a letter informing you of the decision of the screening of your request within 15 working days of receipt of your treatment request form. If your request is being taken to the NHS CB Area Team IFR Panel you 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.

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

All correspondence on the outcome at each stage of the IFR process will be copied to the patient or parent/guardian or carer and to their GP. The rationale for the decision will be included at each stage of the process.

11. 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.

12. Can I or my patient appeal, against the NHS CB decision?

There is no right to appeal against the decision at the ‘screening’ stage although it is possible to complain under the NHS CB Complaints Policy. However, this will not overturn the decision of the screening stage but will examine whether the IFR procedure was properly followed. If the NHS CB Area Team 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 NHS CB. The Review Panel will decide if the NHS CB Area Team followed the correct procedures and whether the IFR Panel reached a decision that was rational and based on all the evidence that was presented.
13. 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 ask to be involved in the work of the policy review but this cannot be achieved through the IFR process. If the treatment or services relate to those commissioned by the NHS CB, it will need the support of all the relevant clinicians in the specific speciality through the appropriate NHS CB Clinical Reference Group, or by a direct approach to the NHS CB. Please seek advice from your Area Team.

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 away from existing services.
Appendix E: Information for patients

INDIVIDUAL FUNDING REQUESTS: Information for patients in England

This leaflet tells you what happens when you and your consultant think that you might benefit from a treatment that is not usually available on the NHS for people in your circumstances. It outlines the options available to you where the treatment you need is commissioned directly by the NHS Commissioning Board (the NHS CB).

Like other NHS commissioning bodies, the NHS CB has a duty to spend the money it receives from the Government in a fair and efficient way, taking into account the health needs of the whole community.

As there is only a set amount of money available to spend we sometimes have to make difficult decisions about which treatments are routinely provided.

In some instances, your doctor (usually a consultant) may think your case is very different to other people with your condition and that because of that difference you should be able to have a treatment which is not routinely provided. We refer to this as having exceptional clinical circumstances.

Requests for this type of treatment must be made through an Individual Funding Request (IFR). The same NHS CB IFR policy is used across England to ensure we treat patients consistently and fairly no matter where they live.

When can an Individual Funding Request (IFR) be made?

There are two situations when it is possible to make an IFR:

- When the NHS CB does not have a policy stating who is eligible for the treatment that is being requested

- When the NHS CB has a policy - but your clinical circumstances do not meet the policy definition of who is eligible for the treatment.

In either circumstance, your consultant will need to demonstrate that your clinical circumstances are ‘exceptional’ and justify treating you when others would not get the treatment.
What does ‘exceptional’ mean?

In deciding whether your clinical circumstances are ‘exceptional’ the NHS CB will consider two questions:

- Are there any clinical features that make you significantly different from others who have the same clinical condition?

- Are you likely to obtain significantly more clinical benefit from receiving the desired treatment when compared to other patients with the same condition?

Only your medical condition will be considered as part of the IFR process. Although it may seem unusual, your personal situation cannot be taken into account when your case is being considered. This is because everyone has their own individual value and role, so these factors cannot set your case apart from that of another person without implying that one person is somehow more deserving than another, because of who they are or what they do.

Who can make an Individual Funding Request?

If your consultant agrees that a treatment would be of benefit to you, and that there are no alternative treatments or services available for your condition, they can then make a request to the NHS CB on your behalf but only if they consider your individual circumstances are exceptional.

Requests are made on a form which asks questions that allow your consultant to describe your own clinical circumstances, how they think the treatment will specifically benefit you, the evidence that it is both safe and effective, the cost of the treatment and how commonly your condition occurs in the community.

What happens to the application?

The NHS CB follows the same procedure for every IFR to ensure we act fairly. All requests are treated in strict confidence and we remove your personal details from all paperwork.

When we receive a request, a check is made to ensure no service or treatment exists of which your consultant is not aware. If treatment is available then we will inform your consultant so they can discuss it with you.

If there is no service or treatment then the request is screened by a Consultant in Public Health (or their deputy) or (in the case of a request for a drug) a pharmacist and the NHS CB IFR Officer to decide whether your case meets the conditions for being considered ‘exceptional’. A decision on the outcome of the screening process
will normally be sent to your consultant within 15 working days (copied to you and your GP) unless the form is incomplete or more information is needed.

**What can I do if my request does not get past the screening stage?**

If your clinical circumstances are not considered to be exceptional you have the right to lodge a complaint through the NHS CB complaints process. The complaints process will not review whether the screening decision was correct, but will check that the IFR policy was correctly followed.

**How does the IFR Panel work?**

If the screening team agrees that there may be grounds to consider your request as exceptional, your case will be considered by the NHS CB IFR Panel within 20 working days of the screening decision, unless the clinical circumstances indicate that a quicker decision is needed.

The panel is made up of health professionals, lay members and NHS CB managers who consider the request against an agreed set of criteria to ensure the decision making is fair, consistent and transparent.

The panel reviews whether the treatment is likely to be beneficial and is safe (known as ‘clinical effectiveness’), how much it will cost to achieve the health benefit that is predicted (known as ‘cost effectiveness’) and the cost of the treatment in relation to the total NHS CB budget for providing health care (known as ‘affordability’).

**How will I find out the outcome of my request?**

The IFR Officer will write to your consultant with the IFR panel’s decision within 5 working days of the panel meeting giving the reasons for the decision that was reached. You and your GP will also be sent a copy of the letter. If funding is approved, your doctor will then arrange with when your treatment can begin.

**What can I do if the request is not funded?**

In the first instance you should speak to your consultant. You and your consultant can ask for a review of the IFR Panel’s decision on the following grounds:

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

The request for a review must be made in writing to the NHS CB Regional Medical Director within 20 working days of the date of the IFR Panel’s decision letter. The NHS CB may accept requests outside this time limit if there are good reasons for the delay.

If the NHS CB does accept the grounds put forward then a Review Panel will be convened. To ensure a fair process, all reviews are considered by different people from those who made the original IFR decision.

If the NHS CB does not accept the grounds put forward for a review, a letter will be sent to the referring consultant explaining the reasons.

The Review Panel will not consider new clinical evidence. If new evidence becomes available your consultant should make a new Individual Funding Request submission.

The Review Panel cannot overturn the IFR Panel decision. However, if the Review Panel decides that the decision was not reached correctly then it can instruct the IFR Panel to reconsider your case.

**Can I or my doctor attend the IFR or Review Panel in person?**

No. Only IFR Panel or Review Panel members may be present. However, all written evidence will be carefully considered before decisions are made. You can submit information in writing to be considered by the Panel. This should only contain information about your medical condition.

Awaiting the outcome of a funding request is likely to be a very worrying time for you. It would not be helpful for you to be placed in a position that could lead you to conclude that the approval or otherwise of the request relied in some part on your ‘performance’ on the day. Equally, your distress may have an effect on the panel where identification with your circumstances may influence their decision in a way that would not happen for similar cases where the patient is not present.

**What if the Review supports the original decision?**

You have no further right of appeal through the IFR procedure but you may make a complaint about the handling of your request by NHS CB at any time.
What if there is new information I think the IFR panel should have been aware of?

Your consultant, in discussion with you, can submit new information regarding your medical condition or the treatment you are requesting at any time. If the consultant in Public Health (or their deputy) or the Pharmacist and the PCT’s IFR Officer consider that this information might have changed the decision that was previously reached by the NHS CB then the case will be reconsidered following the process outlined above.

Do I have to pay a fee to make an Individual Funding Request or an appeal against a decision?

There are no fees payable to the NHS CB for any part of the IFR process.

To whom should I address my complaint?

Your complaint should be submitted in writing to the Regional Medical Director in the region where your clinician works.

If you choose, you can also write to the Health Service Ombudsman at:

The Parliamentary and Health Service Ombudsman

Millbank Tower

Millbank

London SW1P 4QP

Where can I get further advice and support?

For specific questions about your individual case please contact your clinician in the first instance.

If you wish to find out about the progress of an IFR request which is already being processed by the NHS CB please contact the IFR Officer at xxxxx writing to the address listed above.

More information about the Individual Funding Request process is available at

http://www.england.nhs.uk/ourwork/d-com/policies/
Appendix F: Decision framework document for Individual Funding Request panel

IN STRICTEST CONFIDENCE IFR DECISION FRAMEWORK DOCUMENT

PANEL MEETING
DATE__________________________________________ PATIENTNo: __________________________________________

NHS CB Area Team ..............................................

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:

<table>
<thead>
<tr>
<th>Brief background to intervention requested</th>
</tr>
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<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No</th>
<th>Points for consideration</th>
<th>Discussion notes</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Individual Need for Care</td>
<td></td>
<td>Yes/No</td>
</tr>
</tbody>
</table>

 1. Does the NHS CB have a policy to cover the treatment which is made available to patients with the medical condition of the patient?

  Did the panel reach the view that the patient had demonstrated exceptional clinical circumstances in this individual case?

**NB:** If the NHS CB 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 and the process stops here.
<table>
<thead>
<tr>
<th>Evidence of effectiveness: Clinical / Cost</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Does the panel consider that there is robust evidence of the clinical effectiveness of this drug/intervention?</td>
</tr>
<tr>
<td>3</td>
<td>Is there robust evidence that this drug/intervention has been or will be effective in this individual case and that they will gain significantly greater clinical benefit than other patients with the same clinical condition and stage of disease?</td>
</tr>
<tr>
<td>4</td>
<td>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?</td>
</tr>
<tr>
<td>No</td>
<td>Affordability</td>
</tr>
<tr>
<td>----</td>
<td>--------------</td>
</tr>
</tbody>
</table>
| 5  | What are the absolute costs involved in funding this treatment?  
    Does the total or annual cost of the treatment requested for this patient exceed £150,000? If so, the request will need to be considered by the NHS CB Clinical Effectiveness Team | | |
| 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?  
* e.g. the balance of benefit and harm from the intervention

### SUMMARY

<p>| Funding Approved: | Any conditions / review mechanisms required. |</p>
<table>
<thead>
<tr>
<th>Funding Denied</th>
<th>Reasons</th>
</tr>
</thead>
</table>

Outcome measures to be monitored and date of review.

RETURN THIS FORM TO THE PANEL ADMINISTRATOR AFTER THE MEETING
Appendix G: Terms of reference of the Individual Funding Request Panel

1. Membership

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

- NHS CB Area Team Medical Director or nominated deputy
- NHS CB Area Team Nursing Director or nominated deputy
- NHS CB Area Team Public Health Consultant / Specialist
- NHS CB Area Team Pharmacy lead for specialised services
- NHS CB Area Team Service Lead or Supplier Manager
- NHS CB Regional SS Programme of Care Leads (1 of 5 in rotation)
  (or equivalent for other prescribed services for M&OH e.g. representatives from the Ministry of Defence or Department of Justice)
- Lay representative

In attendance:
For particularly complex cases, other individuals with clinical expertise and skills may also be included on the panel e.g. Clinical Members of appropriate Clinical Reference Groups or other specialist clinicians unconnected with the requesting provider.

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.

Public Health trainees can also contribute to the work of the IFR panel as part of their training. They can attend panels as non-voting members.

The panel membership will be representative of a range of competencies, as outlined in the National Prescribing Centre Competencies Framework.\(^g\)

The IFR panel and its processes should reflect best practice as outlined in the NPC Handbook of Good Practice Guidance.\(^h\)

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 IFR Panel who have had any clinical involvement with an individual case can not be part of the panel hearing for that request.

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

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2. Purpose

The purpose of the IFR Panel is to consider individual requests for NHS CB commissioned and funded treatment. Each individual funding request will be handled by following the NHS CB IFR process (see NHS CB IFR Policy: NHSCB/CP/03) which will ensure the request is considered in a fair and transparent way, with decisions based on the best available evidence and the NHS CB 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 NHS CB Area Team Medical Director, 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 an authorised senior health professional and a Clinical Member of the NHS CB Area Team, 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. Quoracy

The panel will be quorate if three of the core members are present, including the NHS CB Medical Director (or nominated deputy) and one other clinical member.

For urgent cases requiring an ‘extraordinary’ IFR meeting, the meeting will be quorate if the membership consists of an authorised senior health professional and
one other clinical member. Other panel members can attend, if available.

6. Documentation

Individual Funding Requests will be date stamped and logged onto the NHS CB 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. A clinical member of the screening panel (public health consultant / specialist or pharmacy lead as appropriate to the case) will present the clinical background to the case, including relevant syntheses of the evidence. Recognised published sources of evidence should be used where available. 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 and/ or the screening panel 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 NHS CB 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 NHS CB 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 NHS CB.

8. Accountability

The minutes of the IFR Panel will be approved by the Chair of the Panel. The IFR Panel is accountable to the NHS CB 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 Review process and to consider any improvements that could be made. The IFR Officer will produce a quarterly report which will be considered by the NHS CB Medical Directorate Clinical Effectiveness Team and inform the need for clinical policy development. The Terms of Reference of the Panel will be reviewed annually by the NHS CB.

10. Training

All members of the IFR Panel must undergo mandatory induction training approved by the NHS CB. This will cover both the legal and ethical framework for IFR decision making, the NHS CB commissioning processes and structures, and the interpretation of clinical evidence. This training will be refreshed annually to ensure that all panel members maintain the appropriate skills and expertise to function effectively.
Appendix H: Terms of reference of the Review Panel

1. Membership

The Review Panel will consist of:

- NHS CB Regional Medical Director or nominated deputy
- NHS CB SS National Programme of Care Lead for the clinical area (or equivalent for other prescribed services for M&OH)
- NHS CB Area Team Public Health Consultant / Specialist

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 Procedures document
- The decision reached by the IFR Panel:
  - was consistent with the NHS CB Commissioning Principles
  - had taken into account and weighed all the relevant evidence
  - had not taken into account irrelevant factors
  - indicates that members of the panel acted in good faith
  - 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 NHS CB 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.
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.

The IFR Review Panel and its processes should reflect best practice as outlined in the NPC Handbook of Good Practice Guidance.¹

3. Frequency of meetings

The Review Panel will be scheduled monthly. A case may need to be considered urgently on the advice of an authorised senior health professional 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:

a) the original Treatment Request Form submitted to the NHS CB Area Team
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 3.19 Reconsideration above. All information will be anonymised before consideration by the Review Panel.

7. Authority

The Review Panel is a sub-committee of the NHS CB and has delegated authority to undertake a review of IFR Panel decisions in respect of funding of individual cases. 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 NHS CB.

8. Accountability

The Review Panel is accountable to the NHS CB.

9. Reporting and Monitoring

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. The IFR Officer will produce a quarterly report which will be considered by the NHS CB Medical Directorate Clinical Effectiveness Team and inform the need for clinical policy development. The Terms of Reference of the Review Panel will be reviewed annually by the NHS CB.

10. Training

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