Mid and South Essex Sustainability and Transformation Partnership
CCG Joint Committee

Individual Funding Requests Policy

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1 **Contents**

2 Introduction

The NHS exists to serve the needs of all of its patients but also has a statutory duty to break even financially (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.

NHS Basildon and Brentwood, NHS Castle Point and Rochford, NHS Mid Essex, NHS Southend and NHS Thurrock Clinical Commissioning Groups each receive 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, equipment) 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 a 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 that CCG is breaching its statutory obligations.

CCGs are 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:

- Requests for funding treatments for medical conditions where the CCG has no established commissioning policy (commonly called IFR requests), and
- 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.

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 e.g. 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 and clinical effectiveness.

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.

NHS Basildon and Brentwood, NHS Castle Point and Rochford, NHS Mid Essex, NHS Southend and NHS Thurrock Clinical Commissioning Groups are accountable for the management of Individual Funding Requests. This policy will 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’.

Working in collaboration, NHS Basildon and Brentwood, NHS Castle Point and Rochford, NHS Mid Essex, NHS Southend and NHS Thurrock Clinical Commissioning Groups established this policy to consider such applications.

Overall responsibility for the management and administration of the process has been delegated to the Individual Funding Request team in NHS Basildon and Brentwood CCG by NHS Castle Point and Rochford, NHS Mid Essex, NHS Southend and NHS Thurrock Clinical Commissioning Groups.

3 **Purpose and scope**

This policy will be used to consider individual requests for funding where a service, intervention or treatment falls outside existing service agreements or requests for any form of medical treatment or care where the treatment or care proposed could not be considered to be 'mainstream'.

All CCG commissioning decisions need to be made in accordance with these principles:

- 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 Individual Funding Request, the 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.

The CCG considers the 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.

These principles and the following process will ensure that each request for individual funding is considered in a fair and transparent way.

This policy covers Individual Funding Requests pertaining to patients in the catchment areas of NHS Basildon and Brentwood, NHS Castle Point and Rochford, Mid Essex, NHS Southend and NHS Thurrock Clinical Commissioning Groups.

4 **Definitions**

4.1 Individual Funding Request

An Individual Funding Request is a request to an NHS commissioning organisation (such as a Clinical Commissioning Group) to fund healthcare for an individual who falls outside the range of services and treatments that the organisation has agreed to commission (NHS Confederation 2008).

4.2 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?

In line with the principle that patients with rare conditions should neither be advantaged nor disadvantaged simply because their condition is uncommon where treatments, devices or pieces of equipment can be used to treat various conditions it is the presenting need that will assessed against the same criteria as everyone else requiring the intervention. This applies particularly to equipment requests.

Example

A woman has a rare form of a disease which requires her to use a wheelchair. There are no other patients with this form of the disease which require their use of a wheelchair. She will be assessed for wheelchair funding against the same eligibility criteria in the same way that other people with more common conditions requiring similar equipment is undertaken, ie for her mobility needs rather than the rarity of her form of the disease.

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.

4.3 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 an 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, 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.

4.4 Incidence

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.

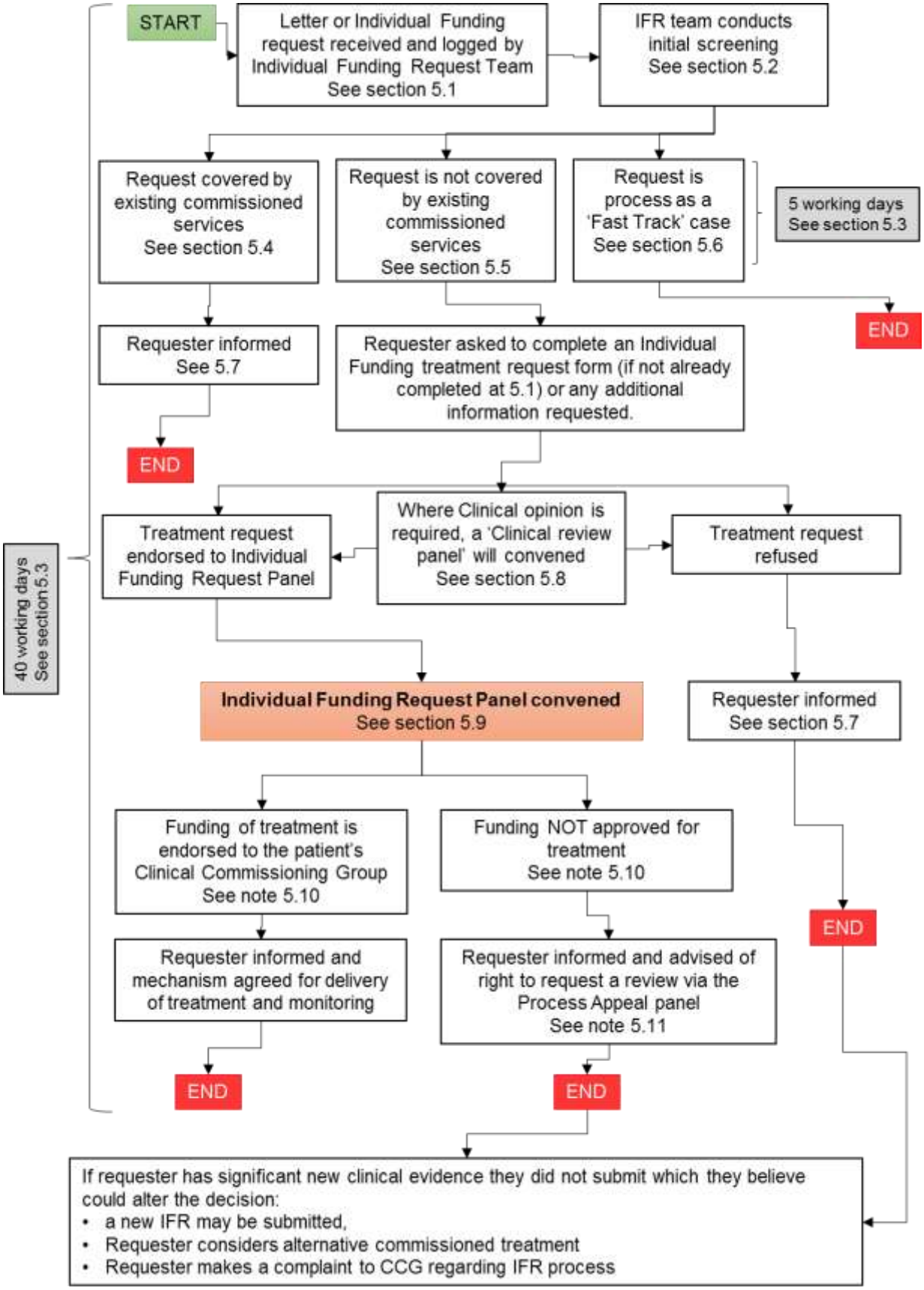
4.5 Prevalence

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.

4.6 Cohort

For the purpose of this policy a cohort is a group of patients who have shared a particular event together during a particular time span.

5 The process for managing Individual Funding Requests



5.1 Letter or Individual Funding request received and logged by Individual Funding Request Team

An NHS doctor, or other health care professional directly involved in the care of a patient, can make a request for an intervention not routinely funded by the CCG. 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. However, the IFR team will provide guidance to any patient who submits a request for treatment.

Correspondence from patients and requesters can be via email or letter.

All correspondence will be date stamped, processed and logged onto the CCG secure database by the IFR team at this point.

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 each CCG Governing Body.

5.2 IFR team conducts initial screening

Cases are initially dealt with, and screened, by the IFR team who will advise the referrer whether the Service Restriction Policies, portfolio of contracts, Service Level Agreements, or current commissioning policies would cover the request.

The IFR team will determine which set of CCG policies need to be applied to each case.

5.3 Timeframes

Requests will be managed within a maximum period of 40 working days from the date of the receipt of an IFR Treatment Request Form to the date of the letter from either CCG or the IFR Panel (excluding appeals and undue delays in responding to requests for further information).

Where the request is screened as a 'Fast Track' IFR, (see 5.6 Request is processed as a 'Fast Track' case) the request will be managed within a maximum period of 5 working days from the date of the receipt of a Request Form to the date of the communication from the CCG informing the requestor of the decision.

The decision of an IFR panel will be communicated to the patient, requester or advocate within 10 working days of a panel.

At certain points in the process the IFR team have the option to “pause” the 40-day target; e.g. when the IFR team are awaiting further correspondence from the patient or requester.

5.4 Request covered by existing commissioned services

If a policy exists, and where appropriate, the IFR team will check whether the criteria within the policy can be applied and inform the requester.

If a policy exists, and where appropriate, the IFR team will check whether the criteria within the policy can be applied.

If an individual meets the criteria within a policy, and a decision to agree funding can be made at this point by the IFR team, then a response will normally be sent to the requester. The IFR team is unable to authorise referrals outside existing contractual arrangements.

5.5 Request is not covered by existing commissioned services

Where the request is not covered by an existing commissioned service, the request is progressed to the next stage.

If the IFR team has reason to consider that simple application of SLAs and/or current commissioning policies would be inappropriate for a case, then the IFR team will advise the requester, and the patient (or guardian / carer) that an Individual Funding Request should be submitted to the IFR team using the IFR Treatment Request Form (Appendix 1). A copy of the Guidance Notes for submission of a Treatment Request Form should be included (Appendix 5) and the Patient Information Leaflet explaining the process (Appendix 6). 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 team.

5.6 Request is processed as a ‘Fast Track’ case

Some cases will require consideration on a shorter timescale. For example, where a patient has limited life expectancy or a treatment is required in circumstances of urgent clinical need. These will often be requests directly from providers for the funding of high-cost drugs for conditions such as cancer.

Where the IFR team determines that a case requires an urgent decision, they will fast-track that case ahead of others and convene a panel at short notice if required. It is expected that the IFR team will consult the Head of Corporate Governance, or equivalent, within the respective CCG on the handling of any cases which are either

marked as urgent by the referring clinician or which the IFR team considers may warrant urgent consideration.

Ideally all urgent cases will be considered by a face-to-face meeting, but exceptionally, where the clinical need makes this impossible, communication via phone or e-mail will be deemed appropriate. Decisions that are made urgently outside of a formal IFR Panel meeting will be taken for ratification to the next meeting of the IFR Panel.

Fast-track panels will also have different quoracy arrangements to facilitate convene at short notice. See Appendix 3: Terms of Reference for the Individual Funding Request Panel for more information.

Patients (or supporting clinicians on their behalf) will have full access to the External Review Process as with non-fast-track cases.

5.7 Requester informed

A letter of acknowledgement will be sent to the requester as soon as possible after the decision.

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**.**

The requester 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 team to manage all requests received and correspondence with the requester and where required the patient (or carer / guardian).

5.8 Triage of IFR Treatment Request Form

The IFR Treatment Request Form will be screened by the IFR team. The IFR team has the competencies to be able to appropriately triage the request. Where clinical advice is required, the IFR team has access to a 'Clinical Review Panel' who will provide clarity or guidance as to whether or not the request should progress to an IFR panel.

5.8.1 Clinical Review Panel

Where the IFR Team determine that the guidance of a Clinician is required, a Clinical Review Panel will be convened to:

- Ask for further information from the requester
- Refuse the request without reference to the IFR Panel
- Refer to the IFR Panel
- Agree the request

5.9 Individual Funding Request Panel convened

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

The IFR team 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 invite them to attend in person. The patient may also provide written information to the Panel if preferable.

The IFR team shall 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 requester who completed the application with this. The patient will also have an opportunity to ask the panel questions about the process.

The IFR team 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 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 requester will be provided with a written explanation of the Panel's decision within 10 working days of the panel date.

The IFR team, with the support of panel members 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 in an anonymised form to protect confidentiality.

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.

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.

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.

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:

- The likely clinical outcomes for the individual patient of the proposed treatment; and
- The quality of the evidence to support that decision and/or the degree of confidence that the IFR Panel has about the likelihood of the proposed treatment delivering the proposed clinical outcomes for the individual patient.
- 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.
- 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 IFR request). In the event that the case does not refer to an Individual Patient the IFR Panel shall consider the request for policy variation to be considered through the relevant 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.

The IFR team will record the decision of the IFR Panel against each of the questions on the Decision Framework Document (see Appendix 4: Decision framework document for Individual Funding Request panel, together with the record of attendance, will form the minutes of the meeting. The minutes will be approved by the Chair of the Panel.

5.10 Outcome of the IFR Panel

5.10.1 Funding of treatment is endorsed

- The IFR team will inform the patient/guardian or carer that funding was agreed.
- The IFR team will develop a mechanism to monitor the clinical outcome in order to determine whether the treatment has resulted in benefit to the patient.

5.10.2 Funding is not approved for treatment

- If funding was not agreed, the IFR team will inform the referring clinician, and the patient/guardian or carer, detailing the appeals process.

5.11 Appeal process

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; and not the decision itself.

The IFR team will determine when new information or other additional representations can be presented.

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,

If the original IFR Panel decision is upheld, the IFR team will inform the referring clinician, and the patient or guardian / carer, of their remaining options - either to pursue a complaint through the relevant CCG Complaints Procedure or to take their case to the Parliamentary and Health Service 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.

6 **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 on-going 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 Clinicians on the IFR panel, Fast track panel and appeal panel will have up to date registrations or equivalent.

All members of an IFR Panel (and Process Appeal Panel), in addition to their mandatory and statutory training, will undergo induction training organised by NHS Basildon and Brentwood 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.

7 **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 team will present a quarterly report for the Governance Committees (or equivalent) of the CCGs that reviews:

- compliance with the timescales laid out in this policy, and

- consistency of decision making,

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 on-going process improvement.

An annual report will also be presented to the Governance Committee (or equivalent).

8 **Roles and responsibilities**

8.1 CCG Governing Bodies / Boards

Each CCG Governing Body is responsible for ensuring that the CCG has systems and processes in place to meet its statutory requirements with respect to IFRs.

8.2 Nominate individuals to serve on the panel that have the appropriate delegated authority.

8.3 Accountable Officer

The Accountable Officer for each CCG is the Executive responsible for the day-to-day implementation of this policy.

8.4 Head of Corporate Governance

The Basildon and Brentwood CCG Head of Corporate Governance is responsible for the oversight of the operational implementation of policy and line management of the IFR / CHC Governance Officer and to lead on the monitoring and compliance with this policy.

8.5 IFR / Continuing Healthcare Governance Officer

The post holder's duties include:

- Date stamping and logging the initial letter or IFR upon receipt.
- Conduct the 'Initial screening process' to determine which CCGs catchment area the patient is under and therefore which services are / are not commissioned by that CCG.
- Liaise with the requester on all case related communications and requests for additional information.
- Manage all requests received and correspondence with the requester and where required the patient (or carer/guardian).
- Conduct screening and triage of cases, referring to the Clinical Review Panel where appropriate
- Facilitate the IFR panels including production of agenda's and preparation of cases and provision of minute taking.
- Organise induction training for IFR panel members

8.6 Public Health Representatives, GP, Medicines Management Representatives and Chief/Senior Nurses

These post holders will provide clinical advice and support to the IFR Service and Panel

8.7 IFR Administrator

To deputise for the IFR / Continuing Healthcare Governance Officer where appropriate or necessary.

8.8 The requesting clinician

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 requester.

The referring clinician shall:

- 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;
- 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.
- 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.

8.9 All Employees and Governing Body Members

All Governing Body members and CCG staff have a responsibility to appraise themselves of the correct action to take in the event that they receive an IFR or wish to make such a request on behalf of a patient / client.

8.10 Essex STP IFR Panel

The Essex STP IFR Panel is responsible for considering IFRs which have been assessed through the CCG's screening process as falling outside approved policy and where no precedent can be established as a basis for approving funding.

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 Governing Body.

Write a quarterly report of cases considered by the IFR Panel and Appeal Panel will be submitted to the Governance Committee (or equivalent in each CCG).

The panel is responsible for making recommendations on Individual Funding Requests that enable each CCG's delegated authorised representative to make decisions on behalf of their own CCG.

The IFR Panel does not make policy decisions for the CCGs, it will endorse the funding of treatment to the relevant CCG.

8.11 Delegated CCG representative

The mandated officer, who is authorised by that CCG's Governing Body to make decisions on behalf of the CCG in relation to IFRs.

9 **CCG commissioning principles that underpin IFR decision making**

9.1 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.

All panel members should follow their local conflicts of interest policy.

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.

The panel will consider on individual basis; what action is required where the panel member knows the patient.

9.2 Decision making framework of the IFR Panel

The IFR Panel is a Committee of the CCG Governing Body and its membership is made up of individuals with 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 CCGs. 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.

9.3 Introduction of New Drugs and Technologies

The CCGs 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 destabilise other areas of health care which have been identified as priorities by the CCG/s. The CCGs 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.

9.4 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.

9.5 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 each CCG website.

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.

9.6 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.

9.7 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.

9.8 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.

9.9 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.

9.10 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 one of the CCGs) 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 mid and south Essex CCGs' IFR policy is that, subject to resource constraints, it will normally agree to continue the treatment where the CCG is the responsible commissioner in line with policies in place at the time of application to the new CCG. Approval for applications to continue treatment will only be given if to do so is equitable and in line with treatments commissioned for the CCG population. The care pathway will have 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.

9.11 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.

10 Equality and Quality Impact Assessment

The CCGs are committed to carrying out a systematic review of all its existing and proposed policies to determine whether there are any equality implications.

This policy has been assessed using the CCG's Equality and Quality Impact Assessment framework and identified as having the following impact/s upon equality, diversity and quality issues:

	Area of Quality	Impact question	P/N	Impact	Likeli-hood	Score	Full Assessment required
1	**Duty of Quality**	Could the proposal impact positively or negatively on any of the following - compliance with the NHS Constitution (**see appendix 3),** partnerships, safeguarding children or adults ?	N	3	2	6	No
2	**Equality and Diversity**	Could the proposal impact positively or negatively on any of the protected characteristics under the Equality Act 2010 (**see appendix 2**)	N	3	2	6	No
3	**Patient Experience**	Could the proposal impact positively or negatively on any of the following - positive survey results from patients, patient choice, personalised & compassionate care?	N	2	2	4	No
4	**Carers experience**	Could the proposal impact positively or negatively on informal carers? (if negatively, is there an identified resource to meet the need, or does the need require flagging to the CCG carers lead)?	N	2	2	4	No
5	**Patient Safety**	Could the proposal impact positively or negatively on any of the following – safety, systems in place to safeguard patients to prevent harm, including infections?	N	3	2	6	No
6	**Clinical Effectiveness**	Could the proposal impact positively or negatively on evidence based practice, clinical leadership, clinical engagement and/or high quality standards?	N	2	3	6	No
7	**Prevention**	Could the proposal impact positively or negatively on promotion of self-care and health inequality?	N	2	2	4	No
8	**Productivity and Innovation**	Could the proposal impact positively or negatively on- the best setting to deliver best clinical and cost effective care; eliminating any resource inefficiencies; low carbon pathway; improved care pathway?	P	3	2	6	No

11 **Version control**

	Version	Author: Name & Title	Date Policy Issued	Date Policy Due to be Reviewed
	1.0	Policy approved by the Governing Bodies of all South Essex CCGs	August 2013	August 2014
	1.1	Policy subject to slight amendments as requested by CP&R CCG Governing Body	28th November 2013	1st November 2014
	1.2	Policy reviewed to reflect change in organisational home for the South Essex IFR Service	27th February 2015	1st October 2016
	1.3	Annual review of policy to reflect post CSU changes.		August 2016
	2.0	Review of policy across south Essex CCGs	November 2016	August 2018
	3.0	Policy amended to cover mid and	March 2018	March 2021

		south Essex CCGs. Exceptionality definition clarified and example given especially in regard to equipment requests		

12 Appendix 1: Individual Funding Request Form

Individual funding request (IFR)

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

Return to: IFR Team, [Contact details]

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

What needs to be filled out:

1. If you are seeking funding for a treatment that is usually excluded or partially excluded from the NHS as indicated in the Service Restriction Policy (SRP), **only complete Section 1.**
2. If you are seeking funding for a new treatment/technology you must **complete in full Sections 1 and 2** of this application.

- 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 exceptionality will be taken into consideration.

The patient

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

AND

2. **As a result of this clinical difference is more likely to benefit from this treatment/intervention than might be expected for the average patient with the diagnosis/condition.**

- It is the responsibility of the requesting clinician to demonstrate exceptionality.
- 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. 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.
- The following criteria should be used to identify how urgent a request is:
    - **Urgent/Fast track** response within 5 working days (refer to policy for definition/criteria)
    - **Routine** application received to decision 2 months

A: Patient details

Patient NHS Number:

Patient first names:

Patient last name:

UBRN:

Date of birth (DD/MM/YY):

Gender: ☐ Female ☐ Male

Patient address (1st Line):

Patient town:

Patient postcode:

Patient contact number (home):

Patient contact number (mobile): (not mandatory)

Patient email address: (not mandatory)

Interpreter required: ☐ No ☐ Yes, language:

Transport required: ☐ No ☐ Yes, state type:

B: GP details

P name:

GP Practice address:

GP practice code:

GP contact no.:

GP email address:

C: Applicant clinician details

GP/Consultant's name:	
Address:	
Contact no.:	
Email address:	

Section 1: All applicant clinicians must complete this section

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

2. Patient BMI: (if relevant)

3. What is the proposed treatment?

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

5. Exceptionality Test 1

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

6. Exceptionality Test 2

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

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

8. How much does the intervention cost?

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

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

The Panel will base its deliberations on the information provided.

1. Safety

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

2. Effectiveness

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

3. Equity and fairness

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

Treatment Requested:

Clinical Information:

Patient BMI: (if relevant)

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

To obtain an electronic copy of this form, please email
Fundingrequests.south@nhs.net

Guidance for the use of the individual funding request submission form

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

Completing the form:

- This form must be completed by the requesting consultant for all off-protocol requests requiring CCG funding.
- 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 clinically significantly different from the general population of patients with the same diagnosis/condition in question.**

AND

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

- The fact that the diagnosis is very rare, or that the treatment might be efficacious for the patient is not, in itself, grounds for exceptionality. If a patient's clinical condition matches the 'accepted indications' for a treatment that is not funded, they are by definition, not exceptional.
- Only evidence of clinical need will be taken into consideration . Factors such as gender, ethnicity, age, lifestyle or other social factors such as employment or parenthood will not be considered on grounds of equality.
- It is the responsibility of the requesting clinician to demonstrate exceptionality.

1. Requests can only be made on an individual, 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. Mid and south Essex CCGs will not normally fund novel or uncertain treatments. Funding for new, rarely used, **unlicensed** and/or investigational drugs outside of a research trial will remain the responsibility of the provider unless a business case is submitted in advance to the commissioner to take through the due process.

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

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

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

Deadline:

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

Submitting the 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 to	Basildon and Brentwood CCG	
	Castle Point and Rochford CCG	
	Mid Essex CCG	
	Southend CCG	
	Thurrock CCG	

Appendix 2: Individual Funding Request for review of an exception to CCG policy

INDIVIDUAL FUNDING REQUEST

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:**	
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 Attach most recent correspondence between GP and referring consultants if appropriate. (Please extend space if necessary)	

8. Details of intervention (for which funding is requested). If the intervention forms part of a regimen, please document the full regimen.	**Name of intervention**:	
	Dose and frequency	
	Planned duration of intervention:	
	Route of administration:	
	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**: 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? See 10 (c) above			
(f) What is the patient's clinical severity? (Where possible use standard scoring systems e.g. WHO, DAS scores, walk test, cardiac index etc.)			
11. 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**
12. Anticipated start date	Each CCG has a monthly meeting; deadline is 1 week before. You will be informed of the decision, within 4 weeks of this meeting. Please contact the relevant CCG to establish the Panel process timeline or to confirm that an urgent decision is required.		

CLINICAL EVIDENCE

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

equivalent Committee approved the requested intervention for use? (if drug or medical device).	Drugs and Therapeutics Committee **Yes/No** If **No,** Committee Chair or Chief Pharmacist approved: **Yes / No**
15. Give details of National or Local Guidelines/ recommendations or other published data supporting the use of the requested intervention for this condition?	***PUBLISHED[1] trials/data - please furnish electronic copies of journal articles/ scanned/ faxed/weblinks**
16. (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.	
17. What is the anticipated toxicity of the intervention for this patient?	
18. What are your criteria for stopping treatment? Define fully using objective measurements or recognised assessment scales.	
19. Are there any additional patient factors (clinical) that need to be considered?	**Delete as appropriate: Yes/No** **If Yes, please give details:**

[1] *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*

21. Form completed by	**Name:**
	Signature or email confirmation:

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:……..**

13 Appendix 3: Terms of Reference for the Individual Funding Request Panel

Mid and South Essex Clinical Commissioning Groups Individual Funding Requests (IFR) Panel

Terms of Reference

1 Role

1.1 Purpose

- To ensure decisions are made about commissioning healthcare interventions for individual patients that are based on the best available evidence of their clinical effectiveness.
- To review requests for treatment or services not routinely funded by the relevant NHS Commissioning organisation.

1.2 Objectives:

To review individual funding requests and make recommendations as to whether treatment should be commissioned in the following circumstances:

- Cases where a refusal to treat decision has been made by the Referral Management Centre or a provider on the basis that the patient does not meet the agreed criteria
- Cases where a request has been made for treatment or services not normally provided in the mainstream NHS.

2 Status

The IFR panel is a working group of the mid and south Essex CCGs who comprise NHS Basildon and Brentwood, NHS Castle Point and Rochford, NHS Mid Essex, NHS Southend and NHS Thurrock CCGs. It is not a committee of the CCGs and its role is advisory only. It does not have delegated authority to exercise functions on behalf of the CCGs.

3 Accountability

The panel is accountable to the Quality & Governance Committees (or equivalent) of the CCGs.

3.1 Key Relationships:

- CCG Governance Leads and Clinical Governing Body Members
- Referral Management Centre where applicable
- External Review Panel

4 Decision making and delegated authority

In these terms of reference, the expression “authorised representative” means a member of a CCG’s Governing Body, or a mandated officer, who is authorised by that CCG’s Governing Body to make decisions on behalf of the CCG in relation to IFRs. It is the responsibility of each CCG to nominate individuals to serve on the panel and to ensure that they have the appropriate delegated authority.

Each of the CCGs has agreed that when an authorised representative of its CCG is serving on an IFR panel, he or she will have a delegated limit of £50,000 per case, irrespective or his or her usual delegated limit (as set out in the relevant CCG’s Scheme of Delegation).

The panel must take reasonable steps to estimate the total cost of any decision to approve an IFR, including travel and similar costs as well as any costs that are likely to span more than one financial year.

If the total estimated cost is less than £50,000, then a CCG’s authorised representative will make a final decision for his or her CCG, taking account of the recommendation of the IFR panel.

If the total estimated cost exceeds £50,000 then the panel will make a recommendation to the relevant CCG. The final decision will rest with either the Clinical Executive Group or Governing Body of the relevant CCG.

5 Priorities

To consider each case individually, while making the best and fairest use of resources available for healthcare within the mid and south Essex area.

Where panel members have a conflict of interest either by virtue of a connection with the patient or in terms of a vested interest as a potential service provider, the CCG should send an alternative individual.

6 Monitoring and reporting

6.1 Monitoring:

The Panel will monitor itself against its objectives and undertake a review of its performance annually. This review will be led by one of the Panel Chairs and will involve all panel members and the IFR Co-ordinator. An annual report from the panel will be submitted each year to the Quality & Governance Committees (or equivalent) of the CCGs.

6.2 Reporting:

IFR Panel cases will only be reported to a CCG’s Governing Body where an appeal has been submitted and considered by the External Appeal Panel and where the External Appeal Panel has disagreed with the original decision.

In cases where the External Appeal Panel disagrees with the original decision, the CCG's Governing Body (excluding the authorised representative who made the original decision) shall determine whether to uphold the original decision or to accept the recommendation of the External Appeal Panel.

In cases where the External Appeal Panel uphold the decision of the authorised representative, then the authorised representative's decision will be the final decision and there will be no recourse to the CCG's Governing Body.

7 **Membership**

The core members of the panel consist of

(1) An authorised representative from the CCG for which the case originates; and

(2) insofar as the authorised representatives who are present do not between them hold the following positions, members of one or more of the CCGs who hold the following positions:

- A lay member;
- A public health specialist;
- A senior commissioner;
- A GP;
- A chief nurse.

In the event that more than one authorised representative of a CCG attends a meeting of the panel, the authorised representatives shall agree which of them shall act as the CCG's authorised representative for the purpose of the relevant Panel meeting and the decision shall be recorded in the minutes of the meeting.

7.1 Chair

A CCG lay member shall chair the meetings of the Panel.

7.2 Co-opted members (attendees by invitation):

- CCG Governance Leads
- Medicines Management Team
- Children's Service's team

The panels will be arranged and administered by the IFR Coordinator or his/her deputy.

8 **Quorum**

8.1 For regular scheduled IFR panels

The quorum shall be the core members as set out in section 7.

8.2 For panels convened to consider urgent cases

Panels that are convened to consider cases defined as urgent/fast-track have a reduced quorum to facilitate quick decision-making. In such cases the following members will be required:

- The authorised representative of the CCG with responsibility for the patient in question; and
- Either a public health specialist or a GP or Executive Nurse from any mid or south Essex CCG.

There is no requirement for the same individuals to attend the panel on each occasion. Whilst in some respects this would be preferable in order to maintain continuity and consistency, the main tool for ensuring consistency and organisational memory is through the IFR Co-ordinator who will attend panels and will advise members as to the existence of any relevant previous case decisions.

8.3 Voting rights

Only the core members have a vote on recommendations to authorised representatives and CCGs.

The delegated representative for the CCG whose case the case relates to can choose to accept the recommendations or not, based on their own professional opinion.

9 Frequency of meetings

The Panel will meet as frequently as required by its caseload. The indicative frequency will be monthly and panels will be arranged in advance.

10 Review of terms of reference

The Terms of Reference will be reviewed at the same time as the IFR Policy is reviewed and need to be agreed by the Panel and ratified by the Governance Committees (or equivalent) of the mid or south Essex CCGs.

15 Appendix 4: Decision framework document for Individual Funding Request panel

IN STRICTEST CONFIDENCE IFR DECISION FRAMEWORK DOCUMENT

*PANEL MEETING DATE*_____*PATIENT No:*_____

Essex STP CCGs

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 Coordinator
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?		

16 **Appendix 5: 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.

In line with the principle that patients with rare conditions should neither be advantaged nor disadvantaged simply because their condition is uncommon where treatments, devices or pieces of equipment can be used to treat various conditions it is the presenting need that will assessed against the same criteria as everyone else requiring the intervention. This applies particularly to equipment requests.

Example

A woman has a rare form of a disease which requires her to use a wheelchair. There are no other patients with this form of the disease which require their use of a wheelchair. She will be assessed for wheelchair funding against the same eligibility criteria in the same way that other people with more common conditions requiring similar equipment is undertaken, ie for her mobility needs rather than the rarity of her form of the disease.

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 http://basildonandbrentwoodccg.nhs.uk/about-us/policies-and-procedures/service-restriction-policy/1111-3-0-ifr-policy or the IFR department on 01268 594480 or email [Contact details]. 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 [Contact details] or email @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?

If your request is being taken to the CCG IFR Panel you will be informed of the date of the panel and will receive a letter outlining the decision of the panel within 10 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 the referring Clinician (Consultant or GP) and the patients 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 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.

17 **Appendix 6: Patient Information Fact Sheet**

INDIVIDUAL FUNDING REQUEST (IFR) PATIENT INFORMATION FACT SHEET

NHS Clinical Commissioning Groups (CCGs) are responsible for looking after the health needs of the local population within the funds allocated.

Your CCG has close working relationships with healthcare professionals such as GPs and pharmacies, as well as with hospital consultants.

What is the Individual Funding Request (IFR) Panel?

If you have received this information leaflet your doctor or consultant is probably asking your CCG to consider funding a treatment that is outside the normal range of treatments funded by the NHS.

These treatments are often considered to be of low priority and include, for example, cosmetic surgery.

The IFR Panel will not consider an application without the support of a patient's GP or hospital doctor.

Screening Process?

Upon receipt, all IFRs will undergo a screening process by the IFR Team with clinical or public health input as required.

Who sits on the panel?

The Panel normally consists of a Lay representative (Chair), Public Health Advisor, Doctor, Nurse, Prescribing Advisor and CCG Commissioning Manager.

Any colleagues new to the IFR Panel Process may be present for training purposes. This ensures that patients experience minimal delays when awaiting their case to be considered.

In addition, an administrator will always be present to take the minutes of the Panel meeting.

Each case is treated in the strictest confidence.

What are the Panel looking for?

The IFR Panel looks at cases where there may be exceptional circumstances, and to ensure that decisions are made about treatments that:

- Are based on the best available evidence (for example, medical research)
- Look to improve the patient's condition and not make it worse
- Take account of the views of the patient and their doctor, inviting patients to give evidence in person to the Panel if they wish
- Make best use of the resources available for healthcare within the Essex STP area

The definition of exceptionality used under the IFR policy is:

- The patient is significantly different to the general population of patients with the condition in question; and
- The patient is likely to gain significantly more benefit from the intervention than might be normally expected for patients with that condition

In line with the principle that patients with rare conditions should neither be advantaged nor disadvantaged simply because their condition is uncommon where treatments, devices or pieces of equipment can be used to treat various conditions it is the presenting need that will assessed against the same criteria as everyone else requiring the intervention. This applies particularly to equipment requests.

Example

A woman has a rare form of a disease which requires her to use a wheelchair. There are no other patients with this form of the disease which require their use of a wheelchair. She will be assessed for wheelchair funding against the same eligibility criteria in the same way that other people with more common conditions requiring similar equipment is undertaken, ie for her mobility needs rather than the rarity of her form of the disease.

How does the panel work?

Panel meetings are normally held at the local NHS offices in [Contact details]. You will have a choice whether to attend the panel in person, state your case in a letter or speak to one of the Panel members on the telephone.

Your invitation to attend the Panel is your opportunity to discuss your case and explain your view as to why your circumstances are exceptional, to supplement the information submitted by your doctor.

The Panel members may ask a few questions to help them understand your circumstances better.

It might feel formal attending the Panel meeting; you are welcome to bring someone with you if you feel this would help.

When you have finished explaining why you want a particular treatment you will be able to leave. A decision is not made while you are there. You will be informed of the Panel's decision within 10 working days of the meeting.

The IFR Panel will not take account of personal, demographic or social factors and will only consider factors which are clinical in nature.

What happens if I disagree with the Panel's decision?

If you feel the process followed by the Panel was not correct you have the right to appeal. This will need to be put in writing to the IFR Team within 28 days of receiving a letter notifying you of the Panel's decision.

Please note that appeals will only be accepted if there is any indication that the appeal is based on a flaw in the process followed by the Panel. Appeals based purely on a

disagreement with the panel's decision are not permitted. A panel from a neighbouring CCG will review appeals that are accepted.

Contact details:	**Telephone number for Individual Funding enquiries:**
IFR Team	
[Contact details]	Tel:

18 References

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   www.nhsconfed.org/publications/prioritysetting/pages/prioritysettinglegal.aspx