



**Nottingham and  
Nottinghamshire**  
Integrated Care Board

# **Individual Funding Requests (IFR) Commissioning Policy**

**July 2022 - July 2024**

<b>CONTROL RECORD</b>			
<b>Reference Number</b> COM-004	<b>Version</b> 1.1	<b>Status</b> Final	<b>Author</b> Individual Funding Request Manager/ Service Restriction Manager
			<b>Sponsor</b> Director of Integration
			<b>Team</b> IFR Team
<b>Title</b>	Individual Funding Requests (IFR) Commissioning Policy		
<b>Amendments</b>	Review Date amended to July 2024		
<b>Purpose</b>	This policy sets out to ensure that each request for individual funding is considered in a fair and transparent way		
<b>Superseded Documents</b>	Individual Funding Requests (IFR) Commissioning Policy v1.0		
<b>Audience</b>	ICB Clinical Leaders, Care Trust Chief Executives, Foundation Trust Chief Executives, NHS Trusts, Medical Directors, Directors of Public Health, Directors of Nursing, Director of Integration, Directors of Finance, Healthcare professionals who wish to apply for treatments under the IFR Policy		
<b>Consulted with</b>	None		
<b>Equality Impact Assessment</b>	See section 16		
<b>Approving Body</b>	ICB Board	<b>Date approved</b>	1 July 2022
<b>Date of Issue</b>	July 2022		
<b>Review Date</b>	July 2024		
<p><b>This is a controlled document and whilst this policy may be printed, the electronic version available on the ICB's document management system is the only true copy. As a controlled document, this document should not be saved onto local or network drives.</b></p>			

**NHS Nottingham and Nottinghamshire Integrated Care Board (ICB)'s policies can be made available on request in a range of languages, large print, Braille, audio, electronic and other accessible formats from the Engagement and Communications Team at [nnicb-nn.comm@nhs.net](mailto:nnicb-nn.comm@nhs.net)**

# Contents

	<b>Page</b>
<b>1 Introduction</b>	5
<b>2 Purpose</b>	6
<b>3 Scope</b>	6
<b>4 Definitions</b>	7
<b>5 Roles and Responsibilities</b>	9
<b>6 ICB Commissioning Principles that Underpin IFR decision-making</b>	10
<b>7 Policy Guidance</b>	11
• Introduction to new drugs and technologies	11
• Treatments covered by ICB Commissioning Policies	12
• Treatments not covered by ICB Commissioning Policies	12
• Requests to continue funding for Patients coming off drugs trials	13
• Requests to continue funding for treatments commenced ‘at risk’ by Providers or by others (including patients)	13
• Requests to continue funding of care commenced privately eg, reverting to NHS care	14
• Decisions inherited from other ICBs eg, patients who move	15
• Second Opinions	15
• Treatment in another country	15
<b>8 Defining Exceptionality and an Individual Patient</b>	16
• Exceptionality	16
• An Individual Patient	17
<b>9 The Process for Managing Individual Funding Requests (IFR)</b>	18
• Who can submit an IFR?	18
• Administration and Reporting	18
• Timescale for Managing an IFR	18
• Initial Handling of an IFR	19
• Submission of a Treatment Request Form (TRF)	19

•	Triage of a Treatment Request Form	20
•	Identifying Urgent Cases	21
•	Organisation of an IFR Meeting	22
•	Membership of the IFR Panel	22
•	Conflict of Interest	23
•	Decision-making Framework of the IFR Panel	23
•	Demonstrating Exceptional Circumstances	24
•	The likely Clinical Outcomes of the Proposed Treatment	25
•	The Costs of the Proposed Treatment	25
•	Similar Patients	26
•	Recording the Decision	26
•	Outcome of the IFR Panel	26
•	Reconsideration	27
<b>10</b>	<b>Review of IFR Panel Decisions</b>	<b>27</b>
•	Grounds for requesting a review of the IFR Panel Decision	27
•	Initial Consideration of a Request for a Review of the IFR Panel Decision	28
•	Membership of the Review Panel	28
•	Purpose of the Review Panel	28
•	Outcome of the Review Panel	29
<b>11</b>	<b>Equality and Diversity Statement</b>	<b>30</b>
<b>12</b>	<b>Communication, Monitoring and Review</b>	<b>31</b>
<b>13</b>	<b>Staff Training</b>	<b>31</b>
<b>14</b>	<b>Interaction with other Policies</b>	<b>32</b>
<b>15</b>	<b>References</b>	<b>32</b>
<b>16</b>	<b>Equality Impact Assessment</b>	<b>33</b>

## 1. Introduction

- 1.1. This policy applies to the NHS Nottingham and Nottinghamshire Integrated Care Board, hereafter referred to as 'the ICB'.
- 1.2. The NHS exists to serve the needs of all of its patients but also has a statutory duty financially to break even (National Health Service Act 2012). NHS Nottingham and Nottinghamshire Integrated Care Board (ICB) has a responsibility to uphold the pledges of the NHS Constitution, to provide health benefit for the whole of their population, and to commission appropriate care to meet the clinical needs of individual patients. The ICB receives a fixed budget from Central Government with which to commission the healthcare required by its population. Commissioned services include those provided through primary, secondary and tertiary care NHS providers, the independent sector, voluntary agencies and independent NHS contractors and in house service providers.
- 1.3. The ICB does not expect to make significant decisions about funding outside the process that is routinely used and in particular does not expect to commit significant new resources in year to the introduction of new healthcare technologies (including drugs, surgical procedures, public health programmes), since to do so risks ad hoc decision making and can destabilise previously identified priorities.
- 1.4. The Commissioning process, by its very nature, focuses on cohorts of patients with the more common clinical conditions. It cannot meet every healthcare need of all patients in any one clinical group; or address the specific needs of patients with less common clinical conditions. The fact that the ICB is not meeting a healthcare need due to resource constraints is an inevitable fact of life in the NHS and not indicate that the ICB is breaching its statutory obligations.
- 1.5. The ICB is required to have a process for considering funding for individuals who seek NHS commissioned services outside established commissioning policies. There are in general two types of requests that come before an Individual Funding Request (IFR) Panel, namely:
  - Requests for funding treatments for medical conditions where the ICB has no established commissioning policy (as shown by ICB policy or the treatments which are approved for routine funding in service agreements).
  - Requests for funding treatments for medical conditions where the ICB does have an established commissioning policy for that condition but where the requested individual treatment is not in the ICB policy or does not meet the criteria set out in the policy.
- 1.6. This policy requires requests in the first category to be considered against the tests of clinical effectiveness, cost effectiveness and affordability provided the requesting clinician is able to demonstrate that the patient represents an Individual Patient (as defined in this policy who does not have exceptional clinical circumstances). For patients in the second category the policy requires, as a threshold condition, the

requesting clinician to demonstrate that the patient has exceptional clinical circumstances. If the clinician demonstrates that the patient has exceptional clinical circumstances (as defined in this policy) the request will be considered against the tests of clinical effectiveness, cost effectiveness and affordability.

- 1.7. This approach ensures that decisions relating to resource allocation are made transparently and consistently in relation to treatment for those patients with rare conditions, those patients for whom treatments of uncertain or unproven medical benefit are sought, or where treatment costs requested may be out of proportion with the benefit to the patient.
- 1.8. The ICB is responsible for the management of Individual Funding Requests. This policy must be used to consider:
  - Requests for any form of medical treatment or care which is not included within existing service agreements;
  - Requests for any form of medical treatment or care which, for this particular patient, are outside the parameters set by existing service agreements;
  - Requests for any form of medical treatment or care where the treatment or care proposed could not be considered to be 'mainstream'.
- 1.9. NHS Nottingham and Nottinghamshire ICB has established a single IFR process to consider such applications. This may include consideration by an Individual Funding Requests Panel. In considering an individual case the Panel will apply the ICB Commissioning Principles for decision-making set out in Section 6 and the underpinning policies of the ICB.

## **2. Purpose**

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

## **3. Scope**

- 3.1 This policy applies to:
  - All employees of the ICB, any staff who are seconded to the ICB
  - Contract and agency staff and any other individual working on ICB premises.
  - Employees of the ICB, who are seconded to the IFR team, contract and agency staff together with other staff who contribute to the IFR process.

- All referring clinicians within primary, secondary and tertiary care.
- Those treatments and services which are subject to ICB commissioning but are not routinely funded by the ICB and funding needs to be considered on an individual basis. This might include:
  - Interventions not supported by NICE
  - Requests to continue funding for patients previously treated by self-funding or 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 a ICB 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)

3.2 There are, however, a range of specialised services which are currently the commissioning responsibility of NHS England and this policy does not apply to such services and treatments. NHS England will manage any Individual Funding Requests relevant to policies or specialised services they commission.

#### 4. Definitions

Term	Definition
<b>Cost Effectiveness</b>	The cost effectiveness of a treatment or intervention is the ration of its cost to a relevant and accepted clinical measure of its benefit. Cost effectiveness is concerned with gaining maximum health impact for the resource used on a treatment.
<b>Clinical Effectiveness</b>	The clinical effectiveness of a treatment or intervention is best measured using published randomised controlled trials comparing it with “usual”/ control (or no) treatment. Evidence of a lower standard is often used and a “hierarchy” exists to indicate how robust it might be.
<b>Individual Patient</b>	For the purposes of this policy, an Individual Patient is determined by reviewing the incidence and prevalence of the requested intervention for a particular condition at the same stage of progression of that condition.  This is where there is no relevant clinical commissioning policy, NICE Technology Appraisal (TA) guidance or Highly Specialised Technology (HST) Appraisal guidance in place

Term	Definition
	for the management of the patient's condition or combination of conditions, and the patient's clinical presentation is so unusual that they could not be considered to be part of a defined group of patients in the same or similar clinical circumstances for whom a service development should be undertaken.
<b>Incidence and Prevalence</b>	<p><b>Incidence</b> e.g. the number of new cases of a disease in a defined population within a specified period of time the intervention for a particular condition at the same stage of progression of that condition is expected to be initiated for <b>two or fewer</b> patients per million population per year (10 patients across the East Midlands SHA ICB s population per year).</p> <p><b>Prevalence</b> e.g. the number of cases of a disease in a defined population at a point in time. The total number of patients on the intervention for a particular condition at the same stage of progression of that condition is <b>less than 10 patients per million</b> population at any one time (40 patients across the East Midlands population).</p>
<b>Defining Exceptionality</b>	This is where there is a clinical commissioning policy, NICE Technology Appraisal (TA) guidance or Highly Specialised Technology (HST) Appraisal guidance that governs whether to fund or not fund the treatment for the patient's condition, and a clinician can demonstrate that their patient is in a different clinical condition when compared to the typical patient population with the same condition and (if relevant) at the same stage of progression, and because of that difference their patient is likely to receive material additional clinical benefit from treatment that would not be plausible for any typical patient.
<b>IFR Panel</b>	Is the Individual Funding Request Panel that represents the Nottingham ICB that has been authorised to take decisions on its behalf on Individual Funding Requests.



## 5. Roles and Responsibilities

Role	Responsibilities
<b>IFR Panel Chair - Independent Non-Executive Director</b>	Has delegated responsibility to ensure that the IFR Panel works within the process set out in the IFR Policy. Facilitates contributions from panel members ensuring equity among stakeholders. Ensures a balance is struck between time keeping and space for discussion, business is dealt with and actions agreed, actions are clearly assigned and monitored. Keeps up to date on developments in the IFR process.
<b>Director of Nursing / Deputy Director of Nursing</b>	Has delegated responsibility to ensure this policy is applied and adhered to. Deputy Director of Nursing has delegated responsibility in the absence of the Director for Nursing and Quality to ensure this policy is applied and adhered to and provides support to the IFR Panel.
<b>Senior Finance Officer</b>	To ensure and take into account the clinical decision and the cost effectiveness of the treatment.
<b>GP Advisors</b>	The GP Member will contribute to the decision making of the Individual Funding Requests (IFR) regarding the funding of healthcare interventions for individual patients who wish to access treatment not usually funded by the Nottingham and Nottinghamshire ICB. The key responsibility of this role is to ensure that the approved IFR policies, processes and procedures by the ICB are followed.
<b>Public Health</b>	Provides PH support and independent advice to the IFR team, pre-screen panel meetings and IFR Panel. Their role is to give public health advice in relation to clinical appropriateness, clinical effectiveness and cost effectiveness of a treatment. They also perform systematic reviews of the literature and perform individual case reviews based on clinical evidence. Public Health support currently sits with Nottingham

Role	Responsibilities
	City Council for the period August 2021 until September 2022.
<b>Pharmacy Advisors</b>	Provides specialist pharmaceutical support and advice concerning drug IFR cases to the IFR team, pre-screen panel meetings and IFR Panel. Provides specialist input on IFR drug cases including efficacy, safety, cost and cost effectiveness.
<b>IFR Panel</b>	The panel will consider requests on an individual named basis for treatments either not covered by commissioning arrangements or where a treatment is specifically excluded from those arrangements. The panel will be responsible for assessing the clinical effectiveness of the procedure and then the cost effectiveness of the requested treatment based on the evidence available to them at the time. For requests where a treatment is excluded from commissioning arrangements the panel will review the evidence to determine whether the request under consideration is exceptional and should therefore have access to that treatment funded by the NHS

## 6. ICB Commissioning Principles that Underpin IFR decision-making

- 6.1. It is important that the ICB ensures a consistent approach is used to guide the allocation of its resources in both population based and individual commissioning decisions.
- 6.2. A principle based decision-making process supports the strategic planning and the effective use of resources within the ICB. All ICB decisions need to be made in accordance with these principles.
- 6.3. The principles that the ICB seeks to support are:
  - The ICB requires clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
  - The ICB requires clear evidence of cost effectiveness before NHS resources are invested in the treatment;
  - The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;

- The ICB will consider the extent to which the individual or patient group will gain a benefit from the treatment;
- The ICB will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community;
- The ICB will consider all relevant national standards and take into account all proper and authoritative guidance;
- Where a treatment is approved, the ICB will respect patient choice as to where a treatment is delivered.

6.4. When considering an IFR, the ICB will also ensure that decisions:

- Comply with relevant national policies or local policies and priorities that have been adopted by the ICB concerning specific conditions or treatments
- Are based on the available evidence concerning the clinical and cost effectiveness of the proposed treatment, including any NICE publications and;
- 1 principle: a basic truth or a general law or doctrine that is used as a basis of reasoning
- Or a guide to action or behaviour is taken without undue delay; a pragmatic approach may need to be taken when dealing with urgent requests i.e. where a delay in reaching a decision to fund adversely affects the clinical outcome.

6.5. The ICB considers all lives of all patients to be of equal value and in making decisions about funding treatments will seek not to discriminate on the grounds of age, sex, sexuality, race, religion, lifestyle, occupation, family and caring responsibilities, social position, financial status, family status (including responsibility for dependents), intellectual/cognitive functioning or physical functioning save where a difference in the treatment options made available to patients is directly related to the patient's clinical condition or is related to the anticipated clinical benefits for this individual to be derived from a proposed form of treatment.

## **7. Policy Guidance**

7.1. In considering individual cases, the ICB will apply the Commissioning Principles, the underpinning policies of the ICB and the following guidance which expands upon them.

### **Introduction of New Drugs and Technologies**

7.2. With the exception of NICE Technology Appraisals, the ICB will not introduce new drugs/technologies in an ad hoc basis through the mechanism of individual case

funding. To do so risks inequity, since the treatment will not be offered openly and equally to all with equal need. There is also the risk that diversion of resources in this way will de-stabilise other areas of health care which have been identified as priorities by the ICB. The ICB expects consideration of new drugs/technologies to take place within the established planning frameworks of the NHS (for example the Local Operational Plan). This will enable clear prioritisation against other calls for funding and the development of implementation plans which will allow access for all patients with equal need.

### **Treatments covered by ICB Commissioning Policies**

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

### **Treatments not covered by ICB Commissioning Policies**

- 7.5. Specific groups of patients may not be covered by ICB Commissioning Policy including:
  - Patients with conditions for which the ICB does not have an agreed policy, including patients with rare conditions and whose proposed treatment is outside agreed service agreements
  - Patients with conditions for which the ICB does have an agreed policy but who may have exceptional clinical circumstances which lead to their clinician seeking a treatment that is not routinely available.
- 7.6. In such circumstances the ICB will not have given approval in advance to fund the treatment and approval will therefore be required under this policy. The treating clinician should consider, before making the application, whether the requested treatment is an appropriate request judged against the ICB Commissioning Principles.
- 7.7. The role of IFR Panel is to make decisions on individual cases. It cannot be used as a means of 'creeping implementation' for new technologies. Consideration therefore needs to be given as to the likelihood of other patients having the same clinical need who could also benefit from the proposed treatment. If there are or are likely to be other patients then, properly considered, the request is for a

service development and not an individual application. Where a decision may affect other patients, the application should be considered as a service development and not through the IFR process.

- 7.8. Patients with rare conditions should neither be advantaged nor disadvantaged simply because their condition is uncommon. This means that the same approach will be taken in applying the principles of clinical effectiveness and cost effectiveness to patients with rare conditions as should be applied to all other patients.

### **Requests to continue funding for Patients coming off drugs trials**

- 7.9. The ICB does not expect to provide funding for patients to continue medication/treatment commenced as part of a clinical trial. In line with the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Declaration of Helsinki, the responsibility lies with those conducting the trial to ensure a clear exit strategy from a trial AND that those benefiting from treatments provided within the trial setting will have on-going access to those treatments. The initiators of the trial (provider trusts and drug companies) have a moral obligation to continue funding patients benefiting from treatment until such time as the ICB agrees to fund through the commissioning process. Where the treatment is not prioritised through the commissioning process, the responsibility remains with the trial initiators. The Research Ethics Committee should require this assurance as part of the approval for the trial.

### **Requests to continue funding for treatments commenced 'at risk' by Providers or by others (including patients)**

- 7.10. On occasions, a request is received where a provider trust has commenced an unfunded treatment prior to asking for or receiving confirmation that the ICB will approve funding. Evidence that the patient is responding to the treatment is then presented as part of the case for ICB funding.
- 7.11. The provider trust's decision to commence treatment in advance of any decision by the ICB to fund is a clear risk taken by the trust and/or patient. The ICB accepts no responsibility for the decision taken by the provider trust in these circumstances.
- 7.12. In considering a request for funding the ICB will apply the criteria set out in this policy as it would for any other request, and accords no special privileges because the unfunded drug was given by a provider trust.
- 7.13. The ICB policy is that, unless a decision has been taken to approve routine funding for a treatment, the treatment will only be commissioned for an individual patient if the clinician is able to demonstrate that the patient has exceptional clinical circumstances. The fact that a patient has responded to a drug or other treatment in a manner which was anticipated for a proportion of patients who are commenced on

the treatment is unlikely to be sufficient to demonstrate exceptional clinical circumstances.

- 7.14. Where such an application is approved on the basis of the clinician demonstrating that the patient has exceptional clinical circumstances (as defined in this policy), the ICB will not accept responsibility for the costs of any treatment provided by the provider trust prior to authorisation being given by the ICB.
- 7.15. A similar approach will be adopted if a treatment has been funded initially by a pharmaceutical company or other third party.
- 7.16. There are occasions where the initial stages of an unfunded treatment have been funded privately by the patient. The ICB will consider any information submitted on behalf of a patient in support of their case that the patient has exceptional clinical circumstances.
- 7.17. This may include evidence derived from treatment that has been purchased privately and used by the patient. However, this potentially opens the way for a limited group of patients who can afford to fund a treatment that the ICB does not usually fund to be able to demonstrate benefit by virtue of access to private care and then submit this as a reason to justify NHS funding for the treatment in their particular case.
- 7.18. This is a potentially inequitable approach and, in order to ensure that the ICB does not act in an inequitable manner, the issue of exceptional clinical circumstances will therefore continue to be the criteria applied by the IFR process. Accordingly, the ICB adopts no presumption in favour of continuing treatment which has been previously paid for privately by the patient. As stated above, evidence that a treatment works as anticipated for a proportion of patients in the patient's clinical circumstances is unlikely to provide evidence of exceptionality.

#### **Requests to continue funding of care commenced privately eg, reverting to NHS care**

- 7.19. Patients who are having private treatment have a right to revert to NHS funded treatment at any point during their care. However, if they wish to exercise this right, the ICB will expect their care to be transferred to local pathways. Funding for the individual to continue care in a private facility, or to transfer to an NHS provider with which a clinician consulted privately has a contract of employment will not routinely be authorised unless they form part of local pathways. Where personal clinical circumstances may make such funding appropriate the case will require consideration by the IFR process.

### **Decisions inherited from other ICBs eg, patients who move**

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

### **Second Opinions**

- 7.21. A patient has no legal right to a second consultant opinion under current NHS guidance. However, they are entitled to request one and this should normally be approved if:
1. The request is supported by the patient's GP or consultant (the "first consultant opinion");

#### **AND**

2. The second opinion is available from a clinical specialist who practices within a relevant mainstream NHS commissioned specialist service. This opinion needs to provide a balanced view of the benefits and risks and for care which is not routinely commissioned it should be from a specialist who is:
  - independent of the first "consultant opinion" provider;
  - independent of the specific service, service provider or provider of the intervention that is being requested (unless no other specialist is available who could provide that balanced opinion).

#### **AND**

3. The patient is seeking to establish access to care on the grounds of clinical ability to benefit and not social factors (that are not taken into account under Individual Funding Request processes).
- 7.22. Third or fourth opinions for the same clinical condition will not normally be supported unless there are extenuating circumstances.

### **Treatment in another country**

- 7.23. Requests for NHS funded treatment abroad will be considered by NHS England in accordance with the current processes for accessing treatment in European Economic Area (EEA) countries via the S2 route and the Directive route.

## **8. Defining Exceptionality and an Individual Patient**

### **Exceptionality**

- 8.1. The words 'exceptional', 'exceptionality' and 'exceptional clinical circumstances' bear their natural meanings as defined in Oxford English Dictionary. In addition, the NHS Confederation (2008) defined exceptionality as follows: Exceptionality is essentially an equity issue that is best expressed by the question 'on what grounds can funding be justified for this patient when others from the same patient group are not being funded?'
- 8.2. There is a difference between 'individual' and 'exceptional'. Every patient has features of his or her condition which are specific to that individual and are not likely to be repeated in other patients with the same clinical condition at the same stage of progression of the condition. Exceptionality is not the same as individuality.
- 8.3. In order to be able to consider whether a patient has exceptional clinical circumstances the IFR Panel may find it helpful to focus on the following issues:
  - Are there any clinical features of the patient's case which make the patient significantly different to the general population of patients with the condition in question at the same stage of progression of the condition?
  - Would the patient be likely to gain significantly more clinical benefit from the requested intervention than might be normally expected for the general population of patients with the condition at the same stage of the progression of the condition?
- 8.4. The implications of this approach are that if a patient can be seen to be part of a group of patients for whom a treatment is not made available by the ICB under the ICB 's existing policies then exceptionality for this individual patient is unlikely to be demonstrable. In this case the appropriate process for obtaining funding for the requested treatment will be for the ICB to change its policy. Such a change must happen through the normal commissioning process (which will require the development of a business case and for the treatment to be prioritised against other developments) or through the ICB agreeing to make a change to its policy outside the LOP process. Once the change is made it will apply to all similar patients. However, the IFR Process is not the procedure for the ICB to make such policy changes.
- 8.5. The ICB is required to achieve financial balance each year and therefore has a default policy of not funding a treatment where no specific policy exists to approve funding for the treatment. If the ICB has not previously been asked to fund an intervention that has the potential to affect a number of patients, the application should be made by clinicians for the ICB to consider the intervention through its general commissioning policy and not by way of an IFR application.



- 8.6. The ICB policy is that the IFR Team should consider requests for treatments that are not routinely available based on the patient's clinical circumstances. This means that social and personal factors such as age, gender, education, caring responsibilities and family circumstances can only be taken into account where they are relevant to the patient's clinical outcome. Whilst a patient's professional, economic, or social standing or their family responsibilities are important to individuals, the ICB policy is that they are not relevant in assessing whether a patient has exceptional clinical circumstances.

### **An Individual Patient**

- 8.7. For the purposes of this policy, an Individual Patient is determined by reviewing the incidence and prevalence of the requested intervention for a particular condition at the same stage of progression of that condition. If the ICB has no policy for the intervention being requested for a particular condition, then the IFR Panel can only consider the request if both the incidence and prevalence criteria that are set out below are met or the patient has exceptional clinical circumstances compared to the cohort of patients (however small) with the presenting condition. In some cases, ICBs may have adopted policies for small numbers of patients which have often been developed regionally. If the request is covered by such a policy then it should be viewed as a request to change the policy and therefore will not be considered by the IFR policy, even if the incidence and prevalence criteria are met.
- 8.8. An IFR request for an individual patient will be considered by the IFR Panel on its individual merits with the decision on whether to fund a requested intervention based on the evidence of clinical and cost effectiveness and affordability. If both the prevalence and incidence criteria are not met, then the ICB will not consider that the request represents an individual patient. In these circumstances, funding can only be provided if a decision is made by the ICB to develop a policy for the requested intervention for a group of patients, including the requesting patient; unless the patient has exceptional clinical circumstances compared to the cohort of patients (however small) with the presenting condition. Such a change must happen through the LOP process (which will require the development of a business case and for the treatment to be prioritised against other developments) or through the ICB agreeing to develop a policy outside the LOP process. Once the policy is developed it will apply to all similar patients. However, the IFR Process is not the procedure for the ICB to develop such policy.
- 8.9. **Incidence:** e.g., the number of new cases of a disease in a defined population within a specified period of time the intervention for a particular condition at the same stage of progression of that condition is expected to be initiated for two or fewer patients per million population per year (10 patients across the East Midlands SHA ICBs population per year).

- 8.10. **Prevalence:** eg, the number of cases of a disease in a defined population at a point in time. The total number of patients on the intervention for a particular condition at the same stage of progression of that condition is less than 10 patients per million population at any one time (40 patients across the East Midlands population).

## **9. The Process for Managing Individual Funding Requests (IFR)**

### **Who can submit an IFR?**

- 9.1. This policy will apply to any patient for whom the ICB is the responsible commissioner. A doctor, or other health care professional directly involved in the care of a patient, can make a request for an intervention not routinely funded. It is the referring clinician's responsibility to ensure the treatment request form is completed as accurately and comprehensively as possible to avoid possible delays in considering the request. A patient, or a non-clinical representative, may not submit an IFR as a clinical sponsor is required. On receipt of a submission the following IFR process should be followed.

### **Administration and Reporting**

- 9.2. Requests will be date stamped, processed and logged onto the ICB IFR database (Blueteq) by the responsible IFR Officer (normally an IFR Manager).
- 9.3. Acknowledgement will be sent to the referrer within 5 working days, with a copy to the patient/carer or guardian. It will be the responsibility of the IFR Officer to manage all requests received and correspondence with the referrer and patient/carer or guardian.
- 9.4. For each request received, a unique numbered case file will be generated with all paperwork pertinent to the case kept in chronological order. All decisions will be fully documented, and all communication will be in writing whenever possible. When telephone conversations take place, a file note will be added as a record of the conversation. Both the evidence considered, and the decision made will be recorded in writing. All national and local NHS policies regarding confidentiality, retention and destruction of records will be adhered to. The case files will be regularly reviewed by the IFR Panel and an annual report of cases considered by the IFR Panel and Review Panel will be submitted to the ICB Board.

### **Timescale for Managing an IFR**

- 9.5. Requests will be managed within a maximum period of 40 working days from the date of the receipt of a Treatment Request Form to the date of the letter from the ICB informing the requesting clinician of the decision of the IFR Panel. Within this time period, a number of recommended maximum time periods for stages of the

IFR process are set out but these are advisory, rather than mandatory, providing the overall process is completed within the 40-day period.

### **Initial Handling of an IFR**

- 9.6. Cases are initially dealt with, and screened, by the IFR Officer who will advise the referrer whether the existing portfolio of contracts, SLAs or current commissioning policies would cover the request. If a policy exists, and where appropriate, the IFR Officer will check whether the criteria within the policy can be applied. Where clinical advice is required, the IFR Officer will seek advice from the screening pair. Clinically urgent requests will be determined by a senior Public Health professional, nominated by the screening pair, and will be managed under 6.7, „Identifying Urgent Cases“.
- 9.7. If an individual meets the criteria within a policy, and a decision to agree funding can be made at this point by the IFR Officer, then a response will normally be sent to the referrer within 10 working days of the date of acknowledgement of the initial request by the ICB. The IFR Officer is unable to authorise referrals outside existing contractual arrangements.
- 9.8. If the IFR Officer has reason to consider that simple application of SLAs and/or current commissioning policies would be inappropriate for a case, then the IFR Officer should advise the referrer, and the patient/guardian or carer, normally within 10 working days, that an Individual Funding Request must be submitted to the IFR Officer at the ICB using the IFR Treatment Request Form.
- 9.9. A copy of the Guidance Notes for submission of a Treatment Request Form should be included and the Patient Information Leaflet explaining the process (produced by the ICB). If a clinician wishes to discuss whether submission of a Treatment Request Form is appropriate, or would like help with completing the Treatment Request Form, then they should contact the IFR Officer who will then liaise with the screening pair if further advice is required.

### **Submission of a Treatment Request Form (TRF)**

- 9.10. Only a clinician directly involved in the clinical care of the patient (usually their Consultant or GP) can submit a Treatment Request Form. On receipt of a Treatment Request Form, the ICB IFR Officer will acknowledge receipt within 5 working days using a standard letter outlining the ICB IFR process. The patient's GP will be sent a copy of all correspondence regarding the case if they are not the requesting clinician.
- 9.11. Each section of the IFR Form needs to be completed IN FULL in order for the request to progress. Any IFR form which is incomplete will be returned to the requester and the application will not progressed any further until completed and resubmitted as a new request.

### **Triage of a Treatment Request Form**

9.12. The Treatment Request Form will be triaged by the screening pair, consisting of an IFR Manager and a public health consultant. (The Screening Pair).

9.13. The skills and expertise required of the screening pair are the ability to:

- Determine whether an existing policy or SLA adequately covers the treatment request;
- Interpret the ICB definitions of exceptionality and an individual patient in the context of the clinical information that is presented.

The pair will be able to consider four options;

- Approve the request if covered by an existing SLA/ commissioning policy
- Signpost clinicians to specialised commissioning services if applicable
- Refuse the request without reference to the IFR Panel
- Refer to the IFR Panel.

9.14. The criteria that are used to triage a Treatment Request Form is whether there is an arguable case, based on the evidence presented in the application, that the IFR Panel could consider approving funding for the requested treatment under this policy.

9.15. The application will be refused at the triaging stage if:

- The requested treatment arises in relation to a medical condition where there is ICB policy and (a) the requested treatment is not a treatment that is approved under the policy, and (b) there is no arguable case on the evidence presented that the patient can show exceptional clinical circumstances.
- The requested treatment arises in relation to a medical condition where there is no ICB policy and (a) on the evidence presented the requested intervention for that particular condition may affect other patients in the ICB population as defined in this policy under 5.2 and (b) is no arguable case on the evidence presented that the patient can show exceptional clinical circumstances (which will normally be determined by comparing this patient to the cohort of patients (however small) with the presenting condition. so that the request should be properly treated as a request to change the ICB policy.

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

9.17. A routine request will normally be triaged within 10 working days of the date of receipt of the Treatment Request Form by the ICB unless additional information is required when an additional 10 working days will be granted. The requesting

clinician will be contacted by letter and asked to comment on whether any additional information should be included in the Treatment Request Form.

- 9.18. If a request is refused a letter will be sent to the clinician and the patient explaining the reasons for the decision and outlining the options that are available, including using the NHS Complaints Procedure.
- 9.19. If a request is refused at the triaging stage this policy does not provide a right of appeal to the IFR Committee and does not provide a right to request that the decision should be reviewed by the Review Committee. However, the patient has a right to make a complaint under the NHS Complaints Procedure. One outcome of such a complaint could be to require the triaging process to be reconsidered or for the case to be referred to the IFR Panel for consideration. However, if a requesting clinician believes they have significant new clinical evidence that they did not provide in their first submission which they feel may have made a difference to the decision made, then the clinician can submit a new IFR application with this new evidence.
- 9.20. If a request is referred for consideration by the IFR panel a meeting will normally be convened within 20-working days of the date of the triage meeting.

### **Identifying Urgent Cases**

- 9.21. The screening pair can determine that a case is clinically urgent at any point in the IFR process after consultation with the patient's clinician. The timing of an urgent IFR Panel will be based on the individual clinical circumstances and the risks of an adverse clinical outcome if a funding decision on treatment is delayed. Urgent meetings of the IFR panel will be convened at the request of the Chair and will be formally recorded. Ideally all urgent cases will be considered by a face-to-face meeting, but where necessary, communication will be conducted virtually. Decisions that are made urgently outside of a formal IFR Panel meeting will be taken for information to the next meeting of the IFR Panel.
- 9.22. Where an urgent request is required to be considered, the IFR Panel shall continue to follow the procedure set out in this policy. In particular, if a request, even if urgent, may affect other patients with the condition in question at the same stage of progression of the condition, and thus is inappropriate for an IFR request, it shall be refused. Where, in order for the ICB to be able lawfully to commission the requested treatment, the ICB is required to change its commissioning policy, this can only happen if the clinician and/or the patient request the ICB to make an in-year change to its commissioning policy. Such an application must be made outside the IFR policy.

### **Organisation of an IFR Meeting**

- 9.23. The IFR Officer will arrange the date of the meeting and contact the requesting clinician to ask if they wish to submit any further information.
- 9.24. The IFR Officer will provide written correspondence to the patient/carer or guardian to inform them of the date set for consideration by the Panel, to list the items of information that will be presented to the Panel, and to ask them if they wish to provide written information to the Panel. However, the IFR Officer should remind the patient that decisions can only be made on the grounds of the patient's clinical circumstances and not on the basis of the patient's social or personal circumstances. If a patient wishes to provide written information, they should be directed to where they can seek assistance with this eg, to the Patient Experience Team.
- 9.25. The patient/carer or guardian, or their clinical or non-clinical representative, are not entitled to attend the panel in person.
- 9.26. The IFR Officer may also write to other health professionals with clinical involvement in the patient's care (for example consultant, therapist etc.), or to others with specialist knowledge with regard to the condition/intervention, for clarification of the patient's needs, evidence base etc, if appropriate.
- 9.27. A summary of the case will may be produces and considered by the IFR Panel. All documentation that has been received regarding the request will be made available to the panel at least 5 days before the meeting in an anonymised form to protect confidentiality or by way of "Diligent".

### **Membership of the IFR Panel**

- 9.28. NHS Nottingham and Nottinghamshire ICB will have an Individual Funding Request (IFR) Panel. The IFR Panel will consider all cases referred to it by the Screening Pair.
- 9.29. Members of the IFR panel should together have the skills and expertise necessary to make effective, fair and rational decisions by considering the evidence in the Decision Framework Document. The key competencies and experience required within a Panel are:
  - Ability to understand and interpret the clinical information regarding the individual case and place it in the context of a wider clinical population.
  - Ability to understand and interpret clinical and cost effectiveness data (critical appraisal skills;
  - A lay/societal perspective.

- Ability to understand and advise on the broader commissioning policy implications for the ICB including consideration of the intervention in the LOP process.

9.30. The core panel will consist of:

- Independent Chair Non-Executive Director, Nottingham and Nottinghamshire ICB.
- Chief Nurse or Deputy Chief Nurse, Nottingham and Nottinghamshire ICB.
- 4 x General Practitioners, NHS Nottingham and Nottinghamshire ICB.
- Public Health Consultant.
- Senior Finance Officer.

9.31. **In attendance:** Other individuals with specific expertise and skills may also be included on the panel eg, pharmacist, commissioning manager in order to ensure effective and robust decision-making.

9.32. The chair will be an independent lay representative appointed by the ICB. If the chair is unable to attend a meeting the ICB representatives will appoint a Deputy Chair from one of the ICB lay representatives to deputise in the Chairs absence. ICB Representatives must be director level officers of the ICB and will be appointed by the ICB.

9.33. The IFR Officer/Public Health will present the case to the members of the panel. Decisions will be reached by consensus where possible, but if a consensus cannot be achieved, will be decided by a vote of the panel members. If the panel is equally split, then the chair will have a casting vote. The chair will be an independent lay representative appointed by the ICB. If the chair is unable to attend a meeting the ICB representatives will appoint a Vice Chair from one of the ICB lay representatives to deputise in the Chairs absence. ICB Representatives must be director level officers of the ICB and will be appointed by the ICB.

### **Conflict of Interest**

9.34. If any of the members, or any observer, or attendee has a conflict of interest they must declare that conflict as soon as they become aware of it. Any such declaration will be recorded in the minutes together with a summary of the action taken. The Chair will be responsible for determining how any declarations will be dealt with.

### **Decision-making Framework of the IFR Panel**

9.35. The IFR Panel will consist of members of the ICB with mandated authority to make decisions. It is not the role of the IFR Panel to make commissioning policy on behalf

of the ICB. Consideration by the IFR Panel will always state from the overall policy position (whether or not the interventions has been prioritised) and will seek to determine exceptionality on that basis.

9.36. The IFR Panel shall only be entitled to approve requests for funding of treatment for individual funding requests where each of the following conditions are met, either:

1. The clinician makes an individual request for funding for treatment in connection with a patient's presenting medical condition for which the ICB has no policy and where the clinician has demonstrated that the patient represents an Individual Patient (as defined in paragraph 8.7)

**OR**

2. The clinician makes an exceptionality request for funding for treatment in connection with a patient's medical condition for which the ICB has a policy

**AND**

where the clinician has demonstrated that the patient has exceptional clinical circumstances (as defined in paragraph 8.1 above)

**OR**

The clinician makes an exceptionality request for funding for treatment in connection with a medical condition for which the ICB has no policy and where the patient has demonstrated exceptional clinical circumstances (as defined in paragraph 8.1 above). This option would arise if the patient was not an Individual Patient (as defined in paragraph 8.2 above).

- There is sufficient evidence to show that, for the individual patient, the proposed treatment is likely to be clinically effective.
- Applying the approach that the ICB takes to the assessments of costs for other treatments outside this policy, the cost to the ICB of providing funding to support the requested treatment is justified in light of the benefits likely to be delivered for the individual patient by the requested treatment.

### **Demonstrating Exceptional Circumstances**

9.37. The requesting clinician is required to present a full report to the IFR Panel using the Treatment Request Form which sets out a comprehensive and balanced clinical picture of the history and present state of the patient's medical condition, the nature of the treatment requested and the anticipated benefits of the treatment.

9.38. The IFR Panel shall determine, based upon the evidence provided to the panel, whether the patient has demonstrated exceptional clinical circumstances. The evidence to show that, for the individual patient, the proposed treatment is likely to be clinically effective may be part of the case that the patient's clinical circumstances are asserted to be exceptional.



- 9.39. In determining whether a clinician is able to demonstrate that a patient has exceptional circumstances the IFR Panel shall compare the patient to other patients with the same presenting medical condition at the same stage of progression.
- 9.40. The IFR Panel shall take care to avoid adopting the approach described in the “the rule of rescue”. The fact that a patient has exhausted all NHS treatment options available for a particular condition is unlikely, of itself, to be sufficient to demonstrate exceptional circumstances. Equally, the fact that the patient is refractory to existing treatments where a recognised proportion of patients with same presenting medical condition at this stage are, to a greater or lesser extent, refractory to existing treatments is unlikely, of itself, to be sufficient to demonstrate exceptional circumstances.

### **The likely Clinical Outcomes of the Proposed Treatment**

- 9.41. The referring clinician shall:
- describe the anticipated clinical outcomes for the individual patient of the proposed treatment and the degree of confidence of the referring clinician that the outcomes will be delivered for this particular patient;
  - refer to, and preferably include, copies of any clinical research material which supports, questions or undermines the case that is being made that the treatment is likely to be clinically effective in the case of the individual patient.
- 9.42. The IFR Panel shall be entitled but not obliged to commission its own reports from any duly qualified or experienced clinician, medical scientist or other person having relevant skills concerning the case that is being made that the treatment is likely to be clinically effective in the case of the individual patient.
- 9.43. The IFR Panel is not required to accept the views expressed by the referring clinician concerning the likely clinical outcomes for the individual patient of the proposed treatment but is entitled to reach its own views on:
- The likely clinical outcomes for the individual patient of the proposed treatment; and
  - The quality of the evidence to support that decision and/or the degree of confidence that the IFR Panel has about the likelihood of the proposed treatment delivering the proposed clinical outcomes for the individual patient.

### **The Costs of the Proposed Treatment**

- 9.44. The referring clinician shall set out the full attributable costs of and connected to the treatment. The IFR Panel shall be entitled but not obliged to commission its own

reports from any duly qualified or experienced clinician or other duly qualified person concerning the full attributable costs of and connected to the treatment.

- 9.45. The IFR Panel shall, so far as it is able to do so, on the information before it, apply the principles set out in the ICB policy on cost effectiveness when reaching a view as to whether the requested treatment is likely to be cost effective.
- 9.46. In making the decision as to whether the costs of a requested treatment are justified, the IFR Panel shall refer itself to the approach concerning Quality Adjusted Life Years (QALYs) and Incremental Cost Effectiveness Ratio's (ICERs) that the ICB has adopted for other treatments and is required to bear in mind that the resources requested to support the individual patient will reduce the availability of resources for other investments. The IFR Panel shall have a broad discretion to determine whether the proposed treatment is a justifiable expenditure of the ICB 's resources.

### **Similar Patients**

- 9.47. The IFR Panel shall consider whether the request is for a policy variation. If the IFR Panel determines that the case does not refer to an Individual Patient as defined in this policy, then it shall not be entitled to make a decision on the request (unless the patient demonstrates exceptional clinical circumstances in which case the matter shall be considered as an exceptionality request). In the event that the case does not refer to an Individual Patient the IFR Panel shall refer the request to be considered by the ICB Service Development process.
- 9.48. This step is required because the IFR process is not designed to create precedents which may result in the ICB providing or being obliged to provide the same or similar treatment to other patients. Accordingly, if the IFR Panel considers this is not a request about an individual patient then funding can only be provided for the requested treatment if a decision is made by the ICB to amend its policies to provide the treatment for a group of patients, including the requesting patient.

### **Recording the Decision**

- 9.49. The IFR Officer will record the decision of the IFR Panel against each of the above questions on the Decision Framework Document. The completed Decision-making Framework, together with the record of attendance, will form the minutes of the meeting. The minutes will be approved by the Chair of the Panel.

### **Outcome of the IFR Panel**

- 9.50. The IFR Officer will provide written correspondence on behalf of the Chair of the IFR Panel to the referring clinician, and the patient/guardian or carer, within 5

working days to inform them of the outcome of the IFR Panel meeting with the reasons for the panel decision.

- 9.51. If funding was agreed, the IFR Officer will ensure that the clinician is able to deliver the treatment in a timely manner and that a mechanism is in place to monitor the clinical outcome in order to determine whether the treatment has resulted in benefit to the patient.
- 9.52. If funding was not agreed, the IFR Officer will inform the referring clinician, and the patient/guardian or carer, outlining the further options that are available - either reconsideration or review.

### **Reconsideration**

- 9.53. If the referring clinician and/or the patient/guardian or carer believes that there is further relevant information that was not considered by the Panel they may ask the ICB to reconsider the case specifically in the light of this information. The additional information must be submitted to the IFR Officer within 10 working days of the date of the letter from the ICB setting out the panel decision. The ICB Screening Pair will determine, normally within 10 working days, whether the additional information significantly alters the nature and strength of the evidence that was submitted to the initial panel meeting.
- 9.54. If the new information is considered to be significant, a further panel meeting will be convened within the timescales set out for the first panel. If the new information is not considered to be significant, the referring clinician and the patient/guardian or carer will be informed by letter with reasons for the decision not to refer the request back to the IFR Panel.

## **10. Review of IFR Panel Decisions**

### **Grounds for requesting a review of the IFR Panel Decision**

- 10.1. The referring clinician and/or the patient/guardian or carer can make a request to the ICB for a review of the IFR panel decision. The request should be made in writing to the Chief Officer of the ICB and must be lodged within 20 working days of the date of the letter from the ICB setting out the IFR Panel decision. The Chief Officer may exercise discretion in accepting requests outside this time limit if there are good reasons for the delay.
- 10.2. The request for review must set the grounds on which the IFR panel decision is being challenged. A review can be requested on two grounds. It is believed that:
  - The IFR Panel failed to follow due process and, as a result, the decision reached by the panel was different to the one that would be reached if due process had been followed.

- The IFR Panel did not take into account, or weigh appropriately, all relevant evidence when applying the ICB Decision Making Framework.

### **Initial Consideration of a Request for a Review of the IFR Panel Decision**

- 10.3. The request for a review will be initially considered by an officer designated by the ICB to consider these requests. This officer will not have been involved in the original IFR decision. If the officer considers that there is an arguable case to support the review, then a formal Review Panel meeting will normally be convened within 20 working days of the ICB accepting the need for Review. If the ICB does not accept the grounds put forward for a review, a letter will be sent on behalf of the Chief Officer of the ICB to the referring clinician and/or the patient/guardian or carer explaining the reasons for the decision not to review the IFR panel decision.

### **Membership of the Review Panel**

- 10.4. NHS Nottingham and Nottinghamshire ICB will have a Review Panel. The Review Panel will consist of:
- Independent Chair Non-Executive Director, Nottingham and Nottinghamshire ICB;
  - Chief Officer or nominated Executive Director;
  - Senior Medicines Management Representative.
- 10.5. None of these members should have been involved in the case prior to the Review Panel. The panel will only be quorate if all three members are in attendance and decisions will be reached by consensus.

### **Purpose of the Review Panel**

- 10.6. The Review Panel will determine whether the original decision is valid in terms of process followed, the evidence/factors considered and the criteria applied. In deciding the outcome of a review, the Review Panel will consider whether:
- The process followed by the IFR Panel was consistent with that detailed in the IFR Policy
  - The decision reached by the IFR Panel:
    - was consistent with the ICB Commissioning Principles;
    - had taken into account and weighed all the relevant evidence;
    - had not taken into account irrelevant factors;
    - indicates that members of the panel acted in good faith;
    - was a decision which a reasonable IFR panel was entitled to reach.

- 10.7. The Review Panel will only consider the following written documentation:
- The original Treatment Request Form submitted to the ICB;
  - The IFR process records in handling the request;
  - The IFR Panel records, including the Decision Framework Document and any additional supporting information considered by the IFR Panel;
  - The grounds submitted by the referring clinician and/or the patient/guardian or carer in their request for review.
- 10.8. There will be no other representation at the Review Panel from the IFR Panel or the referring clinician and/or the patient/guardian or carer. The Review Panel will not consider new information or receive oral representations. If there is significant new information, not previously considered by the IFR panel, it will be considered as set out in paragraph 9.50 (Reconsideration) above.
- 10.9. The Review Panel will be able to reach one of two decisions:
- To uphold the decision reached by the IFR Panel.
  - To refer the case back to the IFR panel with detailed points for reconsideration
- 10.10. In the event that the Review Panel consider that either:
- The decision may not have been consistent with the ICB Commissioning Principles; or
  - The IFR Panel may not have taken into account and weighed all the relevant evidence; or
  - The IFR Panel may have taken into account irrelevant factors; or
  - The IFR Panel may have reached a decision which a reasonable IFR panel was not entitled to reach.
- 10.11. Then the Review Panel shall refer the matter to the IFR Panel if they consider that there is an arguable case that the requested treatment will be approved by the IFR Panel when it reconsiders the case.
- 10.12. If the Review Panel considers that, notwithstanding their decision on the procedure adopted by the IFR Panel, there is no arguable case that the decision would have been different; the Review Panel shall uphold the decision of the IFR Panel.

### **Outcome of the Review Panel**

- 10.13. The outcome of the Review Panel will be either to uphold the decision of the IFR Panel or to refer the case back to the IFR Panel for reconsideration.
- 10.14. The Review Panel chair will write to the referring clinician, the patient/guardian or carer, and the IFR Panel Chair within 5 working days to inform them of the outcome of the Review Panel meeting with the reasons for the panel decision. Reasons

given should only refer to the IFR policy as this is the basis on which the original decision is made.

- 10.15. If the original IFR Panel decision is upheld, the IFR Officer will inform the referring clinician, and the patient/guardian or carer, of their remaining options - either to pursue a complaint through the ICB Complaints Procedure or to take their case to the Healthcare Ombudsman. The ICB Complaints Policy may be used to review the decision-making process for an individual case and may result in the matter being reconsidered by the IFR Panel.
- 10.16. If the Review Panel determines that the IFR panel needs to reconsider the case, the IFR Panel should reconvene within 10 working days of the date of decision letter from the Chair of the Review Panel. The IFR Panel will reconsider its decision and in doing so will formally address the detailed points raised by the Review Panel. The IFR panel is not bound to change its decision as a result of the case being referred for reconsideration, but if it confirms its original decision, then clear reasons must be given for not agreeing to fund the treatment request.

## **11. Equality and Diversity Statement**

- 11.1. NHS Nottingham and Nottinghamshire ICB pays due regard to the requirements of the Public Sector Equality Duty (PSED) of the Equality Act 2010 in policy development and implementation as a commissioner and provider of services, as well as an employer.
- 11.2. The ICB is committed to ensuring that the way we provide services to the public and the experiences of our staff does not discriminate against any individuals or groups on the basis of their age, disability, gender identity (trans, non-binary), marriage or civil partnership status, pregnancy or maternity, race, religion or belief, gender or sexual orientation.
- 11.3. We are committed to ensuring that our activities also consider the disadvantages that some people in our diverse population experience when accessing health services. Such disadvantaged groups include people experiencing economic and social deprivation, carers, refugees and asylum seekers, people who are homeless, workers in stigmatised occupations, people who are geographically isolated, gypsies, roma and travellers.
- 11.4. As an employer, we are committed to promoting equality of opportunity in recruitment, training and career progression and to valuing and increasing diversity within our workforce.
- 11.5. To help ensure that these commitments are embedded in our day-to-day working practices, an Equality Impact Assessment has been completed for, and is attached to, this policy.

## **12. Communication, Monitoring and Review**

- 12.1. The IFR process will be monitored and reviewed every three years both to ensure that decision-making is fair and consistent, and to ensure that the panel are considering the appropriate cases e.g., that both the triage of requests and the panel work effectively. The IFR panel will hold a quarterly meeting to review the IFR database with the IFR Officer to evaluate the process ,either face to face or virtually including the consistency of decision-making, and to consider any improvements that could be made.
- 12.2. The ICB will also put in place a mechanism to receive feedback by patients and requesting clinicians as part of the evaluation of the IFR policy and to contribute to on-going process improvement.
- 12.3. This policy will be reviewed and approved by the Strategic Planning and Integration Committee every three years and published on the ICB's Website and internal Intranet site for staff to view.
- 12.4. Any individual who has queries regarding the content of this policy, or has difficulty understanding how this policy relates to their role, should contact the IFR Team on [nnicb-nn.ifrteam@nhs.net](mailto:nnicb-nn.ifrteam@nhs.net).

## **13. Staff Training**

- 13.1. Members of an IFR Panel (and Review Panel) should together have the skills and expertise necessary to enable them to make effective decisions. Members will need on-going training to undertake this role, in particular to enable them to comprehend and interpret complex data, and also in the legal and ethical aspects of the panels work. It is also important to establish a "core" group of individuals who are regularly involved in IFR decision-making to gain the necessary breadth of experience from handling a wide range of clinical cases.
- 13.2. All members of an IFR Panel (and Review Panel) will undergo mandatory induction training organised by the Public Health Directorate of the ICB. This will cover both the legal and ethical framework for IFR decision making, the ICB commissioning processes and structures, and technical aspects of the interpretation of clinical evidence and research. This training will be regularly refreshed to ensure that all panel members maintain the appropriate skills and expertise to function effectively.

## 14. Interaction with other Policies

14.1. This policy should be read in conjunction with the following:

- NHS England Manual for prescribed specialised services;
- The ICB's fertility policies;
- Service Restriction Commissioning Policy;
- Standards of Business Conduction Policy;
- NICE Guidance.

## 15. References

15.1. The following references have been used in the creation of this policy:

- Supporting rational local decision-making about medicines (and treatments)

Available from: [Developing and updating local formularies \(nice.org.uk\)](https://www.nice.org.uk/guidance/developing-and-updating-local-formularies)

- Defining DH guiding principles for processes supporting local decision-making about medicines (January 2009).

Available from [Context | Developing and updating local formularies | Guidance | NICE](https://www.nice.org.uk/guidance/context-developing-and-updating-local-formularies)

- Improving Access to medicines for NHS patients.

Available from: [prof-richards-report.pdf \(publishing.service.gov.uk\)](https://www.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/414817/prof-richards-report.pdf)

- Priority setting: an overview. 2021

Available from: [NHS England » Priority setting](https://www.nhs.uk/priorities/priority-setting/)

- Priority setting: managing individual funding requests. (2017).

Available from: [comm-policy-individual-funding-requests.pdf \(england.nhs.uk\)](https://www.england.nhs.uk/comm-policies/individual-funding-requests/)

- IFR Policy NHS England

[comm-policy-individual-funding-requests.pdf \(england.nhs.uk\)](https://www.england.nhs.uk/comm-policies/individual-funding-requests/)



## 16. Equality Impact Assessment

An Individual Funding Request (IFR) is a request to fund a healthcare intervention for an individual that falls out of the range of services and treatments that the local ICB has agreed to commission.

This Policy describes the principles and framework by which the IFR process operates, the processes by which NHS Clinicians make funding requests on behalf of their patients and refers to the commissioning policies which guide the IFR Panel through their decision-making.

It sets out a framework which is designed to ensure consistently fair and equitable consideration of requests for funding or treatment outside routine contractual agreements.

<b>Date of assessment:</b>	June 2022			
<b>For the policy, and its implementation, please answer the questions against each of the protected characteristic and inclusion health groups:</b>	Has the risk of any potential adverse impact on people in this protected characteristic group been identified, such as barriers to access or inequality of opportunity?	If yes, are there any mechanisms already in place to mitigate the adverse impacts identified?	Are there any remaining adverse impacts that need to be addressed? If so, please state any mitigating actions planned.	Are there any positive impacts identified for people within this protected characteristic group? If yes, please briefly describe.
<b>Age<sup>1</sup></b>	None identified	N/A	None	None
<b>Disability<sup>2</sup></b>	No discrimination within policy, however this group of patients may require additional support from clinicians to have the processes within the policy	N/A	None	None

<sup>1</sup> A person belonging to a particular age (for example 32 year olds) or range of ages (for example 18 to 30 year olds).

<sup>2</sup> A person has a disability if she or he has a physical or mental impairment which has a substantial and long-term adverse effect on that person's ability to carry out normal day-to-day activities.

	explained. As this policy is for clinicians no plain text or large print version available as far as I am aware? Continued commitment to hidden disabilities and most certainly learning disabilities			
<b>Gender reassignment<sup>3</sup></b>	None identified. Trans, continued inclusivity in services, GP support and potential increase in demand on mental health services	N/A	None	None
<b>Marriage and civil partnership<sup>4</sup></b>	None identified	N/A	None	None
<b>Pregnancy and maternity<sup>5</sup></b>	None identified			
<b>Race<sup>6</sup></b>	Increase in non-English Speakers over the last few years and emerging	N/A	None	None

<sup>3</sup> The process of transitioning from one gender to another.

<sup>4</sup> Marriage is a union between a man and a woman or between a same-sex couple. Same-sex couples can also have their relationships legally recognised as 'civil partnerships'.

<sup>5</sup> Pregnancy is the condition of being pregnant or expecting a baby. Maternity refers to the period after the birth, and is linked to maternity leave in the employment context. In the non-work context, protection against maternity discrimination is for 26 weeks after giving birth, and this includes treating a woman unfavourably because she is breastfeeding.

<sup>6</sup> Refers to the protected characteristic of race. It refers to a group of people defined by their race, colour, and nationality (including citizenship) ethnic or national origins.

	communities, such as Asylum seekers and Refugees. Considerations in communication and interpreter services, including for GPs, increase in demand for Mental Health Support			
<b>Religion or belief<sup>7</sup></b>	None identified	N/A	None	None
<b>Sex<sup>8</sup></b>	None identified	N/A	None	None
<b>Sexual orientation<sup>9</sup></b>	Continued inclusivity in services	N/A	None	None
<b>Carers<sup>10</sup></b>	None identified	None	None	None

<sup>7</sup> Religion refers to any religion, including a lack of religion. Belief refers to any religious or philosophical belief and includes a lack of belief. Generally, a belief should affect your life choices or the way you live for it to be included in the definition.

<sup>8</sup> A man or a woman.

<sup>9</sup> Whether a person's sexual attraction is towards their own sex, the opposite sex, to both sexes or none. <https://www.equalityhumanrights.com/en/equality-act/protected-characteristics>

<sup>10</sup> Individuals within the ICB which may have carer responsibilities.