

**Individual Funding Request Policy  
North and East London CCGs**

**V.0.5.**

Operational 1 September 2014 to 1 September 2017

## Version Control

<b>Date</b>	<b>Status</b>	<b>Summary of Changes</b>	<b>Version</b>	<b>Owner</b>
21.07.14	Proposed changes to current policy for CCG to review and comment	Please refer to Areas for Update briefing note	v.0.1	Tim Baker
15.08.14	Updated draft	Changes made according to CCG engagement and feedback	v.0.2	Tim Baker
29.08.14	Updated draft	Final changes made according to CCG engagement and feedback	v.0.3	Tim Baker
26.09.14	Updated draft	Changes made according to legal advice	v.0.4	Tim Baker

## Contents

<b>1. Introduction</b>	<b>5</b>
<b>2. The scope of this policy</b>	<b>6</b>
2.1 This policy applies to:	6
2.2 Policy exclusions	6
2.2.1 Retrospective funding	6
2.2.2 Cohorts of patients	6
2.2.3 Clinical trials	6
<b>3. Definitions</b>	<b>7</b>
3.1 Individual Funding Request (IFR)	7
3.2 Appropriate IFRs	7
3.3 Inappropriate IFRs	7
3.4 Inadequate IFRs	7
3.5 Urgent applications	7
3.6 Exceptionality	7
3.7 Cohorts of patients	8
3.8 Service development	8
3.9 Retrospective funding requests	8
<b>4. Roles and responsibilities</b>	<b>9</b>
4.1 NEL CSU IFR team	9
4.2 IFR senior manager	10
4.3 The clinical applicant	10
4.4 The CCGs	10
4.5 IFR panel and appeal panel	11
4.6 IFR panel and appeal panel Chair	11
4.7 General responsibilities – safeguarding adults and children	11
<b>5. The IFR process</b>	<b>12</b>
5.1 Submitting an IFR	12
5.2 Patient consent to share information	12
5.3 Information required from clinical applicant	12
5.4 The triage process	13
5.4.1 Screening for incomplete submissions	13
5.4.2 Screening for urgent applications	13
5.4.3 Process for local clinical policies	14
5.4.4 Screening for service developments	14
5.5 Evidence evaluation and case preparation	15

---

5.6	The IFR panel.....	15
5.6.1	Principles of decision making.....	15
5.6.2	Rare treatments and indications .....	16
5.6.3	Considering exceptionality .....	16
5.6.4	Hierarchy of evidence.....	17
5.6.5	Rule of rescue.....	17
5.6.6	Retrospective requests.....	17
5.6.7	Continuation of funding .....	18
5.6.8	Non-clinical factors .....	18
5.7	Notification of the IFR panel decision .....	19
<b>6.</b>	<b>The appeals process .....</b>	<b>19</b>
6.1	The remit of the appeal process .....	19
6.2	Grounds for appeal .....	19
6.3	How to make an appeal .....	19
6.4	Procedure .....	20
6.5	Notification of decision .....	20
<b>7.</b>	<b>Information governance and confidentiality .....</b>	<b>20</b>
<b>8.</b>	<b>Review .....</b>	<b>21</b>
	<b>Appendices .....</b>	<b>22</b>
	Appendix A - Legal context to decision making .....	22
	Appendix B – Individual Funding Request process flowchart .....	26
	Appendix C – IFR application forms .....	27
	Appendix D - Terms of Reference.....	28

## 1. Introduction

The following policy has been adopted individually by the following Clinical Commissioning Group (CCG) Governing Bodies:

- Barking & Dagenham CCG
- Barnet CCG
- Camden CCG
- City & Hackney CCG
- Enfield CCG
- Haringey CCG
- Havering CCG
- Islington CCG
- Newham CCG
- Redbridge CCG
- Tower Hamlets CCG
- Waltham Forest CCG

The NHS exists to serve the needs of all patients but also has a statutory duty not to exceed the resources allocated to it by central government (NHS Act 2006). CCGs therefore need to use their limited resources effectively to obtain the best healthcare possible for their population. This sometimes results in difficult decisions having to be made about how resources should be prioritised when services are commissioned. There may be individual cases where a patient's needs cannot be met through existing contracts and commissioning arrangements but their clinician considers that they have a need for an un-commissioned treatment, and wishes to request funding on their patient's behalf. When such requests occur, CCGs must have a robust and transparent system in place to assess and determine whether the request should be funded, demonstrating a rational decision making process for each individual patient. These are referred to as individual funding requests (IFRs).

This policy sets out each individual CCG governing body's decision making process for managing IFRs, the delegated responsibility and legal framework for decision-making within the CCG constitution. It is underpinned by a detailed operational procedure which outlines how the process will be administrated on each CCG's behalf by NEL Commissioning Support Unit (CSU) IFR team.

The policy is guided by the legislative duties bestowed on CCGs under the National Health Service 2006 (as amended by the Health and Social Care Act 2012), NHS Constitution, The Human Rights Act 1998, and Equality Act 2010 amongst others. It also notes the relevant national guidance including "The Mandate", a mandate from the Government to the NHS Commissioning Board (NHS CB) April 2013 – March 2015 and "Developing and updating local formularies" guidance by NICE. Please refer to Appendix A for further information on the legal context to IFR decision making.

In a changing health care economy there is a need to keep the IFR policy and related policies under review and to commission services in line with new guidelines, national policy and needs of the local population. This policy will therefore be adopted for a time limited period and reviewed no later than September 2017, to ensure that it can be updated to reflect any feedback and learning from the way that NEL CSU, NHS England and CCGs work together to commission healthcare services.

## 2. The scope of this policy

This policy is for implementation and use by the NEL CSU IFR administration team, by CCG triage leads and by IFR and appeals panels to promote timeliness, fairness, transparency and rationality in IFR management and decision-making. This policy will specify the principles, processes and procedures for considering whether or not to approve IFRs.

### 2.1 This policy applies to:

This policy applies to IFR applications submitted on behalf of any patient registered to one of the North and East London CCGs, by NHS contracted clinicians, for treatment at a Care Quality Commission (CQC) registered service provider. Applications requested for treatment at non-CQC registered providers in England will not be approved.

This policy applies to all clinical interventions which are not funded through CCG Operating Plans and commissioning contracts, where funding needs to be considered on an individual patient basis. This might include:

- Interventions not or not yet supported by NICE
- Requests to continue funding for patients previously treated:
  - by self-funding
  - through funding from the device manufacturer or pharmaceutical industry, provider trusts treating at their own risk, on compassionate grounds
  - through a decision made by another CCG commissioner where the patient has become the commissioning responsibility of a CCG covered by the terms of this policy
- Requests for referral to a service not commissioned locally and not listed on the national menu (including applications for overseas treatment)

### 2.2 Policy exclusions

This policy specifically excludes NHS services directly commissioned by NHS England.

#### 2.2.1 Retrospective funding

This policy excludes requests for funding approval made after an episode of care has commenced. Retrospective funding requests for any care or treatment which has not been given prior approval will not be funded, unless it can be demonstrated that the treatment was needed urgently to avoid a life threatening situation or significant harm to the patient. (See section 3.5 for the definition of an urgent application).

#### 2.2.2 Cohorts of patients

The IFR process is not the route through which CCG commissioning policy for a group of patients (a cohort) can be made, as it is not entitled to make policy decisions on behalf of the CCGs. Therefore, this policy does not apply to any individual application which can be classified as being part of a larger cohort. Any decision which might have the consequence of committing the CCGs to funding other similar patients in that cohort, is referred to as a service development. (See section 3.7 and 3.8 for definitions of cohorts and service developments).

#### 2.2.3 Clinical trials

This policy will not be used to fund ongoing treatment for patients whose treatment has started as part of a clinical trial. The responsibility for ensuring a clear exit strategy from a trial and whether

those benefiting from the treatment will have on-going access to it lies with those conducting the trial (as in the Medicines for Human Use (Clinical Trials) Regulation 2004 and the Declaration of Helsinki).

### 3. Definitions

#### 3.1 Individual Funding Request (IFR)

An IFR is a request to fund, for an individual patient, a treatment that falls outside existing contracts and commissioning arrangements.

#### 3.2 Appropriate IFRs

An appropriate IFR is where:

- A patient's treatment falls outside generic or treatment-specific policies where an unusual ('exceptional') clinical circumstance applies to the individual
- A particular treatment or intervention could benefit a patient with a very rare clinical condition.

#### 3.3 Inappropriate IFRs

An inappropriate IFR is where:

- The request represents a service development and therefore needs to be triaged into the appropriate population decision making group
- The treatment requested is covered by another CCG policy or process
- The request is for a service or procedure that is commissioned by another organisation where funding is not the responsibility of the CCG
- A patient is referred for physical treatment (for example, cosmetic surgery) on the grounds of psychological problems, which should in the first instance be treated through the mental health route.

#### 3.4 Inadequate IFRs

Examples of inadequate IFRs include:

- A request where no information is submitted in support of the individual's exceptionality
- A request where no information is submitted to demonstrate the clinical effectiveness of the treatment.

#### 3.5 Urgent applications

- An urgent request is one which requires an urgent decision because the patient faces a substantial risk of death or significant harm if a decision is not made before the next scheduled meeting of the IFR panel
- Urgency under this policy cannot arise as a result of a failure by the clinical team expeditiously to seek funding through the appropriate route and/or where the patient's legitimate expectations have been raised by commitment being given by the provider trust to provide a specific treatment to the patient. In such circumstances the CCG expect the provider trust to proceed with treatment and for the provider to fund the treatment.

#### 3.6 Exceptionality

For the purposes of this policy and the IFR decision making process, a patient's clinical condition will be agreed as exceptional if they are:

- Significantly different to the general population of patients with the condition in question; **AND** are

- Likely to gain significantly more benefit from the intervention than might be expected for the average patient with the condition.

The fact that a treatment is likely to be efficacious for a patient is not, in itself a basis for exceptionality.

### 3.7 Cohorts of patients

A cohort is an identifiable group of patients with a similar clinical condition, for which approval to fund treatment for one patient would result in a commitment to fund an identifiable group of future patients with the same clinical circumstances.

Examples of a cohort might include:

- When it is likely that the CCG could expect to receive more than one application per year on an ongoing basis for the same treatment and clinical indication.
- When a group of similar requests have already been made to neighbouring CCGs.

### 3.8 Service development

A service development is any aspect of health care which the NHS has not historically agreed to fund and which will require additional and predictable recurrent funding. The term refers to all decisions which have the consequence of committing the CCGs to new expenditure for a cohort of patients, including:

- new services
- new treatment including medicines, surgical procedures and medical devices
- developments to existing treatments including medicines, surgical procedures and medical devices
- new diagnostic tests and investigations
- quality improvements
- expanding treatment access

These are prioritised during the annual commissioning round.

### 3.9 Retrospective funding requests

A retrospective funding request is an IFR application which is received after the requested treatment has already commenced, i.e. without funding approval.

See section 5.4: The triage process for the IFR process with regards to these definitions.

## 4. Roles and responsibilities

The responsibilities for implementation of this policy are set out in this section.

### 4.1 NEL CSU IFR team

It is the responsibility of the NEL CSU IFR team, on behalf of the CCG, to:

- Receive, acknowledge and process IFR requests submitted to the CCG within agreed timescales (see Appendix B for an overview of typical timescales).

#### Triage:

- Manage the triage process for CCGs where a Referral Management Service (RMS) has not been commissioned
- Screen all applications according to the provisions in this policy (section 5.4, triage process)
- Re-direct applications as appropriate
- Send recommendations for clinical decisions from the triage meeting to the relevant CCG member or manager with delegated responsibility for decision making for the triage process.

#### IFR panels:

- Schedule regular IFR panels to ensure that delay to decision making is minimised. Increase frequency if necessary to accommodate unexpected peaks
- Co-ordinate the thorough preparation of an IFR application to take to the IFR panel through liaison with pharmacists and public health representatives (case lead)
- Co-ordinate the provision of additional information through contact with the clinical applicant or associate clinicians, to allow the case to be considered by the IFR panel. Where IFR case management sits with the CCG, this should be undertaken by CCG case leads, who should provide an audit trail to the CSU to ensure comprehensive record keeping
- Report precedence of any previous funding decisions for similar cases to the case lead where necessary
- Co-ordinate the administration of the IFR panel papers and their distribution to IFR panel members, maintaining patient confidentiality and timeliness
- Ensure high-quality minutes from the IFR panel through established quality assurance measures
- Securely archive and catalogue individual case documentation so that they can be made available when considering new applications.

#### Notification of outcomes:

- Communicate the outcome of the triage, IFR or Appeal panel to the applicant, and to other associated clinicians where necessary.

#### Service developments:

- Identify potential service developments by keeping accurate records of treatments requested for same or similar conditions, noting where patterns appear to be emerging
- Support a process for evaluating the clinical and cost-effectiveness of provider business-cases with the same rigour as an IFR to enable CCGs to make commissioning decisions for a wider population.

#### Reporting and training:

- Process and report claims for overseas treatment to the CCG member or manager with delegated responsibility for the triage process for information only, due to the seven day constraint implemented by NHS England
- Deliver appropriate training to all members of the IFR panels and appeals panels and those within the CSU responsible for the administration of the process, as well as Public Health colleagues within local authorities contributing to the process. The training will include the ethical and legal aspects of resource allocation.

#### 4.2 IFR senior manager

It is the responsibility of the IFR senior manager to support IFR panels as a non-voting member in order to:

- Ensure consistency in decision making across IFR panels, maintaining a record of prior decisions and referring to precedent where relevant
- Share experience gained in dealing with requests for individual patients within and across CCGs
- Support the chair to ensure IFR panels operate according to best practice with regard to this policy
- Provide regular reports to CCG commissioners on the decisions made by the panels, including patterns and trends in requests for individual funding.

#### 4.3 The clinical applicant

It is the responsibility of the clinical applicant on behalf of their patient, to:

- Fully demonstrate that the patient meets eligibility criteria according to local access policies, or detail why the patient differs from others with the same clinical condition such that the treatment should be considered for them when it is not available to others with a similar clinical condition, according to the definition of exceptionality outlined in this policy
- Ensure consent to share information has been sought from the patient and highlighted in the application
- Attempt to ensure that all information that is likely to be immaterial to the decision, including non-clinical information, or information which does not have a direct connection to the patient's clinical circumstances, shall not be included in the application (see section 5.6.8 non clinical factors)
- Ensure that requests from the IFR team for additional information are responded to in a timely manner according to the deadlines communicated, to avoid delay to the patient
- Inform the patient and any other relevant healthcare professionals of the decision; this is to ensure effective on-going arrangements for the patient's care. The clinician making the referral is also responsible for notifying the patient of the appeal process (including the time frame for the appeal).

#### 4.4 The CCGs

The responsibility of the CCG includes:

##### Triage:

- To identify a member or manager with delegated responsibility to make decisions based on the recommendations made by the CSU through the triage process, including urgent cases needing accelerated consideration
- To make funding decisions based on, but not limited by, the IFR team triage recommendations via the secure IFR NHS net account. The CCG can raise queries on triage

recommendations and request further information from the IFR team. If the agreed timescale is likely to be breached, the CCG member or manager should make this known to the IFR team and, where necessary, appoint a deputy to sign off the recommendations.

#### **IFR panels:**

- To appoint IFR panel members to act on behalf of the CCG
- To ensure that sufficient panel members are available from the CCG for panels to be quorate
- To attend appropriate panel training as co-ordinated by the IFR team
- To determine the financial limits to which the IFR panels can make funding decisions. To define the process for application outside financial limits in line with local Standing Financial Instructions (SFIs) ensuring that the CCG can act quickly to confirm authorised expenditure over the approved threshold.

#### **Policy:**

- Agree and sign-off clinical policies against which applications for some procedures are considered, e.g. Procedures of Limited Clinical Value (PoLCV) or Procedures of Limited Clinical Effectiveness (PoLCE).

### **4.5 IFR panel and appeal panel**

The responsibility of the IFR panel and appeal panels includes:

- To uphold and work within the legal context to decision making, as set out in Appendix A
- Consider and determine eligible IFRs where the clinical commissioning group is the responsible commissioner of NHS care, according to the principles set out in the CCG's IFR policy, and in the IFR panel and appeal panel terms of reference (Appendix D)
- Refer to the relevant CCG adopted clinical policies to determine whether a patient who does not meet the criteria in the policy can be considered to be exceptional taking the information provided within the application into account
- The appeal panel will review applications where the applicant appeals the decision making process of the IFR panel and does not provide any new information for consideration.

### **4.6 IFR panel and appeal panel Chair**

The chair is responsible for ensuring that:

- Reasonable effort has been made to acquire adequate data and intelligence to inform the decision
- All material factors have been taken into account and that immaterial factors have been appropriately handled
- The rationale for the decision has been explicitly recorded, against the terms of this policy, and that the conflicting arguments have been managed
- They are available to approve the minutes and letters within the specified time frame following IFR panel meetings and to ensure that decisions made are correctly reflected
- The IFR panel meetings are quorate in line with the Terms of Reference.

The Chair will be accountable to their CCG Governing Body for the delivery of this role.

### **4.7 General responsibilities – safeguarding adults and children**

All partners involved in the IFR process must follow local protocols regarding the safeguarding of vulnerable adults and children.

If any potential abuse and neglect to an adult and or child is identified though an IFR application then a safeguarding referral should be made to the local authority where the individual is resident, in accordance with the local CCG safeguarding policies for adults and children.

The person identifying the concern should contact the CCG safeguarding lead for further advice if necessary.

## 5. The IFR process

The flowchart in Appendix B provides an overview and typical timescales for the IFR process.

### 5.1 Submitting an IFR

Clinicians, on behalf on their patients, are entitled to submit an IFR to the CCG, via the NEL CSU. Applications should be made by the:

- Patient's GP or another GP from the practice
- Clinician to whom the patient has been referred.

Due to the level of clinical detail required in the application form, requests from individual patients will not be accepted. Patients are able to submit supplementary written information supporting their clinician's application if they wish, bearing in mind the principles set out in section 5.6.8, non-clinical factors.

Due to the highly sensitive nature of the information being sent (and for reasons of efficiency), applicants are required to make IFR applications between NHS.net email accounts.

### 5.2 Patient consent to share information

In accordance with the NEL CSU Confidentiality Code of Conduct and Data Protection Policy, and CCG and CSU Information Governance policies, the IFR team cannot process applications submitted without evidence that the patient has given consent for their personal information to be shared.

Clinicians should therefore submit IFR applications on the most current form (see Appendix C), which allows applicants to provide evidence by way of an electronic signature or ticked box, to indicate that they have discussed the Information Governance Statement with their patient. Applications will not be accepted or processed without evidence of patient consent to share information, and will be returned to the applicant explaining the reasons why.

### 5.3 Information required from clinical applicant

It is the clinical applicant's responsibility to ensure that the appropriate information is provided to the panel according to the type of request being made. The IFR application forms are designed to capture all material information to enable due consideration according to this policy.

Implementation of this policy requires sufficient information on each patient to ascertain whether:

- The patient complies with the agreed generic or treatment-specific policies threshold criteria (e.g. Procedures of Limited Clinical Value/Effectiveness) OR
- There are valid reasons to justify consideration of funding for this patient when the treatment in question is not available for other similar patients in the CCG area.

Submission of the complete information will minimise avoidable delay in the assessment process.

The application form should be accompanied by electronic copies of, or electronic links to, published evidence of clinical effectiveness and likelihood of benefit. These should be attached to the secure email.

## 5.4 The triage process

All funding requests will be subject to initial triage to ensure the request falls within the scope of this policy. Appropriate requests will be reviewed to assess whether sufficient information has been provided either to make a recommendation based on existing commissioning policy, or whether further consideration by the IFR panel is necessary.

### 5.4.1 Screening for incomplete submissions

Applications will be screened to determine whether the request has sufficient clinical and other information in order for the IFR to be processed. Where information is lacking, the IFR will be declined and returned to the applicant specifying the information which would be required in order to enable this request to proceed. Further information can be submitted at any point, and will trigger a review of the application.

### 5.4.2 Screening for urgent applications

All requests will be reviewed at the point of receipt to ascertain whether an urgent funding decision needs to be made outside of normal timeframes. The request will be assessed as to whether the cause of the urgency is clinical or administrative.

Administrative urgency is defined as a funding request which has now become urgent because the provider has failed to seek funding approval in advance of any arrangement to treat the patient. The provider trust, having given a commitment to treat the patient, is expected to go ahead with treatment and bear the costs itself. Alternatively, an IFR application can be submitted which will be considered routinely within normal timeframes.

The decision to accelerate the processing of a clinically urgent application will be based on the definition of urgency set out in section 3.5, and on completion of the steps below:

The referring clinician for an urgent application should:

- Identify the application as urgent and confirm this by phone to the IFR team
- Inform the IFR team of the clinical rationale for the urgency, for example the nature and severity of the patient's clinical condition
- Ensure their contact details are available to the IFR team so that the CCG lead with delegated responsibility or a clinician within the IFR team can discuss the urgency and an accelerated timeline can be agreed should this be considered to be appropriate.

The IFR process is designed for planned care and cannot give adequate consideration to cases in less than three working days. If the clinical decision needs to be made within this timescale on the basis of clinical urgency, the trust should proceed at its own financial risk and submit an IFR application retrospectively. There is no guarantee in this circumstance that funding will be approved. Provider trusts are expected to take all reasonable steps to minimise the need for urgent requests to be made through the IFR process.

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

### 5.4.3 Process for local clinical policies

Applications for treatments included in CCG adopted clinical policies will be reviewed against the agreed criteria or treatment threshold as appropriate as agreed by the relevant CCG. Examples of these policies include:

- Procedures of Limited Clinical Value (PoLCV) policy for BHR and WELC CCGs
- Procedures of Limited Clinical Effectiveness (PoLCE) policy for NCL CCGs
- IVF policies

Applications where the patient is ineligible for funding under these policies will be referred to the IFR panel provided that the applicant has completed the appropriate section on patient exceptionality, giving the reasons why the CCG could justify funding the procedure for this particular patient when it is not routinely offered to others. If this clinical exceptionality information is not submitted a recommendation will be made to the lead member or manager within the CCG with delegated responsibility for the IFR triage process that the application be rejected at the triage stage.

### 5.4.4 Screening for service developments

All funding requests will be subject to screening to determine whether the request represents an unfunded service development.

The IFR team will:

- Keep accurate records of treatments requested for same or similar conditions, noting where patterns appear to be emerging
- Use sources of intelligence, such as outputs of North East London Medicines Management Network (NELMM) and North Central London Joint Formulary Committee (NCL JFC); NICE guidance and POD contracts colleagues, for early alerts to potential service developments.

For example, the decision to identify an application as part of a cohort might be triggered if it could be anticipated that:

- It would be likely that the CCG could subsequently expect to receive more than one application per year on an ongoing basis for the same treatment and indication
- If a group of similar requests had already been made to neighbouring CCGs.

Where it is identified that an IFR application might relate to a cohort of patients with similar clinical characteristics, rather than a single individual, the IFR team will:

Report the potential cohort to the CCG, including the number of applications received from which trusts, either to:

- 1) The CCG IFR member or manager with delegated responsibility for triage and/ or
- 2) The IFR panel Chairs

This representative will confirm that the CCG agrees the identification of this cohort. The NEL CSU IFR team will then advise all likely providers that any future IFR applications will be declined. Through this process, the provider will be invited to submit a business case for a service development. The test of exceptionality as defined in this policy will still be applied to subsequent individual cases, to ensure that IFRs can be made for patients who are clinically exceptional to the group of patients defined within the cohort.

To support the identification of service developments, applicants will be asked to state how many patients they might expect to see each year with similar clinical presentation and who would thus require the same intervention.

## 5.5 Evidence evaluation and case preparation

For cases referred to the IFR panel for consideration, the relevant CCG will commission provision for thorough case preparation by pharmacists or public health representatives, who carry out an evidence evaluation of the requested treatment in line with the accepted hierarchy of evidence (See section 5.6.4 hierarchy of evidence). This case preparation will also include an assessment of the evidence of clinical and cost effectiveness, and refer to any precedent set through previous funding decisions.

The onus is on the clinical applicant to provide sufficient information as to why the CCG should consider funding treatment for their patient where it is not generally available. In some cases, further information will be sought from the GP or secondary care clinicians in order to inform the IFR panel's decision making. Deadlines will be communicated for receipt of this information as outlined in the IFR panel terms of reference.

## 5.6 The IFR panel

The key issue for most IFR panel decisions will be, on what grounds can the CCG justify funding this treatment for this patient when the treatment in question is not available for similar patients within the CCG area?

### 5.6.1 Principles of decision making

In making a decision on funding the IFR Panel will take the following into account:

1. Is the treatment lawful – i.e. within the CCG's legal powers and takes into consideration relevant legal principles such as the Human Rights Act?
2. Is the treatment safe? – (*first do no harm*). Commissioners must ensure it is not complicit in exposing patients to unsafe healthcare and will look to licensing Authorities (especially the Medicines and Healthcare Products Regulatory Agency (MHRA) and other organisations (such as the National Institute for Clinical Excellence (NICE) and the British National Formulary (BNF) for guidance.
3. Is the treatment effective – i.e. of proven benefit for this category of patient?

*The panel will take into consideration the principles outlined in section 5.6.4, Hierarchy of evidence, when considering this point.*

4. In what way is the clinical condition of this particular patient significantly different from the group of patients with the condition in question?
5. What is the evidence that this particular patient is likely to gain significantly more health benefit than others with the same condition?
6. What is the comparable clinical and cost effectiveness of any reasonable alternative intervention and/or provider?
7. What are the equality considerations of funding this particular patient in relation to:

- a) Precedent for funding other similar patients
  - b) Previous decisions of the relevant panel or predecessor panels
  - c) Reducing any inequality between this patient and others in a similar position
8. What is the priority in relation to the opportunity costs and potential alternative spend to meet other needs of the whole population?

Whilst specific economic assessments will not be carried out, the IFR panels will note the national (NICE) threshold of £30,000/QALY of generally acceptable cost effectiveness.

### 5.6.2 Rare treatments and indications

Assessment of requests to fund procedures not covered by existing policy due to the rarity of the procedure, and/or clinical condition, should be distinguished from requests on the grounds of exceptionality.

In assessing these cases, the test for exceptionality (that the patient's condition is significantly different from the group of similar patients, and there is evidence that this particular patient is likely to gain more health benefit from the treatment compared to others) may not be relevant. The IFR panel may therefore base their judgement on the biological plausibility of benefit based on the evidence base given, and the cost effectiveness of treating the patient when considered against the CCG's other competing demands.

The IFR panel should ensure that a decision to approve funding for a rare treatment or indication as an exception to the general rule is made for very clear and explicit reasons which are consistent with the CCG's priority setting principles.

IFR panel decision making will take into account the incidence and prevalence of the condition and the evidence of effectiveness.

### 5.6.3 Considering exceptionality

The IFR panel should bear in mind that, whilst everyone's individual circumstances are, by definition, unique, very few patients have clinical circumstances which are exceptional, so as to justify funding the treatment for that patient which is not available to other patients. The following points constitute general guidance to assist the panel in making assessments about clinical exceptionality. The overriding question which the panel needs to ask itself remains: has it been demonstrated that this patient's clinical circumstances are exceptional?

- a) It may be possible to demonstrate exceptionality where the patient has a medical condition or circumstance that is so rare that there is no established treatment care pathway for that treatment
- b) If the patient has a condition for which there is an established care pathway, the panel may find it helpful to ask itself whether the clinical circumstances of the patient are such that they are exceptional as compared to the relevant subset of patients with that medical condition
- c) The fact that the patient failed to respond to, or is unable to be provided with, one or more treatments usually provided to a patient with his or her medical condition (either because of another medical condition or because the patient cannot tolerate the side effects of the usual treatment) may be a basis upon which panel could find that the patient is exceptional.

However, the panel would normally need to be satisfied that the patient's inability to respond to, or be provided with, the usual treatment was genuinely an exceptional circumstance. For example:

a) If the usual treatment is only effective for a proportion of patients (even if a high proportion), this leaves a proportion of patients for whom the usual treatment is not available or it is not clinically effective. If there is likely to be a significant number of patients for whom the usual treatment is not clinically effective or not otherwise appropriate (for any reason) the fact that the requesting patient falls into that group is unlikely to be a proper ground on which to base a claim that the requesting patient is exceptional.

The most appropriate response in each of the above situations, is to consider whether there is sufficient justification (including consideration of factors such as clinical effectiveness, value for money, priority and affordability) to make a change to the policy adopted by the CCG for funding that patient pathway so that a change can be made to that policy to benefit a sub-group of patients (of which the requesting patient is potentially one such person). This change needs to be considered as a service development.

#### 5.6.4 Hierarchy of evidence

The IFR panel will note the views expressed by the patient or the clinical team concerning the likely clinical outcomes of the individual patient of the proposed treatment, but will 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 that IFR panel has about the likelihood of the proposed treatment delivering the proposed clinical outcomes for the individual patient.

When considering the clinical effectiveness of the proposed treatment, the following hierarchy of evidence will be taken into consideration:

1. Well-conducted meta-analysis of several, similar, large, well-designed RCTs
2. Large well-designed RCT
3. Meta-analysis of smaller RCTs
4. Case-control and cohort studies
5. Case reports and case series
6. Consensus from expert panels
7. Individual opinion

\*Hierarchy of Evidence (Taken from NPC 'Supporting rational local decision-making about medicines (and treatments) First Edition Feb 2009).

#### 5.6.5 Rule of rescue

The IFR panel shall take care to avoid identification bias, often called the "rule of rescue". This can be described as the imperative people feel to rescue identifiable individuals facing avoidable death or a preference for identifiable over statistical lives.

#### 5.6.6 Retrospective requests

The IFR panel may on occasion review an urgent application for which treatment has already commenced. The CCG position with regards to urgent applications is clear: if a clinical decision

needs to be made before the next available panel on the basis of clinical urgency, the trust should proceed at its own financial risk and submit an IFR application retrospectively, and there is no guarantee in this circumstance that funding will be approved.

In considering retrospective applications, IFR panel members will be made aware that treatment has commenced and include in their consideration any treatment outcomes submitted after the treatment start date (if available).

The IFR panel chair will lead the discussion according to their responsibilities as set out in this policy, to ensure that all material factors have been taken into account and that immaterial factors have been appropriately handled. It will be the IFR panel's responsibility to ascertain whether any outcomes observed from treatment given without funding approval should be considered material, and to appropriately consider the equality implications that this may have for other similar patients who have not had access to this treatment.

### **5.6.7 Continuation of funding**

The IFR panel may on occasion review a request to continue funding for a patient who has previously self-funded, received funding on compassionate grounds from provider trusts, or for equipment provided for a time limited trial by the provider. The IFR panel should consider each of these cases on its merits according to the decision making principles set out in this policy. Future funding for treatment which has been previously been purchased privately should be limited to the date at which a request is either made or approved.

### **5.6.8 Non-clinical factors**

Exceptional personal circumstances (as opposed to clinical circumstances) are commonly stated as the basis for an IFR. The CCG recognises that everyone's life is different and that such factors may seem to be of vital importance to patients in justifying investment for them in the individual case. However, including non-clinical factors in any decision-making raises significant equality problems for the commissioning organisation.

Generally, the NHS does not take into account non-clinical factors in deciding what treatment to provide. It treats the presenting medical condition and does not enquire into the background and risk factors which led to that condition as the basis on which to decide whether to make treatment available or not. The CCGs will therefore seek to commission treatment based on the presenting clinical condition of the patient and not based on the patient's non-clinical circumstances. These may include age, gender, employment status, being a carer, or relationship status.

The CCG is committed to a policy of non-discrimination in the provision of medical treatment. If, for example, treatment was to be provided on the grounds that it would enable an individual to stay in paid work then this would potentially discriminate in favour of those working compared to those not working. The same can be said of many other non-clinical factors such as having children/not having children, being a carer/not being a carer and so on. Requests to fund treatment of adolescents on the grounds that not funding treatment would prevent the individual from fulfilling their true educational potential or because of a person's role in society are also potentially discriminatory and would contribute to inequality.

Where clinical evidence indicates variation of effectiveness across demographic groups (age groups; gender), it may be appropriate for the IFR panel to take into account such non-clinical factors in its decision making as indicated by the evidence base.

## 5.7 Notification of the IFR panel decision

The clinical applicant will be notified of the IFR panel decision by email within 24 hours of the meeting.

A formal outcome letter outlining the IFR panel decision in more detail, will normally follow within 10 working days (two working days for urgent decisions) and copied to associate clinicians where appropriate. It is expected that, unless specifically requested, all communication between the CSU team administering the IFR process and the clinical applicant will be via the secure nhs.net email accounts.

It is the responsibility of the clinical applicant to notify the patient of the panel outcome decision. This is because in the event that the funding request is refused, the clinician is in the best position to convey this information and discuss alternative treatment options. It is the decision of the clinical applicant as to whether they then share the outcome letter with the patient, noting the patient's rights under the NHS Constitution.

In the event of a decision not to approve funding, the notification will include the criteria by which applications are assessed and include details of the procedure for registering an appeal against the process by which the decision was taken.

If the clinical applicant or patient feels that there is additional relevant clinical information that was not submitted and thus not considered by the IFR panel as part of their decision making process, they can submit this as new information and the case will be re-opened as a new application.

## 6. The appeals process

### 6.1 The remit of the appeal process

The purpose of the appeals process is not to consider the clinical merits of the case, but whether due process has been followed in the IFR decision-making process (as described in this policy). This is a quality assurance scrutiny and as such is comparable to the Judicial Review and NICE Appeals processes. The accountability and duties of the IFR appeal panel are set out in the Terms of Reference (Appendix D).

### 6.2 Grounds for appeal

The grounds for appeal are as follows:

- The CCG has acted beyond its lawful powers
- The decision was one that no other reasonable CCG could have reached
- The CCG acted unfairly because it did not follow proper procedures (this policy)
- The CCG breached the patient's human rights
- The CCG breached the Equality Act 2010.

### 6.3 How to make an appeal

In most circumstances it is anticipated that the original applicant would initiate an appeal. In rare circumstances it may be initiated by a patient, although they would still need to have the written support of the clinician who made the original application.

Appeals should be made in writing, and clearly labelled "IFR appeal" to the relevant email address or postal address given on the application forms.

The appeal should be made within 90 days of the date that the original IFR panel decision was notified, stating the grounds on which the appeal is based and submitting any supporting information. The date of notification is the date of the email or letter, whichever is later. The grounds for appeal must be reasonable or the case will not be considered by the appeal panel.

#### **6.4 Procedure**

The CSU IFR team, taking advice from the CCG chair of the IFR panel committee of the governing body where needed, will undertake a preliminary review of the appeal basis to ensure that if new information is submitted the appeal is appropriately diverted back to the IFR panel.

The CSU IFR team will consider the grounds for appeal and make a recommendation to the CCG chair of the IFR panel committee of the governing body. If the chair determines that these are not reasonable (for example, the applicant merely disagrees with the decision without putting up a reasonable argument as to why procedure was not followed) then an appeal panel will not be convened and the applicant will be informed why and of their right to make a complaint under the complaints process.

In all other circumstances the CSU IFR team will convene an appeals panel meeting as expeditiously as possible (ideally within 20 working days from receipt of the appeal). The applicant or the patient may submit supporting information, however only supporting information relevant to the grounds for appeal will be considered.

If the applicant considers that there is greater clinical urgency for the appeal panel this should be specified in the appeal referral letter (sent by secure email) and a phone call to the CSU IFR team to alert them to the urgent request.

The outcome of the appeal will either be to uphold the IFR panel decision appealed against or to refer the decision back to the original IFR panel in light of the findings of the appeal.

#### **6.5 Notification of decision**

The process and timescale for notification of a decision will be the same as with the IFR panel. The letter will detail the grounds for this decision and the circumstances under which the complaints procedure of the responsible CCG may be relevant.

### **7. Information governance and confidentiality**

The CSU will hold patient level information on behalf of the CCGs to support the IFR process. All patient information will be handled in confidence and stored in accordance with the Information Governance Framework relating to person identifiable information.

IFR panel members will take into account the need for confidentiality and operate under the Caldicott guidelines. All patient specific electronic communication will be via a secure nhs.net connection.

The CSU will on behalf of CCGs, keep a full set of information electronically under a single record number. Telephone calls relating to IFR enquiries will be logged and notes kept with the case file, where appropriate. Relevant email communication and hard copy documents will be stored with the electronic file.

Electronic records and IFR panel minutes will be saved securely and access will be available to authorised staff only. Panel member hard copy records must be disposed of as confidential waste.

NEL CSU IFR processes will comply at all times with information privacy, confidentiality and security legal and regulatory requirements and best practice. NEL CSU will fully respect patient confidentiality and ensure that patient information is not collected, processed or shared without valid patient consent or other legal basis.

## **8. Review**

This policy and procedure will be reviewed as required or at the latest by September 2017.

## Appendices

### Appendix A - Legal context to decision making

This document sets out the legal and ethical considerations relevant to the IFR process.

#### 1.1 CCG Responsibilities and Regulations

The foremost amongst these considerations are the following patient rights, specified under the NHS Constitution<sup>1</sup> and underpinned by law:

*“You [the patient] have the right to access NHS services. You will not be refused access on unreasonable grounds.”*

*“You [the patient] 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.”*

Part 7 of the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012<sup>2</sup> make specific provision in relation to the funding and commissioning of drugs and other treatments by CCGs, including providing for a duty to give reasons for funding decisions.

#### 1.2 Legal and financial duties and the duty to provide services

Under the NHS Act 2006<sup>3</sup> (as amended by the Health and Social Care Act 2012 (“HSCA)) the CCGs; NHS England and the Secretary of State have a concurrent duty to provide a comprehensive health service. For CCGs, the following applies<sup>4</sup>:

*“A clinical commissioning group must arrange for the provision of the following to such extent as it considers necessary to meet the reasonable requirements of the persons for whom it has responsibility:*

*...*

*(c) medical, dental, ophthalmic, nursing and ambulance services,*

*...*

*(e) such other services or facilities for the prevention of illness, the care of persons suffering from illness and the after-care of persons who have suffered from illness as he considers are appropriate as part of the health service,*

*(f) such other services or facilities as are required for the diagnosis and treatment of illness.”*

---

<sup>1</sup> The NHS Constitution March 2010

[http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/@dh/@en/@ps/documents/digitalasset/dh\\_113645.pdf](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_113645.pdf)

<sup>2</sup> National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012/2996 February 2012

<sup>3</sup>The NHS Act 2006

[http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/@dh/@en/documents/digitalasset/dh\\_063171.pdf](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_063171.pdf)

<sup>4</sup>Section 3 of the NHS Act 2006 (as amended)

In addition to this duty to meet the above requirements, CCGs have a statutory obligation to maintain financial balance. When considering whether or not to commission specific treatments for groups of people with the same medical condition, CCGs will assess the clinical and cost effectiveness of the treatment, the benefits to patients in terms of quality of life and the priority of this treatment or service in relation to others already commissioned or proposed for commissioning.

So a treatment of very little benefit is unlikely to be commissioned simply because it is the only treatment available, this ensures that limited resources are used to provide the greatest health benefit.

At an individual or patient group level, treatment will not generally be funded solely because a patient requests it. CCGs will not normally fund treatment for one patient, which is not available to all other patients with the same clinical need, except in the context of this policy.

CCGs will not discriminate on grounds of personal characteristics, such as age, gender, sexual orientation, race, religion, lifestyle, social position, family or financial status, intelligence or cognitive functioning and will act in compliance with duties under the Equality Act 2010. However, funding decisions will be made on the basis that the patient is more likely to benefit significantly more than other patients with the same clinical condition.

### 1.3 Administrative Law

Decisions made by public bodies including CCGs can be challenged in the Administrative Court by way of judicial review. The traditional grounds for judicial review are that the public body:

- acted beyond its lawful powers
- came to a decision which no other reasonable CCG could have reached
- acted unfairly, because it did not follow proper procedures
- breached the patient's human rights
- breached the Equality Act 2010.

These grounds are the basis for the Appeals Process set out in this document.

### 1.4 Equality Duties

The main impact of the Equality Act 2010<sup>5</sup> has been the duty on health bodies to monitor their compliance – extending the race equality monitoring to gender, religious belief and sexual orientation where this is relevant – and to give due regard to the public sector equality duty. This policy complies with the Equality Act 2010.

The CCG has a duty to comply with public sector equality duty, part of the Equality Act 2010, and must, in the exercise of their functions, have due regard to the need to:

- Eliminate unlawful discrimination, harassment and victimisation and other conduct prohibited under the Act
- Advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it
- Foster good relations between persons who share a relevant protected characteristic and persons who do not share it.

---

<sup>5</sup><http://www.legislation.gov.uk/ukpga/2010/15/contents>

## 1.5 The Human Rights Act 1998

The Human Rights Act 1998<sup>6</sup>, Article 6 requires a fair hearing for determining civil rights and proportionality of decision-making which the courts consider a fair balance between protection for individual rights and the interests of the community. The proportionality test involves balancing different interests – such as those of the individual applicant for treatment funding with those who await service improvements that depend on the availability of new funding. Other key considerations are Articles: 2 (the right to life); 3 (the right not to be subjected to inhumane or degrading treatment); 8 (the right to respect for privacy and family life); 12 (the right to marry); and 14 (the requirement for non-discrimination against groups because of their sex, race, religion, disability, disease).

## 1.6 Statutory duty of quality

CCGs need to demonstrate compliance with a statutory duty of quality, in accordance with the NHS Act 2006 (as amended by the HSCA) with specific consideration of the following points in section 14:

- s.14P (Duty to promote NHS Constitution);
- s14Q (Duty as to effectiveness, efficiency and economically);
- s14R (Duty as to improvement in quality of services);
- s14T (Duties as to reducing inequalities);
- s 14U (Duty to promote involvement of each patient) and
- s 14V (Duty as to patient choice).

As part of the statutory duty of quality the CCG will ensure that the process for assessing and making decisions about individual funding requests should be timely and flexible enough to respond rapidly where the health of an applicant mandates a more urgent decision.

## 1.7 Ethical Considerations

The four principles widely used in medical ethics are:

- Autonomy: respecting the decision-making capacities of individual people to make their own reasoned informed choices
- beneficence: considering the balance between the benefits of an intervention against its risks and costs and choosing the one with greater benefit to the individual patient
- non maleficence: avoiding the causation of harm and ensuring any is proportionate to the benefits of treatment
- distributive justice: sharing benefits equitably, and risks and costs fairly; so that patients in similar positions should be treated in a similar manner irrespective of age, sex, race, disability and employment.

## 1.8 Patient's Right to Choice

CCGs have a statutory duty as to patient choice under section 14V of the NHS Act, which sets out that each CCG must, whilst carrying out its functions, act with a view to enabling patients to make choices in respect of aspects of health services provided to them.

The NHS Constitution sets out certain rights that patients have in relation to choice. In addition, the Department of Health (2014/15) Choice Framework outlines the services where patients have a right to choice.<sup>7</sup>

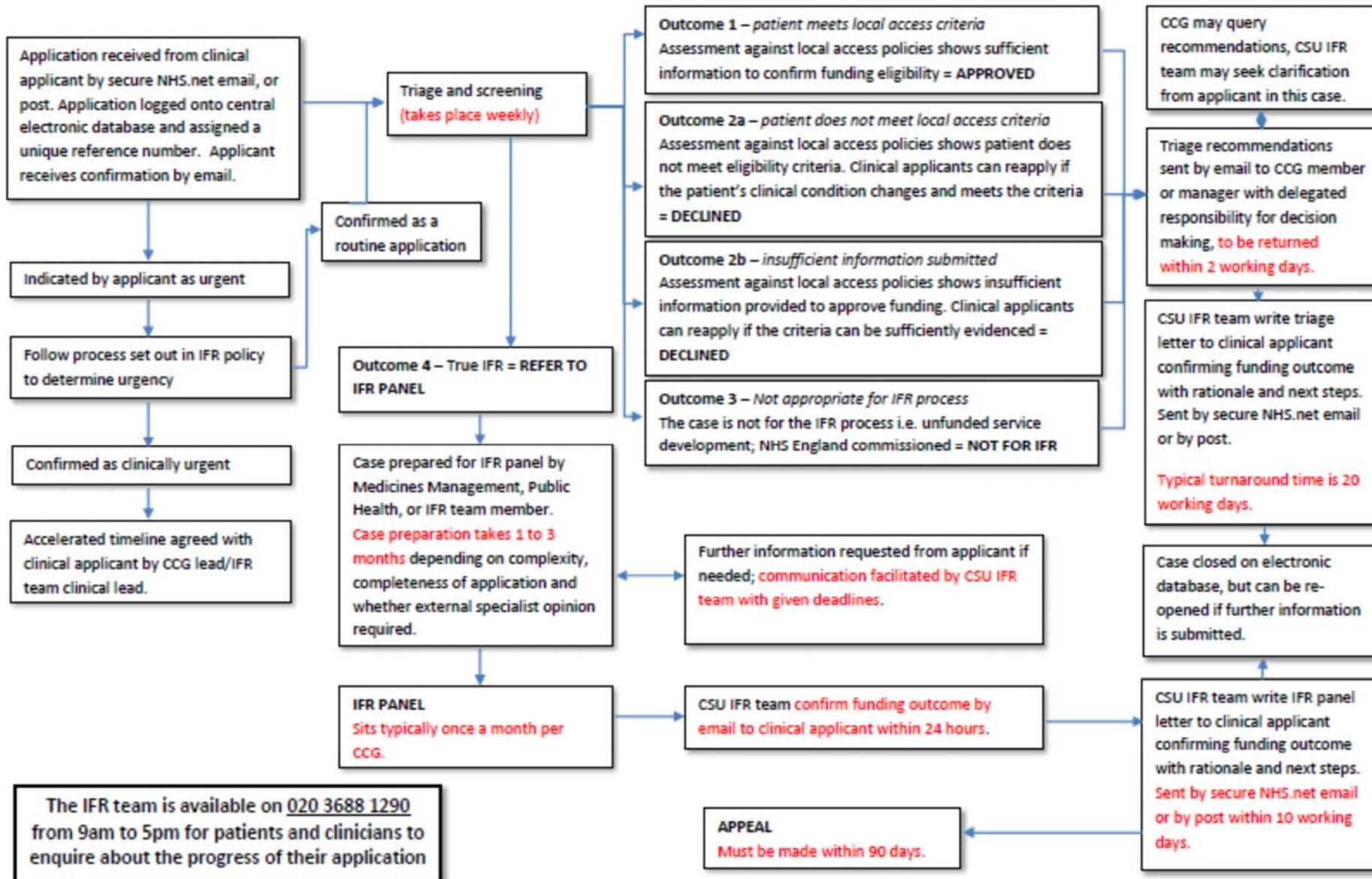
<sup>6</sup>[http://www.opsi.gov.uk/acts/acts1998/ukpga\\_19980042\\_en\\_3#sch1](http://www.opsi.gov.uk/acts/acts1998/ukpga_19980042_en_3#sch1)

<sup>7</sup> [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/299609/2014-15\\_Choice\\_Framework.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/299609/2014-15_Choice_Framework.pdf)

CCGs must also consider Part 8 of the NHS CB and CCGs (Responsibilities and Standing Rules) Regulations 2012, which provides a specific duty of choice in relation to elective referrals, and the NHS (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013/500 in relation to choice of alternative provider.

The right to choice excludes referrals for persons needing urgent or emergency treatment; persons detained under the Mental Health Act 1983, serving members of the Armed Forces and prisoners (including those on temporary release), those needing urgent or emergency care, maternity services, high secure psychiatric services or drug and alcohol misuse services commissioned or provided by local authorities.

Appendix B – Individual Funding Request process flowchart



## **Appendix C – IFR application forms**

### **IFR application form (secondary care)**



IFR application  
form with IG statement

### **IFR application form (primary care)**



IFR application  
form with IG statement

## Appendix D - Terms of Reference

### IFR Panel and Appeal Panel

Meeting	Individual Funding Requests Panel
<b>Constitution</b>	The Governing Body hereby resolves to establish a Committee of the Governing Body to be known as the Individual Funding Requests (IFR) panel. The panel is a multi-disciplinary, non-executive committee of the Governing Body and has no executive powers, other than those specifically delegated in this Terms of Reference.
<b>Accountability</b>	<p>The IFR panel is the decision-making body that is a component of the CCG commissioning decision-making process. This policy complies with the CCG constitution.</p> <p>Accountability for the operational management of the IFR process within the CSU is through the Director of Contracting and Quality.</p>
<b>Role of the panel</b>	The panel shall consider and determine eligible IFRs where the CCG is the responsible commissioner of NHS care, according to the principles set out in the CCG's IFR policy.
<b>Duties</b>	<p>In reaching a decision the panel must take into account the principles of the NHS Constitution, which sets out the rights of NHS patients. These rights cover how patients access health services, the quality of care, the treatments and programmes available, confidentiality, information and the right to complain if things go wrong.</p> <p>The panel must ensure that it has acted in good faith, weighed all the relevant evidence, given proper consideration to the claims of patients and clinicians and the evidence prepared by the presenters (representatives from Pharmacy, Public Health, and in some cases the IFR team). It must accord proper weight to the needs of other groups, given the total resources the CCG has available.</p> <p>The panel will strive to reach consensus on a judgement, which is in every sense reasonable. Where there is not a consensus decision, a vote of the panel's membership should be taken, with a decision agreed by a simple majority of the voting panel members present. Votes of individual members will be recorded and minuted in relation to their role rather than by name. Where there is equal voting, the casting vote will be with the Chair.</p> <p>The IFR panel may make the following decisions on a case:</p> <ul style="list-style-type: none"> <li>• Funding declined</li> <li>• Funding approved without caveats</li> <li>• Funding approved with caveats</li> <li>• Case deferred pending further information</li> </ul> <p>If a situation arises where the IFR panel is unable to make a decision due to insufficient information being provided by the clinical applicant or associated</p>

	<p>clinicians on which to make a fully informed decision (and if any further information requested fails to clarify this or is not submitted), the IFR panel is entitled to decline funding.</p>	
<b>Meeting arrangements</b>	<p>Meetings of the IFR panel will be held in common with other CCG's IFR panels in the groupings set out below, which reflect the CSU point of delivery (POD) structures:</p> <ul style="list-style-type: none"> <li>➤ Barnet, Camden, Enfield, Haringey and Islington</li> <li>➤ Barking and Dagenham, Havering and Redbridge</li> <li>➤ City and Hackney, Newham, Tower Hamlets and Waltham Forest</li> </ul> <p>The business to be conducted for each CCG will be clearly separated and during consideration of each CCG's cases, the panel will be Chaired by a member of the relevant CCG. The members of other CCGs can be voting members (but not Chair) for other CCG's panels.</p> <p>Where joint panels are established each CCG must agree the governance of the panel and in particular ensure that there is a clear policy regarding delegated decision making.</p>	
<b>Membership</b>	<b>Barnet, Camden, Enfield, Haringey and Islington</b>	
	Chair	CCG nominated member (clinical director, GP, nursing director, secondary care consultant or lay member)
	Voting members	<ul style="list-style-type: none"> <li>• Panel Chair</li> <li>• Chief pharmacist/senior medicines management lead (CSU/CCG)</li> <li>• Senior contracting representative (CSU/CCG)</li> <li>• Lay member from one of the NCL CCGs</li> <li>• CCG GP (must be present if the Chair is not a clinician i.e. lay member)</li> </ul>
	<b>Barking and Dagenham, Havering, and Redbridge</b>	
	Chair	CCG nominated member (secondary care consultant)
	Voting members	<ul style="list-style-type: none"> <li>• Panel Chair</li> <li>• Chief pharmacist (CCG)</li> <li>• Lay member from one of the BHR CCGs</li> </ul>
	<b>City and Hackney, Newham, Tower Hamlets and Waltham Forest</b>	
	Chair	CCG nominated member (clinical director, GP, nursing director, secondary care consultant or lay member)
	Voting members	<ul style="list-style-type: none"> <li>• Panel Chair</li> <li>• Chief pharmacist/senior medicines management lead (CSU/CCG)</li> <li>• Senior contracting representative (CSU/CCG)</li> <li>• Lay member from one of the WELC CCGs</li> </ul>

	<p><i>Please note, for Newham and City and Hackney CCGs, the Chief/pharmacist/senior medicines management lead must be a CCG representative.</i></p> <p>All panels will be supported where appropriate by:</p> <ul style="list-style-type: none"> <li>• CSU IFR team administrative support</li> <li>• Pharmacy/medicines management</li> <li>• Public health</li> <li>• Additional GP expertise</li> <li>• Any other specialist as requested by the Chair as necessary or beneficial to the decision making process.</li> </ul> <p>Members must nominate a suitable deputy if they are unable to attend, but these must be named at least two weeks in advance and, in order to have the ability to vote, must be suitably experienced and trained. The membership will be subject to review, as required.</p> <p>Clinical applicants or patients will not be invited to attend the IFR panel. Any information submitted by a patient will be given due respect by the panel.</p>
<b>Quorum</b>	The quorum shall be <b>all voting members</b> and a duly convened meeting of the panel at which a quorum is present shall be competent to exercise all or any of the authorities, powers and discretions vested in or exercisable by the panel.
<b>Conflict of interest</b>	<p>If the application originates from a CCG panel member (or a practice in which they have an interest), then a replacement shall be sought to chair the meeting and that member should exclude themselves from the proceedings whilst that funding request is being discussed. All panel members must comply with the CCG's Conflict of Interest policy.</p> <p>To avoid such a situation arising and risk making a panel inquorate, panel members must check the meeting papers in advance and contact the IFR team to arrange for a deputy to be in attendance. Delay may be unavoidable in this instance while an alternative member is sought.</p>
<b>Frequency of meetings</b>	Panel meetings will be scheduled regularly by the CSU IFR team to ensure that delay to decision making is minimised.
<b>Urgent panels</b>	This panel meeting should meet face to face, and only where this is impossible, will it be done by teleconference with all panel members present. Urgent panels will not be carried out virtually by email.
<b>Notice of meetings</b>	<p>Notice of panel meetings shall be forwarded to each member, and any attendees, no later than 5 working days before the meeting.</p> <p>Notice of the meeting shall comprise venue, time and date of the meeting, together with an agenda of items to be discussed and anonymised supporting papers.</p>

<b>Administration and minutes of meetings</b>	The CSU IFR team shall administer and support the panel, shall attend to take minutes of the meeting and provide appropriate support to the Chair and panel members.
<b>Reporting responsibilities</b>	The minutes of the panel meetings shall be reported to the panel Chair.
<b>Other</b>	

<b>Meeting</b>	<b>IFR Appeals Panel</b>		
<b>Constitution</b>	The Governing Body hereby resolves to establish a sub-committee of the Individual Funding Requests (IFR) panel to be known as the IFR Appeals panel (the Appeals panel). The Appeals panel is a multi-disciplinary, non-executive sub-committee of the Governing Body and has no executive powers, other than those specifically delegated in the Terms of Reference.		
<b>Role of the committee</b>	The purpose of the appeals process is not to consider the clinical merits of the case, but whether due process has been followed in the IFR decision-making process (as described in this policy). This is a quality assurance scrutiny and as such is comparable to the Judicial Review and NICE Appeals processes.		
<b>Duties</b>	<p>The Appeal panel will review all relevant information including:</p> <ul style="list-style-type: none"> <li>the decision-making processes and procedures that informed the original IFR panel decision, against the criteria set out in the IFR policy</li> <li>the minutes of original IFR panel meeting and the factors taken into account in the original decision</li> <li>any supporting information submitted by the applicant or the patient.</li> </ul> <p>The Appeal panel will assess whether or not the IFR panel decision:</p> <ul style="list-style-type: none"> <li>was made following the required standards set out in the IFR policy</li> <li>took into account all relevant information available at the time</li> <li>was reasonable and in line with the evidence.</li> </ul> <p>If there is a question about the reasonableness of the IFR decision, the Chair may request additional expert input.</p> <p>The outcome of the appeal will either be to uphold the IFR panel decision appealed against or to refer the decision back to the original IFR panel in light of the findings of the Appeal.</p>		
<b>Membership</b>	<table border="1"> <tr> <td>Chair</td> <td> <ul style="list-style-type: none"> <li>CCG nominated member (clinical director, GP, nursing director, secondary care consultant or lay member)</li> </ul> </td> </tr> </table>	Chair	<ul style="list-style-type: none"> <li>CCG nominated member (clinical director, GP, nursing director, secondary care consultant or lay member)</li> </ul>
Chair	<ul style="list-style-type: none"> <li>CCG nominated member (clinical director, GP, nursing director, secondary care consultant or lay member)</li> </ul>		

	Voting members	<ul style="list-style-type: none"> <li>• Panel Chair</li> <li>• Executive Director representative (CSU or CCG)</li> <li>• Public health representative</li> <li>• Lay member</li> </ul>
	Support	<ul style="list-style-type: none"> <li>• CSU administrative support</li> <li>• Additional expert input as determined by the Appeals panel Chair</li> </ul>
	None of the members of the Appeals panel will have been involved in the decision-making related to the IFR in question.	
<b>Quorum</b>	The quorum shall be <b>all voting members</b> and a duly convened meeting of the Appeals panel at which a quorum is present shall be competent to exercise all or any of the authorities, powers and discretions vested in or exercisable by the Appeals panel.	
<b>Conflict of interest</b>	The Appeal panel will ensure that any conflicts of interest are dealt with in accordance with the process set out in the IFR panel Terms of Reference.	
<b>Frequency of meetings</b>	If the Appeal is considered appropriate, the CSU IFR team will convene a panel as expeditiously as possible (ideally within 20 working days from receipt of the Appeal).	
<b>Notice of meetings</b>	<p>Notice of meetings of the Appeals panel shall be forwarded to each member, and any attendees, no later than 5 working days before the meeting.</p> <p>Notice of the meeting shall comprise venue, time and date of the meeting, together with an agenda of items to be discussed and supporting papers.</p>	
<b>Administration and minutes of meetings</b>	The CSU IFR team shall administer and support the Appeals panel, shall attend to take minutes of the meeting and provide appropriate support to the Chair and members.	
<b>Reporting responsibilities</b>	The minutes of the Appeals panel meetings shall be reported to the IFR panel.	
<b>Other</b>		