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<th><strong>Document title:</strong></th>
<th>Individual Funding Request Operating Policy</th>
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<td><strong>CCG document ref:</strong></td>
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<tr>
<td><strong>Author / originator:</strong></td>
<td>Su Green</td>
</tr>
<tr>
<td><strong>Date of approval:</strong></td>
<td>February 2013</td>
</tr>
<tr>
<td><strong>Approving committee:</strong></td>
<td>Clinical Assurance Panel</td>
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<tr>
<td><strong>Responsible director:</strong></td>
<td>Linda Izquierdo</td>
</tr>
<tr>
<td><strong>Category:</strong></td>
<td>Commissioning</td>
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<td><strong>Sub category:</strong></td>
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<tr>
<td><strong>Date policy is due for review:</strong></td>
<td>January 2016</td>
</tr>
<tr>
<td><strong>Target audience:</strong></td>
<td>CCG staff and Shropshire GP practices</td>
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**Individual Funding Request Operating Policy**
VERSION CONTROL

Document Location

This document is only valid on the day it was printed.

The current version of this document will be found at www.shropshireccg.nhs.uk/policies

Revision History

Date of this revision: February 2013

Date of next revision: January 2016

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Approvals

This document requires the following approvals:

<table>
<thead>
<tr>
<th>Name / Committee</th>
<th>Title (if individual)</th>
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Distribution

This document has been distributed to:

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<td>Oct 2013</td>
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INDIVIDUAL FUNDING REQUEST OPERATIONAL POLICY
For
Shropshire Clinical Commissioning Group

January 2013
# Individual Funding Request Operating Policy

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**Shropshire Clinical Commissioning Group (CCG)**

**Policy for Managing Individual Funding Requests**

**Introduction**

The vast majority of health care commissioned for residents of Shropshire County CCG is covered by NHS Service Level Agreements or other Contracts. However, there are a small number of requests for treatment by individual patients each year not covered by a Service Level Agreement or other contract. These requests are considered under this policy.

This policy seeks to ensure and demonstrate that the CCG has robust processes by which these decisions are taken.

Where there are individual cases where a patient’s needs cannot be met through the existing commissioned services, the CCG is required to put in place arrangements for the consideration of such individual requests. The NHS Constitution sets out the following public commitment:

“You have the right to expect local decisions on funding of 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.”

**Legal context**

- A CCG is under a statutory duty to provide services to such an extent as it considers necessary to meet all reasonable requirements for: medical, dental and nursing services.

- Such facilities for the prevention of illness, the care of patients suffering from illness and the after care of those who have suffered from illness as it considers appropriate as part of the Health Service.

- Other services required for the diagnosis and treatment of illness.

The CCG needs to be satisfied that the decision follows the process described in this policy. Each request must be considered on its own merits in accordance with this policy.

The courts have established that a CCG is not under an absolute obligation to provide every treatment that a patient demands. A CCG can develop a policy which prioritises treatment to take account of the resources available to it and the competing demands on those resources.

Patients with rare or unusual medical conditions have as much right to care as anyone else and have the right to have their requests considered properly, on their own merits and against the CCG’s policy in each individual case.

‘The NHS exists to serve the needs of all of its patients but also has a statutory duty financially to breakeven’ (National Health Service Act 2006).
Commissioning principles

CCGs are required to provide health care for their responsible population and in doing so have to take account of the resources available. CCGs’ commissioning principles therefore:

- Reflect equitable access to services based on need.
- Are based on evidence of effectiveness of interventions.
- Operate on the principle that in matters of life or death, every life is to be treated as being of equal value and will not seek to make a distinction between patients on social grounds in allocating potentially life saving treatments.
- Aims to reduce inequalities in health in the population.

Commissioning decisions for individual funding request.

The process of decision taking must be:

- Concise - often requests for funding are related to care which is required relatively urgently, within a few days
- Transparent and explicable
- Defensible – based on sound evidence

The following policy allows an objective and defensible decision to be made.

Budget

A budget is set up each year for managing individual requests.

Request Stages

There will be three distinct stages for individual patient requests:

1. Stage One is the CCG’s Initial Screening Stage
2. Stage Two is the CCG’s Individual Funding Requests Panel (IFRP)
3. Stage Three is the Individual Funding Requests Review Panel (IFRRP)

Requests may be from the patient, the patient’s parent, guardian, carer, General Practitioner or a Member of Parliament, but before consideration is given a clinical referral must be received.

There is a pro-forma for completion by the referring clinician to obtain the relevant information which shall be known as appendix one.

If this is not included with the request the Designated IFR Lead will seek clinical support for the request from one or more of the appropriate qualified clinicians (e.g. GP, Consultant) who are involved in the case. The clinical team will be required to set out a comprehensive and balanced clinical picture of the
history and present state of the patient’s medical condition, the nature of the treatment requested and the anticipated benefits of the treatment.

The clinical team should refer to and include copies of any clinical research material which supports, questions or undermines the case that is being made that the treatment is likely to be clinically effective in the case of the individual patient.

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 CCG.

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 CCG, 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. 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.
Initial Screening – Stage One

The purpose of the initial consideration stage is to ensure that only appropriate IFR requests are referred to the IFR panel for consideration of funding.

- All requests for funding should be referred in the first instance to the Designated IFR Lead.
- The Designated IFR Lead (DIFRL) will determine whether the CCG has responsibility for delivering care to the individual patient.
- The DIFRL will be able to advise whether the referral would be covered by the CCG’s existing portfolio of SLAs or current Individual Case Commissioning Policies. Where the CCG already has a specific commissioning policy, e.g. Aesthetic Surgery, In Vitro Fertilisation (IVF), the DIFRL will review the request against the CCG policy and if the patient meets the criteria set out within the policy, may authorise funding at the discretion of the Director of Strategy and Service Redesign/Director of Quality, Nursing, Patient Safety and Experience.
- The DIFRL is unable to authorise referrals outside existing pathways and is not able to take an individual’s personal circumstances into account.
- The DIFRL should determine whether additional information is required and if required request that information is provided.
- In addition, the DIFRL may request an internal CCG evaluation of the evidence of effectiveness and cost effectiveness to supplement that provided by the referring clinician. This evaluation and recommendations are to be provided to the IFRP.
- Where a request falls outside SLAs and/or other commissioning policies, the DIFRL will consider the request jointly with the appropriate panel members.

In order for the panel to be quorate at least two of the following members should attend and this should include the Designated IFR Lead:

- Director of Public Health/nominated deputy
- Head of Medicines Management/nominated deputy
- A board member of the Clinical Commissioning Group
- Director of Strategy and Service Redesign
- Director of Quality, Nursing, Patient Safety and Experience

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

1. Agree to fund/support the request
2. Refuse to support/fund the request
3. Defer decision pending further information/investigation
4. Identify a service development which will be referred on to the appropriate CCG Commissioning/LDP group. (Service development requests should not be referred on to the second stage of the process.)

5. Refer to the IFR Stage Two panel

**Service development**

A request for a treatment should be classified as a request for a service development if there are likely to be a cohort of “similar patients”:

- who are in the same or similar clinical circumstances as the requesting patient;
- whose clinical condition means that they could make a like request (regardless as to whether such a request has been made); and
- who could reasonably be expected to benefit from the requested treatment to the same or a similar degree.

Where a request is not supported the DIFRL will inform the requester within 10 working days. The submission of further information from the requester regarding exceptional circumstances which are clearly defined may be re-considered.

Further information and detailed exceptional circumstances should be submitted within three months of the date of the panel meeting.

**Frequency of meetings**

Meetings shall be held fortnightly or as required, in order to ensure that there is a timely response to all funding requests but with a minimum of 12 meetings (as required) per annum.

In order to comply with this, requests that are submitted to Medicines Management/Public Health for preparation should be returned to the DIFRL within a seven day period. This timescale is to ensure that requests are dealt with in a timely manner so that patients are not kept waiting for treatment, and do not result in systems failure.

**Requirement for Urgent Decisions**

It is recognised that on occasions emergency and urgent decisions will be required. Only in exceptionally urgent situations will the panel operate virtually, e.g. using mail/telephone, to reach speedy decisions if it is necessary. It is important that no member of the group makes decisions on their own. The decision will be recorded by the DIFRL following discussion with panel members.

The CCG reserves the right to raise a serious incident investigation when an inappropriate delay in the request for funding has resulted in an urgent decision having to be made. If this proves to be the case, a delay in requesting funding in the future in order to circumvent the process, may result in the CCG refusing funding, and the Trust from which referral originates will be expected to fund treatment until the process can be followed effectively.
Individual Funding Request Panel (IFRP) – Stage Two

The Individual Funding Request Panel has delegated authority from the CCG Board to make decisions in respect of funding for individual cases.

In instances where the matter is to proceed to the IFRP, the DIFRL will write to the patient/referring clinician informing them of this and may request further information if the required and relevant information has not been fully covered.

The DIFRL may also write to other health professionals with clinical involvement in the patient's care for clarification of the patient's needs, if appropriate.

The DIFRL will write to the patient/referring clinician informing them of the date set for consideration by the Panel and offering the patient or his guardian, carer or clinician involved in the case the opportunity to attend. The patient/representative/clinician will be asked to notify the CCG within 48 hours of the hearing whether they plan to attend.

The DIFRL will produce a summary of the request to assist the Panel. The DIFRL will attend panel meetings to deal with questions on process and any other queries as appropriate that may arise but will not be a voting member of the panel.

Composition of Panel

Quorum
In order for the panel to be quorate at least three of the following members should attend, this must include a Director, and a Clinical Commissioning Board member.

- A member of the Clinical Commissioning Board
- A Non-Executive
- Director of Public Health/ or designated Deputy
- Patient Representative Organisation
- Director of Quality, Nursing, Patient Safety and Experience
- Director of Planning and Service Redesign
- CCG Chief Operating Officer
- Director of Governance and Involvement
- Director of Finance

The Panel may be chaired by a CCG GP, a Director or a Non Executive.

At its discretion the panel may permit others to attend where it is deemed it would be necessary or helpful for those to be invited to provide additional information, e.g. Medicines Management for relevant requests.

The panel should be made aware beforehand if it is necessary for observers to attend the meeting.
**Frequency of meetings**

Meetings shall be held monthly or as required in order to ensure that there is a timely response to all funding requests but with a minimum of 12 meetings per annum (if necessary). Agendas and all accompanying papers will be sent to members no less than three working days prior to the meeting of the panel.

In order to comply with this requests that are submitted to Medicines Management for preparation should be returned to the DIFRL within seven days.

**Reporting**

The Panel meeting will be formally minuted. The minutes shall be comprehensively and formally recorded and retained in a confidential file. A record of all decisions will be made using a standard format and will be held on the patient’s file. Records must be retained for six years. Copies of minutes will not be distributed to panel members for their retention and will not be placed in the public domain in order to preserve patient confidentiality.

**Decision for approval or non approval**

If the request for funding is approved, the originator of the request will be informed in writing of the panel’s decision within seven working days of a decision being made.

If the funding request is not approved, the patient and the originator of the request will be informed of the decision and the reasons for the decision within seven working days of the meeting.

The Panel will set out their decision and the reasons for it both to the patient and the referring clinician.

If the patient considers that all the relevant information was available to the Panel when the decision was made, they may ask for the case to be reviewed by the CCG’s Review Panel. The Review Panel is constituted to review the process followed, not the decision made by the IFRP.

Should the patient remain unhappy with the Review Panel’s decision, it is open to him/her to pursue the matter through the NHS Complaints Procedure. Information on how to do this is available from the CCG’s Complaints Manager.
Stage Three- Individual Funding Request Review Panel (the Review Panel)

Review Panel Procedure:

Membership:
- Accountable Officer
- 2 Executive Directors (who have not been involved in the case previously)

This Panel will be chaired by the Accountable Officer and will be supported by the Designated IFR Lead.

1. The Review Panel will be convened when necessary to consider appeals against Individual Funding Requests Panel decisions. The remit of such appeals is set out below.

2. Individuals wishing to appeal against an Individual Funding Request Panel decision must notify the Designated IFR Lead of their intention, in writing, within three months of the date of the Panel meeting.

3. The Designated IFR Lead will supply the following information for the review panel at least one week prior to the meeting taking place:
   - Background to the request
   - Personal details of the patient
   - Information in relation to the condition
   - Notes of the meeting of the Stage Two Individual Funding Request Panel
   - The decision and the rationale of the decision conveyed to the patient
   - The letter of appeal
   - All other relevant information

4. The Review Panel will consider whether the original decision of the Individual Funding Request Panel was valid in terms of process, factors considered and criteria applied. In deciding an appeal, the Review Panel will consider whether:
   a) the decision was consistent with the Individual Funding Request Policy;
   b) the decision was consistent with previous similar decisions;
   c) in reaching the decision the Panel had:
      i) taken into account and weighed all relevant evidence;
      ii) given proper consideration to the claims of the patient (or group of patients) under discussion and accorded proper weight to their claims against those of other groups competing for scarce resources;
      iii) taken into account only material factors;
      iv) acted in utmost good faith;
v) taken a decision that is in every sense reasonable.

5 It is important to note that the Review Panel will not consider new information in support of a case. If new information becomes available, the Individual Funding Request Panel should be asked to reconsider the case in light of this.

6 The Review Panel Chair will write to the appellant and referring clinician within two working days with the Panel decision.

7 The Review Panel will not be able to refer a decision back to the Individual Funding Request Panel for further consideration. If the Review Panel finds that there was a failing in the process, they will also have the responsibility of making the definitive decision on whether the CCG should approve the treatment being requested. A failure in the process of handling an individual case request does not necessarily mean that the decision that was made was incorrect.

8 Patients who remain unhappy with the Review Panel decision may pursue the matter through the NHS Complaints Procedure. Information on this can be obtained from the CCG Complaints Manager.

**Reporting**

The minutes of Panel meetings shall be comprehensively and formally recorded and retained in a confidential file. A record of all decisions will be made using a standard format and will be held on the patient’s file. Records must be retained for six years. Copies of minutes will not be distributed to panel members for their retention and will not be placed in the public domain in order to preserve patient confidentiality.

**Definitions**

_Treatment_ means any form of healthcare intervention which has been proposed by a clinician and is proposed to be administered as part of NHS commissioned and funded healthcare.

_An individual funding request_ is a request received from a provider, or a patient with explicit support from a clinician, which seeks funding for a single identified patient for a specific treatment.

_Clinical circumstances_ means a full history of the patient’s medical condition, a full description of the patient’s present medical condition and as comprehensive an assessment of the patient’s future medical condition and prognosis as the Clinical Team treating the patient is able to provide.

The _IFR Panel_ is the committee of the Clinical Commissioning Group that has been authorised by the CCG Board to take decisions on its behalf on _individual funding requests_.

_Case by case decision making_, in the context of priority setting, occurs when a decision maker decides to allocate NHS resources for a specified treatment for one or more specified patients as a substitute for policy making. This is generally regarded as poor practice because it avoids making an explicit policy.

_Exceptional clinical circumstances_ refers to a patient who has clinical circumstances which, taken as a whole, are outside the range of clinical circumstances presented by a patient within the normal population of patients with the same medical condition and at the same stage of progression as the patient.
Responsible Clinical Commissioning Group means the Clinical Commissioning Group which discharges the Secretary of State’s functions under the National Health Service Act 2006 for an individual patient.

Rule of rescue is the observation that human beings, in situations where an individual’s life is at risk, have the proclivity to take action to rescue the individual regardless of the cost and the chances of success. Action taken, therefore, is in part about meeting the emotional needs of the decision maker. In the healthcare setting the term has been used in a number of ways. In the West Midlands the term refers to agreeing funding for treatments for patients whose prognosis is grave on the basis that their prognosis is grave and without regard to cost or ability to benefit.

Experimental and unproven treatments are medical treatments or proposed treatments where there is no established body of evidence to show that the treatments are clinically effective. The reasons may include the following:

- The treatment is still undergoing clinical trials for the indication in question.
- The evidence is not available for public scrutiny.
- The treatment does not have approval from the relevant government body.
- The treatment does not conform to an established clinical practice in the view of the majority of medical practitioners in the relevant field.
- The treatment is being used in a way other than that previously studied or for which it has been granted approval by the relevant government body.
- The treatment is rarely used, novel, or unknown and there is a lack of evidence of safety and efficacy.
- There is some evidence to support a case for clinical effectiveness but the overall quantity and quality of that evidence is such that the commissioner does not have confidence in the evidence base and/or there is too great a measure of uncertainty over whether the claims made for a treatment can be justified.

A service development is any aspect of healthcare which the CCG has not historically agreed to fund and which will require additional and predictable recurrent funding. The term refers to all new developments including new services, new treatments (including medicines), changes to treatment thresholds, and quality improvements. It also encompasses other types of investment that existing services might need, such as pump-priming to establish new models of care, training to meet anticipated manpower shortages and implementing legal reforms. Equitable priority setting dictates that potential service developments should be assessed and prioritised against each other within the annual commissioning round. However, where investment is made outside of the annual commissioning round, such investment is referred to as an in-year service development.

An in-year service development is any aspect of healthcare, other than one which is the subject of a successful individual funding request, which the Clinical Commissioning Group agrees to fund outside of the annual commissioning round. Unplanned investment decisions should only be made in exceptional circumstances because, unless they can be funded through disinvestment, they will have to be funded as a result of either delaying or aborting other planned developments.

A policy variation occurs when an existing policy is changed. When there is a proposal which would result in increased access to a treatment (for example by lowering the threshold for treatment or adding a new indication for treatment) the policy variation is a service development and will be treated as such.

A Similar Patient refers to the existence of a patient within the patient population who is likely to be in the same or similar clinical circumstances as the requesting patient and who could reasonably be expected to benefit from the requested treatment to the same or a similar degree. When the treatment meets the regional criteria for regional policy making, then the similar patient may be in another CCG in the West Midlands region. Most often there is more than one patient in this category.

The existence of one or more similar patients indicates that a policy position is required of the CCG.
Documents used to inform this policy

West Midlands Commissioning Policy (WM9) Individual Funding Requests
Adopted by Shropshire County Primary Care Trust and NHS Telford and Wrekin November 2012

11 Author:
Su Green, Senior Commissioning Manager Funding and Policy

12 Responsible Director:
Linda Izquierdo, Director of Quality, Nursing, Patient Safety and Experience

13 Review Date
This policy should be reviewed in three years’ time or where there is a change in legislation which constitutes an earlier review.
SHROPSHIRE CLINICAL COMMISSIONING GROUP

Individual patient requests form

On completion, please email to ccgsafehaven@nhs.net

Patient and Contact Information

<table>
<thead>
<tr>
<th>1. Trust Name &amp; address</th>
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<table>
<thead>
<tr>
<th>2. Applicant Details</th>
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<tr>
<td></td>
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<td></td>
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<td>Email:</td>
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<tr>
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<td></td>
<td>NHS no:</td>
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<td></td>
<td>DoB:</td>
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<td></td>
<td>Registered Consultant:</td>
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<td>Registered GP name:</td>
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<td>Registered GP practice:</td>
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### INTERVENTION REQUESTED
(nb: Intervention refers to requested treatment, investigation, etc)

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<tr>
<th>5. Patient Diagnosis (for which intervention is requested)</th>
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| 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 |

<table>
<thead>
<tr>
<th>Date/s</th>
<th>Intervention e.g. drug/surgery</th>
<th>Reason for stopping*</th>
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<td>Response achieved</td>
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<th>7. Details of intervention (for which funding is requested)</th>
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<td><strong>Name of intervention:</strong></td>
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<table>
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<th>If a drug, dose and frequency:</th>
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<th>Planned duration of intervention:</th>
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<th>Route of administration:</th>
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<tr>
<th>Anticipated cost (inc VAT) – seek advice from pharmacy</th>
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<tr>
<th>8. Is requested intervention part of a clinical trial?</th>
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<tr>
<td>The CCG does not fund treatments deemed to be experimental/part of a trial or research.</td>
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<tr>
<td><strong>No</strong></td>
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<tr>
<th>Yes (and give details (e.g. name of trial, is it an MRC/National trial?))</th>
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8. Anticipated start date: (Processing requests can take up to 4 weeks from the date received by the CCG). If the case is more urgent than this, please state why:

<table>
<thead>
<tr>
<th>Key criteria required for consideration of request</th>
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<tbody>
<tr>
<td>10. If a drug treatment is requested, is the drug licensed for the requested indication?</td>
</tr>
<tr>
<td>If not licensed, is the request supported by the trust’s drug and therapeutics committee or equivalent, and is the drug listed as a PBR exclusion?</td>
</tr>
<tr>
<td>11. Is there published RCT evidence demonstrating effectiveness of the intervention for the proposed indication?</td>
</tr>
<tr>
<td>12. Please submit full details of evidence of clinical effectiveness of the treatment/procedure with this application.</td>
</tr>
<tr>
<td>A summary of the evidence base underpinning the interventions should be included and any assessments by advisory bodies or research papers should accompany the application.</td>
</tr>
</tbody>
</table>
12. Has NICE published guidance/guidelines? The CCG will not normally, in the absence of compelling evidence as to both clinical and costs effectiveness, fund treatments prior to approval by NICE.

13. Has the intervention being requested been presented to, considered by and prioritised by the appropriate LIT/Network? The individual patient request process should not be used to by-pass other prioritisation and decision-making processes of the CCG.

14. Are there any exceptional circumstances to consider in this case:

Where care is not routinely funded by the CCG, 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.

How is this patient different to the patient population with this condition?

- Clinical grounds e.g. where an individual patient may expect to achieve a significantly better outcome than others with the same condition
- **Personal circumstances**: The PCT adopts a policy of regarding all lives as of equal value and therefore does not distinguish between people on personal grounds where life saving treatments are being considered.

- **Systems failure**: i.e. where a breakdown in usual clinical or administrative systems has placed a patient outside usual time limits on treatment.

15. Any other exceptional circumstances of which the panel should be aware

16. (a) How will you monitor the effectiveness of this intervention?

   (b) What would you consider to be a successful outcome for this intervention in this patient?

17. What is the prevalence of ‘similar patients’ within the locality?

17. Date request submitted

18. Date received by CCG