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Section 1 BACKGROUND

1.1 Since the introduction of the NHS internal market in 1991, and as part of the development of contracting procedures to underpin World Class Commissioning in the NHS, Health Authorities, and later their successor Primary Care Trusts (PCTs), have introduced mechanisms for dealing with access to treatments outside the scope of their standard contracts and commissioning policies. PCTs now have responsibility to consider requests for individual patients' treatments, which are not funded through their commissioned services. The NHS Constitution confirms that patients have the right to expect local decisions about the funding of medicines and treatments to be made rationally, following a proper consideration of the evidence. This policy describes Oxfordshire PCT's procedures, ensuring compliance with principles laid out in the Handbook of Good Practice Guidance published by the National Prescribing Centre in February 2009.

1.2 The PCT receives a fixed budget from central government with which to commission NHS health care for the population of Oxfordshire. The PCT cannot fund all types of health care that might be available or requested by their population. It is therefore inevitable that the PCT has to make choices about which healthcare interventions to commission.

In line with the NHS Constitution, Oxfordshire PCT strives to make these choices in a clear and transparent way. Processes have therefore been put in place to assess *new health care treatments* to determine whether they should routinely be funded and to deal with individual requests for *"treatments which are not routinely commissioned"*.

1.3 The first step towards achieving a forum for explicit decision-making in Oxfordshire came in 1994 when the Health Authority established a panel including GPs and representatives from NHS Trusts, to consider requests for extra-contractual referrals (ECRs) of individual patients. In 1995, the 'ECR Panel' became the Priorities Forum and has evolved into a policy making body. The Oxfordshire Priorities Forum advised the PCT on current and new treatments. From April 2010, a joint Priorities Committee was established for the five northern PCTs in the South Central region. Treatments not recommended for funding are designated as being *"Low Priority Treatments"*, and this is normally based on their limited clinical or cost effectiveness.

1.4 The publication of an annual 'Operational Plan' enables the PCT to agree and make available its commissioning intentions for the (registered) population in Oxfordshire. The Healthcare Priorities Unit (HCPU), which is part of the Public Health Directorate, is the PCT's body that deals with requests for consideration of funding for an individual patient to receive a treatment where there is no general policy, or in cases where a specific policy dictates that the requested treatment is "not normally funded". HCPU receives and considers requests in accordance with the procedures set out below.

Section 2 PRINCIPLES AND POLICIES

The term “treatment” as used throughout this document is intended to include all health technologies and interventions, such as drugs, surgical procedures, diagnostic tests, other investigative procedures, rehabilitation, immunisations and screening. This is provided as an illustrative, not an exhaustive, list. The Individual Funding Request (IFR) process shall not normally be used to consider requests for funding of equipments to supplement individual care packages, funded following consideration within the PCT’s Continuing Care service, for patients with complex health care needs.

2.1 Principles

The NHS Constitution (Section 2a) states that patients ***“have the right to expect local decisions on funding of other¹ 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.”***

When considering IFRs, the PCT will take into account, as appropriate, statute law, statutory directions, national guidance and guidelines, and will apply the South Central Ethical Framework (see Appendix 1) and the following principles:

2.1.1 The PCT will not normally commit new resources to the introduction of new or enhanced treatments during a financial year, since doing so would risk *ad hoc* decision making and could destabilise previously identified priorities.

2.1.2 To support the Operational Planning process, the PCT will use its advisory groups (such as the Priorities Committee² and Oxfordshire Area Prescribing Committee) to make recommendation on the clinical and cost-effectiveness of new healthcare technologies, on opportunities for disinvestment from less effective services and also on prioritisation of treatments. These groups will do this through an ongoing programme of work throughout the year. It may be that not all interventions supported by these groups will be affordable within available budgets. The Operational Planning process will be the final determiner of those technologies prioritised for investment in the coming year.

2.1.3 If, on the basis of policy, a treatment is “not normally funded”, the PCT will consider requests for treatment to be provided for an individual patient as an exception to that policy. The PCT’s IFR process is the means by which an assessment is made as to whether the case for an exception has been established.

It is important to recognise that IFRs may be made in several circumstances (see section 2.3 for further detail). These include:

¹ i.e *Other* than those funded as a result of a NICE Technology Appraisal recommendation

² From April 2010 the Oxfordshire Priorities Forum amalgamated with the priorities committees of Milton Keynes PCT; Buckinghamshire PCT; Berkshire East and Berkshire West PCTs.

- Where the PCT has in place an explicit commissioning policy statement, a doctor (or other NHS clinician) may present, on behalf of their patient, a request for funding as an exception to the general rule.
- Where the PCT has no policy, e.g.
 - i when an NHS clinician proposes treatment for a patient who has a very rare condition for which the PCT has not previously needed to make services available
 - ii in cases where the normally commissioned treatment for a patient's condition is for whatever reason considered inappropriate (e.g. requests, normally made by a Consultant, for approval of tertiary referral outside normally contracted services);
 - iii where there is limited evidence of the effectiveness in the clinical circumstances of an individual patient's case , (e.g. novel, developing or otherwise unproven treatments: this may include off-licence and un-licensed treatments);

2.1.4 When terms such as “Exceptional funding” or “Exceptional clinical circumstances” are used in this policy document, they are used in the context of Oxfordshire PCT’s Policy Statement 80c (*Guidance for considering exceptions in Individual Funding Requests* - see Appendix 2). This indicates that “If funding is to be agreed (*on an exceptional basis*), there must be some unusual or unique factor about the patient’s clinical circumstances, which suggests 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.

2.1.5 Applications for individual funding of treatment will be considered by the Treatment Request Panel (TRP). The Cancer Treatments Panel (CTP) has been established as a separate specialist entity on a pilot basis to consider requests for individual cancer drug treatments. The Decision Review Committee’s (DRC) role is to consider appeals against decisions made by the TRP or CTP. The IFR process shall not be used to circumvent commissioning procedures for a new treatment that might be provided for a group of patients rather than an individual patient. The Panels (TRP, CTP and DRC) are not empowered to make a decision to fund a patient where, by so doing, a precedent would be set that would, in effect, establish new policy (i.e. where the patient’s circumstances are not, in fact, exceptional, but representative of a group of patients). Where the Panels receive evidence which appears to support the more general use of a particular health technology, they should make a recommendation for further consideration of that treatment through the Priorities Committee or Operational Planning process; in these circumstances individual funding for the specific

patient's case will not normally be approved. The PCT cannot introduce new treatments through the process of IFRs. To do so would risk inequity since the treatment may not be offered openly and equally to all with equal clinical need. There is also the risk that diversion of resources in this way will destabilise areas of healthcare which have been identified as priorities by the PCT.

2.1.6 Information Governance

IFRs will be managed in line with national and local NHS policies regarding confidentiality, retention and destruction of records.

2.2 Policies and Guidance

When considering IFRs, the PCT will take into account the following:

2.2.1 PCT Operational Plan (OP) and Healthcare Contracts

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

2.2.2 "Lavender" policies statements

Treatments not currently included in established pathways or identified for funding through the OP process are "not normally funded". For a number of these treatments the PCT has published specific policy statements (called "Lavender"), setting out restrictions on access, based on evidence of effectiveness or relative priority for funding. These include, but are not limited to, interventions such as aesthetic surgery, in vitro fertilisation and associated techniques, varicose vein surgery, bariatric surgery.

A current list of Lavender Statements can be obtained from HCPU and is available on Oxweb or via the PCT website (www.oxfordshire.nhs.uk/lavender.asp). Clinicians or patients uncertain about the status of a particular treatment should contact HCPU for advice.

2.2.3 NICE Guidance/Guidelines

The NHS Constitution confirms that technologies approved as a result of a NICE **Technology Appraisal Guidance** (TAGs) must normally be funded within three months of the final TAG being published. The PCT is not obliged to fund any treatment on the basis of draft TAG guidance and will not normally do so.

Interventional Procedures Guidance (IPGs) take into account safety and efficacy of a treatment, but not clinical- and cost-effectiveness. They do not constitute a recommendation that the procedure should be used, merely an indication of the circumstances in which it may be used (see Lavender policy no 115a).

The PCT assesses and takes account of recommendations in NICE **Clinical Guidelines** when commissioning services and drawing up policy statements.

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The PCT is not obliged to implement or fund recommendations in the NICE Clinical Guidelines.

2.3 Types of IFR Requests

2.3.1 Treatments not Covered by PCT Commissioning Guidance

Patients with rare conditions and/or patients for whom established treatments are inappropriate for some reason are unlikely to have potential treatment options that are covered by NICE or by local policies. Such situations should be considered by the Panels. Patients with rare conditions should neither be advantaged nor disadvantaged simply because their condition is uncommon.

2.3.2 Requests to Continue Funding for Patients Coming off Drugs Trials

The PCT does not expect to provide funding for patients to continue treatment commenced as part of a clinical trial. In line with the Medicines Act 2004³ and the Declaration of Helsinki⁴, the responsibility for ensuring a clear exit strategy from a trial and that those benefiting from treatment will have ongoing access to it, lies with those conducting the trial. The PCT will expect the initiators of the trial (including provider Trusts) to have an obligation to continue funding patients benefiting from treatment. Where the treatment is not prioritised through the PCT's Operational Plan, the responsibility remains with the trial initiators indefinitely (see Lavender policy no 69).

³ <http://www.legislation.hmso.gov.uk/si/si2004/20041031.htm>

⁴ <http://www.wma.net/e/policy/b3.htm>

2.3.3 Requests to Continue Funding of Care Commenced Privately

Patients who are entitled to NHS-funded treatment have a right to revert to NHS treatment at any point during their care. However, the PCT will expect their treatment to follow local NHS treatment pathways. Funding for an individual to continue care in a private facility or to transfer to an NHS provider where a privately consulted clinician has a link, will not be routinely authorised. Where individual clinical circumstances may make such funding appropriate, the case will require consideration by the Panels. The PCT will not reimburse costs for private treatment undertaken without prior PCT's approval. See Lavender Policy Statement 67a.

2.3.4 Requests for Referral to a Specialist Provider

The majority of referrals to specialist centres are made by secondary care consultants. The PCT expects consultants to refer patients for tertiary/specialist care using established pathways covered by Service Level Agreements and in line with national guidance on Patients' Choice. Accordingly, requests for referrals to specialist providers, outside existing pathways, will usually only be considered after an assessment by appropriate specialists, within the existing pathway. Should a local consultant decide that a referral outside existing pathways is a priority for a particular patient, the consultant should ask for the case to be considered by the Panels.

2.3.5 Requests for Second Opinion

Patients are entitled to *request* a second consultant opinion, but this must be within an NHS funded clinic. A resultant treatment plan must be in accordance with treatment options normally available within Oxfordshire care pathways or be the subject of an IFR.

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

2.3.6 Decisions Inherited from Other Primary Care Trusts

Occasionally patients move in to Oxfordshire when a package of care or treatment, which would not normally be funded for Oxfordshire patients, has already been approved by their previous PCT. The Oxfordshire PCT may honour such decisions, providing the care pathway has been initiated (for example an appropriate referral has already been made and approved). In considering applications for funding in these circumstances, the PCT will take account of, and adhere to, Department of Health Guidance including the principles set out in "Who Pays? Establishing the Responsible Commissioner" (Dept of Health September 2007).

2.3.7 Choose and Book Referrals (Patient Choice)

Patients requiring a first elective referral *for a first non-urgent outpatient appointment* in an NHS-commissioned Consultant-led service will be offered a choice of provider in line with national guidelines, made explicit within the NHS Constitution. Choose and Book does not apply to requests for a second opinion or tertiary referrals. (see above 2.2.6 and 2.2.7)

Patients can choose *where* they go, but there are limitations with regard to *what* treatment they may receive in their chosen Hospital. Following assessment of the patient's condition, if the proposed treatment would normally be commissioned in Oxfordshire, the PCT will pay the national tariff price to the chosen provider. The PCT will not fund treatments elsewhere that would not normally be provided in local NHS contracts. Patients are not free to choose *who* they see; it is not possible to guarantee that patients will see a particular clinician. Whilst an appointment may be made to attend a named Consultant's clinic, it is not certain that the patient will be seen nor can it be guaranteed that any commissioned treatment will be carried out by that Consultant.

2.3.8 Mental Health IFRs

IFRs for mental healthcare interventions, which are not available within agreed care pathways for Oxfordshire patients, must be submitted for consideration to the Extra-contractual Referral Administrator at Oxfordshire and Buckinghamshire Mental Health NHS Foundation Trust. Requests for these interventions are not considered under the PCT's IFR arrangements.

Section 3 OVERVIEW - THE IFR PROCESS

Oxfordshire PCT has had a process for the consideration of exceptional funding requests since its inception on 1 October 2006, building on arrangements previously applied by the five former Oxfordshire PCTs. The PCT's former IFR Policy was published in May 2008. Amendments contained in this policy document reflect learning at a local level and national developments. In particular, the policy takes account of the publication of the National Prescribing Centre's "Handbook of Good Practice Guidance" and references in the NHS Constitution to the handling of IFRs. As a result, this document includes some changes in terminology and practice. However, the principles underlying the national guidance have previously underpinned Oxfordshire practice.

A decision has also been made to rename the committee previously called the "Case Review Committee" to "Decision Review Committee". The formerly named "Appeals Panel" is renamed "PCT Appeals Panel." The roles of these committees are fundamentally unchanged. However, the new names more accurately reflect their functions. It is therefore hoped that this will make the way in which the PCT's IFR process works more understandable to its users.

The rationale which underpins the IFR process is as follows:

If the PCT does not normally fund a treatment but an NHS clinician considers that there are clinical grounds for *an individual patient* to receive that treatment, the IFR process enables the clinician to present a case for funding. This policy provides a framework for the consideration of the patient's clinical circumstances and whether they may provide grounds for individual funding, in line with the PCT's guidance on exceptions in individual cases (Appendix 2).

3.1 Treatments which are "Not Normally Funded" Include:

- New interventions not yet explicitly funded in the PCT's Operational Plan (OP) (or a service intervention or treatment which falls outside existing contracts)
- Low priority treatments – "Lavender" policy statements
- Requests for treatments where specified clinical criteria for funding are not met
- Use of unlicensed and off-label drugs outside standard clinical practice
- Requests to continue funding of low priority treatments for patients who have received them within a clinical trial
- Requests to continue funding of low priority treatments for patients who have received them privately

3.1.1 Potential Service Developments

If a clinician considers that a *cohort of patients* rather than an individual patient should receive a treatment which is not normally funded, they may present a business case to the PCT for a service development. If there are known to be a number of patients who have apparently similar clinical needs, requests for their collective treatment must be submitted to

Oxfordshire PCT for consideration through the established priority setting and annual commissioning (Operational Plan) process (includes business cases submission). The IFR process may not be used as an alternative mechanism for achieving a change in the PCT's commissioning policy.

3.2 Retrospective Funding Requests

The PCT will **not** consider requests for exceptional funding which are retrospective in nature, including:

- Requests from NHS providers for approval of funding made after an episode of care has commenced;
- Requests from patients for reimbursement of the costs of a treatment which has been purchased privately.

3.3 Making an Individual Funding Request

If a clinician (usually the patient's GP or hospital consultant) considers that their patient may benefit from a "treatment not normally funded", they should send a request for funding to the Healthcare Priorities Unit. It is the responsibility of the requesting clinician to set out the case for funding; the patient can also provide supporting information.

*(Whilst a patient or a private healthcare practitioner may initiate a request for funding, the request will **not** receive formal consideration unless/until the request has been endorsed in writing by the patient's GP Practice/NHS Consultant.)*

It is the responsibility of the clinician making a request to ensure that all relevant information is forwarded to the PCT. This will normally include:

- 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 clear statement of the referral/treatment plan proposed for the patient, to include the point at which the patient should return to local treatment pathways (**or** including 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? (Appendix 2);
- e) a statement of evidence of clinical and cost-effectiveness if this is a new treatment not yet funded;
- f) the cost of the treatment (and associated costs) if it is outside the NHS tariff;
- g) the expected healthcare benefits (e.g. impact of likely outcomes on the Activities of Daily Living [ADL]) if the treatment is provided, set against expected outcome if the patient remains within the service/continues with treatment provided within existing PCT contracts.

3.4 The Stages of the IFR procedure

The IFR process comprises potentially four stages: (1) Triage, (2) Treatment Request Panel or Cancer Treatments Panel and (3) the Decision Review Committee. The fourth stage, the PCT Appeals Panel is available to patients

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who have unresolved concerns about the way in which their IFR has been managed. The stages are described below:

3.5 Stage 1 – Healthcare Priorities Unit (HCPU) –Triage: Initial consideration

The HCPU team, which includes a clinician and a manager, screens all requests. A HCPU team member (usually the Healthcare Priorities Practitioner) will make an assessment of the completeness of the information received, seeking clinical advice as necessary. If further information is required, this will be requested from the referring clinician and/or the proposed provider of treatment. All such contacts must be recorded within the correspondence or in a contemporaneous note and filed in the patient's HCPU case file. Actions arising from the screening may include:

- Initial rejection of the request on the basis that no substantive evidence of exceptional clinical circumstances has been provided to date; the requesting clinician would then be advised that they may submit additional information;
- Rejection of the request on the basis that funding is being sought retrospectively;
- Referral back to the requesting clinician for further clinical information;
- Provision of suitable advice if the request falls outside the remit of the IFR process;
- Submission of the request to the TRP/CTP;
- Confirmation of approval of funding if it is clear that the patient meets clinical criteria for treatment and is eligible for funding.

3.5.1 Timescales:

Receipt of a valid request will usually be acknowledged in writing, within 5 working days, unless the request is to be considered by a Panel within the same period, in which case the Panel's decision will be conveyed in writing within 5 working days of the meeting.

Clinicians submitting requests which are outside Oxfordshire's IFR arrangements will also usually be informed within 5 working days of receipt of the request. To minimise any delays in the referral pathway, the HCPU will, at the same time, if appropriate, copy the response to the responsible commissioning authority.

3.6 Stage 2 - Treatment Request Panel (TRP) / Cancer Treatments Panel (CTP)

(See also sections 4 and 5).

The HCPU will write to the clinician and patient informing them in advance, whenever practicable, of the date set for consideration by the TRP/CTP.

The HCPU will produce a summary of the case from the information received. The patient's case will then be presented, in an anonymised form, to the Panel, by a member of the HCPU. The full case file will be available for reference to Panel members. Confidentiality will be maintained. In considering each request

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members of the Panel will take into account any policy/guidance/guideline which is relevant to the requested treatment (sources might include, for example, local Lavender policy or NICE TAGs).

If the Panel conclude, on the basis of all the available evidence, that the clinical circumstances of the patient's case are exceptional, funding will be approved. If the Panel conclude that the clinical circumstances are not exceptional, 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.

If the request has been turned down and new clinical information is subsequently submitted, the patient's case can be re-considered by the Panel.

If the Panel decline funding for a treatment, but the clinician and/or the patient remain of the view that the clinical circumstances of the case are exceptional, they may request a review by the DRC. A request should be made within three months of the letter from the HCPU advising that funding has been declined.

If a request has been considered by the DRC and substantive new clinical information is subsequently provided, the request will be referred back to the Panel.

3.7 Stage 3 - Decision Review Committee (DRC) – Appeals (See also section 6)

HCPU will write to the clinician and patient informing them in advance, whenever practicable, of the date set for consideration by the DRC.

The HCPU will produce an anonymised copy of the papers associated with the case from the information received. The patient's case will then be presented to the Committee, by a member of the HCPU. The full case file will be available for reference by DRC members. Confidentiality will be maintained.

The DRC's role is to consider **appeals** against the decisions of the TRP. Members of DRC who are also members of TRP attend in a non-voting capacity (see Terms of Reference – Section 6). The DRC will take into account any policy/guidance/guideline which is relevant to the requested treatment (sources might include, for example, Lavender policy or NICE TAG). The DRC may also consider, as appropriate, the handling of an IFR by the PCT up to the point of its consideration of the case. If the DRC conclude on the basis of available evidence that the clinical circumstances of the case are exceptional, funding will be approved. If the DRC conclude, that the clinical circumstances of the case are not exceptional (Appendix 2), the DRC will uphold the decision of the TRP and funding will not be approved. The patient and their clinician(s) will be advised of the Committee's decision in writing and the rationale for the decision.

3.8 PCT Appeals Panel (PAP)

If a patient has unresolved concerns about the way in which their IFR has been handled, they can request consideration by the PAP. The PAP will consider whether the original decisions of the TRP and DRC were valid in terms of process and if all relevant information was considered. Patients wanting a review of process must notify the PCT's Chief Executive of their intention, in writing, within three months of the date of the DRC meeting.

3.9 Recourse to NHS Complaints Procedure

If a patient remains dissatisfied with the PCT's decision and response after the PCT Appeals Panel has considered their case, they retain the right to register a formal complaint with the PCT.

3.10 Training/Competencies of Panel/Committee members

It is important to establish a 'core' group of individuals who are regularly involved in IFR decision making and who, together have the skills and expertise necessary to make effective, fair and rational decisions. The key competencies and experience required within a Panel are:

- to understand and interpret the clinical information regarding IFRs, placing them in the context of the relevant populations.
- to understand and critically appraise evidence, including clinical and cost effectiveness data
- to understand and apply the principles contained in the Ethical Framework
- to understand the PCT's commissioning process
- to understand the legal context of the consideration of IFRs.

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 a minimum of 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/Committee members.

Section 4a TREATMENT REQUEST PANEL (TRP)

Terms of Reference

4a.1 Purpose

The TRP has been established as decision making group, responsible to Oxfordshire PCT for consideration of IFRs, i.e. where the requested treatment falls outside the established commissioning categories and therefore is “not normally funded” (See Section 3):

4a.2 Responsibility

The Panel has a delegated responsibility from the Board for decision-making.

4a.3 Membership

Officers of the PCT. Members will determine who is to chair the Panel.

The TRP will include (all voting):

- Consultant in Public Health Medicine - Healthcare Priorities
- Medical Adviser - Healthcare Priorities
- Clinical member of the Clinical Executive – up to two members at any one meeting
- Senior manager from the PCT’s Specialist Commissioning team
- A Senior Commissioning Manager
- NICE Implementation Principal
- A Pharmacist from the Medicines Management team
- A Finance/Contracting Manager

4a.4 Frequency of Meetings: TRP will meet usually every two weeks; or more frequently if needed, as indicated by request caseload. In the case of the need for an urgent decision, an emergency meeting will be held. It can be carried out by telephone, fax or email if necessary, and in such circumstances a decision will be taken on a consensus view; the final decision can be delegated to the chair of the Panel.

4a.5 Quorum Requirement.

A minimum of four members, two of whom must have a clinical background (to include at least one GP member of the Clinical Executive).

4a.5.1 Extraordinary Arrangements. If an IFR is received which requires an urgent decision and, in the opinion of the referring clinician, delaying the decision on the proposed treatment until the next scheduled TRP meeting might cause significant harm to the patient’s health, the HCPU will consider holding an extraordinary meeting of the TRP.

If this is not practicable (e.g. a quorum cannot be obtained) alternative options open to the HCPU are *to consider the request “ex-committee” by means of.*

- A meeting with available TRP members present and telephone conferencing with other available members to achieve a quorate discussion;
- A discussion with a Consultant in Public Health and/or the Medical Adviser together with the Medical Director and/or a clinical member of the Clinical Executive;
- An email discussion with contribution from a quorate number of available members.

Whichever option is chosen, the HCPU must ensure that (1) participating members/co-optees have received a summary of all available information and (2) there has been appropriate opportunity for discussion of the case enabling members to make an informed decision. A record shall be made of the discussion, the decision reached and the rationale for it, which shall be conveyed in writing to the patient and his/her clinicians at the earliest opportunity (see 4.9) and will be reported to the TRP's next scheduled meeting.

4a.6 Administrative Support

This will be provided by the Healthcare Priorities Unit.

4a.7 Key Tasks

- To consider any requests as listed above under "Purpose". The key question may be posed as:
"Why should this treatment be provided for this patient when the treatment in question is not normally funded by the PCT?"
- To consider any other appropriate individual case requests;
- To make its decisions within the Ethical Framework (Appendix 1);
- To ensure consistency in decision making;
- To seek clarification, if this is required, on how a policy or guideline should be interpreted from the body responsible for it (e.g. Priorities Committee , or Oxfordshire Area Prescribing Committee (APCO))
- To 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 to the referring clinician, the appropriate commissioning team, Priorities Committee, APCO and/or the proposed provider NHS Trust(s);
- To share within and across PCTs experience gained in dealing with requests for individual patients.

4a.8 Process

- Patient information will be dealt with in confidence.
- Anonymised patients' case summaries will be sent to the Panel members in advance of the meeting. The full case file will be available for reference, whilst maintaining anonymity.
- The TRP will consider each request in the context of the relevant policy where this exists or as a "treatment not normally funded" where there is no explicit policy.

- The request will be considered on the basis of the submitted written evidence of the patient's clinical circumstances and of the clinical- and cost-effectiveness of the proposed treatment (see Appendix 3).
- Where there appears to be no 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, funding will not be approved.
- Members of TRP who have any personal interest with a particular patient or clinical condition will be excluded from the discussion of that case.
- The Panel will *not* consider requests that represent a service development. If there are known to be a number of patients who have apparently similar clinical needs, all requests for their collective treatment must be submitted to Oxfordshire PCT for consideration through the established priority setting and annual commissioning (Operational Plan) process.

If the clinician or patient considers there are clear grounds for their request to receive further consideration under the IFR arrangements, they have two options open to them:

- a) If the doctor or patient feels that they have further relevant information available which has not been considered by the TRP, they may ask the TRP to reconsider the case specifically in the light of this further information.
- b) If the doctor or patient feels that all the relevant information was available to the TR Panel when the decision was made, but they remain unhappy with the decision, they may appeal to the Decision Review Committee (DRC).

4a.8.1 Openness and Transparency

Panel discussions are based on the consideration of anonymised summaries/paperwork. There is no right of attendance by the requesting clinician, the patient or their representative. It is essential that the process is, nonetheless, both open and transparent - this is achieved in the following ways:

- a) by ensuring that relevant information which has been provided and opinions which have been expressed by treating clinicians, their patients and their representatives are considered by the TRP before a decision is made and
- b) by provision of a written explanation of the decision reached and the reasons for it.

4a.9 Decisions

In reaching a decision on individual funding, the Panel will apply the PCT's relevant policy (policies) and the South Central Ethical Framework (Appendix 1). The Panel will set out their decision and the reasons for it in writing to both the referring clinician and the patient, normally within five 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 PCT's "Information Governance procedure".

Section 4b CANCER TREATMENTS PANEL (CTP)

Terms of Reference

4b.1 Purpose

The Cancer Treatments Panel is established as a pilot, to consider 'exceptional' requests, from NHS clinicians, for funding of 'one-off' drug cancer treatments for **Oxfordshire residents**, where such drugs are not normally commissioned and therefore not funded by the PCT. If required, the Treatment Request Panel can also consider such requests, if there is an urgent need. If the pilot is discontinued, the Treatment Request Panel will resume routine consideration of IFRs for cancer drugs.

Examples of such requests may include:

- the "off-licence" use of drugs
- the use of a drug outside of ORH protocols
- cases which may be considered exceptional to current NICE or PCT policy
- rare cancers, where clinical trial evidence base is lacking and there is no Technology Appraisal Guidance (NICE) or relevant PCT commissioning policy
- tertiary referrals for highly specialist treatment at appropriate treatment centres
- patients moved to Oxon whilst already on a drug "not normally funded" here.

The Panel will *not* consider requests for funding of drugs that support a patient's continuing treatment, but which are not an active treatment for the patient's malignant condition (e.g. Granulocyte Colony-Stimulating Factor following chemotherapy). Costs associated with these drugs must be borne within existing Clinical Oncology service contracts.

The Panel will *not* consider requests that represent a service development. If there are known to be a number of patients who have apparently similar clinical needs, all requests for their collective treatment must be submitted to Oxfordshire PCT for consideration through the established priority setting and annual commissioning (Operational Plan) process.

4b.2 Responsibility

The Panel was established in 2008 as a decision-making group for consideration only of drug treatments (not new devices or other interventions which might be proposed) for *adult malignant disease*. The Panel is accountable to Oxfordshire PCT and advisory to the ORH Medicines Advisory Committee. The Panel will continue to monitor the use, effectiveness, outcomes and costs of any 'one off' drug treatments which may be approved for Oxfordshire patients; and provide a

report for the PCT's Clinical Executive on an annual basis (as part of the IFR Annual Report).

4b.3 Membership

ORH	Cancer Centre manager Chair of Medicines Advisory Committee Haematologist x 2 Oncologist x 5 Pharmacist x 2
PCT	Commissioning manager x 2 Consultant in Public Health Medicine Medical adviser
Chair	Elected by the Panel

4b.4 Frequency of Meetings

The Panel will normally meet monthly.

From time to time, the clinical circumstances of an individual patient's case may mean that delaying a decision to the next scheduled meeting of the Panel is could have a significant detrimental effect on the patient's health and/or wellbeing. In the case of the need for an urgent decision, an emergency meeting/discussion will be held. All relevant information provided by the requesting clinician will be distributed in advance to available members, in an anonymised form, by the Panel Secretary. An emergency meeting may then be carried out by telephone, fax or email if necessary. A decision will be taken on the basis of a consensus view; the final decision can be delegated to the Chair of the Panel. In cases where a request has been considered in advance of a formal meeting, the decision will be reported to and ratified by members of the Panel at the next meeting; this will be recorded in the Minutes. The Treatment Request Panel can also consider such requests, if there is an urgent need.

4b.5 Quorum Requirement

Three ORH clinicians (medical and/or a pharmacist) and one PCT member.

4b.6 Administrative Support

This will be provided by the PCT's Healthcare Priorities Team. Agendas and minutes will be prepared and distributed. Patients' information will be tabled at the meetings; but evidence relating to a new treatment, as provided by the requesting clinician, should be circulated in advance.

4b.7 Principles

- This Panel provides final decision on funding for an individual patient's treatment.

- The Panel will make their decisions in the context of the South Central Ethical Framework (Appendix 1).
- Patient information will be dealt with in confidence.
- Requests will be considered on the basis of patients' "exceptional" clinical circumstances, using the Exceptional Status Drug Request Form and patients' case summaries.
- There is no right of attendance by the requesting clinician, the patient or their representative at the Panel.

4b.8 Process

- All requests for individual funding of treatment will be sent by the referring clinician to the Panel Secretary (PCT Healthcare Priorities Team) by post or using the secure Email address – priorities.oxfordshirepct@nhs.net. Clinical information should be collated using the Exceptional Status Drug Request form.
- On receipt of each request the Secretary will, unless the clinician identifies a need for urgent consideration of their patient's case, add the patient's case to the agenda for discussion at the next scheduled meeting.
- It is the referring clinician's responsibility to provide one copy of any supporting evidence relating to the treatment for which funding is being requested.
- One week before each meeting the Secretary will distribute by Email a copy of the Minutes of the previous meeting, together with an Agenda for the next meeting. In cases where new treatment(s) have been requested, the Abstract of relevant papers will also be distributed to Panel members. The Secretary will make copies of reference articles available for consideration at the next meeting.
- At the meeting - in cases where the Panel conclude that the individual clinical circumstances of the case are exceptional, funding will be approved. If the information which has been made available does not demonstrate that the circumstances are exceptional when compared with other patients who have the same or a substantively similar condition at the same stage of progression, funding will not be approved.
- Members of the Panel who have any personal interest with a particular patient will be excluded from the discussion of that case.
- A simple majority of members present will carry the decision; the Chair will have a casting vote should this be needed.
- If the patient and/or their clinician is dissatisfied with the Panel's decision they have a right either to renew the request for funding by submitting new clinical information for consideration or to lodge an appeal with the Decision Review Committee. If the patient remains dissatisfied following reconsideration or review of their case by DRC they may make use the PCT's complaints procedure. Unresolved concerns about the process followed in the consideration of their request can also be submitted to the Chief Executive for consideration by the PAP.

4b.9 Decisions

The Panel's Chair will personally inform the referring clinician, using telephone or Email, of the decision and the reason for it, normally within two or three working days. The referring clinician will inform the patient. At or about the same time, the Secretary will write to provide the referring clinician with a formal statement of the Panel's decision for the patient's clinical record.

At or about ten days after each meeting the Secretary will write to provide each patient with a formal statement of the Panel's decision. If funding has not been approved, the patient will be provided with information about the PCT's procedures for reconsideration and/or appeal at this stage.

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 the PCT's Information Governance procedures.

Section 5 DECISION REVIEW COMMITTEE (DRC)

Terms of Reference

5.1 Purpose

The Committee's role is to review IFRs which have previously been considered by either the Treatment Request Panel (TRP) or the Cancer Treatments Panel (CTP) in cases where the patient or their clinician has appealed against the Panel's decision. The DRC may uphold or overturn decisions made by the TRP or CTP. It may also defer a decision and recommend that further information is sought. In this event it may refer a case back to the TRP or CTP to consider the additional information.

5.2 Responsibility

The Committee has a Board-delegated responsibility for decision-making.

5.3 Membership

Members will determine who is to chair the Committee.

The DRC will include (all voting):

- Two lay members, including a Non-executive Director
- Up to three General Practitioners at any one meeting
- PCT senior manager (from Commissioning, Contracting or Public Health Directorate)
- Up to two secondary care clinicians

Non-voting members include Consultant in Public Health Medicine and Medical Adviser, from Healthcare Priorities Unit, in an advisory capacity. Additional members (non-voting) may be co-opted as necessary. Clinicians may be invited to provide specialist clinical advice on a specific treatment, but not in relation to one of their patients.

5.4 Frequency of Meetings

The DRC will meet every six to eight weeks; or more frequently if needed, as indicated by request caseload. In the case of the need for an urgent decision, an extraordinary meeting can be held. It can be carried out by telephone, fax or email if necessary, and in such circumstances a decision will be taken on a consensus view; the final decision can be delegated to the chair of the Committee.

5.5. Quorum Requirement

A minimum of three members, including a lay member, one clinician and a PCT senior manager.

5.6 Administrative Support

This will be provided by the Healthcare Priorities Unit.

5.7 Key Tasks

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- To consider, as a group, any requests arising from the TRP or CTP, as listed above under “Purpose”. The key question may be posed as:

“Why should this treatment be provided for this patient, when it would not normally be funded for other patients who have the same, or a substantively similar, condition?”

- To make its decisions within the South Central Ethical Framework (Appendix 1).
- To aim to ensure consistency in decision making.
- To refer any treatments identified as requiring review or policy to the Priorities Committee or Area Prescribing Committee for consideration.
- To share within and across PCTs experience gained in dealing with requests for individual patients.
- To assess whether due process has been followed in the handling of each IFR it considers.

5.8 Process

- Clinicians/patients wishing to request a review of a decision made by the TRP or CTP not to fund the requested treatment must submit their request to the HCPU, in writing, within three months of the date of the letter which advised them of the decision.
- If a request for a review is received after three months have elapsed, it will normally only be considered if there is substantive new clinical information.
- Patient information will be dealt with in confidence.
- Anonymised case papers will be sent to DRC members in advance of the meeting. The full case file will be available for reference, whilst maintaining anonymity.
- The DRC will consider each request in the context of policies formally adopted by the PCT, or as a “treatment not normally funded” in cases where there is no explicit policy.
- The request will be considered on the basis of the submitted written evidence of the patient’s clinical circumstances and the clinical- and cost-effectiveness of the proposed treatment. The DRC will also consider, as appropriate, the handling of an IFR by the PCT up to the point of its (the DRC’s) consideration of the case.
- Where there appears to be no 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, funding will not be approved.
- If a committee member believes they may have a conflict of interest in a particular case, this must be disclosed to the committee before that case is discussed. Conflicts of interest may arise, for example, if the member has recently been involved with the care of the patient. In the event of a potential conflict of interest, the Committee will take a view as to whether the member should be involved in, or debarred from, their consideration of the request.
- A member of the DRC who was a decision-maker when a case was discussed at TRP or CTP can provide advice to DRC members if required, but may not vote.

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- There is no right of attendance by the requesting clinician, the patient or their representative at the DRC. However, all information and views set out by the patient and by their clinicians will be made available to DRC members as an integral part of the consideration of the request.

5.8.1 Openness and Transparency

Whilst DRC discussions are based on the consideration of anonymised paperwork and there is no right of attendance by the requesting clinician, the patient or their representative, it is essential that the process is, nonetheless, both open and transparent. The PCT's process enables this to be achieved in the following ways:

- a) ensuring that relevant information which has been provided and opinions which have been expressed by treating clinicians, their patients and their representatives are considered by the DRC before a decision is made, and
- b) providing written explanation of the decision that has been reached and the reasons for it.

5.9 Decisions

In reaching a decision on individual funding, the DRC will apply the PCT's relevant policy (policies) and the South Central Ethical Framework (Appendix 1). The DRC will set out their decision and the reasons for it in writing to both the referring clinician and the patient, normally within five 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 PCT's "Information Governance procedure".

Section 6 PCT APPEALS PANEL (PAP)

Terms of Reference

6.1 Purpose

The PCT Appeals Panel will be convened to consider **formal appeals** concerning the handling of IFRs and whether due process has been followed.

6.2 Accountability

The Committee is accountable to the Board.

6.3 Membership

PCT Chief Executive or nominated executive director
PCT Chair or nominated non- Executive Director
PCT Executive Committee Chair or another nominated clinical member,
none of whom should have been previously involved in the case.

6.4 Frequency of meetings

The PCT Appeals Panel will be convened as required following receipt of a valid request. The date should be set within four weeks of the request for a process review has been received.

6.5 Quorum

Full membership.

6.6 Administrative support

This will be provided by the Strategy and Quality Directorate.

6.7 Process

- Individuals wishing to challenge the process followed in the handling of their IFR case must notify the PCT Chief Executive of their intention, in writing, within three months of the date of the CRC meeting. All appellants will be given information about the Patient Advice Liaison Service (PALS) and the Independent Complaints Advocacy Service (ICAS) for additional support.
- The PCT Appeals Panel will consider whether due process was followed in the consideration of their request (see below – Key tasks).
- The person requesting the review and/or their clinician cannot attend the Committee meeting in person. All evidence to be considered must be submitted in writing.
- The HCPU will provide the PCT Appeals Panel with the case file. It is important to note that the PCT Appeals Panel will not consider new information in support of a case. If substantive new information becomes available, the HCPU may be asked to arrange for the case to be reconsidered in the light of this.

- Following the PCT Appeals Panel decision, patients may pursue the matter through the NHS Complaints Procedure. Information on this can be obtained from the PCT Complaints Manager.

6.8 Key tasks

The PCT Appeals Panel will consider if:

- **the PCT correctly followed its own procedures**
(all received documentation was available and considered within a reasonable timescale)

and/or

- **all important facts were taken into account when the decision was made.**

6.9 Decision

If the Committee finds that the above **criteria were met**, they will dismiss the appeal.

- If the PCT Appeals Panel finds that some aspect of the **procedure** was not followed, the Committee will assess the significance of the procedural breach and decide on the appropriate action.
- If the PCT Appeals Panel finds that **important facts** were not taken into account, they shall refer the case back to Decision Review Committee for re-consideration.
- If, on the basis of the existing (clinical) information, the PAP **disagrees** with the Decision Review Committee's decision, they cannot overturn the original decision "not to fund". In such a case, they may refer the patient's request back to the Decision Review Committee, with their recommendation and reasoning. However, following the re-consideration of the case, the Decision Review Committee's decision will then be final.

The Chair of the PCT Appeals Panel will normally write to the appellant within five working days setting out the Committee's decision.

Section 7 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 PCT Commissioning Policy.

Patients who wish to complain may contact the PCT's Complaints Manager and register a complaint at any stage. If a complaint is made before a case has been fully considered under the IFR arrangements, depending on the nature of the complaint, they may be advised to consider deferring the complaint until the IFR process has been concluded.

The Complaints Manager will arrange an investigation of the complaint and, following completion of that investigation, for the complainant to receive a written response ratified and signed by a PCT Director. The complaints investigator is not empowered to overturn a decision made under the IFR process, but any recommendations arising from the complaints investigation will be reported to the HCPU for action as appropriate.

SOUTH CENTRAL ETHICAL FRAMEWORK

Berkshire East PCT	Berkshire Priorities Committee (BPC)
Berkshire West PCT	
Buckinghamshire PCT	Buckinghamshire and Milton Keynes Priorities Committee (BMKPC)
Milton Keynes PCT	
Oxfordshire PCT	Oxfordshire Priorities Forum (OxPF)
Hampshire PCT	Hampshire and Isle of Wight Priorities Committee (HIOWPC)
Isle of Wight PCT	
Portsmouth City Teaching PCT	
Southampton City PCT	
South Central Specialised Services Commissioning Group (SCG)	
Central South Coast and Thames Valley Cancer Networks (CN)	

Background

The Priorities Committees are committees of representatives of the NHS organisations across all nine South Central NHS Primary Care Trusts (PCTs) and include lay members as well as clinicians and managers. The purpose of the 'Priorities Committees' is to advise the local NHS health economy as to the Healthcare interventions and policies that should be given high or low priority.

Primary Care Trusts are under a statutory duty to promote the health of the local community. They are also under a duty not to exceed their annual financial allocation. These legal requirements mean that, from time to time, difficult choices have to be made. The Priorities Committees help PCTs choose how to allocate their resources to promote the health of the local community. Individual cases are considered by each respective PCT.

A review of the existing ethical frameworks of the Thames Valley and Hampshire and Isle of Wight has contributed to the development of a South Central wide ethical framework to support decision making across all of South Central both within the established Priorities Committees and also within the SCG/networks or individual PCTs. For the purposes of this document, all the above organisations will be referred to collectively as the 'Committees'.

Purpose of the Ethical Framework

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

- Providing a coherent structure for discussion, ensuring all important aspects of each issue are considered

- Promoting fairness and consistency in decision making from meeting to meeting and with regard to different clinical topics, reducing the potential for inequity
- Providing a means of expressing the reasons behind the decisions made.
- Reducing risk of judicial review by implementation of robust decision-making processes that are based on evidence of clinical and cost effectiveness and an ethical framework
- Supporting and integrating with the development of PCT Commissioning Plans

Formulating policy recommendations regarding Healthcare priorities involves the exercise of judgment and discretion and there will be room for disagreement both within and outwith the Committees. Although there is no objective or infallible measure by which such decisions can be based, the South Central Ethical Framework enables decisions to be made within a consistent setting which respects the needs of individuals and the community. The Committees recognise that their discretion may be affected by National Service Frameworks, National Institute for Health and Clinical Excellence (NICE) technology appraisal guidance and Secretary of State Directions to the NHS.

The Ethical Framework is especially concerned with the following:

1. EVIDENCE OF CLINICAL AND COST EFFECTIVENESS

The Committees will seek to obtain the best available evidence of clinical and cost 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 Committees. Choice of appropriate clinically and patient-defined outcome needs to be given careful consideration, and where possible quality of life measures and cost utility analysis should be considered.

The Committees will promote treatments for which there is good evidence of clinical effectiveness in improving the health status of patients and will not normally recommend treatment that is shown to be ineffective. Issues such as safety and drug licensing will also be carefully considered. 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 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. They will consider technical cost-

benefit calculations (e.g. quality adjusted life years), but these will not by themselves be decisive. The Priorities Committees may use the ethical framework to guide context-specific judgements about the relative priority that should be given to each topic.

2. EQUITY

The Committees believe 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 Committees will not discriminate on grounds of personal characteristics, such as age, gender, sexual orientation, gender identity, race, religion, lifestyle, social position, family or financial status, 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.

3. HEALTH CARE NEED AND CAPACITY TO BENEFIT

Health care should be allocated justly and fairly according to need and capacity to benefit, such that the health of the population is maximised within the resources available. The Committees will consider the health needs of people and populations according to their capacity to benefit from health care interventions. So 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.***

4. COST OF TREATMENT AND OPPORTUNITY COSTS

Because each PCT is duty-bound not to exceed its budget, the cost of treatment must be considered. The cost of treatment is significant because investing in one area of health care inevitably diverts resources from other uses. This is known as opportunity costs and is defined as benefit foregone, or value of opportunities lost, that would accrue by investing the same resources in the best alternative way. The concept derives from the notion of scarcity of resources. A single episode of treatment may be very expensive, or the cost of treating a whole community may be high.

5. NEEDS OF THE COMMUNITY

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Public health is an important concern of the Committees 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 National Service Frameworks). Others are produced locally. The Committees also support 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 PCT that there are exceptional circumstances which mean that the patient should receive the treatment.

6. POLICY DRIVERS

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 PCTs. The Committees operate with these factors in mind and recognise that their discretion may be affected by National Service Frameworks, 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 PCT and these will be described in their Operational Plan.

7. EXCEPTIONAL NEED

There will be no blanket bans on treatment since there may be cases in which a patient has special circumstances which present an exceptional need for treatment. Each case of this sort will be considered on its own merits in light of the clinical evidence. PCTs have procedures in place to consider such exceptional cases on their merits.

Authors:	South Central Priorities Support Unit Steering Group
Discussed at OxFP:	February 2008
Adopted by Oxfordshire PCT Board:	March 2008
Review Date:	1st February 2011

**Oxfordshire Priorities Forum
(NHS Oxfordshire)**

**Policy Statement 80c: Guidance for considering ‘exceptions’ in
Individual Funding Requests (IFRs)**

Clinical Executive decision:

Date of Issue: October 2010

Clinicians may submit requests for treatments which the PCT does not normally fund. Central to the PCT’s consideration of IFRs is the question:

“Why should this treatment be provided for this patient, when it would not be funded for other patients who have the same, or a substantively similar, condition?”

If funding is to be agreed for the proposed treatment, there must be some unusual or unique factor about the patient’s clinical circumstances, which suggests 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.***

In addition to this:

- ***There should be sufficient evidence of the effectiveness of the treatment in question.*** (See table overleaf for levels of evidence normally required for consideration of funding).

IFRs must be supported, where relevant, by a summary statement of evidence for the proposed treatment.

NB It is the requesting clinician’s responsibility to set out the case for an exception to be made.

Please note:

- It is not possible to predict in advance what might provide a basis for exceptional funding, given the individual nature of each patient’s clinical circumstances.

- Meeting the accepted indications for a treatment does not, in itself, provide a basis for an exception.
- The fact that a patient is likely to respond to the requested treatment does not, in itself, provide a basis for an exception.
- Non-medical or social factors will rarely be considered as a basis for an exception.
- Social value judgements will not be considered as a basis for an exception.

Levels of Available Evidence and Consideration of IFRs

Hierarchy of Evidence		Grading of Recommendations	IFR Decision Making Principle
Category	Type of Evidence		
la	Evidence from systematic reviews or meta analysis of randomised controlled trials	Level A	This level of evidence is normally REQUIRED for funding of treatment.
lb	Evidence from at least one controlled trial		
IIa	Evidence from at least one controlled study without randomisation	Level B	Funding MAY be approved, <i>on an individual and exceptional case basis</i> , for treatments where the evidence is at this level.
IIb	Evidence from at least one other type of quasi-experimental study		
III	Evidence from non-experimental studies, such as comparative studies, correlation studies and case control studies	Level C	It is UNLIKELY that funding will be approved for treatments requested on the basis of evidence at or below the level of hierarchy III (grading C).
IV	Evidence from expert committee report or opinion, and/or clinical experience of respected individual authorities	Level D	

Adapted from Eccles M and Mason J (2001) How to develop cost-conscious guidelines, *Health Technology Assessment* 5 (16), 1-78.

This Guidance is an Appendix to Oxfordshire PCT's "Individual Funding Requests (IFR) Process" Policy – www.oxfordshire.nhs.uk/prioritysetting.asp.