Commissioning Policy
Individual Funding Requests (IFR) and Exceptional Cases Applications
ME CCG Policy Reference:
MECCG21

Target Audience	All members of Clinical Commissioning Group staff and other organisations acting on behalf of the Clinical Commissioning Group
Brief Description (max 50 words)	
Action Required	To be approved by the CCG Board and then made available to staff.

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Responsible Officer	Chief Pharmacist
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Amendment History

Version	Date	Reviewer	Comments
1.0	10/03/14	Chief Pharmacist	Policy developed to produce version 1.0
1.1	17/07/14	Chief Pharmacist	Contact details amended to produce version 1.1
1.2	23/09/15	Chief Pharmacist	Link to Service Restriction Policies updated; removal of restriction re circulation of decision framework document to produce version 1.2
1.3	15/12/15	Chief Pharmacist	Inclusion of section on declaration of interests and conflicts of interest to produce version 1.3
1.4	20/03/18	MECCG Board	Amendments made to appendix H Terms of Reference

	Contents Page	Page

INTRODUCTION

The NHS exists to serve the needs of all of its patients but also has a statutory duty financially to break even (National Health Service Act 2006). Clinical Commissioning Groups (CCGs) have a responsibility to provide health benefit for the whole of their population, whilst commissioning appropriate care to meet the clinical needs of individual patients. Mid-Essex Clinical Commissioning Group is a CCG and receives a fixed budget from Central Government with which to commission the healthcare required by its population. Commissioned services include those provided through primary, secondary and tertiary care NHS providers, the independent sector, voluntary agencies and independent NHS contractors.

CCG investment and disinvestment decisions are driven by the annual planning guidance and set out in its commissioning intentions. CCGs do not expect to make significant decisions outside this process and in particular do not expect to commit significant new resources in year to the introduction of new healthcare technologies (including drugs, surgical procedures, public health programmes) since to do so risks ad-hoc decision making and can destabilise previously identified priorities.

The commissioning process, by its very nature, focuses on cohorts of patients with more common clinical conditions. It cannot meet every healthcare need of all patients in any one clinical group or address the specific needs of patients with less common clinical conditions. The fact that the CCG is not meeting a healthcare need due to resource constraints is an inevitable fact of life in the NHS and does not indicate that the CCG is breaching its statutory obligations.

The CCG is required to have a process for considering funding for individuals who seek NHS commissioned services outside established commissioning policies. There are in general two types of requests that come before an Individual Funding Request (IFR) Panel, namely:

1. Requests for funding treatments for medical conditions where the CCG has no established commissioning policy (as shown by CCG policy or the treatments which are approved for routine funding in service agreements). (Commonly called IFR requests)

2. Requests for funding treatments for medical conditions where the CCG does have an established commissioning policy for that condition but where the requested individual treatment is not in the CCG policy or does not meet the criteria set out in the policy. (Commonly called Exceptions or Exceptionality requests)

This policy requires requests in the first category to be considered against the tests of clinical effectiveness, cost effectiveness and affordability provided the requesting clinician is able to demonstrate that the patient represents an Individual Patient and not typical of a group of patients eg the first in a cohort.

For patients in the second category the policy requires, as a threshold condition, the requesting clinician to demonstrate that the patient has exceptional clinical circumstances. If the clinician demonstrates that the patient has exceptional clinical circumstances (as defined in this policy) the request will also be considered against tests of affordability.

This approach ensures that decisions relating to resource allocation are made transparently and consistently in relation to treatment for those patients with rare conditions, those patients for whom treatments of uncertain or unproven medical benefit are sought, or where treatment costs requested may be out of proportion with the benefit to the patient.

Each CCG is accountable for the management of Individual Funding Requests. This policy must be used to consider:

- requests for any form of medical treatment or care which is not included within existing commissioned service agreements;
- requests for any form of medical treatment or care which, for this particular patient, are outside the parameters set by existing commissioned service agreements;
- requests for any form of medical treatment or care where the treatment or care proposed could not be considered to be 'mainstream'.

MECCG has established an IFR and exceptional cases application process to consider such applications. This may include consideration by an Individual Funding Requests Panel. In considering an individual case the Panel will apply the CCG Commissioning Principles for decision making set out in Section 3 and the underpinning policies of the CCG.

Prior approval

In addition, MECCG has a number of policies which require prior approval before treatment can commence. Clinicians apply to the IFR department for approval and requests are screened by the IFR Co-ordinator and/or clinical advisors where appropriate upon request from the IFR Co-ordinator against the relevant policy. Applications are considered in a timely fashion in line with the CCG Prior Approval Policy and decisions are communicated to clinicians in writing and recorded on a secure local database. (see CCG Prior Approval Policy)

2. PURPOSE

The IFR process set out in this policy will be used to consider individual requests for funding where a service, intervention or treatment falls outside existing service agreements.

This process will ensure that each request for individual funding is considered in a fair and transparent

way with decisions based on the best available evidence and in accordance with the CCG commissioning principles.

3. CCG COMMISSIONING PRINCIPLES THAT UNDERPIN IFR DECISION MAKING

It is important that a CCG ensures a consistent approach is used to guide the allocation of its resources in both population based and individual commissioning decisions.

A principle[1] based decision making process supports the strategic planning and the effective use of resources within a CCG. All CCG commissioning decisions need to be made in accordance with these principles.

The Principles that the CCG seeks to support are:

- the CCG requires clear evidence of clinical effectiveness before NHS resources are invested in the treatment
- the CCG requires clear evidence of cost effectiveness before NHS resources are invested in the treatment
- the cost of the treatment for this patient and others within any anticipated cohort is a relevant factor.
- the CCG will consider the extent to which the individual or patient group will gain a benefit from the treatment
- the CCG will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
- The CCG will consider all relevant national standards and take into account all proper and authoritative guidance
- Where a treatment is approved, the CCG will respect patient choice, within existing commissioned pathways and CCG policies, as to where a treatment is delivered.

When considering an IFR, a CCG will also ensure that decisions:

- comply with relevant national policies or local policies and priorities that have been adopted by the CCG concerning specific conditions or treatments
- are based on the available evidence concerning the clinical and cost effectiveness of the proposed treatment, and;
- are taken without undue delay; a pragmatic approach may need to be taken when dealing with urgent requests i.e. where a delay in reaching a decision to fund adversely affects the clinical outcome.

The CCG considers all lives of all patients to be of equal value and in making decisions about funding treatments will seek not to discriminate on the grounds of age, sex, sexuality, race, religion, lifestyle, occupation, family and caring responsibilities, social position, financial status, family status (including responsibility for dependents), intellectual/cognitive functioning or physical functioning save where a difference in the treatment options made available to patients is directly related to the patient's clinical condition or is related to the anticipated clinical benefits for this individual to be derived from a proposed form of treatment.

[1] principle: *a basic truth or a general law or doctrine that is used as a basis of reasoning or a guide to action or behaviour*

4. POLICY GUIDANCE

In considering individual cases, the CCG will apply the Commissioning Principles, the underpinning policies of the CCG and the following guidance which expands upon them.

4.1 Introduction of New Drugs and Technologies

The CCG will not introduce new drugs/technologies on an ad-hoc basis through the mechanism of individual case funding. To do so risks inequity, since the treatment will not be offered openly and equally to all with equal need. There is also the risk that diversion of resources in this way will de-stabilise other areas of health care which have been identified as priorities by the CCG. The CCG expects consideration of new drugs/technologies to take place within the established planning frameworks of the NHS. This will enable clear prioritisation against other calls for funding and the development of implementation plans which will allow access for all patients with equal need.

4.2 NICE New Technology Appraisals (TAs).

Drugs and technologies that are approved as the result of a NICE Technology Appraisal (TA) need to be implemented within 3 months of the appraisal being published. The CCG will, within resource constraints, seek to ensure implementation of NICE TAs without delay but recognises that the CCG may take the full period of 3 months before a new commissioning policy can be brought into place where significant service change and/or development are required as part of the implementation. NICE also produces other guidelines which are a valuable source of good practice which the CCG will take into account in developing policy but the CCG retains discretion and is not mandated by Directions to implement such Guidance within a fixed time period or at all.

4.3 Treatments Covered by CCG Commissioning Policies

The CCG policy is that treatments not currently included in established care pathways (as identified for example in the Schedules to the service agreements with acute care providers) or identified for funding through the commissioning process are not routinely funded. For a number of these interventions the CCG has published specific policy statements setting out restrictions on access based on evidence of effectiveness or relative priority for funding. These are available on the MECCG website:
http://midessexccg.nhs.uk/your-nhs/medicines-management/service-restriction-policies and
http://www.midessexccg.nhs.uk/your-nhs/medicines-management

Policy development is an on-going process and future policy on further treatments, in response to NICE Guidance/Guidelines, health technology assessments etc will be produced and published periodically.

4.4 Treatments Not Covered by CCG Commissioning Policies

Specific groups of patients may not be covered by CCG Commissioning Policy including:

- Patients with conditions for which the CCG does not have an agreed policy, including patients with rare conditions and whose proposed treatment is outside agreed service agreements.
- Patients with conditions for which the CCG does have an agreed policy but who may have exceptional clinical circumstances which lead to their clinician seeking a treatment that is not routinely available
- Patients with conditions that are the commissioning responsibility of NHS England, including patients with rare conditions and whose proposed treatment is outside agreed service agreements. Many of these will be covered by the National commissioning Board Specialist Commissioning Policies. http://www.england.nhs.uk/ourwork/d-com/policies/ Consideration of funding against these policies is outside the remit of the CCG.

In such circumstances the CCG will not have given approval in advance to fund the treatment and approval will therefore be required under this policy. The treating clinician should consider, before making the application, whether the requested treatment is an appropriate request judged against the CCG Commissioning Principles.

The role of the IFR Panel is to make decisions on individual cases. It cannot be used as a means of 'creeping implementation' for new technologies. Consideration therefore needs to be given as to the likelihood of other patients having the same clinical need who could also benefit from the proposed treatment. If there are or are likely to be other patients then, properly considered, the request is for a service development and not an individual application. Where a decision may affect other patients, the application should be considered as a service development and not through the IFR process.

Patients with rare conditions should neither be advantaged nor disadvantaged simply because their condition is uncommon. This means that the same approach will be taken in applying the principles of clinical effectiveness and cost effectiveness to patients with rare conditions as should be applied to all other patients.

4.5 Requests to Continue Funding for Patients Coming Off Drugs Trials

The CCG does not expect to provide funding for patients to continue medication/treatment commenced as part of a clinical trial. In line with the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Declaration of Helsinki, the responsibility lies with those conducting the trial to ensure a clear exit strategy from a trial AND that those benefiting from treatments provided within the trial setting will have on-going access to those treatments. The initiators of the trial (provider trusts and drug companies) have a moral obligation to continue funding patients benefiting from treatment until such time as the CCG agrees to fund through the commissioning process. Where the treatment is not

prioritised through commissioning, the responsibility remains with the trial initiators. The Research Ethics Committee should require this assurance as part of the approval for the trial.

4.6 Requests to Continue Funding for Treatments Commenced 'at risk' by Providers or by others (Including Patients)

On occasions, a request is received where a provider trust has commenced an unfunded treatment prior to asking for or receiving confirmation that the CCG will approve funding. Evidence that the patient is responding to the treatment is then presented as part of the case for CCG funding.

The provider trust's decision to commence treatment in advance of any decision by the CCG to fund is a clear risk taken by the trust and/or patient. The CCG accepts no responsibility for the decision taken by the provider trust in these circumstances.

In considering a request for funding the CCG will apply the criteria set out in this policy as it would for any other request, and accords no special privileges because the unfunded drug was given by a provider trust.

The CCG policy is that, unless a decision has been taken to approve routine funding for a treatment, the treatment will only be commissioned for an individual patient if the clinician is able to demonstrate that the patient has exceptional clinical circumstances. The fact that a patient has responded to a drug or other treatment in a manner which was anticipated for a proportion of patients who are commenced on the treatment is unlikely to be sufficient to demonstrate exceptional clinical circumstances.

Where such an application is approved on the basis of the clinician demonstrating that the patient has exceptional clinical circumstances (as defined in this policy), the CCG will not accept responsibility for the costs of any treatment provided by the provider trust prior to authorisation being given by the CCG.

A similar approach will be adopted if a treatment has been funded initially by a pharmaceutical company or other third party.

There are occasions where the initial stages of an unfunded treatment have been funded privately by the patient. The CCG will consider any information submitted on behalf of a patient in support of their case that the patient has exceptional clinical circumstances. This may include evidence derived from treatment that has been purchased privately and used by the patient. However, this potentially opens the way for a limited group of patients who can afford to fund a treatment that the CCG does not usually fund to be able to demonstrate benefit by virtue of access to private care and then submit this

as a reason to justify NHS funding for the treatment in their particular case. This is a potentially inequitable approach and, in order to ensure that the CCG does not act in an inequitable manner, the issue of exceptional clinical circumstances will therefore continue to be the criteria applied by the IFR process. Accordingly, the CCG adopts no presumption in favour of continuing treatment which has been previously paid for privately by the patient. As stated above, evidence that a treatment works as anticipated for a proportion of patients in the patient's clinical circumstances is unlikely, in itself, to provide evidence of exceptionality.

4.7 Requests to Continue Funding of Care Commenced privately e.g. reverting to NHS care

Patients who are having private treatment have a right to revert to NHS funded treatment at any point during their care. However, if they wish to exercise this right, the CCG will expect their care to be transferred to local pathways but not necessarily with the same clinician who the patient had consulted with when a private patient even if the clinician is contracted by the NHS. Where personal clinical circumstances may make such funding appropriate the case will require consideration by the IFR process.

4.8 Decisions Inherited from Other Commissioners e.g. patients who move

Occasionally patients move into the area and become the responsibility of the CCG (by registering with a GP in Mid-Essex) when a package of care or treatment option has already been approved by the CCG that was previously responsible for the patient's care. The CCG's policy is that, subject to resource constraints, it will normally agree to continue the treatment providing the care pathway has been initiated by a responsible NHS consultant and the requested treatment remains clinically appropriate. The CCG retains the right to ask for a review of treatment and benefit.

4.9 Second opinions A patient has no legal right to a second consultant opinion under current NHS guidance. However, they are entitled to request one and this should normally be approved if:

1. the request is supported by the patient's GP or consultant (the 'first consultant opinion')

AND

2. the second opinion is available from a clinical specialist who practices within a relevant mainstream NHS commissioned service. This opinion needs to provide a balanced view of the benefits and risks and for care which is not routinely commissioned it should be from a specialist who is:

- independent of the first 'consultant opinion' provider
- independent of the specific service, service provider or provider of the intervention that is being requested (unless no other specialist is available who could provide that balanced opinion).

AND

3. the patient is seeking to establish access to care on the grounds of clinical ability to benefit and not social factors (that are not taken into account under Individual Funding Request processes).

Third or fourth opinions for the same clinical condition will not normally be supported unless there are extenuating circumstances.

4.10 Treatment in another country

Requests for treatment in another EU, EEU country or Switzerland will be considered in accordance with arrangements set out by NHS England. Applications must be submitted by the patient to the NHS England European Team using the application form available on the NHS Choices website: www.nhs.uk/NHSEngland/Healthcareabroad/plannedtreatment Enquiries can be addressed to: england.europeanhealthcare@nhs.net.

5. DEFINING EXCEPTIONALITY AND AN INDIVIDUAL PATIENT

5.1 Exceptionality

The words “exceptional”, "exceptionality" and “exceptional clinical circumstances” bear their natural meanings as defined in Oxford English Dictionary. However the CCG recognises that the meaning of these words has given rise to considerable difficulty in the past and offers the following guidance to assist the IFR Panel and clinicians as to how to approach the meaning of the words

There is a difference between “individual” and “exceptional”. Every patient has features of his or her condition which are specific to that individual and are not likely to be repeated in other patients with the same clinical condition at the same stage of progression of the condition. Exceptionality is not the same as individuality.

In order to be able to consider whether a patient has exceptional clinical circumstances the IFR Panel will focus on the following issues:

1. Are there any clinical features of the patient’s case which make the patient significantly different to the general population of patients with the condition in question at the same stage of progression of the condition?
2. Would the patient be likely to gain significantly more clinical benefit from the requested intervention than might be normally expected for the general population of patients with the condition at the same stage of the progression of the condition?

The implications of this approach are that if a patient can be seen to be part of a group of patients for whom a treatment is not made available by the CCG under the CCG’s existing policies then exceptionality for this individual patient is unlikely to be demonstrable. In this case the appropriate process for obtaining funding for the requested treatment will be for the CCG to change its policy. Such a change must happen through the commissioning process (which will require the development of a business case and for the treatment to be prioritised against other developments) or through the CCG agreeing to make a change to its policy outside the commissioning process. If the change is made it will apply to all similar patients. However the IFR Process is not the procedure for the CCG to make such policy changes.

The CCG is required to achieve financial balance each year and therefore has a default policy of not funding a treatment where no specific policy exists to approve funding for the treatment. If the CCG has not previously been asked to fund an intervention that has the potential to affect a number of patients, the application should be made by clinicians for the CCG to consider the intervention through its general commissioning policy and not by way of an IFR application.

The CCG policy is that the IFR Panel should consider requests for treatments that are not routinely available based on the patient's clinical circumstances. This means that social and personal factors such as age, gender, education, caring responsibilities and family circumstances can only be taken into account where they are relevant to the patient's clinical outcome. Whilst a patient's professional, economic or social standing or their family responsibilities are important to individuals, the CCG policy is that they are not relevant in assessing whether a patient has exceptional clinical circumstances.

5.2 An Individual Patient

For the purposes of this policy, an Individual Patient is determined by reviewing the incidence and prevalence of the requested intervention for a particular condition at the same stage of progression of that condition. If the CCG has no policy for the intervention being requested for a particular condition, then the IFR Panel can only consider the request if both the incidence and prevalence criteria that are set out below are met or the patient has exceptional clinical circumstances compared to the cohort of patients (however small) with the presenting condition. In some cases, CCGs may have adopted policies for small numbers of patients which have often been developed regionally. If the request is covered by such a policy then it should be viewed as a request to change the policy and therefore will not be considered by the IFR Panel l, even if the incidence and prevalence criteria are met.

An IFR request for an individual patient will be considered by the IFR Panel on its individual merits with the decision on whether to fund a requested intervention based on the evidence of clinical and cost effectiveness and affordability. If both the prevalence and incidence criteria are not met then the CCG will not consider that the request represents an individual patient. In these circumstances, funding can only be provided if a decision is made by the CCG to develop a policy for the requested intervention for a group of patients, including the requesting patient; unless the patient has exceptional clinical circumstances compared to the cohort of patients (however small) with the presenting condition. Such a change must happen through the commissioning process (which will require the development of a business case and for the treatment to be prioritised against other developments) or through the CCG agreeing to develop a policy outside the commissioning process. Once the policy is developed it will apply to all similar patients. However the IFR Process is not the procedure for the CCG to develop such policy.

Incidence e.g. the number of new cases of a disease in a defined population within a specified period of time

The intervention for a particular condition at the same stage of progression of that condition is expected to be initiated for two or fewer patients per million population per year.

Prevalence e.g. the number of cases of a disease in a defined population at a point in time

The total number of patients on the intervention for a particular condition at the same stage of progression of that condition is less than 10 patients per million population at any one time.

6. THE PROCESS FOR MANAGING INDIVIDUAL FUNDING REQUEST (IFR)

6.1 Who can submit an IFR?

This policy will apply to any patient for whom the CCG is the responsible commissioner. An NHS doctor, or other NHS health care professional directly involved in the care of a patient, can make a request for an intervention not routinely funded (as defined in Section 2.). It is the referring NHS 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, cannot submit an IFR as a NHS clinical sponsor is required. Tertiary referrals will typically need submission by a NHS consultant. On receipt of a submission the following IFR process should be followed. The IFR process is described in the table in Appendix A. and diagrammatically in the flowchart in Appendix B.

6.2 Administration and Reporting

Requests will be date stamped, processed and logged onto the CCG IFR secure database by the responsible IFR Co-ordinator. Acknowledgement of the IFR or Exceptional Case Application will be sent to the referrer within 3 working days, with a copy to the patient if contact details are available. The referrer is responsible for ensuring that the patient (or carer / guardian) is notified of the progress of the application.. It will be the responsibility of the IFR Co-ordinator to manage all requests received and correspondence with the referrer and where required the patient (or carer/guardian)

For each request received, a unique numbered case file will be generated with all paperwork pertinent to the case kept in chronological order. All decisions will be fully documented and all communication will be in writing. When telephone conversations take place, a file note will be added as a record of the conversation. Both the evidence considered and the decision made will be recorded in writing. All national and local NHS policies regarding confidentiality, retention and destruction of records will be adhered to. The case files will be regularly reviewed by the IFR Panel and an annual report of cases considered by the IFR Panel and Appeal Panel will be submitted to the CCG Quality and Governance Committee.

6.4 Timescale for Managing an IFR

Requests will be managed within a maximum period of 40 working days from the date of the receipt of a Treatment Request Form to the date of the letter from the CCG informing the requesting clinician of the decision of the IFR Panel (excluding appeals and undue delays in responding to requests for further information). Within this time period, a number of recommended maximum time periods for stages of the IFR process are set out in Appendix A, but these are advisory, rather than mandatory, providing the overall process is completed within the 40 working day period.

6.4 Initial Handling of an IFR

Cases are initially dealt with, and screened, by the IFR Co-ordinator who will advise the referrer whether the existing portfolio of contracts, SLAs or current commissioning policies would cover the request. If a policy exists, and where appropriate, the IFR Co-ordinator will check whether the criteria within the policy can be applied. Where clinical advice is required, the IFR Co-ordinator will seek advice from one of the IFR clinical advisors.

Clinically urgent requests will be determined by the Medical Director (or in his/her absence a clinician deputy), and will be managed under 6.7 'Identifying Urgent Cases'.

If an individual meets the criteria within a policy, and a decision to agree funding can be made at this point by the IFR Co-ordinator, then a response will normally be sent to the referrer within 10 working days of the date of acknowledgement of the initial request. The IFR Co-ordinator is unable to authorise referrals outside existing contractual arrangements.

If the IFR Co-ordinator has reason to consider that simple application of SLAs and/or current commissioning policies would be inappropriate for a case, then the IFR Co-ordinator should advise the referrer, and the patient (or guardian / carer), normally within 10 working days, that an Individual Funding Request must be submitted to the IFR Co-ordinator using the IFR Treatment Request Form (Appendix C). A copy of the Guidance Notes for submission of a Treatment Request Form should be included (Appendix D) and the Patient Information Leaflet explaining the process (Appendix E). If a clinician wishes to discuss whether submission of a Treatment Request Form is appropriate, or would like help with completing the Treatment Request Form, then they should contact the IFR Co-ordinator. If this application is not received within 10 working days of the date of the letter then the case will be closed as it will be assumed that there is no wish to pursue the case.

6.5 Submission of an IFR Treatment Request Form (TRF)

Only an NHS clinician directly involved in the clinical care of the patient (usually their Consultant or GP) can submit a Treatment Request Form. On receipt of a Treatment Request Form, the IFR Co-ordinator will acknowledge receipt within 3 working days using a standard letter outlining the IFR process. The patient's GP will be sent a copy of all correspondence regarding the case if they are not the requesting

6.6 Triage of an IFR Treatment Request Form

The IFR Treatment Request Form will be screened by the IFR Co-ordinator and / or clinical advisor e.g. clinical or pharmacy lead (Screening Pair) as necessary, and will be triaged by the Clinical Review Group.

The skills and expertise required of IFR Co-ordinator and or the clinical advisor are the ability to:

- Determine whether an existing policy or SLA adequately covers the treatment request
- Interpret the CCG definitions of exceptionality and an individual patient in the context of the clinical information that is presented

The Clinical Review Group will be able to consider four options;

- Approve the request
- Ask for further information from the referrer
- Refuse the request without reference to the IFR Panel
- Refer to the IFR Panel

The criteria that are used to triage a IFR Treatment Request Form is whether there is an arguable case, based on the evidence presented in the application, that the IFR Panel could consider approving funding for the requested treatment under this policy.

The application will be refused at the triaging stage if:

1. the requested treatment relates to a medical condition where there is CCG policy and (a) the requested treatment is not a treatment that is approved under the policy, and (b) there is no arguable case on the evidence presented that the patient can show exceptional clinical circumstances.
2. The requested treatment relates to a medical condition where there is no CCG policy and (a) on the evidence presented the requested intervention for that particular condition may affect other patients in the CCG population as defined in this policy under 5.2. and (b) there is no arguable case on the evidence presented that the patient can show exceptional clinical circumstances (which will normally be determined by comparing this patient to the cohort of patients (however small) with the presenting condition) so that the request should be properly treated as a request to change the CCG policy.

Where there is uncertainty, the case should be referred to the IFR Panel. All decisions made by the Clinical Review Group will be recorded and reported to the IFR Panel on a quarterly basis.

A routine request will normally be triaged within 10 working days of the date of receipt of the IFR Treatment Request Form by the CCG unless additional information is required. The requesting NHS clinician will be contacted by letter and asked to comment on whether any additional information should be included in the IFR Treatment Request Form. This information should be provided within 10 working days of the date of the letter from the CCG and the amended request will be triaged within 10 working days of receipt of this additional information.

If a request is refused a letter will be sent to the clinician and the patient explaining the reasons for the decision and outlining the options that are available, including using the NHS Complaints Procedure**.**

If an application is refused by the IFR Panel a letter will be sent by the IFR Co-ordinator within a maximum of 5 working days of the IFR Panel. The applicant NHS clinician is invited to provide additional relevant clinical information supporting the exceptionality of the patient in order that the case may be reconsidered within 20 working days of the date of refusal. After this point a new application will be required.

If a request is referred for consideration by the IFR panel a meeting will normally be convened within 20 working days of the date of the triage meeting

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6.8 Organisation of an IFR Panel

The IFR Co-ordinator will arrange the date of the panel and contact the requesting clinician to ask if they wish to submit any further information.

The IFR Co-ordinator will provide written correspondence to the patient (or guardian / carer) to inform them of the date set for consideration by the Panel, to list the items of information that will be presented to the Panel, and to ask them if they wish to provide written information to the Panel. However, the IFR Co-ordinator should remind the patient that decisions can only be made on the grounds of the patient's clinical circumstances and not on the basis of the patient's social or personal circumstances. If a patient wishes to provide written information, they should be directed to seek assistance from the clinical referrer who completed the application with this.

The IFR Co-ordinator may also write to other health professionals with clinical involvement in the patient's care (for example consultant, therapist etc), or to others with specialist knowledge with regard to the condition/intervention, for clarification of the patient's needs, evidence base etc, if appropriate

The patient (or a nominated representative) has the opportunity to attend the Panel to give a 5 minute presentation of their case. The patient may be accompanied by a supporter (who may be a relative, friend or independent advocate) who can assist the patient in the presentation of their case. However, the patient cannot be formally represented and may not be accompanied by a member of the press. The patient may submit any further evidence they feel may support the funding request.

Having received all the evidence, submissions and representations, the Panel will consider the case privately. The patient and referrer will be provided with a written explanation of the Panel's decision within 5 working days of the panel date.

The IFR Co-ordinator, with the support of a clinical advisor, Public Health and Medicines Management, will produce a summary of the case which will be considered by the IFR Panel. All the documentation that has been received regarding the request will also be made available to the panel but in an anonymised form to protect confidentiality.

6.9 Membership of the IFR Panel

MECCG will have an Individual Funding Request (IFR) Panel. The IFR Panel will consider all cases referred to it by the Screening Pair / Clinical Review Group.

Members of the IFR panel should together have the skills and expertise necessary to make effective, fair and rational decisions by considering the evidence in the Decision Framework Document. The key competencies and experience required within a Panel are:

- Ability to understand and interpret the clinical information regarding the individual case and place it in the context of a wider clinical population
- Ability to understand and interpret clinical and cost effectiveness data (critical appraisal skills)
- A lay/societal perspective
- Ability to understand and advise on the broader commissioning policy implications for the CCG including consideration of the intervention in the commissioning process

The core panel will consist of:

- CCG Board Lay Member (Chair)
- Public health consultant (or SpR)
- Pharmacist
- Commissioning / contracts manager

- Governance Lead
- GP
- Clinical Commissioner
- Nurse

The panel will only be quorate if there are four of the core members are present, namely a lay member of the CCG Board, a governance lead, a doctor and a senior manager. Where members are unable to attend, they will provide a trained nominated attendee. Membership for quoracy of urgent panels is different (please see section 6.7).

A commissioner will present the case to the members of the panel and the IFR Co-ordinator will take minutes of the panel. Decisions will be reached by consensus where possible, but if a consensus cannot be achieved, will be decided by a vote of the panel members. The Chair will hold a deciding vote, where necessary. Clinical members who have had any clinical involvement with an individual case cannot be part of the panel hearing for that request.

6.10 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, or personal experience/ involvement with support/charitable groups relating to the condition for which treatment is being requested.

If an IFR 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

6.11 Decision making framework of the IFR Panel

The IFR Panel is a sub-committee of the CCG Board and has delegated authority to make decisions in respect of funding for individual cases. It is not the role of the IFR Panel to make commissioning policy on behalf of the CCG. Consideration by the IFR Panel will always start from the overall policy position (whether or not the intervention has been prioritised through commissioning) and will seek to determine exceptionality on that basis using the definition in Section 5.

The IFR Panel shall only be entitled to approve requests for funding of treatment for individual funding requests where each of the following conditions are met:

a) Either

(1) the clinician makes an individual request for funding for treatment in connection with a patient's presenting medical condition for which the CCG has no policy and where the clinician has demonstrated that the patient represents an Individual Patient (as defined in paragraph 5.2 above) or

(2) the clinician makes an exceptionality request for funding for treatment in connection with a patient's medical condition for which the CCG has a policy and where the clinician has demonstrated that the patient has exceptional clinical circumstances (as defined in paragraph 5.1 above) or

(3) the clinician makes an exceptionality request for funding for treatment in connection with a medical condition for which the CCG has no policy and the patient has demonstrated exceptional clinical circumstances (as defined in paragraph 5.1 above). This option would arise if the patient was not an Individual Patient (as defined in paragraph 5.2 above).

b) There is sufficient evidence to show that, for the individual patient, the proposed treatment is likely to be clinically effective.

c) Applying the approach that the CCG takes to the assessments of costs for other treatments outside this policy, the cost to the CCG of providing funding to support the requested treatment is justified in light of the benefits likely to be delivered for the individual patient by the requested treatment.

6.12 Demonstrating exceptional circumstances.

a) The requesting clinician is required to present a full report to the IFR Panel using the IFR Treatment Request Form 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. If the report does not illustrate exceptional circumstances then it will be returned to the referrer

b) The IFR 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.

c) In determining whether a clinician is able to demonstrate that a patient has exceptional circumstances the IFR Panel shall compare the patient to other patients with the same presenting medical condition at the same stage of progression.

d) The IFR 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 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 to demonstrate exceptional circumstances.

6.13 The likely clinical outcomes of the proposed treatment.

The referring clinician shall:

a) describe the anticipated clinical outcomes for the individual patient of the proposed treatment and the degree of confidence of the referring clinician that the outcomes will be delivered for this particular patient;

b) refer to, and preferably 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.

The IFR 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 IFR Panel is not required to accept the views expressed by 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:

a) The likely clinical outcomes for the individual patient of the proposed treatment; and

b) The quality of the evidence to support that decision and/or the degree of confidence that the IFR Panel has about the likelihood of the proposed treatment delivering the proposed clinical outcomes for the individual patient.

6.14 The costs of the proposed treatment.

The referring clinician shall set out the full attributable costs of and those associated costs relating to the treatment. The IFR Panel shall 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 those associated costs relating to the treatment.

The IFR Panel shall, so far as it is able to do so and relying on the information before it, apply the principles set out in the CCG policy on cost effectiveness when reaching a view as to whether the requested treatment is likely to be cost effective.

In making the decision as to whether the costs of a requested treatment are justified, the IFR Panel is required to bear in mind that the resources requested to support the individual patient will reduce the availability of resources for other investments. The IFR Panel shall have a broad discretion to determine whether the proposed treatment is a justifiable expenditure of the CCG's resources.

6.15 Similar Patients

The IFR Panel shall consider whether the request is a request for a policy variation. If the IFR Panel determines that the case does not refer to an Individual Patient, as defined in this policy, then it shall not be entitled to make a decision on the request (unless the patient demonstrates exceptional clinical circumstances in which case the matter shall be considered as an exceptionality request). In the event that the case does not refer to an Individual Patient the IFR Panel shall refer the request for policy variation to be considered through the CCG clinical commissioning process.

This step is required because the IFR process is not designed to create precedents which may result in the CCG providing or being obliged to provide the same or similar treatment to other patients. Accordingly if the IFR Panel considers this is not a request about an individual patient then funding can only be provided for the requested treatment if a decision is made by the CCG to amend its policies to provide the treatment for a group of patients, including the requesting patient.

6.16 Recording the decision

The IFR Co-ordinator will record the decision of the IFR Panel against each of the questions on the Decision Framework Document (see appendix F). The completed Decision Making Framework, together with the record of attendance, will form the minutes of the meeting. The minutes will be approved by the Chair of the Panel.

6.17 Outcome of the IFR Panel

The IFR Co-ordinator will provide written correspondence on behalf of the Chair of the IFR Panel to the referring clinician, and the patient/guardian or carer, within 5 working days to inform them of the outcome of the IFR Panel meeting with the reasons for the panel decision.

If funding was agreed, the IFR Co-ordinator will ensure that the clinician is able to deliver the treatment in a timely manner and that a mechanism is in place to monitor the clinical outcome in order to determine whether the treatment has resulted in benefit to the patient.

If funding was not agreed, the IFR Co-ordinator will inform the referring clinician, and the

patient/guardian or carer, outlining the further options that are available - either reconsideration via a new IFR treatment request form with the additional clinical detail or review via the process appeals panel.

6.18 Reconsideration

If the referring clinician and/or the patient (or guardian / carer) believes that there is further relevant information that was not considered by the Panel the clinician may submit a new IFR treatment request form and ask the CCG to reconsider the case specifically in the light of this information. This new application will be considered in line with the process described in this document

7. APPEAL OF IFR PANEL DECISIONS

7.1 Grounds for requesting an appeal of the IFR Panel Decision

The referring clinician and/or the patient (or guardian / carer) can make a request to the CCG for a review of the IFR process. The request should be made in writing to the IFR Co-ordinator of the CCG and must be lodged within 20 working days of the date of the letter from the CCG setting out the IFR Panel decision. The Medical Director of the CCG may exercise discretion in accepting requests outside this time limit if there are good reasons for the delay.

The request for appeal must set the grounds on which the IFR panel decision is being challenged. An appeal can be requested on the following grounds. It is believed that:

- The IFR Panel failed to follow due process and, as a result, the decision reached by the panel was different to the one that would be reached if due process had been followed. The appeal should specify the reason why it is felt that due process had not been followed.

7.2 Initial Consideration of a Request for a Process Appeal of the IFR Panel Decision

The request for a Process appeal will be initially considered by an officer designated by the CCG to consider these requests; that officer must have familiarity with the IFR process but have not been involved in the original IFR decision. If the officer considers that there is an arguable case to support the appeal, under reciprocal appeal arrangements, the case will be referred to the North East Essex CCG IFR panel for review, accepting the need for process appeal. . If the CCG does not accept the grounds put forward for a review, a letter will be sent on behalf of the Accountable Officer of the CCG to the referring clinician and/or the patient (or guardian / carer) explaining the reasons for the decision not to appeal the IFR panel decision.

7.3 Membership of the Process Appeal Panel

Under reciprocal arrangements, the NEECCG IFR panel will act as the Process Appeal panel for MECCG.

7.4 Purpose of the Process Appeal Panel

The Process Appeal Panel will determine whether the original decision is valid in terms of process followed, the evidence/factors considered and the criteria applied. In deciding the outcome of an appeal, the Process Appeal Panel will consider whether:

- The process followed by the IFR Panel was consistent with that detailed in the IFR Policy
- The decision reached by the IFR Panel:
    i. was consistent with the CCG Commissioning Principles

ii. had taken into account and weighed all the relevant evidence
iii. had not taken into account irrelevant factors
iv. indicates that members of the panel acted in good faith
v. was a decision which a reasonable IFR panel was entitled to reach.

The Appeal Panel will only consider the following written documentation:

a) the original Treatment Request Form submitted to the CCG
b) the IFR process records in handling the request
c) the IFR Panel records and any additional supporting information considered by the IFR Panel
d) the grounds submitted by the referring clinician and/or the patient/guardian or carer in their request for review.

There will be no other representation at the Process Appeal Panel from the referring clinician and/or the patient (or their guardian / carer). The Process Appeal Panel will not consider new information or receive oral representations. If there is significant new information, not previously considered by the IFR panel, it will be considered as set out in 6.17 Reconsideration above.

The Process Appeal Panel will be able to reach one of two decisions:

- To confirm that the correct process was followed by the IFR Panel and therefore the decision reached is legitimate, or
- It shall refer the matter back to the IFR Panel with specific points for reconsideration in the event that the Appeal Panel consider that either
    - the decision may not have been consistent with the CCG Commissioning Principles; or
    - the IFR Panel may not have taken into account and weighed all the relevant evidence; or
    - the IFR Panel may have taken into account irrelevant factors; or
    - the IFR Panel may have reached a decision which a reasonable IFR panel was not entitled to reach,

7.5 Outcome from the Process Appeal Panel

The outcome of the Process Appeal Panel will be either to uphold the decision of the MECCG IFR Panel or to refer the case back to the MECCG IFR Panel for reconsideration.

The Process Appeal Panel chair will write to the MECCG IFR Co-ordinator within 5 working days to inform them of the outcome of the Process Appeal Panel, the IFR Co-ordinator will then write to the referring clinician, the patient or guardian / carer, and the IFR Panel Chair within 5 working days from

the date of the letter from the Process Appeal Panel to inform them of the outcome of the Process Appeal Panel meeting with the reasons for the appeal decision. Reasons given should only refer to the IFR policy as this is the basis on which the original decision is made.

If the original IFR Panel decision is upheld, the IFR Co-ordinator will inform the referring clinician, and the patient or guardian / carer, of their remaining options - either to pursue a complaint through the CCG Complaints Procedure or to take their case to the Healthcare Ombudsman. The CCG Complaints Policy may be used to review the decision making process for an individual case and may result in the matter being reconsidered by the IFR Panel.

If the Process Appeal Panel determines that the IFR panel needs to reconsider the case, the IFR Panel should reconsider at the next scheduled IFR Panel. The IFR Panel will reconsider its decision and in doing so will formally address the detailed points raised by the Process Appeal Panel. The IFR panel is not bound to change its decision as a result of the case being referred for reconsideration, but if it confirms its original decision, then reasons will be given for not agreeing to fund the treatment request.

8. TRAINING

Members of a Clinical Review Group, IFR Panel and Process Appeal Panel should together have the skills and expertise necessary to enable them to make effective decisions. Members will need ongoing training to undertake this role, in particular to enable them to comprehend and interpret complex data, and also in the legal and ethical aspects of the panel's work. It is also important to establish a 'core' group of individuals who are regularly involved in IFR decision making to gain the necessary breadth of experience from handling a wide range of clinical cases.

All members of an IFR Panel (and Process Appeal Panel) will undergo induction training organised by their CCG. This will cover both the legal and ethical framework for IFR decision making, the CCG commissioning processes and structures, and technical aspects of the interpretation of clinical evidence and research. This training will be regularly refreshed to ensure that all panel members maintain the appropriate skills and expertise to function effectively.

9. MONITORING

The IFR process will be monitored and reviewed, both to ensure that decision-making to be fair and consistent, and to make sure that the panel are considering the appropriate cases e.g. that both the triage of requests and the panel work effectively. The IFR panel will hold a quarterly meeting to review the IFR database with the IFR Co-ordinator to evaluate the process, including the consistency of decision making, and to consider any improvements that could be made.

The CCG will also put in place a mechanism to receive feedback by patients and requesting clinicians as part of the evaluation of the IFR policy and to contribute to ongoing process improvement.

10. References

1. National Prescribing Centre and Department of Health. Supporting rational local decision-making about medicines (and treatments) (February 2009). Available from: www.npc.co.uk/policy/resources/handbook_executive.pdf

2. National Prescribing Centre and Department of Health. Defining DH guiding principles for processes supporting local decision-making about medicines (January 2009). Available from: www.dh.gov.uk/en/managingyourorganisation/commissioningdh_093414

3. Improving Access to medicines for NHS patients. A report for the Secretary of State for Health by Professor Mike Richards CBE. (November 2008). Available from: www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/dh_089927

4. NHS Confederation. Priority setting: an overview. (2007). Available from: www.nhsconfed.org/publications/prioritysetting/pages/prioritysettingoverview.aspx

5. NHS Confederation. Priority setting: managing new treatments. (2008). Available from: www.nhsconfed.org/publications/prioritysetting/pages/prioritysettingnewtreatments.aspx

6. NHS Confederation. Priority setting: managing individual funding requests. (2008). Available from: www.nhsconfed.org/publications/prioritysetting/pages/prioritysettingfunding.aspx

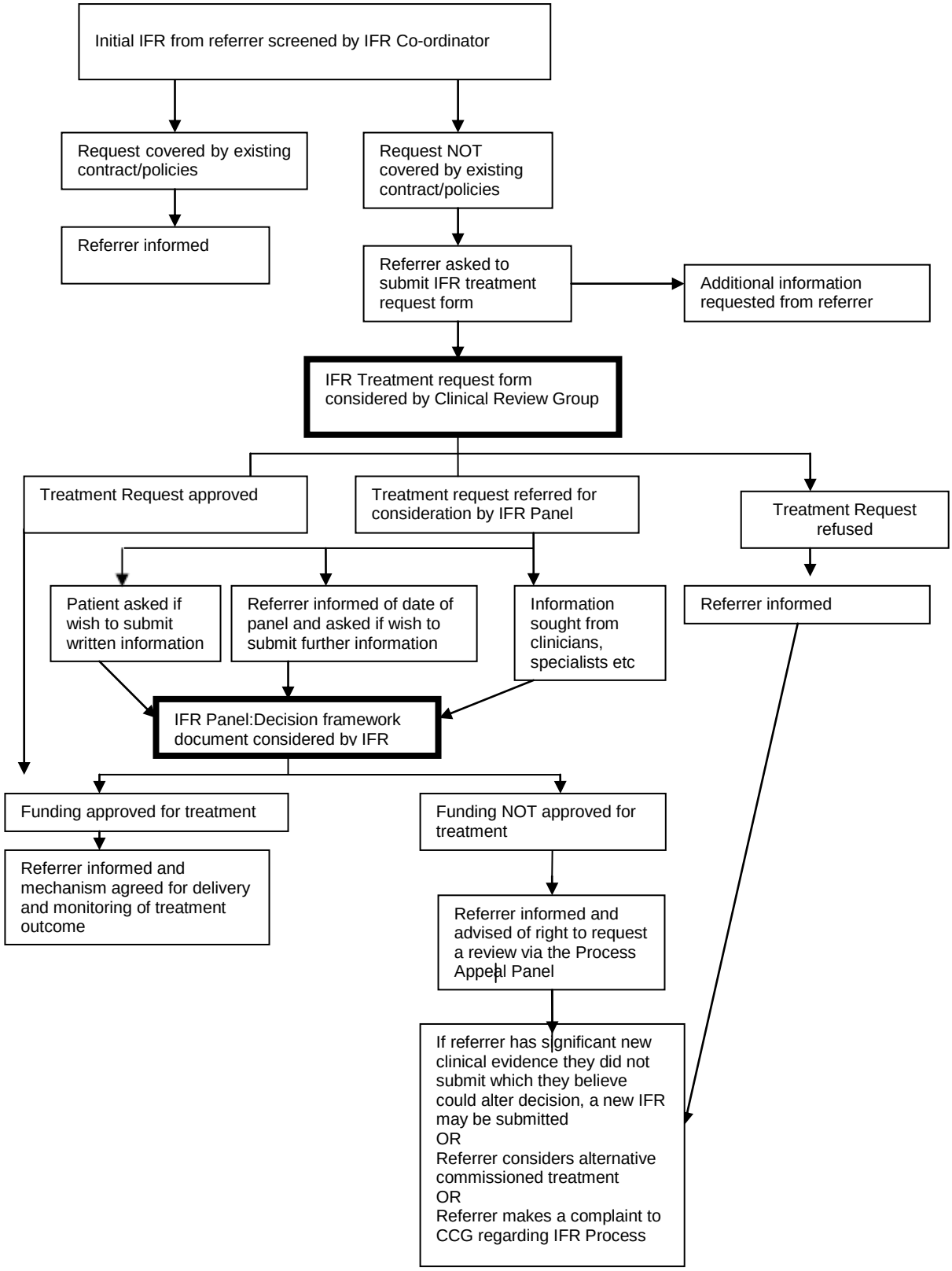
7. NHS Confederation. Priority setting: legal considerations. (2008). Available from: www.nhsconfed.org/publications/prioritysetting/pages/prioritysettinglegal.aspx

Appendix A: Stages/Suggested timelines of the IFR process for routine requests

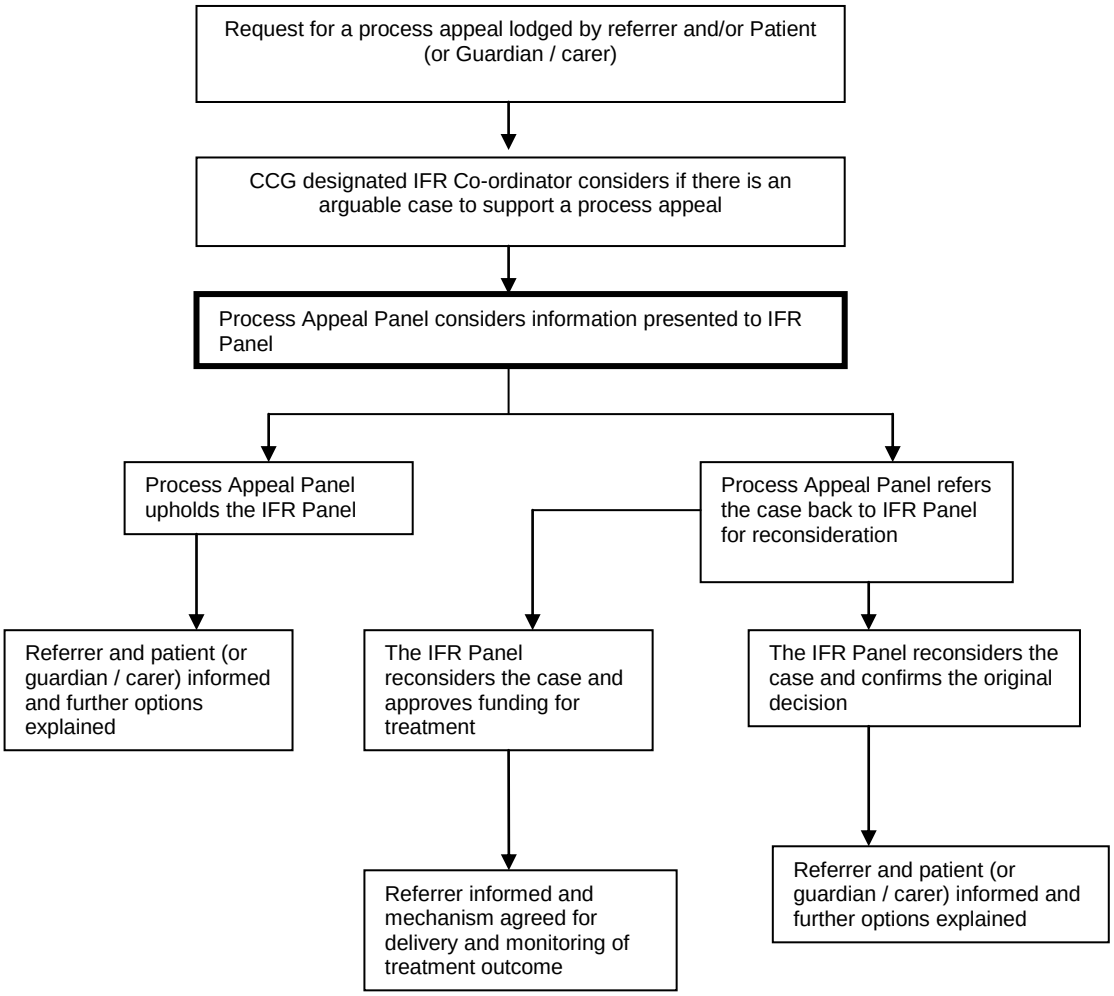
	Responsible Co-ordinator	Decision Making Body	Action and Timescales
Initial Receipt of IFR Request	IFR Co-ordinator	None	IFR request date stamped and logged on IFR database. Acknowledgement to referrer* within 3 working days.
Screening of IFR request to determine whether covered by existing contracts, SLAs etc.	IFR Co-ordinator	IFR Co-ordinator	IFR Co-ordinator to advise referrer within 10 working days of date of acknowledgement letter if request covered by existing contracts OR need to submit Treatment Request form.
Referrer wishes to discuss request/help to complete Treatment Request form	IFR Co-ordinator	None	All communication recorded in writing.
Referrer submits Treatment Request form	IFR Co-ordinator	None	Acknowledgement to referrer of Treatment Request form within 5 working days.
Triage of Treatment Request form	IFR Co-ordinator	IFR Co-ordinator and IFR Clinical Lead (Screening Pair) / Clinical Review Panel	Request either approved if covered by existing policy OR referred to IFR Panel OR rejected within 10 working days, unless additional information requested from referrer, when a further 10 working days is granted.
IFR Panel	Chair of the IFR Panel	Members of the panel	Panel to be convened within 20 working days of triage meeting. Panel decision to referrer from Chair of IFR Panel within 5 working days.
Reconsideration	IFR Co-ordinator	IFR Co-ordinator and IFR Clinical Lead (Screening Pair)	Further information from referrer considered. upon submission of a new IFR treatment request form
Process Appeal Panel	Chair of the Review Panel	Members of the Panel	Request for a Review must be lodged within 20 working days (with discretion). Review Panel to be convened within 20 working days of CCG accepting the need for review. Review Panel decision to appellant from Chair of Panel within 5 working days.

***** Outcome correspondence is copied to the patient/carer or guardian and the GP of the patient

Appendix B1: Flowchart of IFR process for routine cases



Appendix B2: Flowchart of Process Appeal Panel process



Appendix C: Individual Funding Treatment Request form

1. PATIENT PERSONAL DETAILS

Patient Name:

Date of Birth:

NHS Number:

GP Name & Practice Details:

CCG location:

Please note that all personal information will be removed prior to the consideration by the Individual Funding Request process.

2. TREATMENT REQUESTED

3. DIAGNOSIS

4. DETAILS OF REQUESTER (include referring clinician. Contact details in the event of query or

need for clarification)

Name: Designation:

Trust/Surgery:

Contact 'phone number:

Secure email or postal address for correspondence:

Provider Trust Clinical Director Support:
(signature of Clinical Director)

Provider Trust approval (please indicate as appropriate).

DTC…….	YES	NO
Ethics……...	YES	NO
MDT…….	YES	NO

Date to DTC / MDT/Ethics:
If discussed and supported by an appropriate MDT, please provide notes here:

5. CONSENT

I confirm that this Individual Funding Request has been discussed in full with the patient and it would / would not be appropriate (please delete as necessary) for the patient to be copied into all correspondence*.

Please provide details of what the patient understands about the treatment options, including benefits and risk and potential consequences?

Please provide details of what the patient understands about this treatment not being routinely commissioned for a cohort of patients?

The patient is aware that they are consenting for the Individual Funding Request Team to access confidential clinical information held by clinical staff involved with their care about them as a patient to enable full consideration of this funding request

Signature of Requester: Date:

* Please note, the CCG is under obligation to let the patient know the outcome of all IFR applications. Where the patient has requested the IFR submission, it is good practice to ask the patient if they wish to be copied into other correspondence between the clinician and the CCG. Where the patient has not made the request, the patient should be copied into other correspondence between the clinician and the CCG unless it is clinically inappropriate to do so.

The onus lies with the requesting clinician to present a full submission to the IFR Team 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. All necessary information including research papers must be submitted with this form.
Requests can only be considered based on the information provided. Incomplete forms providing insufficient information will be returned.

6. CLINICAL BACKGROUND

Outline the clinical situation. Please include:

- Previous therapies tried and current treatment including intolerance and response
- Current performance status/symptoms
- Anticipated prognosis if treatment requested is not funded (include what treatment will be given to the patient)

A. BALANCING THE INDIVIDUAL NEED FOR CARE WITH THE NEEDS OF THE COMMUNITY

7. EXCEPTIONALITY

To meet the definition of 'exceptional clinical circumstances' your patient must demonstrate that they are both:

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

AND

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

Do you consider this patient to have exceptional clinical circumstances? (Please refer to the CCG definition of what constitutes an exceptional case.) If so please give your reasons.

8. INCIDENCE & PREVALENCE

Incidence is expected to be initiated for two or fewer patients per million population per year

Prevalence is less than 10 patients per million population at any one time

References are to be provided for stated incidence & prevalence.

What is the anticipated need for this treatment per 1000 head of population i.e. how often would you expect to request this treatment for this condition at this stage of progression of the condition for a given size of population? (Please refer to the CCG definition of what constitutes an individual case.)

9a. Is this a service development that has been discussed with commissioners? Do you plan to submit a future business case for funding of this treatment (rather than submit individual requests for single patients)?

9b. If this treatment were to be funded for this patient on an individual basis, would the decision set a precedent for other requests?

B. EVIDENCE OF CLINICAL AND COST EFFECTIVENESS/ SAFETY

10. If drug therapy is requested, is the drug licensed for the intended use?

11. What is the evidence base for the clinical and cost effectiveness/safety of this procedure/treatment? Has it been subjected to NICE appraisal or other scrutiny? Please include copies of all relevant clinical research.

Is the procedure/treatment part of a current or planned national or international clinical trial or audit?

12. What previous therapies have been tried and what was the response?

13. What are the anticipated clinical benefits <u>in this individual case</u> of the particular treatment requested over other available options?

14. Why are standard treatments (those available to other patients with this condition/stage of the disease) not appropriate for this patient?

15. How will the benefits of the procedure/treatment be measured? What are the intended outcomes and how will these be determined? What 'stopping' criteria will be in place to decide when the treatment is ineffective? (The CCG will require regular feedback on the outcome if the treatment is approved).

16. How frequently has your unit undertaken this treatment/procedure and what were your results? Is this treatment/procedure subject to Trust audit? Please include any available data on the use of this treatment/procedure by your unit.

C. AFFORDABILITY

17. What is the cost of the treatment/procedure and how does this compare with the cost of the standard therapy it replaces? Please ensure you include all attributable costs that are connected to providing the treatment/procedure e.g. drug/staff/follow up/diagnostics etc.

D. ACCESS TO TREATMENT

18. How will the treatment/procedure be given to the patient (e.g. oral/iv etc) and where will

the treatment take place?

19. Is this a single treatment/procedure or part of a course? If part of a treatment course, what is the number of doses that will be given and at what intervals? What is the total length of time of the proposed course of treatment?

E. OTHER

20. Clinicians are required to disclose all material facts to the CCG as part of this process. Are there any other comments/considerations that are appropriate to bring to the attention of the IFR Team?

Please complete and return this form to: IFR Team, Central Eastern CSU, 8 Collingwood Road, witham, Essex CM8 2TT, or via email on Rachel.anderson8@nhs.net or laura.mckenna6@nhs.net.
For queries, please contact the IFR Co-ordinator on 01245 398 740.

MID-ESSEX CCG
INDIVIDUAL FUNDING REQUEST
Guidance for the use of the individual funding request submission form

Individual funding requests for medication should only be made where the patient has **exceptional clinical circumstances**, or meets the criteria to be an Individual Patient and will be subject to audit.

- This form must be completed by the requesting consultant for all off-protocol requests requiring CCG funding (for example: anti-TNF treatments outside NICE TAs).
- The form must be completed electronically giving full details. Boxes will expand. Failure to provide full information may result in a delay in reaching a final decision.
- 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 clinically from the group of patients with the same diagnosis/condition in question and at the same stage of progression of the condition.**

AND

2) **As a result of this clinical difference is more likely to gain significantly more clinical benefit from this treatment/intervention than might be expected for others in the group of patients with the diagnosis/condition in question and at the same stage of progression of the 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, named 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.

Deadline:

- The CCG has a monthly meeting to review these submissions; the deadline is 2 weeks before the meeting in order to allow time to collect relevant information..
- 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 inform the CCG directly when you submit this form.

Applications to be sent to: Please note that emails must be sent from an nhs.net address to an nhs.net address. Alternatively fax request.	Mid Essex CCG	MECCG.IFR@nhs.net 01245398710@fax.nhs.net will fax directly from an nhs.net account.	Fax: 01245 398710

livewell **INDIVIDUAL FUNDING REQUEST**

NHS Mid Essex Clinical Commissioning Group

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

Form to be completed electronically giving full details. Boxes will expand.

CONTACT INFORMATION

Trust Name		
1. Address		
2. Applicant Details	**Name:**	
	Designation:	
	Tel:	
	Email:	
3. Address to which funding decision to be sent. N.B. Land address must be given for hard copy. Electronic copy may be sent to nhs.net email addresses only.	**NHS.net email:**	**Address:**
4. Patient Details	**Initials:**	
	NHS No:	
	Hospital ID number:	
	Postcode:	
	DoB:	
	Registered Consultant:	
	Registered GP name:	
	Registered GP postcode:	
	Referred by (other than GP):	
	Referred from:	
	Date of referral:	
5. Application reviewed by **Chief Pharmacist** 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)

6. **Patient Diagnosis** (for which intervention is requested)		
7. Clinical history* Please provide a brief clinical history of the patient outlining • current problems, • any co-morbidities, • investigation results for current problem, • treatments given so far • abilities in independence and self-care • In cases of **cancer** the staging and disease status (1st/ 2nd/ 3rd relapse) Attach most recent correspondence between GP and referring consultants if appropriate. (Please extend space if necessary)	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.	
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:	
	HRG (activity)code	N.B. This must be completed
	Anticipated cost of drug (inc VAT)	N.B. 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 clinical circumstances that make the standard intervention inappropriate for this patient?			
(d) How does this patient differ clinically from the general population of patients with this condition?			
(e) Why is this patient more likely to respond to the requested therapy (as a result of this clinical difference) than the population of interest with the same condition?			
11. (a)In case of intervention for **cancer**:	What is disease status? (eg. at presentation,1st/2nd or 3rd relapse)		
	What is the WHO performance status?		
	How advanced is the cancer? (stage)		
	Describe any metastases:		
(b) In case of intervention for **non-cancer**:	What is the patient's clinical severity? (Where possible use standard scoring systems e.g. WHO, DAS scores, walk test, cardiac index etc.)		
12. 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**
13. Anticipated start date	The CCG has a monthly meeting; deadline is 2 weeks before. You will informed of the decision, within 4 weeks of this meeting. Please contact the CCG to establish the Panel process timeline. Please note that under PbR guidance providers must not delay treatment on the basis of awaiting a funding decision where clinical treatment is considered to be urgent.		

CLINICAL EVIDENCE

14. Is requested intervention licensed for use in the requested indication in the UK?	Delete as appropriate: **Yes/No** (refer to pharmacy if required)
15. Has the Trust Drugs and Therapeutics Committee or equivalent Committee approved the requested intervention for use? (if drug or medical device). For Cancer has the local Cancer Network Board approved the requested intervention for use.	Delete as appropriate: Drugs and Therapeutics Committee **Yes/No** Local Cancer Network Board **Yes/No** If **No,** Committee Chair or Chief Pharmacist approved: **Yes / No**
16. Give details of National or Local Guidelines/ recommendations or other published data supporting the use of the requested intervention for this condition?	***PUBLISHED[2] trials/data - please furnish electronic copies of journal articles/ scanned/ faxed/weblinks**
17. (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 clinical 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.	
18. What is the anticipated toxicity of the intervention for this patient?	
19. What are your criteria for stopping treatment? Define fully using objective measurements or recognised assessment scales.	
20. Are there any additional patient factors (clinical) that need to be considered?	Delete as appropriate: **Yes/No** If **Yes**, please give details: .
21. Form completed by	**Name:**
	Signature or email confirmation:

[2] *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*

CCG USE ONLY

Received by: **Date:**

Reviewed by: **Chief Pharmacist or nominee: Date:……**

Record of communication:	
Points for Discussion:	
▪	
Recommendation from Exceptional Clinical Circumstances Panel (or other route):	
Clinical:	
Financial:	

Signature: **Chief Pharmacist** **Date:……..**

Appendix D: Guidance notes for Clinicians

1. How should I decide whether to make an Individual Funding Request?

The criteria on who is eligible to be considered as an Individual Funding Request have been clarified by the IFR policy and will now be applied consistently across the CCG. The key consideration is whether the treatment that you wish to request for your individual patient will meet the definition for '*exceptional clinical circumstances'* that is set out in the policy.

2. What is meant by 'exceptional clinical circumstances'?

The CCG cannot fund requests that should be fairly applied to other patients who have similar clinical circumstances and who should rightly also be offered the treatment if your patient was to be approved. This would require the CCG to agree a new commissioning policy (or amend an existing one) setting out that the treatment was now available for a new group of patients and setting out how this group had been identified. Therefore, to meet the definition of 'exceptional clinical circumstances' you must demonstrate that your patient is both:

- Significantly different clinically to the group of patients with the condition in question and at the same stage of progression of the condition e.g. metastatic bowel cancer not just bowel cancer

AND

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

In other words, you must show that your patient is very different from others in group of patients with the same condition/stage of the disease and has clinical features that mean that they will derive much more benefit from the treatment you are requesting.

3. Why are only clinical features taken into account?

The CCG must make decisions fairly about funding treatments and not on the basis of age, sex, sexuality, race, religion, lifestyle, occupation, family status (including responsibility for caring for others) social position, financial status etc. unless these directly affect the expected clinical benefit that an individual will derive from a treatment e.g. the effect of the increasing age of a woman on fertility.

4. How do I make an Individual Treatment Funding Request (IFR)?

All requests must be made on a standard treatment request form which can be obtained electronically from www.midessexccg.nhs.net It is the responsibility of the referring clinician to ensure that the form is completed accurately by seeking specialist information from other clinicians as required.

The form aims to ensure that all the necessary information is obtained so it is important that it is completed comprehensively and accurately, along with any relevant research papers, by the referring clinician to avoid delays in reaching a decision. The form can either be returned electronically using nhs.net secure email or by post.

5. How can I get advice on what to include when completing a treatment request form?

You can phone or e-mail the IFR department on 01245 398740 or email meccg.ifr@nhs.net for advice on whether to submit a treatment request form and what to include.

6. Who will make the decision on whether the Individual Funding Request (IFR) is approved?

All new Individual Funding Requests are 'screened' by the Clinical Review Panel. If there is no evidence of exceptional circumstances (often because the patient is clearly part of a definable cohort) then the request is declined at this stage. If evidence of exceptionality is presented, or if the screeners are uncertain whether the case is exceptional or not, then the case will be forwarded to the CCG IFR Panel. They will determine whether there is a case for exceptionality and whether the intervention is safe and clinically and cost-effective.

7. How will I be informed of the CCG decision?

You will receive a letter informing you of the decision of the screening of your request within 20 working days of receipt of your treatment request form. If your request is being taken to the CCG IFR Panel you will be informed of the date of the panel, usually within a further 20 working days, and will receive a letter outlining the decision of the panel within 5 working days after the panel meeting.

8. How will my patient be informed of whether the request has been approved?

All correspondence relating to the outcomes of Panels will be copied to the patient and to their GP if they are not making the request.

9. Can either the patient, or a clinician involved in their care, attend the panel?

Yes. The patient (or a nominated representative) has the opportunity to attend the Panel to give a 5 minute presentation of their case. The patient may be accompanied by a supporter (who may be a relative, friend or independent advocate) who can assist the patient in the presentation of their case. However, the patient cannot be formally represented and may not be accompanied by a member of the press. The patient may submit any further evidence they feel may support the funding request. Having received all the evidence, submissions and representations, the Panel will consider the case privately.

10. Can I or my patient appeal, against the CCG decision?

There is no right to appeal against the decision at the 'screening' stage although it is possible to complain under the CCG Complaints Policy. However, this will not overturn the decision of the screening stage but will examine whether the IFR policy was properly followed.

If the IFR Panel does not approve your request you, or your patient, are entitled to ask for a review of the process that was undertaken by the IFR Panel. The Process Appeal Panel will decide if the IFR Panel followed the correct procedures and the IFR Panel reached a decision that was rational and based on all the evidence that was presented.

If the original IFR Panel decision is upheld, you or your patient, may either to pursue a complaint

through the CCG Complaints Procedure or to take the case to the Healthcare Ombudsman. The CCG Complaints Policy may be used to review the decision making process for an individual case and may result in the matter being reconsidered by the IFR Panel.

11. What can I do if my patent is not exceptional e.g. represents a group of patients in similar clinical circumstances

If you disagree with an existing policy then you can try to change it but this cannot be achieved through the IFR process. If the treatment or services is covered by CCG, it will need the support of all the relevant clinicians through a clinical network, if one exists, or by a direct approach to the CCG.

Please note that it would be unusual to introduce a new development in year as each year resources are already committed through an annual round of prioritisation. Hence new developments will usually require reallocation of resources from existing services.

Appendix E: Information Leaflet

livewell

NHS
Mid Essex
Clinical Commissioning Group

INDIVIDUAL FUNDING REQUESTS

Information for patients in Mid-Essex CCG

This leaflet tells you what happens when you and your GP or Consultant think that you might benefit from a treatment that is not usually available on the NHS.

NHS Mid-Essex CCG has a duty to spend the money it receives from the Government in a fair and efficient way, taking into account the health needs of the whole local community.

As there is only a set amount of money available to spend we sometimes have to make difficult decisions about which treatments are routinely provided.

In some circumstances, your clinician (usually a GP or consultant) may think you have **exceptional clinical circumstances** and may benefit from a treatment which is not routinely provided.

Requests for such treatments must be made through an Individual Funding Request (IFR).

When can an Individual Funding Request (IFR) be made?

There are two situations when it is possible to make an IFR:

- When the CCG does not have a policy stating who is eligible for the treatment that is being requested
- When the CCG has a policy -but your clinical circumstances do not meet the policy's definition of who is eligible for the treatment.

In either circumstance, your GP or consultant will need to demonstrate that your clinical circumstances are '**exceptional'** and justify treating you when others would not get the treatment

What does 'exceptional' mean?

In deciding whether your clinical circumstances are 'exceptional' the CCG will consider two questions:

- Are there any clinical features that make you significantly different from others who have the same clinical condition?
- Are you likely to obtain significantly more clinical benefit from receiving the desired treatment when compared to other patients with the same condition?

Social factors are not considered as part of the IFR process.

Who can make an Individual Funding Request?

If your GP or Consultant agrees that a treatment would be of benefit to you, and that there are no alternative treatments or services available for your condition, they can then make a request to the CCG on your behalf but only if they consider your individual circumstances are exceptional.

Requests are made on a form which asks questions that allow your GP or Consultant to describe your personal clinical circumstances, how they think the treatment will specifically benefit you, the evidence that it is both safe and effective, the cost of the treatment and how commonly your condition occurs in the community.

How is an IFR managed?

The CCG follows the same procedure for every IFR to ensure we act fairly. All requests are treated in strict confidence and we remove your personal details from all paperwork.

When we receive a request, a check is made to ensure no service or treatment exists locally. If treatment is available then we will inform your GP or Consultant so they can discuss it with you.

If there is no service or treatment then the request is screened by a clinician and the CCG's IFR Coordinator to decide whether the conditions for being considered 'exceptional' have been met. A decision will normally be sent to your GP or consultant within ten working days (copied to you and your GP) unless the form is incomplete or more information is needed.

What can I do if my request does not get past the screening stage?

If your clinical circumstances are not considered to be exceptional you have the right to complain through the CCG complaints process. The complaints process will not review whether the screening decision was correct, but will check that the IFR policy was correctly followed.

How does the IFR Panel work?

If the screening team agrees that there are grounds to consider your request as exceptional, your case will be considered by the CCG's IFR Panel within 20 working days of the screening decision, unless the clinical circumstances indicate that a quicker decision is needed.

The panel is made up of health professionals, lay members and CCG managers who consider the request against an agreed set of criteria to ensure the decision making is fair, consistent and transparent.

Call now for more information

01245 398 740/01245 398 106

The panel reviews whether the treatment is likely to be beneficial and is safe (known as 'clinical effectiveness'), how much it will cost to achieve the health benefit that is predicted (known as 'cost effectiveness') and the cost of the treatment in relation to the total CCG budget for providing health care (known as 'affordability').

How will I find out the outcome of my request?

The panel will write to your GP or consultant informing them of the panel's decision within five working days of the panel meeting giving the reasons for the decision that was reached. You will also be sent a copy of the letter.

What can I do if the request is not funded?

In the first instance you should speak to your GP or consultant. You and your GP or Consultant can ask for a review of the IFR Panel's decision on the following grounds:

Mid Essex Clinical Commissioning Group

- The IFR Panel failed to follow due process and, as a result, the decision reached by the panel was different from the one that would be reached if due process had been followed.

- The IFR Panel did not take into account, or weigh appropriately, all the relevant evidence when making its decision.

The request for a review must be made in writing to IFR Co-Ordinator of the CCG within 20 working days of the date of the IFR Panel's decision letter. The CCG may accept requests outside this time limit if there are good reasons for the delay.

If the CCG **does** accept the grounds put forward then a Process Appeal Panel will be convened. To ensure a fair process, all reviews are considered by different people from those who made the original IFR decision.

If the CCG **does not** accept the grounds put forward for a review, a letter will be sent to the referring GP or Consultant explaining the reasons.

The Process Appeal Panel will not consider new clinical evidence. If new evidence becomes available your GP or Consultant should make a new Individual Funding Request submission.

The Process Appeal Panel cannot overturn the IFR Panel decision. However, if the Process Appeal Panel decides that the decision was not reached correctly then it can instruct the IFR Panel to reconsider your case.

Can I, or a clinician, attend the IFR panel in person?

Yes. You or your clinician may attend and present your case to the panel. The information provided by you, or your clinician, at the panel, in addition to the written evidence provided, will be carefully considered before decisions are made.

Can I , or a clinician, attend the Process Appeal Panel in person?

No. Only members of the panel may be present. The panel will review the process using written records of the original IFR panel.

What if the Review supports the original decision?

You have no further right of appeal through the IFR procedure but you may make a complaint about the handling of your request by NHS Mid-Essex CCG at any time. Details of where to submit your complaint can be found on the back page of this leaflet.

What if there is new information I think the IFR panel should have been aware of?

Your GP or consultant, in discussion with you, can submit new information regarding your medical condition or the treatment you are requesting at any time. If the Medical Director and the CCG's IFR Co-ordinator consider that this information might have changed the decision that was previously reached by the CCG then the case will be reconsidered following the process outlined above.

Do I have to pay a fee to make an Individual Funding Request or an appeal against a decision?

There are no fees payable to the CCG for any part of the Individual Funding Request process.

To whom should I address my complaint?

Your complaint should be submitted in writing to: Patient Advice Liaison Service (PALS) and Complaints, NHS Mid-Essex CCG, Wren House, Hedgerows Business Park, Chelmsford CM2 5PF

If you choose, you can also write to the Health Service Ombudsman at:

The Parliamentary and Health Service Ombudsman

Millbank Tower

Millbank

London SW1P 4QP

Where can I get further advice and support?

If you wish to find out about the progress of an IFR request which is already being processed by the CCG please contact the IFR Co-ordinator at *meccg.ifr@nhs.net* or by writing to us at IFR Dept, NHS Mid-Essex CCG, Wren House, Hedgerows Business Park, Chelmsford CM2 5PF

Appendix F: Decision framework document for Individual Funding Request panel

IN STRICTEST CONFIDENCE IFR DECISION FRAMEWORK DOCUMENT

*PANEL MEETING DATE*_____*PATIENTNo:*_____

Mid-Essex CCG

DECISION FRAMEWORK DOCUMENT FOR INDIVIDUAL FUNDING REQUEST PANEL

STRICTLY PRIVATE & CONFIDENTIAL

Notes of Guidance:

1. This form is completed for each person in respect of whom an application is being considered
2. The completed form will be retained by the Individual Funding Request Co-ordinator
3. The Framework will be used to inform the letter to be written by the Chair of the IFR Panel

Panel Members:

Intervention Requested

Documents pertaining to the case:

Brief background to intervention requested

No	Points for consideration	Discussion notes	Decision
	Individual Need for Care		**Yes/No**
1	Does the CCG have a policy to cover the treatment which is made available to patients with the medical condition of the patient? Did the panel reach the view that the patient had demonstrated exceptional clinical circumstances in this individual case?		**NB: If the CCG has a policy for the condition in question and the patient has not demonstrated exceptional clinical circumstances, the IFR Panel are required to turn down the application.**
	Evidence of effectiveness: Clinical / Cost		
2	Does the panel consider that there is robust evidence of the clinical effectiveness of this drug/intervention?		
3	Is there robust evidence that this drug/intervention has been or will be effective in this individual case and that they will gain significantly greater clinical benefit than other patients with the same clinical condition and stage of disease.		
4	Does the panel consider that there is enough		

	evidence to make a decision regarding the cost effectiveness of this drug/intervention? (NICE, Appraisals) and does that evidence indicate the treatment requested will be cost-effective in this individual case?		
No	**Affordability**	**Discussion notes**	**Decision**
5	What are the absolute costs involved in funding this treatment, in relation to the overall resources of the CCG for health care?		
	Equity/ Needs of the Community		
6	What will the anticipated impact be on the rest of the patient population should this treatment be funded?		
7	Will it be equitable to the wider population to fund this treatment after consideration of the		

	clinical needs of this patient?		
	Other factors		
	Are there any other factors which were considered relevant by the Panel?		

Appendix G: Glossary

Word/Abbreviation	Meaning
Affordability	To have enough money to pay for something, without going over budget.
Anonymous	Personal information is not included
Clinical Advisor	A person with the relevant clinical knowledge
Clinical effectiveness	How well a specific test or treatment works when used in the 'real world' (for example, when used by a doctor with a patient at home), rather than in a carefully *controlled clinical trial*. Trials that assess clinical effectiveness are sometimes called management trials. Clinical effectiveness is not the same as *efficacy*. (NICE)
Clinical Referrer	An clinician working under NHS contract for the referral being made on behalf of an NHS patient.
Cohort	A group used as part of a research study. The group is made up of people sharing a common characteristic (for example, pupils in the same school year). (nice)
Collaborative	To work with another on a project (Collins English Dictionary, 1994).
Commissioning	The *process* used by health services and local authorities to: identify the need for local services; assess this need against the services and resources available from public, private and voluntary organisations; decide priorities; and set up contracts and service agreements to buy services. As part of the commissioning process, services are regularly evaluated.(NICE)
Consensus	A statement based on the collective views of a body of experts.(NICE)
Cost effective	Value for money. A test or treatment is said to be 'cost-effective' if it leads to better health than would otherwise be achieved by using the resources in other ways. (nice)
Criteria	Standard of judgement (Collins, 1994).
Exceptional	As defined in section 5.1 of the policy
Health technology appraisal	A health technology appraisal, as undertaken by NICE, is the process of determining the clinical and cost effectiveness of a health technology. NICE health technology appraisals are designed to provide patients, health professionals and managers with an authoritative source of advice on new and existing health technologies. (nice)
IFR Co-ordinator	This can be the IFR coordinator or IFR administrator
Incremental Cost Effectiveness Ratio (ICER)	This is a measure of the additional cost per additional unit of health gain produced by one intervention in comparison to another. (NICE)
Incidence	The number of new cases of a disease divided by the total *population* at risk during a certain period. It is often expressed as numbers per million. See also *prevalence*. (NICE)
Individual patient	As defined in 5.2 of the policy
Inequity	A health inequity is an unnecessary, avoidable, unfair and unjust difference between the health or healthcare of one person, and that of

Word/Abbreviation	Meaning
	another. (NICE)
Local Operating Plan (LOP)	This contains an NHS organisations proposed priorities for investment to ensure delivery of local and national requirements.
Mandated	Official commend/authorisation (Collins, 1994).
National Institute for Health and Clinical Excellence (NICE)	NICE is an independent organisation responsible for providing national guidance on promoting good health and preventing and treating ill health. (NICE).
Clinical Commissioning Group (CCG)	A Clinical Commissioning Group is responsible for buying and overseeing many of the health services for the area it covers.
Pragmatic	Concerned with practical consequences rather than theory (Collins, 1994)
Prevalence	Used to describe the proportion of people in a *population* who have a particular habit, a particular disease or another characteristic. For example, smoking prevalence relates to the proportion of people who smoke in a given population. Prevalence may be expressed in relation to a range of factors including age, sex, socioeconomic and ethnic group. See also *incidence*. (NICE)
Quality Adjusted Life Years (QALY)	A measure of the state of health of a person or group in which the benefits, in terms of length of life, are adjusted to reflect the quality of life. One QALY is equal to 1 year of life in perfect health. QALYS are calculated by estimating the years of life remaining for a patient following a particular treatment or *intervention* and weighting each year with a quality of life score (on a zero to one scale). It is often measured in terms of the person's ability to perform the activities of daily life, freedom from pain and mental disturbance.(NICE)
Quorate	Minimum people required to be present at a meeting before any transactions can take place (Collins, 1994).
Rare	Uncommon (Collins, 1994)
Ratification	Approve
Refractory	Unresponsive or resistant to treatment (Blacks Medical Dictionary, 42nd ed).
Service Level Agreement (SLA)	A service level agreement (SLA) is essentially a communication document that makes clear what the supplier will deliver and what the trust will ensure. It is based on the conditions of contract and specification and does not in any way replace them. (www.pasa.nhs.uk).
Statutory	Required or authorised by law (Collins, 1994).

Appendix H:

Individual Funding and Exceptional Cases Panel

Terms of Reference

1 Purpose

The purpose of the IFR panel is to consider individual requests for NHS commissioned and funded treatment. Each individual funding request will be handled by the CCG IFR process as detailed in the IFR/EC policy which will ensure the request is considered in a fair and transparent way, with decisions based on the best available evidence and the CCG commissioning principles.

The IFR Panel will also act as the Review Panel on behalf of North East Essex CCG (reciprocal arrangement) upon request, and in doing so will determine whether a decision made by the NEECCG IFR Panel is valid in terms of process followed, the evidence/factors considered and the criteria applied.

2. Membership

The core panel will consist of:

- CCG Board Lay Member (Chair)
- Public health consultant (or SpR)
- Pharmacist
- Commissioning / contracts manager
- Clinical Governance Lead
- GP
- Clinical Commissioner
- Nurse

In attendance:

- IFR Co-Ordinator to record the decision of the IFR Panel against each of the questions in the Decision Framework Document

3. Frequency of meetings

The IFR Panel will normally be held monthly.

A case may need to be considered urgently between meetings on the advice of the Medical Director, or nominated deputy, after consultation with the patient's clinicians. The timing of the urgent IFR Panel will be based on the individual clinical circumstances and the risk of an adverse clinical outcome if a funding decision on treatment is delayed. An 'extraordinary' IFR meeting can be convened of the Chair and either Chief Pharmacist or nominated GP as a minimum membership, with other panel members attending if available in order to reach an

Ideally, all urgent cases will be considered by a face-to-face meeting, but, exceptionally, where the clinical urgency makes this impossible, communication by phone or e-mail will be deemed appropriate

4. Declaration of Interests 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, or personal experience/ involvement with support/charitable groups relating to the condition for which treatment is being requested.

If an IFR 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

5 Voting Rights

IFR Panel members will seek to reach decisions by consensus where possible, but if a consensus cannot be achieved, decisions will be taken by a majority vote with each core panel member present having an equal vote. If the panel is equally split then the chair of the panel will have the casting vote.

6. Quorum

The panel will only be quorate if there are four of the core members are present, namely a lay member of the CCG Board, a governance lead, a doctor and a senior manager. Where members are unable to attend, they will provide a trained nominated attendee.

For urgent cases requiring an 'extraordinary' IFR meeting, the meeting will be quorate if the membership consists of the Chair of the IFR panel (Lay member of the CCG Board) and a clinician (doctor, pharmacist or nurse)

7. Documentation

Individual Funding Requests will be date stamped and logged onto the CCG IFR database by the IFR Coordinator. It is the responsibility of the IFR Coordinator to manage all requests received and correspondence relating to each case.

All cases will be anonymised before consideration by the IFR panel. The IFR Coordinator will produce a summary of the key information using the Decision Framework Document which will be considered by the IFR Panel. All other documentation that has been received regarding the case will also be available to the panel.

Patients may set out their views in writing to the Panel if they so wish. Save to the extent that is required to ensure anonymity is preserved, the IFR Coordinator shall not be entitled to redact any written material provided by the patient. However the IFR Coordinator shall be entitled to put any observations in writing before the IFR Panel that the IFR Coordinator may have concerning material submitted by a patient including:

- Observations on any areas where issues are raised which do not appear to be supported by the clinical evidence
- Advice to the panel concerning any social, caring or other personal factors raised by the patient which the IFR Panel are not entitled to consider under the terms of the CCG Policy.

The patient shall be entitled on request to a copy of any observations by the IFR coordinator

The patient (or a nominated representative) has the opportunity to attend the Panel to give a 5 minute presentation of their case. The patient may be accompanied by a supporter (who may be a relative, friend or independent advocate) who can assist the patient in the presentation of their case. However, the patient cannot be formally represented and may not be accompanied by a member of the press. The patient may submit any further evidence they feel may support the funding request.

The Review Panel will only consider the following written documentation:

- the original Treatment Request Form submitted to the CCG
- the IFR process records in handling the request
- the IFR Panel records, including the Decision Framework Document and any additional supporting information considered by the IFR Panel
- the grounds submitted by the referring clinician and/or the patient/guardian or carer in their request for review.
- evidence review prepared by the CCG/Public Health to support panel decision making.

There will be no other representation at the Review Panel from the IFR Panel or the referring clinician and/or the patient/guardian or carer. The Review Panel will not consider new information or receive oral representations.

8. Authority

The IFR Panel is a sub-committee of the CCG Board and has delegated authority to make decisions in respect of funding of individual cases. It is not the role of the IFR Panel to make commissioning decisions or agree commissioning policy on behalf of the CCG.

9. Accountability

The minutes of the IFR Panel will be approved by the Chair of the Panel. The IFR Panel is accountable to the Quality and Governance Committee.

10. Reporting and Monitoring

The IFR Coordinator will record the decision of the IFR Panel against each of the questions in the Decision Framework Document. The completed Decision Making Document, together with the record of attendance, will form the minutes of an individual case. Decisions that are made urgently outside a formal IFR Panel meeting will be taken to the next routine meeting of the IFR Panel for ratification.

The IFR Panel will on a quarterly basis review the IFR database with the IFR Coordinator in order to evaluate the process, including the consistency of panel decision making, and to consider any improvements that could be made.

The IFR Coordinator will produce an annual report which will be approved by the IFR panel and considered by the Quality and Governance Committee.

The Terms of Reference of the IFR Panel will be reviewed annually and any changes agreed by the Quality and Governance Committee.

11. Review Panel

When acting in its capacity as the Review Panel for NEECCG, the panel will determine whether the decision made by the NEECCG IFR Panel is valid in terms of process followed, the evidence/factors considered and the criteria applied.

In deciding the outcome of a review, the Review Panel will consider whether:

- The process followed by NEECCG IFR Panel was consistent with that detailed in the NEECCG IFR Policy
- The decision reached by the NEECCG IFR Panel:
    - was consistent with NEECCG Commissioning Principles
    - had taken into account and weighed all the relevant evidence
    - had not taken into account irrelevant factors
    - indicates that members of the panel acted in good faith
    - was a decision which a reasonable IFR panel was entitled to reach.

The Review Panel will be able to reach one of two decisions:

- To uphold the process undertaken, and hence the decision reached by the NEECCG IFR Panel.

OR

- To uphold the appeal that the full process was not followed and refer the case back to the NEECCG IFR panel for reconsideration.

Detailed minutes will be taken of the panel's consideration of each case and recommendations re process, and these will be provided to NEECCG with the panel's decision.

12. Patients right to appeal

If a patient or clinician wishes to appeal an IFR Panel decision, they may do so by requesting a review of the IFR process in writing to the IFR Co-ordinator of the CCG within 20 working days of the date of the outcome letter.

The request for appeal must set the grounds on which the IFR panel decision is being challenged. An appeal can be requested on the following grounds.

1. A matter of **process** was not adhered to; or
2. Not all of the available evidence was taken into account in reaching the decision; or
3. 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 them).

Mid Essex CCG appeal hearings are carried out by NEECCG as per point 11 above. The appeal hearing will only consider the case in terms of whether or not due process was followed; it does not reconsider the case on its merits.

13. Training

All members of the IFR Panel must undergo mandatory induction training organised by the CCG. This will cover both the legal and ethical framework for IFR decision making, the CCG commissioning processes and structures, and the technical aspects of interpretation of clinical evidence and research. This training will be regularly refreshed to ensure that all panel members maintain the appropriate skills and expertise to function effectively.