NHS
North East Essex
Clinical Commissioning Group

PRIOR APPROVAL, INDIVIDUAL FUNDING AND EXCEPTIONAL CASES REQUESTS POLICY

NEE/CCG/2014/037

Brief Description (max 50 words)	This policy aims to ensure that the Clinical Commissioning Group: • Has a system in place to manage funding request applications • Supports providers of commissioned services and the general public to understand NHS North East Essex CCG's position with regards to managing funding requests for certain treatments, devices and drugs
Target Audience	All NHS North East Essex staff, member practices, provider organisations commissioned by NHS North East Essex CCG and the patient population of North East Essex
Action Required	• Following approval at the CCG Quality Committee the policy will be shared on the CCG public website and communicated to its commissioned providers. • All members of staff responsible for commissioning services have a responsibility to familiarise themselves with the content of this Policy. • All members of staff have a duty to work within the standards and guidelines as specified in this Policy, when considering commissioning new services

Document Information

Title /Version Number/(Date)	Prior Approval, Individual Funding and Exceptional Cases Requests Policy / v2.2/ February 2017
Document Status *(for information/ action etc)*and timescale	For implementation with immediate effect
Accountable Executive	Director of Transformation & Strategy
Responsible Post holder/Policy Owner	Clinical Priorities Manager
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Author	Victoria Sawtell
Stakeholders engaged in development/review	Clinical Priorities Policy Clinical Review Group members, Exceptional Clinical Circumstances Panel members, Head of Medicines Management, Head of Contracts, Clinical Priorities Manager– Exceptional Clinical Cases & Individual Funding Requests IFR and Prior Approvals Co-ordinator (Drugs and Devices)
Equality Impact Assessment	**EQUALITY IMPACT ASSESSMENT** This document has been assessed for equality impact on the protected groups, as set out in the Equality Act 2010. This Policy is applicable to the Board, every member of staff within the CCG irrespective of their age, disability, sex, gender reassignment, pregnancy, maternity, race (which includes colour, nationality and ethnic or national origins), sexual orientation, religion or belief, marriage or civil partnership, and those who work on behalf of the CCG

Contact details for further information	All queries to Kathy West, Clinical Priorities Manager

Amendment History

Version	Date	Reviewer Name(s)	Comments
1.0	15.07.2014	Victoria Sawtell	First draft of policy circulated for comments
1.1	02.10.2014	Kathy West	Updated to include changes made to contact details and timescales
1.2	06.10.2014	Kathy West	Updated to include amendment to flowchart in Appendix 5
1.3	10.10.2014	Nicki Whitehorn	Updated to reflect changes made to suggested timescales and correction of typing errors
1.4	29.10.2014	Victoria Sawtell	Updated to reflect drugs and devices process
1.5	06.11.2014	Victoria Sawtell	Minor changes to references
1.6	20.11.2014	Members of the Exceptional Clinical Circumstances Panel	Minor changes to align policy with revised terms of reference
1.7	28.11.2014	Victoria Sawtell	Amendment to job title reference
1.8	28.11.2014	Victoria Sawtell	Further minor changes to align policy with revised terms of reference
1.9	25.02.2015	Corporate Support	Policy put into format and contents page added; no change to context of policy.
2.0	09.08.2016	Kathy West Carol Sampson	Review and update of contact numbers for Clinical Priorities Team. Amendment to job titles.
2.1	09.12.2016	Victoria Sawtell	Timescales for application review amended.
2.2	19.01.2017	Victoria Sawtell Kathy West	Update to flowcharts and revised timescales.

This policy progresses the following Authorisation Domains and Equality Delivery System (tick all relevant boxes).

Clear and Credible Plan		Collaborative Arrangements	
Clinical Focus and Added Value		Engagement with Patients/Communities	
Commissioning processes		Leadership Capacity and Capability	
Equality Delivery System		NHS Constitution ref SFI 17	

Glossary

Term	Definition
Clinical Priorities Policy Clinical Review Group (CRG)	Is the level 2 decision making group
Complete Application	Is an application that contains all information required to support the decision making process, including all relevant health information and relevant policy requirements e.g. BMI and smoking status as required for that referral.
Exceptional	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.
Exceptional Clinical Circumstances (ECC)	These are procedures which are only funded in exceptional circumstances, e.g. breast augmentation. Applications for these procedures should be made to the Exceptional Case Team and should only be made where the patient demonstrates exceptionality.
Exceptional Clinical Circumstances Panel (ECCP)	Panel that hears exceptional cases as part of level 3 decision making
Individual Funding Request (IFR)	is a request to the CCG to commission healthcare for an individual who falls outside the range of services and treatments that the CCG has agreed to commission as a matter of routine/ that is not covered by existing CCG policy.
Individual Prior Approvals	Those procedures which are not routinely provided by the CCG and where provision is only possible on an individual patient basis, e.g. abdominoplasty.
Prior Approval (PA)	A scheme under which the Commissioners give Prior Approval for treatments and services prior to referral or following initial assessment that may form part of the Services required by the Service User following referral.
Threshold Approvals	Those procedures which may be offered on a routine basis but only for patients who meet defined criteria agreed in a clinical protocol, e.g. cataract surgery.
Working Day	a day other than a Saturday, Sunday or bank holiday in England

CONTENTS

1. Introduction and background

Everyone should have equal access to the health care services that they most need. Illnesses that threaten life or cause serious disability are the first priority when considering health service funding. Good public Governance means resources should be directed towards those services offering the most clinical benefits and this requires more control over access to certain services which may be defined as low priority or of limited clinical benefit.

This Policy describes the national policy context for NHS funding applications and sets out North East Essex CCG's standard operating procedures for managing prior approvals, individual funding requests (IFRs) and exceptional case applications for those treatments and drugs which are not routinely commissioned by the CCG, or which are only commissioned according to specific criteria. It sets out the eligibility criteria for patients to receive NHS funding for services for which there is no established contract or where a treatment is considered to be 'Low Priority' for funding (including out of area treatments, interventions and NHS commissioned care and where the CCG has stipulated prior approval is required).

The principles of the NHS constitution have been taken into account in devising this policy.

This document should be read in conjunction with the following commissioning policies of NHS North East Essex CCG and applicable provider documents:

- North East Essex Clinical Priorities Policy
- Terms of reference for the North East Essex Clinical Priorities Policy
- Terms of reference for the North East Essex Exceptional Clinical Circumstances Panel
- Provider Access Policies

2. Policy context and purpose

The scope of this policy is to specify the principles, processes and procedures for considering whether or not to approve prior approval or individual funding requests (IFRs) or exceptional cases.

3. Legal and ethical context to decision making

This section sets out the legal and ethical considerations relevant to the IFR, ECC and Prior Approval process.

3.1 NHS Constitution

The NHS Constitution sets out a number of patient rights that are protected by law, which underpin patients' rights to healthcare; these include:-

"You [the patient] have the right to access NHS services. You will not be refused access on unreasonable grounds."

"You [the patient] 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]

3.2 Legal and financial duties and the duty to provide services

CCGs have a statutory duty to maintain financial balance and consequently any commissioning decision made by the organisation must be evidence based and demonstrate clinical effectiveness and value for money.

When considering whether or not to commission specific treatments for groups of people with the same medical condition, CCGs will assess the clinical and cost effectiveness of the treatment, the benefits to patients in terms of quality of life and the priority of this treatment or service in relation to others already commissioned or proposed for commissioning. Consequently a treatment of very little benefit is unlikely to be commissioned simply because it is the only treatment available; this ensures that limited resources are used to provide the greatest health benefit.

At an individual or patient group level, treatment will not generally be funded solely because a patient requests it. CCGs will not normally fund treatment for one patient, which is not available to all other patients with the same clinical need, except in the context of this policy.

CCGs will not discriminate on grounds of personal characteristics, such as age, gender, sexual orientation, race, religion, lifestyle, social position, family or financial status, intelligence or cognitive functioning and will act in compliance with duties under the Equality Act 2010. However, funding decisions will be made on the basis that the patient is more likely to benefit significantly differently from the cohort of patients with the same clinical condition.

3.3 Other legal considerations

In order for the CCG to uphold the principles of administrative law and for its decision making to be fair, transparent and proportionate, the CCG will also consider, as part of its decision making, its responsibilities under the Human Rights Act 1998, the Equality Act 2010 and other applicable legislation as agreed from time to time.

3.4 Ethical considerations and framework for decision-making

The purpose of the ethical framework is to support and underpin the decision making processes to ensure that CCG take into account the rights and needs of the

[1] The NHS Constitution March 2010
http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_113645.pdf

individual, the duties and responsibilities of the NHS and to ensure that decisions are made in a consistent, fair and transparent manner.

3.4.1 This ethical framework will be used to support and underpin the decision making process through:

- Providing a coherent structure for discussion, ensuring all important aspects of each issue are considered;
- Promoting fairness and consistency in decision making from meeting to meeting and with regard to different clinical topics, reducing the potential for inequity;
- Providing a means of expressing the reasons behind the decisions made;
- Reducing risk of judicial review by implementation of robust decision-making processes that are based on evidence of clinical and cost effectiveness and an ethical framework;
- Supporting and integrating with the development of CCG Commissioning Plans.

3.4.2 North East Essex CCG respects the right of individuals to determine the course of their own lives, including the right to be fully involved in decisions concerning their health care. It will consider patients' autonomy and rights, and the need to provide treatment that is of benefit and does not harm taking note of the views of the patient / carers. However, this has to be balanced against North East Essex CCG's responsibility to ensure equitable and consistent access to appropriate quality healthcare for all the population. In commissioning healthcare, the CCG will:

- Ensure that in assessing the effectiveness of health care, we take account of health outcomes that are important to patients and the patient's experience of the care.
- Ensure, wherever possible, that within the care commissioned or provided there are a range of alternative options available, and that patients are given the necessary support to make an informed choice.
- Recognise that evidence of effectiveness usually relates to groups rather than individuals. The individual case process has been set up to allow individuals to be considered as an exception to commissioning policy where evidence is available to suggest that an intervention not routinely funded may be of particular benefit to them in relation to other patients who might not be funded.
- As a general rule, decline to provide individual funding for care that is not routinely commissioned or is provided solely on the basis that an individual, or a clinician involved in their care, desires it. This is in line with our responsibility to ensure consistent and equitable access to care for all our population. It reflects our concern not to fund for one

individual case which could not be openly offered to everyone in our population with equal clinical need.
- Decline to provide a treatment of little benefit simply because it is the only treatment available.
- Consider treatments which effectively treat 'life time' or long term chronic conditions equally to urgent and life-prolonging treatments.

4.0 Scope of the policy

4.1 This policy applies to patients registered with a North East Essex GP practice, where North East Essex Clinical Commissioning Group is the responsible commissioner.

4.2 This policy excludes NHS services commissioned directly by NHS England. Where a procedure, treatment is the commissioning responsibility of NHS England and falls outside the remit of this policy, this will be covered by the NHS England policies, available on their website:- http://www.england.nhs.uk/wp-content/uploads/2013/04/cp-03.pdf

4.3 The scope of this policy is to set out the decision making process for considering funding approval for prior approval, individual funding and exceptional cases.

4.4 This policy covers the following types of treatments/ interventions/ procedures:

- **Threshold Approvals** – Those procedures which may be offered on a routine basis but only for patients who meet defined criteria agreed in a clinical protocol, e.g. cataract surgery.

  The responsibility for adherence to these policies lies with the referring and accepting clinicians and prior approval should be sought from the CCG (see below) where this is part of the contracting arrangements.

- **Individual Prior Approvals –** These are procedures which are not routinely provided by the CCG and where provision is only possible on an individual patient basis, e.g. Abdominoplasty.

  For these procedures, the criteria listed form guidance to referring clinicians and the CCG commissioner. In instances in which eligibility is unclear the final decision is made through the application of the Exceptional Cases process.

- **Exceptional Clinical Circumstances –** These are procedures which are only funded in exceptional circumstances, e.g. breast augmentation.

  Applications for these procedures should be made to the Exceptional Case Team and should only be made where the patient demonstrates exceptionality.

5.0 An Overview of Prior Approval Requests, Individual Funding Requests and Exceptional Funding Requests

It is important to distinguish between requests for prior approval, individual funding requests and exceptionality.

5.1 Prior Approval: is a scheme under which the Commissioners give Prior Approval for treatments and services prior to referral or following initial assessment that may form part of the Services required by the Service User following referral.

5.2 Individual Funding Request: an individual funding request arises when a treatment is requested for which the CCG has no policy.

5.3 Exceptional Funding: In contrast an exceptional case application seeks to show that a patient is an '**exception to the rule or policy**' and so he/she may have access to an intervention that is not routinely commissioned for that condition.

5.4 There are several reasons why NHS North East Essex CCG may not be commissioning the healthcare intervention for which funding is sought. These are shown below:

- It may not have been aware of the need for this service and so has not incorporated it into the service specification (this can be true for common and uncommon conditions).
- It may have decided to fund the intervention for a limited group of patients that excludes the person making the request.
- It may have decided not to fund the treatment because it does not provide sufficient clinical benefit and/ or does not provide value for money.
- It is a treatment for a very rare condition for which the CCG has not previously needed to make provision.

- In this last instance, when this relates to a cohort of patients, this should prompt the development of a policy/business case on the treatment in question rather than an individual funding request, unless there is grave clinical urgency. The CCG does not expect to introduce new drugs/technologies on an ad hoc basis through the mechanism of the Clinical Priorities Policy Clinical Review Group or Exceptional Clinical Circumstance Panel. Consideration of new treatments (drugs or technologies) should take place within the existing planning framework overseen by the NHS England.

- Locally where requests for cohorts are identified these may be considered as part of the CCG's commissioning priorities process and as part of the annual review of the CCG Clinical Priorities Policy. Commissioning evidence to support medicine cohorts will go to the North East Essex

Medicines Management Committee (NEEMMC) and to the CCG Transformation & Delivery Committee (TDC) for Devices. Appropriate evidence will be required to support any application to the CCG for commissioning the treatment and or device. Evidence shall include but will not be limited to:

- Peer reviewed/published evidence
- expert opinion where there is no published evidence
- Current best practice

5.5 In instances in which a patient is part of a cohort for whom there is no current commissioning decision and the patient is experiencing rapid deterioration in their condition that could result in either, permanent disability or death, the following process will be followed:

- Clinical Priorities Manager or IFR/Prior Approval Co-ordinator (Drugs and Devices) will undertake an urgent communication with the applicant clinician to determine the degree of clinical deterioration/severity.
- Exceptional Cases Panel will reconsider the case as urgent if necessary if new indication of exceptionality is provided.
- If not exceptional, the case will be brought to the attention of the appropriate CCG Director immediately to determine the appropriate corporate course of action on the individual case in light of the clinical information provided and the stage in the commissioning decision making process for the cohort.

5.6 Where a patient has moved into the district or has been receiving care for a specific condition, the treatment will normally be provided for a maximum one year and then a further application for treatment would be required to determine if the patient meets the exceptionality criteria outlined above.

5.7 Referrals for overseas care will be considered only in line with NHS England policies and usually only prior to the patient's travel for the treatment.

6.0 Submission of Prior Approval, Individual Funding and Exceptional Case applications

A detailed explanation of the process for making an application and each subsequent stage in the application process is set out in Appendix 2. An overview of the processes is set out in this section 6.

6.1 Who can submit a funding request?

6.1.1 A doctor, or other health care professional directly involved in the care of a patient, can make a request for funding to support a healthcare intervention which has not been agreed to be funded by the CCG under its existing contracts or commissioning policies.

6.1.2 It is the referring clinician's responsibility to ensure the treatment request form is completed as accurately and comprehensively as possible to avoid possible delays in considering the request. A patient, or a non-clinical representative, may not submit an IFR because the process is to enable an NHS Clinician to apply for funding to support the provision of NHS treatment by that clinician to the patient. They will be familiar with the incidence and prevalence of the condition and have an understanding of their patient's needs in relation to others with the same condition at the same stage of the disease[2].

6.1.3 The CCG cannot accept applications directly from a patient. If Clinical Priorities Team do receive an application directly from a patient, the IFR and Prior Approvals Co-ordinator (Drugs and Devices) or Clinical Priorities Manager will write to the patient explaining that s/he need to contact his/her GP/Consultant to discuss the possibility of making an application. The application then needs to be submitted directly from the referring GP / NHS Consultant with supporting evidence.

CCG process for managing requests for funding: -

6.2 Daily triage of all requests

6.2.1 The majority of cases will be screened by the Clinical Priorities Team, five days a week.

If an individual meets the criteria within the Clinical Priorities Policy as part of a prior approval process or other existing CCG approved contract or commissioning policy, a decision to agree funding can be made at this point by the Clinical Priorities Manager /Senior Commissioning representative (Managerial lead for IFR) or the CCG Head of Medicines Management, for drug requests.

6.2.2 The Clinical Priorities Team will as part of the screening of prior approvals and IFR referrals function:

- Determine whether an existing policy or contract adequately covers the treatment request
- Interpret the CCG definitions of exceptionality and individuality in the context of the clinical information that is presented
- Where information is incomplete or insufficient to enable the CCG to consider the application as a funding request, the Clinical Priorities Team will reject the referral and send back to the original referrer requesting further information. The 18 weeks clock will not start at this point on the basis that a complete referral has not been received.

6.2.3 The Clinical Priorities Manager and or Senior Commissioning representative (Managerial lead for IFR) or Head of Medicines Management will be able to consider three options:

[2] Interim Standard Operating Procedures: The Management of Individual Funding Requests, April 2013, Reference : NHSCB/SOP/02

- Approve the request if covered by an existing contract/ commissioning policy
- Take the request to the Clinical Priorities Policy Clinical Review Group or the Exceptional Clinical Circumstances Panel
- Refer the "refused" cases for the reason stated in clause 6.2.2 to the Clinical Priorities Policy Clinical Review Group

6.2.4 Where there is uncertainty, the case will be referred to the Clinical Priorities Policy Clinical Review Group which meets on a fortnightly basis. Please see Appendix 1 for further information on the stages of the application process.

The sections below set out in more detail how the processes for prior approval, IFRs and exceptional cases are managed by the CCG.

6.3 The Prior Approval Process

6.3.1 Under the terms of their contract providers may not accept restricted prior approval requests unless it is clear that prior approval has been agreed. Before making any referral the referring clinician (this could be the patient's GP or another health professional including secondary care specialist) is required to complete an application to NHS North East Essex CCG with full details of how the patient meets the criteria for 'Prior Approval', using the form included in appendix 3.

6.3.2 As per the daily triage process outlined above, the Clinical Priorities Manager will screen the application to ascertain whether enough information has been provided and whether the request fits within any CCG contracts/ portfolio of commissioned services. Where a request does meet the policy criteria for a treatment or procedure within an agreed CCG commissioned service the Clinical Priorities Manager can confirm agreement of funding

6.3.3 Timescale for Managing a Prior Approval Request

Once all information is received, as part of a complete referral, *most* referrers should expect a decision within 14 working days.

Where the CCG Clinical Priorities Policy sets out threshold approval criteria and where patients are assessed by clinicians to meet the criteria, E.g. Cataracts, these referrals should still be made to the CCG Clinical Priorities Team. Where there is any doubt as to whether prior approval should be sought, referring clinicians should contact the Clinical Priorities Manager for advice.

6.4 The IFR Process

6.4.1 Applications which would be considered an Individual Funding Request are those where the treatment for which funding is sought is not routinely commissioned by the CCG.

6.4.2 Upon receipt of an IFR, the Clinical Priorities Manager will follow the daily triage/ screening process as set out in paragraph 6.3.2, which follows the same process for prior approval requests in terms of ascertaining the correct decision making process.

6.4.1 Timescale for Managing a Prior Approval or IFR

The standard for response times for prior approval and IFRs will be a maximum period of 30 working days from the date of the receipt of a ***complete*** Treatment Request Form to the date of the letter from the CCG informing the requesting clinician of the decision of the Clinical Priorities Policy Clinical Review Group or the Exceptional Clinical Circumstances Panel. This includes a tolerance where the Clinical Priorities Team are awaiting further information sought from the requester. The stages of the PA, IFR and exceptional cases application processes are set out in Appendix 1.

6.5 The Exceptional Cases Funding Process

6.5.1 Exceptional case applications are those that seek to show that a patient is an '**exception to the rule or policy**' and so he/she should have access to an intervention that is not routinely commissioned by the CCG for that condition.

6.5.2 Exceptional cases will be determined by the CRG as appropriate to be submitted to the Exceptional Clinical Circumstances Panel (ECCP).

6.5.3 The remit of the Exceptional Clinical Circumstances Panel is to consider requests for the approval of drug treatments, associated treatments, devices and equipment, which are considered to be outside funded agreed policy, where the requesting clinician considers there to be exceptional clinical circumstances that would be more likely to make this particular patient eligible for treatment

6.5.4 The Exceptional Clinical Circumstances Panel will make decisions on Exceptionality using appropriate National Guidance and the Clinical Priority Policy recommendations as a guide. The group will also be permitted to exercise discretion in its decision-making following consideration of more detailed information on each case. Individual Funding Request and requests for Prior Approval will be heard by the Clinical Priorities Policy Clinical Review Group.

6.5.5 The Panel is also established to undertake reciprocal appeal reviews on behalf of other CCGs at their request.

6.5.5. Timescale for managing an Exceptional Case request

6.5.6 The Panel aims to make a decision on applications within 30 working days of a complete application being received. A complete application means an application that contains all information required to support the decision

making process, including all relevant health information and relevant policy requirements e.g. BMI and smoking status as required for that referral, to enable to panel to make an informed decision. If the application is incomplete or further information is required prior to presenting the application, then referrers will be given 7 days to provide the further information or the case will be closed. All applications will be heard within a maximum of 30 working days from the time that all of the information is received.

7.0 Offers of Treatment

7.1 In line with the NHS constitution, it is expected that agreed treatment will normally start within 18 weeks of the application being supported. There may be legitimate clinical or patient choice factors which may mean that the planned treatment does not start within 18 weeks. However the CCG will follow all national guidance in relation to waiting times to ensure that there are no unnecessary delays to patient waiting times

7.2 All offers of treatment made by the CCG, in relation to applications for treatment made via this policy will only be valid for 12 months. Patients will therefore be required to initiate treatment within the 12 months of the date of the decision to approve funding. If treatment does not commence within this 12 month period a new application will be required to be submitted in order for funding to be authorised.

8.0 Communication with Patients

8.1 At all times the Clinical Priorities Team will keep accurate records of correspondence and decisions taken and ensure these are consistent with any decisions made previously.

8.2 The Clinical Priorities Team will always seek to be timely and informative in their contact with all parties with regards to the processing of the application in question.

8.3 When a request for Exceptional Funding, via the Exceptional Clinical Circumstances Panel, is received by the Clinical Priorities Team, with the exception of devices and drug requests, where this may not be appropriate, the patient will be sent an acknowledgement letter and a request to consent to information being gathered in relation to the application. The case will not be progressed until consent has been received. The patient will also be asked if they would like the outcome of the case to be directly sent to him/her.

8.4 The outcome of all Panel decisions will be communicated directly to the patient if this has been indicated on the consent form. In the absence of the patient indicating that they would like to receive the outcome directly, the outcome of the case will be sent to the applicant clinician. The Patient will then be sent a letter indicating that they should contact their clinician to discuss the outcome of the Panel's deliberations.

8.5 All patient initiated contact with the Clinical Priorities Team will be in writing to ensure that the correct information is available to be presented to the Panel. Patients are asked to discuss any specific issues/concerns that they may have with their application with their referring clinician.

8.6 In situations in which there are concerns about patient safety or provider performance, telephone contact directly with a patient may be initiated at the discretion of the Clinical Priorities Manager

8.7 The Clinical Priorities Team will not discuss the outcome of cases with patients on the telephone. This is to ensure that patients receive accurate information.

9.0 Information Storage and Confidentiality

9.1 The Clinical Priorities Manager will maintain a secure database for all funding requests; this is in order to inform commissioning, service and policy developments. All information relating to funding requests will be stored securely and confidentially and all copied documents will be safely destroyed following the panels.

9.2 Patient sensitive/patient identifiable information passed to the Panel will be handled in a sensitive and lawful manner in line with the Data Protection Act 1998. An application identity code will be used in place of names; where names have been included on documentation it will be redacted. In line with Caldicott Principles, patient identifiable information will only be used by the Panel if:-

- there is a justified purpose for the confidential information being seen
- the use of the information is absolutely necessary to the discussion
- the minimum data for the purpose is used
- there is a need to know, and
- all members of the Panels understand their responsibilities in regard to patient confidentiality.

10.0 Policy Oversight

10.1 Responsibility of Policy

The responsibility of implementing this policy lies with the Resources Directorate within the CCG.

10.2 Monitoring and Reporting

An Annual report will be produced for the Panel and presented to the CCG Quality Committee as a sub-committee to the Board.

- Number of applications reviewed
- Budget areas or speciality of treatments being requested
- Decision outcome
- Time to decision made

- Number and outcomes of appeals
- Indicative expenditure for approved applications
- Trends/Gap Analysis
- Outcomes of interventions agreed

10.3 Review

The policy and its processes will be reviewed annually and signed-off by the CCG Quality Committee, unless NHS England or central guidance requires a review prior to this date.

10.4 Policy Dissemination

- Panel Members
- Copies to Trusts – Medical Director and Director of Operations
- CCG public website

11. References and acknowledgements

- North and East London Commissioning Support Unit Interim Individual Funding Request Policy; March 2013 (http://www.islingtonccg.nhs.uk/Downloads/CCG/BoardPapers/20130403/App%204b%20IFR%20Policy%20v%201%200.pdf)
- NHS England Interim Standard Operating Procedures: The Management of Individual Funding Requests; April 2013, Reference : NHSCB/SOP/02 (http://www.england.nhs.uk/wp-content/uploads/2013/04/cp-04.pdf)
- Prior approval process for GPs flowchart– Brighton and Hove City Teaching PCT (May 2008)

Appendix 1: Stages / timelines of the Prior Approval, IFR and Exceptional cases process for routine requests

	Responsible Officer	**Decision Making Body**	**Action and Timescales**
Referrer wishes to discuss request / help to complete PA/IFR/ Exceptional funding Request form	Clinical Priorities Manager or IFR and Prior Approvals Co-ordinator (Drugs and Devices)	None	All communication recorded in writing.
Referrer submits PA/IFR/ Exceptional funding Request form-	Clinical Priorities Manager	None	Acknowledgement to referrer of PA/IFR/ Exceptional funding Request forms within 2 working days. (N/B for drugs & devices requests the CCG do not send an initial acknowledgement owing to the urgent nature of most drug requests and therefore the first response is likely to be an answer to the request with full advice)
Pre-screening of PA request or IFR request to determine whether covered by existing contracts, clinical commissioning policies etc.	Clinical Priorities Manager	Clinical Priorities Manager and or CCG Senior / Commissioning representative (Managerial lead for IFR) plus nominated Clinical team (PH and / or pharmacy lead) where applicable	Clinical Priorities Manager to advise referrer within 5 days of date of request whether it is covered by existing contracts OR application needs to be submitted to Clinical Priorities Policy Clinical Review Group for consideration. Clinical Priorities Manager to advise referrer if further information is required to support request.

	Responsible Officer	Decision Making Body	Action and Timescales
			For routine cases, where further information has been requested in order to inform a decision, a reminder letter will be sent where this has not been received after 5 days. The case will be closed and notification sent to the applicant clinician if. After this point, a new application will have to be made
Screening of Completed PA or Treatment Request Form if further information requested and supplied	Clinical Priorities Manager	Screening panel- IFR Officer and Senior Commissioning representative (Managerial lead for IFR) plus nominated Clinical team (PH and / or pharmacy lead) where applicable	Request either approved if further information submitted evidences request is covered by existing policy OR rejected if still incomplete. OR referred to Clinical Priorities Policy Clinical Review Group Panel within 5 days. If additional information requested from referrer, timeline of request is suspended until received. The IFR timeline allows for flexibility in the process: if additional research is needed by the screening panel

	Responsible Officer	Decision Making Body	Action and Timescales
			to aid decision making this can be allowed for but the requester will be notified of the reason for the delay in the screening outcome.
Clinical Priorities Policy Clinical Review Group (CRG)	Chair of CRG	Members of the CRG	CRG to be convened within 7 days of Screening Panel decision. CRG Panel decision to referrer* from Chair of CRG within 5 working days. The applicant clinician is invited to provide additional relevant clinical information supporting the exceptionality of the patient in order that the case may be reconsidered.
Reconsideration on the grounds of exceptionality	Clinical Priorities Manager / ECCP Co-ordinator	Screening panel- IFR Officer and Senior Commissioning representative (Managerial lead for IFR) plus nominated Clinical team (PH and / or pharmacy lead) where applicable	Further information from referrer providing evidence of exceptionality Considered within 7 days and if deemed significant by the CRG will be submitted to the next convened Exceptional Clinical Circumstances Panel within 7 days.
Drugs and Devices process:-			
Pre-screening of drugs or device request	IFR and Prior Approvals Co-ordinator (Drugs and Devices)	None	Liaison by IFR and Prior Approvals Co-ordinator (Drugs and Devices) with Senior Pharmacist (responsible for evidence based

	Responsible Officer	Decision Making Body	Action and Timescales
			medicine) and or Head of Medicines Management within 24 hours of drug request and 2 working days for devices (if non-urgent) to agree if case to be submitted to ECC Panel
Exceptional Clinical Circumstances Panel	Chair of ECC Panel	Members of the ECC Panel	Request for a case to be heard as an exceptional case from CRG or initial drugs or devices request must be lodged within 7days. ECC Panel to be convened within 7 days of NHS North East Essex CCG accepting the application as an exceptional case. ECC Panel decision to appellant from Chair of Panel will be sent within a maximum of 10 working days. However the aim will be for most letters to be sent within 5 working days .
Appeal on grounds of process	ECC Panel Co-ordinator	None	Request for an appeal to be heard on the grounds of the decision making process must be lodged within 30 days (with discretion) with the IFR and Prior Approvals Co-ordinator (Drugs and Devices) Appeals will,

	Responsible Officer	Decision Making Body	Action and Timescales
			wherever possible and where it is reasonable, be heard by another Essex CCG by reciprocal agreement within a reasonable period of the appeal request being received by NHS North East Essex CCG. This process however will be subject to the timescales of the other CCG's appeal panel dates.

Appendix 2- Funding Applications Process- standard operating procedures

These standard operating procedures should be read in conjunction with the terms of reference for the North East Essex Clinical Priorities Policy Clinical Review Group and the North East Essex Exceptional Clinical Circumstances Panel.

1. Applications- format and content

All funding applications must be submitted directly by the referring clinician. In order for a request to be considered, the referring clinician must complete in full the relevant form: - the Prior Approval Request form, Individual Funding Request form or the Exceptional Funding Request form (see attached Appendix 3). This form can be accompanied by a referral letter and any other relevant clinical information. Applications can be submitted electronically to the Clinical Priorities Manager, the Clinical Priorities Assistant or the IFR and Prior Approvals Co-ordinator (Drugs and Devices) IFR and Prior Approvals Co-ordinator (Drugs and Devices)via the contact details below:

Clinical Priorities Manager
North East Essex CCG
Aspen House
Stephenson Rd
Severalls Business Park
Colchester
CO4 9QR

Tel: 01206 918734
Safe haven Fax: 01376 530989
Email: NEECCG.fundingrequests@nhs.net

Clinical Priorities Assistant
North East Essex CCG
Aspen House
Stephenson Rd
Severalls Business Park
Colchester
CO4 9QR
Tel: 01206 918735
Safe haven Fax: 01376 530989
Email: NEECCG.fundingrequests@nhs.net

IFR and Prior Approvals Co-ordinator (Drugs and Devices) North East Essex CCG
Primary Care Centre
Aspen House
Stephenson Rd
Severalls Business Park
Colchester
CO4 9QR
Tel: 01206 918722

Safe haven Fax: 01376 530989

Email: NEECCG.fundingrequests@nhs.net

Referrals will be accepted from:

- The patient's GP
- A relevant NHS consultant
- A relevant autonomous NHS practitioner

The appropriate referring clinician will usually be the person with clinical responsibility for the treatment being proposed. Where an application is for non NHS provision, a local NHS clinician should have assessed the patient's need, the treatment, and local provision.

If the request is for an out-of-area NHS service, we ask that a relevant local NHS clinician write in support of the application and clarify why the service cannot be provided locally. This is not relevant in situations in which Patient Choice applies.

The Panel cannot accept applications directly from a patient. If the Clinical Priorities Team does receive an application directly from a patient, the Clinical Priorities Assistant will write to the patient explaining that s/he need to contact his/her GP/Consultant to discuss the possibility of making an application. The application then needs to be submitted directly from the referring GP / NHS Consultant with supporting evidence

2. Initial preparation and consideration of applications

2.1 The Clinical Priorities Manager will coordinate (with support from the , Clinical Priorities Assistant, Director of Transformation & Strategy and the Clinical Priorities Policy Clinical Review Group when needed) the gathering of any necessary supporting evidence required to consider a funding application. All information must be in written format; verbal exchange between clinicians and CCG staff will not be included in the application but should be followed up with written or electronic summary of key points discussed. In some circumstances a second clinical opinion may be required before the application is decided.

2.2. For routine cases, where further information has been requested in order to inform a decision, a reminder letter will be sent where this has not been received after 20 working days /4 weeks. The case will be closed and notification sent to the applicant clinician if, after 30 working days/ 6 weeks from the original request for additional information, the Clinical Priorities Team have not received this information. After this point, a new application will have to be made.

3. Decision Making – Delegated Authority

a) Level 1 Delegated Decision Making: Initial triage of request by Clinical Priorities Manager

- Prior Approval and IFR applications will initially be pre- screened by the CCG Clinical Priorities Manager to ensure that they are not within policy (please see main document section 6 for an overview of this process).

- The Clinical Priorities Manager may seek support and advice from the Senior / Commissioning representative (Managerial lead for IFR) and Head of Medicines Management and clinical advice as required as part of the pre-screening of applications process

- If the request is able to be resolved by the Clinical Priorities Manager, the outcome will be communicated to the patient's clinician. The Clinical Priorities Manager has authority to approve applications of the following nature:

    - Where prior approval is needed as patient is inside explicit criteria as set out in the Clinical Priorities Policy or other similar CCG approved pathway
    - Within existing contracts

- If the request is unable to be resolved through existing contracts or alternative arrangements, the Clinical Priorities Manager will present the application to the Clinical Priorities Policy Clinical Review Group.

- A holding letter will be dispatched, by the Clinical Priorities Manager or Clinical Priorities Assistant, to the patient's referring clinician with information about the next steps together with information about how the outcome of the Panel's deliberations will be communicated.

b) Level 2 Delegated Decision Making: Clinical Priorities Policy Clinical Review Group

- The Clinical Priorities Manager will present cases for consideration to the ECC/IFR Group with support from the Clinical Priorities Policy Clinical Review Group where necessary.

- A summary of cases will be circulated to Group members whenever possible 48 hours prior to the meeting.

- The Clinical Priorities Policy Clinical Review Group (CRG) will ensure applications are outside policy, not a cohort and that all evidence is available to support the decision-making process.

- The CRG will meet every 2 weeks to screen applications and advise the requesting referrer whether the outcome of the application can be agreed without recourse to the Exceptional Cases Panel or whether further information is required before the application can be presented. The CRG will be composed of the Senior / Commissioning representative (Managerial lead for IFR), the Clinical Priorities Manager and a GP. Depending on the application it may also include a Pharmacist.

- The CRG can make decisions in the following circumstances:
  - Applying discretion in line with interpretation of the Clinical Priorities Policy and in accordance with previous decision making in order not to make any precedent setting decision, for prior approval and Individual Funding Requests
  - Screening out individual funding requests for new treatments for which there can be an anticipated cohort of patients with the same clinical need to be considered as part of the general planning process for commissioning priorities (see above main document, paragraph 5).
  - To enact a precedent that has been set by the Exceptional Cases and Individual Funding Request's Panel.
  - They are not empowered to take precedent setting decisions with respect to individual applications. These cases will be referred to the Exceptional Clinical Circumstances Panel.
  - To refuse applications in cases in which exceptionality has clearly not been established.

- Where the Clinical Priorities Policy Clinical Review Group cannot make a unanimous decision the application will automatically be referred to the Exceptional Clinical Circumstances Panel.

- A holding letter will be written by the Clinical Priorities Manager or Clinical Priorities Assistant to the patient's clinician with information about the next steps together with information about how the outcomes will be communicated.

- If an application has been refused by the Clinical Priorities Policy Clinical Review Group a letter will be sent by the Clinical Priorities Assistant within a maximum of 5 working days of the meeting. The applicant clinician is invited to provide additional relevant clinical information supporting the exceptionality of the patient in order that the case may be reconsidered within 7 days of the date of refusal. After this point, a new application will be required.

- The Clinical Priorities Assistant will keep a record of the documents presented and the outcomes of the Clinical Priorities Policy Clinical Review Group meetings with information on the decision making process being detailed in the outcome letter.

- RECONSIDERATION: Applications will be reheard by the CRG if new clinical evidence demonstrating exceptionality is provided. Applications

that are declined at this stage will not be heard by the full Exceptional Cases Panel unless new clinical evidence is provided and the CRG agree that the application could potentially meet the burden of evidence for demonstrating exceptionality.

- APPEALS: Patients/applicant clinicians can seek an appeal on the basis of process within 30 days of the date of his/her outcome letter. An Appeal will be considered only if the patient/applicant clinician believes:
  - A matter of process (as detailed in this Policy) was not adhered to, or
  - Not all of the available evidence was taken into account in reaching the decision

- Applicants seeking appeal must clearly outline the grounds for appeal as indicated above. Applications for an appeal should be made in writing to the IFR and Prior Approvals Co-ordinator (Drugs and Devices).

c) Level 3 Delegated Decision Making: Exceptional Cases & Exceptional Clinical Circumstances Panel

i) The purpose of the Panel is to:
   - To consider requests for the approval of drug treatments, associated treatments, devices and equipment, which are considered to be outside funded agreed policy, where the requesting clinician considers there to be exceptional clinical circumstances that would be more likely to make this particular patient eligible for treatment
   - To make decision on Exceptional Funding Requests using appropriate National Guidance and the Clinical Priorities Policy recommendations as a guide, but exercising discretion following a consideration of more detailed information on each case
   - To undertake reciprocal appeal reviews on behalf of other CCGs at their request

ii) Membership
   - North East Essex CCG Head of Medicines Management or representative
   - Two GPs or Medically Qualified Clinicians
   - CCG Contract Manager or Business Manager or representative from those teams
   - Optional- NED/Lay Member (non-voting member)
   - Others may be co-opted by agreement of the committee where there are particular issues under consideration which require additional or specialist expertise

iii) A quorate meeting will include 3 members which must include representatives of the following
   - CCG Head of Medicines Management or authorised deputy
   - CCG Contract Manager or Business Delivery Manager (or representative from those teams) and
   - GP Representative/ medically qualified clinician

Where members are unable to attend, they will endeavour to provide a nominated attendee with the delegated authority to make a decision on that person's behalf.

iv) When consensus is not reached in the Panel, the Panel will vote. A majority is needed for a case to be considered "exceptional" with the Chair having a casting vote if necessary.

v) The Panel may co-opt a specialist advisor in addition to seeking the views of the referring/treating clinician if this is required as part of a particularly complex case. The specialist advisor will not have voting rights or be party to the panel's decision.

vi) The ECC Panel aims to make a decision on all applications within 30 working days of a completed application being received in accordance with the complete timescales for the funding decision-making process as set out earlier within this policy. If the application is incomplete or further information is required prior to presenting the application, then referrers will be given 7 days to provide the further information or the case will be closed. All applications will be heard within a maximum of 30 working days/ 6 weeks from the time that all of the information is received.

4. Exceptionality criteria

The Exceptional Clinical Circumstances Panel will be required to make a decision as to whether a funding application should be funded on the basis that the patient is 'exceptional'. These are cases where the application or the patient's condition is outside existing commissioning policy but they are considered to be clinically exceptional compared to other patients excluded from funding as set out in a particular policy.

4.1 Decision Making Criteria – Exceptional Cases and the Exceptional Clinical Circumstance Panel

There are two tests for exceptionality that must BOTH be met for a case to be considered exceptional:

Exceptionality Test 1

How is the patient significantly different from other patients in this patient population? (*The onus is on the applicant clinician to demonstrate that this patient is significantly different from other patients in a similar situation to justify departure from the usual clinical management*)

Exceptionality Test 2

Will this patient benefit to a greater degree from receiving this treatment than others in this patient population/cohort? (*The onus is on the applicant clinician to demonstrate that there are factors about this specific patient that indicate a*

departure from the usual clinical management will result in a gain for this patient that is significantly greater than that normally expected of this patient population in general.)

The ECC Panel will have regard for:

- How is this patient significantly different from the population of patients with similar clinical circumstances who would not normally be offered this treatment?
- Is this patient likely to gain significantly more benefit from this treatment than would be expected from other patients who are not currently offered it?
- Clear evidence of clinical effectiveness of the proposed intervention for this particular patient has been demonstrated.

It should be noted that:

- The fact that treatment is likely to be effective for a patient is not, in itself, a basis for exceptionally or approval
- If a patient's clinical condition matches the "accepted indications" for a treatment that is not funded, they are by definition, not exceptional

The Panel will not take into account irrelevant considerations in evaluating each case. In particular, the Panel will not normally consider social issues *alone* as part of its evaluation of exceptionality.

The Panel will take into account the ethical considerations of

- autonomy (respect for individual choice),
- beneficence (duty to promote good which includes balancing benefits and risks), non-malfeasance (duty to do no harm) and
- justice (both distributive justice, and fair access / non-discriminatory principles) where not already explicit within the criteria noted in paragraph 20.

The Panel will also take into account the impact of the Human Rights Act 1998 and the relevant Articles referred to therein but these will be balanced against proportionality and the statutory responsibilities of the CCG

It is the responsibility of the person submitting the application to provide sufficient evidence to demonstrate the patient's exceptionality and to provide evidence of the clinical and cost effectiveness of the treatment being requested.

The 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.

The Panel is not required to accept the views expressed by the patient or the referring clinician concerning the likely clinical outcomes for the individual patient of the proposed treatment but is entitled to reach its own views on:

- The likely beneficial 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 Panel has about the likelihood of the proposed treatment delivering the proposed clinical outcomes for the individual patient.

In each individual case, it is the decision of the Panel, whether the circumstances of the individual patient are "exceptional" although these should be consistent with similar decisions made previously and should be based on the principles of exceptionality defined above.

When considering referrals the Panel has four options:

1) agree the request because exceptional circumstances have been demonstrated;

2) refuse the request where there is a clear policy concerning the situation and there is no evidence that the individual constitutes an exception to the policy;

3) request additional information where this information is thought to have a bearing on any decision that will be made; or

4) conclude that the patient is not, in fact, exceptional, but representative of a group of patients.

In cases which could relate to a group of patients and the Panel feels strong evidence has been provided in support of a particular treatment, the clinician/provider will be asked to submit a business case in support of the routine use of the treatment. Where appropriate, this process will be supported by the Pharmaceutical Advisor and/or Business Delivery Manager (e.g. where the service development involves more than one provider).

This business case, following consideration at the appropriate forums, will be reviewed by NEE CCG for a commissioning decision to be taken. In order not to disadvantage a particular patient, where a decision is clinically urgent, the panel may agree funding in this circumstance. This however will not form a precedent or set a policy decision for a cohort of patients or the CCG. Where the case is not clinically

urgent this will be referred to the appropriate decision making body for consideration. Please see section b) above and paragraph 5 of the main document.

In cases where a patient is part of a cohort for whom there is no current commissioning decision and the patient is experiencing rapid deterioration in their condition that could result in permanent disability or death, the following process will be followed:

- Undertake an urgent communication with the applicant clinician to determine the degree of clinical deterioration/severity.
- ECCP will reconsider the case as urgent if necessary if new indication of exceptionality is provided.
- If not exceptional, the case will be brought to the attention of the Chief Operating Officer and Director of Nursing immediately to determine the appropriate corporate course of action on the individual case in light of the clinical information provided and the stage in the commissioning decision making process for the cohort.

Positive exceptional funding decisions are not an absolute approval for the treatment to go ahead. A decision to treat is a clinical decision and responsibility rests with the clinician to whom the patient is referred in consultation with the patients themselves.

5. Exceptional Clinical Circumstance Panel Meetings

5.1 The Panel will meet on a regular basis, usually 2 weekly but as a minimum monthly. The Panel may establish time limited sub-groups with professional and managerial expertise appropriate to the issue under review to support its work.

5.2 In making its decisions, the Panel will have reference to a continuous record of previous decisions to ensure consistency.

5.3 Any individual who has previously been involved in any part of the patient's care should declare involvement and a decision should be made regarding if it is appropriate for the individual to be involved in the decision. Declarations of interest or involvement in the patients care should be made prior to the panel to enable this discussion to occur.

5.4 An agenda and all supporting documents will be circulated 48 hours before the Panel meeting. Papers will not usually be tabled at meetings in order to ensure that all decision makers have had an opportunity to read and comprehend all pertinent information. Any application that is not complete one week prior to the meeting date will be deferred to the next meeting unless clinically the case cannot wait.

5.5 The patient's applicant clinician is invited to make a teleconference representation on their behalf if he/she feels that this is appropriate.

5.6 Having received all the evidence, submissions and representations, the Panel will consider the case privately. The referrer will be provided with a written explanation of the Panel's decision within 10 working days of the panel date.

5.7 The IFR and Prior Approvals Co-ordinator (Drugs and Devices) will produce suitably detailed minutes/notes from the Exceptional Cases Panel meetings, which will detail a record of attendees, case numbers discussed and processes and outcomes agreed.

5.8 Following the Panel meeting, the outcome will be communicated, by the IFR and Prior Approvals Co-ordinator (Drugs and Devices) to the applicant clinician. A letter from the Chair of the Panel, indicating the outcome of the Panel's deliberation will be sent within a maximum of ten working days but the CCG will aspire to provide outcomes within five working days.

5.9 Outcome letters will be in a standard format to include information on the appeals process. Patients can request a copy of the minutes of the meeting as pertaining to them.

6. Appeals Process

How to make an appeal

Appeals will only be heard on the basis of the challenge to the decision making process. Disagreeing with the decision alone is insufficient grounds for appeal. The Appeals Panel does not reconsider the merits of the original application, but evaluates whether or not the original decision followed procedure, considered all the available evidence and was reasonable. If a patient wishes to contest the decision/ outcome of the respective CCG decision making panels they should follow the NHS North East Essex Complaints Process.

In cases where an exceptional case for funding is refused by the Exceptional Clinical Circumstance Panel, the letter sent to the applicant clinician will also include details of the process by which a decision can be appealed. Where a patient wishes to appeal they should give notice of their intention to do so in writing within 30 days of being notified of the decision. Appeals should be sent to the IFR and Prior Approvals Co-ordinator (Drugs and Devices) electronically or in writing. The reasons proposing the appeal (see paragraph 6.2 below) should be clearly set out in writing. Requests which do not indicate the grounds for appeal will not be considered.

6.1 An External appeals panel will be convened *only* if the patient/applicant clinician believes:

- A matter of process (as detailed in this Policy) was not adhered to, or
- Not all of the available evidence was taken into account in reaching the decision or

- Where an individual is able to demonstrate that the decision reached by the Exceptional Cases Panel was unreasonable (for example, not properly based on the evidence set before the committee).

6.2 Appeals can be requested by the patient and/or the applicant clinician.

6.3 The CCG will not entertain appeals outside the 30 - day time limit, unless the applicant clinician can show that it was not possible to apply within that timescale.

6.4 Upon receiving an appeal request, **NEE CCG** will remit the appeal to another **CCG**. Patients will be sent a holding letter informing them of the date of their appeal.

6.5 The IFR and Prior Approvals Co-ordinator (Drugs and Devices) will prepare the following papers for consideration by the Process Appeals Panel:

- The papers presented to the Exceptional Clinical Circumstance Panel together with their decision (as minuted & including details of panel attendance)
- a chronological statement of events
- the letter requesting the appeal from the applicant clinician.
- any further material submitted by the patient (a statement of grounds for appeal)

6.6 The Appeal Panel will consider the original reports and the process undertaken and will not make a decision on the merits of the application itself. If it concludes that any of the steps outlined in this paragraph were not followed then it will direct the Exceptional Cases and Individual Funding Requests Panel to reconsider that specific point(s) only.

Appeals of an Exceptional Cases and Individual Funding Requests Panel decision by the Appeals Panel will not be heard in public and the patient is unable to make personal representations.

6.7 The Appeals process does not affect a patient's rights under the NHS complaints procedure and the right for a patient to take their case to their Member of Parliament or to the Ombudsman is not affected.

Following an unsuccessful Appeal, North East Essex CCG will not accept a submission for the same treatment unless the patient's clinical circumstances have changed and these changes have the potential to demonstrate exceptionality within the context of the specific request. Any resubmissions of

applications involving new clinical information will be reviewed by the Clinical Priorities Policy Clinical Review Group who will take an opinion on whether or not the new information warrants a substantial change in the application and should be fully reconsidered.

6.8 The referrer will receive a written response from the patient's Exceptional Cases Commissioning team informing them of the outcome of their appeal within a maximum 10 working days of the decision of the Process Appeals Panel.

6.9 The patient has the right to make a complaint to NEE CCG regarding the administration of the appeal process using North East Essex CCG's Complaint's Procedure.

6.10 Thereafter the patient may have recourse to the Parliamentary and Health Service Ombudsman.

6.11 Please see below for Appeals for Urgent Applications.

7. Urgent Requests

7.1 For clinically urgent requests (where a patient's health may be seriously adversely affected if a decision is not taken before the next scheduled meeting of the Panel), the Exceptional Clinical Circumstance Panel delegates its authority to the Clinical Priorities Policy Clinical Review Group. The Panel will be informed of such cases at the next scheduled meeting.

7.2 Urgent requests are expected to come in the form of an urgent clinical letter or a phone call from the responsible consultant to the CCG Head of Medicines Management or the CCG Senior / Commissioning representative (Managerial lead for IFR), who will be advised by the remaining members of the CRG providing their advice can be sought in a timely manner. The request will be assessed as to whether the funding request is because of clinical urgency or administrative urgency.

7.3 Urgent requests are required to be sanctioned by the provider trust during normal working hours.

7.4 A contact name and number of the applicant clinician should be provided to enable the CCG to gather further information if needed.

7.5 Funding will not be approved due to administrative urgency. Administrative urgency is defined as a funding request which has now become urgent because the provider has failed to seek funding approval in advance of any arrangement to treat the patient. The provider Trust, having given a commitment to treat the patient, is expected to go ahead with treatment and bear the costs itself.

7.6 Clinical emergency is where a genuine unplanned and urgent clinical need requires an urgent decision. A nominated member of the CRG will aim to establish:
- The nature and severity of the patient's clinical condition.
- The window of opportunity for treatment and subsequently agree with the clinician the deadline for decision making.
- As much information about both the patient's illness and the treatment as feasible in the available time scale.
- Identify any commissioning policy/policies which are engaged in this situation.

7.7 A decision will be made on the basis of the above information. **Urgent decisions are not precedent setting**. There may be times when the decision needs to be escalated up beyond delegated duties as set out here.

7.8 The appeals process for decisions on urgent cases will follow steps as above but will be heard on an expedited basis by the Director of Nursing and the Chief Operating Officer.

8 Information Systems to support Exceptional Case Panel

8.1 The Exceptional Case Team will maintain a database containing the following minimum dataset:

- Application identifier
- Referring clinician
- Date request received
- Date of consideration by ECP
- Date of decision
- Decision
- Reconsideration (date and decision)
- Appeal (date and decision)
- Cost
- Date of trial period if required
- Number of treatments and period until review

8.2 A process for monitoring cases will be established to ensure that further information is pursued on a timely basis, and where this is not forthcoming, that cases are closed and referrers are informed.

8.3 Any further information on existing cases that is requested and received will be updated on the database, and a file note entered into the patient's record. All communication relating to cases either written or verbal will be fully documented and added to the patient case file in chronological order.

8.4 Quarterly reports on performance will be provided with respect to timeliness and outcomes of case load managed in that period.

8.5 All hardcopy ECCP files will be kept in locked cupboards.

8.6 All electronic ECCP files/information will be kept in a designated and protected folder on the M-drive. All electronic files must be kept exclusively in this folder. Access to this folder will be limited to members of the Clinical Priorities Team.

9 Communication with Patients Regarding Appeals

9.1 Team members will always seek to be timely, polite and informative in their contact with all parties with regards to the processing of the application in question.

9.2 All patient initiated contact with the Exceptional Cases Administrative Team will be in writing to ensure that the correct information is available to be presented to the Panel. Patients are asked to discuss any specific issues/concerns that they may have with their application with their referring clinician.

9.3 In situations in which there are concerns about patient safety or provider performance, telephone contact directly with a patient may be initiated at the discretion of the Head of Medicines Management.

9.4 The Clinical Priorities Team will not discuss the outcome of cases with patients on the telephone. This is to ensure that patients receive accurate information.

Exceptional funding or Individual funding request (Procedures) for BMI or smoking exceptions

Please complete all relevant sections in full in a typed format. Please attach all relevant clinical evidence. Please return to the Exceptional Cases and Individual Funding Team

	Kathy West, Clinical Priorities Manager - North East Essex CCG Aspen House, Stephenson Road, Severalls Business Park, Colchester, CO4 9QR Tel: 01206 918734 Fax: 01376 530989 Email:neeccg.fundingrequests@nhs.net

Incomplete applications will be returned and may result in a delay in the decision making process.

A: Patient details

Patient NHS Number:

UBRN:

Date of birth (DD/MM/YY):

CCG Ref No (if known):

Gender: ☐ Female ☐ Male

Interpreter required: ☐ No ☐ Yes, language:

Transport required: ☐ No ☐ Yes, state type:

B: GP details

GP name:

GP Practice address:

GP practice code:

GP contact no.:

GP email address:

C: Applicant clinician details

GP/Consultant's name:

Address:

Contact no.:

Email address:

Date of Application to CCG

Section 1: All applicant clinicians must complete this section

Is this application for exceptional funding requested in relation to a patient outside the criteria for BMI for elective General Surgery or Spinal, Hip or Knee procedures and or smoking status? Please tick

BMI

Smoking status

Patient BMI: (if relevant)

Smoking status: Smoker Non-Smoker

1. What is the patient's condition/diagnosis?

2. What is the proposed treatment?

3. What treatments has the patient received to date for this condition?

4. Exceptionality Test 1

How is the patient significantly different from other patients in this patient population? (The onus is on the applicant clinician to demonstrate that this patient is significantly different from other patients in a similar situation to justify department from the usual clinical management)

5. Exceptionality Test 2

Will this patient benefit to a greater degree from receiving this treatment than others in this patient population/cohort? (The onus is on the applicant clinician to demonstrate that there are factors about this specific patient that indicate a departure from the usual clinical management will result in a gain for this patient that is significantly greater than that normally expected of this patient population in general.)

Other Clinical Information: (please attach prescription history, clinical letters, etc.)

North East Essex
Clinical Commissioning Group

Exceptional funding or Individual funding request (Procedures)

What needs to be filled out:

1. If you are seeking funding for a treatment that is usually excluded or partially excluded from the NHS as indicated in the Clinical Priorities Policy, **only complete Section 1.**

2. If you are seeking funding for a new treatment/technology you must **complete in full Sections 1, 2 and 3** of this application.

Please complete all relevant sections in full in a typed format. Please attach all relevant clinical evidence.

Please return to the Exceptional Cases and Individual Funding Team

	Kathy West, Clinical Priorities Manager - North East Essex CCG Aspen House, Stephenson Road, Severalls Business Park, Colchester, CO4 9QR

Tel: 01206 918734 Fax: 01376 530989 Email:neeccg.fundingrequests@nhs.net

Incomplete applications will be returned and may result in a delay in the decision making process.

A: Patient details

Patient NHS Number:

UBRN:

Date of birth (DD/MM/YY):

CCG Ref No (if known):

Gender: ☐ Female ☐ Male

Interpreter required: ☐ No ☐ Yes, language:

Transport required: ☐ No ☐ Yes, state type:

B: GP details

GP name:

GP Practice address:

GP practice code:

GP contact no.:

GP email address:

C: Applicant clinician details

GP/Consultant's name:

Address:

Contact no.:

Email address:

Date of Application to CCG

Section 1: All applicant clinicians must complete this section

1. What is the patient's condition/diagnosis?

2. What is the proposed treatment?

3. What treatments has the patient received to date for this condition?

4. Exceptionality Test 1

How is the patient significantly different from other patients in this patient population? (The onus is on the applicant clinician to demonstrate that this patient is significantly different from other patients in a similar situation to justify department from the usual clinical management)

5. Exceptionality Test 2

Will this patient benefit to a greater degree from receiving this treatment than others in this patient population/cohort? (The onus is on the applicant clinician to demonstrate that there are factors about this specific patient that indicate a departure from the usual clinical management will result in a gain for this patient that is significantly greater than that normally expected of this patient population in general.)

6. How many patients in a 12 month period would you expect to seek similar treatment for?

7. How much does the intervention cost?

Section 2: Must be completed for applications involving new treatments or techniques

The proposed intervention should have a high likelihood of success or should substantially reduce the risk associate with the standard intervention. Please provide evidence (e.g. papers outlining the intervention outcome with patient specific information sufficient to identify the proposed patient as being similar to the study in which the benefit was seen).

The Panel will base its deliberations on the information provided.

1. Safety

a. Is the proposed intervention safe?
b. Is the treating clinician adequately qualified/experienced to perform this treatment? Please provide evidence.

2. Effectiveness

a. Is the intervention effective?
b. Why is the proposed intervention thought to be superior to the standard treatment in this patient's case?
c. Have clear outcomes been set with the patient?
d. What level of response will be considered ineffective?
e. How is response to the intervention to be monitored?
f. What is the end point at which the intervention will stop?
g. What are the longer-term follow-up arrangements?
h. Are these the responsibility of the unit in which the intervention took place or a unit more local to the patient's home?
i. Do the follow-up arrangements attract additional resource?

3. Equity and fairness

a. What are the local treatment options for this patient?
b. What is the cost of the standard intervention vs. the proposed intervention?

Treatment Requested:

Clinical Information:

Patient BMI: (if relevant)

Smoking Status: smoker non-smoker

Other Clinical Information: (please attach prescription history, clinical letters, etc.)

North East Essex
Clinical Commissioning Group

INDIVIDUAL FUNDING REQUEST/EXCEPTIONAL CLINICAL CIRCUMSTANCES

Guidance for the use of the IFR/ECC submission form

Individual funding requests should only be made where the patient has **exceptional clinical circumstances**, and will be subject to audit.

Completing the form:

- This form must be completed by the requesting consultant for all off-protocol requests requiring CCG funding (for example: cancer chemotherapy protocols that are not on the Network approved list).
- Your submission will be greatly supported if you directly answer these two 'tests' of exceptionality in section 10, and give appropriate evidence in the other sections.

The patient

1) **is significantly different from the general population of patients with the same diagnosis/condition in question.**

AND

2) **is more likely to benefit from this treatment/intervention than might be expected for the average patient with the diagnosis/condition.**

- The fact that the diagnosis is very rare, or that the treatment might be efficacious for the patient is not, in itself, grounds for exceptionality. If a patient's clinical condition matches the 'accepted indications' for a treatment that is not funded, they are by definition, not exceptional.

- Only evidence of clinical need will be taken into consideration. Factors such as gender, ethnicity, age, lifestyle or other social factors such as employment or parenthood will not be considered on grounds of equality.
- It is the responsibility of the requesting clinician to demonstrate exceptionality.

1. Requests can only be made on an individual patient basis and should be completed by an appropriate referring clinician **prior** to referral for treatment. Trusts should treat all urgent and life-threatening situations based on the clinical need. It is not guaranteed that such treatment will be necessarily funded in the case of similar subsequent cases if the CCG does not consider it as clinically effective or cost effective.

2. The CCG will not normally fund a patient's treatment to continue following a clinical trial. In line with the Medicines Act 2004 and the Declaration of Helsinki, the responsibility for ensuring a clear exit strategy from a trial and that those benefiting from treatment will have ongoing access to it, lies with those conducting the trial.

3. The CCG will not normally fund novel or uncertain treatments. Funding for new, rarely used, **unlicensed** and/or investigational drugs outside of a research trial will remain the responsibility of the provider unless a business case is submitted in advance to the commissioner to take through the due process.

4. The following criteria should be used to identify how urgent a request is:

   - **Most urgent** response within 3 working days as the patient's life may be in danger
   - **Immediate** decision needed within 3 weeks as delay will not be clinically appropriate
   - **Routine** decision needed in 4 to 6 weeks

The requesting clinician is asked to provide clinical feedback on the outcomes of treatment (ideally following clinical review in 3 months or as appropriate).

Deadline:

- NEE CCG holds a monthly meeting to review submissions; the deadline is 1 week before the meeting.
- You will be informed of the decision, at the very latest, within 4 weeks of this meeting.
- If your patient needs to have a decision before this deadline, please advise directly when you submit this form.

Submitting the form:

Please note that emails must be sent from an nhs.net address to an nhs.net address. Alternatively please fax the request.	Email: NEECCG.fundingrequests@nhs.net

	Safehaven Fax: 01376 530989
If you have any queries please contact	Carol Sampson, Evidence Base Pharmacist Tel: 01206 918722

EXCEPTIONAL CIRCUMSTANCES SUBMISSION FORM

For review of an exception to CCG policy

Full published papers, rather than abstracts, should be submitted, unless the application relates to the use of an intervention in a rare disease where published data is not available

Completed form to be returned to NEECCG.fundingrequests@nhs.net

Safehaven Fax: 01376 530989

CONTACT INFORMATION

Trust Name		
1. Address		
2. Applicant Details	**Name:**	
	Designation:	
	Tel:	
	Email:	
3. Patient Details	**Initials:**	
	NHS No:	
	Hospital ID number:	
	Postcode:	
	DoB:	
	Registered Consultant:	
	Registered GP name:	
	Registered GP postcode:	
	Registered Practice Code:	

	Referred by (other than GP):	
	Referred from:	
	Date of referral:	
4. Application reviewed by Trust Chief Pharmacist of the requesting organisation or nominated deputy (in the case of a drug intervention)	**Name:**	
	Signature or email confirmation:	

INTERVENTION REQUESTED (NB: Intervention refers to requested treatment, investigation, etc)

5. Patient Diagnosis (for which intervention is requested)			
6. Summary of previous intervention(s) this patient has received for the condition. * Reasons for stopping may include: • Course completed • No or poor response • Disease progression • Adverse effects/poorly tolerated	**Dates**	**Intervention (e.g. drug / surgery)**	**Reason for stopping* / Response achieved**
7. Clinical history Please provide a brief clinical history of the	What is the patient's clinical status at this point? What is the severity of the current and any co-existing problem? Where possible use standard scoring systems e.g. WHO status, DAS scores, 6 minute walk test, cardiac index etc.		

patient outlining • current problems, • any co-morbidities, • investigation results for current problem, • treatments given so far • abilities in independence and self-care Attach most recent correspondence between GP and referring consultants if appropriate. (Please extend space if necessary)		
8. Details of intervention (for which funding is requested). If the intervention forms part of a regimen, please document the full regimen.	**Name of intervention**	
	Dose and frequency:	
	Planned duration Of intervention:	
	Route of administration:	
	Anticipated cost (inc VAT)	NB: This must be completed

9. Is requested intervention part of a clinical trial?	Delete as appropriate: **Yes/No** If **Yes**, give details (e.g. name of trial, is it an MRC/National trial?)
	Is the drug funded through a clinical trial? Delete as appropriate: **Yes/No**

10.(a) What would be the standard intervention at this stage?	
(b) What would be the expected outcome from the standard intervention?	
(c) What are the exceptional circumstances that make the standard intervention inappropriate for this patient?	
(d) How does this patient differ from the general population of patients with this condition?	
(e) Why is this patient more likely to respond to the requested therapy than the general population with the same condition?	
11.Anticipated start date	The CCG holds a monthly meeting; deadline is 1 week before. You will be informed of the decision, within 4 weeks of this meeting. Please advise if urgent and a response is needed before that time .

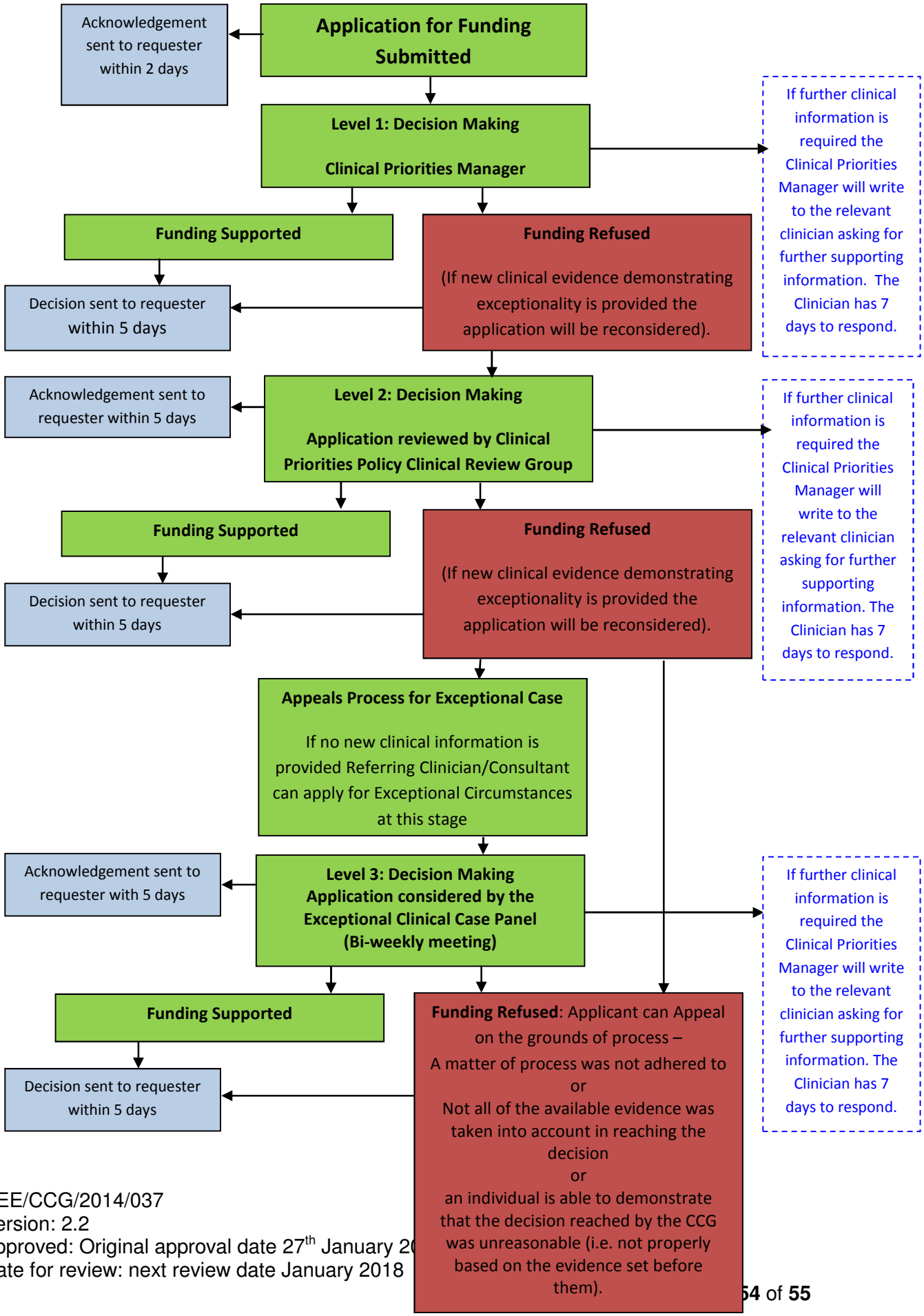
CLINICAL EVIDENCE

12.Is requested intervention licensed for use in the requested indication in the UK?	Delete as appropriate: **Yes/No** (refer to pharmacy if required)
13.Has the Trust Drugs and	Delete as appropriate: **Yes/No**

Therapeutics Committee or equivalent Committee approved the requested intervention for use? (if drug or medical device)	If **No,** Committee Chair or Chief Pharmacist approved: **Yes / No**
Give details of National or Local Guidelines/ recommendations or other published data supporting the use of the requested intervention for this condition?	**PUBLISHED trials/data** (please forward papers / web links for peer-reviewed papers where available)
14.(a) How will you monitor the effectiveness of this intervention?	
(b) Detail the current status of the patient according to these measures.	
(c) What would you consider to be a successful outcome for this intervention in this patient? Please state added benefits of this treatment, e.g. QOL, life expectancy, impact on or facilitating subsequent treatment, etc.	
15.What is the anticipated toxicity of the intervention for this patient?	
16.What are your criteria for stopping treatment? Define fully using objective measurements or recognised assessment scales.	

17.Are there any patient factors (clinical or personal) that need to be considered?	Delete as appropriate: **Yes/No** If **Yes**, please give details:
19. Form completed by	**Name:**
	Signature or email confirmation:

Appendix 4- Internal Management of Application Process for PRIOR APPROVAL / IFR / EXCEPTIONAL CASE APPLICATION (Non-Clinically Urgent Cases)



Appendix 5 Prior Approval (PA)/Individual Funding/ Exceptions Process