

Exceptional and Individual Funding Request Policy

Ratification Process

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| Lead Authors | Exceptional Cases Team Manager and Exceptional Cases Specialist Administrator |
| Developed by | Clinical Policies Programme Manager |
| Approved by | Fortnightly Review Panels: Drug and Non Drug Integrated Performance and Assurance Committee (IPAC) |
| Ratified by | CCG Governing Body |
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Document Control Sheet

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|--------------------------------------|---|
| Development and Consultation: | <p>Policy developed:</p> <ul style="list-style-type: none"> • to ensure a clear and transparent approach is in place for exceptional/individual funding request decision making; • provide reassurance to patients and clinicians that decisions are made in a fair, open, equitable and consistent manner. <p>The Fortnightly Review Panels and Integrated Performance and Assurance Committee were involved in the revision and approval of this document.</p> |
| Dissemination | <p>The policy is available to all CCG staff, independent contractors and members of the public via the CCG web site. Information about the policy is provided by email notification to GP Practices and secondary care commissioners and is also available as documentation associated with the main provider contracts.</p> |
| Implementation | <p>This policy is implemented by the Exceptional Cases Team and Funding Request Panels, and all clinicians, primary and secondary care, submitting an exceptional or individual funding request on behalf of their patient.</p> |
| Training | <p>Training on:</p> <ul style="list-style-type: none"> • Equality and Diversity • Information Governance • Case Law and European Community Law |
| Monitoring | <p>A record of policies is maintained by the Corporate Affairs Directorate, including details of when a policy is due for renewal.</p> |
| Review | <p>Fortnightly Review Panels will review this policy every 2 years or sooner if significant amendments are made.</p> |
| Links with other documents | <p>The policy should be read in conjunction with:</p> <ul style="list-style-type: none"> • CCG Clinical Policies - drug and non drug interventions: https://www.cambridgeshireandpeterboroughccg.nhs.uk/health-professionals/clinical-policies-and-thresholds/clinical-policies/ https://www.cambridgeshireandpeterboroughccg.nhs.uk/health-professionals-homepage/prescribing-information/ • Exceptional and Individual Funding Request Form – see Appendix 1 and available on the following web site: https://www.cambridgeshireandpeterboroughccg.nhs.uk/health-professionals/clinical-policies-and-thresholds/exceptional-and-individual-funding/ • The NHS Constitution (July 2015): https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/480482/NHS_Constitution_WEB.pdf • Cambridgeshire and Peterborough CCG Constitution March 2019: https://www.cambridgeshireandpeterboroughccg.nhs.uk/EasySiteWeb/GatewayLink.aspx?allId=4360 • EoE Prescribing Advisory Committee (PAC) Commissioning Policies: https://www.prescqipp.info/headline-areas/priorities-advisory-committee-pac (Note: not all policies are available unless registered and will shortly be reviewed.) • Ethical Framework to Support the Development of Clinical Policies: https://www.cambridgeshireandpeterboroughccg.nhs.uk/health-professionals/clinical-policies-and-thresholds/ |
| Equality and Diversity | <p>The CCG is committed to meeting its duties under the Equality Act (2010) by having due regard in all they do to the need to eliminate unlawful discrimination; advance equality of opportunity and to foster good relations across all protected groups.</p> <p>The Exceptional Cases Clinical lead and Team Manager have carried out an Equality Impact Assessment and concluded the document is compliant with the CCG Equality and Diversity Strategy.</p> |

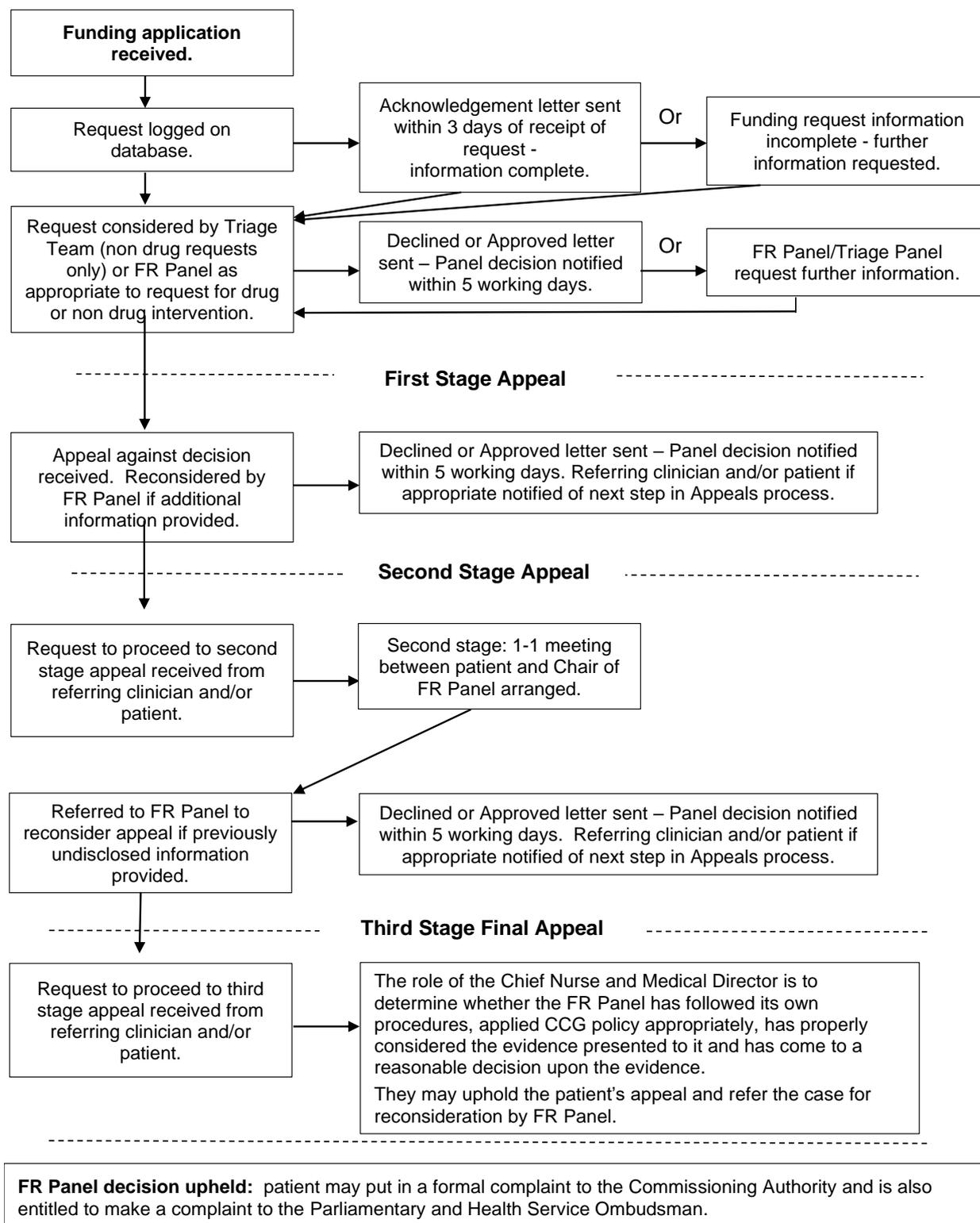
Revisions

| Version | Page/Para No | Description of Change | Date Approved |
|----------------|--------------------------|---|----------------------|
| 2 | Whole document | Consistency with Panel titles: Fortnightly Review Panels for Drugs and Non Drugs, Monthly Panel Meeting. | December 2013 |
| | Page 2, para 1.8 | Clarification that only clinicians are entitled to make a funding request on behalf of the patient to the Commissioning Authority | |
| | Page 5, para 7.2 | Note to reflect that the Fortnightly Review Panels have no lay membership. | |
| | Page 8 and 9, section 11 | Clarification of the appeals process. | |
| | Page 10, para 12.1 | Amendment to confirm NHS England are now responsible for administering the application process for patients seeking treatment abroad. | |
| 3 | Whole document | Document converted to CCG policy style. Equality Impact Assessment and flow chart of IFR process added to document | January 2014 |
| 4 | Whole document | Process review. | September 2015 |
| 5 | Whole document | Process review | September 2017 |
| 6 | Page 8, Para 5.1.5 | Added reference to the NHSE definition of 'exceptional' | November 2019 |
| 6 | Page 8, Para 5.1.6 | Increase of approval limit. | November 2019 |
| 6 | Page 9, Para 5.4.1 | Membership update | November 2019 |
| 6 | Page 16, Para 5.14.3 | Change to third stage appeal process to review by CCG Chief Nurse and Medical Director | November 2019 |
| 6 | Page 9, Para 5.6.1 | Clarification about which clinicians should be submitting the requests. | November 2019 |
| 6 | Page 24 | Edit to reflect new CCG telephone number on Funding Request Form. | April 2021 |

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Flow Chart of the Management of Exceptional and Individual Funding Requests



1. Introduction

Note: this policy uses the following terms:

- 'Commissioning Authority' to denote Cambridgeshire and Peterborough CCG.
- 'Funding request' to denote an individual funding request or exceptional funding request.
- 'Applicant' to denote the clinician providing NHS services making the funding request.
- 'Panel' to denote the Exceptional/Individual Funding Request Panel described in this policy as Fortnightly Review Panels (Drug and Non Drug).

- 1.1 The NHS Constitution for England (Updated March July 2015) informs patients of the following:

'Nationally approved treatments, drugs and programmes

Your rights

You have the right to drugs and treatments that have been recommended by NICE for use in the NHS, if your doctor says they are clinically appropriate for you.

You have the right to expect local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you, they will explain that decision to you.'

- 1.2 This Policy, applies to all patients registered with a Cambridgeshire and Peterborough GP in the CCG geographical area and covers those treatments and services which are within the commissioning responsibility of the CCG. It sets out:

- The arrangements to consider funding requests that do not fall within existing contracts or are considered low priority.
- The processes in place to respond to these requests and appeals.
- The structure and function of the Exceptional and Individual Funding Team.

- 1.3 A doctor or other health care professional directly involved in the care of a patient can make a request for funding to support a health care intervention which is outside of the CCG's established policies on one of two grounds, namely:

- Individual Funding Request; **or**
- Exceptional Funding Request.

2. Equality Statement

- 2.1 Cambridgeshire and Peterborough CCG is committed to meeting its duties under both: The Equality Act 2010 and The Equality Act Public Sector Duty 2011. This means we will have due regard to eliminating unlawful discrimination, advancing equality of opportunity and fostering good relations for people who share characteristics protected by The Equality Act.

- 2.2 NHS Cambridgeshire and Peterborough CCG consider each individual within our populations to be of equal value. We will not discriminate between individuals or groups on the basis of any protected characteristics. However, where treatments have a differential impact as a result of age, disability, sex or other characteristics of the patient, it is legitimate to take such factors into account.

3. Purpose and Scope

- 3.1 Requests for such non-commissioned care usually come under Exceptional and Individual Funding Requests and this policy is designed to provide assurance that the Commissioning Authority processes are compatible with the requirements in the NHS Constitution.
- 3.2 The Commissioning Authority has adopted the East of England Priorities Advisory Committee commissioning policies to inform processes for handling Exceptional and Individual Funding Requests consistently.
- 3.3 Monitoring and reporting on Exceptional Funding Requests is as follows:
- Bimonthly reporting to the Integrated Performance & Assurance Committee (IPAC).
 - Reporting by IPAC to the CCG Governing Body.

4. Duties and Responsibilities

- 4.1 This policy applies to any patient for whom the Commissioning Authority is the Responsible Commissioner. As such, the Commissioning Authority is responsible for commissioning services to meet the health needs of its population and is required to commission services which are evidence based, clinically and cost effective, improve health outcomes and reduce health inequalities whilst representing value for money.
- 4.2 Patients will be considered on the grounds of exceptionality if routinely commissioned treatments would not be appropriate.
- 4.3 This policy will ensure a clear and transparent process is in place for decision making and provide reassurance to patients and clinicians that decisions are made in a fair, open, equitable and consistent manner.

5. Guidance

5.1 Definitions

- 5.1.1 **An individual funding request (IFR)** is a request to a CCG to fund healthcare for an individual who falls outside the range of services and treatments that the CCG has agreed to commission.
- 5.1.2 In IFR cases, the patient is suffering from a presenting medical condition and the Commissioning Authority has no policy for the treatment requested.

- 5.1.3 **An exceptional funding request (EFR)** is a request where a patient is deemed to have *exceptional clinical circumstances*, ie a patient who has clinical circumstances which, taken as a whole, are outside the range of clinical circumstances presented by a patient within the normal population of patients with the same medical condition and at a similar stage of progression as the patient.
- 5.1.4 In EFR cases, the patient is suffering from a presenting medical condition for which the Commissioning Authority has a policy for the medical condition and/or its treatment, but where the patient's particular clinical circumstances fall outside what the Commissioning Authority has agreed to fund ('an exceptionality request; an exception to the policy').
- 5.1.5 NHSE (Commissioning Policy: Individual Funding Requests 2017) describe 'Exceptional' in funding request terms to mean a person to whom the general rule should not apply. In this context the 'general rule' might be a policy that describes those patients who can access the intervention (EFR) or it may be that there is no policy governing the treatment (IFR), in the interests of fairness to all patients, the position is that it will not be commissioned ahead of policy development. This implies that there is likely to be something about their clinical situation which was not considered when formulating the general rule. Very few patients have clinical circumstances which are genuinely exceptional.
- 5.1.6 **The Exceptional and Individual Funding Request Panel (the Panel)** is a committee of the Commissioning Authority that has been authorised by the Commissioning Authority's Governing Body to take decisions on its behalf on exceptional and individual funding requests up to a delegated amount of £20,000, per treatment within any 12-month period. Funding requests over the delegated amount will be referred to the CCG's Chief Nurse and Medical Director to consider the Panel's recommendations. Any requests exceeding £25,000 will also need to be approved by the CCG's Chief Finance Officer.
- 5.1.7 In considering the funding requests, the Panel will aim to:
- Promote consistency, fairness and equity.
 - Ensure effective use of resources, but also ensure that the decisions are based on clinical evidence and not solely on budgetary constraints.
 - Improve the rigour of the processes ensuring decisions are rational, reasonable and transparent.

5.2 Structure and Membership of the Exceptional Cases Office Team

- 5.2.1 The Exceptional Case Office Team will be managed by the Clinical Policies Programme Manager and staffed as follows:
- Exceptional Cases/IFR Manager.
 - Exceptional Cases/IFR Specialist Officer.
 - Exceptional Cases/IFR Senior Administrative Support Officer.
 - Exceptional Cases/IFR Team Administrator
- 5.2.2 The Exceptional Cases Office Team will be responsible for the administration of funding requests that are presented to Panel, eg managing the funding request database, preparing the paperwork for various Panel meetings, dealing with correspondence, etc.

5.3 Structure and Membership of the Non Drugs Triage Team

Triage of applications will be conducted by the following at all times

- Clinical Policies Programme Manager or Exceptional Cases/IFR Manager.
- Clinical Lead for EC/IFR.
- GP Member.

5.4 Structure and Membership of Fortnightly Review (FR) Panels

5.4.1 Membership of FR Drugs and Non Drugs Panels:

| FR Non Drugs Panel | FR Drugs Panel |
|--|--|
| <ul style="list-style-type: none">• Chair of the Panel – Clinical Lead for EC/IFR Requests - GP Member• Deputy Chair - GP Member• Public Health Research Officer• Clinical Policies Programme Manager• Exceptional Cases/IFR Manager• Exceptional Cases/IFR Specialist Officer• Exceptional Cases/IFR Senior Administrative Support Officer• Exceptional Cases/IFR Team Administrator | <ul style="list-style-type: none">• Chair of the Panel – Clinical Lead for EC/IFR Requests - GP Member• Deputy Chair - GP Member• Public Health Research Officer• Specialist Pharmacist (Medicines Optimisation representative)• Clinical Policies Programme Manager• Exceptional Cases/IFR Manager• Exceptional Cases/IFR Specialist Officer• Exceptional Cases/IFR Senior Administrative Support Officer• Exceptional Cases/IFR Team Administrator |

5.4.2 Quorum - FR Drugs and Non Drugs Panels

Non Drug Panel

As a minimum the Panel should have four members in attendance; at least two clinically qualified.

Drug Panel

As a minimum the Panel should have four members in attendance; at least two clinically qualified, one of which will be a GP member (Chair or Deputy Chair) and a pharmaceutically qualified member (Specialist Pharmacist or representative).

5.5 One to One Appeal Meeting

One to One Appeal Meetings are held between the Chair or Deputy Chair of the Fortnightly Review Panel (Clinical Lead or GP Member) and the patient – the patient may be accompanied by a family member or representative. The EC/IFR Manager or EC/IFR Specialist Officer will be in attendance to take notes.

5.6 Applications to the Exceptional and Individual Funding Request Panel

5.6.1 The application must be made by a clinician providing NHS services and the funding request should be in support of a treatment by that clinician or an onwards referral by that clinician. The responsibility to make an application sits with the clinician who identifies that a patient needs a procedure requiring exceptional funding.

5.6.2 All applications to the Panel must be on an approved request form:

- exceptional and individual funding requests using the Exceptional and Individual Funding Request Form – see Appendix 1; or
- exceptional request using the relevant policy referral proforma – see Appendix 2.

Details on completion and on where to send the form/referral proforma are available on the front of each. It is important that Applicant's ensure that the patient consent section of the form is fully completed, acknowledging that the patient is fully aware of a request for funding being raised on their behalf and the appropriateness for the patient to be informed of the Panel decision by the Panel Office Team. Where it is not appropriate, it is the responsibility of the Applicant to inform the patient of the outcome.

- 5.6.3 Written support and evidence should be provided by the clinical team treating the patient using the request form and explaining:
- a. Whether the request is an individual funding request or an exceptional funding request.
 - b. The clinical circumstance of the patient.
The Clinical Team are required to present a full report to the Panel which sets out a comprehensive and balanced clinical picture of the history and present state of the patient's medical condition, the nature of the treatment requested and the anticipated benefits of the treatment.
 - c. The planned treatment and the expected benefits and risks of treatment.
The Clinical Team should describe the anticipated clinical outcomes for the individual patient of the proposed treatment and the degree of confidence of the Clinical Team that the outcomes will be delivered for this particular patient.
 - d. The evidence on which the clinical opinion is based.
The Clinical Team should refer to, and include, copies of any clinical research material which supports, questions or undermines the case that is being made that the treatment is likely to be clinically effective in the case of the individual patient.
 - e. The Costs of Treatment.
The Clinical Team should set out the full attributable costs and connected costs of the treatment. The Panel should be entitled, but not obliged, to commission its own reports from any duly qualified or experienced clinician or other duly qualified person concerning the full attributable costs of and connected to the treatment.
 - f. Are there likely to be similar patients within the local population?
For exceptionality requests the Applicant must also provide the case for treating this patient and no other apparently similar patients.
 - g. Any other clinical information to support the case.
- 5.6.4 Information that is immaterial to the decision, including information about the social or personal circumstances of the patient which does not have a direct connection to the patient's clinical circumstances, shall not be considered by the Panel.
- 5.6.5 The Commissioning Authority and/or the Panel shall routinely screen individual funding requests to see whether they represent a service development. The key question used to screen out as a service development will be 'are there likely to be other similar patients in the Commissioning Authority or East of England?' If there is evidence that this patient is representative of other similar patients, the individual funding request will be sent back to the provider with a request to follow normal procedures for introducing new services, in line with the Commissioning Authority Commissioning Principles.
- 5.6.6 Retrospective exceptional/individual funding requests (requests from providers made after an episode of care has commenced) and approved by Panel will be funded from the date of Panel approval.

5.6.7 Requests from patients for reimbursement of costs of a treatment which has been purchased privately will not be accepted for retrospective funding.

5.7 Co-operation of Provider Trusts

5.7.1 The Commissioning Authority requires provider trusts and clinicians to take the commissioning policies of the Commissioning Authority into account in the advice and guidance given to patients prior to making the decision to treat a patient, as set out in the NHS Contract.

5.7.2 The Commissioning Authority expects the provider trusts to have oversight of this process. The Commissioning Authority would expect every exceptional and individual funding request to be sanctioned by a provider authorised clinician before sending it to the Commissioning Authority and reserves the right to refer recurrent inappropriate funding requests to the Chief Executive of the relevant provider trust.

5.7.3 The CCG expects consultants to refer patients for specialist care using established pathways covered by contract agreements and in line with national guidance on patient choice. Request for referrals to specialist providers for treatment outside the normal patient pathway will usually only be considered after an assessment by an appropriate specialist clinician. Should the specialist clinician decide that a referral outside the normal pathway is a priority for a particular patient, then the specialist must submit a funding request form to the EC Panel for consideration.

5.8 Process for Considering Funding Requests

5.8.1 On receipt of the funding request, the case is recorded on the exceptional/IFR cases administrative database and an acknowledgement is sent to the Applicant within three working days.

5.8.2 The Exceptional Cases Office Team will verify whether sufficient information is included in the request form and ask the Applicant for more information if required.

5.8.3 Once it is clear that all necessary clinical information on the case is available, in the interests of confidentiality of patient information, the office staff will prepare an anonymised case summary file of the funding requests to be considered by the Panel. Case summary files are sent to FR Panel members on the Friday before the regular Panel meeting. The deadline for receipt of requests from applicants is 12 noon on the Friday before the Panel meeting.

5.9 Clinical Triage Panel (Non Drug Requests)

Note: Drug funding requests are not subject to initial clinical triage and are referred to FR Drug Panel for consideration unless notified as urgent – see 5.10.

5.9.1 The purpose of triage is to determine if the application is eligible to go the FR Panel or if a decision can be made without recourse to the full panel. The Clinical Triage Panel will consider the cases via the online database portal. GP and EC Team representation will be required to confirm decisions for quoracy.

5.9.2 The Clinical Triage Panel will consider the following options:

- Approve the request based on the clinical evidence provided without reference to the FR Non Drug Panel.
- Decline the request without reference to the FR Non Drug Panel.
- Refer to the FR Non Drug Panel.
- Request further information.

5.9.3 Triage approved non drug funding requests will be reported at each non drug FR Panel for governance purposes.

5.10 Fortnightly Review (FR) Panel Meetings for Drugs (High Cost Drugs) and Non Drugs

5.10.1 Funding requests will be considered fortnightly by the non-drugs and the high cost drugs review panels. The cases will be reviewed and decisions taken using the same methodology as detailed in this policy, and will make one of the following decisions:

- Approve the funding request.
- Decline the funding request.
- Defer the funding request and ask for more information from the referring clinician.
- Reassess the funding request on appeal.

5.10.2 The case summary file and additional notes taken at the Panel meeting will form the minutes for these cases.

5.10.3 The Commissioning Authority expects and empowers the FR Panels to make decisions and act on most cases (see 5.1.5). The FR Panel decisions will be sent to the Applicant, and/or the GP, and/or the patient - providing consent has been provided by the clinician - within 5 working days of the meeting. If the FR Panel decides not to fund a drug or treatment the decision letter will include an appropriate explanation.

5.11 Approval of Funding Requests

5.11.1 The FR Panel shall be entitled to approve **individual funding requests** where all the following conditions are met:

- The FR Panel concludes that there are likely to be no similar patients to the requesting patient. The FR Panel is not authorised to make case by case decision making for service developments.
- There is sufficient enough evidence to show that, for the individual patient, the proposed treatment is likely to be clinically effective and cost-effective.

5.11.2 The FR Panel is not required to accept the views expressed by the patient or the clinical team concerning the likely clinical outcomes for the individual patient of the proposed treatment. The FR Panel is entitled to reach its own views on the likely clinical outcomes for the individual patient of the proposed treatment; and the quality of the evidence to support that decision and/or the degree of confidence that the FR Panel has about the likelihood of the proposed treatment delivering the proposed clinical outcomes for the individual patient.

5.11.3 The FR 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 individual patient.

- 5.11.4 The FR Panel shall be entitled to approve **exceptional funding requests** where the following condition is met:
- The FR Panel concludes that the criteria for exceptionality in the context of the relevant commissioning policy/policies and guidance note(s) have been met.
- Note:** All applications will be reviewed against the relevant policy in place at the time the application was received.
- 5.11.5 In determining whether a patient is able to demonstrate exceptional circumstances the FR Panel shall compare the patient to other patients with the same presenting medical condition at a similar stage of progression. The applicant needs to demonstrate that the patient is likely to gain significantly more benefit from the intervention than might normally be expected for patients with that condition. The FR Panel shall determine, based upon the evidence provided to the panel, whether the patient has demonstrated exceptional clinical circumstances. The evidence to show that, for the individual patient, the proposed treatment is likely to be clinically effective may be part of the case that the patient's clinical circumstances are asserted to be exceptional.
- 5.11.6 In deciding whether to approve funding, the FR Panel shall remind itself that the policies of the Commissioning Authority provide that medical treatment is made available to patients generally on the basis of their presenting medical conditions and on the likely benefits anticipated to accrue to a patient from a proposed treatment.
- 5.11.7 The Commissioning Authority does not discriminate on grounds of sex, age, sexual orientation, ethnicity, educational level, employment, marital status or religion. The Commissioning Authority does not generally make treatment for patients under its policies dependent on the patient's social or personal circumstances. Accordingly, when making decisions as to whether treatment should be provided to a patient which is not provided to patients generally, the Panel shall adopt the same approach.
- 5.11.8 The Panel shall take care to avoid adopting the approach described in the 'the rule of rescue'. The fact that a patient has exhausted all NHS treatment options available for a particular condition is unlikely, of itself, to be sufficient to demonstrate exceptional circumstances. Equally, the fact that the patient is refractory to existing treatments where a recognised proportion of patients with the same presenting medical condition at this stage are, to a greater or lesser extent, refractory to existing treatments is unlikely, of itself, to be sufficient enough to demonstrate exceptional circumstances.
- 5.11.9 The FR Panel will consider whether treating the patient is higher priority than other unfunded developments and the treatment can be afforded.
- 5.11.10 The FR Panel shall have a broad discretion to determine whether the proposed treatment is a justifiable expenditure of the Commissioning Authority resources. The FR Panel is, however, required to bear in mind that the resources requested to support the individual patient will reduce the availability of resources for other investments.
- 5.11.11 The FR Panel may make such approval contingent on the fulfilment of such conditions as it considers fit. Very occasionally an individual funding request presents a new issue which needs a substantial piece of work before the Commissioning Authority can reach a conclusion upon its position. This may include wider consultation. Examples in the past have included surrogacy and aspects of genetic testing. Where this occurs the FR Panel may adjourn a decision on an individual case until that work has been completed.

5.11.12 The Panel will not consider requests for interventions that would be provided under the NHS England Specialised Commissioning arrangements. This policy operates in line with the NHS England Standard Operating Procedures:

NHS England Standard Operating Procedures: Individual Funding Requests
Publication date 22 May 2018.

(<https://www.england.nhs.uk/wp-content/uploads/2017/11/ifr-standard-operating-procedure-v4.pdf>); and

NHS England Manual for Prescribed Specialised Services 2018/19

(<https://www.england.nhs.uk/publication/manual-for-prescribed-specialised-services/>).
Publication date 17 September 2018.

- 5.11.13 Patients who are entitled to NHS funded treatment, but are receiving care privately have a right to revert to NHS treatment at any point during their private care. In these circumstances the Commissioning Authority expects their treatment to follow local NHS treatment pathways. Funding for an individual to continue care in a private facility or to transfer to an NHS provider where the privately consulted clinician has a link will not be routinely authorised. Where individual clinical circumstances may make such funding appropriate, the case will require consideration under the IFR process. The Commissioning Authority will not reimburse costs for private treatment undertaken without prior Commissioning Authority approval.
- 5.11.14 A patient can ask their GP, consultant or hospital unit for a second opinion or further opinion (an opinion about your health condition from a different doctor). Although patients do not have a legal right to a second opinion, a healthcare professional will consider the patient's circumstances and whether a second opinion is needed.
- 5.11.15 Where a patient moves into the Commissioning Authority locality from another area and is receiving a package of care or treatment which has been approved by their previous CCG, but which would not normally be funded for the Commissioning Authority patients, the Commissioning Authority may honour such decisions, providing the care pathway has been initiated, eg an appropriate referral has already been approved. In matters of this nature the Panel will take into account and adhere to the principles set out in NHS England guidance: Who Pays? Determining Responsibility for Payments to Providers. August 2013: <http://www.england.nhs.uk/wp-content/uploads/2014/05/who-pays.pdf>

5.12. Safeguarding

Throughout the EC/IFR process all those involved will bear in mind their duties under safeguarding. At any stage of a submission the Panel may seek advice on the case from the CCG safeguarding leads.

5.13 Urgent Treatment Decisions

- 5.13.1 The Commissioning Authority 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 Commissioning Authority policies. In such circumstances the Commissioning Authority recognises that an urgent decision may have to be made before the FR Panel can be convened. The following provisions apply to such a situation.

- 5.13.2 An urgent request is one which requires urgent consideration and a decision because the patient faces a substantial risk of significant harm if a decision is not made before the next scheduled meeting of the FR Panel. The FR Panel Chair and Deputy Chair are responsible for agreeing whether a case requires urgent decision after considering the nature and severity of the patient's clinical condition. Urgency under this policy cannot arise as the result of a failure by the clinical team expeditiously to seek funding through the appropriate route 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 Commissioning Authority expects the provider trust to go ahead with the treatment at its own risk.
- 5.13.3 Provider trusts must take all reasonable steps to minimise the need for urgent requests to be made through the FR Panel process. If clinicians from any provider trust are considered by the Commissioning Authority not to be taking all reasonable steps to minimise urgent requests to the FR Panel, the Commissioning Authority may refer the matter to the provider Trust Chief Executive.
- 5.13.4 Where an urgent decision needs to be made to authorise treatment for an individual patient, the FR Chair will request the office staff to initiate a virtual discussion on the case. The time period within which the decision needs to be taken will be 5 working days of receiving the case request, or earlier depending on the individual case.
- 5.13.5 The urgent decision will be made by virtual discussion via email or phone between the FR Panel members. In exceptionally urgent circumstances the FR Chair and Deputy Chair will decide on the case if urgent input from other panel members is not possible. The virtual discussion will, as far as possible within the constraints of the urgent situation, follow the policy set out above in making the decision. The Exceptional Cases Office Team shall collect as much information about both the patient's illness and the treatment as is feasible in the time available.
- 5.13.6 The FR Chair and Deputy Chair 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.
- 5.13.7 The FR Chair and Deputy Chair shall be entitled to reach the view, after the request is properly analysed, that the request is for a service development and so should be refused and/or appropriately referred for policy consideration.
- 5.13.8 The FR Panel decisions will be sent to the Applicant, via the provider's designated personnel and/or the GP and patient within 5 working days of receiving the case request for a Virtual Panel meeting. If the FR Panel decides not to fund a drug or treatment the decision letter will include an appropriate explanation.

5.14 Appeals

The patient or Applicant shall be entitled to lodge an appeal against the decision of the Panel. Any such appeal in relation to the stages detailed below should be submitted within 6 weeks (30 working days) of the date of the Panel decision letter. Appeals will be considered at three stages as follows:

5.14.1 First Stage - Reconsideration of the Decision (Appeal by FR Panel)

- a. If the FR Panel declines funding for a treatment or approves it subject to conditions and the Applicant and or the patient is not satisfied with the outcome, the Applicant may have the option of having the request reconsidered. The request for reconsideration must be supported by new clinical information.

- b. The EC/IFR Manager and Chair of the FR Panel will screen the additional information submitted to support the reconsideration request to determine whether it significantly alters the nature or strength of the evidence originally submitted to the Panel. If it does the request will be resubmitted to the next available FR Panel meeting which will consider the new information alongside the original request.

5.14.2 Second Stage - One to One Meeting

- a. For a patient who wishes to appeal further, a one to one meeting will be offered between the Panel Chair/Deputy Chair and the patient. The Chair/Deputy Chair will attend the meeting with a member of the Panel Office Team. The patient is entitled to bring along a family member or representative for this meeting. The purpose of the meeting is for the Chair/Deputy Chair to explain the Commissioning Authority policy and process, and the reasons that the FR Panel reached its decision not to approve funding. It also allows the Chair/Deputy Chair to listen to the concerns of the patient and answer any queries they may have. In rare circumstances it also gives an opportunity for the patient to provide any new information that was not presented to the FR Panel before.
- b. Following the one to one meeting, the case will be referred back to the next available Fortnightly Review Panel meeting to acknowledge the One-One meeting held and to reconsider any new information that may have been provided. The applicant will be advised of the decision by FR Panel.

5.14.3 Third Stage – Chief Nurse and Medical Director Review

- a. A request for review of the decision can be made by the Applicant, the patient or their carer or relative. The request must be supported by the referring clinician who must explain the reasons for the review.
 - that the decision of the panel was procedurally improper; and/or
 - the decision of the panel was not based on the use of the correct policy; and/or
 - that the decision of the Panel, was in the opinion of the referring clinician, one which no reasonable Panel could have reached (if this challenge and its reasoning has been put to the panel after the initial assessment, appeal or one to one meeting and the panel disagrees in its reconsideration).
- b. The Chief Nurse and Medical Director Review forms part of the CCG's corporate governance process. They will consider the grounds for the review request and will examine all the documentation considered by the FR Panel, the case file of the meeting at which the decision was made and the decision letter. No new written or oral information will be considered and there will be no representation by either the Applicant, the patient or their carer or relative.
- c. In reviewing the decision, the Chief Nurse and Medical Director will consider the following:
 - Whether the process followed by the FR Panel was consistent with the CCG's Corporate Governance Arrangements.
 - Whether the decision reached by the FR Panel:
 - was taken following a process which was consistent with the policies of the CCG;
 - had taken into account and considered all the relevant evidence;
 - had not taken into account irrelevant factors;
 - was a decision which a reasonable FR Panel was entitled to reach.

- d. The Chief Nurse and Medical Director will make one of the two following decisions:
 - 1. To uphold the decision made by the FR Panel. They will be able to choose this option even if they consider there have been procedural errors or inconsistency with applying commissioning policy, if they believe that there would not be a prospect of the requested treatment being approved by the FR Panel, if it were to reconsider the case.
 - 2. **To refer the case back to the FR Panel with detailed points for reconsideration.** The case will then be considered at the next scheduled meeting of the relevant FR Panel.
- e. The Chief Nurse and Medical Director will write to the Applicant and the patient or their carer or relative informing them of the outcome and the reasons for the decision. If the FR Panel decision has been upheld, the letter will provide details of the right of the Applicant or patient or their carer or relative to complain to the CCG about the policy, but any complaint about the process or the decision should be made to the Parliamentary and Health Service Ombudsman.
- f. Any challenges to the Clinical Priorities Policies or statements will be referred to the Clinical Priorities Forum via the Forum Secretary to review the policy and request a report once the policy is reviewed.

5.15 Guidance Notes

5.15.1 Seeking Treatment Abroad

NHS England is responsible for administering the application process for patients seeking funding for healthcare in the European Union, European Economic Areas or Switzerland ('cross border healthcare'). The CCG is responsible for making guidance available to referrers and patients and for handling associated issues arising from such requests.

When applying for cross border healthcare, there are two funding routes that patients may be able to access; they are known as the 'S2' (formerly 'E112') route and the 'EU Directive' route. NHS England is responsible for administering the application process for both.

Further information on seeking medical treatment in Europe is available on the NHS web site:

<http://www.nhs.uk/nhsengland/healthcareabroad/plannedtreatment/pages/the-s2-route.aspx>

5.15.2 East of England Priorities Advisory Committee Policies

Where relevant, the Panel will apply the relevant East of England Priorities Advisory Committee commissioning policies, adopted by the CCGs in the East of England. Some important points from these policies are given below:

Commissioning Policy PAC 2 - Ongoing Access to Treatment Following Completion of Non-Commercially Funded Trials

The Commissioning Authority will not pick up funding of treatments, at the end of clinical trials or when company sponsored funding is withdrawn, without prior agreement of an NHS commissioning organisation (past or present). Providers trusts will need to provide evidence of any such agreement.

The responsibility for providing ongoing access to a treatment is the responsibility of those individuals or parties that have initiated and sponsored treatment.

It is the clinician's responsibility to ensure that 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.

Should the Commissioning Authority agree to pick up funding, in this context, it does not represent 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.

Commissioning Policy PAC CP05 - Defining the Boundaries between NHS and Private Healthcare

A patient's entitlement to access NHS healthcare should not be affected by a decision by a patient to fund part or all of their healthcare needs privately.

An individual who is receiving treatment that would have been commissioned by the Commissioning Authority, but who has commenced that treatment on a private basis, can at any stage request to transfer to complete the treatment within the NHS. In this event, the patient will, as far as possible, be provided with the same treatment as the patient would have received if the patient had had NHS treatment throughout. However, at the point that the patient seeks to transfer back to NHS care, the patient should: be reassessed by the NHS clinician; not be given any preferential treatment by virtue of having accessed part of their care privately; and be subject to standard NHS waiting times.

The Commissioning Authority will not reimburse the patient for any treatment received as a private patient before a request is made to move back into the NHS.

If a patient commences a course of treatment that the Commissioning Authority would not normally fund, the Commissioning Authority will not pick up the costs of the patient either completing the course of treatment or to receive ongoing treatment.

Commissioning Policy PAC CP06 - Experimental, Uncertain and Unproven Treatments

Treatments which are judged experimental, uncertain or not to be of proven effectiveness will not routinely be funded.

Commissioning Policy PAC CP07 - Orphan Drugs

An orphan drug is one that could treat a disease with a prevalence of less than five per 10,000 of the population. The Commissioning Authority will, in the absence of 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.

Commissioning Policy PAC CP08 - Choice

The Commissioning Authority will offer choice only within services normally commissioned by the Commissioning Authority.

Commissioning Policy PAC CP10 - In-year Service Developments and the Commissioning Authority's Approach to Treatments not yet Assessed or Prioritised

Until a service development has been assessed and a policy decision has been taken as the result of prioritisation, whether in-year or during the annual commissioning round, the Commissioning Authority default policy will usually be not to fund a treatment unless otherwise stated.

6. References

1. East of England Priorities Advisory Committee, Advisory Commissioning Recommendation Policies. October 2010 <https://www.prescgipp.info/commissioning-policies/category/33-commissioning-policies>
Note: this documentation is accessed via a password protected web site - you are required to be a healthcare professional to access this web site. The policies are currently under review.
2. The NHS Constitution (July 2015): <https://www.gov.uk/government/news/nhs-constitution-and-handbook-updated>
3. Cambridgeshire and Peterborough CCG Constitution March 2019:
<https://www.cambridgeshireandpeterboroughccg.nhs.uk/EasysiteWeb/getresource.axd?AssetID=4360&type=Full&servicetype=Attachment>
4. NHS England guidance: Who Pays? Determining Responsibility for Payments to Providers. August 2013:
<http://www.england.nhs.uk/wp-content/uploads/2014/05/who-pays.pdf>
5. NHS web site: <http://www.nhs.uk/pages/home.aspx>
6. NHS web site information on seeking medical treatment in another European country or Switzerland:
<http://www.nhs.uk/nhsengland/healthcareabroad/plannedtreatment/pages/the-s2-route.aspx>
7. Priority setting: managing individual funding requests. NHS Confederation Publications 2012:
<http://www.nhsconfed.org/~media/Confederation/Files/Publications/Documents/Priority%20setting%20managing%20individual%20funding%20requests.pdf?dl=1>

*CPF pols & working area\ifr exceptions policy related papers\CCG files\
EXCEPTIONAL IFR RQSTS POLICY NOV 19 – CCGGB RTFD*

Appendix 1 - Terms of Reference of the Fortnightly Review (FR) Panels – Drug and Non Drug

Fortnightly Review Panel Terms of Reference

Purpose

The FR Panel is a decision-making group, responsible to Cambridgeshire and Peterborough CCG Governing Body for the consideration of exceptional and individual funding requests, ie where a treatment falls outside the established commissioning categories and is not normally funded.

Responsibility

The Exceptional and Individual Funding Request Panel is a committee of the Commissioning Authority that has been authorised by the Commissioning Authority's Governing Body to take decisions on its behalf on exceptional and individual funding requests up to a delegated amount of £20,000, per treatment within any 12-month period. Funding requests over the delegated amount will be referred to the CCG's Chief Nurse and Medical Director to consider the Panel's recommendations. Any requests exceeding £25,000 will also need to be approved by the CCG's Chief Finance Officer.

Objectives

To consider exceptional and individual funding requests for drug and non drug interventions in a clear, consistent and equitable manner taking into account:

- Promote consistency, fairness and equity.
- Ensure effective use of resources, but also ensure that the decisions are based on clinical evidence and not solely on budgetary constraints.
- Improve the rigour of the processes ensuring decisions are rational, reasonable and transparent.

Membership

Membership of the FR Panels (Drug and Non Drug) is as follows:

Non Drug Panel

- Chair of the Panel - Clinical Lead for EC/IFR Requests - GP Member
- Deputy Chair - GP Member
- Clinical Policies Programme Manager
- Exceptional Cases/IFR Manager
- Exceptional Cases Specialist Officer
- Exceptional Cases/IFR Senior Administrative Support Officer
- Exceptional Cases Team Administrator

Drugs Panel

Similar to the above Non Drug Panel except a Medicines Optimisation Specialist Pharmacist, will be in attendance.

The following attendees will be available, as and when required, in an advisory capacity but are not decision-making members of the Panel:

- Public Health Specialist or representative
- Mental Health Specialist or representative

Quoracy

Non Drug Panel

The Panel will be quorate if **four** members are in attendance; at least two clinically qualified

Drug Panel

The Panel will be quorate if **four** members are in attendance; at least two clinically qualified, one of which will be a GP member (Chair or Deputy Chair) and a pharmaceutically qualified member (Specialist Pharmacist or representative)

Frequency of Meetings

FR Panels for Drug and Non Drug funding requests shall be held every two weeks

Voting Rights

The FR Panel members will seek to reach a decision by consensus. If this is not possible a decision will be made by a vote with each member having one vote and the Chair of the Panel will have the casting vote.

Virtual Panels

If a funding request is received that requires an urgent decision and, in the opinion of the referring clinician, delaying the decision on the proposed treatment until the next scheduled FR Panel meeting might cause significant harm to the patient's health, the Chair, in discussion with the IFR Manager, will consider instigating a Virtual Panel. The urgent decision will be made by virtual discussion via email or phone between the FR Panel members. In exceptionally urgent circumstances the FR Chair and Deputy Chair will decide on the case if urgent input from other panel members is not possible.

The responsible IFR Manager must ensure that all participating members of the FR Panel have received an anonymised summary of all available information and that there has been an appropriate opportunity for discussion of the case, enabling members to make an informed decision. A written record will be made of the decision reached and the rationale for it. The Virtual Panel decision will be reported to the next available relevant FR Panel meeting for formal approval. The Virtual Panel decision will be notified to the applicant and if appropriate to the patient at the earliest possible opportunity.

Administrative Arrangements

Support to the funding request process for drug and non drugs is provided by the Exceptional Cases Team.

Confidentiality of Patient Information

The Exceptional Cases Team operate a paperless office, therefore, all funding request documentation is logged, scanned and loaded to the secure funding request administrative database.

All applications are considered on an anonymised basis. Anonymised case summaries, known as the case file, and any relevant supporting documentation will be emailed to the FR Panel members using NHSnet encrypted email.

Ensuring Full and Fair Consideration of Funding Requests

For a full interpretation of the approval process please refer to the paragraph 5.12 of the Exceptional and Individual Funding Request Policy.

- The FR Panel will consider each request in the context of the relevant policy, where one exists, or as a 'treatment not normally funded' where there no explicit policy.
- The request will be considered on the basis of the submitted written evidence of the patient's clinical circumstances and of the clinical and cost-effectiveness of the proposed treatment.
- Panel members will be provided with the anonymised case file detailing all funding requests to be considered by the Panel. The case file will be emailed to Panel Members at least 2 working days prior to the Panel Meeting.
- The applicant, the patient or their representative has no right of attendance at the Panel meeting. All information and views expressed by the patient and their clinician(s) is made available to the Panel members as an integral part of the consideration of the request.
- Where there appears to be no evidence or insufficient evidence that the clinical circumstances of the patient's case are exceptional, when compared with other patients who have the same or a substantively similar condition, funding will not be approved.

Service Developments

The Commissioning Authority and/or the Panel shall routinely screen individual funding requests to see whether they represent a service development. The key question used to screen out as a service development will be 'are there likely to be other similar patients in the Commissioning Authority or East of England?' If there is evidence that this patient is representative of other similar patients, the individual funding request will be sent back to the provider with a request to follow normal procedures for introducing new services, in line with the Commissioning Authority Commissioning Principles.

Declarations of Interest and Conflicts of Interest

Declarations of interest are requested at the beginning of Panel meetings. Such declarations of interest may relate to involvement with pharmaceutical companies or membership of committees that may potentially conflict with Panel Member's role on the funding request panel.

If an FR Panel member believes they may have a conflict of interest in a particular case, this must be disclosed to the Panel before that case is discussed. Conflicts of interest may arise, for instance, if the member has recently been involved with the care of the patient. In the event of a potential conflict of interest, the Panel will take a view as to whether the member should be involved in consideration of the request.

Decision Making

In reaching a decision on exceptional and individual funding requests, the FR Panel will apply the CCGs relevant clinical policy(s) and the Ethical Framework defined in the document: Ethical Framework to Support the Development of Clinical Policies:

<https://www.cambridgeshireandpeterboroughccg.nhs.uk/health-professionals/clinical-policies-and-thresholds/clinical-policies-forum/>

Communication

A written explanation of any decision made by the FR Panel and the reasons for it will be communicated to the referring clinician, patient or patient's parent or guardian if indicated on the funding request form, within 5 working date of the Panel meeting.

Where encrypted email services are not available, letters sent to the clinician(s) will be marked '**Private and Confidential**'. Letters sent to patients and to places where confidentiality arrangements may not be in place, will be marked '**Private and Confidential, to be opened by Addressee Only**' in line with the CCG's information governance procedure. Where the clinician has indicated that the patient should not be communicated with directly it is the responsibility of the clinician to advise the patient of the Panel decision.

Appendix 2 - Form for Exceptional and Individual Funding Requests

Form for Exceptional and Individual Funding Requests



- Sections 1 - 2 should be completed fully.
- Complete Section 3 for high cost interventions.
- All sections including consent should be fully completed and sent electronically as a word document to the CCG Exceptional Cases Team using the following secure email address: cpccge-ifr@nhs.net
- Incomplete forms will be returned to you.
- The Exceptional Cases Team will acknowledge receipt of forms and allocate a unique identifying number to the request.

For information:

Please click [here](#) for this form and further guidance on the Exceptional and Individual Funding Request process.

Please click [here](#) for the CCG clinical policies and referral proforma.

Enquiries about completion of the form can be directed to the Exceptional Cases Team on: 03 300 571 027.

SECTION 1: Contact Details and Patient Consent

| | |
|----------------------|--|
| Date of application: | |
|----------------------|--|

Patient Details

| | |
|------------------|--|
| Name of Patient: | |
|------------------|--|

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|----------------|--|
| Date of Birth: | |
|----------------|--|

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|-------------|--|
| NHS Number: | |
|-------------|--|

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|------------------|--|
| Hospital Number: | |
|------------------|--|

| | |
|----------|--|
| Address: | |
|----------|--|

| | |
|--------------------|--|
| Tel No (optional): | |
|--------------------|--|

GP Details

| | |
|----------------|--|
| Registered GP: | |
|----------------|--|

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| Address: | |
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|---------|--|
| Tel No: | |
|---------|--|

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|--|--|
| Email (please provide secure nhs.net email address): | |
|--|--|

Referring Clinician Details (if not GP)

| | |
|-------|--|
| Name: | |
|-------|--|

| | |
|-----------|--|
| Position: | |
|-----------|--|

| | |
|-------------------|--|
| Tel No and Bleep: | |
|-------------------|--|

| | |
|--|--|
| Email (please provide secure nhs.net email address): | |
|--|--|

| | |
|---------------------------------------|--|
| Organisation Name and Address: | |
|---------------------------------------|--|

| | |
|--|--------|
| Is this an urgent request? ¹ ie decision needed within 5 working days as the patient's life may be in danger. | YES/NO |
| All other requests will be considered at the next available Review Panel if all the paperwork is complete. | |

¹ For treatments that are urgently required, where significant harm may occur through delay, it must be provided to the patient. See paragraph [5.6.6](#) of the EC/IFR policy

PATIENT CONSENT

Mark or tick boxes below to confirm

| | |
|---|-----------------------|
| I confirm the patient has consented to sharing of personal and clinical information contained within this proforma with clinical staff involved in their care and for the Exceptional Cases Team or Panel, as part of the exceptional cases process or Group Prior Approval processes, to request further information, clarify data and communicate where applicable with the patient, and for future audit purposes. | |
| By submitting this request you are confirming that you have reviewed this request against the relevant policy and believe the patient meets the relevant threshold criteria or exceptionality criteria. You have fully explained to the patient the proposed treatment and they have consented to you raising this referral on their behalf. | Enter date of request |
| I confirm that it is clinically appropriate for the patient to be copied into all correspondence. | |
| Please confirm that you have brought the CCG patient leaflet on the collection and use of patient data for the funding request process to the patient's attention: 'Why we need to collect your personal confidential information and your rights'. Click here to access the patient leaflet. | |

SECTION 2: Funding Request and Relevant Case Details

To be completed for all cases

| | | |
|---|--|--|
| 1 | What is the funding request for? | |
| 2 | Brief History Include the patient's diagnosis, co-existing conditions, current health status and any other relevant health problems. | |
| 3 | Previous interventions Summarise the previous interventions the patient has received for this condition. When did they occur? What were the outcomes of these interventions? What was the reason for stopping? | |
| 4 | Impact of refusal What are the implications of not providing the proposed intervention for the patient or carer, eg potential future illness or disability or costs? | |
| 5 | Alternatives What other treatment options are available for this condition? Please provide details and state reasons why they are considered inappropriate in this | |

| | | |
|---------------------------|--|-------------------------|
| | case. Are any alternatives commissioned by the CCG? | |
| 6 | Cost Effectiveness Please state the estimated duration and total costs (cost of drug/procedure and service costs). | |
| 7 | Please state any cost savings to be gained from this procedure such as likely downstream procedures/admissions avoided. When would you expect these savings to be realised against current treatment costs? | |
| 8 | Evidence and policies Are there any local or national policies for the use of the proposed treatment? (Please include local policies, NICE, SIGN, Royal College guidance if any). | |
| 9 | Applicability How is the evidence/policies quoted above applicable specifically to this patient? Does the patient meet the relevant inclusion criteria and if so how? | |
| 10 | Is this request made because the case is regarded an exception to a policy mentioned above? <ul style="list-style-type: none"> • Please explain why the benefit from this treatment for the patient in terms of health gain and/or improvement in the quality of life would be significantly greater than would be expected for a typical patient with a similar condition. • Why is this patient or their clinical condition significantly different when compared with a similar group of patients who are suffering from the same condition. | Yes/No. Please explain. |
| 11 | Governance Please set out by whom treatment effectiveness will be reviewed. | |
| 12 | Location of proposed intervention, (eg which hospital, treatment centre). | |
| 13 | Is the location accredited for providing this treatment and are there appropriate clinical governance systems in place? | |
| 14 | Any additional information relevant to the case? | |
| Smoking statement: | | |
| 15 | Patient is a non-smoker. | |
| or | Patient has been advised of the surgical and post-surgical risks associated with smoking and referred to stop-smoking services – see stop smoking policy | |
| or | Smoker was offered but declined to be referred to the SSS. | |

SECTION 3: High Cost Interventions and Drugs

Standard treatment and proposed new treatment:

| | | |
|----|---|--|
| 16 | What would be the standard treatment at this stage? | |
| 17 | What would be the expected outcome from the standard treatment? | |
| 17 | Is the requested treatment additional to the standard interventions(s) or a deviation from the standard? | |
| 19 | What are the circumstances that make standard treatment inappropriate for this patient? | |
| 20 | What is the anticipated benefit of the new treatment as compared to the standard treatment or best supportive care? | |
| 21 | What is the anticipated risks/harm of this new treatment as compared to the standard? | |
| 22 | Are there any other patient factors that you would like to be considered? | |

Further evidence and policies

| | | |
|-----|--|--|
| 23 | Is there further evidence denoting decision/approval status for this treatment? Please attach relevant policies, minutes or guideline documents. | |
| 23a | Clinical Policies Forum or Cambridgeshire and Peterborough Joint Prescribing Group Policies/Minutes or other local commissioning policies. | |
| 23b | Specialised Commissioning Group or other regional policies. | |
| 23c | Drugs and Therapeutics Committee or Chairman's action. | |
| 23d | Peer Review – with other consultants or MDT: Date of peer review: Consultants present/MDT: Recommendations: | |
| 24 | Is there any other evidence for the effectiveness of the intervention proposed? (This can include peer-reviewed articles and internal audit). <i>It is vital to provide electronic copies for the evidence provided to prevent delay in decision making.</i> | |
| 25 | Applicability What is the rationale for use of the proposed treatment and relevant clinical evidence? How is the evidence/policies quoted above applicable specifically to this patient? Does the patient meet the relevant inclusion criteria and if so how? | |

Clinical severity and quality of life (QoL):

| | | |
|---|---|--|
| 26 | What is the clinical severity – using standard scoring systems where possible? | |
| 27 | How does the current disease status affect abilities of independence and self-care, QoL, etc and is the proposed treatment going to have any effect on this? | |
| Drug treatment details: If the treatment forms part of a regimen, please document full regimen. | | |
| 28 | Dose, frequency and route of administration: | |
| 29 | Planned duration of treatment: | |
| 30 | Is the treatment likely to be repeated? How often? | |
| 31 | What is the anticipated total number of treatments for this patient? | |
| 32 | Give details of the full regimen if relevant (including concomitant therapies). | |
| 33 | What would you consider to be a successful clinical outcome for this treatment, eg QoL life expectancy, etc? | |
| 34 | Is this treatment likely to facilitate subsequent treatment? | |
| 35 | How will you monitor the effectiveness of this treatment, after how many doses and how frequently? What are the criteria for continuing treatment? | |
| 36 | What are the stopping/exit criteria for this treatment? Define fully using objective measurements or recognised assessment scales. | |
| 37 | If this is a drug that is secondary care initiated and then prescribing might be continued in primary care, have appropriate shared care protocols been agreed? If yes, please provide details. | |
| 38 | Is the treatment licensed for use for the requested indication in the UK? | |
| 39 | Please give information about NNT, NNH – ask your pharmacist if the data is required. | |
| 40 | Is the requested intervention part of a clinical trial, and what does the trial protocol say about continuation of treatment after the trial ends? | |
| 41 | Has private funding previously been provided? If yes, why is NHS funding now being sought? | |
| 42 | Are there any arrangements with the manufacturer regarding provision of the requested treatment, eg the drug is being provided free or under favourable terms? | |

| | | | | | |
|----------------------------------|---|---|-------|------------------|----------------------------------|
| 43 | <p>Please state the number of cases submitted for funding of this intervention by the Trust in the last 12 months and how this patient differs from others with the same condition.</p> <p>How many other similar patients you may see over the next 12 months?</p> <p>Note: If there are other similar patients (more than 2), please submit a business case or seek 'group prior approval'. Your pharmacist and/or commissioning manager can advise you on this.</p> | | | | |
| 44 | <p>Please declare any potential conflict of interest. See guidance on last page. Support in research projects should also be declared.</p> | | | | |
| 45 | <p>In the case of drug treatments only: All information checked and supplemented where required and application approved by Chief Pharmacist or nominated deputy, eg directorate pharmacist, after checking that all the questions are completed.</p> | <table border="1"> <tr> <td data-bbox="858 801 1485 853">Name:</td> </tr> <tr> <td data-bbox="858 864 1485 916">Contact details:</td> </tr> <tr> <td data-bbox="858 927 1485 1028">Signature or email confirmation:</td> </tr> </table> | Name: | Contact details: | Signature or email confirmation: |
| Name: | | | | | |
| Contact details: | | | | | |
| Signature or email confirmation: | | | | | |

Exceptional and Individual Funding Request Form Oct 2019

Appendix 3 - Example Policy Referral Proforma

Cambridgeshire and Peterborough Clinical Commissioning Group

Referral Proforma for Ganglion

Does the patient meet the referral criteria?

YES COMPLETE SECTION 1 and refer via e-RS to MSK triage service.

NO COMPLETE SECTION 2 - procedure is not routinely funded. Refer to Exceptional Case Panel.

| | |
|----------------------------|--|
| Name: | |
| NHS Number: | |
| Date of Birth: | |
| Address: | |
| Telephone Number (patient) | |
| Email Address (patient) | |
| Referring Clinician: | |
| Practice Address: | |
| Practice Telephone Number: | |
| Practice Email: | |

| | |
|-----------------------------|--|
| Patient Choice of Provider: | |
|-----------------------------|--|

Patient consent must be confirmed for all referrals

| | |
|---|---|
| PATIENT CONSENT | Mark or tick to confirm below |
| Applicable to Section 1 | |
| I confirm the patient has consented to share the personal and clinical information contained within this proforma with clinical staff involved in their care, and for future audit purposes. The patient has been informed that this intervention is only funded where criteria are met or exceptionally demonstrated. | <input type="checkbox"/> |
| Applicable to Section 2 – exceptional case referrals only | |
| I confirm the patient has consented to share the personal and clinical information contained within this proforma with the Exceptional Cases Team or Panel, as part of the exceptional cases process or Group Prior Approval processes, to request further information, clarify data and communicate where applicable with the patient. | Enter date of request <input type="text"/> |
| I confirm that it is clinically appropriate for the patient to be copied into all correspondence. | <input type="checkbox"/> |
| I confirm that I have brought the CCG patient leaflet on the collection and use of patient data for the funding request process to the patient's attention: 'Why we need to collect your personal confidential information and your rights'. Click here to access the patient leaflet. | <input type="checkbox"/> |

SECTION 1: Referral Information

Please enter referral letter text here (optional). *(Please enter text below.)*

| | |
|---|---------------------|
| Referral criteria: | Tick as appropriate |
| <p>Note: The policy and this policy proforma do not cover fast track referral where there is diagnostic uncertainty. A cystic swelling is likely to be a ganglion. However, a lump which is solid on USS or is not definitely cystic may be malignant. These lumps require MRI scan. In particular, any lump which is painful, history of increasing size and is deep to the fascia should be referred urgently.</p> | |

| | | |
|---|---|--|
| The CCG will only fund surgery for ganglion meeting the following criteria: | | |
| Location of Ganglion (Please enter detail below.) | | |
| | Referral is not being made for cosmetic purposes. | |
| AND | Persistent symptoms that are not relieved by aspiration – symptoms should include: | |
| | significant pain requiring regular analgesia (give clinical detail); | |
| OR | severe functional impairment affecting activities of daily living (give clinical detail); | |
| OR | significant skin breakdown (give clinical detail); | |
| OR | tingling/numbness (give clinical detail). | |
| The CCG will only fund surgery for mucous cysts on the distal interphalangeal joint if there is: | | |
| | recurrent spontaneous discharge of fluid; | |
| OR | significant nail deformity. | |
| AND | Smoking Statement: (Tick as appropriate) | |
| | Non-smoker. | |
| OR | Has been referred to a Stop Smoking Service. | |
| OR | Was offered, but declined to be referred to a Stop Smoking Service. | |

| |
|--|
| SECTION 2: Exceptional Case Referral – send to cpcce-ifr@nhs.net in Word format. |
| Please provide full clinical detail as to why CCG Exceptional Funding is considered appropriate in this case. (Please enter text below.) |
| |

| | | | |
|--|----|---|---------------------|
| For completion by Exceptional Cases Administrator | | | Tick as appropriate |
| EC Number: | CP | Date of Exceptional Cases Panel: | |
| Exceptionality demonstrated. | | Funding approved. | |
| Exceptionality not demonstrated | | Funding declined. | |
| Inadequate information provided. | | Return proforma to GP. | |
| Other: The policy does not apply. | | GP to refer through commissioned pathway. | |
| Reason: | | | |
| Form returned to GP confirming EC Panel decision: | | Date: | |

| | |
|---|---------------------|
| Section 3: For completion by MSK Triage Clinician | Tick as appropriate |
| MSK Triage Service has approved referral for onward transmission to Orthopaedic Specialist. | |

Appendix 4 - Equality Impact Assessment

Equality Impact Assessment - Form

| | |
|---|---|
| Name of Proposal (policy/strategy/function/service being assessed) | Exceptional and Individual Funding Requests Policy |
| Those involved in assessment: | Exceptional Cases Fortnightly Review Panels for Drugs and Non Drugs |
| Is this a new proposal? | Review of policy approved by CCG Governing Body on XX |
| Date of Initial Screening: Date of Screening Review | 17 December 2013 24 August 2019 |
| What are the aims, objectives? | To ensure a consistent and equitable approach with the administration of and the decision-making process for exceptional and individual funding requests. |
| Who will benefit? | CCG, primary care, providers, members of the public. |
| Who are the main stakeholders? | CCG, primary care, providers, members of the public. |
| What are the desired outcomes? | To ensure maximum health gain for the population within the CCG budgets. |
| What factors could detract from the desired outcomes? | Lack of awareness and/or non-enforcement of the policy. |
| What factors could contribute to the desired outcomes? tertiary | Awareness raising of the Policy via the CCG's websites. Awareness through GP newsletters. Awareness raising at locality meetings. Notification of review of the policy by email to practices and secondary care providers through official email gateways. |
| Who is responsible? | Director of Transformation & Delivery: Primary and Planned Care |
| Have you consulted on the proposal? If so with whom? If not, why not? | Policy reviewed by Exceptional Cases Panel and approved by IPAC, ratified by CCG GB. |

| Which protected characteristics could be affected and be disadvantaged by this proposal (Please tick) | | Yes | No |
|--|---|-----|----|
| Age | <u>Consider:</u> Elderly, or young people | | ✓ |

| | | | |
|--------------------------------|--|--|---|
| Disability | <u>Consider:</u> Physical, visual, aural impairment, Mental or learning difficulties | | ✓ |
| Gender Reassignment | <u>Consider:</u> Transsexual people who propose to, are doing or have undergone a process of having their sex reassigned | | ✓ |
| Marriage and Civil Partnership | <u>Consider:</u> Impact relevant to employment and /or training | | ✓ |
| Pregnancy and maternity | <u>Consider:</u> Pregnancy related matter/illness or maternity leave related mater | | ✓ |
| Race | <u>Consider:</u> Language and cultural factors, include Gypsy and Travellers group | | ✓ |
| Religion and Belief | <u>Consider:</u> Practices of worship, religious or cultural observance, include non-belief | | ✓ |
| Sex /Gender | <u>Consider:</u> Male and Female | | ✓ |
| Sexual Orientation | <u>Consider:</u> Know or perceived orientation | | ✓ |

What information and evidence do you have about the groups that you have selected above?

Cambridgeshire and Peterborough CCG consider each individual within our populations to be of equal value. We will not discriminate between individuals or groups on the basis of any of the above protected characteristics. However, where treatments have a differential impact as a result of age, disability, sex or other characteristics of the patient, it is legitimate to take such factors into account.

Consider: Demographic data, performance information, recommendations of internal and external inspections and audits, complaints information, JNSA, ethnicity data, audits, service user data, GP registrations, CHD, Diabetes registers and public engagement/consultation results etc.

How might your proposal impact on the groups identified? For example, you may wish to consider what impact it may have on our stated goals: Improving Access, Promoting Healthy Lifestyles, Reducing Health Inequalities, Supporting Vulnerable People

Examples of impact are given below:

- a) Moving a GP practice, which may have an impact on people with limited mobility/access to transport, etc.
- b) Planning to extend access to contraceptive services in primary care without considering how their services may be accessed by lesbian, gay, bi-sexual and transgender people.
- c) Closure or redesign of a service that is used by people who may not have English as a first language and may be excluded from normal communication routes.

Please list the positive and negative impacts you have identified in the summary table on the following page.

| | |
|---|---|
| 1 Summary | |
| Positive impacts (note the groups affected) | Negative impacts (note the groups affected) |
| N/A | N/A |

Summarise the negative impacts for each group:

N/A

What consultation has taken place or is planned with each of the identified groups?

N/A

What was the outcome of the consultation undertaken?

N/A

What changes or actions do you propose to make or take as a result of research and/or consultation?

Briefly describe the actions then please insert actions to be taken on to the given Improvement Plan template provided.
N/A

Will the planned changes to the proposal:

Please state Yes or No

| | |
|---|-----|
| Lower the negative impact? | N/a |
| Ensure that the negative impact is legal under anti-discriminatory law? | N/a |
| Provide an opportunity to promote equality, equal opportunity and improve relations i.e. a positive impact? | N/a |

Taking into account the views of the groups consulted and the available evidence, please clearly state the risks associated with the proposal, weighed against the benefits.

N/A

What monitoring/evaluation/review systems have been put in place?

Overview by Exceptional Cases Team Manager and Monthly Exceptional Cases Panel

When will it be reviewed?

x, or earlier if required by changes in local or national requirements.

| | |
|----------------------------------|--|
| Date completed: | August 2019 |
| Signature: | Charlie Miller / Nicola Miller |
| Approved by: | Soomitra Kawal, Equality & Diversity System Advisor, CCG |
| Date of first approval: | August 2015 |
| Date of reviewed approval | 14 August 2019 |