

## Individual Funding Requests

### Corporate Policy CO052

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#### POLICY VALIDITY STATEMENT

**This policy is due for review on the latest date shown above.  
After this date, policy and process documents may become invalid.**

**Policy users should ensure that they are consulting the currently valid  
version of the documentation.**

## Document Information

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# Individual Funding Requests

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## 1. Introduction

NHS County Durham and Darlington (NHSCDD) aspires to the highest standards of corporate behaviour and professional competence, to ensure that safe, fair and equitable procedures are applied to all organisational transactions, including relationships with patients their carers, public, staff, stakeholders and the use of public resources. In order to provide clear and consistent guidance, NHS County Durham and Darlington will develop documents to fulfil all statutory, organisational and best practice requirements and support the principles of equal opportunity for all.

NHSCDD is required to have a process for considering funding individual patients for services outside established commissioning policies. These are called Individual Funding Requests (IFRs). There are in general two types of IFRs, namely:

1. Requests for funding for treatments for medical conditions where NHSCDD has no established commissioning.
2. Requests for funding for treatments for medical conditions where NHSCDD does have an established commissioning policy but where the requested individual treatment is not in the NHSCDD policy or does not meet the criteria set out in the policy.

For patients in the first category the request will be considered against the tests of clinical effectiveness, cost effectiveness and affordability.

For patients in the second category the clinician must be able to demonstrate that the patient has exceptional clinical circumstances. If the patient has exceptional clinical circumstances (as defined in this policy) then the request will be considered against the tests of clinical effectiveness, cost effectiveness and affordability.

This policy covers the process for managing these requests and the principles underlying the funding decisions. This policy does not cover the process for making decisions about the introduction of new treatments.

### 1.1. 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 NHSCDD commissioning principles.

## 1.2 Status

This is a corporate policy

## 2. Definitions

The following terms are used in this document:

### 2.1 Individual funding requests (IFRs)

These are requests made by clinicians on behalf of individual patients. The request is for NHSCDD to fund a treatment or service outside established commissioning policies.

### 2.2 Screening

This is an assessment by the Screening Manager and Consultant in Public Health Medicine to see if an IFR is covered by existing contracts.

### 2.3 Exceptionality

A patient is exceptional if they have clinical features which make the patient significantly different to the general population of patients with the condition at the same stage of progression and is likely to gain significantly more clinical benefit from the requested intervention than might be normally expected.

### 2.4 Exceptional Cases Committee (ECC)

The ECC acts with delegated authority of the NHS County Durham and Darlington Integrated Business Board (IBB). The ECC considers all cases referred by the Screening Manager to decide if a patient has exceptional clinical circumstances and for the requested treatment to be funded by the PCT.

### 2.5 Review Panel

The Review Panel acts with delegated authority of the IBB. It considers all requests from clinicians for a decision made by the ECC to be reviewed.

### 2.6 NICE

NICE is the National Institute for Health and Clinical Excellence who are an 'arm's length' body of the NHS which was established in 1994 by the Department of Health as. Its primary responsibility has since been set out in 'Choosing health: making healthier choices easier' (2005) – this is to help people 'make healthier and more informed choices about their health'. To achieve this, the Department of Health commission NICE to produce clinical guidelines, technology appraisals, interventional procedures, public health guidance, cancer service guidance and patient safety guidance.

### 2.7 Clinical effectiveness

Clinical effectiveness is the extent to which specific clinical interventions do what they are intended to do, i.e. maintain and improve the health of patients securing the greatest possible health gain from the available resources.

## 2.8 Cost effectiveness

We assess the cost-effectiveness of a treatment by comparing the cost of the treatment against the gain in health outcome (benefit) it is expected to produce.

# 3. Individual Funding Requests: Principles and Process

## 3.1 NHSCDD Commission Principles

It is important that NHSCDD has a consistent approach to guide the allocation of resources in both population based and individual commissioning decisions. All NHSCDD commissioning decisions need to be made in accordance with these principles.

The principles that NHSCDD seeks to support are:

- NHSCDD requires clear evidence of clinical effectiveness before NHS resources are invested in the treatment,
- NHSCDD requires clear evidence of cost effectiveness before NHS resources are invested in the treatment,
- the cost of the treatment is a relevant factor,
- NHSCDD will consider the extent to which the individual or patient group will gain a benefit from the treatment,
- NHSCDD will balance the needs of each individual with the needs of the community,
- NHSCDD will consider all relevant national standards and take into account all proper and authoritative guidance,
- where a treatment is approved, NHSCDD will respect patient choice as to where a treatment is delivered.

When considering an IFR, NHSCDD will also ensure that decisions:

- comply with relevant national policies or local policies and priorities that have been adopted by NHSCDD concerning specific conditions or treatments,
- are based on the available evidence concerning the clinical and cost effectiveness of the proposed treatment, including any NICE publications 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.

NHSCDD 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, gender, 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.

## 3.2 Policy Guidance

In considering individual cases, NHSCDD will apply the commissioning principles, the underpinning policies of NHSCDD and the following guidance which expands upon them.

### 3.2.1 Introduction of new drugs and technologies

NHSCDD will not introduce new drugs/technologies on an ad hoc basis through the mechanism of individual funding requests. NHSCDD expects consideration of new drugs/technologies to take place within the established planning frameworks of the NHS (for example the Annual Operating Plan (AOP)).

All requests to fund new drugs must have already been considered by the relevant Drugs and Therapeutics Committee (DTC) with regard to prescribing policy around the safety and effectiveness of the drug.

### 3.2.2 Treatments covered by NHSCDD commissioning policies

NHSCDD 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 AOP process are not routinely funded. For a number of these interventions NHSCDD has adopted a regional set of specific policy statements setting out restrictions on access based on evidence of effectiveness or relative priority for funding.

### 3.2.3 Treatments not covered by NHSCDD commissioning policies

Specific groups of patients may not be covered by NHSCDD commissioning policy including:

- patients with conditions for which NHSCDD does not have an agreed policy, including patients with rare conditions and whose proposed treatment is outside service agreements,
- patients with conditions for which NHSCDD 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.

Consideration 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 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.

### 3.2.4 Requests to continue funding for patients coming off drugs trials

NHSCDD does not expect to provide funding for patients to continue medication/treatment started as part of a clinical trial. 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 ongoing access to those treatments. The initiators of the trial (provider trusts and drug companies) have an obligation to continue funding patients benefiting from treatment until such time as NHSCDD agrees to fund the treatment through the AOP process.

Where the treatment is not prioritised through the AOP, the responsibility remains with the trial initiators. The Research Ethics Committee should require this assurance as part of the approval for the trial.

### 3.2.5 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 started a treatment prior to asking for or receiving confirmation that NHSCDD will approve funding. Evidence that the patient is responding to the treatment is then presented as part of the case for NHSCDD funding.

The provider trust's decision to start treatment in advance of any decision by NHSCDD is a clear risk taken by the trust. NHSCDD accepts no responsibility for the decision taken by the provider trust in these circumstances.

NHSCDD 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 patient is able to demonstrate 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 receiving the treatment is unlikely to be sufficient to demonstrate exceptional clinical circumstances.

Where such an application is approved on the basis that the patient has demonstrated exceptional clinical circumstances, NHSCDD will not accept responsibility for the costs of any treatment provided by the provider trust prior to authorisation being given by the PCT. A similar approach will be adopted if a treatment has been funded initially by a pharmaceutical company or other third party.

### 3.2.6 Requests to continue funding of care commenced privately e.g. reverting to NHS care

There are occasions where the initial stages of a treatment have been funded privately by the patient. NHSCDD 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 NHSCDD 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 NHSCDD does not act in an inequitable manner, the issue of exceptional clinical circumstances will be the criteria applied by the IFR process.

NHSCDD adopts no presumption in favour of continuing treatment which has been previously paid for privately by the patient. 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.

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, NHSCDD will expect their care to be transferred to local NHS pathways.

### 3.2.7 Decisions inherited from other Primary Care Trusts

Occasionally patients move into the area and become the responsibility of NHSCDD (by registering with an NHS County Durham and Darlington GP) when a package of care or treatment option has already been approved by the PCT that was previously responsible for the patient's care. NHSCDD'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 NHS consultant and the requested treatment remains clinically appropriate.

### 3.2.8 Second opinions

Patients are entitled to request a second consultant opinion but this must be within an NHS funded clinic. Third or fourth opinions for the same clinical condition will not normally be supported unless there are exceptional circumstances.

## 3.3 Exceptionality

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

- 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?
- 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 progression?

If a patient is one of a group of patients for whom a treatment is not made available by NHSCDD under NHSCDD'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 NHSCDD to change its policy. Such a change must happen through the AOP process (which will require the development of a business case and for the treatment to be prioritised against other developments) or through NHSCDD agreeing to make a change to its policy outside the AOP process. Once the change is made it will apply to all similar patients. The IFR Process is not the procedure for NHSCDD to make such policy changes.

NHSCDD policy is that requests for treatments that are not routinely available should be assessed on the basis of the patient's clinical circumstances. This means that social and personal factors such as age, gender, 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, NHSCDD policy is that they are not relevant in assessing whether a patient has exceptional clinical circumstances.

### **3.4 The process for managing individual funding requests**

#### **3.4.1 Who can submit an IFR**

This policy will apply to any patient for whom NHSCDD is the responsible commissioner. A doctor, or other health care professional directly involved in the care of a patient, can make a request for an intervention not routinely funded. A patient, or a non-clinical representative, may not submit an IFR.

#### **3.4.2 Administration and reporting**

Requests will be date stamped, processed and logged onto NHSCDD IFR database. Acknowledgement will be sent to the referrer within 3 working days, with a copy to the patient/carer or 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 whenever possible. 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 and an annual report of cases will be submitted to the IBB.

### 3.4.3 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 informing the requesting clinician of the decision of the PCT.

### 3.4.4 Initial handling of an IFR

Cases are initially dealt with, and screened, by the Screening Manager who will advise the referrer whether the existing contracts or commissioning policies would cover the request. If a policy exists, the Screening Manager will check whether the criteria within the policy can be applied. Clinically urgent requests will be determined by a senior public health professional, nominated by the Director of Public Health, and will be managed under 3.4.7 '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 Screening Manager, then a response will normally be sent to the referrer within 5 working days of the date of acknowledgement of the initial request by the PCT. The Screening Manager is unable to authorise referrals outside existing contractual arrangements.

If the Screening Manager has reason to consider that simple application of current commissioning policies would be inappropriate for a case, then the Screening Manager should advise the referrer normally within 5 working days, that an Individual Funding Request must be submitted to the Screening Manager at NHSCDD using the IFR Treatment Request Form (Appendix B). A copy of the Guidance Notes for submission of a Treatment Request Form should be included (Appendix C) and the Patient Information Leaflet explaining the process. 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 Screening Manager.

### 3.4.5 Submission of a treatment request form

Only a member of the clinical team who are directly involved in the clinical care of the patient (usually their Consultant or GP) can submit a Treatment Request Form. The patient's GP will be sent a copy of all correspondence regarding the case if they are not the requesting clinician.

### 3.4.6 Screening of a Treatment Request Form

The Treatment Request Form will be screened by the Screening Manager and Consultant in Public Health Medicine to:

- determine whether an existing policy adequately covers the treatment request,
- interpret NHSCDD definitions of exceptionality and an individual patient in the context of the clinical information that is presented.

The Screening Manager and Consultant in Public Health Medicine will be able to consider three options:

- approve the request if covered by an existing commissioning policy,
- refuse the request without reference to the ECC,
- refer to the ECC.

The application will be refused at the screening stage if:

- the requested treatment arises in relation to a medical condition where there is NHSCDD 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 has exceptional clinical circumstances,
- the requested treatment arises in relation to a medical condition where there is no NHSCDD policy and on the evidence presented the requested intervention for that particular condition may affect other patients in NHSCDD population so that the request should be properly treated as a request to change NHSCDD policy.

Where there is uncertainty, the case should be referred to the ECC. All decisions made by the Screening Manager will be recorded and reported to the ECC on a quarterly basis.

A routine request will normally be completed within 10 working days of the date of receipt of the Treatment Request Form by NHSCDD unless additional information is required when an additional 10 working days will be granted. The requesting clinician will be contacted by letter and asked to comment on whether any additional information should be included in the Treatment Request Form.

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

If a request is refused at this stage the referring clinician can ask for the case to be reconsidered if there is additional information about the patient's clinical circumstances. The patient also has a right to make a complaint under the NHS Complaints Procedure. One outcome of such a complaint could be to require the screening process to be reconsidered or for the case to be referred to the ECC for consideration.

If a request is referred for consideration by the ECC a meeting will normally be convened within 20 working days of the date of the screening meeting.

#### 3.4.7 Identifying urgent cases

A senior public health professional, nominated by the Director of Public Health (DPH), can determine that a case is clinically urgent at any point in the IFR process. This will be based on the individual clinical circumstances and the risks of an adverse clinical outcome if a funding decision on treatment is delayed. An

'extraordinary' ECC meeting can be convened with a senior public health professional, nominated by the DPH, and a Clinical Member as a minimum membership, with other panel members attending, if available, in order to reach an immediate decision.

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

### **3.5 The Exceptional Cases Committee (ECC)**

The ECC Administrator will arrange the date of the meeting and contact the requesting clinician to ask if they wish to submit any further information.

The patient/carer or guardian, or their clinical or non-clinical representative, are not entitled to attend the panel in person.

The DPH or nominated deputy may 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 ECC Administrator, with support from Public Health, will produce a summary of the case using the Decision Framework Document (Appendix D) which will be considered by the ECC. 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 patient confidentiality.

#### **3.5.1 Membership of the ECC**

The ECC acts with delegated authority from the IBB (see Appendix E for the Terms of Reference). The ECC will consider all cases referred to it by the Screening Manager.

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

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

The members of the ECC include:

- Director of Public Health or nominated deputy
- Executive Director or nominated deputy
- Clinical Member
- Non-Executive Director (Chair)
- Other individuals with specific expertise and skills may also be included on the panel (e.g. pharmacist, commissioning manager) in order to ensure effective and fair decision making.

The panel will be quorate if three of the core members are present, including the Director of Public Health (or nominated deputy) and the clinical member.

### 3.5.2 Decision making framework of the ECC

The ECC can only approve Individual Funding Requests where each of the following conditions are met:

- the request is in connection with a medical condition for which NHSCDD has no policy ,  
Or  
the request is in connection with a medical condition for which NHSCDD has a policy and where the patient has exceptional clinical circumstances (as defined in paragraph 3.3 above),
- there is sufficient evidence to show that, for the individual patient, the proposed treatment is likely to be clinically effective,
- applying the approach that NHSCDD takes to the assessments of costs for other treatments outside this policy, the cost to NHSCDD of providing funding to support the requested treatment is justified in the light of the benefits likely to be delivered for the individual patient by the requested treatment.

### 3.5.3 Demonstrating exceptional circumstances

The clinician submits the request using the Treatment Request Form which sets out a clinical history and present state of the patient's medical condition, the nature of the treatment requested and the anticipated benefits of the treatment.

In determining whether a patient is exceptional the ECC shall compare the patient to other patients with the same presenting medical condition at the same stage of progression.

The ECC will 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.

### 3.5.4 The likely clinical outcomes of the proposed treatment

The clinician submitting the request will be asked to:

- describe the anticipated clinical outcomes for the individual patient of the proposed treatment and the degree of confidence of the clinical team that the outcomes will be delivered for this particular patient,
- refer to, and preferably include, copies of any clinical research material showing that the treatment is likely to be clinically effective in the case of the individual patient.

The ECC shall be entitled but not obliged to commission its own reports concerning the case that is being made that the treatment is likely to be clinically effective in the case of the individual patient.

The ECC is not required to accept the views expressed by the clinical team 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 ECC has about the likelihood of the proposed treatment delivering the proposed clinical outcomes for the individual patient.

### 3.5.5 The costs of the proposed treatment

The clinical team shall set out the full attributable costs of the treatment. The ECC shall be entitled but not obliged to commission its own reports concerning the full attributable costs of and connected to the treatment.

The ECC will apply accepted principles on cost effectiveness when reaching a view as to whether the requested treatment is likely to be cost effective.

The ECC shall have a broad discretion to determine whether the proposed treatment is a justifiable expenditure of the PCT's resources.

### 3.5.6 Recording the decision

The ECC Administrator will record the decision of the ECC against each of the questions on the Decision Framework Document. 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.

### 3.5.7 Outcome of the ECC

The ECC Administrator will write on behalf of the DPH or nominated deputy to the referring clinician within 5 working days on the outcome of the ECC meeting with the reasons for the panel decision.

If funding is agreed, in the letter to the clinician the ECC can request a report on the clinical outcome in order to determine whether the treatment has resulted in benefit to the patient.

### 3.5.8 Reconsideration

If the referring clinician believes that there is further relevant information that was not considered by the ECC then they may ask NHSCDD to reconsider the case specifically in the light of this information. The additional information must be submitted to the ECC Administrator within 10 working days of the date of the letter from NHSCDD setting out the panel decision. The DPH or nominated deputy will determine whether the additional information significantly alters the nature and strength of the evidence that was submitted to the initial ECC meeting.

If the new information is considered to be significant, then the request will be discussed at the next ECC meeting. If the new information is not considered to be significant, the referring clinician will be informed by letter with reasons for the decision not to refer the request back to the ECC.

## 3.6 Review of ECC decisions

### 3.6.1 Grounds for requesting a review of the ECC decision

The referring clinician can make a request to NHSCDD for a review of the ECC decision. The request should be made in writing to the Chief Executive of NHSCDD and must be lodged within 20 working days of the date of the letter from NHSCDD setting out the ECC decision. The Chief Executive may exercise discretion in accepting requests outside this time limit if there are good reasons for the delay.

The request for a review must state the grounds on which the ECC decision is being challenged. A review can be requested on two grounds:

- the ECC failed to follow due process and, as a result, the decision reached by the panel was different to one that would be reached if due process had been followed,
- the ECC did not take into account, or weigh appropriately, all relevant evidence when applying NHSCDD Decision Making Framework.

### 3.6.2 Initial consideration of a request for a review of the ECC decision

The request for a review will be initially considered by an officer designated by NHSCDD to consider these requests. If the officer considers that there is an arguable case to support the review, then a formal Review Panel meeting will normally be convened within 10 working days of the date of receipt of the request by NHSCDD. If NHSCDD does not accept the grounds put forward for a review, a letter will be sent on behalf of the Chief Executive of NHSCDD to the referring clinician explaining the reasons for the decision not to review the ECC decision.

### 3.6.3 Membership of the Review Panel

The Terms of Reference for the NHS County Durham and Darlington Review Panel are in Appendix F.

The Review Panel will consist of:

- Chairman or nominated Non-Executive Director (Chair)
- Chief Executive or nominated Executive Director
- Medically qualified Board level Director

None of these members should have been involved in the case prior to the Review Panel. The panel will only be quorate if all three members are in attendance and decisions will be reached by consensus.

### 3.6.4 Purpose of the Review Panel

The Review Panel will determine whether the original decision is valid in terms of the 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 the ECC was consistent with that detailed in the IFR Policy.
- The decision reached by the ECC:
  - a) was consistent with NHSCDD commissioning principles,
  - b) had taken into account and weighed all the relevant evidence,
  - c) had not taken into account irrelevant factors,
  - d) members of the panel acted in good faith,
  - e) the decision was reasonable and one that the ECC was entitled to reach.

The Review Panel will only consider the following:

- a) the original Treatment Request Form submitted to the PCT,
- b) the IFR process records in handling the request,
- c) the ECC records, including the Decision Framework Document and any additional supporting information considered by the ECC,
- d) the grounds submitted by the referring clinician in their request for a review.

There will be no other representation at the Review Panel from the ECC or the referring clinician and/or the patient/guardian or carer. The Review Panel will not consider new information or receive oral representations. If there is significant new information, not previously considered by the ECC, it will be referred back to the ECC as set out in 3.5.8 Reconsideration above.

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

- to uphold the decision reached by the ECC,
- to refer the case back to the ECC with detailed points for reconsideration.

The Review Panel will refer the case back to the ECC for reconsideration if:

- the decision may not have been consistent with NHSCDD commissioning principles; or
- the ECC may not have taken into account and weighed all the relevant evidence; or
- the ECC may have taken into account irrelevant factors; or
- the ECC may have reached a decision which a reasonable ECC was not entitled to reach.

### 3.6.5 Outcome from the Review Panel

The outcome of the Review Panel will be either to uphold the decision of the ECC or to refer the case back to the ECC for reconsideration.

The Review Panel chair will write to the referring clinician and the ECC Chair within 5 working days to inform them of the outcome of the Review Panel meeting with the reasons for the panel decision.

If the original ECC decision is upheld, the Review Panel Administrator will inform the referring clinician of their remaining options - either to pursue a complaint through NHSCDD Complaints Procedure or to take their case to the Healthcare Ombudsman. NHSCDD 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 ECC.

If the Review Panel determines that the ECC needs to reconsider the case, then it will be discussed at the next ECC meeting. The ECC will reconsider its decision and in doing so will formally address the detailed points raised by the Review Panel. The ECC is not bound to change its decision as a result of the case being referred for reconsideration. If the ECC confirms its original decision, then clear reasons must be given for not agreeing to fund the treatment request.

## 4. Duties and responsibilities

### Statutory Board

The Statutory Board has delegated responsibility to the Joint Board (JB) for setting the strategic context in which organisational process documents are developed, and for establishing a scheme of governance for the formal review and approval of such documents.

**Joint Chief Executive:**

The Joint Chief Executive has overall responsibility for the strategic direction and operational management, including ensuring that Trust process documents comply with all legal, statutory and good practice guidance requirements.

**Director of Public Health:**

The Director of Public Health is the sponsoring director for this document and is responsible for ensuring that:

- The document is drafted, approved and disseminated in accordance with the Policy for the Development and Approval of Policies.
- The necessary training or education needs and methods required to implement this policy are identified and resourced or built into the delivery planning process.
- Mechanisms are in place for the regular evaluation of the implementation and effectiveness of this policy.
- The IFR Screening process and Exceptional Cases committee have appropriate public health advice and support.

**Screening Manager:**

The Screening Manager is responsible for:

- Maintaining an accurate and timely database of all Individual Funding Requests
- With support from the Consultant in Public Health Medicine, make initial screening decisions about Individual Funding Requests.
- Ensure that clinicians are kept informed about these decisions within the agreed timescales.
- Ensure that all the relevant documents are completed before passing on an Individual Funding Request to the Exceptional Cases Committee.

**Consultant in Public Health Medicine:**

The Consultant in Public Health Medicine will:

- Provide technical advice and support for the Screening Manager.

**IFR Manager:**

The IFR Manager is responsible for:

- Ensuring that all decisions made by the Exceptional Cases Committee are accurately recorded.
- Ensuring that the decisions are communicated to clinicians within the agreed timescales.
- Producing an Annual Report on the work of the Exceptional Cases Committee on behalf of the Director of Public Health.

**All staff:**

All staff, including temporary and agency staff, are responsible for:

- Compliance with relevant process documents. Failure to comply may result in disciplinary action being taken.

- Co-operating with the development and implementation of policies and procedures and as part of their normal duties and responsibilities.
- Identifying the need for a change in policy or procedure as a result of becoming aware of changes in practice, changes to statutory requirements, revised professional or clinical standards and local/national directives, and advising their line manager accordingly.
- Identifying training needs in respect of policies and procedures and bringing them to the attention of their line manager.
- Attending training / awareness sessions when provided.

## 5. Implementation

The policy and supporting documents will be available to clinicians on NHSCDD website. The Screening Manager, IFR Manager and Review Panel Administrator are responsible for implementing this policy at the different stages of the decision making process.

## 6. Training

Members of an ECC (and Review 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 in handling a wide range of clinical cases.

All members of the ECC (and Review Panel) will undergo mandatory induction training organised by the Public Health Directorate. This will cover both the legal and ethical framework for IFR decision making, NHSCDD 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. Documentation

### 7.1 Related Policy/procedure documents

Criteria and Prioritisation Tool. Integrated Business Board paper December 2009 IBB/09/35.

### 7.2 Best practice recommendations

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](http://www.npc.co.uk/policy/resources/handbook_executive.pdf)

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](http://www.dh.gov.uk/en/managingyourorganisation/commissioningdh_093414)

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](http://www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/dh_089927)

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

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

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

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

### **7.3 Legislation and Statutory requirements**

NHS County Durham and Darlington is required to have a process for considering funding individual patients for services outside established commissioning policies.

## **8. Monitoring, Review and Archiving**

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

## 9. Impact Assessments

### EQUALITY IMPACT ASSESSMENT

Please refer to the corporate checklist for further information.

**Name of function/strategy/policy/service:** Individual Funding Requests Policy

**Date of Review:** 4 June 2010

a) Please provide a brief description of the function/strategy/policy/service:

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 NHSCDD commissioning principles.

b) What Type of positive and negative equality & diversity implications are you aware of that arise from your function/strategy/policy/service?

This policy applies equally to all. There are no negative equality implications within the document.

c) In line with our statutory duty under equality legislation do your functions/strategies/policies/services make reference to equality wherever relevant?

- If yes - provide examples of how they aim to:
- If no – what action is required:

In line with the Race Equality Duty to eliminate discrimination, harassment, promoting equality of opportunity and good relations between people of different racial groups	NHS County Durham aspires to the highest standards of corporate behaviour and clinical competence, to ensure that safe, fair and equitable procedures are applied to all organisational transactions, including relationships with patients their carers, public, staff, stakeholders and the use of public resources. In order to provide clear and consistent guidance, NHS County Durham will develop documents to fulfil all statutory, organisational and best practice requirements and support the principles of equal opportunity for all.
<b>In line with the Disability Equality Duty to promote positive attitudes towards disabled persons and encourage participation by disabled people</b>	Applied equally to all employees
<b>In line with the Gender Equality Duty to eliminate unlawful discrimination and harassment &amp; promote equality of opportunity between men and women</b>	Applied equally to all employees
<b>Other relevant equality legislation/best practice?</b>	

**OUTCOMES OF THIS NEED TO BE INCLUDED IN THE ACTION PLAN**

- d) **What relevant groups have a legitimate interest in the function/strategy/policy/service?  
Does it impact differently on particular minority groups?  
If Yes – Which Groups are affected, and how are they affected?**

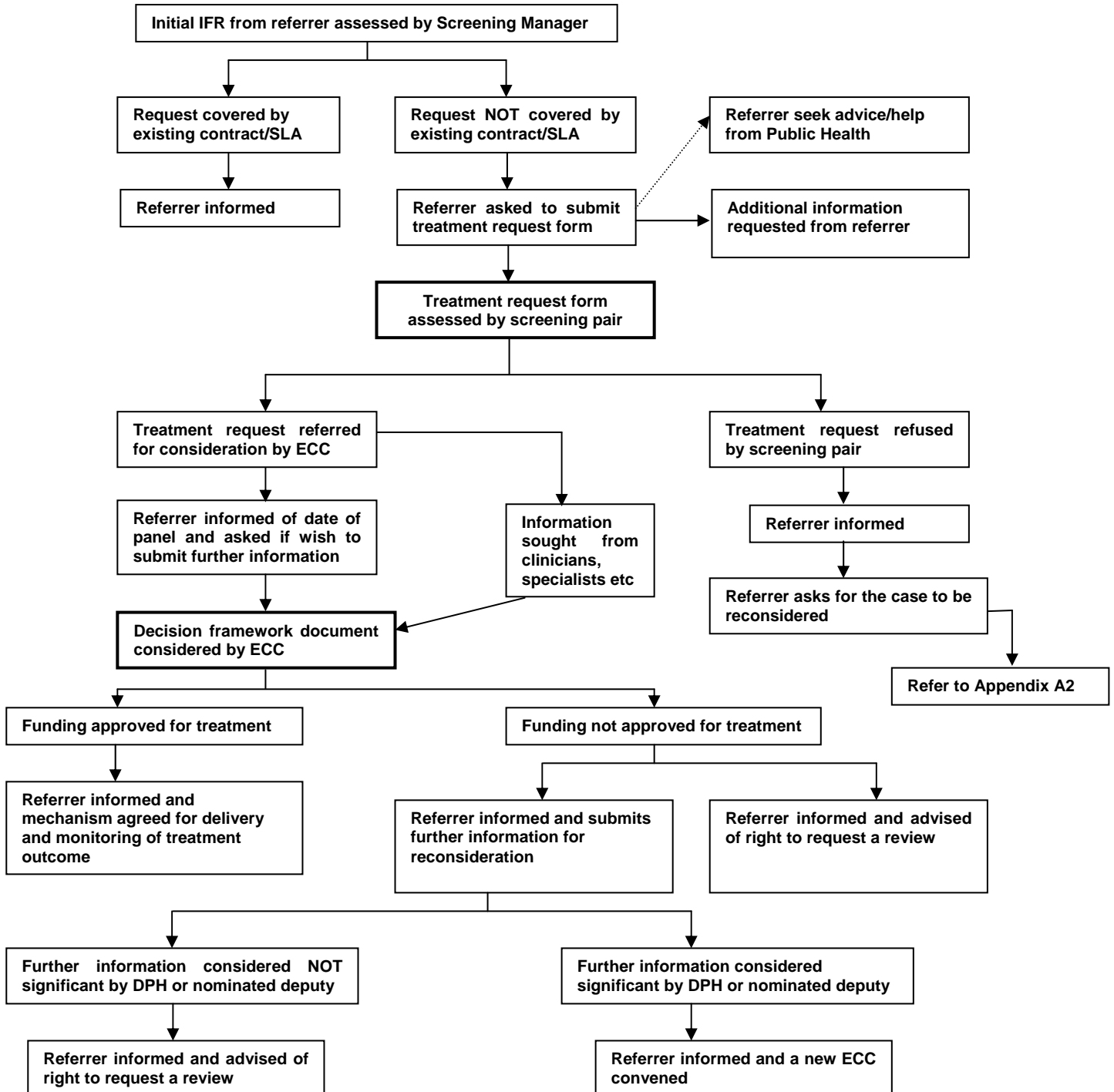
<b>Group</b>	<b>Impact</b>
All members of staff	All groups will be affected in the same way following an agreed, defined process

- e) Please outline below any work you have carried out to assess, monitor, address and review the equality implications of your function/strategy/policy/service and identify additional work that needs to be carried out to meet requirements of our statutory duties.

*This may include work around the following areas (list not exhaustive)*

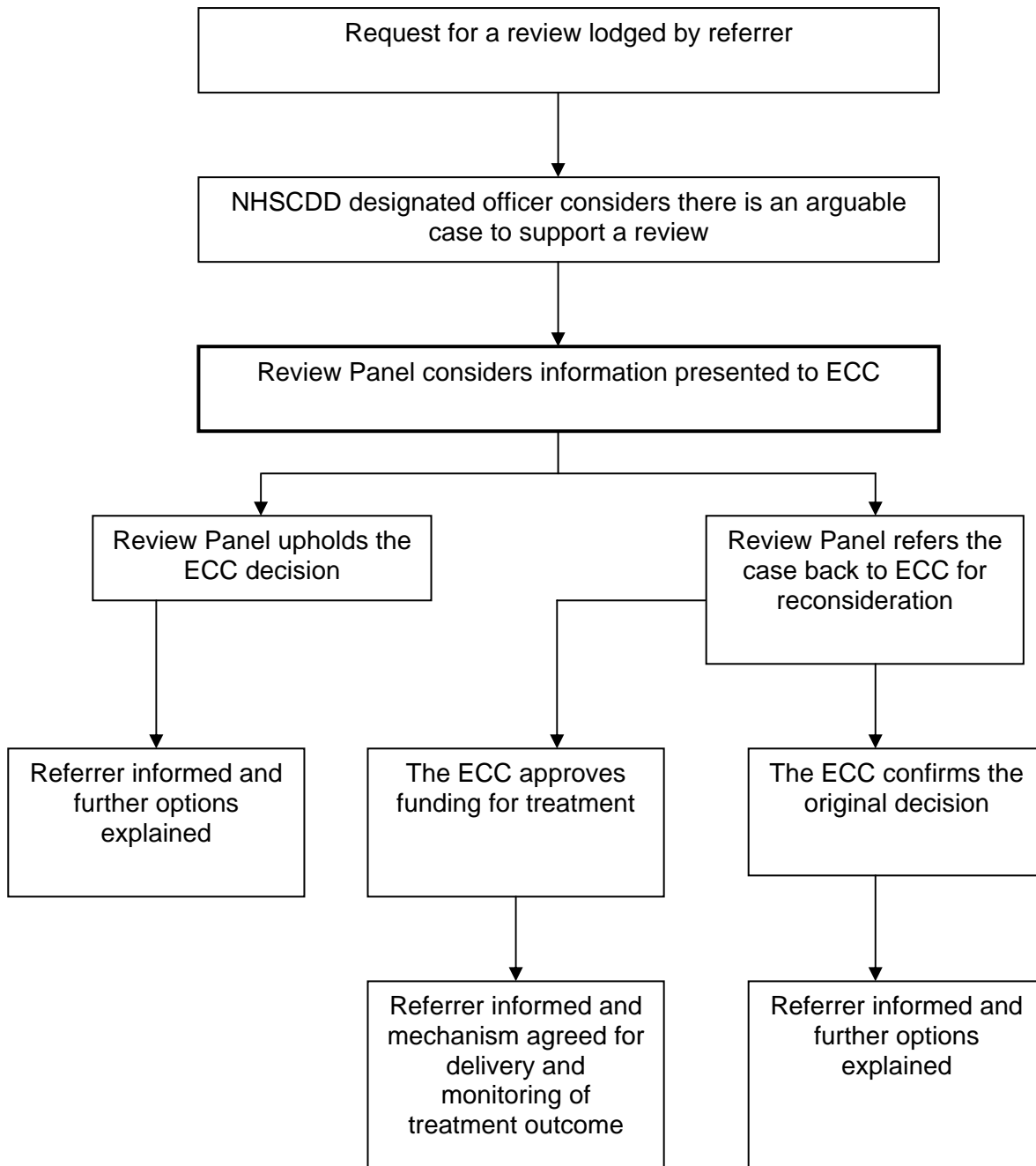
Area of Work	Work already carried out / Measures in Place	Work Required	Timescales
<b>Consultation</b>	Consulted with members of the Exceptional Cases Committee, the Management Executive, Integrated Business Board and LMC	Management Executive to approve  Integrated Business Board to approve	June 2010  June 2010
<b>Monitoring &amp; Target Setting</b>		Review May 2012	May 2012
<b>Access to Information/Services</b>		Available to staff via the Intranet and hard copy of policy. Signpost access to services and support.	Following approval
<b>Marketing &amp; promotion</b>		All staff informed of approval and publication of the policy	Following approval
<b>Training/Briefing staff Employment Issues</b>		N/A	
<b>Review and Evaluation</b>		Review May 2012	May 2012

## Appendix A1: Flowchart of IFR process for routine cases



**\*The referrer must be a doctor or other health care professional directly involved in the patient's care. All correspondence is copied to the patient's GP.**

## Appendix A2: Flowchart of review process for routine cases



## Appendix B: Individual Funding Treatment Request Form

### PATIENT PERSONAL DETAILS

Patient Name:

Date of Birth:

NHS Number:

GP Details:

Please note that all personal information will be removed prior to the consideration by the Individual Funding Request process. This information is collected for monitoring purposes only.

### TREATMENT REQUESTED

**DETAILS OF REQUESTER** (include Consultant contact details in the event of query or need for clarification)

Name:

Trust/Surgery:

Contact phone number:

### 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)

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

**EVIDENCE OF CLINICAL AND COST EFFECTIVENESS/ SAFETY**

If drug therapy is requested, is the drug licensed for the intended use?  
 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?  
 What previous therapies have been tried and what was the response?  
 What are the anticipated clinical benefits in this individual case of the particular treatment requested over other available options?  
 Why are standard treatments (those available to other patients with this condition/stage of the disease) not appropriate for this patient?  
 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? (NHSCDD will require regular feedback on the outcome if the treatment is approved).  
 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.

**AFFORDABILITY**

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.

**ACCESS TO TREATMENT**

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

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?

**OTHER**

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

## Appendix C: Guidance Notes for Clinicians

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

The key consideration is whether the treatment that you wish to request for your patient will meet the definition for 'exceptional clinical circumstances' that is set out in the Individual Funding Request policy.

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

NHSCDD 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 NHSCDD 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' 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 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 the group of patients with the same condition/stage of the disease and has clinical features that mean that they will derive greater benefit from the treatment you are requesting.

### 3. Why are only clinical features taken into account?

NHSCDD 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 Funding Request (IFR)?

All requests must be made on a standard treatment request form which can be obtained electronically from The Individual Funding Request Manager at the PCT. The form aims to ensure that all the necessary information is obtained to avoid delays in reaching a decision. It is the responsibility of the referrer to ensure that the form is completed accurately by seeking specialist information from other clinicians as required. The form can either be returned electronically 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 Individual Funding Request Manager at NHSCDD 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 a Commissioning Manager and consultant in Public Health Medicine to decide whether "exceptional clinical circumstances' have been demonstrated. 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 Commissioning Manager is uncertain whether the case is exceptional or not, then the case will be forwarded to NHSCDD Exceptional Cases Committee. The ECC will include a Non-Executive Director, Executive Director, Public Health Specialist and a Clinical Member. They will determine whether there is a case for exceptionality and whether the intervention is safe, clinically effective and cost-effective.

## **7. How will I be informed of NHSCDD 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 ECC 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. Can either the patient, or a clinician involved in their care, attend the panel?**

No. The panel will only consider the written evidence that has been submitted so it is very important that all the evidence is presented in the treatment request form.

## **9. Can I, or my patient appeal, against NHSCDD decision?**

There is no right to appeal against the decision at the 'screening' stage although it is possible to ask for the case to be reviewed. When requesting a review you should provide additional information with evidence that the patient has exceptional clinical circumstances. If the ECC does not approve your request you, or your patient, are entitled to ask for a review of the process that was undertaken by NHSCDD. The Review Panel will decide if NHSCDD followed the correct procedures and the ECC reached a decision that was rational and based on all the evidence that was presented.

## **10. What can I do if my patient is not exceptional e.g. represents a group of patients in similar clinical circumstances**

If the treatment or services is covered by Specialised Commissioning, it will need the support of all the relevant clinicians in the region either through a clinical network, if one exists, or by a direct approach to North East Specialised Commissioning Group:

North East Specialised Commissioning Team (NESCT)  
NHS North of Tyne  
Bevan House  
1 Esh Plaza  
Sir Bobby Robson Way  
Great Park  
Newcastle upon Tyne  
NE13 9BA

Tel: 0191 217 2807  
Email: [Norscore@nescg.nhs.uk](mailto:Norscore@nescg.nhs.uk)  
Fax: 0191 217 2511  
Bevan House reception: 0191 217 2500

For all other services and treatments you should contact the PCT.  
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 D: Decision Framework Document for the Exceptional Cases Committee

IN STRICTEST CONFIDENCE: IFR DECISION FRAMEWORK DOCUMENT

PANEL MEETING

DATE \_\_\_\_\_ PATIENTNo: \_\_\_\_\_

**NHS County Durham and Darlington**  
**DECISION FRAMEWORK DOCUMENT FOR EXCEPTIONAL CASES COMMITTEE**

STRICTLY PRIVATE & CONFIDENTIAL – NOT FOR RELEASE OUTSIDE THE PANEL

All attendees should be aware of NHS County Durham and Darlington's compliance with the Freedom of Information Act. The minutes and papers from this meeting could be published on the Publication Scheme and be made available to the referring clinician and patient.

Notes of Guidance:

1. A copy of this form is to be provided to each panel member for each person in respect of whom an application is being considered
2. The copies will, at the end of the meeting, be collected and retained by the ECC Administrator
3. The Framework will be used to inform the letter to be written on behalf of the Chair of the ECC

**Panel Members**

**Intervention Requested**

**Documents pertaining to the case**

**Brief background to intervention requested**

Points for consideration	Discussion notes	Decision
Does NHSCDD 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?		
Does the panel consider that there is sufficient evidence of the clinical effectiveness of this drug/intervention?		
Is there sufficient 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?		
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?		

What are the absolute costs involved in funding this treatment, in relation to the overall resources of NHSCDD for health care?		
What will the anticipated impact be on the rest of the patient population should this treatment be funded?		
Will it be equitable to the wider population to fund this treatment after consideration of the clinical needs of this patient?		
Are there any other factors which were considered relevant by the Panel?		
<b>Summary</b>		
Funding approved:	Any conditions / review mechanisms required.	Outcome measures to be monitored and date of review.
Funding denied:	Reasons	

## **Appendix E: Terms of Reference of the Exceptional Cases Committee**

### **1. Membership**

The Exceptional Cases Committee will have a core membership of:

- Director of Public Health or nominated deputy
- Executive Director or nominated deputy
- Clinical Member
- Non-Executive Director (Chair)

In attendance:

- IFR Manager
- ECC Administrator

Other individuals with specific expertise and skills may also be included on the panel e.g. pharmacist, commissioning manager in order to ensure effective and fair decision making.

### **2. Purpose**

The purpose of the ECC is to consider individual requests for NHS commissioned and funded treatment. Each individual funding request will be handled by following NHSCDDIFR process (see NHSCDD IFR Policy) which will ensure the request is considered in a fair and transparent way, with decisions based on the best available evidence and NHSCDD commissioning principles.

### **3. Frequency of meetings**

The ECC will normally be held monthly. A case may need to be considered urgently between meetings on the advice of the Director of Public Health, or nominated deputy, after consultation with the patient's clinicians. The timing of the urgent ECC 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' ECC can be convened of a senior Public Health professional, nominated by the Director of Public Health, and a Clinical Member of the ECC, or equivalent, as a minimum membership, with other panel members attending if available in order to reach an immediate decision.

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. Voting Rights**

ECC 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 panel member present having an equal vote. If the panel is equally split then the chair of the panel will have the casting vote.

## **5. Quorum**

The panel will be quorate if three of the core members are present, including the Director of Public Health (or nominated deputy) and the Clinical Member.

## **6. Documentation**

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

All cases will be anonymised before consideration by the ECC.

The ECC Administrator will coordinate the production of a summary of the key information using the Decision Framework Document (Appendix D). The summary will be produced by the Public Health Department and will be considered by the ECC. All other documentation that has been received regarding the case will also be available to the panel.

## **7. Authority**

The ECC is a sub-committee of the IBB and has delegated authority to make decisions in respect of funding of individual cases. It is not the role of the ECC to make commissioning policy on behalf of the PCT.

## **8. Accountability**

The minutes of the ECC will be approved by the Chair of the Panel. The ECC is accountable to the IBB.

## **9. Reporting and Monitoring**

The ECC Administrator will record the decision of the ECC 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 ECC meeting will be taken to the next routine meeting of the ECC.

The ECC will meet on a quarterly basis to review the IFR database with the IFR Manager in order to evaluate the process, including the consistency of panel decision making, and to consider any improvements that could be made. The IFR Manager will produce an annual report which will be considered by the IBB. The Terms of Reference of the ECC will be reviewed annually by the IBB.

## 10. Training

All members of the ECC must undergo mandatory induction training organised by the Public Health Directorate of the PCT. This will cover both the legal and ethical framework for IFR decision making, NHSCDD 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.

## Appendix F: Terms of Reference of the Review Panel

### 1. Membership

The Review Panel will consist of:

- Chairman or nominated Non-Executive Director (Chair)
- Chief Executive or nominated Executive Director
- Medically qualified Board level Director

None of the panel members should have been involved in the case prior to the Review Panel. The Review Panel will not consider either new information that was not available to the ECC or receive oral representations.

### 2. Purpose

The Review Panel will determine whether the original decision is valid in terms of the 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 the ECC was consistent with the IFR Policy
- The decision reached by the ECC:
  - i. was consistent with NHSCDD 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 ECC was entitled to reach.

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

- To uphold the decision reached by the ECC.
- To refer the case back to the ECC with detailed points for reconsideration.

Where the Review Panel consider that the decision may not have been consistent with NHSCDD Commissioning Principles, the ECC may not have taken into account and weighed all the relevant evidence, have taken into account irrelevant factors or reached a decision which a reasonable ECC was entitled to reach the Review Panel shall refer the matter to the ECC if they consider that there is an arguable case that requested treatment will be approved.

If the Review Panel considers that, notwithstanding their decision on the procedure adopted by the ECC, there is no arguable case that the decision would have been different, the Review Panel shall uphold the decision of the ECC.

### **3. Frequency of meetings**

The Review Panel will be scheduled monthly. A case may need to be considered urgently on the advice of a senior Public Health professional, nominated by the Director of Public Health, after consultation with the patient's clinicians. The timing of the urgent Review 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. Ideally, all urgent cases will be considered by face-to-face meeting, but where the clinical urgency makes this impossible, communication by phone or e-mail will be deemed appropriate.

### **4. Voting Rights**

The Review Panel members will seek to reach a decision by consensus. If this is not possible a decision will be made by a vote with each member having one vote.

### **5. Quorum**

All three panel members must be present for the Review Panel to be quorate.

### **6. Documentation**

The Review Panel will only consider the following written documentation:

- i. the original Treatment Request Form submitted to the PCT
- ii. the IFR process records in handling the request
- iii. the ECC records, including the Decision Framework Document and any additional supporting information considered by the ECC
- iv. 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 Review Panel from the ECC or the referring clinician and/or the patient/guardian or carer. The Review Panel will not consider new information or receive oral representations. If there is significant new information, not previously considered by the ECC, it will be considered as set out in 3.5.8 Reconsideration. All information will be anonymised before consideration by the Review Panel.

### **7. Authority**

The Review Panel is a sub-committee of the IBB and has delegated authority to undertake a review of ECC decisions in respect of funding of individual cases. It is not the role of the Review Panel to reach a decision on funding of an Individual Funding Request nor does the Panel make commissioning policy on behalf of the PCT.

### **8. Accountability**

The Review Panel is accountable to the IBB.

## 9. Training

All members of the Review Panel must undergo mandatory induction training organised by the Public Health Directorate of the PCT. This will cover both the legal and ethical framework for IFR decision making, NHSCDD 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.