Operating Framework for

Managing Individual Funding Requests

Version / Status	**7.0**
Responsible Clinical Commissioning Group (CCG):	**Greater Huddersfield CCG** **North Kirklees CCG** **Calderdale CCG**
Responsible Chief Officers:	**Carol McKenna (GHCCG)** **Richard Parry (NKCCG)** **Matt Walsh (CCCG)**
Responsible Committee:	**Greater Huddersfield CCG Governing Body** **North Kirklees CCG Governing Body** **Calderdale CCG Governing Body**
Date Approved:	**GHCCG 12 October 2016** **NKCCG 13 October 2016** **CCCG 14 June 2018**
Author	**Assistant Manager - Individual Funding Requests**
Review Date	**June 2020**

Version Control:

Version	Date	Author	Document Status	Comment
6.0	Apr 2014	Claire Gordon – Project Officer GHCCG	FINAL	Approved by Greater Huddersfield and North Kirklees CCG Governing Bodies.
6.1	Sept 2016	Claire Wood – Assistant Manager IFR GHCCG	Draft	Revised and circulated to the GHCCG, NKCCG and CCCGs SMT and the Joint Exceptional Cases Committee – September 2016.
6.2	Oct 2016	Claire Wood – Assistant Manager IFR GHCCG	Draft	Revised with comments from GHCCG and NKCCG SMT. Approved by GHCCG and NKCCG Governing Bodies – October 2016. Circulated to staff and public via website.
6.3	Apr 2017	Claire Wood – Assistant Manager IFR GHCCG	Draft	The Operating Framework updated to incorporate comments from Calderdale CCG SMT Meeting - April 2017 Presented to Calderdale CCG Governing Body for approval – June 2018.
7.0	Jun 2018	Claire Wood – Assistant Manager IFR GHCCG	FINAL	Approved by Calderdale CCG Governing Body – 14 June 2018 Circulated to staff and public via website.

Contents

Operating Framework Statement..... **3**
Introduction..... **3**
Scope of this Operating Framework..... **3**
Legal Context..... **4**
Commissioning Principles..... **5**
Associated Policies and Procedures..... **6**
Accountability and Responsibilities..... **6**
CCG Leads..... **6**
Committee Accountability..... **6**
Delegated Responsibilities..... **6**
Structure of Reporting..... **6**
Responsibility for Operating Framework review..... **7**
Screening and Decision Making Principles..... **7**
Exceptionality..... **8**
Procedures..... **10**
Stage One – Screening Process..... **11**
Urgent or Emergency Cases..... **12**
Membership Of The Screening Panel..... **13**
Stage Two- Exceptional Cases Committee..... **13**
Membership Of The Exceptional Cases Committee..... **14**
Stage Three – Appeals Committee..... **14**
Membership Of The Appeals Committee..... **15**
Precedence..... **15**
Treatment Outside The European Economic Area (EEA)..... **16**
Equality Impact Assessment..... **16**
Training Needs Analysis..... **16**
Monitoring Compliance with this Operating Framework..... **16**
References..... **17**

Operating Framework Statement

NHS Greater Huddersfield Clinical Commissioning Group (GHCCG), NHS North Kirklees Clinical Commissioning Group (NKCCG) and NHS Calderdale Clinical Commissioning Group (CCCG) throughout this document will be known as 'the CCGs'.

GHCCG is the host commissioner for the implementation of the Individual Funding Requests (IFR) operating framework, on behalf of GHCCG, NKCCG and CCCG as covered within the Memorandum of Understanding dated January 2016.

The CCGs have a systematic and documented process for considering all Individual Funding Requests that will take into account national, regional and local guidance to support decision making.

All Individual Funding Requests will be considered via this documented process.

This will ensure decisions are consistent and based on the best available evidence and enable the most appropriate care to be delivered within the context of individual clinical need.

The operating framework will be made publically available on each CCGs website with links to clinical guidance documents where these are available.

Introduction

This document sets out the CCGs procedures for managing requests for an individual to receive a health care intervention that is not routinely funded by the CCGs. The vast majority of health care commissioned by the CCGs is covered by NHS Service Level Agreements or other Contracts. However, there are a small number of requests for treatment by individual patients each year that are not covered by either of these.

For the purpose of this document, and in common with the Secretary of State's Directions to CCGs and NHS Trusts concerning decisions about drugs and other treatments 2009, the term "health care intervention" includes use of a medicine or medical device, diagnostic technique, surgical procedure and other therapeutic intervention.

Scope of this Operating Framework

This operating framework applies to all employees of the CCGs, any staff who are seconded to the CCGs, contract and agency staff and any other individual working on the CCGs premises or on behalf of the CCGs who are involved in the administration processes for IFRs.

Clinicians making an IFR request on behalf of their patient are expected to adhere to the procedure outlined in this document. Advice and support is available from the IFR Team based at Broad Lea House.

The scope is to have a clear operating framework to:

- Manage Individual Funding Requests
- Consider the legal aspects of priority setting
- Have a systemic and consistent approach to the management of Individual Funding Requests

This will be achieved by the following objectives:

- To be compliant with the NHS Confederation guidelines on interpretation of legislation
- To have systems in place that enable a consistent approach to decision making within appropriate timescales
- To ensure decisions made are based on the best available evidence at the time of consideration

The process for managing new treatments will not be considered as part of this because it is a separate process within the CCGs. This operating framework will aim to provide a robust process of decision making by which all Individual Funding Requests can be considered.

In responding to an Individual Funding Request the CCGs accept no clinical responsibility for the health care intervention or its use, or for the consequences of not using the intervention.

Legal Context

The CCGs have a duty:

- To allocate healthcare resources, utilising a consistent framework for decision making
- To promote and provide a comprehensive healthcare service within its allocations and consider how this is best done
- To be aware of differences in neighbouring CCGs and be able to justify them if necessary

(NHS Confederation, 2008a)

The CCGs need to be satisfied that any decision follows the procedures and processes described in this document and in doing so ensure requests are considered on their own merits.

The courts have established that a CCG is not under an absolute obligation to provide every treatment that a patient demands, although they must be able to clearly demonstrate why a treatment has been refused (NHS Confederation, 2008a). A CCG can develop a policy which prioritises treatment to take account of the resources available to it and the competing demands on those resources. Patients with rare or unusual medical conditions have as much right to care as anyone else and have the right to have their requests considered properly, on their own merits and against the CCGs policy in each individual case.

The need for priority setting processes to be central to CCGs corporate governance in relation to Individual Funding Requests and commissioning decisions cannot be underestimated because the potential for Judicial Review is increasing. Judicial Review is the process by which the lawfulness of decision making can be challenged and can occur as a result of major service change or refusal to fund treatments for individual patients. There are grounds for a review if:

- Decisions may be unlawful – acting outside statutory power (e.g. not following direction of the Secretary of State)
- Decisions may be irrational – considering irrelevant/excluding relevant factors

- Decisions are procedurally improper – (e.g. failure to comply with the CCGs policy or the CCGs policy itself being unlawful or irrational) (NHS confederation, 2008a)

Commissioning Principles

The CCGs have a statutory duty to provide health care for their population and in doing so have to take account of the resources available, usually a fixed budget from central government to commission health care and services. The CCGs commissioning principles are used to make decisions in a consistent, fair and transparent way, given that funds are not endless and choices inevitably need to be made. The criteria for commissioning treatments are:

- Clinical Needs – Consideration should be given to understanding the need and whether we are likely to achieve the greatest possible health outcome for the patient. Health care interventions which produce the greatest benefit in terms of clinical improvement and/or improvements in quality of life should be prioritised.
- Lawful – As previously discussed in this document as part of the legal responsibilities of the CCGs. In addition, as part of this process a Clinician makes a request on behalf of the patient and therefore must be aware of the need to obtain informed consent for the referral as well as ensuring the patient is aware of both the potential benefits and risks of any treatment being requested.
- Clinically Effective – Commissioning decisions should be based on evidence of effectiveness wherever possible. For example, this could come from sources such as NICE, Cochrane reviews, meta-analysis or randomised control trials.
- Cost-effective – Given limited resources, the CCGs must receive optimum value from available resources and recognises that QALY (Quality Adjusted Life Years) would help judge this, with NICE using a maximum value of £30,000 per QALY. However it is important to note that cost alone will not be a reason for refusing an Individual Funding Request. The Exceptional Cases Committee shall have a broad discretion to determine whether the proposed treatment is a justifiable expenditure for the CCGs. The CCGs are however required to bear in mind that the allocation of any resources to support any individual patient will reduce the availability of resources for investments in previously agreed care and treatments.
- Equitable – In this context equity means that if an Individual Funding Request is agreed for a new treatment/drug trial then it could lead to service development which could benefit the wider population. In addition, once a precedent has been set, it is likely that future requests for the same treatment would also qualify for funding, subject to the clinical presentation of the patient.
- Accessible – While accessibility implies utilisation of local services the CCGs also need to take into account patient choice. The CCGs would expect referrals to be made to the NHS services wherever possible but a choice list will be provided to highlight where the CCGs will fund treatment outside the local NHS if available and where requested by the patient.
- Good quality of care and patient experience – Decisions should be based on the potential to deliver good and safe care, improve health outcomes and enhance patient experiences. Individual Funding Requests should be agreed if it meets this criteria and will achieve or has the potential to achieve explicit measures of quality, including:

    1. Patient feedback through local and national surveys, PALS and complaints
    2. Local and national standards, targets and quality indicators

Associated Policies and Procedures

This operating framework and the procedures outlined within it are related to:

- Policy and procedure for commissioning treatments not covered by existing service level agreements
- Medicines (and technologies) commissioning policy

Accountability and Responsibilities

The Chief Officer and Governing Body of the CCGs are accountable for the discharge of CCG statutory duties and have a scheme of delegation in place that is set out in the CCGs Standing Orders and Standing Financial Instructions.

CCG Leads

The Lead Manager with overall responsibility for this operating framework and the procedures within it is the Head of Strategic Planning, Service Transformation and Integration for GHCCG.

Committee Accountability

Overall responsibility for the development and implementation of this operating framework and its procedures remain with each CCGs Governing Body. The annual report will be made available to the Finance & Performance and Quality and Safety Committees and reported formally to the Governing Bodies of each CCG to enable them to:

- Ensure the systems in place are sufficient to meet patient's needs
- Ensure that decisions made throughout the process are consistent and appropriate
- Ensure positive health outcomes are being achieved as a result of the decisions made

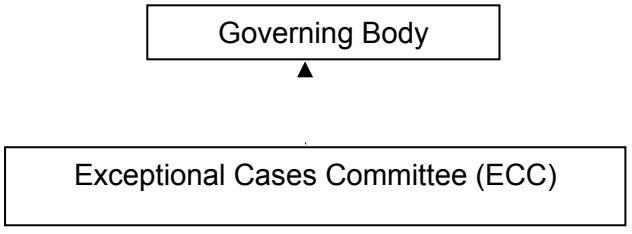
Delegated Responsibilities

Responsibility for making decisions regarding Individual Funding Requests on behalf of the CCGs has been delegated by the Governing Bodies of each CCG to:

- The Exceptional Cases Committee (ECC)

The membership, roles and responsibilities of each of these bodies is set out in the procedures section of this document.

Structure of Reporting



Responsibility for Operating Framework review

Where a need to change any aspect of the structure or process of decision making is identified, the IFR Team will co-ordinate a review of this policy. A review may also be required in response to new local, regional and national guidelines as they become available.

Changes to other policies within the CCGs may occur as part of this process. This could occur following the introduction of new national guidelines or where a significant number of people are applying for funding for the same treatment or intervention, leading to a review of routinely commissioned treatments / services. When a policy decision needs to be made recommendations will go to:

- Senior Management Team – for decisions involving policy changes that impact on the management of the CCGs
- Quality & Safety Committee – for clinical decisions
- Finance & Performance Committee – for financial impacts
- Governing Body

Screening and Decision Making Principles

The Screening Panel will assess each individual request taking into account:

Appropriateness, comprehensiveness, effectiveness (including that of safety), size of intended benefit (outcomes), alternative interventions and consequences of not having the treatment/intervention.

Individuals requesting funding are screened for:

- Whether the CCG or NHS England are the responsible commissioner.
- Treatment or drugs not covered by existing Service Level Agreements or are specifically identified as exceptions within the Service Level Agreement
- Treatment availability locally but requested from another provider where additional costs will lead to uncertain extra clinical benefit
- Treatments or drugs that are not routinely commissioned
- Treatment or drugs that are new or experimental
- Complex or unusual cases

The following guidance should also be taken into account when considering appropriateness of a request:

High Cost Drugs: IFRs for high cost drugs. On receiving a request for high cost drug treatment the Screening Panel will consider available evidence based reviews to inform the decision making process. The request will also be reviewed by a Medicines Management Representative to provide key information that should be considered. A representative from Medicines Management will attend the Screening Panel to present any information and discuss these cases as required.

Introduction of New Drugs or Treatments: Consideration of new drugs/treatments should be referred into established planning frameworks but a decision should be made as to whether an interim commissioning policy is needed to enable the clinician/patient to access treatment.

Restricted Treatments: Treatments not included in existing pathways are not routinely funded but policy statements on restricted treatments are available. IFRs can be considered in relation to these restricted treatments to assess whether the request fits the criteria or if exceptional circumstances exists.

Rare Conditions: NHS England has the responsibility for commissioning treatments for many rare conditions as set out in their Specialised Services Manual and accompanying documents. The CCG will be the responsible commissioner where NHS England is not responsible for commissioning the service. These patients are unlikely to have treatment options covered by NICE guidance or commissioning policies and therefore, Individual Funding Requests should be considered against the commissioning principles.

Drug Trials: The CCGs will not usually provide funding for individuals coming off drug trials unless prior agreement has been obtained before commencement of the trial. In accordance with the Medicines Act (2004) responsibility for an exit strategy from a trial lies with those conducting it (NHS Confederation, 2008b).

Continuing Private Care: Funding for individuals to continue care purchased privately, where an individual has exhausted their own resources or chosen to terminate a private arrangement, will not routinely be funded by the CCGs. Applications for funding can be considered via the funding request process in the usual way.

Inheriting decisions from other PCTs / CCGs: Patients moving into either of the CCG areas and registering with a GP in that CCG area, become the responsibility of that CCG and therefore decisions for treatment already agreed by the previous PCT / CCG would normally be upheld as long as it is consistent with the principles in this framework and the Department of Health publication "Establishing a Responsible Commissioner".

Retrospective Payment: The CCGs would not support applications for patients who have paid for private treatment and then asked for reimbursement of these costs from the CCG because prior approval for funding should have been sought through the processes outlined in this document.

Co-payment: Patients who pay for some aspects of treatment while being treated in the Public Sector. The NHS Act (2006) does not allow for recovery of charges for healthcare and the Code of Conduct for Private Practice: Guidance for NHS Medical Staff (2003) states that patients wishing to become private patients cannot be treated as both a private and NHS patient during the same visit to an NHS Organisation. The government's current position is to rule out co-payment and it is recommended that CCGs follow this guidance because it would provide access to a treatment that the CCGs were not making available to others (NHS Confederation, 2008b).

Patient Safety: The CCGs have a responsibility for patient safety when being treated in healthcare settings. The Care Quality Commission (CQC) governs the suitability of providers of NHS services and therefore patients should only be referred to providers registered with the CQC.

Exceptionality: Exceptionality should be considered in the context of the CCGs general policy for a health care intervention and specified indication.

In general, the CCGs must justify the grounds upon which they are choosing to fund a health care intervention for a patient when that intervention is unavailable to others with the condition.

A patient may be considered exceptional to the general policy if:

- The patient has demonstrated exceptional clinical circumstances in comparison to the cohort of other patients in the same clinical condition[1] (Patient is significantly different to the general population of patients with the condition in question who would normally be refused the health care intervention)
- There are good grounds to believe that the requested health care intervention will be clinically effective (there are good grounds to believe the patient is likely to gain significantly more benefit from the intervention than might be expected for the average patient with that particular condition. e.g. may not tolerate standard treatment options)
- It is likely that the requested health care intervention will be a cost effective use of NHS resources (David Lock 2011)

When considering Individual Funding Requests the CCGs will use the same ethical framework and guidelines for decision-making that underpin its general policies for health care interventions, see commissioning principles above. Where social, demographic or employment circumstances are not considered relevant to population based decisions, these factors will not be considered for Individual Funding Requests. Any assessment of exceptionally will therefore be based primarily on the consideration of clinical need.

When a patient has already been established on a health care intervention, for example as part of a clinical trial or following payment for additional private care, this will be considered to neither advantage not disadvantage the patient. Response to an intervention will not be considered to be an exceptional factor.

1 Though this test may need some revision in the case of a patient with a rare condition where there is no policy

Procedures

An Individual Funding Request (IFR) is a request to a CCG to fund a health care intervention for an individual who falls outside the range of services and treatments that the CCG has agreed to commission (NHS Confederation 2008b). The process should be both thorough and comprehensive taking into account the legal issues and commissioning principles outlined in the operating framework above. The process of decision making in all cases should therefore be:

- **Consistent – in line with agreed policy**
- **Concise – often requests for funding are related to care which is required relatively urgently, but not so concise that key issues are marginalised**
- **Transparent and explicable**
- **Defensible – based on sound evidence from national or legal guidance**

The Individual Funding Request Procedure

The IFR procedure can only be initiated by a Clinician i.e. the General Practitioner, Consultant or Dentist making a request for funding for a treatment to the CCG. It is the responsibility of the individual seeking funding in conjunction with the referring Clinician to ensure that all relevant information is forwarded to the IFR Team. This should include:

1. An outline of the patient's problem and the circumstances of the case, including any previous treatment
2. A clear statement of the referral/treatment plan proposed
3. Consideration of whether the patient's needs could be met within existing pathways
4. If the care could be provided within existing pathways, a statement of why an alternative referral, which would not be offered to others with a similar clinical need, is a priority in this case
5. If the case is not routinely funded by the CCG through existing care pathways, evidence to show why this patient is exceptional

An IFR referral form should be completed by the referring clinician in all cases in order to ensure all the above information is received. The only exception to this is when an alternative proforma is available from individual Trusts requesting high cost drugs for individual patients.

If a referral form is not completed the referral will not be considered until the CCG has received the information that they require to enable a decision to be made.

All requests for funding should be referred in writing, preferably typed, in the first instance to the IFR Team. All requests must be legible in order to avoid delays in consideration of the request. On receiving a request the IFR Team will:

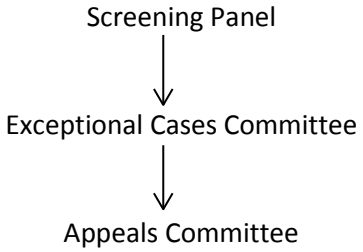
- Enter the request onto a secure database which will automatically assign a unique IFR reference number
- Create a file within which to keep all correspondence and information relating to the request
- Log all correspondence onto the secure database

The IFR Team should collate the information supplied for each case and ensure it is passed on to the Screening Panel to enable them to consider each case. All decisions made by the Screening Panel are logged on the IFR database as comprehensively as possible.
The role of the IFR Team is an administrative role tasked with co-ordinating the IFR process.

Any queries relating to a specific case at any stage of the process should be communicated by the IFR Team, in writing via the GP or referring Clinician. This will enable accurate records of each case to be maintained and enquires to be answered by the most appropriate person.

The IFR Team can be contacted either by the patient or referring clinician if clarification is required regarding the IFR process.

There will be three stages for considering IFR requests;



Stage One – Screening process

Screening cases is recommended as good practice by the NHS Confederation (2008b). The role of screening is to review all applications in relation to current national, regional or local guidance and/or policies as well as identifying any previous precedents that have been set. The screening process will operate within principles set out in this operating framework.

Outcomes from the Screening Process[2]

Recommendations for Approval

IFRs can be recommended for approval to the Exceptional Cases Committee (ECC) as part of the screening process, if the referring Clinician is requesting approval for treatment on the restricted treatments list where the patient already meets agreed criteria. Requests can also be recommended for approval if the request clearly meets the criteria specified for that indication in NICE guidance. The referring Clinician and the patient will be informed in writing within 5-10 working days of the Screening Panel meeting.

Requests for high cost drugs can be recommended for approval by the Screening Panel if the request is supported by local, regional or national policy or guidance.

The Screening Panel will also refer a request to the ECC for high cost drugs or rare conditions where there is no clear guidance or criteria available to enable them to make a recommendation. To aid the decision making process, the Screening Panel may request an evidence review to be carried out by the Public Health Team as per the Memorandum of Understanding dated April 2014.

The Chair of the Exceptional Cases Committee will take responsibility for signing off approved requests for GHCCG and NKCCG. The Head of Finance at CCCG will take responsibility for signing off approved requests for CCCG.

2 It should be noted that in severe financial difficulties the following has occurred in 2006 by Huddersfield PCT's and thereafter by Kirklees PCT until early 2007:
Moratorium: In circumstances of severe financial constraint, consideration of Individual Funding Requests can be suspended by the CCGs. It is lawful and fair to restrict treatments on the basis of costs in extreme circumstances. However it will still be necessary to screen requests and continue to support those that the ECC agree meet the following criteria:

- The condition is immediately life threatening
- That undue delay would result in a real and imminent risk of harm, e.g. death, infirmity or handicap
- That the procedure needs to be carried out within a strict time frame as delay would result in it becoming ineffective

Refused

IFRs can be refused as part of the IFR process if:

- The individual does not meet the agreed criteria
- There is no clear evidence supporting the treatment
- Where the request does not clearly demonstrate exceptionality

In the event of refusal to fund a request, the referring Clinician and the patient will be informed in writing within 5-10 working days of the Screening Panel meeting. The reason and clear rationale will be documented within the letter along with the relevant appeals process to follow.

IFRs in the following circumstances will normally be refused:

- Where the patient does not take up treatment within one year of approval being granted, then the case will be closed and a new application for funding must be made
- Where an IFR is made by a non NHS clinician based in a private provider with whom the CCGs do not hold a contract
- Where an IFR is made for treatment within a non-contracted private provider, when equivalent NHS commissioned services are available

Urgent or Emergency Cases

It is recognised that there may be occasions when the Screening Panel receive cases for consideration that need a decision urgently. Given that there would be difficulties in convening the Exceptional Cases Committee at short notice in cases of extreme emergency (for example, someone's life is dependent on a decision being made) the Screening Panel will pass on its recommendations to the Chief Officer of the CCG or the Head of Strategic Planning, Service Transformation & Integration. The Clinical Lead or nominated deputy will also be involved in the decision making process of urgent or emergency requests.

The decision will be documented and formally reported to the Exceptional Cases Committee at the next meeting.

While the CCGs will endeavour to respond to such urgent requests as quickly as possible, this should not compromise the quality and validity of the decision making process.

At all times the provider is able to fund a health care intervention pending a decision from the CCGs and the CCGs accept no responsibility for the clinical consequences of any delay in responding to the request.

Membership of the Screening Panel

- Head of Service for GHCCG (Chair)
- IFR Support Officer
- Senior Medicines Commissioning Pharmacist

This is the core membership of the Screening Panel and if for any reason a member of the Panel cannot attend then an agreed deputy will attend the meeting. The Panel will meet on a weekly basis.

Other officers from the CCGs or the Public Health Team can be invited to attend the Panel as necessary.

Stage Two – Exceptional Cases Committee

In making a decision the Committee will consider all available clinical history and examine the evidence base where necessary. The Committee will:

- Review each patient request on an individual basis
- Take into account relevant factors which are unique to the patient, e.g. current health status and existing co-morbidities
- Consider if the treatment is necessary and appropriate in relation to individual clinical need, with expected benefits outweighing any risks, and whether there are any exceptional needs or circumstances
- Consider the evidence base for safety and efficacy and if the request is drug related, its licensed indication
- Consider if the treatment is clinically and cost effective with equity of access and provision across the CCG, utilising clinical information (provided by patient's GP, Consultant or other appropriate clinical staff) and evidence base (regarding clinical and cost effectiveness of the intervention).
- Consider consistent with agreed guidance whether CCG, regional or national that may be available
- Consider other alternative options available for the patient including whether the request can be met by local or alternative providers or whether they are inappropriate for that individual
- Consider if this establishes a precedent or whether there is an existing precedent

The Panel will use the following information to make the decision as to whether the case referred is an exception:

- Information provided by the patient's GP/referring Clinician
- Clinical effectiveness reviews of the intervention requested
- Evidence that all alternative clinical strategies have been exhausted, e.g. conservative and primary care management of the patient's condition

Decision for Approval or Non Approval

Whether the request for funding is approved or not, the patient, the referring Clinician and the patients GP (where they are not the referring clinician) will be informed in writing of the decision within 5-10 working days of the Exceptional Cases Committee meeting.

Where the request was refused the Committee will set out their decision and the reasons for it to the referring Clinician and GP. The patient will be informed of the decision and encouraged to speak to their GP to discuss the reasons behind the decision. If the patient does not accept the outcome they can appeal **VIA THE REFERRING CLINICIAN ONLY** to the Appeals Committee.

Membership of the Exceptional Cases Committee

Membership of the Exceptional Cases Committee is detailed below. It is the expectation that all of these people or their deputies will attend every Committee meeting.

Chief Officer GHCCG (Chair) or nominated deputy
Chief Financial Officer NKCCG or nominated deputy
Lay member (GHCCG or NKCCG)
A maximum of 4 Clinical Leads (GHCCG and NKCCG)

Each of the above nominated Committee members will have a deputy.

The Committee is quorate with the presence of the following:

Chief Officer GHCCG (Chair) or nominated deputy
Chief Financial Officer NKCCG or nominated deputy
Lay member (GHCCG or NKCCG)
2 Clinical Leads (GHCCG and NKCCG)

The Committee will be chaired by the Chief Officer of GHCCG or their Deputy. The Chair will be responsible for checking that the decisions made are accurately recorded and for signing any letters sent to patients and Clinicians reflecting those decisions. In case of disagreement, the Chair has the casting vote if necessary.

Stage three - Appeals Process

Individuals wishing to appeal against a decision made by the Exceptional Cases Committee must notify the CCG of their intention in writing to the IFR Team, within 40 working days of the date of the initial decision via their GP or initial referring Clinician.

The GP or referring Clinician must demonstrate on what grounds they wish to appeal against the decision. An appeal can be made on the following grounds;

- Procedural irregularities (eg. due process has not been followed or that a Committee has not been quorate to make a decision) or all of the information has not been considered, or new / additional information is to be considered
- The Clinician / patient is not happy with the outcome decision. In this case the appeal will be treated as a formal complaint and passed to the complaints department at the relevant CCG.

If the Clinician does not lodge an appeal within the allocated timescales the case will be closed and any further correspondence would start the process again.

Decision Making Process

The Appeals Committee considers and decides on appeal applications which challenge due process by reference to this operating framework.

The duties of the Appeals Committee are set out below:

- To consider and review the Exceptional Cases Committee's decision in relation to the funding of an individual's treatment by reference to fair and appropriate application of the process.
- To receive and review all documentation considered by the Exceptional Cases Committee and further submissions received from parties.
- To make a decision to uphold the original decision of the Exceptional Cases Committee or refer the case back to the Exceptional Cases Committee for reconsideration, if there is evidence that all of the relevant information was not considered or that due process has not been followed. In this instance this will be supported by a written recommendation from the Appeals Committee.

A failure in the process of handling an IFR does not necessarily mean that the decision that was made was incorrect (Guidelines from the NHS Confederation 2008b).

Decision for Approval or Non Approval

The IFR Team will write to the patient, referring Clinician and GP (where this is not the referring Clinician) within 5-10 working days with the Appeals Committee's decision and their reasons.

Patients who remain dissatisfied with the Appeal Committee decision will be given the information on potential courses of action as part of the letter detailing the Appeals Committee decision.

Membership of the Appeals Committee

It is the expectation that all of these people or their deputies will attend every Appeals Committee meeting. The Appeals Committee is quorate with the presence of the following:

Clinical Lead
Senior Manager (GHCCG)
Senior Manager (NKCCG)
Lay Member (GHCCG or NKCCG)

Other representatives, for example from Public Health, can also be invited to be part of the Appeals Committee as required.

The chair of the Appeals Committee will be one of the Senior Managers detailed above.

The IFR Team will co-ordinate the meeting, circulate papers and minute and record the actions / recommendations from the meeting.

Precedence

At any point in the decision making process of the Exceptional Cases Committee or the Appeals Committee a precedent could be set. This means that any decision made can be used to inform future decisions for similar requests. If previous decisions are not taken into account this could form the basis for legally challenging the CCG and the decision made on an IFR. Given the significance of setting precedence and its potential impact on future decisions all decisions will be recorded on a secure database by the IFR Team. However a decision to allow or refuse funding will not be

absolutely binding on the CCG but where the CCG departs from a previous decision, clear evidence must be available to justify and support this departure (examples of this might include a patient presenting with slightly different symptoms, or someone who due to age/weight/sex/other medication might not respond to treatment in the same way).

Where IFRs are to be referred to the Exceptional Cases Committee the Screening Panel will review all previous decisions for the same treatment and indication.

Any relevant decisions made about previous cases that could have an impact on the decision making process for an individual case will be made available to the Committee.
An IFR should not be seen as a mechanism to introduce a new treatment. The request should be seen as genuinely individual. The requesting clinician should also demonstrate that the request is an individual request to fund a treatment, and not about introducing a treatment to a group – however small.

Treatment outside the European Economic Area (EEA)

Requests for treatment outside the EEA will be considered in line with the Department of Health Guidelines.

Equality Impact Assessment (EIA)

The CCGs aim to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others.

This policy is not intended to discriminate against any group or individual on the grounds of ethnicity, gender, age, disability, sexual orientation or religion/belief. In order to meet these requirements, a single EIA is completed.

Training Needs Analysis

No specific training is required before this operating framework and the procedures outlined within it can be implemented.

Monitoring Compliance with this Operating Framework

The administration of this process continues beyond the stages described above in order to make informed commissioning decisions in the future. It will be the role of the IFR Team to track all agreed requests to enable the CCGs to collate information on patient flows and costs associated with IFRs.

Any information collected will be collated for an annual report in Q1 of each financial year. The report will include reporting the number of individual requests, those approved and declined by procedure at each stage of the process (Screening Panel, Exceptional Cases Committee and Appeals Committee). Information will also be collated in relation to numbers of IFR requests by GP Practice.

In certain circumstances it may be necessary to trial a treatment or high cost drug prior to a decision being made. Where this is the case the outcome of the trial will be obtained prior to any decision about further treatment being made.

References

Department of Health (2004) A Code of Conduct for private practice: Recommended Standards of Practice for Private Consultants
http://www.nhsemployers.org/~/media/Employers/Documents/Pay%20and%20reward/DH_085195.pdf

Lock, D 2011, What does the duty on PCT's to give reasons for an individual treatment decision mean in practice ; Barrister and Head of Public Law at No5 Chambers

NHS Constitution March 2013
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/170656/NHS_Constitution.pdf

NHS England, 'Defining the Boundaries between NHS and Private Healthcare'
http://www.england.nhs.uk/wp-content/uploads/2013/04/cp-12.pdf

National Prescribing Centre, 'Supporting rational local decision making about medicines (and treatments)'
http://www.npc.co.uk/local_decision_making/resources/handbook_complete.pdf

North Yorkshire and York PCT, High Cost Healthcare Commissioning Policy. November 2007

The NHS Confederation (2008a) Priority Setting: Legal Considerations.
http://www.nhsconfed.org/resources/2008/12/priority-setting-legal-considerations

The NHS Confederation (2008b) Priority Setting: Managing Individual Funding Requests.
http://nhsconfed.org/~/media/Confederation/Files/Publications/Documents/Priority%20setting%20managing%20individual%20funding%20requests.pdf

The National Health Service Bill (2006)
www.dh.govuk/en/publicationsandstatistics/publications/publicationslegislation/DH4134387

The Stationary Office (2004) 2004: The medicines for Human use (Clinical Trials) Regulations.
www.opsi.gov.uk/si/si2004/20041031.htm

Yorkshire and the Humber Specialised Commissioning Group, 'Policy for Individual Funding Requests'
www.yhscg.nhs.uk/Policy/IFR%20common%20policy%20final%20v2.doc