Oxfordshire Clinical Commissioning Group

Policy: The Management of Individual Funding Requests

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INTRODUCTION

“You have the right to expect local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you, they will explain that decision to you” 

NHS Constitution

Clinicians, on behalf of their patients, are entitled to make a request to Oxfordshire Clinical Commissioning Group (OCCG) for individual funding for a treatment or service which is not normally commissioned by OCCG under defined conditions. This document sets out the principles and process for the consideration of individual funding requests (IFRs). It should be read in conjunction with the Ethical Framework (see Appendix1).

The Policy ensures the decisions made are, equitable, represent value for money, and are in the interest of the whole population.

EQUALITY STATEMENT

Oxfordshire Clinical Commissioning Group (OCCG) is committed to meeting its duties under both The Equality Act 2010 and The Equality Act Public Sector Duty 2011. This means we will have due regard to eliminating unlawful discrimination, advancing equality of opportunity and fostering good relations for people who share characteristics protected by The Equality Act.

Specifically, OOCG is committed to providing equality of access and non-discrimination to people in connection with their Race, Age, Gender, Disability, Religion or Belief, Sexual Orientation, Transgender, Marriage / Civil Partnership or Pregnancy / Maternity status.

However, in certain circumstances, the above ‘Characteristics’ may also be a relevant consideration in assessing the likely clinical effectiveness of an intervention / treatment or the potential capacity of an individual to benefit from the same. The CCG therefore ultimately reserves the right to either promote or restrict it services to an individual or selected groups of people. We may decide to do this where:

(i) There is a genuine determining reason for doing so.

(ii) The action is proportionate to the legitimate aims of OCCG.

PURPOSE

The purpose of the policy is to provide the CCG with a coherent, consistent and structured approach for IFRs which will assure patients and clinicians that requests are dealt with in a timely and equitable way. The policy will;

- Define the circumstances in which an Individual Funding Request can be made
- Set out the process for managing IFRs
- Describe the decision making process
- Set out the appeals process that can be invoked if necessary
ROLES AND RESPONSIBILITIES

I. The Quality Committee will be accountable on behalf of the CCG Governing Body for the IFR process
II. The Director of Quality will have oversight of the IFR process
III. The NICE Lead will have managerial responsibility for the IFR process
IV. The IFR Manager will have responsibility for the application of the IFR process
V. The IFR Panel Chair will have responsibility for the IFR Panel
VI. Decision Review Committee has the responsibility, on request, to review the decision of the IFR Panel

THE POLICY

This Policy applies to patients of constituent GP practices of Oxfordshire CCG for those treatments and services which are within the commissioning responsibility of OCCG. Clinicians, on behalf of their patients, may make an Individual Funding Request for a treatment or service which is not normally commissioned, if they believe that their patient may benefit more than those who would not receive the treatment and who have a broadly similar clinical condition.

ELIGIBILITY FOR CONSIDERATION UNDER THE POLICY

Individual Funding Requests are eligible for consideration in the following circumstances.

The treatment or service is not routinely commissioned because it is one or more of;

I. Outside the CCG’s contractual agreements with providers
II. Subject to an OCCG Commissioning (Lavender) Statement and has been deemed to be “Low Priority”
III. Subject to a National Institute of Health and Care Excellence (NICE) Technology Appraisal but has not been recommended for use in the NHS
IV. Is a drug which is not approved on the OCCG Formulary (Traffic Lights)
V. A mental healthcare intervention which is not available within an agreed care pathway for Oxfordshire patients
VI. Used for a small number of patients with a rare condition and normal service development routes cannot be used. This includes circumstances where the Thames Valley Priorities Committee has been unable to consider the treatment or service and NICE is not reviewing the treatment. Rare conditions in the context of this policy are those which affect no more than 1 in 50,000 of the population.
VII. A new treatment which has not been formally assessed by OCCG

Or the patient’s clinical circumstances are one or more of;

I. Outside the criteria or thresholds set within an Oxfordshire Commissioning (Lavender) Statement
II. Outside the criteria set in a NICE Technology Appraisal

III. Outside the criteria set in OCCG referral guidelines

Or the request is for one or more of;

I. A package of care or treatment not normally funded within Oxfordshire but which has been approved by an NHS commissioning body in another part of England. In considering these applications OCCG will tackle account of, and adhere to, national guidance including that set out in *Who Pays? Determining Responsibility for Payments to Providers* (NHS Commissioning Board 2013)

II. A referral to a specialist provider not covered by an established pathway

III. A second opinion in circumstances which are not covered by the NHS Constitution

Patients seeking NHS-funded Hospital Treatment in the European Union, European Economic Area or Switzerland

NHS England has issued guidance with effect from April 2013 on this type of request and will now handle all such requests. CCGs are responsible for making guidance available to referrers and patients and for handling any associated issues arising from these requests in line with NHS England guidance.

Individual Funding Requests **will not be accepted** in the following circumstances;

The treatment or service is;


II. The commissioning responsibility of Public Health England or Local Authority Public Health

III. A service development. That is there are known to be a number of patients (a cohort) who have the same clinical condition and similar clinical needs. All requests for their collective treatment must be submitted to Oxfordshire CCG for consideration though the established priority setting and annual commissioning (operational plan) process. The exception to this is for rare conditions as defined above.

Or the request is;

I. For retrospective funding i.e. requests from providers made after an episode of care has commenced or requests from patients for reimbursement of the costs of a treatment which has been purchased privately.

II. For continuation of funding for patients coming off drugs trials. In line with the Medicines Act 2004\(^2\) and the Declaration of Helsinki\(^3\), the responsibility


\(^3\) [http://www.wma.net/e/policy/b3.htm](http://www.wma.net/e/policy/b3.htm)
for ensuring a clear exit strategy from a trial lies with those conducting the trial. OCCC Commissioning (Lavender) Statement 69a Research trials and NHS funding: the funding of medicines on trial completion for participating patients has given a low priority to the funding of 'post trial' medicines for patients who have participated in a clinical trial, regardless of the benefits of the treatment.

GENERAL PRINCIPLES

All requests for consideration as IFRs will be handled in line with the CCG’s Standard Operating Procedure for IFRs (attached at Appendix 4).

The following principles will apply:

- All requests will be considered in the light of the Thames Valley Priorities Committee Ethical Framework.
- The correct application of the process of managing all requests received and correspondence with the referrer and patient/carer or guardian will be the responsibility of the IFR Manager.
- All aspects of the IFR process will be fully documented and any confidential personal information will be managed in line with the CCG’s policies on management of confidential data and the retention and destruction of records. Data and information governance principles will be followed.
- Information relating to patients which is provided for consideration by the IFR Panel will be fully anonymised.
- Communication with patients or their representatives (parent or guardian or carer) will be limited to information about the process.
- Communication of a clinical nature should be the responsibility of the Chair of the IFR Panel or an appropriate alternative member of the Panel and should be via the clinician making the request, copied to the patient, carer or relative as appropriate and to the GP.
- Communication will be in writing whenever possible, emails should be securely archived and when telephone conversations take place a file note will be added as a record of the conversation.
- All NHS policies will be adhered to in full.

THE APPLICATION

1. Applications may only be made by the doctor or other health care professional (“clinician”) responsible for the treatment being requested. A GP responsible for the overall care of a patient will not otherwise be expected to make an application on behalf of secondary care but may contribute supporting information.
2. The application should only be made if the clinician considers that there is a case to be made under OCCC’s Commissioning (Lavender) Statement 80c Guidance for considering “exceptions” in Individual Funding Requests
3. The application should be made using the relevant OCCC IFR form and supporting documentation should be attached.
4. GP applications should be made electronically using the DATIX IFR form and supporting documentation should be attached.
5. It is the referring clinician’s responsibility to ensure the IFR form is completed as accurately and comprehensively as possible.
6. The IFR form should be sent to the OCCG IFR Manager.
7. An IFR request will not receive formal consideration unless and until an application completed in full has been submitted by the patient’s GP or other clinician.
8. The referring clinician is responsible for providing evidence of efficacy, effectiveness, cost and, where available, cost-benefit or cost-effectiveness. Full documents or hyperlinks to full documents of evidence should be provided with the application.
9. The IFR Manager (and their team) and Panel members will not be responsible for providing evidence beyond that specified in the Standard Operating Procedure.
10. In accordance with the Thames Valley Ethical Framework social circumstances should only be included if, in the opinion of the requesting clinician, they are relevant to the clinical effectiveness of the treatment and the individual’s capacity to benefit from the treatment.
11. The patient/patient’s carer or family member may contribute, through the clinician, a statement explaining the impact of the condition on the patient’s Activities of Daily Living or Quality of Life.

THE STAGES OF THE IFR PROCESS
The IFR process comprises potentially the following stages:
   1. Receipt and screening check
   2. Triage
   3. IFR Panel
   4. Decision Review Panel (Appeal)

Stage 1 Receipt and Check
All requests will be entered into the database and given a unique identifier which will be used in all correspondence. Applications received on paper will be date stamped.

The purpose of screening is to determine if the application is the responsibility of OCCG, if it requires an urgent decision and if all parts of the application form have been completed. Handwritten applications will not be accepted to reduce the risk of errors in interpretation.

The process will then follow the Standard Operating Procedure.

If a request is received which requires an urgent decision and in the written opinion of the referring clinician delaying the decision to the next scheduled Panel meeting might cause significant harm to the patient’s health the Panel Chair will be consulted as to the need for an urgent meeting, under the Standard Operating Procedure.

Actions arising from the screening may include:
• Rejection of the request on the basis that funding is being sought retrospectively or for continuation of a drug following a clinical trial
• Return of the request with suitable advice on the basis that the treatment requested does not fall within the commissioning responsibility of OCCG
• Return the request with suitable advice if the patient is not registered with a constituent practice of OCCG
• Return the request with suitable advice if the request falls outside the remit of the OCCG IFR process
• Return of the request with suitable advice if the application is not on a recognised IFR form

Stage 2 Triage

The purpose of triage is to determine if the application is eligible go to the IFR Panel or if a decision can be made without recourse to the full Panel. The triage will be performed and recorded in accordance with the Individual Funding Request Standard Operating Procedure.

Actions arising from triage may include:
• Refusal of the request on the basis that the information provided, including the reason for exceptionality, is insufficient for consideration by the Panel.; the requesting clinician would then be advised that they may re-submit the request if the required information is provided
• Approval of the request where it is clear that the patient is eligible for treatment within OCCG clinical funding policies or commissioned services
• Acceptance of the request and submission to the IFR Panel

A quarterly report will be made to the Panel of all requests agreed or declined at the Screening stage.

Stage 3: Individual Funding Request Panel (IFRP)

The IFR Panel will meet monthly. It is the responsibility of the IFR Manager to provide the information to the Panel in accordance with the Standard Operating Procedure. Papers will be anonymised with the patient’s name and address and the GP name and address being redacted.

It is the responsibility of the Panel chair to ensure that the Panel operates in accordance with the Terms of Reference.

Funding, with or without conditions will be approved if the Panel concludes, on the basis of all the available evidence, that:

a) the presentation/ effect of the condition in the patient differs significantly from that found in the general population of patients with the conditions; and
b) as a result, the patient is likely to gain significantly more benefit from that treatment than might generally be expected for these patients; and

c) that there is sufficient evidence for the effectiveness of the treatment in bringing about the expected benefit for the patient; and
d) the cost of the requested treatment is unlikely to be disproportionate compared to the benefit anticipated. The Panel will have broad discretion to determine whether a proposed treatment is a justifiable expenditure for OCCG. The Panel is however required to bear in mind that the allocation of resources to support any individual patient will reduce the availability of resources for other patients and services.

OCCG’s policy is set out in Commissioning (Lavender) Statement 80c Guidance for considering “exceptions” in Individual Funding Requests If the Panel concludes that the above criteria have not been met, funding will not be approved. The patient and their clinician(s) will be advised in writing of the Panel’s decision and the rationale for the decision.

The Panel may make one of the following decisions;
I. to approve funding
II. to approve funding with conditions for example for a limited period or with a requirement for regular updates
III. to defer a decision when further information is required
IV. to refuse funding where there appears to be no evidence or insufficient evidence that the clinical circumstances of the patient’s case are exceptional, when compared with other patients who have the same or a substantively similar condition

Reconsideration of the Request
If the referring clinician and/or the patient is not satisfied with the outcome because the clinical information presented was insufficient the referring clinician may have the request reconsidered if substantive new clinical information is available and is likely to support the case for funding the requested treatment. The requesting clinician may resubmit the request along with the new information and ask the IFR Panel to reconsider the case in the light of the new information provided.

The new information will be triaged in accordance with the Standing Operating Procedure to determine whether it significantly alters the nature and strength of the evidence originally submitted to the Panel. If it does, the request will be submitted to the next available IFR Panel meeting which will consider the new information alongside the original request.

Stage 4: Review of the Decision (Appeal)

A request for a review of the decision can be made by the referring clinician, the patient or their carer or relative within 3 months of the date of the Panel decision letter. The request must be supported by the referring clinician who must explain the reasons for review. Review of decisions can only be made on the following grounds:
a) that the decision of the panel was procedurally improper; and/or
b) that the Panel members misunderstood the medical evidence; and/or
c) the decision of the Panel was, in the opinion of the referring clinician, one which no reasonable IFR Panel could have reached.

Requests for review of decisions of the IFR Panel will be considered initially by the Assistant Director of Quality and/or the Director of Quality. If it is felt that there may be grounds for a review, a meeting of the Decision Review Committee (DRC) will be convened to consider the application. If it is considered that there are insufficient grounds for a review, the Director of Quality will write to the applicant explaining the reasons for the decision not to review. The Decision Review Committee will operate within its terms of reference and the IFR Standard Operating Procedure.

The DRC will be able to make one of the two following decisions:

1. **To uphold the decision made by the IFR Panel.** The DRC will be able to choose this option even if it considers there have been procedural errors or inconsistency with commissioning policy, if it believes that there would be no reasonable prospect of the requested treatment being approved by the IFR Panel if it were to reconsider the case.

2. **To refer the case back to the IFR Panel with detailed points for reconsideration.** The case will then be considered at the next scheduled monthly meeting of the IFR Panel.

The Chair of the DRC will write to the referring clinician and the patient or their carer or relative informing them of the outcome of the meeting and the reasons for the DRC’s decision. If the IFR Panel decision has been upheld, the letter will set out the remaining option for pursuing a complaint through the NHS Complaints Procedure.

**NHS COMPLAINTS PROCEDURE**
Under the NHS Complaints procedure and in line with the NHS Constitution, a patient who has been refused funding for treatment is entitled to complain and to have their complaint investigated. They can complain if they are unhappy with the way in which their request for funding has been handled. They may also complain if they are unhappy with the relevant CCG Commissioning Policy.

**CONSISTENCY AND AUDIT**
The IFR Manager and Panel Chair will ensure internal consistency with previous decisions, using available evidence including reports of past decisions and minutes of meetings.
It will be the responsibility of the IFR Manager to participate in audit and review of the process. The IFR Manager and their team will participate in pan-CCG meetings and liaison to promote best practice and to learn from colleagues.

**SAFEGUARDING**
Throughout the IFR process all those involved will bear in mind their duties under safeguarding. At any stage of a submission the IFR Manager may seek advice on the case from the OCCG safeguarding leads.

**ARMED FORCES COVENANT**
The IFR process will pay due regard to the Armed Forces Covenant when it is relevant to a submission.
ANNUAL REPORT
An annual report will be produced and presented to the Quality Committee. The annual report will balance the need for patient confidentiality, accountable governance and transparency.

PATIENT INFORMATION AND EXPERIENCE
The CCG public website will contain sufficient information for members of the public to be fully informed of the IFR process. It will be the responsibility of the IFR Manager to ensure that the information provided is up-to-date and comprehensive. Patients and the public will be entitled to know the job titles of those involved in making decisions in their case but their names will not be released.

All those involved in the IFR Process will remain aware of the potential for patient and/or carer distress. Patients will be treated by OCCG in accordance with Statements 1 and 2 of NICE Quality Standard 15 Patient Experience in Adult NHS Services.

Statement 1. Patients are treated with dignity, kindness, compassion, courtesy, respect, understanding and honesty.

Statement 2. Patients experience effective interactions with staff who have demonstrated competency in relevant communication skills.
THAMES VALLEY PRIORITIES COMMITTEE
ETHICAL FRAMEWORK

Background
A primary responsibility of the commissioners of NHS health care in England is to make decisions about which treatments and services should be funded for their designated populations. This includes making decisions about the continued funding of currently-commissioned treatments and services, as well as the introduction of new treatments and approaches to the delivery of care.

Commissioners are subject to a statutory duty not to exceed their annual financial allocation. Further, despite an incremental increase in funding, the NHS needs to make substantial financial savings in order to continue to meet increasing demands for care and treatment. As the demand for NHS health care exceeds the financial resources available, commissioners are faced with difficult choices about which services to provide for their local populations.

The Priorities Committee has representatives of the NHS organisations across ten Thames Valley Clinical Commissioning Groups (CCGs) and includes lay members as well as clinicians and managers. The purpose of the Priorities Committee is to make recommendations, in the form of policies, to the local CCGs as to the services and health care interventions that should or should not be funded.

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To help in this process, health care commissioners in the Thames Valley region have developed a decision-making tool - the ‘Ethical Framework’, to facilitate fairness and transparency in the priority-setting process.

The Ethical Framework was originally developed in 2004 by the NHS public health organisation Priorities Support Unit (now Solutions for Public Health5) and the Berkshire PCTs. Since then, the Framework has been revised to take account of policy developments in the NHS and changes in the law, and has been adopted more widely.

The purpose of the Ethical Framework

The purpose of the ethical framework is to support and underpin the decision making processes of constituent organisations and the Priorities Committee to support consistent commissioning policy through:

- Providing a **coherent structure** for the consideration of health care treatments and services to ensure that all important aspects are discussed.

- Promoting **fairness and consistency** in decision making from meeting to meeting and with regard to different clinical topics, reducing the potential for inequity.

- Ensuring that the **principles and legal requirements of the NHS Constitution**6 and the **Public Sector Equality Duty**7 are adhered to.

- Providing a transparent means of **expressing the reasons** behind the decisions made to patients, families, carers, clinicians and the public.

- Supporting and integrating with the development of CCG Commissioning Plans.

Formulating policy recommendations regarding health care priorities involves the exercise of judgment and discretion and there will be room for disagreement both within and outwith the Committee. Although there is no objective measure by which such decisions can be based, the Ethical Framework enables decisions to be made within a consistent setting which respects the needs of individuals and the community.

The following Ethical Framework consists of 8 principles or relevant considerations that will be taken into account in the development of each recommendation. It does not prejudge the weight that any one consideration is given nor does it require that all should be given equal weight.

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5 [http://www.sph.nhs.uk/ebc/about-us](http://www.sph.nhs.uk/ebc/about-us)
1. **EQUITY**
The Committee believes that people should have access to health care on the basis of need. There may also be times when some categories of care are given priority in order to address health inequalities in the community. However, the Committee will not discriminate, or limit access to NHS care, on grounds of personal characteristics including: age, race, religion, gender or gender identity, sex or sexual orientation, lifestyle, social position, family or financial status, pregnancy, intelligence, disability, physical or cognitive functioning. However, in some circumstances, these factors may be relevant to the clinical effectiveness of an intervention and the capacity of an individual to benefit from the treatment.

2. **HEALTH CARE NEED AND CAPACITY TO BENEFIT**
Health care should be allocated justly and fairly according to need and capacity to benefit. The Committee will consider the health needs of people and populations according to their capacity to benefit from health care interventions. As far as possible, it will respect the wishes of patients to choose between different clinically and cost effective treatment options, subject to the support of the clinical evidence.

This approach leads to three important principles:

- In the absence of evidence of health need, treatment will not generally be given solely because a patient requests it.
- A treatment of little benefit will not be provided simply because it is the only treatment available.
- Treatment which effectively treats “life time” or long term chronic conditions will be considered equally to urgent and life prolonging treatments.

3. **EVIDENCE OF CLINICAL EFFECTIVENESS**
The Committees will seek to obtain the best available evidence of clinical effectiveness using robust and reproducible methods. Methods to assess clinical and cost effectiveness are well established. The key success factors are the need to search effectively and systematically for relevant evidence, and then to extract, analyse, and present this in a consistent way to support the work of the Committee. Choice of appropriate clinically and patient-defined outcomes need to be given careful consideration, and where possible quality of life measures should be considered.

The Committees will promote treatments and services for which there is good evidence of clinical effectiveness in improving the health status of patients and will not normally recommend treatment and services that cannot be shown to be effective. For example, is the product likely to save lives or significantly improve quality of life? How many patients are likely to benefit? How robust is the clinical evidence that the treatment or service is effective?

When assessing evidence of clinical effectiveness the outcome measures that will be given greatest importance are those considered important to patients’ health status. Patient satisfaction will not necessarily be taken as evidence of clinical effectiveness. Trials of longer duration and clinically relevant outcomes data may be considered more reliable than those of shorter duration with surrogate outcomes. Reliable evidence will often be available from good quality, rigorously appraised studies. Evidence may be available from other sources and this will also be considered. Patients’ evidence of significant clinical benefit is relevant.
The Committee will also take particular account of patient safety. It will consider the reported adverse impacts of treatments and the licence status of medicines and the authorisation of medical devices and diagnostic technologies for NHS use.

4. EVIDENCE OF COST EFFECTIVENESS
The Committees will seek information about cost effectiveness in order to assess whether interventions represent value for money for the NHS. The Committees will compare the cost of a new treatment to the existing care provided and will also compare the cost of the treatment to its overall benefit, both to the individual and the community. The Committee will consider studies that synthesise costs and effectiveness in the form of economic evaluations (e.g. quality adjusted life years, cost-utility, cost-benefit. as they enable the relationship between costs and outcomes of alternative healthcare interventions to be compared, however, these will not by themselves be decisive.

Evidence of cost effectiveness assists understanding whether the NHS can afford to pay for the treatment or service and includes evidence of the costs a new treatment or service may release.

5. COST OF TREATMENT AND OPPORTUNITY COSTS
Because each CCG is duty-bound not to exceed its budget, the cost of a treatment must be considered. A single episode of treatment may be very expensive, or the cost of treating a whole community may be high. This is important because of the overall proportion of the total budget: funds invested in these areas will not be available for other health care interventions.

The Committees will compare the cost of a new treatment to the existing care provided, and consider the cost of the treatment against its overall health benefit, both to the individual and the community. As well as cost information, the Committees will consider the numbers of people in their designation populations who might be treated.

6. NEEDS OF THE COMMUNITY
Public health is an important concern of the Committee and they will seek to make decisions which promote the health of the entire community. Some of these decisions are promoted by the Department of Health (such as the guidance from NICE and Health and Social Care Outcomes Framework). Others are produced locally. The Committee also supports effective policies to promote preventive medicine which help stop people becoming ill in the first place.

Sometimes the needs of the community may conflict with the needs of individuals. Decisions are difficult when expensive treatment produces very little clinical benefit. For example, it may do little to improve the patient’s condition, or to stop, or slow the progression of disease. Where it has been decided that a treatment has a low priority and cannot generally be supported, a patient’s doctor may still seek to persuade the CCG that there are exceptional circumstances which mean that the patient should receive the treatment.
7. NATIONAL POLICY DIRECTIVES AND GUIDANCE
The Department of Health issues guidance and directions to NHS organisations which may give priority to some categories of patient, or require treatment to be made available within a given period. These may affect the way in which health service resources are allocated by individual CCGs. The Committee operates with these factors in mind and recognise that their discretion may be affected by Health and Social Care Outcomes Frameworks\(^8\), NICE technology appraisal guidance, Secretary of State Directions to the NHS and performance and planning guidance.

Locally, choices about the funding of health care treatments will be informed by the needs of each individual CCG and these will be described in their Local Delivery Plan.

8. EXCEPTIONAL NEED
There will be no blanket bans on treatments since there may be cases in which a patient has special circumstances which present an exceptional need for treatment. Individual cases are considered by each respective CCG. Each case will be considered on its own merits in light of the clinical evidence. CCGs have procedures in place to consider such exceptional cases through their Individual Funding Request Process.

Thames Valley Priorities Committee Working Group
Date of issue: 7\(^{th}\) February 2014
Date of review: February 2015

Appendix 2

Oxfordshire Clinical Commissioning Group

Individual Funding Request Panel
Terms of Reference

Vision
By working together we will have a healthier population, with fewer inequalities, and health services that are high quality, cost effective and sustainable.

1. **Introduction**
The Individual Funding Request (IFR) Panel is established in accordance with NHS Oxfordshire Clinical Commissioning Group’s (OCCG) constitution. These terms of reference set out the membership, remit, responsibilities and reporting arrangements of the Committee.

2. **Purpose**
The consideration of individual funding requests, i.e. where the requested treatment is “not normally funded” as defined in the OCCG Individual Funding Request Policy. To also consider cases referred back to it by the Decision Review Committee.

3. **Authority**
The Panel is a decision making group, responsible to Oxfordshire Clinical Commissioning Group.

4. **Membership**
The following are voting members.
At least two GPs who are members of OCCG practices
Programme Manager – Deputy Director. Head of Primary Care and Medicines Optimisation
NICE Lead
Up to three additional senior managers (Grade 8b or above) with commissioning, finance or contracting responsibilities including a senior programme manager from the Directorate of Delivery and Localities

Each Panel member may appoint a deputy who also fulfills the required competencies

5. **Other Attendees**
The following do not have voting rights.
The IFR Manager
A member of the administrative team

6. **Quorum**
The Panel will be quorate if three voting members are in attendance, at least two being clinically qualified, one of whom must be a GP.

7. Frequency and notice of meetings
The Panel will meet in person once a month. Dates of the meetings will be arranged for a year in advance but may be changed at the discretion of the Chair.

8. Extraordinary meetings
The Chair, in discussion with the IFR Manager, may call an extraordinary meeting in the event of an unusually high number of cases being submitted which might risk delays in the process.

If a face-to-face meeting is not possible (for example if a quorum cannot be obtained), the Chair of the Panel may agree that a meeting be held by means of;

- A teleconference between members who can meet and available members who are unable to attend in person
- An email discussion with contributions from a quorate number of members only if a teleconference cannot be achieved and a decision is needed urgently

The IFR Manager will ensure that there has been appropriate time for members to consider the case/s, including sufficient time before the meeting to read the available papers.

Minutes, including the decision and the rationale for it, will be taken and provided to the next scheduled IFR Panel for formal approval.

The Panel Chair (or acting Chair) will authorise the decision letter to be sent as soon as possible following the extraordinary meeting.

Urgent meetings
If an IFR is received which, in the opinion of the referring clinician, requires an urgent decision and delaying the decision to the next IFR Panel might cause significant harm to the patient’s health, the Chair, in discussion with the IFR manager, will consider holding an extraordinary meeting.

9. Representation by patients, patient representatives and requesting clinician
To prevent some patients being disadvantaged there is no right of attendance by the requesting clinician, the patient or their representative at the IFR Panel. However, all information and views set out by the patient and by their clinicians will be made available to members as an integral part of the consideration of the request. Occasionally a clinician who has made requests may be invited as an observer to the Panel to gain insight into the process but will not be permitted to contribute to a discussion of any request they have made.

10. Remit and responsibilities of the Individual Funding Request Panel
To consider any requests within its remit as described in the IFR Policy. The key question to be answered by the Panel is “Why this treatment should be
provided for this patient when the treatment in question is not normally funded by the CCG?" In answering this question, Panel members have a duty to:

- consider each request in the context of the relevant policy, where one exists, or as a “treatment not normally funded” where there is no explicit policy. The IFR Manager will provide electronic links to all the relevant OCCC clinical and prescribing policies and referral criteria and to any relevant NICE guidance, NICE pathways and other NICE publications. In addition the Panel may consult the British National Formulary, the Drug Tariff and the Summary of Product Characteristics when relevant.

- consider each case on the basis of the submitted written information of the patient’s clinical circumstances and of the evidence of efficacy, clinical-effectiveness, cost and if available the cost-effectiveness or cost-benefit of the proposed treatment. Panel members will be provided with full documentation for each case at least 5 working days in advance of the meeting. It is the responsibility of Panel members to read the documents before the meeting.

- take into account any previous relevant individual case requests and ensure consistency in decision making;

- seek clarification, if this is required, on how a policy or guideline should be interpreted from the body responsible for it (e.g. NICE or Oxfordshire Area Prescribing Committee (APCO), Thames Valley Priorities Committee);

- bear in mind that the allocation of resources to support any individual patient will reduce the availability of resources for other patients and services.

- ensure that, when the potential for a new clinical pathway emerges during consideration of an IFR or series of IFRs, the need for development (or review) of commissioning policy is conveyed, as appropriate, via the relevant panel member to the referring clinician, the appropriate commissioning team, APCO, Priorities Committee and/or the proposed provider NHS Trust(s);

- make its decisions within the Thames Valley Priorities Committee Ethical Framework

- to make one of the following decisions;

  I. to approve funding

  II. to approve funding with conditions for example for a limited period or with a requirement for regular updates

  III. to defer a decision when further information is required

  IV. to refuse funding where there appears to be no evidence or insufficient evidence that the clinical circumstances of the patient’s case are exceptional, when compared with other patients who have the same or a substantively similar condition

- share as appropriate with other CCGs experience gained in dealing with requests for individual patients.

- preserve patient confidentiality by only considering cases where the patient and GP details have been fully anonymised
11. **Competency Requirements for the Panel**

The key competencies and experience required within the IFR Panel are:

- the ability to understand and interpret the clinical information regarding IFRs, placing them in the context of the relevant populations
- the ability to review and critically appraise evidence, including clinical and cost effectiveness data
- understanding of the principles contained in the Ethical Framework and their application in relation to IFRs
- understanding of the CCG’s commissioning and contracting processes
- awareness of the legal context of the consideration of IFRs

12. **Training of Panel members**

The training needs of existing and new members will be assessed and training provided as necessary. New members of Panels will be required to have attended as observers for at least two Panel meetings, before formally becoming voting members. Supplementary and continuing training will be provided to ensure that members continue to develop in their role as Panel members. Panel members will normally be expected to attend a training session at least once a year.

13. **Conflicts of interest**

If a Panel member believes they may have a conflict of interest in a particular case, this must be disclosed to the Panel Chair or deputy before the case is discussed. In the event of a potential conflict of interest the Chair or deputy will make a decision as to whether the member should be involved in consideration of the request.

14. **Communication of decision**

The decision and reasons for it will be set out in writing to the referring clinician and copied to the patient (unless the committee has been informed beforehand that this will be detrimental to the patient’s health and wellbeing) and the patient’s GP within 10 working days.

Letters sent to clinicians will be marked “private and confidential”. Letters sent to patients and to places where confidentiality arrangements may not be in place will be marked “private and confidential, to be opened by addressee only” in line with OCGGs “Information Governance Procedure”. Communications by email will be sent using NHSmail to secure email addresses or will be encrypted.

15. **Accountability of the Individual Funding Request Panel**

The Panel is responsible to the Quality Committee through the Director of Quality.

16. **Role of the IFR Manager at the Panel**

The IFR Manager will present the cases to the Panel and will draw the Panel’s attention to previous decisions, changes in local and national policy and to any other relevant procedural matters. The manager will also present any photographs (which will not have previously been sent to Panel members).
The manager will also inform the Panel of any matters relating to previous decisions and will present any Decision Review Committee decisions.

17. Review of the Committee
The Committee will review its performance, membership and terms of reference annually. Any resulting changes to the terms of reference will be presented for approval to the Quality Committee.

Date agreed
Review date
Appendix 3

Decision Review Committee

Terms of Reference

Vision
By working together we will have a healthier population, with fewer inequalities, and health services that are high quality, cost effective and sustainable.

1. Introduction
The Decision Review Committee (DRC) is established in accordance with NHS Oxfordshire Clinical Commissioning Group’s (OCCG) constitution. These terms of reference set out the membership, remit, responsibilities and reporting arrangements of the Committee.

2. Purpose
The role of Decision Review Committee is to consider requests from referring clinicians for a review of decisions made by the IFR Panel which have been judged by the Director of Quality or Assistant Director of Quality to meet the criteria for review in the OCCG Individual Funding Request (IFR) Policy. Such requests can only be made on the following grounds:
   a) that the decision of the panel was procedurally improper; and/or
   b) that the Panel members misunderstood the medical evidence; and/or
   c) that the decision of the Panel was, in the opinion of the referring clinician, one which no reasonable IFR Panel could have reached.

3. Authority
The Committee forms part of OCCG’s corporate governance and has delegated responsibility from the OCCG Governing Body for decision-making.

4. Membership
Membership must include the following as a minimum:
   Director of the CCG
   Lay member of the CCG Governing Body
   GP who is a member of an OCCG Practice
   Patient Representative

   The chair of the DRC will be a director of OCCG.
   No member of the DRC should have been on the IFR Panel which made the original decision.

5. Administrative support
Administrative support to the DRC will be provided by the Assistant Director of Quality and a member of the administrative team
6. **Quorum**  
The quorum will be at least four members as described under membership.

7. **Conflicts of interest**  
If a committee member believes they may have a conflict of interest in a particular case, this must be disclosed to the Committee Chair or deputy before the committee meeting. In the event of a potential conflict of interest the Chair or deputy will make a decision as to whether the member should be involved in the review.

8. **Frequency and notice of meetings**  
Meetings of DRC will be ad hoc, when required by a valid request for review as defined above. A meeting will be convened for the earliest date following a decision to hold a DRC for which a quorum is available.

9. **R emit and responsibilities of the Decision Review Committee**  
- **To consider the grounds for review as stated in the review request by:**
  - Examining all the documentation considered by the IFR Panel
  - Examining the minutes of the Panel meeting at which the decision was made
  - Examining the decision letter sent to the clinician following the Panel
- **The DRC may not** consider new written or oral information beyond the application for review.
- **The DRC may not** receive representation, beyond that in the application and the documentation seen by the IFR Panel from:
  - Members of the IFR Panel which made the decision
  - The referring clinician
  - The patient
  - A patient carer or representative including an MP
- **The Committee will apply the following tests:**
  - Whether the process followed by the IFR Panel was consistent with the CCG’s approach to Corporate Governance.
  - Whether the decision reached by the IFR Panel was taken following a process which was consistent with the policies of OCCC;
  - Whether the IFR Panel had taken into account and weighed all the relevant evidence;
  - Whether the IFR Panel had not taken into account irrelevant factors;
  - Whether the decision was one which a reasonable IFR panel was entitled to reach

10. **Decision and communication**  
The DRC will be able to make one of the two following decisions:
   I. To uphold the decision made by the IFR Panel. The DRC will be able to choose this option even if it considers there have been procedural errors or inconsistency with commissioning policy, if it believes that there would be no reasonable prospect of the requested treatment being approved by the IFR Panel if it were to reconsider the case.
   II. To refer the case back to the IFR Panel with detailed points for reconsideration. The case will then be considered at the next scheduled monthly meeting of the IFR Panel.
The Chair of the DRC will write to the referring clinician and the patient or their carer or relative informing them of the outcome of the meeting and the reasons for the DRC’s decision. This will be sent within 10 working days. A copy will be sent to the Chair of the IFR Panel. If the IFR Panel decision has been upheld, the letter will set out the remaining options for pursuing a complaint through the NHS Complaints Procedure.

11. Accountability of the Decision Review Committee
   The DRC is accountable to OCCG through the Quality Committee

12. Review of the Committee
   The Director of Quality or Assistant Director of Quality will review the performance, membership and terms of reference of the DRC annually. Any resulting changes to the terms of reference will be presented for approval to the Quality Committee.

Date agreed
Review date
Appendix 4:

STANDARD OPERATING PROCEDURE FOR INDIVIDUAL FUNDING REQUESTS

General Principles

- When the patient is mentioned in this SOP this should also be taken to mean (when relevant) the parent or guardian for patients under 16 years or carer or representative for patients who lack capacity or who have given permission for a representative to be the contact.
- The correct application of the process of managing all requests received and correspondence with the referrer and patient will be the responsibility of the IFR Manager.
- Requests will be dealt with promptly and should be within the timescales within this SOP.
- Members of the IFR team and Panel will be mindful at all times for the potential for patient distress.
- All aspects of the IFR process will be fully documented and any confidential personal information will be managed in line with the CCG’s Information Governance policies.
- Information relating to patients, including the patient’s GP and GP practice which is provided for consideration by the IFR Panel will be fully anonymised.
- Communications regarding the request will be through the requesting clinician and not directly with the patient. The patient will be copied into decision letters unless this would be detrimental to the patient’s wellbeing. Any other communication with the patient should be limited to information on the process.
- Communication of a clinical nature should be the responsibility of the Chair of the IFR Panel or an appropriate alternative member of the Panel and should be via the clinician making the request, copied to the patient, carer or relative as appropriate.
- Communication will be in writing or electronically whenever possible, emails and paper correspondence will be securely archived and when telephone conversations take place a file note will be added as a record of the conversation.
- Letters sent to clinicians will be marked “Private and confidential”. Letters sent to patients and to places where confidentiality arrangements may not be in place, will be marked “Private and confidential, to be opened by addressee only”, in line with OCCG’s Information Governance procedure.
- All NHS policies will be adhered to in full.
Stage 1:  Initial screening of new referrals and requests for reconsideration

1.  All applications will be logged, added to the database and assigned a unique identifier (IFR number) for use in all future correspondence within 2 working days of receipt. If the application is received by post it will be date stamped. The date of receipt for electronic applications must be logged.

2.  Handwritten applications or applications by letter will be returned to the requesting clinician within 4 working days of receipt with an explanation that they cannot be accepted and information on applying using the required IFR form.

3.  The IFR Manager will assess the application for completeness. The application should contain:
   a)  an outline of the patient’s diagnosis/problem and the clinical circumstances of the case, including any previous treatment(s) used and outcomes achieved;
   b)  a statement of the referral/treatment plan proposed for the patient, to include the point at which the patient should return to local treatment pathways and/or the expected duration of the proposed treatment;
   c)  consideration of reason(s) why the patient’s needs cannot be met within existing pathways;
   d)  a statement of the reason(s) why this treatment, which would not be offered to others with similar clinical need, is a priority for funding in the individual patient’s case, i.e. what are the exceptional clinical circumstances and the exceptional capacity of the patient to benefit when compared to others?
   e)  a statement of evidence of clinical efficacy or effectiveness if this is a new treatment not yet funded or is an extended use of a recognised treatment. Evidence should be appended as full papers or there should be an electronic hyperlink to the full paper/s
   f)  the anticipated cost of the treatment (and associated costs) if it is outside the NHS tariff, if evidence of cost-effectiveness is available this should be included
   g)  the expected healthcare benefits (e.g. impact of likely outcomes on the Activities of Daily Living, anticipated improvement in disease activity scores ) if the requested treatment is provided, set against expected outcomes if the patient remains within the service or continues with treatment provided within existing CCG contracts.
   h)  clinical quality photographs if the requesting clinician believes this will assist the Panel, if these have been provided by the patient the requesting clinician should indicate that they are a good representation of the condition

4.  The IFR Manager will return incomplete applications to the requesting clinician within 5 working days of receipt. This is an administrative step and need not be copied to the patient or GP (if the GP is not the applicant).

5.  The IFR Manager will determine if commissioning of the healthcare intervention requested is the responsibility of OCCG and will return requests which are not to the requesting clinician with advice within 5 working days of receipt.
6. The IFR Manager will determine that OCCG is the responsible commissioner for the patient and will return requests which are not to the requesting clinician with advice within 5 working days of receipt.

7. The IFR Manager will collate applications for triage.

Stage 2 Triage

1. The purpose of triage is to distinguish between; applications for treatments which are normally commissioned or which are within policy criteria, applications requiring further information or clarification before they can be considered, applications which could not be considered at Panel and applications which can go forward for consideration.

2. Triage will be performed by at least one Panel GP (Panel Chair or deputy) and the IFR manager (or deputy) and the NICE Lead (or deputy). Additional clinical input may be sought from a Panel pharmacist and/or an OCCG clinical lead.

3. There will be at least one triage meeting each month

4. The triage meeting may follow an agreed template or checklist

5. A record should be made and placed on the electronic record as soon as possible. The record should contain as a minimum; the triage date, role/s of the people involved and the decision, with reasons,

The following actions may follow the triage;

- Refusal of the request on the basis that the information provided, including the reason for exceptionality, is insufficient for consideration by the Panel; the requesting clinician would then be advised that they may re-submit the request if the required information is provided. The letter containing the decision and reasons for it will be sent to the requesting clinician and be copied to the patient and the GP.

- Approval of the request where it is clear that the patient is eligible for treatment within OCCG clinical funding policies or commissioned services. The letter confirming approval will be sent to the requesting clinician and be copied to the patient and the GP.

- Acceptance of the request and submission to the IFR Panel. The requesting clinician will be informed of the Panel date. The requesting clinician will be responsible for informing the patient of the panel date.

Timescales for initial response

Acknowledgments and letters conveying decisions at triage will be sent to the clinician requesting funding, copied to the patient, within 10 working days of the triage meeting. Letters refusing the request will be reviewed by the Panel Chair before being sent.

Stage 3: IFR Panel

Preparation for the meeting

- All eligible requests received at least 10 working days ahead of the date of the next available Panel meeting will be considered at that meeting. Eligible requests received less than 10 working days ahead of the date of the next Panel meeting will usually be considered at the following month’s meeting in
order to allow sufficient time for screening, processing and provision of information to the Panel members.

- Panel members will be provided with the following information at least 5 working days ahead of the date of the meeting
  1. Agenda
  2. Draft minutes of the previous meeting
  3. Draft minutes of any urgent or extraordinary meeting held since the previous meeting
  4. Anonymised summary of all cases to be considered at the meeting
  5. Anonymised copy of the original application and supporting documentation provided by the referring clinician for each case (except photographs).
  6. Relevant policies, guidance etc. relating to each case.
  7. A quarterly report on applications received and dealt with outside the Panel.

The IFR Manager will check that the meeting be quorate and if there is a problem will discuss this with the Panel Chair

**Conduct of the meeting**

- The Chair of the Panel will agree the order of the agenda
- The Panel will agree the minutes
- The Chair of the Panel will sign the agreed minutes of the previous meeting and of any extraordinary meeting which has been held since the previous panel
- Panel members will report back on actions from the previous meeting
- The IFR Manager or designated Panel member will introduce each case
- The IFR Manager or designated Panel member will draw the attention of the Panel to any relevant past cases, national or local guidance and any photographs received
- The Chair of the Panel will invite Panel members to discuss the case using the Exceptionality Policy and Ethical Framework as a guide to the points which should be considered
- The Panel will consider the case in the following order; that the presentation/effect of the condition in the patient differs significantly from that found in the general population of patients with the condition and, as a result, the patient is likely to gain significantly more benefit from that treatment than might generally be expected for these patients. If these criteria are fulfilled then there should be sufficient evidence of the effectiveness of the treatment in bringing about the expected benefit for the patient and finally that the cost of the treatment will not be disproportionate to the benefit anticipated.
- At the end of the discussion of each case the Chair of the Panel will summarise the decision, the reasons for the decision, and any conditions on an agreement to fund a treatment.
- At the end of each Panel the Chair of the Panel will remind members of any agreed actions arising from the discussions
- Panel members will be expected to remain for the duration of the meeting, or where this is impossible will remain to the end of the case under discussion.
- Panel members will not leave the meeting if this will make the meeting inquorate
Reconsideration by the IFR Panel following a Decision Review Committee referral back
The IFR Panel will reconsider its original decision with all the relevant paperwork, ensuring that it addresses all the points raised by the DRC. The DRC does not have power to authorise funding for the requested treatment, but may make recommendations to the IFR Panel. If the IFR Panel confirms its original decision, clear reasons must be given for not agreeing the funding request.

Record of proceedings
- Minutes of the meeting will be completed by the IFR Administrator for each meeting. This will include for each case a record of the documentation provided to Panel members ahead of the meeting; any guidance or policies tabled or referred to during the discussion of the case; the decision reached; and the rationale for the decision.
- The minutes of the meeting will form the basis of the Panel decision letter.

Correspondence with applicants
- Panel decision letters will be drafted by the IFR Manager and agreed by the Chair of the Panel meeting, at which the decision was made or by a designated deputy.
- Each letter should include the outcome of the meeting and the rationale for the decision made.
- Letters will be sent to the clinician requesting funding, copied to the patient and the patient’s GP.
- The preferred method of communication to clinicians is by NHSmail within the OCCG Information Governance Policy.
- A post log will be kept of hardcopy letters

Follow-up of decisions
When a decision to approve with conditions has been made the IFR team will request follow-up information from the relevant clinician within the specified timescale.

The IFR team will co-operate with the contracting team when required.

Stage 3: Decision Review Committee
The Panel decision letter must advise the clinician requesting funding of the patient’s right to a review on the following grounds:

- that the decision of the panel was procedurally improper; and/or
- that the Panel members misunderstood the medical evidence; and/or
- that the decision of the Panel was, in the opinion of the referring clinician, one which no reasonable IFR Panel could have reached.

A request for a review of the decision can be made by the referring clinician or the patient within 3 months of the date of the Panel decision letter. If the request is made by the patient it must be supported by the referring clinician who must explain the reasons for requesting the review.
Requests for review of decisions must be made by letter to the Director of Quality within 3 months of the date of the Panel decision letter.

Requests for review of a decision must be responded to within 5 working days of receipt, acknowledging receipt and explaining the next stage of the process.

**Initial consideration**
The Director of Quality and/or the Assistant Director of Quality will review the case file and the letter requesting the review within 15 working days of the request. They will determine if there is a case for review by the Decision Review Committee under one or more of the grounds listed above.
The patient and requesting clinician will then be advised in writing of the decision. Reasons must be given if the decision is not to review.

If the request is agreed, a meeting of the DRC is to be called. The requesting clinician and the patient will be informed of the date of the DRC. This should be as soon as a quorate meeting can be convened.

**Decision Review Committee Meeting**
The DRC will consider the grounds for the review request and examine:

- all the documentation considered by the Panel;
- the minutes of the meeting at which the decision was made; and
- the decision letter.

No new written or oral information will be considered by the DRC beyond the request for review.

No representation at the meeting either by IFR Panel members or the referring clinician, the patient or their representative will be allowed.

**Tests to be applied by the DRC**
1. Whether the process followed by the IFR Panel was consistent with the CCG’s Corporate Governance arrangements.
2. Whether the decision reached by the IFR Panel:
   - was taken following a process which was consistent with the policies of OCCG;
   - had taken into account and weighed all the relevant evidence;
   - had not taken into account irrelevant factors;
   - was a decision which a reasonable IFR panel was entitled to reach.

DRC will be able to make one of the two following decisions:

1. **Uphold the decision made by the IFR Panel.**

2. **Refer the case back to the IFR Panel with detailed points for reconsideration.** The case will then be considered at the next scheduled monthly meeting of the IFR Panel.
The Chair of the DRC will write to the referring clinician and the patient or their representative **within 5 days** of the DRC meeting and will give the decision and the reasons for the DRC’s decision.

If the IFR Panel decision has been upheld, the letter will set out the remaining options for pursuing a complaint through the NHS Complaints Procedure.

The following documents informed this policy

NHS England operates its own IFR process. However, this policy takes into account the approach of NHS England in managing IFRs and, as far as possible, is aligned with the NHS England Interim Policy for Individual Funding Requests (April 2013) and the associated Interim Standard Operating Procedure (April 2013).