

**Policy for funding of treatments outside  
commissioned services:**

**Individual Funding Requests (IFR) Process**

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## **CONTENTS**

- Section 1**      **Context and principles for Commissioning Decisions in Wolverhampton**
- Section 2**      **Commissioning policies and policy statements underpinning Individual Funding Request decisions**
- Section 3**      **An overview of the IFR process**
- Section 4**      **Responsibilities of referrer and provider organisation making individual funding requests**
- Section 5**      **Stage 1: Screening Individual Funding Requests**
- Section 6**      **Stage 2: Individual Funding Request Panel**
- Section 7**      **Stage 3: Appeals Panel**

## **APPENDICES**

- Appendix 1**    **Commissioning Principles**
- Appendix 2**    **Commissioning Policy for In Year Developments June 2008**
- Appendix 3**    **Guidance on Exceptionality for determining individual funding requests.**
- Appendix 4**    **PCT specific commissioning policies**
- Appendix 5**    **Individual Funding Request proforma**

## Version Control

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3.1	
4	Near final draft Circulated to key stakeholders for comment
5	Additions <ul style="list-style-type: none"><li>• In-year developments policy</li><li>• IFR request proforma</li></ul>
6	Redrafting and incorporating comments
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8.2	All changes accepted Comments from PEC added
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## **Section 1**

### **Context and principles for Commissioning Decisions in Wolverhampton**

The purpose of this policy and procedures is to ensure that the PCT has a clear and rational framework within which to make decisions regarding the funding of treatments outside normally commissioned services: individual funding requests.

#### **1.1 Financial Context**

The PCT receives a fixed **budget** from central government with which to commission all the health care required by their populations. The PCT has insufficient resources to fund all types of health care that might be potentially available or requested for their population. It is inevitable that the PCT has to make **choices** about which healthcare interventions to commission. The PCT needs to have in place a process for assessing new treatments and a process on how to deal with requests for treatments which are not commissioned; this needs to be underpinned by explicit policies.

#### **1.2 Factors to be taken into account when making commissioning decisions**

The PCT's takes into account and seeks to balance following factors when making commissioning decisions:

- Evidence of clinical and cost effectiveness
- Equity
- Healthcare need and capacity to benefit
- Cost of treatment and opportunity costs
- Needs of the wider community
- NHS National Policy

These are described in more detail in Appendix 1.

#### **1.3 Process of agreeing Annual Operational Plan**

The mechanism through which investment and disinvestment decisions on treatments are taken is via the Annual Operational Plan process. To support the Operational Plan (OP) process, the PCT will use a range of advisory groups including Professional Executive Committee and Networked e.g. Greater Midlands Cancer Network and Area Prescribing Committee to advise them 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 them will be affordable from available budgets. The OP process will be the final determiner of those technologies prioritised for investment in the coming year

#### **1.4 In-year Developments**

The PCT will not normally expect to commit new resources to the introduction of new treatments for its population during financial year, since to do so risks ad hoc decision making and can destabilise previously identified priorities (Appendix 2).

## **1.5 Individual Funding Requests**

If, on the basis of policy, a treatment is not normally funded, the PCT will consider requests for treatment to be funded for a patient on the basis of exceptionality (see definition appendix 3). The PCT's Individual Funding Request process is the means by which an assessment is made as to whether the case for an exception has been established. This policy sets out the principles, policies and processes agreed and followed by Wolverhampton City PCT in making decisions on Individual Funding Requests.

The PCT does not expect to introduce new treatments through the process of individual funding requests. To do so risks 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 other areas of healthcare which have been identified as priorities by the PCT.

It is not the role of Individual funding Request panel (IFRP) to make commissioning policy on behalf of the PCT. Consideration of individual requests will always start from the overall policy position (whether or not the intervention has been prioritised through the OP) and will seek to determine exceptionality on that basis. The Panel cannot make a decision to fund a patient where by so doing a precedent would be set that establishes new policy (because the patient's circumstances are not, in fact, exceptional, but representative of a group of patients).

In cases where the Panel considers evidence has been provided in support of a particular health technology, they should make a recommendation for further consideration in the annual Commissioning round/ Operational Plan (OP) Process, but individual funding of the specific case would normally be refused.

## **Section 2**

### **Commissioning policies which inform the decision-making in individual funding requests**

The term “treatment” used throughout this document includes all health technologies and interventions, including drugs, surgical procedures, diagnostic tests, other investigative procedures, rehabilitation, immunisations and screening.

When considering individual funding requests, the PCT will apply the following policies where the service/ intervention requested is outside commissioned services e.g. outside existing Service level agreements (SLAs).

#### **2.1 Specific Commissioning Policies**

Treatments not currently included in established pathways or identified for funding through Services Level Agreements and the OP process are “not normally funded”. For a small number of these treatments the PCT has published specific commissioning policies 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. The current specific commissioning policies are listed at Appendix 4 and will be updated and published on the PCT website.

#### **2.2 Commissioning statement on NICE guidance**

Technology appraisals

Technologies that are approved as a result of a NICE Technology Appraisal Guidance (TAGs) need to be funded within three months of the final TAG being published. The PCT will not usually fund treatment of treatments undergoing appraisal by NICE or on draft TAG guidance, as clinical and cost-effectiveness for the NHS has not been determined.

Interventional Procedures Guidance

Interventional Procedures Guidance (IPGs) take into account safety and efficacy but not 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. Clinicians wishing to request an intervention on the basis of an IPG should submit evidence that the procedure has been assessed and approved through the organisation’s clinical governance and business planning procedures.

#### **2.3 Commissioning on behalf of patients with rare conditions.**

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 may be considered under the IFR policy. Patients with rare conditions should neither be advantaged nor disadvantaged simply because their condition is uncommon.

#### **2.4 Commissioning statement on 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 2004<sup>1</sup> and the Declaration of Helsinki<sup>2</sup>, 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 OP, the responsibility remains with the trial initiators indefinitely

#### **2.5 Commissioning Statement on requests to continue funding treatment commenced privately**

Patients have a right to revert to NHS treatment at any point during their care. However, the PCT will expect the treatment of such patients to follow agreed local pathways. NHS Funding for an individual to continue care in a private facility will not be routinely authorised. Where individual clinical circumstances may make such funding appropriate, the case will require consideration under the IFR policy the PCT will not reimburse costs for private treatment undertaken without prior PCT's approval.

#### **2.6 Commissioning statement on requests for referral to a specific, 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 through the individual funding request processes described in this policy.

#### **2.7 Commissioning statement on decisions inherited from other Primary Care Trusts**

Occasionally, patients move into the area when a package of care or a treatment option has already been approved by their previous PCT. Wolverhampton City PCT may honour such decisions, providing the care pathway has been initiated (for example an appropriate referral has already been made and approved).

#### **2.8 Responding to new and emerging technologies, policies or guidance**

When the need arises, the PCT may receive and adopt additional specific commission policies, interim funding policies or commissioning statements in response to new and emerging technologies, policies or guidance.

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<sup>1</sup> <http://www.legislation.hmsso.gov.uk/si/si2004/20041031.htm>

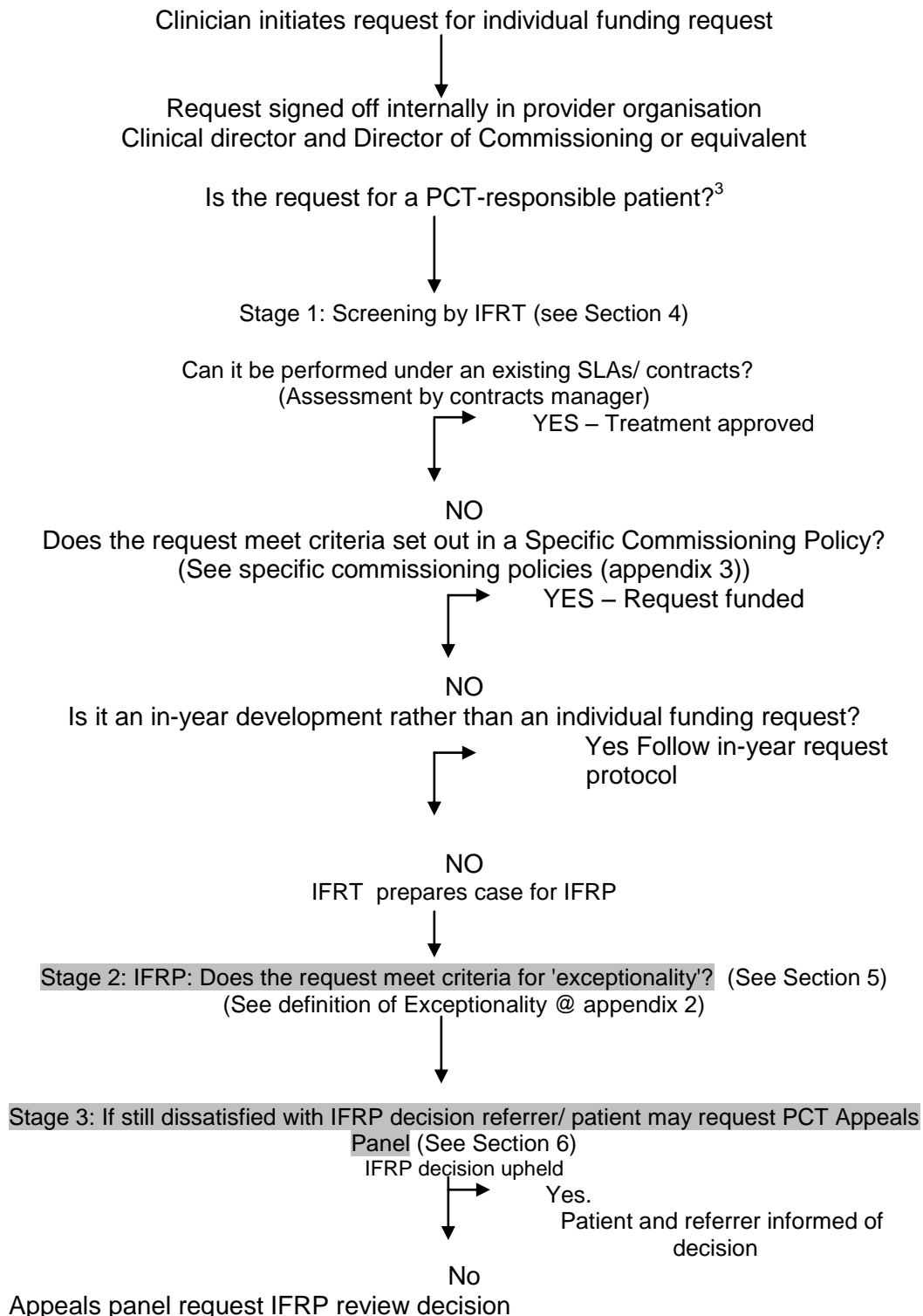
<sup>2</sup> <http://www.wma.net/e/policy/b3.htm>

### Section 3

## OUTLINE OF INDIVIDUAL FUNDING REQUEST (IFR) STAGES

There are up to three stages in the PCT's individual funding request process. Each of these stages is described in more detail in the following sections of this policy.

**Figure 1: Decision-tree for Individual Funding requests**



<sup>3</sup> Establishing the Responsible Commissioner

[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_078466](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_078466)

## Section 4

### Responsibilities of referrer and provider organisation making individual funding requests

Individual patient requests may be initiated by the General Practitioner or an NHS Consultant.

All requests for treatments “not normally funded” need to be submitted in writing, to the Individual Funding Request Team [individualefundingrequests@wolvespct.nhs.uk](mailto:individualefundingrequests@wolvespct.nhs.uk) at Wolverhampton City PCT, using only necessary patient identifiers to comply with Caldicott principles, on the approved proforma. (see Appendix 5)

It is the responsibility of the individual seeking funding in conjunction with the referring clinician to ensure that all relevant information is forwarded to the PCT. This should include:

1. An outline of the patient’s problem and the circumstances of the case, including any previous treatment;
2. A clear statement of the referral/treatment plan proposed
3. Consideration of whether the patient’s needs could be met within existing pathways
4. if the care could be provided within existing pathways, a statement of why an alternative referral, which would not be offered to others with a similar clinical need, is a priority in this case;
5. If the care is not routinely funded by the PCT, evidence to show that the patient is significantly different to the population of patients with similar clinical needs who would also not be offered the treatment. It is the responsibility of the requesting clinician to set out the case for exceptional clinical circumstances (see definition appendix 3). The referring clinician may invite the patient to provide additional supporting information.

All individual funding request proforma must be authorised by the relevant Clinical Director and by the Director of Commissioning or equivalent of the provider organisation prior to submission to the PCT.

All requests should be emailed to the Individual Funding Request Team, [individualefundingrequests@wolvespct.nhs.uk](mailto:individualefundingrequests@wolvespct.nhs.uk) or faxed on 01902 575197.

All requests received without a proforma and any incomplete proforma will be returned to the referring clinician without further consideration.

## **Section 5**

### **Stage 1: Screening individual funding requests**

#### **5.1 Purpose**

To screening individual funding requests in line with the policies and process described in this policy

#### **5.2 Membership of Individual Funding Request Team (IFRT)**

At Stage 1 screening of individual funding requests will be undertaken by the Individual Funding Request Team (IFRT). The team will include:

Individual Funding Request Manager  
Consultant in Public Health  
Pharmaceutical Adviser  
PCT Contracts Manager  
IFR Budget manager

#### **5.3 Frequency of meetings**

Individual funding request team will meet weekly to consider and respond to individual funding requests

#### **5.4 Factor to take into account in considering requests**

To assess whether the patient for whom funding is requested is a Wolverhampton PCT responsible patient

To assess whether all the information required to assess the request has been submitted by the referrer and signed off appropriately by provider organisation.

To evaluate whether request can be funded or is excluded from funding by any existing PCT contracts, service level agreements or commissioning policies.

To assess evidence of clinical and cost-effectiveness submitted by the referrer and where necessary undertake or request further evaluation of the evidence, using criteria in use by NICE at the time of the request for determining the threshold for cost-effectiveness.

To ensure that requests are indeed individual funding requests and not in-year service developments

To assess whether sufficient information to determine exceptionality has been provided

Where the treatment is not normally funded and there is sufficient information provided to determine exceptionality the IFRT undertake the preparation for consideration of requests by Individual Funding Request Panel.

To ensure consistency with previous decisions in the same or similar circumstances made under this policy

To ensure compliance with patient confidentiality and Caldicott principles.

## **5.5 Decision-making**

At this stage there are four different decisions possible for an individual case:

1. Agree to fund the request
2. Defer decision pending further information/investigation
3. Decline fund the request
4. Identify the request as a service development, but funding of the individual request declined. (See appendix 2)

## **5.6 Administration and Timescales**

The IFRT will acknowledge receipt of request to referring clinician within 5 working days of receipt of request

The stage 1 process will be completed no longer than THREE weeks from receipt of request

The decision of the IFRT and date of IFRP if appropriate will be notified within 5 working days of the IFRT meeting.

To notify the referring clinician, the patient and their representative of the date of the IFRT, and to invite the patient to provide additional information and/or to attend in person. All patients will be given information about the Patient Advice Liaison Service (PALS) for additional support.

## Section 6

### Stage 2: Individual funding Request Panel (IFRP) Terms of reference

#### 6.1 Purpose

Wolverhampton City PCT Individual Funding Request Panel has been established as advisory group to Wolverhampton City PCT:

- To determine exceptionality in individual funding requests, where the treatment falls outside commissioned senses categories and therefore is “not normally funded”. The key question is:

*“On what grounds should this treatment be provided for this patient when the treatment in question is not normally funded by the PCT?”*

*(Definition of exceptionality in appendix 2)*

- To ensure decisions made are consistent with PCT’s Commissioning Principles (Appendix 1)
- To ensure decisions are made within the scope and remit of this policy, considering all relevant information and not considering any irrelevant factors

#### 6.2 Accountability

The Individual Funding Request panel is accountable to the PCT Board via the Individual funding Request Appeal Panel. The Panel has a delegated responsibility from the Board for decision-making. (Tim Sadler to review)

#### 6.3 Membership

The members of an IFRP will be:

- A Practising Clinician nominated by the PEC
- A Practising Clinician nominated by the PBC Steering Group
- Senior manager from Commissioning Directorate
- Lay member

The IFRP should be chaired by a practising clinician. Members of IFRP who have any personal interest with a particular patient or clinical condition will be excluded from the discussion of that case. All panel members should have had an appropriate induction into the Individual Funding Request policy and the role of the Individual Funding Request Panel in that process.

Advisers to the members of the IFRP may include:

- Consultant in Public Health
- Pharmaceutical Adviser
- IFR Manager

#### 6.4 Quoracy

A representative from each group included in the membership is required for the IFRP to be quorate.

## **6.5 Frequency of meetings**

IFRP will meet every two weeks or more frequently if needed, as indicated by volume of requests. In the case of the need for an urgent decision, an emergency meeting may 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.

## **6.6 Factors to take into account in considering requests**

The IFRP 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 IFRP will consider the evidence submitted by the referring clinician on the patient’s clinical circumstances and the clinical- and cost-effectiveness of the proposed treatment and evidence of exceptionality (see Appendix 3)

The panel will invite the patient for whom funding is being requested or their representative to present any additional information in support of the case for exceptionality

The panel will consider any additional evaluation of the evidence of clinical effectiveness, or cost effectiveness or other governance issues undertaken by the Individual Funding Request Team.

If new relevant information, which has not been considered by the IFRP, is subsequently submitted, the patient’s case can be re-considered by the IFRP.

## **6.7 Decisions**

Where there is clear evidence of exceptionality in the case being considered and the decision is consistent with PCT policies, the IFRP will agree funding.

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.

The Director of Commissioning will inform the patient and their clinician(s) of the Panel’s decision in writing, setting out the reasons for the Panel’s decision, within five working days.

There are two options available where a patient or the referring clinician wishes to challenge the decision of the IFRP:

1. where the referring clinician or patient considers that there is further relevant information which has not been considered by the IFRP they may ask the IFRP to reconsider the case specifically in the light of this further information.
2. where there is no additional information to consider the patient may request an appeal under Stage 3 of this policy.

## **6.8 Administration**

The IFRP will be supported and administered by IFR manager and administrator. 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 7**

### **Stage 3: Individual Funding Request Appeals Panel (IFRAP)**

#### **Terms of reference**

##### **7.1 Purpose**

The Individual funding Request Appeals Panel will be convened to consider appeals against IFRP decisions.

The purpose of the panel is to consider whether, in considering the individual funding request

The PCT correctly applied its own policies and procedures including complying with agreed timescales  
that all important facts were taken into account in reaching the decision made.  
that no irrelevant facts were taken into account in reaching the decision made

##### **7.2 Accountability**

The Panel is accountable to the Board.

##### **7.3 Membership**

The members of the individual Funding Request Appeals Panel will be:

PCT Chief Executive or nominated director  
PCT Chair or nominated non- Executive Director  
PCT Executive Committee Chair or another nominated clinical member,  
A lay member

none of whom should have been previously involved in the case.

The panel should be chaired by the PCT Chair nominated representative. All panel members should have had an appropriate induction into the Individual Funding Request policy and the role of the Appeal Panel in that process.

Advisor to the panel may include:

Director/ Public Health  
Director of Commissioning

##### **7.4 Quoracy**

A representative from each group included in the membership is required for the IFRP to be quorate.

## **7.5 Frequency of meetings**

The Appeals Panel will be convened when necessary to consider appeals against IFRP decisions. The date should be set within four weeks of the request for an Appeal having been received.

## **7.6 Process**

Individuals wishing to appeal against a IFRP decision must notify the PCT Chief Executive of their intention, in writing, within three months of the date of the IFRP 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 Appeals Panel will consider whether the original decision of the Individual Funding Request Panel (IFRP) followed due process (see factors to be taken into account below).

The individual requesting the appeal and/or their clinician cannot attend the Appeals Panel meeting in person. All evidence to be considered must be submitted in writing.

The IFR Team will provide the Appeals Panel with the a summary of the request and all appropriate documentation, anonymised to comply with patient confidentiality. It is important to note that the Appeals Panel will not consider new information in support of a case. If new information becomes available, the IFRP will be asked to reconsider the case in the light of this.

## **7.7 Factors to be taken into account by the Appeals Panel**

The Appeals Panel will consider if the PCT correctly followed its own procedures i.e.

- that all received documentation was available and considered within a agreed timescales
- that all important facts were taken into account in reaching the decision made.
- that no irrelevant facts were taken into account in reaching the decision made

## **7.8 Decision**

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

If the Panel finds that some aspect of the policy or procedure was not followed, the Panel will assess the significance of the breach and decide on the appropriate action.

If, on the basis of the information provided the Appeals Panel finds that important facts were not taken into account or that irrelevant facts were taken into account or that the criteria for determining exceptionality were incorrectly applied the Panel may uphold the appeal. In such a case, the Appeals Panel must make explicit to the patient and to the Individual Funding Request Panel the reasons for their decision, having given due consideration to the PCT policy framework and the criteria for determining exceptionality.

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

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

### **7.9 Administration**

The administration for the Individual Funding Request Appeal panel will be provided by the Individual Funding Request Team

## **APPENDIX 1**

### **Factors informing commissioning decisions in Wolverhampton City PCT**

#### **Background**

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.

#### **Purpose of the Commissioning Principles**

The purpose of the commissioning principles is to support and underpin the decision making processes of the PCT and PBC commissioners and 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 health care priorities involves the exercise of judgment and discretion and there will be room for disagreement both within and outside the Committees of the PCT. Although there is no objective or infallible measure by which such decisions can be based, the commissioning principles enable decisions to be made within a consistent setting which respects the needs of individuals and the community. All PCT commissioners recognise that their discretion is 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 Commissioning Principles are concerned especially with the following:

#### **1. EVIDENCE OF CLINICAL AND COST EFFECTIVENESS**

The PCT 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 PCT. 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 PCT 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 PCT 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.

## **2. EQUITY**

The PCT 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 PCT 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 PCT 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**

Public health is an important concern of the PCT and it seeks 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 PCT 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, a particular treatment 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. NHS NATIONAL POLICY**

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. EXCEPTIONALITY**

There will be no blanket bans on treatment. Exceptionality has to be considered on a case by case basis. IN Wolverhampton, this responsibility is delegated to the individual funding request panel, described in appendix 2 of this policy.

### Acknowledgement

This appendix is adapted from the Ethical Framework produced by South Central Priorities Support Unit Steering Group February 2008 and Adopted by Oxfordshire PCT Board: March 2008

## **APPENDIX 2**

### **Commissioning Policy for In Year Developments June 2008**

#### **Introduction**

Wolverhampton City PCT receives a fixed budget from central government with which to commission all the health care required by the population. The PCT has insufficient resources to fund all types of health care that might be potentially available or requested for their population. It is inevitable that the PCT has to make choices about which healthcare interventions to commission. The PCT needs to have in place a process for assessing new treatments and a process on how to deal with requests for treatments which are not commissioned; this needs to be underpinned by explicit policies.

This policy covers the Primary Care Trusts decision making process for the commissioning of interventions/treatments that fall outside of current commissioning contracts, and those treatments that are deemed to be new treatments/developments which must be considered for funding through the Local Delivery Plan.

#### **Principles**

When considering individual patients' requests, the PCT will apply the following principles:

The mechanism through which investment decisions on treatments are taken will be considered through the PCT's commissioning and planning systems to include the annual Operating Plan process. The PCT will not expect to commit new resources in the financial year to the introduction of new treatments since to do so risks ad hoc decision making and this can destabilize previously identified priorities.

To support the Operating Plan process, the PCT will use its advisory groups to advise them on the clinical and cost-effectiveness of new healthcare technologies, and also on prioritisation of treatments. These groups will do this through an ongoing programme of work throughout the year. Where developments are proposed by local acute Trusts, initial requests should be received by the monthly Clinical Quality Review Meetings. The provider is expected to take a full business case to this forum outlining the proposed treatment, projected demand for such treatment, associated costs and planned outcome. If the proposal gets the full support of the clinical quality review then it will be assessed by PCT through its advisory groups. If as a result of these assessments the development is considered clinically and cost effective it will then proceed to the annual Operating Plan process for prioritisation. It may be that not all interventions supported by them will be affordable from available budgets. The Operating Plan process will be the final determiner of those technologies prioritised for investment in the coming year.

The PCT reserves the right to refuse to fund any new development that has not been through this process. The PCT does not expect the Individual Funding Request Funding process to be a mechanism to implement or introduce new treatments. To do so risks inequity and would prevent the PCT ensuring that treatments and services are offered in a consistent manner. If on the basis of policy a treatment is not normally funded, the PCT will consider requests for treatment to be provided for a patient on an exceptional basis. The PCT's Individual Funding Request process is the means by which an assessment is made as to whether the case for an exception has been established.

In order for a patient's case to be deemed exceptional, the case will be considered within the Policy for Managing Individual Funding Requests. To consider cases for exceptionality funding, an Individual Funding Request Team (Stage one: IFRT) and an Individual Funding Request Panel (Stage two:IFRP) have been established.

It is not the role of the Individual Funding Request Panels to make commissioning policy on behalf of the PCT. Considerations at stage 1 and Stage 2 will always start from the overall policy position and will seek to determine exceptionality on that basis. The IFRT and IFRP cannot make a decision to fund a patient where by so doing, a precedent would be set that establishes new policy (because the patient's circumstances are not, in fact, exceptional, but representative of a group of patients).

In cases where the IFRT or IFRP considers evidence has been provided in support of a particular health technology, they should make a recommendation for further consideration in the annual Operating Plan process, but individual funding of the specific case would normally be refused.

## APPENDIX 3

### Guidance on Exceptionality for determining individual funding requests

Treatments which are not commissioned by Wolverhampton City PCT are not normally funded. Nevertheless, the PCT will always consider requests from clinicians for such a treatment to be provided for an individual patient. Central to our consideration of individual requests for funding, is the question:

***“Why should this treatment be provided for this patient when the treatment in question is not normally funded?”***

To answer this question, the clinical circumstances of the patient must be assessed to determine if there is a basis for approving treatment when other patients, who have the same (or a substantively similar) condition, would not be funded.

If funding is to be agreed, 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  
the patient is likely to gain significantly more benefit from the proposed treatment than might be expected from the average patient with the condition.

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

#### Please note:

Due to the individual circumstances of each patient, it is not possible to identify “exceptional” clinical circumstances in advance.

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.

#### Acknowledgement

This appendix is derived from definitions developed by South Central Priorities Committee, Oxfordshire PCT and approved May 2008

## **APPENDIX 4**

### **List of specific commissioning policies (to be updated or developed)**

Commissioning policy on assisted conception

Commissioning policy on aesthetic procedures

Commissioning policy on DXA scanning

Reversal of sterilisation policy

West Midlands Regional Commissioning Policies adopted by the PCT

## APPENDIX 5

# Wolverhampton City

## Primary Care Trust

### Individual patient request pro-forma funding

On completion, please email to: [individualfundingrequests@wolvespct.nhs.uk](mailto:individualfundingrequests@wolvespct.nhs.uk) or fax: 01902 575 197

#### Patient and Contact Information

<b>1. Provider Details</b>	
Provider Code:	
Provider Name:	
Requesting Clinician's Name:	
Requesting Clinician's Title:	
Speciality:	
Tel:	
Email:	
<b>2. Patient Details</b>	
Patients Initials:	
NHS number:	
Sex:	
Patients DOB:	
Patients Postcode:	
<b>3. GP Details</b>	
GP name:	
GP practice code:	
GP practice address:	
<b>4. Trust Approval of application</b>	
Referring Consultant Signature:	
Referring Clinical Director Signature:	
Referring Director of Commissioning Signature:	

**INTERVENTION REQUESTED** (nb: Intervention refers to requested treatment, investigation, etc)

**5. Patient Diagnosis (for which intervention is requested)** *including date of diagnosis stage of disease, prognosis.*

**6 Summary of previous intervention(s) this patient has received for the same condition.**  
**\*Reasons for stopping may include:**

- Course completed
- No or poor response
- Disease progression
- Adverse effects/poorly tolerated

Date/s	Intervention (e.g. drug/surgery)	Reason for stopping*/ Response achieved

**7. Details of intervention (for which funding is requested)**

Name of intervention:	
If a drug, dose and frequency:	
Planned duration of intervention:	
Route of administration:	
Anticipated cost (inc VAT) – <i>seek advice from pharmacy</i>	

**8. What standard treatment does this intervention replace?**

**9. What are the anticipated benefits in this case of the particular treatment requested over other available options or why standard treatments are not appropriate?**

**10. In the case of drug therapy requests only, is the drug licensed in the UK for the intended use?**

<p><b>11. What is the evidence base for this procedure/treatment?</b></p>
<p><b>12. Has it been subject to NICE appraisal or other scrutiny? Including Network D&amp;T committee, SMC etc. include any documentation to support this evidence.</b></p>
<p><b>13. Is this procedure/treatment part of a national or international trial or audit?</b></p>
<p><b>14. Is this a single procedure / treatment or what is the length of time of the proposed course of treatment?</b></p>
<p><b>15. How will the benefits of the procedure/treatment be measured? What are the intended outcomes? (If this treatment is approved the PCT would require feedback on the outcome in order to inform future funding decisions) <i>what would you consider to be a suitable outcome of this intervention in this patient?</i></b></p>
<p><b>16. What is the anticipated cost of this procedure/ treatment and how much is this over and above the cost of the standard therapy it replaces?</b></p>
<p><b>17. Are there any exceptional circumstances to consider in this case:</b>  <i>Where care is not routinely funded by the PCT, evidence must be included to show that the patient is significantly different to the population of patients with similar clinical needs who would also not be offered the treatment. This should include evidence that the patient is likely to gain significantly more benefit from the treatment than would be expected for other patients not currently offered it.</i></p>
<p><b>18. In the case of therapeutic interventions – how frequently does your unit perform this procedure/therapeutic intervention or treatment (per year) and what is your success rate?</b></p>
<p><b>19. In a population of 1,000 how many other people are likely to have the same clinical needs requiring this proposed intervention?</b></p>

**20. If this treatment request is not approved what treatment will be given to the patient?**

**Date Requested:**

**Referrer Name:**

**Signature:**

**Title:**