Request Form for the Exceptional Cases Panel

The Exceptional Cases Panel considers whether funding should be granted for individual patients who are being considered for a treatment (procedure or drug) that:

- does not fall within existing contracts; and/or
- is a low priority procedure [http://www.cambsphn.nhs.uk/default.asp?id=142]; and/or
- is a threshold treatment but the patient does not meet the threshold and there are extenuating circumstances where treatment should be considered [http://www.cambsphn.nhs.uk/default.asp?id=144]; and/or
- is not funded for routine prescribing, e.g., drugs outside secondary care contracts which practices may be asked to prescribe or support for their patients. Drugs on the primary care Red List should normally be discussed with your local area Pharmacist Team Manager, who will refer primary care expensive drug requests to the panel if necessary.

Background

Referrals to the Panel can only be made on an individual, named patient basis and should be made by an appropriate referring clinician PRIOR to referral for treatment. For treatments that are urgently required, where significant harm may occur through delay, it must be provided to the patient and retrospective approval for funding should be sought if the cost of the drug is not already in the contract/tariff. Requests for secondary care drugs or therapeutics must have approval by the relevant secondary care committee prior to this referral. Decisions made by the Panel will relate to the individual patient only and are not an indication of NHS Cambridgeshire’s policy for the provision of this treatment for other patients. Neither are positive decisions an absolute approval for the treatment to go ahead. A decision to treat is a clinical decision and responsibility for this rests with the clinician to whom the patient is referred in consultation with the patients themselves.

It is worth remembering that marginally better clinical effectiveness by using new treatments is frequently associated with disproportionately higher costs, thus representing poor value for money. There are many competing demands on NHS Cambridgeshire’s limited financial resources. Thus, disproportionately expensive treatments can threaten the viability of other routine healthcare services that may have greater patient and population benefit.

Action Required

Please fill in all the sections of this form. The review process by the Panel will be expedited by the availability of as much information as you provide in response to each question. If you do not have information, please complete the box to say ‘not applicable’ or ‘not known’. It is also important to include any relevant background information and clinical correspondence to familiarise the Panel on the case. It is essential to complete the sections on the criteria for exceptionality and quantification of the benefits of the proposed treatment. Costs quoted for exceptional treatments should make clear the extra cost for the treatment, including the cost of HRGs associated with delivery of the treatment, compared with the other available treatments for the individual patient.

Please send the completed form to:
Exceptional Cases Administrator
NHS Cambridgeshire
Lockton House
Clarendon Road
Cambridge
CB2 8FH

Tel: 01223 725423
Fax: 01223 725592
Email c-pct.exceptionalcaserequests@nhs.net

We would encourage you to complete the forms electronically (the space given for answers can expand to fit any amount of information) and then send by post, fax or email. Forms submitted via email should have the requesting clinician’s electronic signature (if possible).
## Clinician Requesting Funding:

**Contact details:**

**Tel No and Bleep:**

**Email:**

**Address:**

**Name of Trust providing treatment:**

**Speciality:**

**What is the Funding request for:**

**Submission Date:**

**How urgent is this request? Most urgent / Immediate / Routine**

- Most Urgent – Decision needed within a week as the patient's life may be in danger
- Immediate – Decision needed within 3 weeks as delay will not be clinically appropriate.
- Routine – Decision needed in 4 to 6 weeks

**Signature of requesting clinician and date:**

**Date funding request received by the NHS Cambridgeshire:**

(For NHS Cambridgeshire use only – the clock starts from this date)

The PCT response of how this request will be processed will be sent within 3 working days.

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## Name of Patient:

**Date of birth:**

**NHS number:**

**Address:**

**Registered GP:**

**GP Address and Tel No:**
1. **Patient Diagnosis:**
   Please attach details of relevant clinical correspondence and background information.

2. Please list other co-existing conditions.
   To what extent is each of these likely to improve or impair the patient’s response to the intervention for which funding has been requested?

3. **Treatment / management so far:**
   Include summary of previous intervention(s) for condition to be treated.

4. **Description of proposed treatment:**

5. **What is the clinical indication of this treatment in this particular patient?**

6. **Are there any local Clinical Priority Forum policies and how do these affect this treatment?**

7. **What are the specific goals and expected outcomes of this treatment for this patient?**
   Please quantify the added benefits of using this treatment compared to the alternative options, eg QOL, life expectancy, impact on or facilitating subsequent treatment, etc.

8. **What other treatment options are available for this condition?** Please provide details and state reasons why they are not being considered in this case.

9. **What are the implications of not providing this intervention for the patient or carer, eg potential future illness or disability or costs?**
   | **For Patient:** | **For Carer:** |

10. **Is the reason for this request due to the psychiatric manifestation of a physical condition?**
    - **If yes:** Psychiatric diagnosis and evidence that the psychiatric problem is clearly related to the physical problem.

    Details of the psychiatric and/or psychological interventions that have been tried without success in the past.

11. **Why is this a case for exceptional funding?**
    Please state the exceptional circumstances in this case, eg what evidence is there that this treatment will be more effective for this patient than others with a similar condition?
    Please refer to the guidance for exceptionality on the last page.

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**Trust providers need to complete all the questions.**

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**GPs may feel that the following questions are not applicable for their requests (eg requests for minor procedures below £250). Please state ‘not applicable’ here if this is the case.**
12. Are there any regional/national guidelines on the proposed intervention that should be taken account of? For example, NICE or SIGN. If yes please provide brief summary and/or reference of the relevant paragraphs.

13. What is the evidence to support the use of the proposed intervention? What harms are associated with this treatment? Give information about NNT, NNH. For example a systematic review, major RCT or other research evidence. Please attach copies of literature or relevant paragraphs.

14. Is there any information on the cost effectiveness of this intervention? If yes, please provide details.

15. Please state the estimated duration and total costs (cost of drug / procedure and services). The Panel is required to consider the anticipated health gain and justify the extra cost for this treatment.

16. Please state any cost savings to be gained from this procedure such as likely downstream procedures / admissions avoided. When would you expect these savings to be realised against current treatment costs?

17. Please set out by whom treatment effectiveness will be reviewed, what are the criteria to measure effectiveness, when to measure these and criteria to stop treatment.

18. If this is a drug, when did the NHS Cambridgeshire's Drug and Therapeutic Committee or equivalent approve this request and for what indication(s) have they approved it?

19. If this is a drug that is secondary care initiated and then prescribing might be continued in primary care, have appropriate shared care protocols been agreed? If yes, please provide details.

20. Is the requested intervention part of a clinical trial with LREC approval? If yes please attach trial protocol. What does the trial protocol say about continuation of treatment after the trial ends?

21. Location of proposed intervention, (eg which hospital, treatment centre). Are there appropriate clinical governance systems in place?

22. Has private funding been previously
23. Please state the number of cases submitted for exceptional funding of this intervention by the Trust in the last 12 months and how this patient differs from others with the same condition.

24. How many other similar patients you may see over the next 12 months. Note: if there are other similar patients it may be more appropriate to submit a business case or seek ‘group prior approval’. Your hospital commissioning department can advise you on this.

25. Please declare any potential conflict of interest. See guidance on last page. Support in research projects should also be declared.

26. Is the patient aware of this referral and the contents of this form and supporting documents?

Signature of requesting clinician ........

Oxford Definition of Exceptionality

Definition of ‘exception’: A particular case which falls within the application of a rule, but to which the rule is not applicable.

Definition of ‘exceptional’: of the nature of or forming an exception; unusual or special.

General guidelines: Exceptionality by definition is difficult to define in advance.

- Potentially exceptional circumstances may be considered by the patient’s PCT where there is evidence of significant health status impairment and inability to perform activities of daily living. It is clear that a very significant health gain or a significant improvement in the quality of life compared to others with a similar condition is required to be defined as exceptional.
- Consideration will be given to the evidence that shows that the benefit from the treatment for the patient would be significantly greater than would be expected for an average patient.
- Consideration will be given to the evidence that shows the patient or their clinical condition to be significantly different when compared with a similar group of patients who are suffering from the same condition.
- It is an essential part of the Oxford definition that, in considering whether a patient’s case is exceptional or not, the group against which the patient must be considered is the group of patients who are suffering from that particular condition and not the general population.
- The fact that a patient’s clinical picture matches ‘accepted indications’ for a treatment that is not normally provided is not, in itself, exceptional.
- The fact that the treatment is (or is likely to be) efficacious for a particular patient is not, in itself, exceptional.
• Thus, the fact that someone has an “exceptional medical condition” does not, of itself, justify exceptional treatment.
• It is for the requesting clinician (and sometimes the patient) to demonstrate why they should be considered as an exception.

Information considered by the Exceptional Cases Panel for each case

The answers and information given in the request form forms the basis of the general discussion. The Panel looks specifically for the criteria exceptionality and the discussion also covers the principles of medical ethics.

Criteria for exceptionality:

• The benefit from the treatment for the patient in terms of health gain would be significantly greater than would be expected for an average patient with a similar condition.
• The benefit from the treatment for the patient in terms of improvement in the quality of life would be significantly greater than would be expected for an average patient with a similar condition.
• The patient is shown to be significantly different when compared with a similar group of patients who are suffering from the same condition.
• The patient’s clinical condition is shown to be significantly different when compared with a similar group of patients who are suffering from the same condition.

Principles of medical ethics:

• Autonomy - respect for the individual and their ability to make decisions with regard to their own health and future. Actions that enhance autonomy are thought of as desirable and actions that ‘dwarf’ an individual and their autonomy are undesirable.
• Beneficence - actions intended to benefit the patient or others
• Non-maleficence - actions intended not to harm or bring harm to the patient and others
• Justice - being fair or just to the wider community in terms of the consequences of an action

Case discussion at the Panel:

The answers in the request form should form the basis of the general discussion and the Panel should make sure that the following questions are answered and minuted.

1. What is the funding request for?
2. What is the clinical condition and current treatment?
3. What are the other treatment options and are there any relevant local or national policies for treatment of this condition?
4. What are the expected outcomes of this treatment for this patient? Is there any relevant published evidence?
5. What are the implications of not providing this treatment – clinical as well as social?
6. What are the costs associated and is this treatment clinically as well as cost effective?
7. How does this fit with the principles of medical ethics?
8. Why is this a case for exceptional funding?

Potential conflict of interest
A competing interest exists when professional judgement concerning a primary interest (such as patient’s welfare or the validity of research) may be influenced by a secondary interest (such as financial gain or personal rivalry). It may arise when they have a financial or other interest that may influence – probably without their knowing – their interpretation of their decisions or those of others. (BMJ)

**Appeals process**

An appeal process exists to allow the patient, if they wish, to have their case re-considered and allows NHS Cambridgeshire to examine its own processes to check that they are legally, ethically and clinically robust. If the clinician or patient does not agree with the Panel’s decision, the first step should be to phone or email at the address given on page 1, to get more details about the appeals process. If you wish to proceed further, you need to apply in writing setting out the reasons for the appeal (there are no forms to be filled to appeal).

The Exceptional Requests Policy is available on: [http://www.cambsphn.nhs.uk/default.asp?id=117](http://www.cambsphn.nhs.uk/default.asp?id=117)