

## Regional Policy for individual funding requests

### 1 Purpose

- 1.1 This document describes how the Primary Care Trust (PCT) deals with requests for an individual to receive a health care intervention that is not routinely funded by the PCT.
- 1.2 For the purpose of this policy, and in common with the Secretary of State's *Directions to Primary Care Trusts and NHS trusts concerning decisions about drugs and other treatments 2009*, the term 'health care intervention' includes use of a medicine or medical device, diagnostic technique, surgical procedure and other therapeutic intervention.

### 2 Scope

- 2.1 This policy applies to all employees of the PCT, any staff who are seconded to the PCT, contract and agency staff and any other individual working on PCT premises.
- 2.2 The policy aims to provide a framework for individual funding decisions that is common to all PCTs in the region, but it should be read in conjunction with other relevant procedures and policies for this PCT including the NHS Sheffield Local Decision Making Policy for Individual Funding Requests.

### 3 Accountability and responsibilities

- 3.1 The lead Director with overall responsibility for this policy is the Director of Strategy
- 3.2 Responsibility for individual funding decisions on behalf of the PCT is delegated to those involved in the processes associated with this policy.
- 3.3 All PCT staff are bound by the terms of this policy.
- 3.4 This document has been developed in collaboration with NHS Yorkshire and the Humber and the Yorkshire and the Humber Specialised Commissioning Group as an executive committee of the 14 PCTs in the region.

### 4 Summary

The overall process for dealing with individual funding requests has three key stages:

- Triage
- Individual Funding Request (IFR) Panel
- Appeals Panel

All of these stages are of significant importance and require appropriate resourcing in terms of manpower and skills. An easy reference summary of the key features of the process is attached at appendix A.

## **5 Background**

5.1 This policy has been developed in response to the legal duties set out in the Secretary of State's Directions to PCTs and Trusts, the NHS Constitution, and a range of guidance as set out below:

5.1.1 The NHS Constitution (January 2009); two rights relate specifically to the availability of medicines and other treatments:

- *You have the right to drugs and treatments that have been recommended by NICE for use in the NHS, if your doctor says they are clinically appropriate for you.*
- *You have the right to expect local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you, they will explain that decision to you.*

5.1.2 Directions to primary care trusts and NHS trusts concerning decisions about drugs and other treatment 2009 (Secretary of State, 12 March 2009), which set out primary care responsibilities on funding and commissioning health care interventions, and the duty to give reasons for decisions.

5.1.3 The World Class Commissioning Framework.

5.1.4 Guiding principles for processes supporting local decision-making about medicines and a Handbook of good practice guidance (Department of Health/National Prescribing Centre, February 2009).

5.1.5 Guidance on NHS patients who wish to pay for additional private care (Department of Health, March 2009).

## **6 Development of general policies for interventions**

6.1 The PCT has a statutory responsibility to commission care, including medicines and other treatments, for its population within available resources.

6.2 Each year, the PCT plans investment in health care interventions and services as part of its operating plan development process to meet the needs of its local population. Decisions on funding are usually made in collaboration with provider Trusts and other stakeholders, and are taken in the context of the PCT's available resources to ensure that care is fairly allocated to all patients and, where appropriate, measured against the PCT's other service development priorities, NICE guidance and national priorities.

6.3 When planning its investments, the PCT works with provider partners to identify, as far as possible, those new interventions that are likely to have a significant clinical

impact and require funding in the coming years. This is often referred to as horizon scanning.

- 6.4 Most health care interventions are commissioned as part of service level agreements with provider partners. However, it is likely that, during the year, there will be requests for interventions not covered by the PCT's commissioning policies. The PCT, therefore, needs to be able to make decisions about these requests that are fair and consistent.
- 6.5 The PCT will use a standard individual funding request submission form to receive such requests and will triage all such requests to identify whether a funding request submitted on behalf of an individual would apply to a population of patients. Where that is the case, the request will trigger the development of a new policy for that intervention and indication (called a general policy) or modification of an existing general policy. These requests will not be generally considered by the Individual Funding Request Panel.
- 6.6 Arrangements for the development and revision of general policies by the PCT for health care interventions are available from the PCT.
- 6.7 The PCT will make its general policies available on request or on the NHS Sheffield web address: [www.sheffield.nhs.uk/services/ifr.php](http://www.sheffield.nhs.uk/services/ifr.php)

## **7 Individual funding requests**

- 7.1 An individual funding request (IFR) is appropriate where either the following applies:
  - 7.1.1 the PCT has a general policy not to fund a health care intervention for the specified indication but a doctor considers his/her patient to be 'exceptional' to that policy, or
  - 7.1.2 the PCT has no policy in place for the requested health care intervention and indication and the clinical circumstance is so rare that it is unlikely that any other patients will require the intervention.
- 7.2 In responding to an IFR, the PCT accepts no clinical responsibility for the health care intervention or its use, or for the consequences of not using the intervention.
- 7.3 Decisions about which health care interventions are to be requested are the responsibility of the treating doctor and the provider organisation. In instances where there is disagreement between clinicians or between the patient and their doctor as to which intervention is to be requested or the manner in which it is to be administered, the PCT will take no part in these discussions other than to provide current commissioning policies. It is the duty of the referring provider organisation to obtain appropriate arbitration in instances of disagreement between clinicians or between patients and clinicians.

### **What is 'exceptional'?**

- 7.4 Exceptionality should be considered in the context of the PCT general policy for a health care intervention and specified indication.

- 7.5 In general, the PCT must justify the grounds upon which it chooses to fund a health care intervention for a patient when that intervention is unavailable to others with the condition.
- 7.6 A patient may be considered exceptional to the general policy if both the following apply:
- 7.6.1 He/she is different to the general population of patients who would normally be refused the health care intervention AND
- 7.6.2 There are good grounds to believe the patient is likely to gain significantly more benefit from the intervention than might be expected for the average patient with that particular condition.
- 7.7 In assessing exceptionality, the PCT will not consider social, demographic or employment circumstances.
- 7.8 Where a patient has already been established on a health care intervention, for example as part of a clinical trial or following payment for additional private care, this will be considered to neither advantage nor disadvantage the patient. However, response to an intervention will not be considered to be an exceptional factor.

## **8 Triage of requests for individual funding**

- 8.1 Individual funding requests will be accepted from doctors and, in certain circumstances, other registered health practitioners.
- 8.2 The treating doctor should complete the standard IFR form and submit it to the PCT within the normal provider governance arrangements. This requires responses to a common set of questions that will assist the PCT in determining if the patient is exceptional to the general policy.
- 8.3 The completed form should be sent to the PCT and copied to the patient's GP, if requested. The PCT has an officer that can help with the process if this is required.
- 8.4 The PCT will triage the request to see if the requested health care intervention is funded as part of a general policy. If this is the case, the treating doctor will be advised of the general policy and no further action will be taken.
- 8.5 If the health care intervention is not funded as part of a general policy and the treating doctor has identified appropriate reasons why the patient may be considered to be exceptional to the policy, the triage process will pass the request on to the IFR process for consideration subject to appropriate timescales determined by the urgency of the request. However, if no claim of 'exceptionality' is made, the treating doctor will be advised of the general policy and no further action will be taken.
- 8.6 The triage process will identify the need for any further information so that delays later in the decision-making process can be minimised. If more information is

required, an officer from the PCT will contact the patient or treating doctor directly to request it.

## **9 Consideration of urgent requests**

- 9.1 The need to make urgent funding decisions should be minimised by horizon scanning and the proactive development of general policies in collaboration with provider partners. However, occasionally, clinical circumstances may require urgent use of a health care intervention that requires an individual funding decision.
- 9.2 While the PCT will endeavour to respond to such urgent requests as quickly as possible, this should not compromise the quality and validity of the decision-making process.
- 9.3 At all times, the provider partner is able to fund a health care intervention pending a decision from the PCT and the PCT accepts no responsibility for the clinical consequences of any delay in responding to the request.

## **10 The Individual Funding Request Panel**

- 10.1 The PCT has a panel, called the Individual Funding Request (IFR) Panel, whose members have specific training in the assessment of individual funding requests.
- 10.2 The terms of reference of the panel are available within the NHS Sheffield Local decision Making Policy for Individual Funding Requests, available on request and on the NHS Sheffield web address at [www.sheffield.nhs.uk/services/ifr.php](http://www.sheffield.nhs.uk/services/ifr.php)
- 10.3 Members of the IFR panel can include: director of commissioning, commissioning managers, consultants in public health, senior pharmacist, GP, medical director, PCT board member, and lay representative.
- 10.4 The IFR Panel will receive the request from the treating doctor together with advice from the PCTs clinical advisors and any other relevant information.
- 10.5 The patient and the treating doctor may submit additional information to the IFR Panel that they consider to be relevant and appropriate.
- 10.6 Where possible, the PCT will ensure separation between those who review the clinical evidence for a request and those who make the funding decision.
- 10.7 The treating doctor and the patient will receive copies of the clinical information submitted to the IFR panel but may not attend meetings of the Panel unless specifically invited.
- 10.8 The PCT will keep the treating doctor and the patient informed at all times of the timescales for the process.
- 10.9 The treating doctor will receive a response to his request within the agreed timescale. In most cases, and providing all of the requested information was submitted, this will be with a decision on funding. However, if further information or

clarification is needed, the PCT will advise the treating doctor and the patient of the revised timescale for the decision.

10.10 The decisions made by the IFR Panel are documented.

10.11 The Panel's decision may be to fund the individual request or not to fund the request. If a decision cannot be made, the reasons will be made clear to the treating doctor and patient.

10.12 If the PCT decides to refuse a request to fund a health care intervention for an individual, where the PCT's general policy is not to fund that treatment, a senior officer of the PCT will provide the patient with a written statement of the reasons for the decision.

10.13 The Chair of the Panel, or designated officer, will inform the treating doctor of the decision and, if requested, a copy of this information will be sent to the patient's GP.

### **Principles for decision making**

10.14 In making its decision, the Panel will, as a minimum, consider the following:

- Patient safety
- Clinical and cost-effectiveness and strength of evidence
- Place in therapy relative to available health care interventions
- Affordability
- National guidance and priorities
- Local priorities

The best available evidence will be used to inform decisions.

## **11 Appealing against a decision not to fund**

11.1 Where a decision has been made by an IFR Panel not to fund a health care intervention and the treating doctor feels that all relevant clinical information has been provided and considered, the patient or their doctor may appeal against the IFR Panel decision. Information on how to do this will be provided by the PCT.

11.2 Appeals are referred to the IFR Appeals Panel.

11.3 The terms of reference of the Appeals Panel are available within the NHS Sheffield Local decision Making Policy for Individual Funding Requests, available on request and on the NHS Sheffield web address at [www.sheffield.nhs.uk/services/ifr.php](http://www.sheffield.nhs.uk/services/ifr.php)

11.4 Membership of this Panel is different to the IFR Panel and will usually include a non-executive member of the PCT Board who may chair the meeting. The Appeals Panel is able to access expert evidence as required, including from independent clinicians.

11.5 An appeal against an IFR decision should be made within 3 months of the treating doctor receiving the IFR decision.

11.6 The IFR Appeals Panel provides a procedural review of the IFR Panel decision. The IFR Appeals Panel has access to the all relevant documentation about the request but does not, in general, consider new evidence.

11.6.1 Such review will include:

- Was due process followed? Did the PCT follow its own policies and procedures?
- Did the IFR panel take in to account all of the relevant information available at the time?
- Was the decision reasonable and in line with the evidence

11.7 The patient and the treating doctor will be notified of the date of the appeal hearing and be invited to submit supporting statements to the Appeals Panel.

11.8 Typically, the entire case will be received by the Appeals Panel on paper without either side being present. However, if, in exceptional circumstances, the Appeals Panel believes that it would benefit the Panel to have one side present at the hearing, the other side will also be invited to attend.

11.9 The patient and the treating doctor will be sent the set of papers submitted to the Appeals Panel by the PCT.

11.10 The IFR Appeals Panel may decide to uphold the original decision, to reverse it (that is, agree to fund the health care intervention), or to ask the IFR Panel to reconsider its decision.

11.11 The Chair of the IFR Appeals Panel, or a designated officer, will inform the patient, the treating doctor, the PCT and, if requested, the patient's GP, of the decision of the Appeals Panel.

11.12 If the IFR Appeals Panel upholds the original decision not to fund an intervention, the patient may choose to complain about the decision within the NHS complaints procedure.

## **12 Treatment outside the European Economic Area (EEA)**

12.1 Requests for health care interventions outside the EEA will be considered in line with the Department of Health Patient Information Circular (14 March 2007), which states that

*“Patients do not have a right to have treatment outside the European Economic Area (EEA) paid for by their local PCT. Individuals requesting treatment outside the EEA should be aware that PCTs are advised to consider the following criteria before approving treatment outside the EEA”*

- The condition is of a serious nature.
- Suitable treatment is not available within the UK or the EEA.
- The treatment abroad is well established, not merely experimental.
- There is a probability of significant benefit to the patient.

Clinicians will need to demonstrate how their patient meets these criteria as part of the individual funding request.

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## INDIVIDUAL FUNDING REQUESTS – THREE KEY STAGES

The overall process for dealing with individual funding requests has three key stages; all of which are of significant importance and require appropriate resourcing. These three key stages are summarised below:-

<p><b>Triage</b></p>	<ul style="list-style-type: none"> <li>• Receives and acknowledges individual funding requests from providers</li> <li>• Assesses requests against existing policies and for completeness</li> <li>• Requests for interventions where there is a policy to not fund are returned to the provider unless explicit evidence of exceptionality is provided</li> <li>• New treatments requiring policy development are referred for consideration as part of the PCT planning process</li> <li>• Further information is requested from the provider, if necessary, for requests to be referred to the IFR panel</li> <li>• Provider and patient are informed of timescales for PCT decision</li> </ul>
<p><b>Individual funding request (IFR) panel</b></p>	<ul style="list-style-type: none"> <li>• Receives individual funding requests from Triage</li> <li>• Receives appraisal of the requested intervention from PCT clinical advisors</li> <li>• Funding decision made and communicated to the provider and the patient</li> </ul>
<p><b>Appeals panel</b></p>	<ul style="list-style-type: none"> <li>• Receives case for appeal on paper</li> <li>• Provides procedural review</li> <li>• Decision of the Panel communicated to the PCT, the patient, and the provider</li> </ul>