

Individual Funding Request Policy and Procedure

Version 1.8

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1. Introduction

- 1.1 The NHS has a duty to spend the money it receives from the Government in a fair way taking into account the health needs of the whole community.

The Clinical Commissioning Group (CCG) role is to get the best value for this money by spending it wisely on behalf of the population. Demand for healthcare is growing but there is only a set amount of money available to spend so difficult decisions may have to be made.

CCGs pay for local NHS Health Services and NHS England pays for highly specialised health services. The CCGs have a legal duty to commission health services for patients with the fixed amount of money they have received from the Government.

They have a legal duty not to spend more than this. This means that some hard choices have to be made. Not all treatments can be provided by the NHS. Treatments that are limited by CCGs are shown in their Clinical Commissioning Policies.

However, the CCG know that there will always be times when a patient would benefit from a particular treatment not usually commissioned from the NHS. To apply for this treatment, an Individual Funding Request (IFR) is made to the CCG.

- 1.2. There is considerable variation in the evidence of clinical effectiveness of healthcare interventions. Individual requests for treatment which are not covered by existing contracts are received by the CCG. Some requests are for treatments that are only effective under specific clinical scenarios and are not suitable for whole population commissioning, some are for treatments which are not available from local services and others are for healthcare interventions that the CCG does not routinely commission. However, when the referring clinician believes that there are exceptional circumstances that justify a request for referral the CCG will ensure fairness of access to treatments which may normally be restricted but which may offer specific benefits in an individual context.
- 1.3 In order to carry out its functions The CCG has sought support from the NHS North of England Commissioning Support (NECS) to administer the IFR process. It is nonetheless for the CCG as the responsible commissioner for the panel to decide whether or not an IFR application will be approved.

2. Purpose

- 2.1 This policy applies to any patient for whom the CCG is responsible and covers those clinical conditions that fall within the CCG remit as commissioner.

The IFR process set out in this policy will be used to consider individual requests for funding where a service, intervention or treatment falls outside existing service agreements. This process will ensure that each request for individual funding is considered in a fair and transparent way with decisions based on the best available evidence and in accordance with the CCG commissioning principles.

- 2.2. **The Principles that the CCG seeks to support are:**

- There is clear evidence of clinical and cost effectiveness before NHS resources are invested in the treatment.

- The CCG will consider the extent to which the individual will gain a benefit from treatment.
- The CCG will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community.
- The CCG will consider all relevant national standards and take into account all proper and authoritative guidance.
- Where a treatment is approved, the CCG will respect patient choice as to where a treatment is delivered, but clinical need and exceptionality will be paramount.
- Consultation with designated safeguarding leads where there is a potential safeguarding concern (children or adults)

2.3 **When considering an IFR the CCG will also ensure that decisions:**

- Comply with relevant national policies or local policies and priorities that have been adopted by the CCG concerning specific conditions or treatments.
- Are based on the available evidence concerning the clinical and cost effectiveness of the proposed treatment including any NICE guidance.
- Are taken without undue delay in particular for urgent requests i.e. where a delay in reaching a decision to fund might adversely affect the clinical outcome.

2.4 The CCG considers all lives of all patients to be of equal value and in making decisions about funding treatments will seek not to discriminate on the grounds of age, sex, sexuality, race, religion, lifestyle, occupation, family and caring responsibilities, social position, financial status, family status (including responsibility for dependents), intellectual/cognitive functioning or physical functioning. If there are differences in the treatment options, this will be considered, if it directly relates to the patient's clinical condition or is related to the anticipated clinical benefits.

3. **Scope**

3.1 **This policy applies to:**

All employees of the CCG, any staff who are seconded to the CCG, contract and agency staff and any other individual working on CCG premises.

3.2 Employees of the North of England Commissioning Support (NECS) who work within the IFR team, any staff who are seconded to the IFR team, contract and agency staff together with other staff who contributes to the IFR process.

3.3 All referring clinicians within primary, secondary and tertiary care.

3.4 There are a range of specialised services which are currently the commissioning responsibility of NHS England and this policy does not apply to such services and treatments. NHS England will manage any Individual Funding Request relevant to policies or specialised services commissioned by them.

4. **Responsibilities**

4.1 All CCG staff (especially those involved in commissioning and contracting), all members of staff in the NECS IFR team and referring clinicians (primary, secondary and tertiary care) are responsible for following the procedures as set out in this policy.

4.2 The Chair of the IFR panel will be responsible for overseeing adherence to the Policy as set

out below.

- 4.3 That governance arrangements in place to ensure that the IFR Panel is accountable to the CCG Governing Body

5. **Definitions**

5.1 **Exceptionality**

The meaning of the words “exceptional”, “exceptionality” and “exceptional clinical circumstances” have been variously interpreted.

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

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

- Are there any clinical features of the patients’ case which makes the patient significantly different to the general population of patients with the condition in question at the same stage of progression of the condition?
- Would the patient be likely to gain significantly more clinical benefit from the requested intervention than might be normally expected for the general population of patients with the condition at the same stage of the progression of the condition?
- The implications of this approach are that if a patient can be seen to be part of a group of patients for whom a treatment is not made available by the CCG under the CCG’s existing policies then exceptionality for this individual patient is unlikely to be demonstrable.
- The CCG policy outlines how the IFR panel should consider requests for treatments that are not routinely available based on the patients’ clinical circumstances. This means that the CCG is committed to ensuring equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation.

In carrying out their functions, the CCG will have due regard to the different needs of protected equality groups, in line with the Equality Act 2010. Social and personal factors such as caring responsibilities and family circumstances can only be taken into account where they are relevant to the patient’s clinical outcome. Whilst a patients professional, economic or social standing or their family responsibilities are important to individuals; the CCG policy is that they are not relevant in assessing whether a patient has exceptional clinical circumstances

5.2 **Cost Effectiveness**

The cost effectiveness of a treatment or intervention is the ratio of its cost to a relevant and accepted clinical measure of its benefit. Cost effectiveness is concerned with gaining maximum health impact for the resource used on a treatment and although an intervention may be considered to be cost effective it may not be considered affordable for the organisation to routinely commission it in every case.

Drugs and technologies that are approved as the result of a NICE Technology Appraisal (TA) need to be implemented within 3 months of the appraisal being published. The CCG will, within resource constraints, seek to ensure implementation of NICE TAs without delay

but recognises that the CCG may take the full period of 3 months before a new commissioning policy can be brought into place where significant service change and/or development are required as part of the implementation. NICE also produces other guidelines which are a valuable source of good practice which the CCG will take into account in developing policy but the CCG retains discretion and is not mandated by Directions to implement such Guidance within a fixed time period or at all.

5.3 **Clinical Effectiveness**

A clinically effective intervention is one that has been demonstrated from good quality evidence to be effective for appropriate patients in improving their clinical outcomes, when given in a timely manner.

5.4 **Randomised Controlled Trial (RCT)**

This is a study in which a number of similar people are randomly assigned to 2 (or more) groups to test a specific drug, treatment or other intervention. One group (the experimental group) has the intervention being tested; the other (the comparison or control group) has an alternative intervention, a dummy intervention (placebo) or no intervention at all. The groups are followed up to see how effective the experimental intervention was. Outcomes are measured at specific times and any difference in response between the groups is assessed statistically. This method is used to reduce bias.

6. **Equality and Diversity**

The CCG is committed to:

- Eliminating discrimination and promoting equality and diversity in its Policies, Procedures and Guidelines
- Designing and implementing services, policies and systems that meet the diverse needs of its population and workforce ensuring that no individual or group is disadvantaged.

To ensure the above, this Policy and Procedure has been Equality Impact Assessed. Details of this assessment is available on the CCG's website: <https://www.hullccg.nhs.uk/policies/clinical-commissioning-policies/a-z-of-policies/>

6.1 **NHS Constitution**

The CCG is committed to:

- Achieving the principles, values, rights, pledges and responsibilities detailed in the NHS Constitution and
- Ensuring these are taken account of in all CCG Policies, Procedures and Guidelines

This Policy supports the NHS Constitution (2015)

<https://www.gov.uk/government/publications/the-nhs-constitution-for-england/the-nhs-constitution-for-england>

7. **The Individual Funding Request Policy**

7.1 **Context**

This policy has been developed in response to the legal duties set out in the NHS constitution and a range of guidance as set out below:

The NHS Confederation guidance on managing Individual Funding Requests (The NHS

Confederation 2017-2019) Regulation 35 of the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibility and Standing Rules) Regulations 2012 (SI 2012 No 2996) (Ref 12.2) which imposes a duty to give reasons for either declining to adopt a policy on any particular intervention or declining a particular treatment for a patient where the policy is not to fund that intervention.

The NHS Constitution (Department of Health March 2015): two rights relate specifically to the availability of medicines and other treatments:

- You have the right to drugs and treatments that have been recommended by NICE for use in the NHS if your doctor says they are clinically appropriate for you.
- You have the right to expect local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you; they will explain that decision to you.
- Guidance principles for processes supporting local decision making about medicines and a handbook of good practice guidance (Department of Health/National Prescribing Centre, February 2009)
- Guidance on NHS patients who wish to pay for additional private care (Department of Health March 2009)
- The Operating Framework for the NHS in England 2012/2013 (Department of Health December 2011)
- NHS Hull CCG, Hull Health and Care Place Plan 2018-2019 (Partnership Plan)

8. **Development of General Policies for Interventions**

Each year, the CCG plans investment in health care interventions and services as part of its operating plan development process to meet the needs of its local population. Commissioning decisions are usually made in collaboration with healthcare providers and other stakeholders and are taken in the context of the CCG's available resources to ensure that care is fairly allocated to all patients; and where appropriate, measured against the CCG's other service development priorities, NICE guidance and national priorities.

When planning its investments, the CCG works with provider partners and stakeholders to identify as far as possible those new interventions that are likely to have a significant clinical impact and require potential commissioning. This is often referred to as horizon scanning.

Most Healthcare interventions are commissioned as part of contracts with provider partners; however, it is likely that during the year there will be requests for interventions not covered by the CCG's commissioning policies. The CCG therefore needs to be able to make decisions about these requests that are fair and consistent.

All Individual Funding Requests are triaged to identify whether a request submitted on behalf of an individual would apply to a population of patients. Where that is the case, the request may trigger the development of a new policy for that intervention and indication (called a general commissioning policy) or modification of an existing general commissioning policy. This however, does not remove the obligation to consider the application received.

Arrangements for the development and revision of general commissioning policies by the CCG for healthcare interventions are available from the CCG.

There are some clinical commissioning policies which have been harmonised across the Humber Cost and Vale footprint which are displayed separately on the NHS Hull CCG website <http://humbercoastandvale.org.uk/how/collaborative-commissioning/#alignment>

The CCG will make its general commissioning policies available on request or at <http://www.hullccg.nhs.uk>

9. Definition of an Individual Funding Request

An Individual Funding Request is a request to the CCG to commission for an individual healthcare which falls outside the range of services and treatments that the CCG has agreed to commission as a matter of routine.

9.1 Individual Funding Requests are not the same as:

- Decisions that are related to care packages for patients with complex healthcare needs
- Prior approvals which are used to manage contracts with providers. For example: the CCG might have agreed to a prior approval scheme in a contract with an acute hospital that requires the hospital to obtain approval to treat in cases where the CCG has commissioned a better value service with another provider (such as a community based service).

9.2 Individual Funding Requests generally arise in one of four circumstances:

- The patient has a rare condition and makes the request to commission the usual way of treating the condition (i.e. referrals for the treatment are too low/unpredictable to warrant having a contract with any provider)
- The patient has a specific condition where the usual care pathway or treatment threshold is deemed inappropriate for that individual on clinical grounds (this may include an elective tertiary referral outside agreed pathways).
- The clinicians involved in the patients care want to take advantage of a healthcare intervention that is novel; developing or unproven and which is not part of the CCG's commissioned treatment plans.
- The clinician would like to make available to a patient an intervention which is not medically necessary but is aesthetically desirable and the distinction between clinical and cosmetic need is not clear.

9.3 Occasionally some healthcare providers and clinicians might try to establish early access to new treatments (service developments) via an Individual Funding Request. However, the NHS Contract requires hospital providers to seek commissioning of new treatments through submission of a business case to their commissioners. Thus, clinicians are asked to not use the Individual Funding Request process to circumvent the remit of the Hull and East Yorkshire Hospitals Trust Clinical Practice Development Committee or Drugs & Therapeutics Committee (or equivalent committees in other providers) to approve the introduction of new health care interventions.

Similarly, the Individual Funding Request Panel must not be put in a position where it would be asked to make policy decisions for the CCG. Policy questions should always be referred for consideration to the Governing Body or another appropriate policy-making committee, before the Individual Funding Request is considered.

This Policy in general relates to requests for elective treatments and procedures. A separate contractual obligation applies to providers in cases of emergency lifesaving treatment. In such cases providers are required to notify the CCG retrospectively of any decision to treat outside the Individual Funding Request Policy. A process exists for urgent (but not emergency) Individual Funding Requests where a decision is required outside of the monthly scheduled panel.

9.4 Treatments Covered by CCG Commissioning Policies

The CCG policy is that treatments not currently included in established care pathways (as identified for example in the Schedules to the service agreements with acute care providers) or identified for funding through the commissioning process are not routinely funded. For a number of these interventions the CCG has published specific policy statements setting out restrictions on access based on evidence of effectiveness or relative priority for funding. Policy development is an on-going process and future policy on further treatments, in response to NICE Guidance/Guidelines, health technology assessments etc. will be produced and published periodically.

9.5 Treatments Not Covered by CCG Commissioning Policies

Specific groups of patients may not be covered by CCG Commissioning Policy. Patients with conditions for which the CCG does not have an agreed policy, including patients with rare conditions and whose proposed treatment is outside agreed service agreements:-

- Patients with conditions for which the CCG does have an agreed policy but who may have exceptional clinical circumstances which lead to their clinician seeking a treatment that is not routinely available
- Patients with conditions that are the commissioning responsibility of NHS England, including patients with rare conditions and whose proposed treatment is outside agreed service agreements.

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

In addition to the group of health care interventions that the CCG will not commission as a matter of routine; the CCG **generally**:

- Will not commission the use of new surgical techniques until the Safety and Efficacy Register of New Interventional Procedures (SERNIP) now run by the National Institute of Health and Clinical Excellence (NICE); has awarded category A or B status unless the technique is part of a randomised controlled trial (RCT).
- Will only implement screening programmes approved by the National Screening Committee
- Will follow agreed national policy from NHS England on the continuation of treatment at the end of clinical trials
- Will follow national guidance in respect of co-payments

9.6. **Decisions Inherited from other Commissioning Trusts: i.e. patients who move**

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

10. **Requests for cross-border treatment and treatment outside the European Economic Area (EEA)**

Cross border healthcare requests, i.e. requests for treatment outside of England but within the European Economic Area (EEA) should be made directly to NHS England via nhscb.europeanhealthcare@nhs.net

Guidance available at:

<http://www.nhs.uk/nhsengland/healthcareabroad/plannedtreatment/pages/introduction.aspx>

Requests for healthcare intervention outside of the EEA should be made directly to Specialised Services within NHHS England North Yorkshire and Humber providing the requested intervention is routinely commissioned locally.

For interventions which are not routinely commissioned locally; the request should first be considered through the CCG IFR process. If CCG approval is granted, the case should then be passed to Specialised Services within the NHS England North Yorkshire and Humber for further consideration. <https://www.england.nhs.uk/commissioning/spec-services/>

11. **The Individual Funding Request Process**

Appendix 1 shows the process flowchart for consideration of Individual Funding Requests. Further detail is given below.

- 11.1 Individual Funding Requests should originate either from the patients GP or from a hospital consultant (to whom the patient has been referred), or in certain circumstances (and where agreed by the Panel), other registered health practitioners. Requests will not be accepted from a GP registrar unless endorsed by a salaried GP or partner of the practice. If any safeguarding issues are identified through the process at any stage then these will be escalated as appropriate.
- 11.2 Requests will only be accepted when made through the IFR electronic system on the following web address: <http://ifryh.nescu.nhs.uk>
- 11.3 Supporting information for requests cannot include non-clinical photographs. Any correspondence from patients will not be accepted in any circumstances including that submitted by clinicians on their patients' behalf.
- 11.4 Referring clinicians are asked to note that the Individual Funding Request on the electronic system must be completed in full and submitted with all relevant clinical information and supporting documentation. Failure to provide relevant and clear supporting information with the referral or provision of insufficient details may cause delays in the decision making process and risk the request being declined due to insufficient clinical information.

To define the level of the supporting clinical evidence base the standard hierarchy of

evidence criteria is used (Figure 1). The higher up a methodology is ranked the more robust and closer to objective truth it is assumed to be; (though in cases of rare diseases where small numbers may limit the potential for published studies, the threshold for evidence may be varied).

Figure 1

Rank	Methodology	Description
1	Systematic reviews and meta-analyses	Systematic review: Review of a body of data that uses explicit methods to locate primary studies and explicit criteria to assess their quality. Meta-analysis: A statistical analysis that combines or integrates the results of several independent clinical trials considered by the analyst to be “combinable” usually to the level of re-analysing the original data and also sometimes called: pooling, quantitative synthesis. Both are sometimes called “overviews”.
2	Randomised controlled trials (RCT's)	Individuals are randomly allocated to a control group and a group who receive a specific intervention. Otherwise the two groups are identical for any significant variables. They are followed up for specific end points.
3	Cohort studies	Groups of people are selected on the basis of their exposure to a particular agent and followed up for specific outcomes.
4	Case-control studies	“Cases” with the condition are matched with “controls” without and a retrospective analysis used to look for differences between the two groups.
5	Cross sectional surveys	Survey or interview of a sample of the population of interest at one point in time.
6	Case reports	A report based on a single patient or subject sometimes collected together into a short series
7	Expert opinion	A consensus of experience from the good and the great.
8	Anecdotal	Something someone told you once.

- 11.5 An Individual Funding Request that comes from a GP will not usually be deemed to have started the 18-week Referral to Treatment (RTT) as it would simply be a request for a referral for treatment. Requests from secondary care consultants will need to provide an 18 week RTT ‘clock start date’ (the date of referral into secondary care).
- 11.6 In order to direct requests along the appropriate decision making pathway; the Individual Funding Request Panel will give formal delegated Authority to the IFR team to triage all Individual Funding Requests. Triage must be undertaken by two members of staff one of whom must be a healthcare professional. Where a consensus opinion cannot be reached by the two staff undertaking triage; the request should proceed to Panel for full discussion. An accurate record of all decisions taken at triage will be presented at the Panel meeting for discussion and ratification.

12 The Role of Clinical Triage

To return requests to referrer where:

- The request has not been submitted by an agreed healthcare professional
- Relevant clinical information has been omitted
- The criteria within the commissioning policy has been clearly met or not met for the referral therefore no IFR is required
- The request can be dealt with under another existing contract

Clinical Triage will produce a detailed summary for review and ratification by panel where it appears:

- There clearly is no clinical case

- The request does not meet criteria outlined in an agreed commissioning policy and for which no case has been made for exceptionality
- That treatment can be commissioned because they meet pre-agreed exceptions (some of which are set through precedent)
- The request raises a major policy issue and needs work that is more detailed
- That have not been submitted by a healthcare professional
- Relevant clinical information has been omitted
- They meet criteria outlined in an agreed commissioning policy
- That it can be dealt with under another existing contract
- An alternative satisfactory solution can be found for example a commissioned service is already available

12.1 The CCG will convene a formal Individual Funding Request Panel which will meet at least monthly and will have the following membership:

- Chair of the Individual Funding Request Panel
- Vice-Chair of the Individual Funding Request Panel
- Clinical representative(s)
- Lay-member(s)
- Lead CCG representative

12.2 The following attendees will be available as and when required in an advisory capacity but are not decision-making members of the Panel:

- Public Health Specialist or representative
- Learning Disability and Mental Health Specialist or representative
- Medicines Management lead or representative
- Secondary Care Consultant
- NECS IFR team representative
- Safeguarding representative

The Panel may also seek legal advice from the Legal and Governance team as and when required

12.3 Patients will not be invited to attend the Panel at which their request is being considered but they will be kept informed of progress and outcomes by being copied into all correspondence between the Individual Funding Request Panel and the requesting doctor. Individual exceptions may be made in circumstances where the Panel consider that it would be more appropriate for the outcome of the case to be communicated via the requesting clinician to the patient. In these individual cases the decision not to send the patient copies of any correspondence and the rationale for this decision will be documented in the record of the Panel's discussion of the case. Evidence papers however will not be copied to the patient unless requested.

12.4 Requesting clinicians will not be invited to attend the Panel except in the most unusual cases.

12.5 Administrative support to the Panel will be provided by the IFR team.

12.6 The CCG will provide and document training for all individuals involved in decision making for Individual Funding Requests covering legal and ethical issues as well as the CCG's own approach to priority setting.

- 12.7 The Panel may from time to time ask other CCG staff or other individuals with knowledge of the particular procedure or intervention being considered to attend to further inform the consideration by the Panel of the request. Where possible, the CCG will ensure separation between those who review the clinical evidence for a request and those who make commissioning decisions.
- 12.8 If there is any circumstance where any Panel member may have a conflict of interest in a case put before the Panel; they shall acknowledge this at the outset and will remove themselves from the proceedings for the time required.
- 12.9 To ensure effective, fair and transparent decision making the Panel must be quorate to agree decisions. To ensure this the Chair or Vice-Chair, one clinical representative (GP or Nurse) and a lay-member should be present (i.e. 3 members).
- 12.10 Individual Funding Requests received within the electronic IFR system are identifiable through the reference number generated by the system once the referring clinician has made the submission. Correspondence relating to the Individual Funding Request is managed within the electronic IFR system and referring clinicians are updated on the referral direct from the system which is in line with the General Data Protection Regulation (GDPR).
- Individual Funding Requests are confidential and records will be managed so that access is restricted to the IFR team and members of the Panel.
- 12.11 In advance of each meeting of the Panel, a list of cases will be prepared for consideration at that meeting. Papers will be sent out by secure means one week in advance to enable Panel members to seek clarification or further information as necessary. Where the information provided to support the request is thought to be insufficient for the Panel to undertake a valid consideration of the request; the IFR team will liaise with the relevant clinician to obtain further information. Usually requests will be taken to the next scheduled meeting of the Panel. Where information is required requests may be deferred for consideration until the requested information has been received. Where such additional information has not been received within a reasonable period (which will normally be three months unless the clinician has requested additional time to gather the information); the request will ordinarily be closed.
- 12.12 In considering requests, the Panel may decide to ask for further information from the relevant clinician and may also seek a review of the evidence of the clinical and cost effectiveness of a particular procedure or intervention. This may be as a result of a decision not being reached.

In making a collective decision on the request, the Panel should take the following into account:

Exceptionality

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

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

Clinical Effectiveness and Safety

- Is the treatment effective i.e. of proven benefit for this category of patient?
- What are the nature, extent and significance of the health gain for the individual?
- How have similar cases been dealt with in the past?
- Does the CCG have clear evidence of patient safety before NHS resources are invested in the treatment?

Cost Effectiveness

- The CCG does not undertake individual economic assessments itself but draws on expert reviews, clinical papers and assessments in order to ascertain cost-effectiveness estimates. In the decision making process the cost-effectiveness criteria upper threshold of £20,000 - £30,000 per QALY, which is consistent with NICE decisions is used.
- Are there alternative, comparable and more cost effective interventions and/or providers available?

Appropriateness

- Are there agreed patient selection criteria? Does the patient fit the criteria? If not, what is the case for expanding the selection criteria?
- Are alternative treatments available?
- What would the impact of refusal be?
- Has appropriate clinical advice been sought?

Equity

- Is this patient or patient subgroup being treated differently in relation to others?
- What is the priority in relation to opportunity costs and alternative spend on other needs of the whole population?

The Panel will not:

- Part-commission treatment
- Commission elective treatment requested retrospectively
- Commission equipment ordered prior to Panel approval
- Recommend alternative treatments for a particular condition or patient

12.13 Minutes will be taken at every Panel meeting. The minutes of the meeting will include a record of the discussion and outcome of each case so as to maintain accurate documentation of the whole decision making process. The minutes will then be taken to the next available meeting of the Panel for review of accuracy and ratification. A decision record and outcome will be maintained by the CS IFR team on the secure database for each request the Panel considers.

12.14 Decisions made by the Panel will be communicated by the Chair of the Panel in writing to the requesting clinician and/or to the patients GP (and copied to the patient) within 10 working days of the date of the Panel at which the request was considered.

From time to time, the particular clinical circumstances of an Individual Funding Request may mean that delaying a decision until the next scheduled meeting of the Panel is likely to have a significant detrimental effect on the patients' health and well-being (threat of death or serious disability) or adversely affect eligibility for that treatment. In these circumstances the request will be deemed as URGENT and views of Panel members will be sought in advance of the next scheduled meeting by e-mail phone or in person to consider whether in

the circumstances; the next procedure or intervention should be approved. The agreement of two members of the Panel (including a clinically qualified Panel member) will be required to make a decision outside of a formal meeting of the Panel.

- 12.15 Where necessary for reasons of expediency, virtual meetings will be carried out by telephone or e-mail as necessary. These are not normally a substitute for routine meetings of the IFR panel but will be used only in unavoidable circumstances so as not to compromise the pace of decision-making for urgent individual cases. In such circumstances a decision will be taken on a consensus view with the final decision endorsed by the Chair or Vice-Chair of the IFR panel and confirmed by the membership for the record.
- 12.16 It is understood that at all times, the provider partner is able to fund a healthcare intervention pending a decision from the CCG and the CCG accepts no responsibility for the clinical consequences of any delay in responding to the request.
- 12.17 Where a request has been considered and a decision made in advance of a formal Panel meeting; the decision will be reported and recorded at the next meeting. Decisions made in advance of a Panel meeting will be communicated to the referring clinician and/or the patients GP within 2 working days of the date of the decision (and copied to the patient).
- 12.18 In responding to an Individual Funding Request the CCG accepts no clinical responsibility for the healthcare intervention or its use; nor for the consequences of not using the intervention. It is the responsibility of the treating clinician to determine the most appropriate treatment for a particular patient from amongst those which are available.
- 12.19 All correspondence relating to each request to the Individual Funding Request Panel (irrelevant of outcome) is held securely within the electronic IFR system. Case notes for each request to the Individual Funding Request Panel (irrelevant of outcome) will be electronically filed securely by NECS Individual Funding Request team in accordance with the Records Management: Code of Practice for Health and Social Care (2016). Case files will be securely archived after 2 years and securely destroyed after 8 years (or 8 years after the patient's death).

13 The Process for Appeals

- 13.1 The requesting clinician may appeal against the decision-making process of the IFR panel not to support their request for a procedure or intervention and must submit the appeal in writing within 3 months of the date of the decision letter from the IFR panel.

The CCG will establish a separate clinically led Appeals Panel to consider appeals regarding the decision-making processes of the IFR Panel in relation to individual decisions. The Appeals Panel will meet monthly (where there are cases to be considered) and its business and decisions will be fully recorded.

- 13.2 The Appeals Panel will include the following members (and should be different to the original Panel that considered the change in question):

- CCG Director (Chair)
- CCG Director of Clinical Quality and Governance
- CCG GP Member
- CCG Lay Member

The Appeals Panel will be considered quorate if all 4 members are present.

All requests to appeal against the decision-making processes in relation to individual

decisions of the IFR Panel should be sent to the same contact details for all other IFR requests and will be logged by the NECS IFR team who will prepare all documentation including a timeline detailing each step of the process ensuring receipt of the documentation by Panel members at least 3 working days in advance of the meeting.

The patient or their clinicians should normally not be permitted to introduce additional evidence at the appeal stage but if there is new evidence to support a case this does not mean that the original decision made on the evidence then available was wrong. Instead the case should be referred back to the IFR Panel to decide whether the information is significant enough to merit re-consideration.

- 13.3 Appeals will usually be considered within 30 days of the date of the CCG receiving notification of a request to appeal against the decision-making processes in relation to individual decisions of the IFR panel.

The Appeals Panel will review the correspondence, evidence and any other information considered by the IFR Panel in reaching its original decision.

- 13.4 The Appeals Panel will be established on a 'quality control check' model. Under this model the Appeals Panel would consider whether the IFR Panel:

- Followed the CCG's own procedures and policies
- Considered all relevant factors and did not take into account immaterial factors
- Made a decision that was not so unreasonable that it could be considered irrational or perverse in the light of the evidence
- Had all the relevant evidence before it for consideration

- 13.5 At the discretion of the Appeals Panel, the outcome will be either:

- Reject the appeal and support the original decision of the IFR Panel
- Identify a flaw in the process followed to reach the previous decision and they consider that the evidence needs re-consideration by referral back along with full documentation to the next IFR Panel meeting

The decision of the Appeals Panel will be communicated by the Chair of the Appeals Panel to the requesting clinician and/or patients GP (and copied to the patient) within 3 working days of the date of the appeal decision.

The Appeals Panel decision is the final decision of the CCG.

- 13.6 Patients wishing to challenge the Appeals Panel decision must do so through the NHS Complaints Procedure. Where that process is completed without satisfactory resolution; a complainant may take their case to the NHS Ombudsman and/or to Judicial Review. Where Judicial Review is initiated, the CCG response will be guided by legal advice and all correspondence will be through the CCG's legal representative.

- 13.7 Once a case is with the Ombudsman, it may be referred back into the CCG Panel to consider the Ombudsman's ruling and comply with any suggestions made.
<https://www.ombudsman.org.uk/>

14 **Monitoring Compliance with and Effectiveness of this Policy**

As part of the annual review procedure; there will be an independent internal audit of a selection of Individual Funding Requests which will form part of an annual report from the

Individual Funding Request Panel to the CCG Board. This report will cover compliance, effectiveness and outcomes of the Policy together with a summary of all the Individual Funding Request Panel decisions for that financial year.

15 **References**

“Priority Setting: managing Individual Funding Requests”. The NHS Confederation, 2008. NHS Institute for Innovation and Improvement.

<http://www.nhsconfed.org/~media/Confederation/Files/Publications/Documents/Priority%20setting%20managing%20individual%20funding%20requests.pdf>

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The NHS Constitution for England. Department of Health March 2013.

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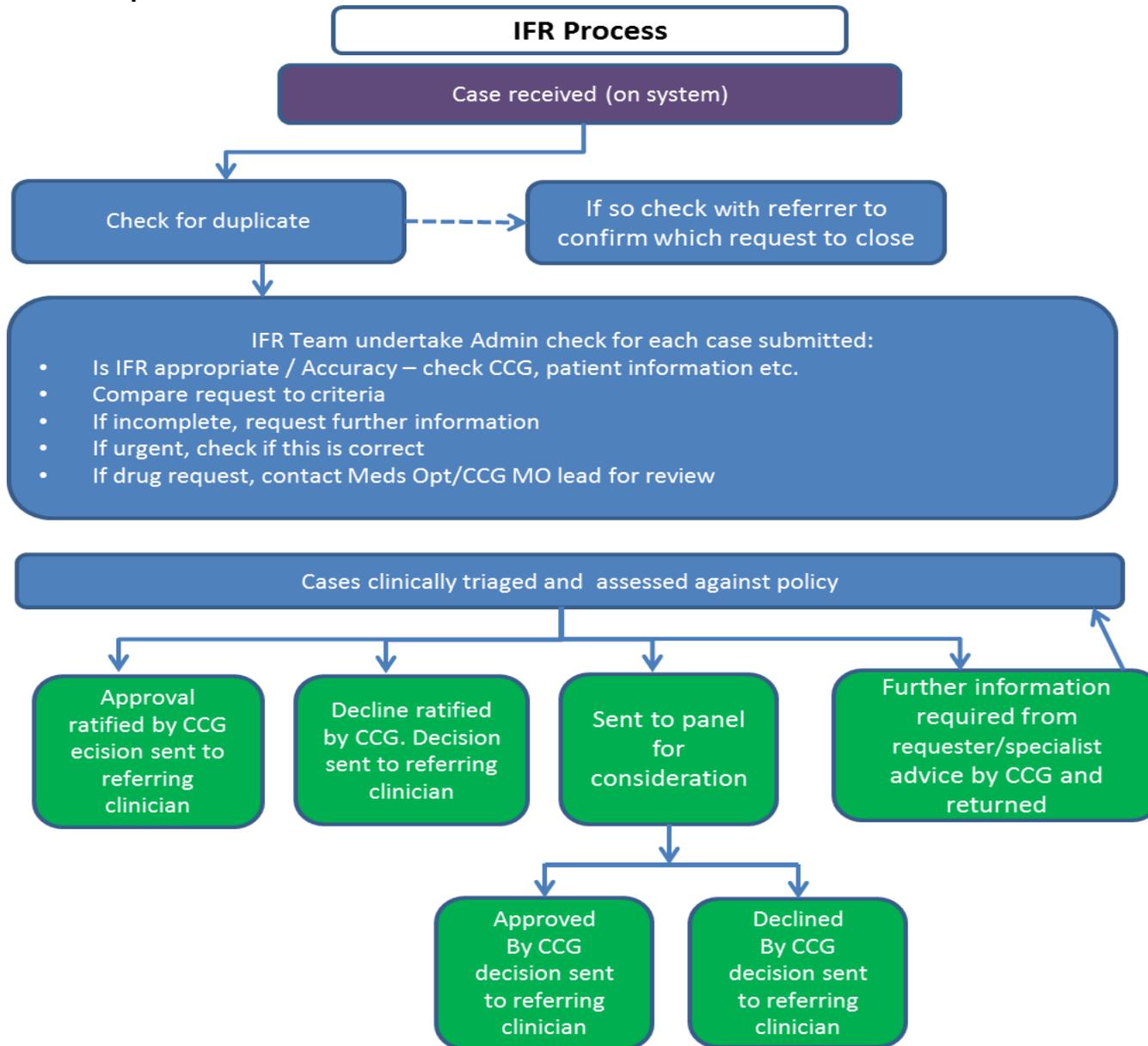
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16 **Review of this Policy**

- 16.1 General commissioning policies and the Individual Funding Request Policy will be reviewed at least every two years (unless otherwise required by national guidance or other imperatives) and will form part of the Individual Funding Request annual report to the CCG Board.

Minor amendments (such as changes in title) may be made prior to the formal review. Details of which will be monitored/approved by the Associate Director Corporate Affairs in consultation with Human Resources and Trade Union Representative(s) where relevant. Such amendments will be recorded in the PPG Register and a new version of the PPG issued.

Appendix 1: IFR Panel Process Map



Appendix 2: Appeals Panel Process Map

