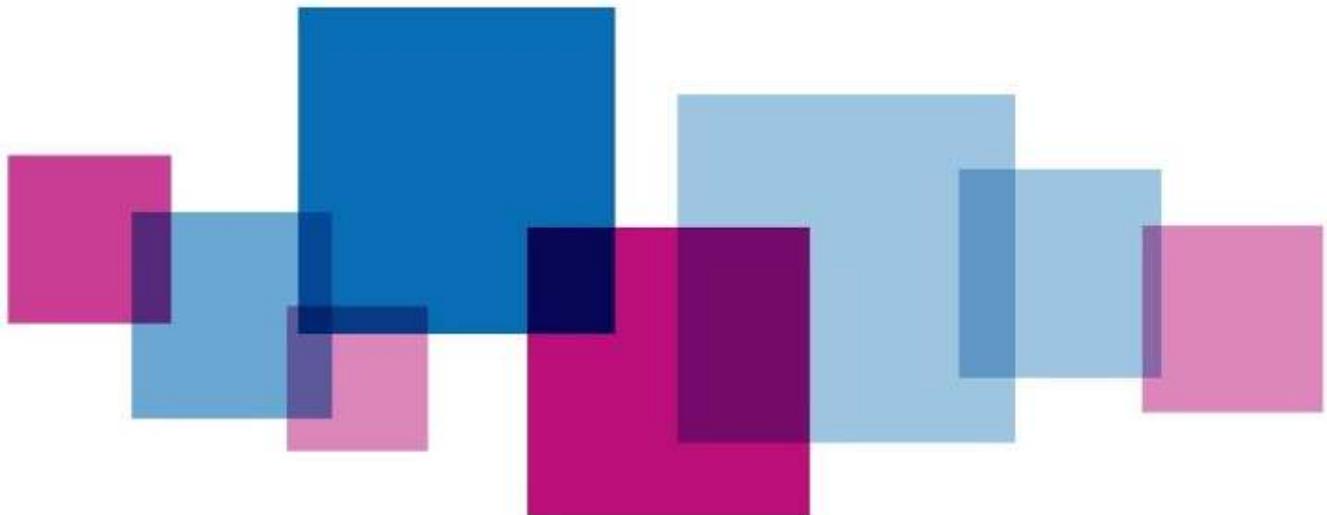




Bristol, North Somerset  
and South Gloucestershire  
Integrated Care Board



# Exceptional Funding Requests Policy and Procedures



April 2019  
Version 1920.2.01

<b>Policy reference no:</b>	I
<b>Responsible Executive Director:</b>	Director of Commissioning
<b>Author and Job Title:</b>	Exceptional Funding Senior Manager
<b>Date Approved:</b>	8 January 2019
<b>Approved by:</b>	BNSSG CCG Governing Body
<b>Date of next review:</b>	2022

## Equality statement

This document demonstrates NHS Bristol, North Somerset and South Gloucestershire ICB's commitment to create a positive culture of respect for all individuals, including staff, patients, their families and carers as well as community partners. The intention, in accordance with the Equality Act 2010, is to identify, and then remove or minimise discriminatory practice in the nine named protected characteristics of age, disability, sex, gender reassignment, pregnancy and maternity, race, sexual orientation, religion or belief, and marriage and civil partnership. The ICB complies with the Human Rights Act 1998 and seeks to promote positive equality practice, valuing the diversity of all individuals and communities.



# Contents

	Page
1. Overview of Exceptional Funding Requests	4
1.1 Purpose	4
1.2 What is an Exceptional Funding Request?	4
1.3 Eligibility for an Exceptional Funding Request	5
1.4 Decision-making criteria	7
2. Making an Exceptional Funding Request	9
2.1 Overview of the process	9
2.2 Who can apply	11
2.3 Application form	11
2.4 Initial screening of applications	12
2.5 Exceptional Funding Request Panel	14
2.6 Urgent or Fast-track Treatment Decisions	17
2.7 Retrospective and Part Funding	17
2.8 Timeframe for Exceptional Funding Requests	17
3. The Appeal Process	19
3.1 Complaints about the screening process	19
3.2 Appealing against a decision by the Exceptional Funding Requests Panel	19
3.3 Timeframe for the appeals process	22
Appendix 1 Glossary	23
Appendix 2 Ethical Framework for Decision Making	25
Appendix 3 Terms of Reference of the Exceptional Funding Requests Screening Group	26
Appendix 4 Terms of Reference of the Exceptional Funding Requests Panel	29
Appendix 5 Terms of Reference of the Exceptional Funding Requests Appeal Panel	31
Appendix 6 Definition and Examples of Clinical Exceptionality	35



# 1. Overview of Exceptional Funding Requests

## 1.1 Purpose

- 1.1.1 This document sets out NHS Bristol, North Somerset and South Gloucestershire Integrated Care Board's (ICB) Exceptional Funding Requests Policy and Procedures. It is designed to help clinicians, people using services and their supporters and ICB team members to understand the principles and approach the ICB uses to manage Exceptional Funding Requests (EFRs).
- 1.1.2 The policy will be applied consistently across Bristol, North Somerset and South Gloucestershire.
- 1.1.3 This section describes what an Exceptional Funding Request is and the criteria that the ICB uses to define 'exceptionality' and 'rarity'. Section 2 describes the approach the ICB uses to address Exceptional Funding Requests and Section 3 describes the approach the ICB uses for appeals against Exceptional Funding Request decisions. Appendix 1 provides a glossary of terms used in the document (signalled in bold within the document) and other appendices provide further detail about parts of the Exceptional Funding Request approach.
- 1.1.4 The NHS Commissioning Board and ICBs (Responsibilities and Standing Rules) Regulations 2012 and the NHS Constitution require commissioners to have a scheme for consideration of EFRs and this policy has been developed to support delivery of that service across Bristol, North Somerset and South Gloucestershire. This policy takes into account all relevant guidance and has benefitted from legal advice.

## 1.2 What is an Exceptional Funding Request?

- 1.2.1 The ICB is responsible for making the best use of the NHS funds allocated to it to meet the health needs of local people. The demand for services is greater than the money available and therefore the ICB must prioritise and make decisions about how to use funds carefully. The ICB uses national and local policies to make sure that the support, treatments, drugs and devices (from now on called '**Interventions**') it funds have a proven benefit in meeting the health needs of the population.
- 1.2.2 Where Interventions provide a limited benefit or are unusual or uncommon, they may not be routinely funded by the ICB. There are many reasons why the ICB may not fund an Intervention for the population, including but not limited to:
  - the ICB may not believe that there is enough evidence that the Intervention provides sufficient clinical benefit and/or value for money;
  - the ICB may not be aware of the need for the Intervention, particularly for rare conditions;
  - the ICB may fund the Intervention for a defined group of patients, where the ICB thinks there is most evidence of benefit or value for money, rather than the whole population.
- 1.2.3 The ICB understands that there may be exceptions to its rules. This policy sets out the ICB's mechanism to allow requests to be considered for funding for an individual for

Interventions that are not routinely commissioned for the population or a subgroup. These requests are referred to as '**Exceptional Funding Requests**'.

- 1.2.4 The ICB has adopted the National Prescribing Centre's 2009 definition of an Exceptional Funding Request:

*"An Exceptional Funding Request is a request to fund, for an individual, an episode of healthcare that currently falls outside existing contracts. The funding request may be asking for any type of healthcare: a service, a piece of equipment or aid, a specific treatment or medicine. In contrast to annual prioritisation and in-year service development decisions, appropriate Exceptional Funding Requests are considered on an individual patient, rather than population, basis. There are two main categories of appropriate Exceptional Funding Request: firstly, where patients fall outside an existing generic or treatment-specific policy where an unusual circumstance applies to the individual; secondly, for patients with a very rare clinical condition."*

(National Prescribing Centre/Department of Health - [Defining Guiding Principles for Processes supporting Local Decision Making about Medicines](#) 2009. This Centre became part of NICE, the National Institute for Health and Care Excellence, in 2011)

- 1.2.5 Making an Exceptional Funding Request is not the same as other routes that a clinician or patient may take to gain funding for an individual patient, such as requesting a Personal Health Budget or participation in a research study. An Exceptional Funding Request is governed by strict criteria as set out in Section 1.3.
- 1.2.6 The ICB will signpost clinicians and patients to appropriate routes for different types of funding requests.

### **1.3 Eligibility for Consideration as an Exceptional Funding Request**

- 1.3.1 To be eligible for consideration as an Exceptional Funding Request, a case needs to be made on medical grounds that the ICB should fund an Intervention for an individual that it does not fund for the whole population or a subgroup because:
- The specific patient has a medical condition or clinical presentation which is considered to be rare and the ICB, in all likelihood, accordingly has no explicit commissioning policy because this is not warranted by the low probability of the condition occurring among the ICB's population. (This is the criterion of 'Rare').

The ICB considers the criterion of Rarity to be satisfied where the patient has a medical condition or clinical presentation which is so uncommon that the ICB would not expect to see more than one other patient in the same or similar clinical circumstances in its geographical area within a 12 month period (unless the Similar Patients were from the same family group, which may occur in the context of a rare genetic disease).

### **OR**

- The ICB does not routinely commission the Intervention sought for the specific patient but that patient has circumstances which are clinically exceptional. There are two situations, broadly, where the ICB does not commission an Intervention routinely. These are where:
  - the ICB does not commission the Intervention for anyone with this condition; or

- the ICB commissions the Intervention for individuals who satisfy certain criteria but the specific patient does not fulfil those criteria.
- 1.3.2 The ICB has published many commissioning policies, both Intervention-specific and condition-specific. A great deal of time and resource goes into the creation of each policy. Where there is no published policy, the default position (in the absence of a statement to the contrary) is that the ICB does not routinely fund. If the Requesting Clinician is in any doubt about the ICB's commissioning position for a particular Intervention or condition, they should discuss this with speciality managers or contact the EFR team for advice initially.
- 1.3.3 Where the ICB does not routinely commission the Intervention sought for the specific patient, the Requesting Clinician may put forward a case that the patient is Clinically Exceptional by demonstrating that the patient is (a) significantly different in some clinical manner from the Cohort of patients with the same disease at the same stage of progression for whom the ICB does not fund the Intervention; and (b) likely to gain significantly more clinical benefit from the intervention than that Cohort. (This is the criterion of 'Clinical Exceptionality').
- 1.3.4 There can be no exhaustive description of Clinical Exceptionality or the situations which are likely to come within the definition of exceptional clinical circumstances. The onus is on the clinician making the request to set out the grounds for clinical exceptionality clearly for the EFR Panel.
- 1.3.5 'Exceptional', in EFR terms, is used to refer to a person to whom (or circumstances in which) the general rule should not apply. In this context the 'general rule' might be a policy that defines those patients who can access the Intervention or it may be that, where there is no policy governing the Intervention for this condition, in the interests of fairness to all patients the position is that it will not be commissioned ahead of policy development. In any situation of genuinely clinical exceptionality, there is likely to be something about the patient's clinical situation which was not considered when formulating the general rule, but which would justify a departure from that rule.
- 1.3.6 Very few patients have clinical circumstances which are genuinely exceptional. To justify funding a treatment for a patient which is not available to other patients, and is not part of the established care pathway, the EFR Panel needs to be satisfied that the clinician has demonstrated that this patient's individual clinical circumstances are clearly different from those of other patients and that, because of this difference, the general rule should not be applied. Simply put, the consideration is whether it is fair to fund this patient's treatment when the treatment is not available to others. It should be stressed that an EFR is not a route to "have another look" at the general rule, or to protest that the general rule is ungenerous.
- 1.3.7 Where a 'not routinely commissioned' clinical commissioning policy is in place in relation to a treatment, the ICB will have been aware when making that policy that, in most studies, some patients will respond better than others to the treatment and, indeed, a small group may respond significantly better than the average. This should have been taken into account in developing the policy. Consequently, in considering whether a request for exceptional funding should be made, the clinician should consider whether this individual patient is likely to respond to the treatment in a way that exceeds the response of other patients in the group to which the general policy or rule applies, and whether there is evidence to support this view.

- 1.3.8 Further clarification of the concept of Clinical Exceptionality is provided in Appendix 5, with the aid of NHS England's definitions and examples.
- 1.3.9 It is the ICB's policy not to accept Exceptional Funding Requests made on the grounds of personal or social circumstances. Only requests based on Clinical Exceptionality or Rarity are eligible to be considered as Exceptional Funding Requests. Personal and social circumstances or the impact of receiving an Intervention on such circumstances will not be taken into account.
- 1.3.10 The ICB will not consider as an Exceptional Funding Request a request for funding for an Intervention that might more appropriately be made available to a wider group (such as a newly licensed drug, for example). The ICB has a process for planning what it will fund each year for its population, known as the annual planning cycle, for such 'Service Developments'. In-year policy development may also occur, when required. In the event that the ICB receives an Exceptional Funding Request that is, in reality, a request for funding for an Intervention that would benefit a whole cohort of individuals in a similar position, the ICB will transfer the Request to be considered as part of wider 'Service Development' planning.
- 1.3.11 The ICB will not consider as an Exceptional Funding Request an Intervention already funded for the individual within an existing ICB commissioning policy, an Intervention for individuals outside the ICB's geographic area, an Intervention covered by another ICB policy such as NHS funding of Interventions after a clinical trial or an Intervention relating to the commissioning policy of another commissioner, e.g. NHS England.

#### **1.4 Decision-making criteria**

- 1.4.1 In deciding whether or not to grant an Exceptional Funding Request, the ICB will examine the extent to which all of the following criteria are met:
  - The application clearly demonstrates that the individual meets the Rarity criteria or the Clinical Exceptionality criteria as described in section 1.3.3.
  - The situation does not, in the opinion of the ICB, have relevance for a wider range of people than the named individual and thus potentially require a policy that meets the needs of the wider group (Service Development proposal).
  - The application clearly demonstrates that for the named individual the proposed Intervention is likely to be clinically effective.
  - The application clearly demonstrates that funding the Intervention is likely to offer value, in line with assessments of value made by the ICB using the Ethical Framework.
- 1.4.2 It is important to the ICB to demonstrate that it makes decisions based on sound principles and after careful consideration of all the relevant factors, with reference to local conditions, regulations and national policy, and with a conscious intent to avoid discrimination. The ICB has set out an 'Ethical Framework for Decision-Making' to guide what it does and does not fund for the population on an area-wide basis. The principles of this Ethical Framework are also used to guide decisions about funding for individuals, including Exceptional Funding Requests. Appendix 2 includes the Ethical Framework for Decision-Making.

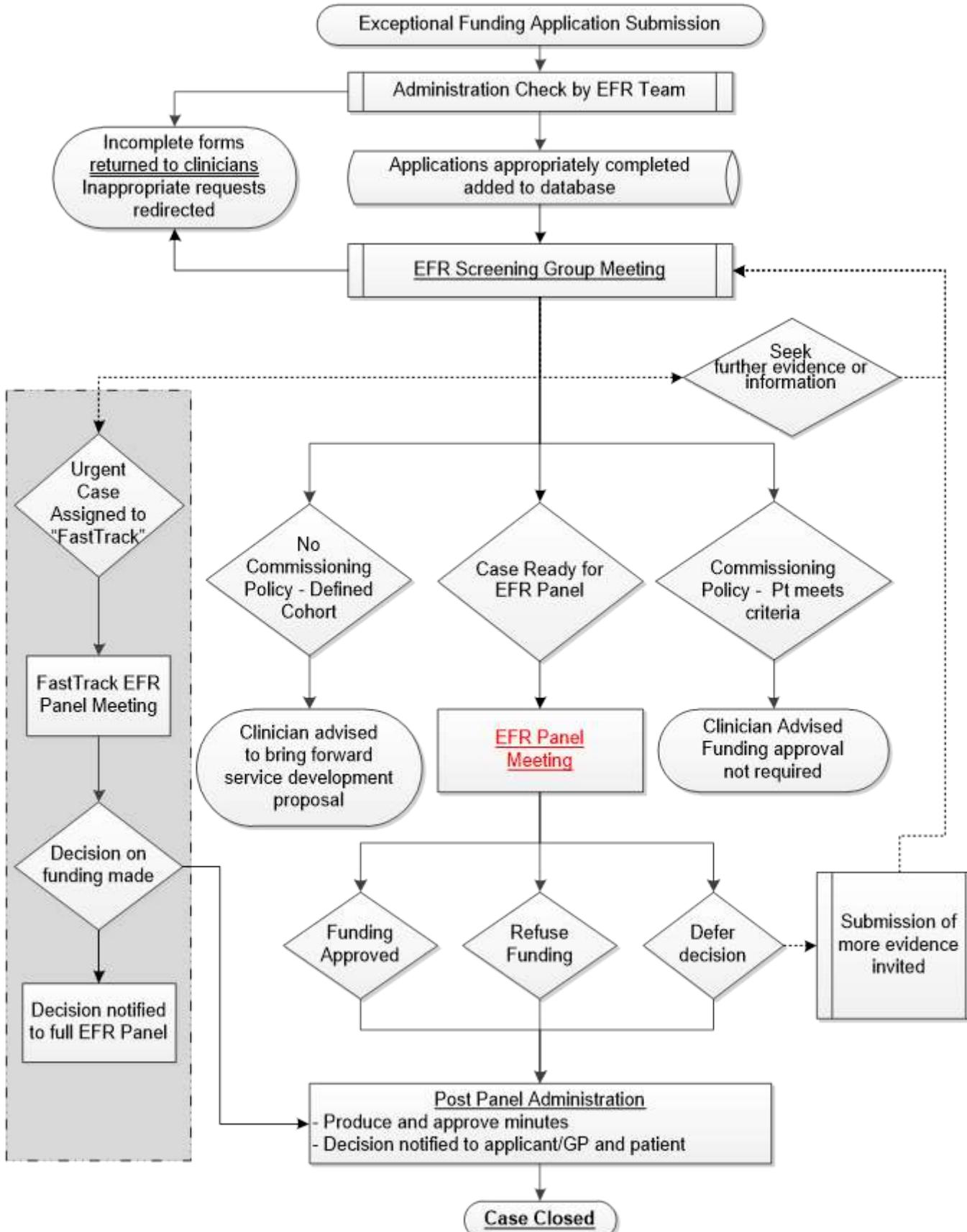
- 1.4.3 The ICB's Ethical Framework for Decision-Making highlights that the ICB should arrive at decisions through a fair and non-discriminatory process and this applies to Exceptional Funding Requests. For instance, it is the ICB's policy to make sure that Interventions are not funded through an Exceptional Funding Request for one individual that would not also be offered to all patients with equal clinical need.
- 1.4.4 The ICB uses a consensus method for decision-making in all aspects of the Exceptional Funding Request process, as set out in the Ethical Framework for Decision Making.

## 2. Making an Exceptional Funding Request

### 2.1 Overview of the process

- 2.1.1 The ICB's Exceptional Funding Requests process gives clinicians a clear route for making a case based on Clinical Exceptionality or Rarity that the ICB should consider funding an Intervention for an individual when that treatment is not routinely funded by the ICB for the population. Figure 1 sets out the process used.
- 2.1.2 The Exceptional Funding Requests process involves using a standardised application form, initial screening of eligibility to apply and the completeness of the information provided, an invitation to patients to contribute and full review of the application within six weeks.
- 2.1.3 At the completion of the decision making process, a letter setting out the decision and process followed will be issued to the applying clinician copied to the patient (unless there is an express request not to do so). Where the decision is not to fund the requested treatment, the letter will include details of the appeals process.
- 2.1.4 An Exceptional Funding Request can be withdrawn at any time by written notice from the clinician who made the application or from the patient.
- 2.1.5 The ICB is committed to making adequate resources available to support this process, including allocating a senior officer as the **Exceptional Funding Requests Lead**, allocating a **Clinical Lead**, making information available to patients and clinicians, assigning a team to undertake all administration for decision-making panels, training all personnel involved in the process, communicating about the process and making decisions in a timely manner.
- 2.1.6 Any enquiries about Exceptional Funding Requests, including eligibility criteria, the application process or progress about decisions should be made to the Exceptional Funding team at the ICB, full contact details of which are published on the ICB website.
- 2.1.7 It is the ICB's policy to provide information to patients and clinicians about the Exceptional Funding Request process and relevant contact details online and in writing. This includes making an easy to understand leaflet available about what the process involves and how patients can contribute; this is available in different formats and languages upon request.

Figure 1: Overview of Exceptional Funding Requests process



## **2.2 Who can apply?**

- 2.2.1 It is the ICB's policy to allow any clinician to make an Exceptional Funding Request for an individual patient whom they are treating or plan to treat. This clinician is deemed the '**Requesting Clinician**' and may be a consultant, GP or an equivalent autonomous NHS practitioner provided they will be responsible for recommending the Intervention for the patient.
- 2.2.2 The Requesting Clinician must make the patient aware that it may take some time before a decision on the Request can be made and, if the patient is considering privately funding the requested treatment in the interim, no retrospective reimbursement will be made even if the Exceptional Funding Request is approved.
- 2.2.3 It is the ICB's policy not to accept Exceptional Funding Requests directly from patients or their representatives, other than a Requesting Clinician. This is because Exceptional Funding Requests need to be based on Clinical Exceptionality or Rarity and their application thus requires medical expertise.
- 2.2.4 The ICB requires Exceptional Funding Requests to have been screened by the Provider's own systems before being passed to the ICB team. When an Exceptional Funding Request is submitted by a NHS consultant or equivalent practitioner, the ICB requires the submission to be approved by the designated representative of the Provider organisation. In the case of an Exceptional Funding Request for a drug, this is likely to be the Chief Pharmacist. For other treatments it may be the business manager of the department where the Intervention will be provided. Applications will be rejected if this appropriate approval is not supplied.
- 2.2.5 When an Exceptional Funding Request is submitted by a GP or other similar autonomous practitioner it is expected that they will have fully considered whether this is the correct process to use.

## **2.3 Application form**

- 2.3.1 The ICB requires the Requesting Clinician to complete an electronic application form for every Exceptional Funding Request so that the same level of relevant information is provided regardless of the nature of the Intervention or the individual's condition. The form is available on the ICB website.
- 2.3.2 It is the responsibility of the Requesting Clinician to ensure that all relevant and required information is submitted, including the argument and clinical evidence to support the case for Clinical Exceptionality or Rarity.
- 2.3.3 The application form must be signed by the Requesting Clinician to confirm that the clinician has:
- discussed alternatives to the requested Intervention with the patient;
  - discussed with the patient the most significant benefits and risks of the requested Intervention;
  - advised the patient that NHS Decision Making Aids are available online should the patient wish to access them at <https://www.england.nhs.uk/rightcare/useful-links/shared-decision-making/>
  - informed the patient that this Intervention is only funded by the ICB where Clinical

Exceptionality or Rarity is demonstrated and where it can be shown that the requested



Intervention is likely to be effective for the patient and offer value for the health and care system;

- confirmed that the patient or their representative has been informed of the details that will be shared for the purpose of decision making by the Exceptional Funding Requests Panel and explicit consent for this information sharing has been given. It is a legal requirement for fully informed consent to be obtained from the patient or a legitimate representative of the patient prior to disclosing their personal details;
- checked that the patient is happy to receive correspondence and contact from the ICB concerning the application;
- discussed with the patient any additional communication requirements when the ICB communicates with them.

2.3.4 The application form asks for personal and confidential information about the patient and the clinician, following explicit consent from the patient to share this information. All information will be treated in strictest confidence by the ICB and used only to support decision-making and to avoid any perceived or actual conflicts of interest amongst the decision-making panel.

2.3.6 Once the ICB has received and reviewed an application to ensure that it meets the criteria for consideration as an Exceptional Funding Request, the ICB will contact the patient to see whether they or an advocate of their choice would like to provide a patient statement for consideration by the Exceptional Funding Request Panel in conjunction with the clinical submissions. Patients will be offered the opportunity to provide their submission in writing or via a telephone call if preferred by the patient, whereby a ICB team member will write down a verbal statement made by the patient. Equal access to the ability to provide a submission to the Panel will be proactively promoted, with information and support given in different languages / formats as needed and on request. It will be made clear to patients that a decision about an Exceptional Funding Request will not be delayed to wait for a statement from a patient or their nominated representative. This is to ensure that decisions can be made about Requests in a timely manner.

## 2.3 Initial screening of applications

2.4.1 When an Exceptional Funding Request is received by the ICB, it is screened to make sure that it is eligible for consideration by the Exceptional Funding Request Panel and that all relevant information has been supplied. Upon receipt of a Request, the ICB's **Exceptional Funding Request Team** ('the Team') will check that funding of the Intervention requested is the responsibility of the ICB; that the ICB is the Responsible Commissioner for the patient; whether or not the ICB has a policy covering the Intervention; whether all appropriate parts of the form have been completed, including instructions for communicating with the patient and whether the application has been made by an appropriate party and approved by the Provider organisation, where relevant. If the application is not sufficiently complete, the team will return it to the Requesting Clinician for completion, using a standard letter, within 5 working days of receipt.

2.4.2 Following this initial check, the application will be allocated to a group responsible for screening Exceptional Funding Requests (hereafter referred to as the '**Screening Group**'). The role of the Screening Group is to filter out applications which are not appropriate to be put before the Exceptional Funding Requests Panel because the application should be determined through another process or where there is insufficient evidence to support a case on the grounds of Clinical Exceptionality or Rarity. In all cases, it is not the Screening Group's role to decide the merits of the case for Clinical Exceptionality or Rarity put forward by the Requesting Clinician, only to check that



evidence for such a case has been provided, as part of the application, for consideration by the Exceptional Funding Requests Panel. The group that screens the applications will be made up of the ICB's Exceptional Funding Requests Clinical Lead/Chair, another Exceptional Funding Requests Panel member and the ICB Exceptional Funding Requests managerial lead (or a suitable nominated deputy). Appendix 3 sets out the Terms of Reference for the ICB's Exceptional Funding Requests Screening Group.

- 2.4.3 Within seven working days of receipt of an Exceptional Funding Request, the Screening Group will:
- confirm that relevant clinical information has been included in the application or identify further information needed;
  - consider whether the application contains clear information about how the criteria for Clinical Exceptionality or Rarity may be met, as defined in Section 1.3.
  - decide whether the application requires an Urgent 'Fast-track' process or the standard Exceptional Funding Review process;
  - identify applications which may more appropriately be considered proposals for Service Development (policy for wider group of people) and direct those to the correct ICB process;
  - redirect inappropriate applications as required;
  - instruct the ICB team to contact the patient involved in an application deemed to be eligible for consideration by the Exceptional Funding Requests Panel to see whether they would like to provide a statement to support the application.
- 2.4.4 For the avoidance of doubt, the Screening Group will examine applications as follows:
- If the Request is for a medical condition for which the ICB has a commissioning policy, the Screening Group will determine whether the requested Intervention is within the categories that the ICB has agreed to fund for a patient in the applicant's clinical circumstances under the relevant commissioning policy. In this case an Exceptional Funding Request is not required and the Intervention will be approved as part of standard funding. If the patient is outside the group to which an existing ICB commissioning policy applies, the Screening Group will judge whether evidence has been provided for a case of Clinical Exceptionality or Rarity as defined in Section 1.3. If so, the application will be scheduled for consideration at the next available Exceptional Funding Requests Panel meeting. If not, the patient will be notified and the application returned to the Requesting Clinician with a clear explanation setting out why this has not progressed to the full Exceptional Funding Requests Panel.
  - If a Request is for a medical condition or Intervention where the ICB has no commissioning policy, the Screening Group will judge whether evidence has been provided for a case of Clinical Exceptionality or Rarity as defined in Section 1.3. If so, the application will be scheduled for consideration at the next available EFR Panel meeting. If not, the patient will be notified and the application returned to the Requesting Clinician with an explanation.
  - If the requested Intervention either expressly or by implication comes within the categories of Interventions which the ICB has decided not to commission routinely for a patient in the applicant's clinical circumstances under an existing ICB commissioning policy, the Screening Group will judge whether evidence has been provided for a case of Clinical Exceptionality or Rarity as defined in Section 1.3. If so, the application will be scheduled for consideration at the next available Exceptional

Funding Requests Panel. If not, the application will be returned to the Requesting Clinician with an explanation.

- As explained at 1.3.10, the ICB will not consider as an Exceptional Funding Request a request for funding for an Intervention that might more appropriately be made available to a wider group (such as a newly licensed drug, for example). In the event that the Screening Group receives an Exceptional Funding Request that is, in reality, a request for funding for an Intervention that would benefit a cohort of individuals in a similar position, the ICB will transfer the Request to be considered as part of wider ‘Service Development’ planning. Any existing commissioning position remains valid while any policy development work is undertaken.
- 2.4.5 The Screening Group may require that the Requesting Clinician, or other clinicians engaged in managing the patient, submits further relevant information and the timeframe within which it should be provided. Where the Screening Group decides that an application meets all the criteria to be considered by the Exceptional Funding Requests Panel, the Requesting Clinician and patient will be advised in writing that the application has been accepted and will proceed to the Panel. The letter will outline the timetable.
- 2.4.6 The Exceptional Funding Requests Team will maintain a record of all applications, noting the date received, the date scrutinised, the date returned, the outcome of screening and, where applicable, the outcome of full consideration.
- 2.4.7 The EFR Team will open an electronic file for each application referred to the Exceptional Funding Requests Panel. Paper copies of applications will not be maintained and any paper copies submitted will be confidentially destroyed. A unique reference number will be assigned to the application. Only the EFR Team will be able to link a unique reference number to the patient’s contact details.

## 2.5 The Exceptional Funding Requests Panel

- 2.5.1 The ICB has a pool of personnel that it draws on to make decisions about Exceptional Funding Requests. This is known as the **Exceptional Funding Requests Panel** (also referred to herein as ‘the Panel’). The Panel has been given authority by the ICB’s Governing Body to make decisions about Exceptional Funding Requests on its behalf. The Panel is responsible for deciding whether the requested Intervention should be funded or not, subject to the eligibility criteria and decision-making principles set out in Sections 1.3 and 1.4. Appendix 4 sets out the Terms of Reference for this Panel, which form a component of this policy.
- 2.5.2 The Panel includes a range of suitably qualified personnel who have received training to make decisions about Exceptional Funding Requests. The pool includes GPs, Public Health employees, ICB representatives, Medicine Optimisation Pharmacists and lay members.
- 2.5.3 All members must have attended induction training and be fully familiar with the ICB’s Exceptional Funding Requests Policy and Procedures outlined in this document before sitting on a Panel. Members will attend a training session at least once every year and sit on Panels at least twice per year in order to retain their expertise to serve. Annual training will cover, at minimum, the Exceptional Funding Requests Policy and Process, including Appeal; legal aspects of the work of the Exceptional Funding Requests Panel; healthcare ethics and applying the ICB’s Ethical Framework to Decision-Making; consensus decision-making; critical appraisal skills; methods of assessment for clinical and cost

effectiveness; confidentiality, data security, Caldicott principles and the requirements of the Data Protection Act, GDPR and the Freedom of Information Act; and the ICB complaints process.

- 2.5.4 Exceptional Funding Requests Panel members are required to declare any potential conflicts of interest before joining the Panel pool and at every meeting. Here conflict of interest means any activity, commitment, or interest that may (or may be perceived to) adversely affect, compromise, or be incompatible with the obligations of a Panel member. This includes but is not limited to situations where a financial or other interest could affect a Panel member's judgment, or a Panel member may have personal knowledge of an Exceptional Funding Requests patient. At the beginning of every meeting, the Chair will ask members to declare any relevant interests. Anyone declaring any interest may, depending on the nature of the interest, be instructed by the Chair not to take any part in any discussion or decision-making.
- 2.5.5 Panel members consider decisions as individuals rather than as representatives of their organisations.
- 2.5.6 The Panel meets monthly. The EFR Team is responsible for providing the agenda and all papers 5 working days prior to meetings.
- 2.5.7 Exceptional Funding Requests Panel meetings will be held in private and all discussions will be confidential. Requesting Clinicians or patients will not be invited to make representations in person. The Panel may ask specialists to attend the meeting to advise members during their deliberations, should they deem this to be necessary.
- 2.5.8 At least four members must be in attendance for Panel meetings to be quorate, including at least one clinically-qualified person and at least one lay person. Panel meetings will normally be chaired by any GP member provided they have been part of a Panel at least four times. The Chair must be identified in advance of the meeting and must be available to approve the minutes and fulfil any other obligations within the expected timeframe (see Section 2.6). Where the Chair of the Panel has a conflict of interest relating to any case, they will excuse themselves from the meeting and another suitably qualified and experienced member of the Panel will deputise for that case discussion.
- 2.5.9 In addition to Panel members, the ICB may call for specialist clinical, legal or other advice as appropriate in considering Exceptional Funding Requests. The ICB reserves the right to share applications with advisors as it deems appropriate.
- 2.5.10 In rare instances, the ICB's Screening Group may decide that a 'fast track' decision is required for an Exceptional Funding Request. This will only occur where there is a clear clinical reason to do so and is described further in section 2.6.
- 2.5.11 Whether the standard Panel process or a fast-track process is used, after considering each Exceptional Funding Request on its own merits, and applying the criteria set out in Sections 1.3 and 1.4, there will be four outcomes available for an Exceptional Funding Request:
  - the request will be funded without conditions;
  - the request will be funded with conditions attached;
  - the request will not be funded; or
  - the outcome will be deferred.

- 2.5.12 Requests may be approved for funding subject to conditions. For example, the Panel may require to be advised of the patient's status at an interim point before approving a second phase of treatment.
- 2.5.13 The Panel may decide to defer a decision because information called for before a meeting is not yet available or because the Panel members decide at the meeting that they need more information. The status of deferred applications must be reviewed within one month of the decision to defer. If the required information is still not available, the Panel may decide to defer a second time. The minutes of the meeting at which the second deferral is made must record detailed reasons why the application cannot be determined. A decision must be reached on all applications within three months of the date of the first decision to defer.
- 2.5.14 The minutes of a Panel meeting will be written up by the EFR team who will perform the role of secretary to the meeting and approved by the Chair within 5 working days of the meeting. Copies of the minutes will not be distributed to Panel members for their retention and will not be placed in the public domain. This is in the interests of preserving patient confidentiality, even though patient names will not be included in minutes. The relevant section of the minutes will be used to report back the decision and decision making process to the Requesting Clinician and patient in each case.
- 2.5.15 The EFR Team will communicate the Panel's decision to the Requesting Clinician and the patient in writing by a secure means. The wording used to describe the Panel's recommendations, conditions and rationales in the minutes will be translated exactly into the outcome letters. Any error or ambiguity in this wording is the responsibility of the meeting Chair. The recommendations of a Panel are attributable to the Panel as a whole.
- 2.5.16 Within 5 working days of the meeting, following the Chair's approval of the minutes, the EFR Team will:
- write to the Requesting Clinician to convey the Panel's outcome, any conditions attached to an approval, and whether the conditions require any interim report on the patient's status;
  - copy the correspondence to the patient or his/her representative to convey the Panel's outcome, provided the patient has indicated they wish to receive such letters;
  - notify the Panel's outcome to the appropriate ICB budget holder;
  - notify the Panel's outcome to the relevant business manager and/or other designated contact at the provider Trust, as appropriate; and
  - update the Exceptional Funding Requests database.
- 2.5.17 Patients and their Requesting Clinician will be able to request a copy of the minutes of the Panel meeting, but only text relating to their case will be disclosed in order to preserve the confidentiality of other cases heard at that meeting.
- 2.5.18 The EFR Team is responsible for storing minutes of meetings; documenting the decision, the reasons behind the decision and the consensus achieved; and for updating the Exceptional Funding Requests database. In keeping with the requirement of the Records Management Code of Practice for Health and Social Care 2016, Exceptional Funding Requests files will be kept electronically in archive for a minimum of 8 years. The EFR Team will report outcomes to the ICB's Quality Committee quarterly and to the Governing Body at least annually.

## **2.6 Urgent or “Fast-track” treatment decisions**

- 2.6.1 The ICB recognises that there will be occasions when an urgent decision needs to be made to consider approving funding for treatment for an individual patient outside the ICB’s normal policies. In such circumstances the ICB recognises that an urgent decision may have to be made before a Panel can be convened. The following provisions apply to such a situation.
- 2.6.2 An urgent request is one which requires urgent consideration and a decision because the patient faces a substantial risk of significant harm or death if a decision is not made before the next scheduled meeting of the EFR Panel.
- 2.6.3 Where an urgent decision needs to be made a Fast-track EFR Panel will be convened.
- 2.6.4 The Fast-Track EFR Panel will comprise a specially convened group acting as a sub-committee of the next scheduled Panel. The subcommittee will comprise four members of the Panel pool, including one lay member and one clinically-qualified person. One of the subcommittee must be suitably experienced in working with the EFR Panel to chair. The subcommittee will make a decision within 5 working days of the decision to fast track the Request. The subcommittee may confer by email and/or telephone and/or in person to facilitate this timeline. The decision of the subcommittee will be reported to and noted by the full Panel during its next scheduled meeting by way of review of the minutes
- 2.6.5 This Fast-track EFR Panel shall, as far as possible within the constraints of the urgent situation, follow the policy set out above in making the decision. The Fast-track EFR Panel shall consider the nature and severity of the patient’s clinical condition and the time period within which the decision needs to be taken. The Fast-track EFR Panel shall collect as much information about both the patient’s illness and the treatment as is feasible in the time available and shall consider the request for funding in accordance with the EFR Policy and EFR Panel Terms of Reference.
- 2.6.6 The Fast-track EFR Panel shall be entitled to reach the view that the decision is not of sufficient urgency or of sufficient importance that a decision needs to be made outside of the usual process.
- 2.6.7 Urgency under this policy cannot arise as the result of a failure by the Clinical Team to seek funding through the appropriate route in a timely manner and/or where the patient’s legitimate expectations have been raised by a commitment being given by the provider trust to provide a specific treatment to the patient. In such circumstances the ICB expects the provider trust to go ahead with treatment at no cost to the ICB.
- 2.6.8 Provider trusts must take all reasonable steps to minimise the need for urgent requests to be made through the EFR process.

## **2.7 Retrospective and Part Funding**

- 2.7.1 The Commissioner does not fund retrospectively, part-fund treatment or fund equipment ordered prior to the Panel’s approval.

## **2.8 Timeframe for Exceptional Funding Requests**

- 2.8.1 Table 1 sets out the target timeframes for each element of the Exceptional Funding Requests process.

Table 1: Time periods for stages of the Exceptional Funding Requests process

<b>Stage</b>	<b>Time Period</b>
Check application is complete – incomplete forms returned	Within 5 working days of receipt of completed form
Screening for appropriateness and level of urgency	Within 7 working days of receipt of completed form
Confirm acceptance or decline of submission to Requesting Clinician	Within 4 working days of screening
Redirect inappropriate requests	Within 6 working days of screening
Panel papers distributed in advance of scheduled meeting	At least 5 working days prior to scheduled meeting
Panel decision	Within one month of screening, or within three months if deferred
Fast track decision by Panel subcommittee	Within 5 working days of receipt
Minutes approved by Panel Chair	Within 5 working days of Panel meeting
Decision communicated to Requesting Clinician/patient	Within 5 working days of Panel meeting
Retention of documents electronically	At least 8 years



### **3. The Appeal Process**

#### **3.1 Complaints about the screening process**

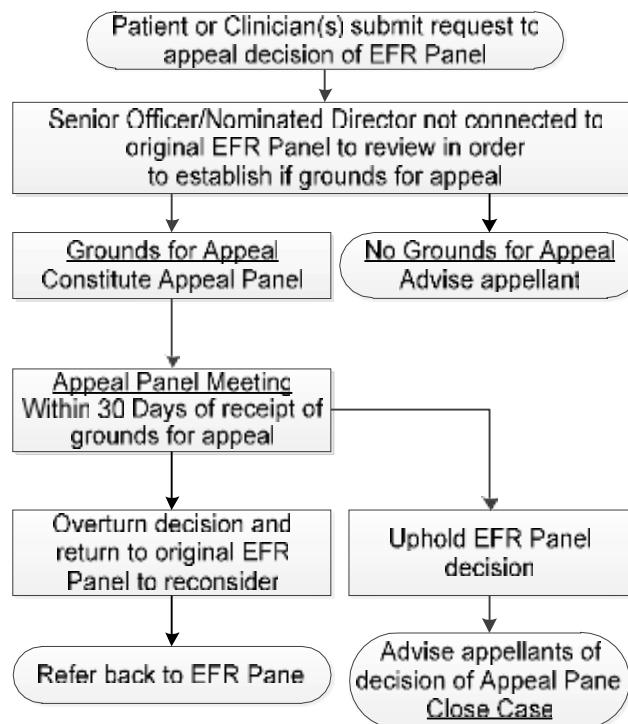
- 3.1.1 Any complaints about the processes used or outcome of the Exceptional Funding Requests screening process should be made through the ICB's complaints procedure. There is no standalone 'appeal' process for the screening process because screening is designed to check the extent to which an application is relevant and complete for consideration as an Exceptional Funding Request, rather than making any decision about the provision of funding. This means it falls under the same complaints procedure as all other ICB processes and procedures. Details of the ICB complaints procedure are available on the ICB website.
- 3.1.2 Requesting Clinicians may submit a new application for an Exceptional Funding Request that was rejected at screening or full consideration stage if new or additional information comes to light. This will be treated as a new Exceptional Funding Request and screened accordingly.

#### **3.2 Appeal against an Exceptional Funding Review decision**

- 3.2.1 The ICB allows patients and Requesting Clinicians to appeal against the decision made by the Exceptional Funding Requests Panel. The Appeal process is independent of the Panel process. Figure 2 sets out the Appeal process.
- 3.2.2 The ICB will provide details about the Appeal process and associated contact details in information for patients and clinicians, making sure this is distinct from contact details about the Exceptional Funding Requests process.
- 3.2.3 An Appeal Request must be lodged within 20 working days of the date that the Exceptional Funding Request decision letter was received. The ICB will acknowledge the Appeal within 5 working days.
- 3.2.4 Appeal requests can be made by:
- the clinician who submitted the Exceptional Funding Request;
  - the patient's GP (if different);
  - the patient;
  - a person with parental responsibility where the patient is a child under 16 years of age;
  - a person appointed with lasting power of attorney if the patient lacks the mental capacity to lodge an appeal themselves; or
  - a third party with the documented consent of the patient.

If the Requesting Clinician or GP lodges the appeal, s/he is required to confirm that s/he has discussed the Appeal process fully with the patient and is acting with his/her consent.

Figure 2: Appeal Process for Exceptional Funding Request Panel decisions



- 3.2.5 The request for an Appeal must be made in writing and should state the way(s) in which the decision is felt to be defective. Appeal requests submitted which do not clearly set out the grounds for appeal will be returned to the appellant who will be invited to resubmit their request stating their grounds for appeal. The ICB acknowledges the following Grounds for Appeal.
- The decision was inconsistent with the ICB’s Ethical Framework for Decision-Making.
  - The decision was inconsistent with the principles set out in this policy.
  - The Exceptional Funding Requests Panel did not act in accordance with the ICB’s operating procedures.
  - In reaching its decision the Exceptional Funding Requests Panel did not take into account or weigh up all the relevant factors in the information it was presented with.
  - In reaching its decision the Exceptional Funding Requests Panel took into account factors that may be argued to be irrelevant in the context of this policy.
  - The Exceptional Funding Requests Panel reached a conclusion that was not open to it on the evidence, acting as a reasonable Exceptional Funding Requests Panel.
- 3.2.6 Patients and/or Requesting Clinicians may not agree with decisions made by the Exceptional Funding Requests Panel. An Appeal request simply seeking to overturn a decision without clear Grounds for Appeal being demonstrated as outlined in 3.2.5 will not be considered.
- 3.2.7 A senior officer (Nominated Director) of the ICB, although not the Director of Commissioning, and a member of Exceptional Funding Requests Appeal Panel ('Appeal Panel') will review the original case papers, the minutes of the Exceptional Funding Requests Panel and the appeal letter to decide whether one or more of the Grounds set out in 3.2.5 may plausibly be advanced. The senior officer will not make a decision about the merit of the appeal, but will decide whether a case has been made in the appeal letter that one or more of the Grounds for Appeal may exist, so that there is a potential case for review.

3.2.8 An Appeal Panel will meet as needed to address any appeals received where it has been agreed that there is a potential case for review, normally meeting within 30 days of the date when the ICB receives the appeal letter. The Appeal Panel will be made up of designated individuals or roles rather than drawn from a pool. For each designation, a deputy will be nominated. All members will have experience with the work of the Exceptional Funding Requests Panel, be familiar with this document and have received appropriate training. During their membership of the Appeal Panel these individuals will not also sit as members of Exceptional Funding Request Panels. The Appeal Panel will comprise a minimum of three members, to include:

- a senior officer (Nominated Director) of the ICB, although not the Director of Commissioning, and
- a clinically-qualified member of the ICB who is also a member of the Commissioning Executive of the ICB and
- an Independent Member of the ICB.

It is expected that an Independent Member of the ICB will chair the Appeal Panel. The Appeal Panel may call for specialist legal or other advice as appropriate.

3.2.9 The Appeal Panel will meet in private. Patients and appealing clinicians will not attend the appeal meeting. The person appealing will be invited to provide a written submission which should contain only information about how the Exceptional Funding Requests process or decision is thought to be flawed by reference to the points in 3.2.5.

3.2.11 The Appeal Panel will receive all documents at least 5 working days before the appeal meeting. The Panel will review all the documents relating to the appeal, the original Exceptional Funding Request application and the Exceptional Funding Requests Panel's decision. All discussion during the Appeal Panel meeting will be confidential. Decisions will be made using a consensus decision-making process. The Appeal Panel may not defer its decision.

3.2.12 The Appeal Panel will not consider new evidence about a person's medical condition or the requested Intervention. If new or more detailed evidence becomes available after the Exceptional Funding Requests Panel decision not to provide funding, the Requesting Clinician may return the case to the Exceptional Funding Requests Panel to be reconsidered on the basis of the new evidence. The presence of new or more detailed evidence is not one of the Grounds for Appeal.

3.2.13 If the Appeal Panel finds that there are Grounds for Appeal as defined in Section 3.2.5 in the decision of the Exceptional Funding Requests Panel or the way that decision was reached, it will refer the original Request back to the Exceptional Funding Requests Panel for further consideration. If the Appeal Panel finds that the Exceptional Funding Requests Panel's decision or process was not flawed in any of the ways set out in 3.2.5, it will not uphold the Appeal. In either case, the reasons for the Appeal Panel decision will be clearly documented.

3.2.14 The Appeal Panel will not have the right to approve funding for the requested Intervention. A 'successful appeal' means that the request will be considered again by the Exceptional Funding Requests Panel, taking into account any specific issues highlighted by the Appeal Panel. The Appeal Panel can also recommend that reconsideration of the decision by the Exceptional Funding Requests Panel is fast-tracked.

- 3.2.15 Members of the Exceptional Funding Requests Panel whose decision is being appealed will have no contact with the work of the Appeal Panel unless called to give clarification or unless the case has been returned to the original panel for reconsideration.
- 3.2.16 In order to maintain separation between the Exceptional Funding Requests process and the Appeal process, an Appeal Panel Manager from within the EFR Team who was not involved with the original Exceptional Funding Requests Panel will be involved in the administration of the Appeal.
- 3.2.17 The Appeal Panel Manager will take formal minutes recording the decisions taken at the Appeal Hearing, the reasons for the Appeal Panel's decision and the consensus achieved. The minutes will be approved by the Chair within three working days of the meeting. The text of the minutes will be used in communicating the Appeal Panel's decision. In the interests of preserving patient confidentiality, copies of the minutes will not be distributed to Appeal Panel members for their retention and will not be placed in the public domain.
- 3.2.18 The decision of the Appeal Panel will be notified in writing and sent by secure means to the person appealing the decision and the patient within five working days of the meeting. If the Appeal Panel found no Grounds for Appeal and upheld the Exceptional Funding Requests Panel's decision, the patient and his/her clinician will be advised that any further recourse would be via the ICB's complaints process. If the Appeal Panel found Grounds for Appeal, the patient and his/her clinician will be advised that their Exceptional Funding Request will be reconsidered by the Exceptional Funding Requests Panel.

### **3.3 Timeframe for the Appeal process**

3.3.1 Table 2 sets out the expected timeframe for the Exceptional Funding Requests Appeal Process.

Table 2: Expected timeframe for stages of the Appeal Process

<b>Stage</b>	<b>Time</b>
Patient/clinician submits appeal in writing	Within 20 working days of receipt of letter communicating Exceptional Funding Requests Panel decision
Letter sent acknowledging appeal including invitation to submit written statement	Within 5 working days of receipt of letter of appeal
All further information to be received person appealing	Within 20 working days of acknowledgement letter
Panel papers circulated	No less than 5 working days before date of Appeal Panel meeting
Appeal Panel decision	Not more than 30 working days after the date of the acknowledgement letter
Minutes approved by Chair of Appeal Panel	Within 5 working days of the date of the meeting
Decision communicated to patients and/or clinician	Within 5 working days of the date of the Appeal Panel meeting
Electronic retention of documents relating to Exceptional Funding Requests Appeal	At least 8 years

# Appendix 1: Glossary

**Clinical circumstances** means the clinical features of the named patient's medical condition or the progression of the named patient's condition as opposed to the named patient's social or personal circumstances, which cannot be taken into account.

**Exceptional clinical circumstances** means that the patient is significantly different from the general population of patients with the condition in question at that stage of the condition's development; and the patient is likely to gain significantly more clinical benefit from the intervention than might be normally expected for patients with that condition at that stage of the condition's development. The fact that a treatment is likely to be efficacious for a patient is not, in itself, a basis for exceptionality.

An **Exceptional Funding Request** or 'Request' is a request received from an NHS clinician which seeks funding for a single identified patient for a specific Intervention where the ICB does not routinely fund that Intervention for the population or subgroup to which the patient belongs.

The **Exceptional Funding Requests Clinical Lead** is a named GP or other clinically-trained person assigned by the ICB to provide leadership support to the Exceptional Funding Requests process, including chairing Panel meetings.

The **Exceptional Funding Requests Lead** is a named, senior post holder of the EFR Team who has the ability to delegate responsibility to the Exceptional Funding Requests Manager (a manager within the team). The Lead and Manager have overall leadership responsibility for the operation of the Exceptional Funding Requests process in line with the policy and processes set out in this document and any additional requirements advised by the ICB's Governing Body or their representatives.

The **Exceptional Funding Requests Panel** or 'Panel' is the committee authorised by the ICB's Governing Body to make decisions on its behalf about Exceptional Funding Requests.

The **Exceptional Funding Requests Screening Group** or 'Screening Group' is a sub-group of the Exceptional Funding Requests Panel that screens applications for completeness and eligibility to apply prior to referring to the full Panel for review.

The **EFR Team** refers to the ICB team as a whole responsible for the administration and management of the ICB's Exceptional Funding Requests policy and process.

**Intervention** means any form of healthcare intervention for which funding has been requested by a clinician for an individual patient. Interventions may include, but are not limited to, drugs, treatments, devices, services and support.

An **Independent Member** is a person recruited from the general population of the ICB's geographic area who has received appropriate training in accordance with this policy but whom is not a ICB staff member, clinician or other professional stakeholder.

The **Requesting Clinician** in this policy refers to the clinician making the Exceptional Funding Request on behalf of a patient, who will administer the Intervention if funding is approved.

A **Service Development** is any aspect of healthcare which the ICB has not historically agreed to fund and which may require additional and predictable recurrent funding. The term refers to all



developments including new treatments, 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 workforce shortages and implementing legal reforms. The ICB's process for equitable priority setting dictates that potential service developments should be assessed and prioritised against each other within the annual commissioning round. Where investment is made outside of the annual commissioning round, such investment is referred to as an **in-year service development**.

**Similar Patients** are people within the population served by the ICB who have similar clinical circumstances to the individual for whom an Exceptional Funding Request is made and who could reasonably be expected to benefit from the requested Intervention to the same or a similar degree. The existence of Similar Patients may indicate that a Service Development policy position is required of the ICB.



# Appendix 2: Ethical Framework for Decision-Making

Final version to be inserted



# **Appendix 3: Terms of Reference for Exceptional Funding Requests Screening Group**

## **1. Purpose**

- 1.1. The purpose of the Exceptional Funding Requests Screening Group is to assess all Exceptional Funding Requests for their eligibility for consideration by the Exceptional Funding Requests Panel, in accordance with the Exceptional Funding Requests Policy and Procedures (“the Policy”).

## **2. Duties**

- 2.1. The Exceptional Funding Requests Screening Group will determine whether Exceptional Funding Requests applications have sufficient content and detail to proceed to an Exceptional Funding Requests Panel in accordance with the Policy.
- 2.2. The Exceptional Funding Requests Screening Group will ensure that applications that do not proceed for consideration by the Exceptional Funding Requests Panel are signposted to the most appropriate route, in accordance with the Policy and other ICB policies.
- 2.3. The Exceptional Funding Requests Screening Group will check each application to see whether the Requesting Clinician has put forward reasons for Clinical Exceptionality or Rarity as defined in the Policy. In all cases, it is not the Screening Group’s role to decide the merits of the case for Clinical Exceptionality or Rarity put forward by the Requesting Clinician, only to check that evidence for such a case has been provided, as part of the application, for consideration by the Exceptional Funding Requests Panel.

- 2.4. Eligible Exceptional Funding Requests will be forwarded for consideration at the next Exceptional Funding Requests Panel, providing sufficient information is available, in accordance with the Policy.

## **3. Accountability and Reporting**

- 3.1. The Exceptional Funding Requests Panel is accountable to the ICB Governing Body for ensuring that Exceptional Funding Requests are processed in accordance with the Policy. The Exceptional Funding Requests Screening Group is a sub-group of the Exceptional Funding Requests Panel.
- 3.2. Decisions of the Exceptional Funding Requests Screening Group will be reported to the Exceptional Funding Requests Panel at each of its meetings. Outcomes of the Exceptional Funding Requests Screening Group will be reported to the ICB Governing Body.
- 3.3. The EFR Team shall minute the proceedings of all meetings of the Exceptional Funding Requests Screening Group, including recording the names of those present and in attendance and decisions made.
- 3.4. All decisions made by the Exceptional Funding Requests Screening Group shall be recorded in writing, including clearly documenting the validity and relevance of the clinical evidence base and explaining fully the rationale for each decision.

#### **4. Membership and Chair**

- 4.1. The Exceptional Funding Requests Screening Group will comprise at least 3 of the following:
  - A GP;
  - A representative of Public Health;
  - Appropriately trained pharmacists from the Medicines Optimisation team;
  - Independent Members
  - ICB Commissioning Managers.
- 4.2. The Exceptional Funding Requests Screening Group will be chaired by the Exceptional Funding Requests Clinical Lead. If the Chair is absent from a meeting or absent temporarily on the grounds of a declared conflict of interest, those present shall select one of their number to act as Chair for the duration of the meeting.
- 4.3. The Exceptional Funding Requests Screening Group reserves the right to request the ad hoc attendance of any other member of ICB staff as it requires and to access specialist clinical or legal advice as it deems appropriate.

#### **5. Quorum**

- 5.1. Meetings of the Screening Group will be considered quorate if the Exceptional Funding Requests Clinical Lead, or their nominated deputy, and two other Exceptional Funding Requests Screening Group members are present, as long as one of the attendees is a clinician.

#### **6. Frequency**

- 6.1. The Screening Group will meet weekly, unless no applications are received, in which case the meeting shall be cancelled. Meetings can be either in person or by conference call.

#### **7. Notice of Meetings**

- 7.1. Unless otherwise agreed, notice of each meeting confirming the venue, time and date, together with an agenda of items to be discussed and supporting papers, will be forwarded to each member of the Exceptional Funding Requests Screening Group and any other person required to attend no later than two working days before the date of the meeting.
- 7.2. Meetings of the Exceptional Funding Requests Screening Group other than those regularly scheduled as above, will be notified by the EFR Team as Secretary of the Exceptional Funding Requests Screening Group at the request of the Chair. The agenda and papers for extraordinary meetings shall be forwarded to each Screening Group member no later than two working days before the date of the meeting.

#### **8. Complaints and Appeal**

- 8.1. Complaints or appeals about decisions of the Exceptional Funding Requests Screening Group will be handled through the relevant ICB Complaints Handling Policy and Procedures.

## **9. Conduct of Meetings**

- 9.1. Except as outlined above meetings of the Exceptional Funding Requests Screening Group shall be conducted in accordance with the provisions of Standing Orders, Reservation and Delegation of Powers and Standing Financial Instructions approved by the ICB and /or the EFR Team as appropriate.

## **10. Review**

- 10.1. The Terms of Reference of the Exceptional Funding Requests Screening Group will be reviewed at least annually.



# **Appendix 4: Terms of Reference for Exceptional Funding Requests Panel**

## **1. Purpose**

- 1.1. The Exceptional Funding Requests Panel considers whether the Intervention requested should be funded or not.

## **2. Accountability**

- 2.1. The Exceptional Funding Requests Panel is accountable to the ICB Governing Body.

## **3. Remit**

- 3.1. The Exceptional Funding Requests Panel will be entitled to approve requests for funding for Interventions for a named patient where the eligibility and decision-making criteria set out in the Exceptional Funding Requests Policy and Procedures are met. In brief, this means that all four of the following conditions are met:

- The Panel accepts that there is sufficient evidence to support either i) funding for an Intervention for a patient in connection with a rare presenting medical condition for which the ICB has no policy or (ii) funding for an Intervention which is not routinely funded, where the patient has demonstrated exceptional clinical circumstances.
- There is sufficient evidence to show that, for the named patient, the proposed treatment is likely to be clinically effective.
- The application clearly demonstrates that funding the Intervention is likely to offer value, in line with assessments of value made by the ICB using the Ethical Framework.
- The request for this patient is not, in reality, a request for a Service Development.

- 3.2. After reviewing Exceptional Funding Requests and applying the eligibility and decision-making criteria set out in the Exceptional Funding Requests Policy and Procedures, the decisions available to the Panel are that:

- the request will be funded without conditions;
- the request will be funded with conditions attached;
- the request will not be funded; or
- the decision is deferred because it cannot be determined at a certain Panel meeting on the information available.

## **4. Membership**

- 4.1. The Exceptional Funding Requests Panel will comprise a pool of suitably qualified and trained members such as:

- GPs, one of whom will be the Exceptional Funding Requests Clinical Lead and will normally chair the Exceptional Funding Requests Panel meetings;
- a representative of Public Health;
- pharmacists from the Medicines Optimisation team;
- Independent Members;
- ICB managers

- 4.2. Members of the Exceptional Funding Requests Panel serve as individuals engaged by the ICB and not as representatives of any particular organisation or interest group.
- 4.3. A member of the EFR Team will be in attendance at meetings to help administer meetings, but will not be a Panel member.

## **5. Training**

- 5.1. Panel members must take part in induction training and ensure that they are fully familiar with the Exceptional Funding Requests Policy and Procedures before sitting on a Panel.
- 5.2. Members should attend a training session on a yearly basis and sit on Panels at least twice a year in order to retain their qualification to serve on the Panel.

## **6. Quorum**

- 6.1. The Panel will be considered quorate if, at a minimum, four members are present, to include one Independent Member, one clinically-qualified person and one commissioner.
- 6.2. Panel meetings will normally be chaired by any GP member provided they have been part of a Panel at least four times. Where the Chair of the Panel has a conflict of interest relating to any case, they will excuse themselves from the meeting and another suitably qualified and experienced member of the Panel will deputise for that case discussion. However the Exceptional Funding Requests Panel may be chaired by any of the members provided that s/he has taken part in Exceptional Funding Requests Panel meetings at least four times.

## **7. Frequency**

- 7.1. The Exceptional Funding Requests Panel will sit monthly

## **8. Confidentiality**

- 8.1. Exceptional Funding Requests information will routinely be exchanged via secure NHS e-mail, letter or by telephone and will not be anonymised but will managed in full compliance with ICB and national information governance standards.

## **9. Reporting**

- 9.1. An Exceptional Funding Requests performance report will be submitted in accordance with defined key performance indicators to the ICB Quality Committee quarterly and to the ICB Governing Body at least annually.

## **10. Review**

- 10.1. The Terms of Reference of the Exceptional Funding Requests Panel shall be reviewed on an annual basis.

# **Appendix 5: Terms of Reference for Exceptional Funding Requests Appeal Panel**

## **1. Purpose**

- 1.1. To set out the process by which appeals against decisions made by the EFR Panel are considered.

## **2. Background**

- 2.1. The ICB has an agreed policy by which individual patient funding decisions are made for treatments falling outside of locally or nationally agreed commissioning policies. Such requests are considered by the Exceptional Funding Requests Panel (EFR Panel).
- 2.2. Provided that the ICB is satisfied that the referring practitioner and the relevant specialist have provided adequate information on all the issues identified in the policy, it will consider individual requests for care that is not normally funded through its EFR Panel.
- 2.3. Where the ICB, through the EFR Panel, has decided not to fund a particular procedure or treatment for an individual, it is open to the individual and/or their referring practitioner to request an appeal, where grounds for appeal exist.
- 2.4. This document sets out the process for handling appeals.

## **3. Remit**

- 3.1. The remit of the Appeal Panel is to review decisions made by the EFR Panel where it might reasonably be argued that the decision was not made in accordance with the Policy. The EFR Appeal Panel may review the decision of the EFR Panel if it can be demonstrated that the EFR Panel:
  - Made a decision that was inconsistent with the ICB's Ethical Framework for Decision-Making.
  - Made a decision that was inconsistent with the principles set out in this policy.
  - did not act in accordance with the ICB's operating procedures.
  - In reaching its decision did not take into account or weigh up all the relevant factors in the information it was presented with.
  - In reaching its decision took into account factors that may be argued to be irrelevant in the context of this policy.
  - The EFR Panel reached a conclusion that was not open to it on the evidence, acting as a reasonable EFR Panel.
- 3.2. The presence of new or more detailed evidence is not one of the Grounds for Appeal.
- 3.3. The EFR Appeal Panel shall have the following options:
  - Uphold the patient's appeal and return the case back to the original EFR Panel to reconsider the case.
  - Dismiss the appeal, and uphold the decision on the EFR Panel.

## **4. Authority**

- 4.1. The Appeal Panel is the final arbiter of a decision for the ICB and acts as a sub-committee of the Governing Body. This does not remove a patient's right to access the NHS complaints procedure and the Ombudsman in order to seek further redress.
- 4.2. The Appeal Panel is constituted to review the circumstances surrounding an individual case and is not authorised to review or formulate routine commissioning policy. Individuals who wish to raise concerns about a Commissioning Policy may approach the ICB's Customer Service team or formally pursue a complaint through the NHS Complaints process by writing directly to the ICB.

## **5. Membership**

- 5.1. Membership of the panel will comprise a minimum of three members, to include:
  - a senior officer (Nominated Director) of the ICB although not the Director of Commissioning, and
  - a clinically-qualified member of the ICB, and
  - an Independent Member of the ICB.
- 5.2. It is expected that the Independent Member will chair the Appeal Panel.
- 5.3. The Panel should not include any member who took part in the original funding decision. If any member of the Panel believes from the information provided, that they may have personal knowledge of the individual they should declare this to the Chair of the appeals panel who will then seek to replace them on the panel.

## **6. Training**

- 6.1. Panel members must take part in induction training and ensure that they are fully familiar with the Exceptional Funding Requests Policy and procedures before sitting on a Panel.

## **7. Access to External Advice**

- 7.1 The Appeal Panel may call for specialist legal or other advice as appropriate.

## **8. Quorum**

- 8.1. All members of the Appeal Panel must be present.

## **9. Frequency of Meetings**

- 9.1. The Panel will meet as required and will hear appeals within 30 working days of the letter of acknowledgement to the appellant, unless there are mitigating circumstances e.g., restricted availability of an independent expert where this is considered material to the decision making process. In the latter scenarios the appellant will be informed, in writing, of the delay and the reason for the delay and given an estimated timescale for their appeal being heard. In any event the appeal will be heard within 6 months of the request, unless there are extenuating circumstances.

## **10. Who may Appeal**

- 10.1 Appeal requests can be made by:
- the clinician who submitted the Exceptional Funding Request;
  - the patient's GP (if different);
  - the patient;
  - a person with parental responsibility where the patient is a child under 16 years of age;
  - a person appointed with lasting power of attorney if the patient lacks the mental capacity to lodge an appeal themselves; or
  - a third party with the documented consent of the patient.
- 10.2 If the Requesting Clinician or GP lodges the appeal, s/he is required to confirm that s/he has discussed the Appeal process fully with the patient and is acting with his/her consent.

## **11 Method of Making an Appeal**

- 11.1 Communication of a decision by the EFR Panel not to fund a procedure/treatment will include advice to the individual of their right to appeal. The letter will set out clearly the grounds upon which such an appeal will be considered and the process through which an appeal should be lodged.
- 11.1.1 Appeals should be made in writing to the ICB within 20 working days of the receipt of the letter communicating the Exceptional Funding Requests Panel decision. The Appeal should clearly state the grounds for the appeal.

## **12 Grounds for Appeal**

- 12.1 Patients and/or Requesting Clinicians may not agree with decisions made by the Exceptional Funding Requests Panel. An Appeal request simply seeking to overturn a decision without clear Grounds for Appeal being demonstrated will not be considered.
- 12.2 A senior officer (Nominated Director) of the ICB who is a member of the Commissioning Executive of the ICB and a member of Exceptional Funding Requests Appeal Panel ('Appeal Panel') will review the original case papers, the minutes of the EFR Panel and the appeal letter to decide whether one or more of the grounds for appeal may plausibly be advanced. The senior officer will not make a decision about the merit of the appeal, but will decide whether a case has been made in the appeal letter that one or more of the Grounds for Appeal may exist, so that there is a potential case for review.
- 12.3 In determining whether grounds for appeal are present the process will take into account whether the EFR Panel:
- The decision was inconsistent with the ICB's Ethical Framework for Decision-Making.
  - The decision was inconsistent with the principles set out in this policy.
  - The EFR Panel did not act in accordance with the ICB's operating procedures.
  - In reaching its decision the EFR Panel did not take into account or weigh up all the relevant factors in the information it was presented with.
  - In reaching its decision the EFR Panel took into account factors that may be argued to be irrelevant in the context of this policy.
  - The EFR Panel reached a conclusion that was not open to it on the evidence, acting as a reasonable EFR Panel.

12.4 In circumstances where during the appeal process new, relevant information that may have materially affected the decision of the EFR panel is presented, the case must be returned for reconsideration by the EFR Panel.

### **13 Confidentiality**

13.1 Exceptional Funding Requests information will routinely be exchanged via secure NHS e-mail, letter or by telephone and will not be anonymised but will managed in full compliance with ICB and national information governance standards.

### **14 Arrangements for the Hearing**

14.1 The Appeal Panel will meet in private. Patients and appealing clinicians will not attend the appeal meeting. The person appealing will be invited to provide a written submission which should contain only information about how the Exceptional Funding Requests process or decision is thought to be flawed by reference to the points in 12.3 of this Terms of Reference.

14.2 Patients are welcome to use advocacy services to assist in the presentation of their case, if they wish though this excludes legal representatives acting in their professional capacity.

14.3 A member of the original EFR Panel may be invited to attend the Appeal Panel hearing to outline what information was considered and to clarify the decision reached. The EFR Panel representative will be then asked to leave the Panel meeting, and will not be included in the decision making process, which will be undertaken by Appeal Panel members only.

14.4 The Appeals Panel will inform the patient, their GP and/or any relevant consultant (in writing) of the decision of the appeal panel within 5 working days of the appeal being heard.

### **15 Reporting**

15.1 Appeal Panel reports will be included in the Exceptional Funding Requests performance report will be submitted in accordance with defined key performance indicators to the ICB Quality Committee quarterly and to the ICB Governing Body at least annually.

### **16 Review**

16.1 The Terms of Reference of the Exceptional Funding Requests Appeal Panel shall be reviewed on an annual basis.

# Appendix 6: Definition and Examples of Clinical Exceptionality

These definitions and examples have been developed using the [NHS England Commissioning Policy: Exceptional Funding Requests](#)

## Clinical exceptionality: failure to respond to standard care

- The fact that a patient has failed to respond to, or is unable to be provided with, all treatment options available for a particular condition (either because of a co-morbidity or because the patient cannot tolerate the side effects of the usual treatment) is unlikely, on its own, to be sufficient to demonstrate exceptional clinical circumstances. There are common co-morbidities for many conditions. These considerations are likely to have been taken into account in formulating the general policy.
- Many conditions are progressive and thus inevitably there will be a more severe form of the condition – severity of a patient's condition does not in itself usually indicate exceptionality. Many treatments have side effects or contraindications, and thus intolerance or contraindication of a treatment does not in itself, usually indicate exceptionality.
- So, in order to support an EFR on the basis of failure to respond to standard care, the EFR 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, which lies outside the natural history of the condition and is not characteristic of the relevant group of patients with the condition. 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 within the group for whom it is already known that the usual treatment is not available or is not clinically effective. The fact that this particular patient falls into that group is unlikely to be a proper ground on which to base a claim that they are exceptional as an individual.
- As regards side effects, as an example, all patients who are treated with long-term high-dose steroids will develop side-effects (typical and well-recognised) and thus developing these side effects and wishing to be treated with something else does not make the patient exceptional.
- If the usual treatment cannot be given because of a pre-existing co-morbidity which is unrelated to the condition for which the treatment is being sought under the EFR or is not unusual in the relevant patient group or generally, the fact that the co-morbidity is present in this patient and its impact on treatment options for this patient is unlikely to make the patient clinically exceptional. As an illustration, some comorbidities are common in the general population, for example, diabetes which affects around 7% of adults, or asthma which affects at least 10% of the population. Diabetes and its treatments affect many other conditions; for example, steroids make glucose control more difficult. With any condition there will be a recognised proportion who also have a comorbidity which is common in the general population, and thus a patient cannot be exceptional by virtue of also having a comorbidity which is common in the general population.



- If the proposed intervention is thought to offer a benefit to patients in these groups generally (i.e. those with more severe disease or those with common co-morbidities), the question is whether there is sufficient justification, including consideration of factors such as clinical effectiveness of the treatment in question, likely value for money, priority and affordability, for making a change to the clinical commissioning policy that covers the patient pathway. In this way, an improvement can be made to that policy to benefit the whole subgroup of patients of which the requesting patient is potentially just one such person. This change needs to be considered as a service development and not as an EFR.

### **Clinical exceptionality: severity**

Should severity be cited by the requesting clinician as part of the argument for exceptionality, the application should make clear:

- Whether there is evidence that the patient's presentation lies outside the normal spectrum for that condition. Preferably, a recognised scoring or classification system should be used to describe the patient's condition;
- Whether there is evidence that the patient has progressed to a very severe form of the condition much more rapidly than the range of progression that is documented and usually observed within the natural history of the condition;
- How the patient is expected to benefit from the treatment sought and in what quantifiable way;
- That there is evidence that the impact of the condition on this patient's health is significantly greater than its impact on the rest of the patient group, e.g. the condition is usually a mild disease but the presenting case is an extremely severe presentation; and
- That there is a plausible argument that the severity of the condition is prognostic of good response to treatment.

### **Clinical exceptionality: genotypes**

- When the argument for clinical exceptionality is based on the patient having a specific genotype (genetic profile), the EFR Panel will require evidence of the prevalence of the genotype in the patient group. The applicant will need to show how the specific genotype would make the patient a) different from others in terms of clinical management and b) able to benefit from the treatment to a greater degree than others with the same or different symptoms of the condition.

### **Clinical exceptionality: multiple grounds**

- There may be cases where clinicians seek to rely on multiple factors to show that their patient's case is clinically exceptional. In such cases each factor will be looked at individually to determine (a) whether the factor is capable, potentially, of making the case exceptional and (b) whether it does in fact make the patient's case exceptional. One factor may be incapable of supporting a case of exceptionality (and should therefore be ignored), but it might be relevant on another factor. That is a judgment within the discretion of the EFR screening group and EFR Panel.
- If it is determined that none of the individual factors on their own mean that the patient's clinical circumstances are considered exceptional, the combined effect of those factors as a

whole will be considered. In this way a decision can be reached on whether the patient's clinical circumstances are exceptional, bearing in mind the difference between the range of factors that can always be found between individuals and the definitions used here of exceptional clinical circumstances.

### **Clinical Exceptionality: non clinical and social factors**

- The EFR process only considers clinical information. Although initially it may seem reasonable to fund treatment based on reasons grounded in a moral or compassionate view of the case or because of the individual's situation, background, ambition in life, occupation or family circumstances, these reasons bring into play a judgement of 'worthiness' for treatment. As a central principle, the NHS does not make judgements about the worth of different individuals and seeks to treat everyone fairly and equitably. Consideration of these non-clinical factors would introduce this concept of 'worth' into clinical decision making. It is a core value that NHS care is available - or unavailable - equally to all. Whilst everyone's individual circumstances are, by definition, unique and, on compassionate grounds, reasons can always be advanced to support a case for funding, it is likely that the same or similar arguments could be made for all or many of the patients who cannot routinely access the care requested.
- Non-clinical and social factors have to be disregarded for this purpose in order for the EFR screening groups and then EFR Panel, to be confident of dealing in a fair manner in comparable cases. If these factors were to be included in the decision making process, the ICB would not know whether it is being fair to other patients who cannot access such treatment and whose non-clinical and social factors would be the same or similar.
- Consideration of social factors would also be contrary to ICB's policy of non-discrimination in the provision of medical treatment. If, for example, treatment were to be provided on the grounds that this would enable an individual to stay in paid work, this would potentially discriminate in favour of those working compared to those not working. These are value judgements which the EFR screening group and EFR Panel should not make.
- Clinicians are asked to bear this Policy in mind and not to refer to social or non-clinical factors to seek to support the application for Exceptional Funding .