North Central London
Integrated Care Board

# NCL ICB
# Individual Funding Request Policy

**V.0.6.1.4**

Operational from July 2022

# Version Control

| Date | Status | Summary of Changes | Version | Owner |
|---|---|---|---|---|
| 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 |
| 09.12.14 | Final version | Sign off by Quality and Safety Committee | v.0.5 | Tim Baker |
| 21.09.21 | Updated draft | Changes made to reflect establishment of NCL CCG, developments in IFR current process, alignment of decision making principles to highlight clinical exceptionality as in IFR policy, and incorporate updated IFR panels terms of reference. | v.0.6. | Alison de Metz |
| 03.03.22 | Updated draft | Changes to reflect transfer of IFR function to NCL ICB | v.0.6.1 | Alison de Metz |
| 10.06.22 | Updated draft | Further changes to reflect transfer of IFR function to NCL ICB following clarification of application and triage arrangements | v.0.6.1.3 | Alison de Metz |
| 20:06:22 | Updated draft | Update with NCL ICB IFR email address | v.0.6.1.4 | Stacey Kennedy |

# Contents

# 1. Introduction

The following policy has been adopted by NCL Integrated Care Board (ICB) Governing Body or equivalent.

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). ICBs 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, ICBs 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 NCL ICB governing body's decision making process for managing IFRs, the delegated responsibility and legal framework for decision-making within the ICB constitution. It is underpinned by a detailed operational procedure which outlines how the process will be administered by the NCL ICB IFR team.

The policy is guided by the legislative duties bestowed on ICBs 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 to ensure that it can be updated to reflect any feedback and learning from the way that the NCL ICB IFR team, NHS England and ICBs work together to commission healthcare services.

# 2. The scope of this policy

This policy is for implementation and use by the NCL ICB IFR administration team, IFR triage group and IFR and Appeal Panels to promote timeliness, fairness, transparency and rationality in IFR management and decision-making; the policy is also accessible to patients and the public. 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 NCL ICB, 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 ICB 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 ICB commissioner where the patient has become the commissioning responsibility of NCL ICB.
- Requests for referral to a service not commissioned locally and not listed on the national menu (including applications for overseas treatment which are consistent with and support the NHS England directive process as follows: requests for treatment in another country will be considered in accordance with arrangements set out by the Department of Health (S2 form and Article 56); and ICB policies and commissioning guidance.).

### 2.2 Policy exclusions

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

#### 2.2.1 Retrospective funding

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 ICB 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 ICB. 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 ICB 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 is not submitted in line with the requirements of this policy. This is a controlled document. Whilst this document may be printed, the electronic version posted on the ICB intranet is the controlled copy. Any printed copies of this document or the application form are not controlled. As a controlled document, this document should not be saved onto local or network drives but should always be accessed from the intranet.
- The request represents a service development and therefore needs to be redirected to the appropriate population decision making group
- The treatment requested is covered by another ICB 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 ICB
- A patient is referred for physical intervention/treatment (for example, cosmetic surgery) on the grounds of psychological problems, where treatment through a mental health service would be more suitable in the first instance.

### 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 on the basis or rarity unsupported by current UK population prevalence or incidence data
- 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. In such circumstances the ICB expects the clinical applicant to proceed in accordance with NHS Approved Provider (Trust) governance mechanisms and the Trust's Duty of Care towards the patient. The clinical applicant & provider trust should proceed with treatment at their own financial risk. In the first instance a retrospective IFR will need to be endorsed by the triage group as clinically urgent for the ICB to consider it. There is no guarantee in this circumstance that funding will be approved or retrospective funding will be paid.
- Clinical applicants must take all reasonable steps to minimise the need for urgent requests to be made through the IFR process, for example, by making requests promptly and providing all necessary information with a request. Urgency under this policy cannot arise as a result of a failure by the clinical team to seek funding through the appropriate route in a timely fashion 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.

### 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 the following two points are fully demonstrated in the IFR application :

- 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 Rare treatments and indications

3.7.1 Rarity relates to when a patient is suffering from a medical condition or clinical presentation which is considered very rare, and for which the ICB has no policy because the low probability of the condition occurring among the ICB's population means that an explicit policy is not warranted.

3.7.2. In the case of a rare indication, incidence, prevalence and evidence of effectiveness will be assessed. This assessment will be made using published epidemiological research and take into account any other similar requests received by the ICB. Assessment of requests to fund procedures not covered by an existing policy due to the rarity of the procedure, and/or clinical condition, should be distinguished from requests on the grounds of exceptionality.

3.7.3 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 triage group and IFR panel may therefore base their judgement on the biological plausibility of benefit based on the evidence of effectiveness and the cost effectiveness of treating the patient when considered against the ICB's other competing demands.

3.7.4 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 ICB's priority setting principles.

### 3.8 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 ICB could expect to receive more than one application per year on an ongoing basis for the same treatment and clinical indication.

### 3.9 Service developments

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 ICBs 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.

## 4. Roles and responsibilities

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

### 4.1 NCL ICB IFR team

It is the responsibility of the NCL ICB IFR team to:

- Receive, acknowledge and process IFR requests submitted to the ICB within agreed timescales and conditions [e.g. online submission] (see Appendix E for an overview of IFR operating timescales).

**Triage:**

- Screen all applications according to the provisions in this policy (section 5.4, triage process)
- Re-direct applications as appropriate.
- Prepare triage group case papers to ensure triage group members have timely and appropriate access to triage documentation.
- Ensure that members are appropriately trained for participation in the triage process.

**IFR panels:**

- Schedule regular IFR panels to ensure timely decision making. 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 as appropriate.
- Co-ordinate the provision of additional information if required, through contact with the clinical applicant or associate clinicians, to ensure the IFR panel has all the relevant information it needs to allow the case to be considered in full.
- 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 it can be made available when considering new applications and/or appeals.

**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.

**Reporting and training:**

- Process and report claims for overseas treatment to the ICB.
- Deliver appropriate training to all members of the IFR panel and appeal panels and those within the ICB IFR team 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 manager to support IFR triage and 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 ICBs.
- Support the chair to ensure IFR panels operate according to best practice with regard to this policy.
- Provide regular reports to ICB 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 timeframe for the appeal).

### 4.4 The ICB

The responsibility of the ICB includes:

**IFR triage group**

- To appoint triage members to act on behalf of the ICB.
- To ensure that sufficient ICB triage members are available for triage to be quorate.

- To provide/attend appropriate triage training as co-ordinated by the IFR team.

**IFR panels:**

- To appoint IFR panel members to act on behalf of the ICB.
- To ensure that sufficient panel members are available from the ICB 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 ICB 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. North Central London Evidence Based Interventions And Clinical Standards (NCL EBICS) policy for procedures not routinely funded or requiring prior approval.

### 4.5 IFR panel and appeal panel

The responsibility of the IFR Panel and Appeals Panel 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 ICB's IFR policy, and in the IFR panel and appeal panel terms of reference (Appendix D)
- Refer to the relevant ICB 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 Appeals 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 in reaching a funding decision.
- The rationale for the decision has been explicitly recorded against the terms of this policy, and that any conflicting arguments have been managed.
- They are available to approve the minutes and letters within the specified timeframe 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 the ICB Governing Body or equivalent 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 made be to the local authority where the individual is resident, in accordance with the ICB safeguarding policies for adults and children.

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

# 5. The IFR process

The flowchart in Appendix B provides an overview for the IFR process. Operating timescales are provided in Appendix E.

## 5.1 Submitting an IFR

Clinicians, on behalf on their patients, are entitled to submit an IFR to the ICB. IFR applications must be submitted online via the NCL ICB IFR database, Blueteq® (see Appendix C for guidance on setting up an account and submitting an IFR application online via the database).

Applications submitted by email to the NCL IFR inbox (nclicb.ifr@nhs.net) will be considered on a case by case basis. Applications submitted by email will only be accepted in extreme circumstances and must be accompanied by a rationale explaining why an online application was not possible. The IFR application form and further details on how to register with Blueteq® and submit an IFR application are given in Appendix C.

Applications should be made by the:

- Patient's GP or another GP from the practice,
  or the
- Treating 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 via their clinical applicant supporting their clinician's application if they wish, bearing in mind the principles set out in section 5.10.8, non-clinical factors.

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

## 5.2 Patient consent to share information

In accordance with the NCL ICB Information Governance policy, 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 on submission of the application 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. NCL Evidence Based Interventions and Clinical Standards Policy) 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 ICB area.

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

The application should include electronic copies of, or electronic links to, published evidence of clinical effectiveness and likelihood of benefit.

### 5.4 Screening for incomplete submissions

The NCL ICB IFR team will screen applications 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 administratively withdrawn from the IFR process at that stage and the applicant informed 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.

### 5.5 Screening for urgent applications

All requests will be reviewed by the NCL ICB IFR team 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 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 ICB 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 seven 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 ICB 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.

## 5.6 The triage process

All funding requests will be subject to initial administrative and clinical triage by the NCL ICB IFR team to ensure the request falls within the scope of this policy. Appropriate requests will be reviewed to assess whether further consideration by the IFR panel is necessary.

### Clinical Triage

5.6.1 The Triage Group must be clinically led. The purpose of triage is to determine if the IFR is eligible for consideration by the IFR Panel. The triage members will reference the following questions:

- Is the requested treatment covered by NHSE&I commissioning responsibilities?
- Is the treatment requested funded within an existing commissioning policy? If so, not for IFR unless submitted under clinical exceptionality.
- Is the treatment requested covered by another ICB policy or process? If so, not for IFR unless submitted under clinical exceptionality.
- Is the treatment an obvious Service Development (i.e. a request pertaining to a cohort of patients and not reflective of an individual's clinical circumstances)?; see sections 3.9 above and 5.8 below. If so, not for IFR unless submitted under clinical exceptionality.
- Does the submission include sufficient information - see above 5.4 'Screening for incomplete submissions'.
- Is the request an appeal or resubmission of a previous case? If an appeal of an IFR panel decision forward for consideration by the IFR Appeals Panel if the submission meets the appeal process criteria and is not new case information.
- Does the submission demonstrate an arguable case of clinical rarity or exceptionality whereby the following two points are fully evidenced:
  - The patient's clinical condition is significantly different to the general population of patients with the condition in question; AND
  - The patient is likely to gain significantly more benefit from the intervention than might be 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.

## 5.7 Process for local clinical policies

Applications for treatments included in the ICB adopted clinical policies should be submitted via the local Referral Management Service or local arrangements as appropriate for review against the relevant criteria or treatment threshold as agreed by the ICB. Examples of these policies are:

- NCL Evidence Based Interventions and Clinical Standards Policy (EBICS)
- NCL Fertility policies

Where the patient is ineligible for funding under these policies an application can be made to the IFR team for processing as an IFR, provided that the applicant has completed the IFR application form, including the appropriate section on patient exceptionality, giving the reasons why the ICB 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 the application cannot progress further and will be closed at the triage stage. The clinical applicant is entitled to submit further information if available at a later stage; in this case the request will be re-opened as a new application.

### 5.8 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 the North Central London Medicines Management Network, NICE guidance and contracts colleagues, for early alerts to potential service developments.

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

- It would be likely that the ICB 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 ICBs.

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, including the number of applications received and from which trusts, to the ICB IFR lead and/or the IFR Panel Chair. This representative will confirm if the ICB agrees the identification of this cohort, potential commissioning arrangements and/or process for management of any future IFR applications. 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 are 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.

### 5.9 Evidence evaluation and case preparation

The onus is on the clinical applicant to provide sufficient information as to why the ICB 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.

For cases referred to the IFR panel for consideration, the IFR team on behalf of the ICB will also commission provision for thorough case preparation by pharmacists or public health representatives, who carry out an independent evidence evaluation of the requested treatment in line with the accepted hierarchy of evidence (See section 5.10.4 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.

### 5.10 The IFR panel

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

### 5.10.1 Principles of decision making

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

1. In what way is the clinical condition of this particular patient significantly different from the group of patients with the condition in question?

2. What is the evidence that this particular patient is likely to gain significantly more health benefit than others with the same condition?

3. Is the treatment lawful – i.e. within the ICB's legal powers and takes into consideration relevant legal principles such as the Human Rights Act?

4. 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.

5. 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.*

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?

9. Is the treatment accessible?

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.

### 5.10.2 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 ICB'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 ICB's priority setting principles.

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

### 5.10.3 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 truly exceptional as defined by the IFR policy and which 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?

If the patient has a condition for which there is an established care pathway, the IFR 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.

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 this 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 the IFR panel could find that the patient is exceptional.

However, the IFR 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, 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 proper grounds 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, commissioning prioritisation and affordability) to change the ICB policy for funding that pathway that would 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 by the relevant commissioning committee of the ICB.

### 5.10.4 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).

### 5.10.5 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.

### 5.10.6 Retrospective requests

The IFR panel may on occasion review an urgent application for which treatment has already commenced. The ICB 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. However, there is no guarantee that funding will be approved in this circumstance.

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.

### 5.10.7 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.

### 5.10.8 Non-clinical factors

Exceptional personal circumstances (as opposed to clinical circumstances) are commonly stated as the basis for an IFR. The ICB 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 ICBs 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 ICB 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 potential future role in society, are also potentially discriminatory to a broader population and would contribute to inequality as a result. However, to prevent discrimination and social inequality in the provision of an intervention/treatment, applications can only be made on the grounds of clinical exceptionality or rarity. Social and other non-clinical factors will not be considered.

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.

### 5.10.9 Notification of the IFR panel decision

The clinical applicant will be notified of the IFR panel decision by email within 48 hours of the meeting.

A formal outcome letter outlining the IFR panel decision in more detail and the rationale for the decision, will normally follow within no more than forty-five (45) working days from receipt of the application. This allows for the panel meeting to take place and for the necessary preparation of case details for the panel consideration. For urgent IFRs the clinical applicant will be notified of the outcome within ten (10) working days from receipt of fully the completed application. It is expected that, unless specifically requested, all communication between the IFR team administering the IFR process and the clinical applicant will be via the Blueteq® database or 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 of the funding request being refused, the clinician is in the best position to convey this information most appropriately 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 decision rationale and the criteria by which applications are assessed. The notification letter will also 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 ICB has acted beyond its lawful powers.
- The decision was one that no other reasonable ICB could have reached.
- The ICB acted unfairly because it did not follow proper procedures (this policy).

## 6.3 How to make an appeal

In most circumstances it is anticipated that the original clinical 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 given on the application forms.

The appeal should be made within 30 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 NCL ICB IFR Triage group will undertake a preliminary assessment of an appeal request assessing the submission against the grounds for appeal criteria listed above. If new information is submitted the appeal will be diverted back to the IFR panel for further consideration of the new information.

If the triage chair determines that the appeal request is not reasonable (for example, the applicant merely disagrees with the decision without putting forward 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 ICB complaints process.

If required the Appeals Panel will be convened as quickly as possible (ideally no more than thirty (30) working days from the date the appeal is referred to the IFR Appeals Panel). If the applicant considers that there is greater clinical urgency for the appeal this should be specified in the appeal referral letter to the NCL ICB IFR team to alert them to the urgent request. The applicant or the patient may submit supporting information, however only supporting information relevant to the grounds for appeal will be considered.

All IFR Appeal Panel members must be independent of any of the original decision making processes and not have been a member of the IFR Panel involved in the original decision.

In working towards a decision, the Appeal Panel Chair will test whether there is a consensus within the meeting. If there is a difference of views, funding decisions shall be determined by a majority of the votes of members present and voting on the request. In the case of an equal vote, the Chair shall have the casting vote.

The appeal Panel may make the following decisions:
- IFR panel decision upheld and case 'closed'; the appellant will be advised that if they wish to take the matter further this must be done through the NHS complaints process
- IFR Panel decision not upheld; the case must be returned to the IFR panel for re consideration with the minutes from the Appeal Panel meeting detailing the grounds for the successful appeal.

Clinical applicants or patients who wish to complain about IFR decisions should contact the relevant complaints team to submit a formal complaint. Applicants/patients should not use the IFR Appeal process to make a complaint about an IFR decision. The IFR appeal process is solely for the purpose of appealing against the IFR decision-making process.

### 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 ICB may be relevant.

## 7. Information governance and confidentiality

The NCL ICB IFR team will hold patient level information on behalf of the ICB 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 NCL ICB IFR team will, on behalf of the ICB, 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.

NCL ICB IFR processes will comply at all times with information privacy, confidentiality and security legal and regulatory requirements and best practice. The NCL ICB IFR team 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 by no later than June 2023.

# Appendices

## Appendix A - Legal context to decision making

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

### 1.1 ICB Responsibilities and Regulations

The foremost amongst these considerations are the following patient rights, specified under the NHS Constitution[1] 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[2] make specific provision in relation to the funding and commissioning of drugs and other treatments by ICBs, 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[3] (as amended by the Health and Social Care Act 2012 ("HSCA)) the ICBs; NHS England and the Secretary of State have a concurrent duty to provide a comprehensive health service. For ICBs, the following applies[4]:

> *"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."*

[1] The NHS Constitution March 2010 http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_113645.pdf
[2] National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012/2996 February 2012
[3]The NHS Act 2006 http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_063171.pdf
[4]Section 3 of the NHS Act 2006 (as amended)

In addition to this duty to meet the above requirements, ICBs 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, ICBs 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.

To ensure that limited resources are used to provide the greatest health benefit for the local ICB population, a treatment of very little benefit is unlikely to be commissioned simply because it is the only treatment available.

At an individual or patient group level, treatment will not generally be funded solely because a patient requests it. ICBs 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.

ICBs 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 ICBs 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 ICB 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[5] 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 ICB 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.

[5]http://www.legislation.gov.uk/ukpga/2010/15/contents

## 1.5 The Human Rights Act 1998

The Human Rights Act 1998[6], 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

ICBs 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 ICB 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

ICBs have a statutory duty as to patient choice under section 14V of the NHS Act, which sets out that each ICB 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.[7]

[6]http://www.opsi.gov.uk/acts/acts1998/ukpga_19980042_en_3#sch1
[7] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/299609/2014-15_Choice_Framework.pdf

ICBs must also consider Part 8 of the NHS CB and ICBs (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

NCL IFR Process Flowchart FINAL

## Appendix C – IFR application form

Clinicians, on behalf on their patients, are entitled to submit an IFR to the ICB.

IFR applications must be submitted online via the NCL ICB IFR database, Blueteq®; see below guidance on setting up an account and submitting an IFR application online via the database.

NCL ICB IFR Blueteq Submission Guidanc

Applications submitted by email to the NCL IFR inbox (nclicb.ifr@nhs.net) will be considered on a case by case basis and will only be accepted in extreme circumstances and must be accompanied by a rationale explaining why an online application was not possible.

For further information or for support with applications please contact the IFR team on nclicb.ifr@nhs.net.

## Appendix D - Terms of Reference for IFR Triage group, Panel and Appeals Panel

NCL IFR Triage ToR

NCL IFR Panel Terms of Reference-Panel

NCL IFR Appeals Terms of Refe

## Appendix E - IFR Operating timescales

NCL IFR Operating Timescales-FINAL