

# INDIVIDUAL FUNDING REQUEST POLICY

## Process for the Funding of Services and Treatments Not Routinely Commissioned by NHS Bedfordshire Clinical Commissioning Group

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## Equality Impact Assessment

The objective of the individual funding request policy is to set out a process by which people whose health needs are not met by the prevailing commissioning policies that the Clinical Commissioning Group (CCG) has adopted can apply for treatments, drugs or devices to be funded on the basis of exceptional clinical circumstances.

The policy applies to all members of the CCG population.

Evidence referred to in considering the policy's potential impact on equality and health inequalities comprises:

- the Ethical and Commissioning Principles that the CCG has adopted
- the NHS confederation guidance document [Priority Setting: managing individual funding requests](#)
- NHS England's IFR policy <https://www.england.nhs.uk/publication/commissioning-policy-individual-funding-requests/> and NHSE standard operating procedure for IFRs <https://www.england.nhs.uk/publication/standard-operating-procedures-individual-funding-requests/>
- The Faculty of Public Health's position statement [Describing exceptionality for funding panels](#)

The policy follows best practice by explicitly stating that non-clinical factors will not be taken into consideration when an opinion on exceptionality is being reached. Protected characteristics which do not have relevance to the clinical condition should not therefore be referred to in the material which is presented to the decision-making panel. Other characteristics which are known to correlate with health inequalities such as income deprivation or homelessness would also be excluded.

Where a protected characteristic does have relevance to the clinical condition, it may be appropriate to take it into consideration. For example, a treatment may be known to be less clinically effective in older people. The panel may therefore refuse to fund it for an older patient where they would fund it for a younger patient, even where exceptionality is established, because the treatment would be less cost effective. It is conceivable that this situation could apply due to direct or indirect effects of any of the nine protected characteristics. The risk that it could be discriminatory in its application should be mitigated by avoiding making assumptions about clinical effectiveness in different groups of patients, but relying instead only on the body of evidence that has been established in the peer-reviewed scientific literature.

If a treatment is requested for a person who does not have an exceptional health need but represents a definable cohort of patients for whom that particular treatment has not been commissioned, the application will be refused and the identified service need will be considered in the usual prior approval process. It is possible that such a cohort of patients could arise due directly or indirectly to a protected characteristic which they shared; for example, a new treatment for an uncommon complication of pregnancy. Until a commissioning policy is agreed, members of the affected cohort would not be able to access the treatment. This situation could conceivably apply to any of the nine protected characteristics. The risk that it would be discriminatory (i.e. be more likely to occur in conditions related to protected characteristics than in any other type of condition) would be mitigated to an extent by thorough horizon-scanning in the routine commissioning cycle. The risk that the speed or likelihood of service development for a service required by such a cohort of patients could be different from a service arising from any other type of need (and therefore discriminatory) would be mitigated if the process for considering service development needs that the IFR process identifies has mechanisms in place to prevent it.

This impact assessment has been considered by Bedfordshire CCG's Equality and Diversity Manager and the following comments made:

“The report author has completed an equalities impact assessment. In the assessment the author has considered the relevant protected characteristics and the potential impact of the proposals. The author has identified that there may, occasionally, be a risk of differential treatment as a result of a person's protected characteristic. The author identifies that this potential differential treatment is not only the result of the proposals in this report but also as a consequence of how these proposals work alongside existing policies and practices. The author has recommended actions to identify and mitigate any potential differential impact.

Consideration of how these proposals can promote equality or improve relations between people who share a protected characteristic and those who do not has identified that these are not relevant at this time.

It is noted that the proposals being put to the panel are in draft. A review of the equalities impact assessment should be undertaken when the finalised proposals are considered to ensure that it is still accurate and relevant.”

Paul Curry, Equality and Diversity Manager, 6 November 2015

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# **PROCESS FOR THE FUNDING OF SERVICES AND TREATMENTS NOT ROUTINELY COMMISSIONED BY BEDFORDSHIRE CLINICAL COMMISSIONING GROUP**

## **Section 1 AIM OF COMMISSIONING**

1.1 Bedfordshire Clinical Commissioning Group (BCCG) receives a fixed budget from central government with which to commission the healthcare services required by its population and has a statutory duty to break even at the end of each financial year. BCCG has insufficient resources to fund all the types of healthcare that might potentially be available or requested for its population and must inevitably, therefore, make difficult choices about which healthcare treatments to commission.

BCCG has a responsibility to make rational decisions in determining the way in which it allocates resources equitably for its population. BCCG has in place processes for prioritising the commissioning of services

Within the resources available, BCCG aims to commission high quality clinical care to which access is available for all its population, equitably and consistently, based solely on clinical need. BCCG believes that the best way to achieve this is by commissioning clear pathways of care which span the interfaces between primary, secondary and tertiary care (and social services, as and when required) and are supported by shared clinical protocols and arrangements for audit and outcome evaluation.

BCCG will pursue this approach to commissioning in line with current government policy<sup>1</sup>. This will enable BCCG to develop a comprehensive range of care pathways, linked to a variety of care providers, to which the population will have consistent and equitable access based on clinical need.

BCCG is also legally obliged to have a process for determining any request for the funding of a healthcare intervention for an individual where there is no relevant National Institute for Health and Care Excellence (NICE) recommendation and BCCG's general policy is not to fund that intervention. This Policy describes BCCG's process for dealing with requests for funding for treatments which are not routinely commissioned. This process will be managed by the IFR Service within South, Central & West Commissioning Support Unit (SCW CSU) on behalf of BCCG.

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<sup>1</sup> Everyone Counts: Planning for Patients 2013/14; available at <http://www.england.nhs.uk/everyonecounts>

## Section 2 WHEN THIS POLICY APPLIES

- 2.1. It is important to understand the BCCG Prior Approval Process which relates to this Policy.
- 2.2. The circumstances which need to be considered on an individual basis, via this process, are requests to fund healthcare for patients which fall outside the range of services and treatments that BCCG has agreed to routinely commission (i.e. an individual funding request). See <http://www.fundingrequests.ccsu.nhs.uk/policies-bedfordshire/> for further details.
- 2.3. This policy does not apply to requests for funding of treatments or services for groups of patients who fall within the commissioning remit of NHS England. Individual funding requests for patients who are the commissioning responsibility of NHS England will not be considered by BCCG's Case Review Panel. NHS England has its own individual funding policy and process for handling requests for treatments and services on behalf of these patients.

## Section 3 PRINCIPLES APPLIED WHEN HANDLING INDIVIDUAL FUNDING REQUESTS

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

- 3.1 When considering individual funding requests, BCCG will apply its Ethical & Commissioning Principles (see Appendix 1) and the following guiding principles:
- 3.1.1 The mechanism through which investment and disinvestment decisions are made as part of the CCG commissioning strategy.
- 3.1.2 BCCG expects consideration of new drugs/technologies to take place within the established local planning framework after consideration by the appropriate committees i.e. the Bedfordshire and Luton Joint Prescribing Committee, the Bedfordshire and Hertfordshire Priorities Forum or other bodies as set out in the CCG commissioning. This will enable clear prioritisation of the new drugs/technologies against other calls for funding and the development of implementation plans which will allow access for all patients with equal clinical need.
- 3.1.3 BCCG accepts that there may be individual cases where a patient's needs cannot be met through existing care pathways. BCCG has set up an individual funding request process to consider the circumstances of individual patients for whom a referral outside existing pathways may be appropriate.

Clinicians are entitled to make an individual funding request for treatment to be funded by the BCCG outside of its established policies in circumstances where:

- The patient is suffering from a presenting medical condition for which the BCCG has no established commissioning policy, or
- The patient is suffering from a presenting medical condition for which the BCCG has an established commissioning position, as shown by CCG policy or practice or the treatments that are approved for routine funding in service agreements, but:
  - the patient's particular clinical circumstances means they do not qualify for funding, or
  - the established commissioning position of BCCG is not to fund that intervention at all.

3.1.4 It is not the role of the Case Review Panel to make commissioning policy on behalf of BCCG. Treatments not currently included in established pathways/policies or identified for funding through the annual priority setting process are not routinely funded. Until a service development has been assessed and a policy decision has been taken as a result of prioritisation, whether in-year or during the CCG co, BCCG's default interim policy will be not to fund a treatment, unless otherwise stated. Where a treatment is not routinely funded, be that explicitly, implicitly or by default, BCCG will only consider funding an individual in respect of whom it is established that their clinical circumstances are exceptional.

3.2 Determination of 'exceptionality':

3.2.1 What is meant by exceptional circumstances?

There can be no exhaustive definition of the phrase 'exceptional clinical circumstances (health need)'. The word 'exceptional' means 'a person', thing or case to which the general rule is not applicable';

- It may be possible to demonstrate exceptionality where the patient has a medical condition or circumstance for which CCG commissioning strategy provides no established treatment care pathway (see 'Section 6.4 Treatments not covered by BCCG's guidance').
- If a patient is suffering from a medical condition for which there is an established care pathway, the Case Review Panel may find it helpful to ask itself whether the clinical circumstances of the patient are such that that patient is exceptional as compared with other patients with that medical condition at the same stage of progression.
- The fact that a patient fails to respond to, or is unable to be provided with, one or more treatments usually provided to patients with that particular medical condition *may* be a basis upon which the Panel could find that a patient is exceptional. However, the Panel would normally need to be satisfied that the patient's inability to respond to, or be provided with, the usual treatment was a genuinely exceptional circumstance.

For example:

If the usual treatment is only effective for a proportion of patients (even if a high proportion), this leaves a proportion of patients for whom the usual treatment is not available or not clinically effective. If there is likely to be a significant number of patients for whom the usual treatment is not clinically effective, or not otherwise appropriate, the fact that the applicant patient falls within that group is unlikely to be a proper ground to show that the applicant patient is exceptional.

If the usual treatment is not an option for the patient because of a pre-existing co-morbidity then, unless having the co-morbidity can itself be described as exceptional within the patient group, the patient is unlikely to represent an exceptional case.

To establish that the patient has 'exceptional clinical circumstances', it must be demonstrated that the patient is both:

- Significantly different, clinically, from the group of patients with the condition in question at the same stage of progression of the condition

AND

- Likely to gain significantly more clinical benefit than others in the group of patients with the condition in question at the same stage of progression of the condition.

3.3 Non-Clinical Factors

It is common for an application for individual funding to be made on the grounds that a patient's personal circumstances are exceptional. This assertion can include details about the extent to which other persons rely on the patient or the degree to which the patient has contributed or is continuing to contribute to society. BCCG understands that everyone's life is different and that such factors may seem to be of vital importance to patients in justifying investment for them in their individual case.

However, the NHS does not generally take into account non-clinical factors in deciding what treatment to provide, unless a service is specifically designed to address health inequality or a prevailing inequity of access to routinely provided care or treatment.

In general, the NHS treats the presenting medical condition and does not inquire into the background and lifestyle choices which may have contributed to that condition as the basis on which to decide whether to make treatment available or not. The policy of BCCG is that it should continue to apply these principles to applications for individual or exceptional funding approval. BCCG will, therefore, seek to commission treatment based on the presenting clinical condition of the patient and not based on the patient's non-clinical circumstances.

The Case Review Panel is, accordingly, required to follow the principle that non-clinical factors, including social value judgments about the underlying medical condition or the patient's circumstances, are not relevant.

Clinicians are asked to bear this policy in mind and not refer to non-clinical factors to seek to support the application for individual funding.

#### 3.4 Proving the case that the patient's circumstances are exceptional

The onus is on the requesting clinician to set out the grounds clearly for the Case Review Panel on which it is said that this patient is exceptional. The grounds will usually arise out of exceptional clinical manifestations of the medical condition, as compared to the general population of patients with the medical condition in question.

These grounds must be set out on the form provided by BCCG and should clearly set out any factors which the clinician invites the panel to consider as constituting a case of exceptional clinical circumstances.

If a clear case is not made as to why the patient's clinical circumstances are said to be exceptional, then the Case Review Panel can only refuse the application. The Case Review Panel recognises that the patient's referring clinician and the patient together are usually in the best position to provide information about the patient's clinical condition as compared to the particular subset of patients with that condition. The referring clinician is advised to set out the evidence in detail because the Case Review Panel will contain a range of individuals with a variety of skills and experiences but may well not contain clinicians of that specialty. BCCG therefore requires the referring clinician, as part of their duty of care to the patient, to explain why the patient's clinical circumstances are said to be exceptional.

The policy of BCCG is that there is no requirement for the panel to carry out its own investigations about the patient's circumstances in order to try to find a ground upon which the patient may be considered to be exceptional nor to make assumptions in favour of the patient if one or more matters are not made clear within the application. Therefore, if a clear case of exceptionality is not made by the paperwork placed before the Case Review Panel, the Panel is entitled to turn down the application.

##### 3.4.1 The Case Review Panel will not usually make a decision to fund a patient's treatment where, by so doing, a precedent would be set that establishes new policy because the patient is not, in fact,

exceptional but is representative of a group of patients. BCCG will not offer treatment to one patient which cannot be afforded for all patients in the same clinical circumstances.

- 3.4.2 BCCG does not expect to introduce new drugs/technologies on an ad-hoc basis through the mechanism of individual case funding. To do so risks inequity since treatment will not be offered openly and equally to all patients 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 BCCG.
- 3.4.3 The IFR Service, in support of the Case Review Panel, shall routinely screen individual funding requests to see whether they represent a service development. The key question used to filter out service developments will be 'are there likely to be other similar patients in the population for which BCCG is responsible?' If there is evidence that the patient is representative of a group of patients the purported individual funding request will be returned to the provider with a request to follow normal procedures for introducing new services. Where this would result in unreasonable delay in care the care would still be considered in parallel to this if appropriate under 3.2

## Section 4 OVERVIEW OF THE INDIVIDUAL FUNDING REQUEST PROCESS

- 4.1 Where a clinician, or a patient *with explicit support from his/her clinician*, wishes to make a referral/request for funding for a treatment not routinely funded within current pathways, the following process should be followed. *NB:* This will compulsorily include any consultant/clinician in a primary, secondary or tertiary centre who wishes to make a referral to another consultant either within or outside his/her own Trust and outside of agreed care pathways. See also section 6.9.
- 4.2 Requests should be submitted using the appropriate application form found on the following website <http://www.fundingrequests.cscsu.nhs.uk/policies-bedfordshire/>. Supporting evidence should also be provided including details of randomised control trials (RCTs) or case studies, academic articles and any correspondence from other clinicians/providers as appropriate. Please note that the panel requires all information submitted to be anonymised, the maximum identifiers should be: NHS Number and General Practitioner (GP) Name & Practice; to protect patient confidentiality and ensure panel objectivity. It is the responsibility of the person submitting the application to ensure that all relevant information is forwarded to the IFR Service within the CSU, and to indicate the level of urgency of the case on the application form. Cases may be:
- a. Most urgent (decision needed within a week as the patient's life may be in danger, although<sup>2</sup> every effort will be made to provide a decision sooner and usually within 48 hours of the funding request received by the CSU);
  - b. Soon (decision needed within 3 weeks as delay will not be clinically appropriate);
  - c. Routine (decision needed in 4-6 weeks).
- 4.3 The process of Individual Funding Request consideration consists of:

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<sup>2</sup> For treatments that are urgently required, where significant harm may occur through delay, the treatment should be provided to the patient at the provider's risk and retrospective approval for funding should be sought.

- 4.3.1 A desktop triage process (to filter out any requests which are not determined to be individual funding requests i.e. requests where patient fully meet the criteria and therefore appropriate to treat; requests representing a service development; requests with a clear lack of information and to recognise and expedite applications where urgent intervention is required). This is undertaken by the IFR service within South, Central & West Commissioning Support Unit on behalf of BCCG.
- 4.3.2 There are two panels, the Clinical Triage Panel and Case Review Panel.
- 4.3.3 The Clinical Triage Panel has delegated authority from the Case Review Panel to triage out applications which meet existing commissioning policies. The Clinical Triage Panel is the initial decision making panel for individual funding requests. The Clinical Triage Panel will consider the cases via the online portal (within NHS Information Governance (IG) rules) and the Panel members may meet face to face or communicate virtually on a regular basis, as and when required.

The membership will comprise of:

- A GP
- Pharmaceutical advisor (for drug cases only)
- Public Health Representative (for drug cases only)
- IFR Service representative

GP and IFR Service representative will be required to confirm decisions for quoracy and the Pharmaceutical advisor views are required for all drug cases.

The Clinical Triage Panel will be able to consider four options:

- Approve the request if covered by an existing SLA/commissioning policy
- Decline the request without reference to the Case Review Panel
- Refer to the Case Review Panel
- Request further information

- 4.3.4 The Case Review Panel will meet every 4-8 weeks, up to a maximum of once a month, depending on the number of cases received, and is responsible for considering the funding decisions, specifically in relation to Individual Funding Request cases that require further input after triage or case decisions that require reconsideration if the requesting party has appealed the initial decision and provided additional information for consideration. The membership will comprise of:

- Bedfordshire Clinical Commissioning Group - Chairman of Panel
- Assistant Director of Planned Care
- Bedfordshire Clinical Commissioning Group Governing Body Lay Member
- Consultant in Public Health
- Minimum of 2 Clinical Commissioning Group GPs (one to act as vice chair if necessary)
- Assistant Head, Medicines Optimisation IFR and Commissioning (for drug cases)
- Head of Quality – Patient Governance Representative
- IFR Service Representative
- Specialist Consultant (as and when required)

Please see Appendix 3 for the case review panel terms of reference. Please see paragraph 4.14 for arrangements in the case of an urgent request.

- 4.4 The Case Review Panel will review the Individual Funding Request applications and decline, approve (within agreed financial limits) or defer a decision pending receipt of further information, as appropriate. Terms of Reference for the Panel are stated in Appendix 3. Case Review Panel members who have any conflicts of interest with a particular case will be excluded from the discussion of that case.
- 4.5 In reaching a decision on individual funding, the Case Review Panel will consider each case in line with BCCG's Ethical and Commissioning Principles (see Appendix 1).
- 4.6 It is the responsibility of the person submitting the application (i.e. the clinician or patient) to provide sufficient evidence to demonstrate the patient's exceptionality and to provide evidence of the clinical and cost effectiveness of the treatment being requested. The Case Review Panel shall be entitled, but not obliged, to commission its own reports from any duly qualified or experienced clinician, medical scientist or other person having relevant skills concerning the case that is being made that the treatment is likely to be clinically effective in the case of the particular patient.
- 4.7 The Case Review Panel is not required to accept the views expressed by the patient or the referring clinician concerning the likely clinical outcomes for the particular patient of the proposed treatment but is entitled to reach its own views on:
  - The likely clinical outcomes for the particular patient of the proposed treatment; and
  - The quality of the evidence to support that decision and/or the degree of confidence that the Panel has about the likelihood of the proposed treatment delivering the proposed clinical outcomes for the particular patient.
- 4.8 Where the Case Review Panel finds that insufficient information has been provided to review the case, the application will be returned to the referring clinician, highlighting the outstanding information required. Should the referring clinician not respond within one month, the case will be administratively closed by the IFR Service within the CSU. If new information is received the case may be re-opened or the referring clinician will be asked to submit a new application, depending on the timeline.
- 4.9 The Case Review Panel will decline the request where:
  - The clinical and/or cost-effectiveness of the proposed treatment has not been demonstrated.
  - There is a clear commissioning policy, the patient's circumstances do not meet the criteria for funding set out in the policy (or the policy states that the intervention is not routinely funded for any patient group) and there is no evidence that the patient has exceptional clinical circumstances.
  - There is no relevant BCCG commissioning policy (and BCCG's position is, therefore, that the treatment is not routinely funded) and where no circumstances of individuality or exceptionality have been demonstrated.
  - The Case Review Panel concludes that the patient does not, in fact, have exceptional health need, but is representative of a group of patients (see section 4.10 below).

- 4.10 The Case Review Panel will be entitled to approve requests for funding for particular patients where the request is in line with BCCG's Ethical & Commissioning Principles (Appendix 1) and the following five conditions are all met:
- The request for funding for treatment is in connection with a medical condition for which BCCG has a policy but the patient falls outside the terms of that policy, or for which BCCG has no policy but the default interim position is that BCCG does not fund the sought intervention and where there is evidence that the patient in question has exceptional clinical circumstances;
  - There is no evidence to suggest that the patient is representative of a group or sub-group of patients and the Case Review Panel concludes that there are likely to be no similar patients to the requesting patient (i.e. no patient within the population served by BCCG who is or is likely to be in the same or similar clinical circumstances as the requesting patient in the same financial year, and who could reasonably be expected to benefit to the same or similar degree from the requested treatment).
  - There is sufficient evidence to show that, for the particular patient, the proposed treatment is likely to be clinically effective;
  - There is sufficient evidence to show that, for the particular patient, the proposed treatment is likely to be cost effective;
  - The intervention is affordable by BCCG at the point of application.
- 4.11 The Case Review Panel will record its decision and the IFR service will write to the person who submitted the request setting out the Case Review Panel's decision and the reasons for it. Where the request has been submitted by the patient's clinician, the Case Review Panel expects the requesting clinician to communicate the outcome of the Case Review Panel to the patient.
- 4.12 In cases where the Case Review Panel finds the patient is not exceptional but is representative of a group of patients, the Case Review Panel will decline funding for the particular patient and will treat the request as a potential service development. In situations where the Case Review Panel is aware that a policy decision is imminent, the Case Review Panel may decide to adjourn the decision and will communicate this to the patient/referring clinician if the timescales within this policy are unlikely to be achieved.

In cases which could relate to a group of patients, where the Case Review Panel finds that strong evidence has been provided in support of a particular treatment, the Chair will advise the assistant director, planned care who will report to the Executive Management Team and the clinician/provider will be asked to submit a business case in support of the routine use of the treatment if there is a local need. Where appropriate, this process will be supported by the Consultant in Public Health and/or Commissioning Pharmacist and/or designated person from the respective CCG commissioning team.

In cases where the Case Review Panel finds poor or insufficient evidence has been provided in support of a particular treatment, the referring clinician will be advised of BCCG's processes for reviewing potential service developments and no further action will be taken by BCCG unless the clinician submits more robust evidence or a business case.

- 4.13 All cases will be treated as 'Routine' unless otherwise specified by the referring clinician. All routine cases will be reviewed and a decision communicated back to the referring clinician within 4-6 weeks from date of receipt of the completed application.
- 4.14 In cases where urgent consideration can be justified, an extraordinary Clinical Triage Panel and/or Case Review Panel may be convened. This could be either in person or virtually, in order to expedite decision making.

In the rare event of a patient's life being in danger, the Medical Director or Director of Quality, following urgent discussion with appropriate members of the Case Review Panel or their named deputy, can take an immediate funding decision in accordance with the principles and the timescales set out in this policy. The decision must then be ratified at the subsequent Case Review Panel meeting.

- 4.15 A report of the meetings of the Individual Funding Panel and its decisions will be submitted to the BCCG Governing Body.
- 4.16 This Policy delegates to the Case Review Panel authority to approve individual episodes or packages of care up to the *per request value* of £100,000. For values greater than this, additional approval will be required from the Chief Finance Officer or nominated deputy as per standard financial instructions.
- 4.17 Where funding for treatment is approved, this approval applies to the specific intervention requested only (e.g. a course of a particular drug/regimen). Clinicians will need to submit a new funding application to extend treatment, including for maintenance, replacement or repair of devices (not within warranty period) and must stipulate the benefits received. BCCG may refuse to fund treatment in these cases if further funding approval has not been sought or the evidence of benefit is poor.
- 4.18 Where funding for treatment is approved, treatment must commence within 6 months of the date of approval. Where a Clinician may feel there are exceptional clinical circumstances why the timeline may not be met, the referring clinician must provide this information with the original funding request. Clinicians will need to submit a new funding application if treatments are not started within this time limit. In that event, the new application will be considered against the policies prevailing at the time, which may differ from those applied in the original decision.
- 4.19 There is no right of attendance at either Panel by the requesting clinician, the patient or their representative.

## Section 5 APPEAL PROCESS

- 5.1 The person who submitted the individual funding request can request reconsideration of the decision made by the Case Review Panel on two grounds:
- If further clinical information is available which has not already been considered by the Case Review Panel, they may ask the Panel to reconsider the case
  - If they believe that due process has not been followed.
- 5.1.1 The person wishing to make an appeal must notify the IFR Service of their intention in writing, within six calendar weeks of the date of notification of the Case Review Panel's decision.
- 5.1.2 It is the responsibility of the person submitting the appeal to ensure that all relevant information is provided to BCCG
- 5.1.3 BCCG has no obligation to commence/continue funding for a treatment whilst an appeal is underway.
- 5.2 With the exception of urgent requests, cases will be considered at the next scheduled Case Review Panel meeting. If additional information is required, for the IFR Service to prepare the case for consideration, this may delay presentation to the Case Review Panel until the subsequent or later meeting. All required information from the patient/Trust/clinician must be sent to CSU IFR Service at least ten working days before the scheduled date of the next meeting of the Case Review Panel.
- 5.2.1 In cases where urgent consideration is required, an extraordinary Case Review Panel may be convened in person or virtually in order to expedite decision making.
- 5.2.2 In reconsidering a request where further clinical information has been made available, the Case Review Panel will follow the same process as laid out in section 4.
- 5.3 Should the referring clinician/patient be dissatisfied with due process i.e. the end-to-end process the case has followed and the decision reached by the Case Review Panel, they may ask for it to be reviewed as a Process Appeal.
- 5.3.1 Process Appeals will be handled on behalf of BCCG by NHS East & North Hertfordshire CCG, Individual Funding. NHS East & North Hertfordshire CCG, Individual Funding, will consider whether the decision of the BCCG, Case Review Panel, was valid in terms of process, factors considered and criteria applied<sup>3</sup>. In deciding an appeal, NHS East & North Hertfordshire CCG, Individual Funding, will consider whether:
- a) the decision was consistent with the principles of BCCG, as set out in the Ethical and Commissioning Principles

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<sup>3</sup> McCloskey, B. Judicial Review, A Good Practice Guide for Health Authorities. (1999)

- b) the decision was reached as the result of a decision-making process which was consistent with that set out in the Individual Funding Request Policy
- c) the decision was consistent with previous similar decisions
- d) in reaching the decision the Case Review Panel had:
  - taken into account and weighed properly all relevant evidence
  - given proper consideration to the claims of the patient or their clinician and accorded proper weight to his or her claims against those of other patients or groups of patients competing for scarce resources
  - taken into account only material factors
  - acted in utmost good faith
  - taken a decision that is in every sense reasonable.

5.3.2 It is important to note that NHS East & North Hertfordshire CCG, Individual Funding, or any successor organisation allocated this role, will not consider new information in support of a case.

If new information becomes available, the BCCG Case Review Panel should be asked to reconsider the case in light of this.

5.2.2 The decision reached by NHS East & North Hertfordshire CCG, Individual Funding will be communicated to the CSU IFR team, who will, in turn, advise the referring clinician. It is the responsibility of the referring clinician to communicate the outcome of the process appeal to the patient.

5.2.4 If NHS East & North Hertfordshire CCG, Individual Funding, finds that there was a failing in the process, as defined in paragraph 5.2.3, they will refer the case back to the BCCG, Case Review Panel for rehearing. A finding of failure in the process of handling an individual case request does not necessarily mean that the decision reached at rehearing will be different.

5.2.5 Complaints will be managed through the BCCG complaints process, details can be found on the webpage <https://www.bedfordshireccg.nhs.uk/page/?id=4076>. Where appropriate the IFR Service will provide information to support any responses required.

## **Section 6 RELEVANT COMMISSIONING POLICIES**

When considering individual funding requests, BCCG will apply the following policies and guidance:

### **6.1 Bedfordshire & Hertfordshire Priorities Forum Guidance**

For a number of treatments BCCG has developed specific policy statements setting out restrictions on access, based on evidence of clinical and cost effectiveness and/or relative priority for funding.

A current list of Priorities Forum guidance is available at <http://www.fundingrequests.cscsu.nhs.uk/policies-bedfordshire/>

Clinicians or patients uncertain about the status of a particular treatment should contact BCCG's IFR Service at [Beds.IFRrequests@nhs.net](mailto:Beds.IFRrequests@nhs.net) for further advice.

## **6.2 Bedfordshire & Luton Joint Prescribing Committee (JPC) (Area Prescribing Committee)**

For a number of medicines, BCCG has developed in partnership with Luton CCG, specific policy statements setting out restrictions on access, based on evidence of clinical and cost effectiveness and/or relative priority for funding.

A current list of JPC Policies can be obtained from [www.gpref.bedfordshire.nhs.uk](http://www.gpref.bedfordshire.nhs.uk). Clinicians or patients uncertain about the status of a particular medicine should contact BCCG's Medicines Management Team, commissioning pharmacist, for further advice via [BEDCCG.bedsmeds@nhs.net](mailto:BEDCCG.bedsmeds@nhs.net)

## **6.3 NICE Guidance**

NICE technology appraisals, approving drugs and technologies for funding within the NHS, need to be implemented within the allocated time frame (one month or three months) of the appraisal being published. BCCG will seek to ensure implementation of NICE technology appraisals as soon as possible within the three month statutory requirement period. BCCG recognises that delays may occur where significant service change and/or development are required as part of the implementation

## **6.4 Treatments not covered by Bedfordshire CCG Commissioning Guidance**

Patients with rare conditions, including patients for whom established treatments are inappropriate for some reason, are unlikely to have potential treatment options that are covered by NICE guidance or local policies. Patients should be neither advantaged nor disadvantaged simply because their condition is uncommon. BCCG does not accept that additional NHS investment is necessarily justified because a medical condition is rare or exceptional. An approach approving differential investment for those with rare conditions would seek to place a value on the lives of patients with rare conditions which was higher than those with more common conditions.

Applications for funding for treatment for patients with rare conditions<sup>4</sup> will also be considered via the Individual Funding Request process. Where such a funding request is made and the Case Review Panel concludes that there are likely to be no similar patients, then the requesting patient may not need to satisfy the requirement of exceptionality.

A similar patient is defined as: a patient within the population served by BCCG who is, or is likely to be, in the same or similar clinical circumstances as the requesting patient in the same financial year and who could reasonably be expected to benefit to the same or to a similar degree from the requested treatment. When the proposed treatment is commissioned by NHS England and covered by a regional policy, similar patients may be located in any of the Clinical Commissioning Groups in the region.

Nevertheless, all such treatment requests must still meet the clinical and cost effectiveness requirements, and be affordable, in order to be approved for funding.

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<sup>4</sup> Clinicians should consider whether a particular rare condition now falls within the commissioning responsibility of NHS England.

Where BCCG receives an Individual Funding Request relating to an experimental treatment for a rare condition, the Case Review Panel will adhere to these principles and the principles set out in “The role of commissioners in the evaluation of individual treatments and the funding of clinical research<sup>5</sup>”. BCCG accepts that evidence of clinical and cost effectiveness may be limited in the case of interventions for rare conditions but will not consider an application for funding in the total absence of evidence.

## **6.5 Requests to continue funding for patients entering into or coming off clinical trials**

This will also include Expanded Access/Compassionate Use Programmes, including ‘trials of treatment’.

- 6.5.1 BCCG does not expect to fund patients entering commercially-funded clinical trials unless prior approval for funding individual patients in such trials has been obtained from BCCG. In approving the funding of individual patients for clinical trials, BCCG will also make it absolutely clear which particular elements of the trial it is willing to fund.

BCCG does not expect to provide funding for patients to continue medication/ treatment commenced as part of a clinical trial or Expanded Access/Compassionate Use Programme. In line with the Medicines for Human Use (Clinical Trials) Regulations 2004<sup>6</sup> and the Declaration of Helsinki<sup>7</sup>, the responsibility for ensuring a clear exit strategy from a trial AND ensuring that those benefiting from treatment will have ongoing access to it lies with those conducting the trial.

The responsibility for providing ongoing access to a treatment is the responsibility of those individuals or parties that have initiated and sponsored treatment, until such time as BCCG agrees to fund through the annual priority setting process. Where the treatment is not prioritised through the annual priority setting process, the responsibility remains with the trial initiators indefinitely.

It is the clinician’s responsibility to ensure that, prior to undertaking the trial, patients are fully informed of, and agree to, their management plan at the end of the trial. This includes making patients aware of this commissioning policy and, where relevant, any unsuccessful request for post-trial funding. The patient’s consent should be documented.

- 6.5.2 Where BCCG receives an individual funding request relating to a patient who has previously received treatment via a trial or Patient Access/Compassionate Use Programme, the Case Review Panel will adhere to the principles set out in section 6.5.

Should BCCG agree to fund an individual patient in this context, this does not constitute a policy decision in relation to that treatment and, as such, sets no precedent for the funding of other patients. The treatment in question will be assessed and prioritised as a service development in the normal way.

- 6.5.3 A ‘trial of treatment’ refers to a situation where a clinician has exposed a patient to treatment for the purpose of assessing whether or not the patient is likely to benefit from longer term treatment.

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<sup>5</sup> The responsibility of funding of research in the NHS rests primarily with the National Institute for Health Research (NIHR) and is not the responsibility of the BCCG [https://www.nihr.ac.uk/documents/?custom\\_in\\_type=9697](https://www.nihr.ac.uk/documents/?custom_in_type=9697)

<sup>6</sup> <http://www.legislation.gov.uk/uksi/2004/1031/contents/made>

<sup>7</sup> <https://www.wma.net/>

BCCG will not provide pick up funding at the end of a 'trial of treatment' unless approval has been given by BCCG or another NHS commissioner before treatment was started. Providers will need to produce evidence that approval was given.

It is the responsibility of providers to ensure that patients are fully informed and consented before they agree to treatment, and that they understand that, even if a treatment is shown to be clinically effective for them as an individual patient, it is not BCCG's practice routinely to provide funding for treatments which have either not been assessed and prioritised in the usual way or which have been rejected for funding through the service development process.

BCCG will not be liable to pay the provider under the acute services contract where the patient has been initiated on treatment, or received temporary treatment, before funding approval was granted by BCCG.

6.5.4 BCCG will continue to provide access to treatment for a patient leaving a clinical trial if, but only if:

- The patient was sponsored by BCCG (or by another NHS commissioner) to take part in the trial; and
- It has been demonstrated that the patient has benefited clinically from treatment.

Should BCCG agree to pick up funding in this context for a particular patient, it does not constitute a policy decision in relation to the treatment in question and, as such, sets no precedent for the funding of other patients. The treatment in question will be assessed and prioritised as a service development in the normal way.

## 6.6 Drugs used outside their licensed indications

Drugs that are used outside their licensed indications in secondary care are included in reference costs and uplifts where such use is common practice. This means these costs are included in the nationally-set tariff paid to healthcare providers. Funding for new, rarely used, unlicensed and/or investigational drugs (novel/uncertain treatments) outside of a research trial will remain the responsibility of the provider. Where there is a sufficient evidence base for such use to be considered for the routine management of patients, a business case should be submitted **in advance** to the commissioner to take through the due process (minimum time usually three to four months). BCCG will not normally fund novel or uncertain treatments (including research trials, other than through nationally agreed systems e.g. Medical Research Council trials).

It is the responsibility of the clinician who prescribes an experimental drug to ensure compliance with his/her Trust's clinical governance processes and research ethics processes. The clinician's employer (e.g. Provider Trust) carries corporate responsibility for the care provided to the patient. The Case Review Panel/Team may seek reassurance of the relevant governance arrangements for individual cases.

## 6.7 Orphan Drugs

The European Union (EU) legislation defines an orphan drug as one that could treat a disease with a prevalence of less than five per 10,000 of the population. Orphan drugs can be designated by the European Medicines Agency (EMA) and in due course may be given marketing authorisation by the EMA. This then allows the drug to be marketed across the EU countries but this does not mean that it has to be funded by healthcare organisations.

The fact that a drug has been licensed by the EMA does not impose any obligation on the BCCG to fund the drug for the target patient group. BCCG has carefully considered the ethical issues around the funding of high cost drugs and other treatments for small numbers of patients but is satisfied that it would not be right to depart from its established procedures for the assessment and prioritisation of treatments.

BCCG will, in the absence of a direction made by the Secretary of State, commission both existing and new orphan drugs using the same decision making principles and processes as are applied to the commissioning of other treatments.

### **6.8 Requests to continue funding of care commenced privately**

Patients who are undergoing private treatment have a right to revert to NHS funding at any point during their care. If they wish to exercise this right, BCCG will expect their care to be transferred to the local NHS pathway for treatment which will include a referral back to the GP in the first instance.

Funding for the patient to continue care in a private facility, or to transfer to an NHS provider with which a clinician consulted privately has a connection, will not routinely be authorised. Where personal circumstances may make such funding appropriate, the case will require consideration by the Case Review Panel, taking full account of the national guidance on NHS patients who wish to pay for additional private care<sup>8</sup> and the BCCG policy, *Defining the Boundaries between NHS and Private Care*.

### **6.9 Requests for referral to a specialist provider**

These will include tertiary, regional or supra-regional centre or specialist private provider.

The majority of referrals to specialist centres are made by secondary care consultants. BCCG expects consultants to refer patients for tertiary/specialist care using established pathways covered by Service Level Agreements. Accordingly, requests for referrals to specialist providers outside existing pathways will need to be pre-authorised by BCCG, after assessment by appropriate specialists within the existing pathway.

Should a local consultant feel that a referral outside existing pathways is a priority for a particular patient, the consultant should ask for the case to be considered by BCCG as an individual funding request. The consultant should not refer the patient to another provider without first obtaining the approval of BCCG.

BCCG will decline to fund any patient referred to another provider where funding approval has not been obtained prior to the referral being made.

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<sup>8</sup> *Guidance on NHS patients who wish to pay for additional private care* (Department of Health, 2009)  
[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_096428](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_096428)

## **6.10 Decisions inherited from other Clinical Commissioning Groups**

Occasionally patients move into the area and become the responsibility of BCCG when a package of care or treatment option has already been started by another Clinical Commissioning Group that was previously responsible for the patient's care. BCCG will normally honour such decisions where the care pathway has already been initiated, providing that the treatment is in line with BCCG's Ethical & Commissioning Principles. The patient's care will be transferred to locally commissioned services as soon as clinically appropriate.

## **6.11 Request for patients seeking treatment in another European Economic Area (EEA) state**

6.11.1 NHS England is responsible for receiving, processing and making determinations for overseas treatment, in line with BCCG policies. Please see webpage for further information:

<http://www.fundingrequests.ccsu.nhs.uk/european-directive/>

6.11.2 BCCG follows the directions on treatment abroad as set out in the NHS (Cross-Border Healthcare) (England) Directions 2013. For more information please refer to "Cross-Border Healthcare and Patient Mobility in Europe" available at

[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/252940/Cross\\_Border\\_Healthcare\\_Information.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/252940/Cross_Border_Healthcare_Information.pdf)

[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/252944/NHS\\_cross\\_border\\_regulations\\_2013.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/252944/NHS_cross_border_regulations_2013.pdf)

## **6.12 One-off Referrals to Non-contracted providers**

When an individual funding request relates to treatment to be provided by a non-contracted provider including independent sector providers not routinely commissioned by BCCG, and all the criteria for funding are met, BCCG will need to receive assurance of the quality and safety of the service provider from the referring clinician before the request can be approved.

## **6.13 Requests for Equipment**

Requests for equipment will only be considered via the Individual Funding Request process, if the request has already been submitted to and considered by the Bedfordshire and Luton Specialist Equipment Panel but rejected, or does not meet the criteria for referral to the Equipment Panel.

## **6.14 Joint Funding Arrangements**

Where joint funding is required between BCCG and one of the Local Authorities, the relevant joint funding procedures between the organisations will be followed. Equally, where there is a dispute regarding funding contributions, the relevant Dispute Resolution Procedure will be followed.

## **6.15 Current Acute Referral Pathways**

BCCG's qualified providers for acute care are detailed on BCCG's 'e-referral directory of services' and can be accessed via patients' General Practitioners. In addition BCCG holds a portfolio of acute Service Level Agreements (SLAs) with providers across the region and across the rest of the UK for a full range of services, should an alternative provider or a second opinion be required. The provision of a referral for a second opinion is, as the term implies, for an opinion as to the appropriateness of future treatment options. It does not imply that BCCG will necessarily commission the treatment option recommended if this is outside of pathways of care that are normally commissioned by BCCG.

Patients requiring an elective referral will be offered a choice of provider in line with the e-referral requirements at the point of referral. Where the referral required is of a specialist nature for which there are capacity issues or where the patient has particular needs it may be appropriate to offer a restricted choice of provider<sup>9</sup>. The provision of choice is to allow patients the opportunity to choose the provider of the service. It does not entitle the patient to choose any form of treatment if this is outside of the care pathways that are normally commissioned by BCCG.

#### **6.16 Current Mental Health Referral Pathways**

These should be made in line with the Service Level Agreements that exist for these services. A list of Service Level Agreements can be obtained from the Mental Health Commissioning Team, see [www.bedfordshirecccg.nhs.uk](http://www.bedfordshirecccg.nhs.uk)

Referrals using these pathways can be made from primary care or secondary care if appropriate. BCCG believes that these pathways will meet the vast majority of care needs for their population in line with BCCG's Ethical and Commissioning Principles.

Patient choice is due to be extended to Mental Health Services, currently only interim guidelines are in place, see website<sup>10</sup>

Any proposed referrals outside of these pathways will first need to be considered by BCCG Mental Health Lead and funding considered before a referral is made.

## **Section 7 EVALUATIONS AND AUDIT**

- 7.1 On-going evaluation will take place through regular reporting to the BCCG Governing Body via BCCG governance route. In addition, process audits of, for example, time taken to consider cases, consistency of decisions, etc., will be undertaken.
- 7.2 BCCG welcomes feedback on this Policy. Clinicians/patients can provide feedback to the IFR Administrator by e-mail to [Beds.IFRrequests@nhs.net](mailto:Beds.IFRrequests@nhs.net) and feedback will be discussed at the Individual Funding Appeal Panel.

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<sup>9</sup> "Choose& Book" – Patients' Choice of Hospital and Booked Appointments. Policy Framework for Choice and Booking at Point of Referral. DH, London, August 2004.

<http://www.chooseandbook.nhs.uk/staff/communications/fact/responsibilities.pdf>

<sup>10</sup> [http://www.england.nhs.uk/2014/05/21/guide-published/?utm\\_source=feedburner&utm\\_medium=email&utm\\_campaign=feed%3AA+NHSCBoard+%28NHS+England%29](http://www.england.nhs.uk/2014/05/21/guide-published/?utm_source=feedburner&utm_medium=email&utm_campaign=feed%3AA+NHSCBoard+%28NHS+England%29)

## **Section 8 TRAINING AND SUPPORT**

- 8.1 Opportunities for training for Case Review Panel members in evaluation of evidence and health care ethics will be established and provided on a rolling basis. It will be the Chair's responsibility with support from the Commissioning Support Unit and the Consultant in Public Health.

## **Section 9 POLICY REVIEW**

- 9.1 This policy will be reviewed every two years from the effective date.

## **Appendix 1      BEDFORDSHIRE CCG ETHICAL AND COMMISSIONING PRINCIPLES**

Bedfordshire Clinical Commissioning Group receives a fixed budget from central government with which to commission all healthcare required by our population. BCCG has insufficient resources to fund all types of healthcare that might be requested for its population. It is inevitable that BCCG has to make choices about which types of healthcare to commission. This document sets out the principles BCCG uses to make these decisions in order to make the process consistent, transparent and fair. These principles have been developed from the original Ethical Framework of the Bedfordshire and Hertfordshire Priorities Forum.

BCCG's commissioning decisions will be based on the following principles:

### **1) Health Outcome**

The aim of commissioning is to achieve the greatest possible improvement in health outcome for our population, within the resources that we have available. In deciding which interventions to commission, BCCG will prioritise those which produce the greatest benefits for patients in terms of both clinical improvement and improvement in quality of life.

### **2) Clinical Effectiveness**

We will ensure that the care we commission is based on sound evidence of effectiveness. We will usually expect this to come from sources such as the National Institute for Health and Care Excellence, well designed systematic reviews and meta-analyses or randomised controlled trials.

The key success factors in evaluating clinical effectiveness 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 prioritisation and commissioning. 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. We 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.

### **3) Cost Effectiveness**

We will take into account cost-effectiveness analyses of healthcare interventions (where available) to assess which yield the greatest benefits relative to the cost of providing them. We 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. We will consider

technical cost-benefit calculations (e.g. quality adjusted life years) but these will not by themselves be decisive.

#### **4) Equity**

We consider each individual within our populations to be of equal value. We will commission and provide healthcare services based solely on clinical need, within the resources available to us. We will not discriminate unlawfully between individuals or groups on the basis of age, gender, gender identity, sexual orientation, race, religion, lifestyle, occupation, social position, financial status, family status (including responsibility for dependents), intelligence, disability, physical or cognitive functioning. However, where treatments have a differential impact as a result of age, sex or other characteristics of the patient, it is legitimate to take such factors into account.

BCCG has a responsibility to address health inequalities across our population. We acknowledge the proven links between social inequalities and inequalities in health, access to healthcare and health needs. Higher priority may therefore be allocated to interventions addressing health needs in sub-groups of our population who currently have poorer than average health experience (e.g. higher morbidity or poorer rates of access to healthcare).

#### **5) Access**

BCCG will ensure that the care we commission is delivered as close to where patients live as possible. Some services cannot be provided in local settings and we may need to commission some services from more distant providers in order to ensure quality, safety and value for money. BCCG will also ensure that it commissions safe services for its population.

#### **6) Patient Choice**

BCCG respects the right of individuals to determine the course of their own lives, including the right to be fully involved in decisions concerning their health care. However, this has to be balanced against BCCG's responsibility to ensure equitable and consistent access to appropriate quality healthcare for all of our patient population. In commissioning healthcare, BCCG will:

- i) ensure that in, assessing the effectiveness of health care, we take account of outcomes that are important to patients and patient's experience of the care commissioned.
- ii) ensure, wherever possible, that within the care commissioned or provided there are a range of alternative options available and that patients are given the necessary support to make an informed choice.
- iii) recognise that evidence of effectiveness usually relates to groups rather than individuals. We have set up an 'individual funding request' mechanism to allow individuals to be considered as an exception to commissioning policy where evidence is available to suggest that an intervention not routinely funded may be of particular benefit to them by comparison with other patients who might not be funded.
- iv) as a general rule, decline to provide individual funding for care that is not routinely commissioned or provided solely on the basis that an individual, or a clinician involved in their care, desires it. This is in line with our responsibility to ensure consistent and equitable access to

care for all our population. It reflects our concern not to fund for one individual care which could not be openly offered to everyone in our population with equal clinical need.

v) decline to provide a treatment of little benefit simply because it is the only treatment available.

vi) consider treatments which effectively treat 'life time' or long-term chronic conditions equally to life-prolonging treatments and those for urgent need.

## **7) Affordability**

BCCG may not be able to afford all interventions supported by evidence of clinical and cost-effectiveness within our available budgets. Where this is the case, further prioritisation will be undertaken based on criteria including national and local policies and strategies and local assessment of the health needs of the population, to ensure that we do not exceed our available resources.

BCCG is duty-bound not to exceed its budget and therefore 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 the opportunity cost 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.

## **8) Needs of the Community**

Public health is an important concern of BCCG and we will seek to make decisions which promote the health of the entire community. Some of these decisions are promoted by the Department of Health (such as the guidance from NICE and National Service Frameworks). Others are produced locally. BCCG also supports effective policies to promote preventive medicine which help stop people becoming ill in the first place.

Sometimes the needs of the community may conflict with the needs of individuals. Decisions are difficult when expensive treatment produces very little clinical benefit. For example, it may do little to improve the patient's condition or to stop, or slow, the progression of disease. Where it has been decided that a treatment has a low priority and cannot generally be supported, a patient's doctor may still seek to persuade BCCG that there are exceptional circumstances which mean that the patient should receive the treatment.

## **9) Quality**

BCCG will aim to commission high quality services as evidenced against national and international best practice. The quality of services will be measured, where possible, not only in terms of quality of outcomes and clinical effectiveness but also in terms of process and organisational efficiency; reducing dependency on health care; the quality of patient care; and the quality of the patient experience.

## **10) Policy Drivers**

The Department of Health and the Secretary of State issue guidance and can impose regulations 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 groups. BCCG operates with these factors in mind and we recognise that our discretion may be affected by National Service Frameworks, NICE technology appraisal guidance, Secretary of State Directions to the NHS and performance and planning guidance.

## **11) Exceptional Need**

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

## **12) Disinvestment**

As well as commissioning new services on the basis of the criteria above, BCCG will keep existing services under review to ensure that they continue to deliver clinical and cost-effective services at affordable cost. Where possible, we will seek to divert resources from less effective services to more effective ones.

## **Appendix 2      INDIVIDUAL FUNDING REQUEST APPLICATION PROCESS**

All cases which require consideration through the IFR process have either a proforma to complete or an NHS pathway to be followed:

1. Applications for high cost drugs are made using the on-line application process, Blueteq, available at <https://www.blueteq-secure.co.uk/Trust/Default.htm>. For Trusts who are not currently operating Blueteq, please complete the relevant proforma available at [www.gpref.bedfordshire.nhs.uk/](http://www.gpref.bedfordshire.nhs.uk/) or email [BEDCCG.bedsmeds@nhs.net](mailto:BEDCCG.bedsmeds@nhs.net)
2. All other intervention/treatment requests for funding approval on an individual basis. This information can be found on the following webpage:  
<http://www.fundingrequests.ccsu.nhs.uk/policies-bedfordshire/>

Information and forms can be found by using the search facility on the right of the table below (just above Process Pathway). Type a word associated with the intervention you require and a limited list of policies and forms to be displayed. For example Assisted Conception would be displayed if any of the following is typed: Assisted, Conception, and IVF.

Fully completed application forms should be saved locally and sent from a secure NHS.net account to [Beds.IFRrequests@nhs.net](mailto:Beds.IFRrequests@nhs.net) for consideration. If you are having difficulties finding the information you require please email [Beds.IFRrequests@nhs.net](mailto:Beds.IFRrequests@nhs.net) where a member of the IFR service will assist you.

### Appendix 3 CASE REVIEW PANEL TERMS OF REFERENCE

Title	Case Review Panel
Accountable to	Bedfordshire Clinical Commissioning Group Governing Body
How is accountability demonstrated?	Reports to the Governing Body describing decisions made.
Purpose:	<ul style="list-style-type: none"> <li>• To assess Individual Funding Requests submitted to Bedfordshire Clinical Commissioning Group, in accordance with Bedfordshire Clinical Commissioning Group's Individual Funding Request Policy.</li> <li>• To refer service development issues where identified to Bedfordshire Clinical Commissioning Group's Executive Management Team</li> <li>• To identify opportunities for improvement in relation to local prescribing and commissioning policies</li> <li>• To provide an opinion to the Bedfordshire and Hertfordshire Priorities Forum on guidance revisions and guidance in development.</li> </ul>
Membership:	<ul style="list-style-type: none"> <li>• Bedfordshire Clinical Commissioning Group - Chairman of Panel</li> <li>• Assistant Director of Planned Care</li> <li>• Bedfordshire Clinical Commissioning Group Governing Body Lay Member</li> <li>• Consultant in Public Health</li> <li>• Minimum of 2 Clinical Commissioning Group GPs (one to act as vice chair if necessary)</li> <li>• Assistant Head, Medicines Optimisation IFR and Commissioning (for drug cases)</li> <li>• Head of Quality – Patient Governance Representative</li> <li>• IFR Service Representative</li> <li>• Specialist Consultant (as and when required)</li> </ul> <p>The Panel will receive administrative support from an Individual Funding officer of South, Central &amp; West Commissioning Support Unit.</p> <p>For all of the above a named, suitable deputy (assigned by the core members) may attend.</p> <p>Bedfordshire Clinical Commissioning Group reserves the right to amend the membership of the Panel, after due consultation with the Bedfordshire Clinical Commissioning Group Governing Body.</p>

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	<p>Representatives from Bedfordshire Clinical Commissioning Group directorates may be requested to attend the Panel meeting on a non-voting basis, as and when necessary, in order to clarify funding issues around difficult and complex cases.</p>
<p>Quorum</p>	<p>Quorum will be attendance by at least four of the following and must include one clinician:</p> <ul style="list-style-type: none"> <li>• Chairman</li> <li>• Lay member</li> <li>• Consultant in Public Health</li> <li>• GP Member (two GP members are required if the chair is not a clinician)</li> <li>• Assistant Director of Planned Care Commissioning</li> <li>• Assistant Head, Medicines Optimisation – IFR/Commissioning (must also be in attendance for drug cases)</li> </ul> <p>The decision of the Case Review Panel will be carried on a majority vote. In the case of a tie in the voting, the Chair will have the casting vote.</p>
<p>Reports from and to</p>	<p>Bedfordshire Clinical Commissioning Group Governing Body</p>
<p>Frequency of meetings</p>	<p>4-8 weekly as required</p>

Unless otherwise agreed, the Panel will be governed by the standing orders and standing financial instructions of Bedfordshire Clinical Commissioning Group.



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