NHS
Nottingham and Nottinghamshire
Integrated Care Board

Individual Funding Requests (IFR) Commissioning Policy

June 2024 - June 2027

CONTROL RECORD	
Title	Individual Funding Requests (IFR) Commissioning Policy
Reference Number	COM-004
Version	2.0
Status	Final
Author	Individual Funding Request Manager / Service Restriction Manager
Sponsor	Director of Integration
Team	Individual Funding Requests Team
Amendments	This publication is an update of the existing published policy on the management of Individual Funding Requests (IFRs) and outlines the criteria which are used for decision-making.
Purpose	This policy sets out to ensure that each request for individual funding is considered in a fair and transparent way
Superseded Documents	Individual Funding Requests (IFR) Commissioning Policy v1.1
Audience	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. Compliance with the ICB policy is a formal contractual requirement and failure to comply with the policy, including any arrangements which are put in place under it, will be investigated and may lead to disciplinary actions being taken.
Consulted with	None
Equality Impact Assessment	Completed
Approving Body	Strategic Planning and Integration Committee
Date approved	6 June 2024
Date of Issue	June 2024
Review Date	June 2027
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.	

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

Contents

1. Introduction

1.1. This policy applies to the NHS Nottingham and Nottinghamshire Integrated Care Board, hereafter referred to as 'the ICB'. ICBs were established under the Health and Care Act 2022 (NHS Act 2022 as amended) Health and Care Act 2022 (legislation.gov.uk). This has the function of arranging the provision of services for the purpose of the health service in England in accordance with this Act.

1.2. The ICB has a statutory duty financially to break even, as detailed in the NHS Act 2006, Section 223CG: National Health Service Act 2006 (legislation.gov.uk) and has a responsibility to uphold the pledges of the NHS Constitution, to provide health benefit for the whole population, and to commission appropriate care to meet the clinical needs of individual patients.

1.3. The IFR Commissioning Policy has been developed in response to the legal duties on financial balance, as set out in the NHS Constitution. The NHS Constitution for England - GOV.UK (www.gov.uk) which identifies two patient rights under the section titled 'Nationally approved treatments, drugs and programmes':

- 'You have the right to drugs and treatments that have been recommended by NICE for use in the NHS, if your doctor says they are clinically appropriate for you';
- You have the right to expect local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you, they will explain that decision to you'.

1.4. 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.

1.5. The ICB does not expect to make significant decisions about funding outside the process that is routinely used and 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.

1.6. The intended audience of this policy is those responsible for the operation of the IFR process and related decision-making. It will also be of interest to those wishing to apply for funding of treatments under the Individual Funding Request Policy. This policy should be read in conjunction with the ICB's Ethical Decision-Making Framework. https://notts.icb.nhs.uk/wp-content/uploads/sites/2/2022/04/COM-002-Ethical-Decision-Making-Framework-v1.0.pdf

1.7. 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.

1.8. 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.

1.9. This policy requires requests in the first category to consider clinical effectiveness, cost effectiveness and affordability provided the requesting clinician is able to demonstrate 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 could be undertaken. 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 evidence for clinical effectiveness, cost effectiveness and affordability.

1.10. 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.

1.11. 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'.

1.12. The ICB has established a single IFR process to consider such applications. This may include consideration by an IFR Panel. In considering an individual case the Panel will apply the ICB Commissioning Principles for decision-making set out in Section 7 and the underpinning policies of the ICB.

2. Purpose

2.1 The purpose of the IFR commissioning policy is to:

- Set the decision-making process within an ethical context and to demonstrate a clear process for decision-making.
- Ensure decisions are made in a fair, open, transparent and consistent manner.
- Provide a firm and robust standard in which requests can be reviewed, via the ICB's complaints process.

2.2 The policy clearly sets out the process to be followed for an IFR request to be made.

2.3. 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.

2.4. This process will ensure that each request for individual funding is considered in a fair and transparent way, with decisions based on the available evidence and in accordance with the ICB commissioning principles.

2.5. Personal Health Budgets (PHBs), Continuing Healthcare (CHC) for adults, Childrens Continuing Care (CCC) and Mental Health medicines and treatments fall outside of the IFR process and as such, are not covered within this policy and applications should not be submitted via the IFR process.

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 Public Health and other staff who contribute to the IFR process.
- All referring clinicians within primary, secondary, independent sector treatment centres 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 ICB commissioning responsibility 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 a range of specialised services which are the commissioning responsibility of NHS England. 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
Clinical Effectiveness	Clinical effectiveness is a measure of the extent to which a treatment achieves pre-defined clinical outcomes in a specific group of patients. 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.
Cost Effectiveness	Cost effectiveness involves an assessment of whether a treatment provides value for money. Costs are balanced against the degree of benefit likely to be obtained from funding the treatment or intervention.
Individual Patient	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.

Term	Definition
	This is where there is no relevant clinical commissioning policy 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.
Incidence and Prevalence	Incidence and prevalence are measures of disease frequency. **Incidence** is the number of new cases of a disease in a defined population within a specified period of time. **Prevalence** is the total number of cases of a disease in a defined population at a point in time. For this policy, if there is no relevant clinical commissioning policy, the patient represents an Individual Patient if the incidence is two or fewer patients (with a particular condition at the same stage of progression) per million population per year and prevalence is less than 10 such patients per million population at any one time (that are at the same stage requiring the same intervention).
Defining Exceptionality	See below in section 5.
IFR Panel	This is the Individual Funding Request Panel that represents the Nottingham and Nottinghamshire ICB that has been authorised to take decisions on its behalf on Individual Funding Requests.
IFR Review Panel	This is the Individual Funding Request Review Panel that represents the ICB and have been authorised to review funding request decisions, to determine whether the original decision made is valid in terms of process followed, the evidence/factors considered, and the criteria applied.

5. Clinical Exceptionality

5.1 There can be no exhaustive description of the situations which are likely to come within the definition of exceptional clinical circumstances. The onus is on the clinician making the request to set out the grounds for clinical exceptionality clearly for the IFR Panel.

5.2 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?
- ‘Exceptional’ in IFR terms means a person to whom the general rule should not apply. This implies that there is likely to be something about their clinical situation which was not considered when formulating the general rule. Very few patients have clinical circumstances which are genuinely exceptional. To justify funding for treatment for a patient which is not available to other patients, and is not part of the established care pathway, the IFR Panel needs to be satisfied that the clinician has demonstrated that this patient’s individual clinical circumstances are clearly different to those of other patients, and that because of this difference, the general policies should not be applied. Simply put, the consideration is whether it is fair to fund this patient’s treatment when the treatment is not available to others. It should be stressed that an IFR is not a route to "have another look" at the general rule, or to protest that the general rule is ungenerous.
- 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.

5.3 Where a ‘not for routine commissioning’ clinical commissioning policy is in place in relation to a treatment, the ICB will have been aware when making that policy that in most studies, some patients will respond better than others to the treatment and indeed, a small group may respond significantly better than the average. This should have been taken into account in developing the policy. Consequently, in considering whether a request for an IFR should be made, the clinician should consider whether this individual patient is likely to respond to the treatment in a way that exceeds the response of other patients in the group to which the general policy applies, and whether there is evidence to support this view.

Clinical exceptionality: failure to respond to standard care

5.4 The fact that a patient has failed to respond to, or is unable to be provided with, all treatment options available for a particular condition (either because of a co-morbidity or because the patient cannot tolerate the side effects of the usual treatment) is unlikely, on its own, to be sufficient to demonstrate exceptional clinical circumstances. There are common co-morbidities for many conditions.

Again, these considerations are likely to have been considered in formulating the general policy.

5.5 Many conditions are progressive and thus inevitably there will be a more severe form of the condition – severity of a patient's condition does not in itself usually indicate exceptionality. Many treatments have side effects or contraindications, and thus intolerance or contraindication of a treatment does not in itself, usually indicate exceptionality.

5.6 To support an IFR on the basis of failure to respond to standard care, 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 a genuinely exceptional circumstance, which lies outside the natural history of the condition and is not characteristic of the relevant group of patients with the condition. For example:

- If the usual treatment is only effective for a proportion of patients (even if this is a high proportion), this leaves a proportion of patients within the group for whom it is already known that the usual treatment is not available or is not clinically effective. The fact that this particular patient falls into that group is unlikely to be a proper ground on which to base a claim that they are exceptional as an individual.
- As regards side effects, as an example, all patients who are treated with long-term high-dose steroids will develop side effects (typical and well recognised). Developing these side effects and wishing to be treated with something else does not make the patient exceptional.
- If the usual treatment cannot be given because of a pre-existing comorbidity which is unrelated to the condition for which the treatment is being sought under the IFR or is not unusual in the relevant patient group or generally, the fact that the comorbidity is present in this patient and its impact on treatment options for this patient is unlikely to make the patient clinically exceptional. As an illustration, some comorbidities are common in the general population, for example, diabetes which affects around 7% of adults, or asthma which affects at least 10% of the population. Diabetes and its treatments affect many other conditions; for example, steroids make glucose control more difficult. With any condition there will be a recognised proportion who also have a comorbidity which is common in the general population, therefore a patient cannot be exceptional by having a comorbidity which is common in the general population.

5.7 If the proposed intervention is thought to offer a benefit to patients in these groups generally (i.e. those with more severe disease or those with common comorbidities), the question is whether there is sufficient justification, including consideration of factors such as clinical effectiveness of the treatment in question, likely value for money, priority and affordability, for making a change to the clinical commissioning policy that covers the patient pathway. In this way, an improvement

can be made to that policy to benefit the whole subgroup of patients of which the requesting patient is potentially just one such person. This change needs to be considered as a service development and not as an IFR.

Clinical exceptionality: severity

5.8 Should severity be cited by the requesting clinician as part of the argument for exceptionality, the application should make clear:

- Whether there is evidence that the patient's presentation lies outside the normal spectrum for that condition. Preferably, a recognised scoring or classification system should be used to describe the patient's condition.
- Whether there is evidence that the patient has progressed to a very severe form of the condition much more rapidly than the range of progression that is documented and usually observed within the natural history of the condition
- How the patient is expected to benefit from the treatment sought and in what quantifiable way
- That there is evidence that the impact of the condition on this patient's health is significantly greater than its impact on the rest of the patient group, e.g., the condition is usually a mild disease, but the presenting case is an extremely severe presentation; and
- That there is a plausible argument that the severity of the condition is prognostic of good response to treatment.

Clinical exceptionality: genotypes

5.9 When the argument for clinical exceptionality is based on the patient having a specific genotype (genetic profile), the IFR Panel will require evidence of the prevalence of the genotype in the patient group. The applicant will need to show how the specific genotype would make the patient a) different to others in terms of clinical management and b) able to benefit from the treatment to a greater degree than others with the same or different symptoms of the condition.

Clinical exceptionality: multiple grounds

5.10 There may be cases where clinicians seek to rely on multiple factors to show that their case is clinically exceptional. In such cases each factor will be looked at individually to determine (a) whether the factor is capable, potentially, of making the case exceptional and (b) whether it does in fact make the patient's case exceptional. One factor may be incapable of supporting a case of exceptionality (and should therefore be ignored), but that factor might be relevant to/in

conjunction with another factor (see also paragraph 5.10). That is a judgment within the discretion of the IFR Screening and IFR Panel.

5.11 If it is determined that none of the individual factors on their own mean that the patient's clinical circumstances are considered exceptional, the combined effect of those factors as a whole will be considered. In this way a decision can be reached on whether the patient's clinical circumstances are exceptional, bearing in mind the difference between the range of factors that can always be found between individuals and the definitions used here of exceptional clinical circumstances.

Clinical exceptionality: non-clinical and social factors

5.12 The IFR process only considers clinical information. Although initially it may seem reasonable to fund treatment based on reasons grounded in a moral or compassionate view of the case or because of the individual's situation, background, ambition in life, occupation or family circumstances, these reasons bring into play a judgement of 'worthiness' for treatment. As a central principle, the NHS does not make judgements about the worth of different individuals and seeks to treat everyone fairly and equitably. Consideration of these non-clinical factors would introduce this concept of 'worth' into clinical decision-making. It is a core value that NHS care is available or unavailable, equally to all. Whilst everyone's individual circumstances are, by definition, unique and on compassionate grounds, reasons can always be advanced to support a case for funding, it is likely that the same or similar arguments could be made for all or many of the patients who cannot routinely access the care requested.

5.13 Non-clinical and social factors have to be disregarded for this purpose, to be confident of dealing in a fair manner in comparable cases. If these factors were to be included in the decision-making process, the ICB would not know whether it is being fair to other patients who cannot access such treatment and whose non-clinical and social factors would be the same or similar.

5.14 Consideration of social factors would also be discriminatory in the provision of medical treatment. If, for example, treatment was to be provided on the grounds that this would enable an individual to stay in paid work, this would potentially discriminate in favour of those working compared to those not working. These are value judgements which the IFR Screening pair and IFR Panel should not make.

5.15 Clinicians are asked to bear this policy in mind and not to refer to social or non-clinical factors to seek to support the application for individual funding. In order to avoid prejudicing the IFR process, such material will be edited out or applications returned to clinicians for editing by the IFR team and on recommendation by the Screening pair.

5.16 In order to be able to consider whether a patient has exceptional clinical circumstances, it is helpful to focus on the following:

- Are there any clinical features/factors 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?

AND (because of this difference)

- 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?

5.17. 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 ICBs existing policies then exceptionality for this 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 happens 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. 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.

An Individual Patient

5.18 For the purposes of this policy, exceptionality of 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, the ICB 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.

5.19 An IFR 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 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 develop a policy outside the ICB's commissioning 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.

5.20 Incidence describes the number of new cases of a disease in a defined population within a specified period of time. To satisfy the incidence criterion, 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 population per year).

5.21 Prevalence describes the number of cases of a disease in a defined population at a point in time. To satisfy the prevalence criterion, the total number of patients on the intervention for a particular condition at the same stage of progression of that condition should be less than 10 patients per million population at any one time (40 patients across the East Midlands population).

6. Roles and Responsibilities

Role	Responsibilities
IFR Panel Chair	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.
Chief Nurse/Deputy Chief Nurse Assistant Director of Nursing and Quality	Has delegated responsibility to ensure this policy is applied and adhered to. Deputy Chief Nurse and Assistant Director of Nursing and Quality has delegated responsibility in the absence of the Chief Nurse to ensure this policy is applied and adhered to and provides support to the IFR Panel.
Senior Finance Officer	To ensure the cost effectiveness of the treatment.
GP Advisors	The GP Member will contribute to the decision-making on the Individual Funding Requests.

Role	Responsibilities
	(IFR) for treatment not usually funded by the Nottingham and Nottinghamshire ICB. The key responsibility of this role is to provide clinical advice and ensure that the approved IFR policies, processes and procedures by the ICB are followed.
Public Health	Provide Public Health support and independent advice to the IFR team and IFR Panel on the intervention requested. Their role is to give public health advice in relation to clinical effectiveness and cost effectiveness of a treatment. This is based on the provided evidence. They also advise on when further evidence may need to be requested and reviews of the literature.
Pharmacy Advisors	Provide specialist pharmaceutical support and advice concerning drug related IFR cases to the IFR team and IFR Panel. Provide specialist input on drug related IFR cases including efficacy, safety, cost and cost effectiveness.
IFR Panel	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 against the IFR Decision Framework.
IFR Review Panel	The review Panel (which consists of different people to the original panel) will review funding request decisions, where a Request for a Review has been submitted, and is considered to be appropriate following re-screening, to determine whether the original decision made is valid in terms of process followed, the evidence/factors considered, and the criteria applied.

7. ICB Commissioning Principles that underpin IFR decision-making

7.1 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.

7.2 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.

7.3 The principles that the ICB seeks to support are linked to the Ethical Decision-Making Framework in relation to principles 1-5.

7.4 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;
- Action 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.

7.5 The ICB considers all lives of all patients to be of equal value and in making decisions about funding treatments will not discriminate on the grounds of protected characteristics except 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.

8. Policy Guidance

8.1 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

8.2 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 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.

NICE New Technology Appraisals (TAs)

8.3 Drugs and technologies that are approved as the result of a NICE TA need to be implemented within three months of the appraisal being published. The ICB will, within resource constraints, seek to ensure implementation of NICE TAs without delay but recognises that the ICB may take the full period of three months before a new commissioning policy can be brought into place where significant service change and/or development are required as part of the implementation. NICE also produces clinical guidelines which are a valuable source of good practice which the ICB will take into account in developing policy, but the ICB retains discretion and is not mandated by directions to implement such Guidance within a fixed time period or at all.

Treatments covered by ICB Commissioning Policies

8.4 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.

8.5 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

8.6 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.

8.7 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.

8.8 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.

8.9 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

8.10 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 (legislation.gov.uk) and the Declaration of Helsinki https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/ , 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)

8.11 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.

8.12 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.

8.13 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.

8.14 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 the patient, if the clinician is able to demonstrate that the patient has exceptional clinical circumstances as per this policy. 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.

8.15 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.

8.16 A similar approach will be adopted if a treatment has been funded initially by a pharmaceutical company or other third party.

8.17 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.

8.18 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.

8.19 This is a potentially inequitable approach and, 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 e.g., reverting to NHS care

8.20 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.

8.21 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 e.g., patients who move

8.22 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

8.23 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).

8.24 Third or fourth opinions for the same clinical condition will not normally be supported unless there are extenuating circumstances.

Treatment in another country

8.25 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 The

Planned Treatment (S2 funding) route - NHS (www.nhs.uk). NHS England will liaise with the ICBs IFR team for information regarding the patient's entitlement to seek treatment abroad.

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 IFR Application form (see Appendix A) 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 processed and logged onto the ICB IFR database (Blueteq) by the responsible IFR Manager/Officer.

9.3 The patient information for all requests are checked against the NHS summary care record to ensure the correct patient data is documented and the ICB are the responsible commissioner.

9.4 Acknowledgement will be sent to the referrer within 5 working days, with a copy to the patient/carer or guardian (if they have formally consented to this in the IFR application form). It will be the responsibility of the IFR Manager/Officer to manage all requests received and correspondence with the referrer and patient/carer or guardian.

9.5 For each request logged, a unique reference number is generated. All paperwork pertinent to the case will be 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.

9.6 All national and local NHS policies regarding confidentiality, retention and destruction of records will be adhered to. An annual report of cases considered by the IFR Panel and Review Panel will be submitted to the ICB.

9.7 It is the responsibility of the IFR Manager/Officer to manage all requests received to conclusion.

Timescale for Managing an IFR

9.8 Requests will be managed within a maximum period of 40 working days from the date of the receipt of a IFR Application Form to the date of the letter from the ICB informing the requesting clinician, via email, 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. This timescale may be exceeded where there is a delay in receiving any required additional information, in order that the request can be appropriately fully considered.

Initial Handling of an IFR

9.9 All IFR Application forms are initially dealt with, and screened, by the IFR Manager/Officer who will advise the referrer whether the existing portfolio of contracts, Service Level Agreements (SLAs) or current commissioning policies would cover the request. If a policy exists, and where appropriate, the IFR Manager/Officer will check whether the criteria within the policy can be applied. Where clinical and public health advice is required, the IFR Manager/ Officer will review requests with a GP clinical advisor to the panel and Public Health nominated member of staff.

9.10 Clinically urgent requests submitted by a referring clinician will be managed under the 9.24 “Identifying Urgent Cases".

9.11 If an individual meets the criteria within a policy, and a decision to agree funding can be made at this point by the IFR Manager/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 Manager/Officer is unable to authorise referrals outside existing contractual arrangements.

9.12 If the IFR Manager/Officer has reason to consider that simple application of SLAs and/or current commissioning policies would be inappropriate, a value-based commissioning prior approval form would be required.

9.13 A copy of the Guidance notes for Clinicians on the Individual Funding Request (IFR) process (see Appendix B) should be included and the Individual funding requests a guide for patients (see Appendix C) explaining the process (produced by the ICB). If a clinician wishes to discuss whether submission of an Individual Funding Request Form is appropriate or would like help with completing the Individual Funding Request Form, then they should contact the IFR Manager/Officer. Requests should be sent via email to the IFR team at nnicb-nn.ifrteam@nhs.net

Submission of an Individual Funding Request Form (IFR)

9.14 An IFR Application form will need to be completed for every request. The completion of an IFR Application form ensures that the same level of relevant clinical information is provided for every IFR, regardless of the nature of intervention/treatment requested or the patient's condition. Using a standard submission form makes a significant contribution to consistency of decision-making by presenting comparable information in a structured format to the IFR Panel if applicable. On receipt of a completed IFR Application 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.

9.15 Each section of the IFR Application Form needs to be completed IN FULL in order for the request to progress. Any IFR Application form which is incomplete will be returned to the requester and the application will not progress until a fully completed form has been resubmitted.

Triage of a IFR Request Form

9.16 The IFR Application Form will be triaged by the screening pair, consisting of an IFR Manager and IFR Officer. The request will be anonymised and forwarded to Public Health Consultant/GP clinical advisor/ Pharmacy Advisor for review, and to obtain their advice.

9.17 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 referring to the IFR Panel.
- Refer to the IFR Panel.

9.18 The criteria that are used to triage an IFR Application 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

9.19 The application will not be progressed at the triage stage if:

- The requested treatment arises in relation to a medical condition where there is ICB policy and

  (a) the requested treatment criteria are not met within the policy for individual patients and

  (b) there is no arguable case to evidence exceptional and/or individual clinical circumstances

- The requested treatment arises in relation to a medical condition where there is no ICB policy and

  (a) There is a cohort of patients - and

  (b) There is no arguable case on the evidence presented that the patient has exceptional clinical circumstances (which will normally be determined by comparing this patient to the cohort of patients (however small) with the presenting condition) These requests should be reviewed as a potential service/commissioning policy development.

9.20 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.

9.21 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.

9.22 If a request is refused at the triaging stage, this policy does not provide the right to Request a Review (appeal). This is because the request has not been progressed for IFR panel consideration. However, the patient does have the right to make a complaint, in line with the ICBs Complaints Policy.

9.23 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 within 10 working days of the outcome decision letter, with this new evidence.

Identifying Urgent Cases

9.24 IFRs must be considered carefully and with the benefit of all the required information, in line with the processes set out in this policy. Clinicians are encouraged to submit IFRs in a timely manner which has regard to the standard decision-making timescale. As far as possible, clinicians should avoid waiting until a case becomes clinically urgent before submitting an IFR.

9.25 IFRs should only be classified as urgent where there is a clear clinical reason to do so. This will usually be that the patient's health will be significantly

compromised by waiting until the next scheduled IFR Panel meeting. It is expected that only a small minority of IFRs will be dealt with in this way, and these will usually involve life-threatening conditions. IFRs will not be classified as urgent on the basis that waiting until the next IFR Panel is inconvenient or problematic for the patient or requesting clinician. Any administrative delay on the part of the referring clinician will not be considered as urgent and the application will be processed through the routine IFR process.

9.26 Clinically urgent IFRs will be determined by the referring clinician. The timing of an urgent IFR will be based on the individual clinical circumstances and the risks of an adverse clinical outcome if a funding decision on treatment is delayed. Normally, urgent IFRs will be referred to the next available IFR Panel meeting for consideration. In instances whereby the timescale of the next IFR Panel is deemed too far in advance, the decision-making process would involve consideration outside of IFR Panel. The decision-making process for urgent IFRs will be determined by the IFR Panel Chair or nominated deputy, an ICB Representative and the Public Health Consultant/GP Clinical Advisor. This is the minimum number required to be quorate for consideration of urgent cases. Decisions that are made outside of an IFR Panel will be submitted to the next IFR Panel for final ratification.

9.27 Where an urgent IFR consideration is required, the IFR Panel will follow the process set out in this policy. The ICB has no obligation to fund treatment that has commenced before approval. Under no circumstances will retrospective funding requests be supported. The outcome of the urgent IFR will be submitted to the IFR Panel at the next scheduled meeting for ratification.

Organisation of an IFR Meeting

9.28 IFR panel meetings are normally scheduled on a monthly basis and the referring clinician will be notified of the date of the IFR Panel meeting. The IFR administration team will arrange the dates of IFR Panel meetings on an annual basis, to allow sufficient time for any date amendments to ensure quoracy.

9.29 The patient/carer or guardian, or their clinical or non-clinical representative, are not entitled to attend the panel either virtually or in person. This is to ensure objective decision-making by the IFR Panel in a fair and equitable manner to all patients.

9.30 The IFR Manager/Officer will compile a complete file of all the clinical documentation received which will be considered by the IFR Panel (in an anonymised format to protect confidentiality), together with advice provided by Public Health.

9.31 The IFR Manager/Officer may also write to other health professionals with clinical involvement in the patient's care (e.g., 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.

9.32 A summary of the case will be produced 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.

Membership of the IFR Panel

9.33 NHS Nottingham and Nottinghamshire ICB has an Individual Funding Request (IFR) Panel (See Appendix E for Terms of Reference). The IFR Panel will consider all cases referred to it by the Screening Pair.

9.34 Members of the IFR panel should together have the skills and expertise necessary to make effective, fair and rational decisions by considering all clinical evidence provided by the referring clinician. 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).
- Ability to understand and advise on the broader commissioning policy implications for the ICB including consideration of the intervention in the LOP process.

9.35 The core panel will consist of:

- Chair ICB Individual Funding Request Manager.
- Chief Nurse or Deputy Chief Nurse, or nominated deputy, as agreed by the ICB Nottingham and Nottinghamshire ICB.
- 3 x General Practitioners, NHS Nottingham and Nottinghamshire ICB.
- Public Health Consultant as agreed by the ICB.
- Senior Finance Officer, as agreed by the ICB.

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

9.37 The IFR Manager/ Public Health will present the anonymised case to the IFR Panel members 5 days prior to the schedule panel meeting via secure email. This will allow panel members sufficient time for them to review each case in advance of the IFR Panel meeting.

9.38 IFR Panel decisions are reached by consensus, with one of the following outcomes:

- Approved

- Declined
- Deferred for further information

9.39 If a consensus cannot be achieved in instances where the IFR Panel is equally split, then the IFR Chair will have an additional casting vote.

Conflict of Interest

9.40 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.

Purpose of the IFR Panel and Decision-Making Framework

9.41 The IFR Panel represents the ICB and has delegated authority from the Executive Team to make decisions in respect of funding for individual cases. It is not the role of the IFR Panel to develop new commissioning policies on behalf of the ICB.

9.42 The IFR Panel shall only be entitled to approve requests for funding of treatment for individual funding requests where each of the following conditions detailed in A, B and C are met:

A. 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 exceptionality as an Individual Patient (as defined in section 5)

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

3. where the clinician has demonstrated that the patient has exceptional clinical circumstances (as defined in section 5)

OR

4.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 section 5). This option would arise if the patient was not an Individual Patient (as defined in section 5).

B. There is sufficient evidence to show that, for the patient, the proposed treatment is likely to be clinically effective.

C. 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

9.43 The requesting clinician is required to present a full report and IFR submission using the IFR Application 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. The onus is on the treating clinician making the request to set out the grounds for clinical exceptionality clearly.

9.44 The IFR Panel shall determine, based upon the evidence provided to the panel, whether the patient has demonstrated exceptional clinical circumstances.

9.45 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.

Rule of Rescue

9.46 The IFR Panel shall take care to avoid "rule of rescue". This is the imperative feeling to "rescue" individuals facing avoidable death or ill health. For example, supporting the effort to prolong life where there is little prospect of improvement, or death is unavoidable or there is little published evidence to support the requested treatment option in relapsed/refractory stages of the individual's disease/condition. Where the IFR Panel consider the application of the rule of rescue would form the basis for treatment, funding will be declined. 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

9.47 The referring clinician shall:

- describe the anticipated clinical outcomes 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 this particular patient.

9.48 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.

9.49 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 patient.

The Costs of the Proposed Treatment

9.50 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.

9.51 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.

9.52 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

9.53 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.

9.54 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

9.55 The IFR Manager/Officer will record the decision of the IFR Panel using the Decision Framework Document (see Appendix D for the Template). A copy of the Decision Framework Document will also be saved to the patient's electronic file. The agreed Decision Framework Document notes will form the basis of the minutes of the IFR Panel meeting, together with the IFR Panel members attendance and any other business. The minutes of the previous IFR Panel meeting will be approved by the IFR Panel at the next IFR Panel meeting.

Outcome of the IFR Panel

9.56 The IFR Manager/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 rationale for the panel decision.

9.57 If funding was agreed, the IFR Manager/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.

9.58 If funding was not agreed, the IFR Manager/Officer will inform the referring clinician, and the patient/guardian or carer, outlining the further options that are available - either reconsideration or review.

Reconsideration of Funding Request

9.59 If the referring clinician believes that there is further relevant information that was not originally provided and 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 IFR Manager/Officer together Public Health Consultant and a GP clinical advisor to the IFR Panel 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.

9.60 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 will be informed by letter with reasons for the decision not to refer the request back to the IFR Panel.

10. Process for managing a Request for Review of IFR Panel Decisions

Grounds for requesting a review of the IFR Panel Decision

10.1. The referring clinician can make a request to the ICB for a review of the original outcome decision. The request for review form must be fully completed, setting out the rationale for the challenge, which is submitted to the IFR team within 20 working days of the outcome letter. A review can be requested on the following two grounds.

10.2. 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.

10.3. 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

10.4. Upon initial receipt of any Request for Review, if new clinical information has been provided which would potentially have an impact on the decision, the IFR team will email the referring clinician. The email will advise that this does not form part of the Request for Review process and that a new request would be submitted in its entirety, which will be considered as a new application.

10.5. The request for a review will be initially considered by the ICB Designated Officer not involved in the original funding request application:

No arguable case:

- If the Designated Officer determines that there is no arguable case to support the request then the case will not be progressed, and the referring clinician will be informed by letter of the reason and the available options. (i.e., to make a Complaint, take the case to the PHSO or submission or a new IFR, if there is new information, see 10.62) The referring clinician is responsible for advising the patient/guardian or carer of the IFR Panel's decision.

Arguable Case:

- If the Designated Officer considers that there is an arguable case to support the Request for Review, a formal review panel will be convened for consideration and the referring clinician will be informed of the outcome.

Membership of the Review Panel

10.6 NHS Nottingham and Nottinghamshire ICB will have a Review Panel. The Review Panel will consist of the following three members:

- Non-Executive lay Representative or the ICB
- ICB Chief Executive or their nominated deputy
- Director of Public Health or nominated Public Health Representative.

10.7 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. Other individuals with specific expertise and skills may also be included on the panel e.g., pharmacist, commissioning manager, GP representative, in order to ensure effective and robust decision-making.

10.8 There will be no representation from the referring clinician and/or the patient/guardian or carer at the Review Panel meeting.

Purpose of the Review Panel

10.9 The purpose of the review process is to provide the referring clinician with the opportunity to have the funding decision request reviewed if they do not agree with the decision. The grounds for submission of a Request for Review are details above.

10.10 The Review Panel will determine whether the original decision is valid in terms of process followed, the evidence/factors considered and the criteria applied. The Review Panel will not consider new information.

10.11 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.
- The Review Panel will only consider the following written documentation:
- The original IFR **Application** Form submitted to the ICB.
- The IFR process records in managing 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.

Possible decision of the Review Panel

10.12 The Review Panel will be able to reach one of two decisions:

- To uphold the decision reached by the IFR Panel, or
- To refer the case back to the IFR panel with detailed points for reconsideration

10.13 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;
- 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.

10.14 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

10.15 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

10.16 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 consideration.

10.17 The IFR Manager/Officer will write to the referring clinician, within 5 working days to inform them of the outcome of the Review Panel meeting with the reasons for the panel decision. The referring clinician is responsible for communicating the outcome to the patient/guardian or carer and the available options. Reasons given should only refer to the IFR policy as this is the basis on which the original decision is made.

10.18 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:-

- To pursue a complaint through the ICB Complaints Procedure 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 the IFR Panel

OR

- To take the case to the Parliamentary Health Service Ombudsman (PHSO).

10.19 If the Review Panel determines that the IFR panel needs to consider the case, the funding request will be referred to the next IFR Panel meeting.

10.20 The IFR Panel will consider the original decision made, and in doing so will formally address the detailed points raised by the Review Panel. The IFR Panel is not bound to change the original decision as a result in the case being referred for reconsideration, but if it upholds the 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 approved on a three yearly basis by the Strategic Planning and Integration Committee.

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

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 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
- Value Based Commissioning Policy
- Standards of Business Conduct 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)**
- Defining DH guiding principles for processes supporting local decision-making about medicines (January 2009).

  Available from **Context | Developing and updating local formularies | Guidance | NICE**
- Improving Access to medicines for NHS patients.

  Available from: **prof-richards-report.pdf (publishing.service.gov.uk)**
- Priority setting: an overview. 2021

  Available from: **NHS England » Priority setting**
- Priority setting: managing individual funding requests. (2017).

  Available from: IFR Policy NHS England

  NHS England » Commissioning policy: Individual funding requests

16. Equality Impact Assessment

16.1 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.

16.2 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.

16.3 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.

Overall Impact on: **Equality, Inclusion and Human Rights**	**Neutral**

Name of Policy, Process, Strategy or Service Change	Individual Funding Request Policy
Date of Completion	April 2024
EIA Responsible Person Include name, job role and contact details.	Name: Jane Urquhart Job Title: Individual Funding Request Manager Email: Jane.urquhart@nhs.net

Summary of Evidence Provide an overview of any evidence (both internal and external) that you utilised to formulate the EIA. E.g., other policies, Acts, patient feedback, etc.	Equality Act 2010 (incl. the PSED) Human Rights Act 1998 Mental Health Act 1983 Gender Recognition Act 2004 Mental Capacity Act 2005 (incl. DOLS 2010) Down Syndrome Act 2022 Children's Act 1989 and 2004 (where applicable) Sexual Orientation Monitoring Standard, NHS England/LGBT Foundation (Sexual Orientation Monitoring - Full Specification)

For the policy, please answer the following questions against each of the Protected Characteristics, Human Rights and health groups:	What are **the actual, expected or potential positive impacts** of the policy, process, strategy or service change?	What are the **actual, expected or potential negative impacts** of the policy, process, strategy or service change?	What **actions have been taken** to address the actual or potential **positive and negative impacts** of the policy, process, strategy or service change?	**Impact Score**
Age	A person-centred approach will achieve better outcomes by promoting health, well-being and independence through choice and control. This policy will include people of **ALL** ages.	There are no actual or expected negative impacts on the characteristic of Age. The IFR Policy is for people of **ALL** Ages.	None.	3 - Neutral

Disability[1] (Including: mental, physical, learning, intellectual and neurodivergent)	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. Commissioning Principles that underpin IFR Decision-Making.	There are no actual or expected negative impacts on the characteristic of Disability.	The ICB will support an individual's communication needs by providing an interpreter and or easy read, large print or recordings to ensure the person is provided with the information they require to be fully involved in the IFR process. Mechanisms are in place via the Communications and Engagement Team to receive the policy in a range of languages, large print, Braille, audio, electronic and other accessible formats.	2 - Undetermined
Gender[2] (Including: trans, non-binary and gender reassignment)	None Identified. The IFR policy document has been designed to ensure that equality aspects are considered so that no-one is adversely affected by the reviewed policy. The purpose of the policy is to ensure that	There are no actual or expected negative impacts on the characteristic of Gender.	None.	3 - Neutral

	all patients are treated in a fair and equitable manner and to ensure consistency in decision-making so it does not impact adversely on people who may have gone through or going through transition. Decision regarding treatment are based on the demonstration of exceptional clinical circumstances and an individual gender identity is not a determinant of whether clinical exceptionality is demonstrated.			
Marriage and Civil Partnership	None Identified. The IFR policy document has been designed to ensure that equality aspects are considered so that no-one is adversely affected by the reviewed policy. The purpose of the policy is to ensure that all patients are treated in a fair and equitable manner and to ensure consistency in decision-making, so it does not impact adversely in terms of Marriage and civil partnership.	There are no perceived negative impacts for this protected characteristic.	None.	3 - Neutral
Pregnancy and Maternity Status	None Identified. The IFR policy document has been designed to ensure that equality aspects are considered so that no-one is adversely affected by the reviewed policy. The purpose of the policy is to ensure that all patients are treated in a fair and equitable manner and to ensure consistency in decision-making, so it does	There are no actual or expected negative impacts on the characteristic of Pregnancy and Maternity Status.	None.	3 - Neutral

	not impact adversely in terms of pregnancy and maternity. Decision regarding treatment are based on the demonstration of exceptional clinical circumstances and an individual's pregnancy or maternity status is not a determinant of whether clinical exceptionality is demonstrated.			
Race[3]	None Identified. The IFR policy document has been designed to ensure that equality aspects are considered so that no-one is adversely affected by the reviewed policy. The purpose of the policy is to ensure that all patients are treated in a fair and equitable manner and to ensure consistency in decision-making, so that it does not impact adversely on Race. Decision regarding treatment are based on the demonstration of exceptional clinical circumstances and an individual's race is not a determinant of whether clinical exceptionality is demonstrated. Consideration may need to be given around providing information to support understanding of the process to specific individuals who have little or no spoken English.	There are no actual or expected negative impacts on the characteristic of Race.	Mechanisms are in place via the Communications and Engagement Team to provide information in a range of languages, and in a range of accessible formats.	3 - Neutral

Religion and Belief[4]	The IFR policy document has been designed to ensure that equality aspects are considered so that no-one is adversely affected by the reviewed policy. The purpose of the policy is to ensure that all patients are treated in a fair and equitable manner and to ensure consistency in decision-making, so it does not impact adversely in terms of religion or belief. Decision regarding treatment are based on the demonstration of exceptional clinical circumstances and an individual's religion or belief is not a determinant of whether clinical exceptionality is demonstrated.	There are no actual or expected negative impacts on the characteristic of Religion or Belief.	None.	3 - Neutral
Sex[5]	None Identified. The IFR policy document has been designed to ensure that equality aspects are considered so that no-one is adversely affected by the reviewed policy. The purpose of the policy is to ensure that all patients are treated in a fair and equitable manner and to ensure consistency in decision-making, so it does not impact adversely in terms of Sex. Decision regarding treatment are based on the demonstration of exceptional clinical circumstances and an individual's sex is not a determinant of whether clinical exceptionality is demonstrated.	There are no actual or expected negative impacts on the characteristic of Sex.	None.	3 - Neutral

Sexual Orientation[6]	None Identified. The IFR policy document has been designed to ensure that equality aspects are considered so that no-one is adversely affected by the reviewed policy. The purpose of the policy is to ensure that all patients are treated in a fair and equitable manner and to ensure consistency in decision-making so it does not have an adverse impact on sexual orientation. Decision regarding treatment are based on exceptional clinical circumstances and an Individuals sexual orientation is not a determinant of whether a patient demonstrates exceptionality.	There is a potential negative impact on people whose sexual orientation is lesbian, gay, bi, or any other sexual orientation other than heterosexual/ straight. The sexual orientation of individual's is not considered in the macro or individualised planning of health services. A lack of patient Sexual Orientation Monitoring means these inequalities and related specific patient needs are often not acknowledged or addressed in mainstream service provision. The IFR application process does not request this information.	None.	3 - Neutral
Human Rights[7]	None Identified. There is no evidence that this policy contravenes and of the relation to health and care, the most commonly applicable of the Articles within the Human Rights Act 1998.	There are no actual or expected negative impacts on the characteristic of Human Rights.	None.	3 - Neutral
Community Cohesion and **Social Inclusion**[8]	None Identified. This policy is an internal organisational policy and there is no	There are no actual or expected negative impacts on	None.	3 - Neutral

	evidence that it impacts community Cohesion or Social inclusion.	the characteristic of Community Cohesion and Social Inclusion.		
Safeguarding[9] (Including: adults, children, Looked After Children and adults at risk or who lack capacity)	None Identified.	There are no actual or expected negative impact of the characteristic of safeguarding.	None.	3 - Neutral
Other Groups at Risk[10] of Stigmatisation, Discrimination or Disadvantage	None Identified. It is recognised that Nottingham and Nottinghamshire communities are diverse in their makeup, and therefore, patients from a diverse range of backgrounds, family structures, and identities may request treatment at some point that involves the IFR Policy and Process.	There are no actual or expected negative impact of the characteristic Other Risk Groups.	None.	3 - Neutral

Impact Score Outcome

Negative Impact	**13 to 19**
Undetermined Impact	**20 to 32**
Neutral Impact	**33 to 45**
Positive Impact	**46 to 52**
Equality Impact Score Total	**38 - Neutral**

Additional Equality Impact Assessment Supporting Information

1. **Disability** refers to anyone who has: "…a physical or mental impairment that has a 'substantial' and 'long-term' negative effect on your ability to do normal daily activities…" (Equality Act 2010 definition). This includes, but is not limited to: mental health conditions, learning disabilities, intellectual disabilities, neurodivergent conditions (such as dyslexia, dyspraxia and dyscalculia), autism, many physical conditions (including HIV, AIDS and cancer), and communication difficulties (including d/Deaf and blind people).

2. **Gender**, in terms of a Protected Characteristic within the Equality Act 2010, refers to: "A person has the protected characteristic of gender reassignment if the person is proposing to undergo, is undergoing or has undergone a process (or part of a process) for the purpose of reassigning the person's sex by changing physiological or other attributes of sex."

3. **Race**, in terms of a Protected Characteristic within the Equality Act 2010, refers to: A person's colour, nationality, or ethnic or national origins. This also includes people whose first spoken language is not English, and/or those who have a limited understanding of written and spoken English due to English not being their first language.

4. **Religion and Belief**, in terms of a Protected Characteristic within the Equality Act 2010, refers to: Religion means any religion and a reference to religion includes a reference to a lack of religion. Belief means any religious or philosophical belief and a reference to belief includes a reference to a lack of belief.

5. **Sex**, in terms of a Protected Characteristic within the Equality Act 2010, refers to: A reference to a person who has a particular protected characteristic and is a reference to a man or to a woman.

6. **Sexual Orientation**, in terms of a Protected Characteristic within the Equality Act 2010, refers to: Sexual orientation means a person's sexual orientation towards persons of the same sex, persons of the opposite sex or persons of either sex.

7. The **Human Rights Act 1998** sets out the fundamental areas that everyone and every organisation must adhere to. In relation to health and care, the most commonly applicable of the Articles within the Human Rights Act 1998 include: Article 2 Right to Life, Article 5 Right to Liberty and Security, Article 8 Right to Respect of Private and Family Life, and Article 9 Freedom of Thought, Conscience and Religion.

8. **Community Cohesion** is having a shared sense of belonging for all groups in society. It relies on criteria such as: the presence of a shared vision, inclusion of those with diverse backgrounds, equal opportunity, and supportive relationships between individuals. **Social Inclusion** is defined as the process of improving the terms of participation in society, particularly for people who are disadvantaged, through enhancing opportunities, access to resources, voice and respect for rights (United Nations definition). For the EQIA process, we should note any positive or negative impacts on certain groups being excluded or not included within a community or societal area. For example, people who are homeless, those from different socioeconomic groups, people of colour or those from certain age groups.

9. **Safeguarding** means: "…protecting a citizen's health, wellbeing and human rights; enabling them to live free from harm, abuse and neglect. It is an integral part of providing high-quality health care. Safeguarding children, young people and adults is a collective responsibility" (NHS England definition). Those most in need of protection are children, looked after children, and adults at risk (such as those receiving care, those under a DoLS or LPS Order, and those with a mental, intellectual or physical disability). In addition to the ten types of abuse set out in the Health and Care Act 2022, this section of the EQIA should also consider PREVENT, radicalisation and counterterrorism.

10. **Other Groups** refers to anyone else that could be positively or negatively impacted by the policy, process, strategy or service change. This could include, but is not limited to: carers, refugees and asylum seekers, people who are homeless, gypsy, Roma and traveller communities, people living with an addiction (e.g., alcohol, drugs or gambling), people experiencing social or economic deprivation, and people in stigmatised occupations (e.g., sex workers).

APPENDIX A

NHS
Nottingham and Nottinghamshire

Individual Funding Request (IFR) Application Form

Please complete in **typed format** ensuring that all relevant information is included.

1. PATIENT PERSONAL DETAILS

Patient Name:

Date of Birth:

Address:

NHS Number:

GP Name & Practice Details (including GP post code):

2. DETAILS OF REQUESTER

Name: Designation:

Provider Trust:

Contact phone number:

Secure email or postal address for correspondence:

Must be **NHS.net email**. Only NHS.net can be used for correspondence re IFR requests.

Provider Trust Clinical Director Support:

(Signature of Clinical Director)

Provider Trust approval (please indicate as appropriate).

Drugs and Therapeutics Committee (DTC) or equivalent	YES / NO
Multidisciplinary Team (MDT)	YES / NO

Date to DTC / MDT:

If discussed and supported by an appropriate DTC / MDT, please provide notes here:

3. CONSENT

I confirm that this Individual Funding Request (IFR) has been discussed in full with the patient. The patient is aware that they are consenting for the Individual Funding Request Team to access confidential clinical information held by clinical staff involved with their care about them as a patient to enable full consideration of this funding request.

NO / YES

[Please indicate]

Please note the Nottinghamshire and Nottinghamshire Integrated Care Board are under obligation to let the patient know the outcome of all IFR applications. The patient and parent/ guardian or carer and their GP will therefore be copied into correspondence between the clinician and the IFR Team unless it is clinically not appropriate to do so. Please indicate as follows:

I confirm that it is clinically appropriate for the patient to be copied into all correspondence.

NO / YES

[Please indicate]

Signature of Requester: **Date**:

Please note that all personal information will be removed prior to the consideration by the Individual Funding Request (IFR) Panel. **Do not use patient or clinician/trust identifiers in the remainder of the form.**

The onus lies with the requesting clinician to present a full submission to the IFR Team 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. All necessary information including research papers must be submitted with this form.

Requests can only be considered based on the information provided. Incomplete forms providing insufficient information will be returned. Do not include patient name from this point forward.

4. TREATMENT REQUESTED

5. DIAGNOSIS

SUPPORTING INFORMATION

Please provide all the information requested to avoid delays in processing this request.

6. CLINICAL BACKGROUND
Outline the clinical situation. Please include: • previous therapies tried and what was the response, including intolerance. • current treatment and response, including intolerance. • current performance status and symptoms • anticipated prognosis if treatment requested is not funded (include what alternative treatment will be given).

A. BALANCING THE INDIVIDUAL NEED FOR CARE WITH THE NEEDS OF THE COMMUNITY

7. INCIDENCE & PREVALENCE
Incidence is expected to be initiated for two or fewer patients per million population per year **Prevalence** is less than 10 patients per million population at any one time. References are to be provided for stated incidence & prevalence. **What is the anticipated need for this treatment per 1000 head of population i.e., how often would you expect to request this treatment for this condition at this stage of progression of the condition for a given size of population?**

8. EXCEPTIONALITY

To meet the definition of 'exceptional clinical circumstances' your patient must demonstrate that they are both:

- significantly different clinically to the group of patients with the condition in question and at the same stage of progression of the condition

AND

- likely to gain significantly more clinical benefit than others in the group of patients with the condition in question and at the same stage of progression of the condition.

Do you consider this patient to have exceptional* clinical circumstances? Yes

If so, please give your reasons.

9. SIMILAR PATIENTS / SETTING PRECEDENT
9a. Is this a service development that has been discussed with commissioners? Do you plan to submit a future business case for funding of this treatment (rather than submit individual requests for single patients)?
9b. If this treatment were to be funded for this patient on an individual basis, would the decision set a precedent for other requests?

B. EVIDENCE OF CLINICAL AND COST EFFECTIVENESS / SAFETY

10. If drug therapy is requested, is the drug licensed for the intended use?

11a. What is the evidence base for the clinical and cost effectiveness/safety of this procedure/treatment? Has it been subjected to NICE appraisal or other scrutiny? Please include copies of all relevant clinical research.

11b. Is the procedure/treatment part of a current or planned national or international clinical trial or audit?

12. What previous therapies have been tried and what was the response?

13. What are the anticipated clinical benefits <u>in this individual case</u> of the particular treatment requested over other available options?

14. Why are standard treatments (those available to other patients with this condition/stage of the disease) not appropriate for this patient?

15. How will the benefits of the procedure/treatment be measured? What are the intended outcomes and how will these be determined? What 'stopping' criteria will be in place to decide when the treatment is ineffective? (NHS Nottingham and Nottinghamshire ICB will require regular feedback on the outcome if the treatment is approved).

16. How frequently has your unit undertaken this treatment/procedure and what were your results? Is this treatment/procedure subject to Trust audit? Please include any available data on the use of this treatment/procedure by your unit.

C. AFFORDABILITY

17. What is the cost of the treatment/procedure and how does this compare with the cost of the standard therapy it replaces? Please ensure you include all attributable costs that are connected to providing the treatment/procedure e.g. drug/staff/follow up/diagnostics etc.
THIS SECTION MUST BE COMPLETED TO AVOID DELAYS IN DECISION-MAKING

D. ACCESS TO TREATMENT

18. How will the treatment/procedure be given to the patient (e.g. oral/IV etc.) and where will the treatment take place?

19. Is this a single treatment/procedure or part of a course?
If part of a treatment course, what is the number of doses that will be given and at what intervals?
What is the total length of time of the proposed course of treatment? Single hospital admission.

E. OTHER

20. Clinicians are required to disclose all material facts to NHS Nottingham and Nottinghamshire ICB IFR Team as part of this process. Are there any other comments/considerations that are appropriate to bring to the attention of the IFR Team?

Please complete and return this form, along with any supporting documentation via secure email to: nnicb-nn.ifrteam@nhs.net

APPENDIX B

Guidance notes for Clinicians on the Individual Funding Request (IFR) process.

When considering which organisation to submit an IFR to it is important to first determine the responsible commissioner.

NHS England will be the statutory body for the consideration of IFRs for Prescribed Specialised Services (including services for Military and Offender Health, specified High Cost Drugs and the Cancer Drugs Fund). Information on the Prescribed Specialised Services is available in the NHS England Manual available to download from :- PRN00115-prescribed-specialised-services-manual-v6.pdf (england.nhs.uk)

If you wish to submit an IFR for a specialised services please contact either your Trust High Cost Medicines pharmacist (if the request is for a medicine) or the NHS England Area Team via england.ifr@nhs.net

IFRs for procedures or medicines commissioned by ICB should be discussed with the IFR team for the Nottingham and Nottinghamshire ICB via nnicb-nn.ifrteam@nhs.net (only for patients registered with a GP within the boundaries of Nottingham and Nottinghamshire).

Please read the FAQs below before making a submission.

1. How should I decide whether to make an Individual Funding Request? An IFR application is appropriate if you:

Consider your patient to be clinically exceptional compared to other patients excluded from funding set out in a particular commissioning policy.

OR

When the ICB do not have a policy stating who is eligible for the treatment that is being requested. The key consideration is whether the treatment that you wish to request for your individual patient will meet the definition for '*exceptional clinical circumstances'* that is set out in the policy.

2. What is meant by ‘exceptional clinical circumstances’?

The ICB cannot fund requests that should be fairly applied to other patients who have similar clinical circumstances and who should rightly also be offered the treatment if your patient was to be approved. This would require the ICB to agree a new commissioning policy (or amend an existing one) setting out that the treatment was now available for a new group of patients and setting out how this group had been identified. Therefore, to meet the definition of ‘exceptional clinical circumstances’ your patient must demonstrate that they are both:

Significantly different clinically to the group of patients with the condition in question and at the same stage of progression of the condition

AND

Likely to gain significantly more clinical benefit than others in the group of patients with the condition in question and at the same stage of progression of the condition.

In other words, you must show that your patient is very different from others in group of patients with the same condition/stage of the disease and has clinical features that mean that they will derive much more benefit from the treatment you are requesting.

3. Why are only clinical features taken into account?

The ICB must make decisions fairly about funding treatments and not on the basis of age, sex, sexuality, race, religion, lifestyle, occupation, family status (including responsibility for caring for others) social position, financial status etc. unless these directly affect the expected clinical benefit that an individual will derive from a treatment e.g., the effect of the increasing age of a woman on fertility.

4. How do I make an Individual Funding Request (IFR)?

All requests must be made on a standard IFR funding request form treatment request form which can be obtained electronically on the ICB website at:- https://notts.icb.nhs.uk/about-us/our-policies-and-procedures/

The request should be typewritten using this form to ensure that all information is legible. The form aims to ensure that all the necessary information is obtained so it is important that it is completed comprehensively and accurately, along with any relevant research papers. You should highlight how the patient compares to the research population in who evidence of a beneficial effect has been demonstrated. These measures will avoid delays in reaching a decision. The form should be returned electronically to the ICBs secure NHS Net email account to preserve patient confidentiality - nnicb-nn.ifrteam@nhs.net

5. How can I get advice on what to include when completing a treatment request form?

Please review the IFR Policy on the ICB website.

You can e-mail the Individual Funding Request Manager at the ICB for advice on whether to submit a treatment request form and what to include. You should ensure that all parts of the IFR request form are completed to avoid delay in the IFR process. The 40-day response timeline for IFR requests is suspended whilst the IFR team is waiting for your response to any queries relating to the request. It is therefore in the interest of a timely response for your patient that you provide accurate contact details and that requests for further information are addressed as soon as possible.

6. Who will make the decision on whether the Individual Funding Request (IFR) is approved?

All new Individual Funding Requests are 'screened' by a Public Health Consultant, IFR Manager and ICB Clinical member to decide whether the request meets the criteria for consideration as an IFR and 'exceptional clinical circumstances' have been demonstrated. If there is no evidence of exceptional circumstances (often because the patient is clearly part of a definable cohort) then the request is declined at this stage.

If evidence of exceptionality is presented, or if the screeners are uncertain whether the case then the case will be forwarded to the ICB's IFR Panel.

The panel will include: -

- Public Health Consultant
- Chief Nurse – or nominate deputy
- Senior Finance Officer
- GP Advisors
- Pharmacy Advisors

Together, the IFR Panel will determine whether there is a case for exceptionality and whether the intervention is safe and clinically and cost effective.

7. How will I be informed of the ICB IFR Panel decision?

Following initial screening of the IFR funding application form, the IFR Tema will acknowledge, via email, advising of the action that will/or has been undertaken within 5 working days of receipt. If the IFR is progressed to the IFR panel for consideration, the referring clinician will be informed when the next panel meeting will take place. The IFR Panel outcome will be sent within 5 working days after the meeting, via letter to the referring clinician. It is the responsibility of the referring clinician to inform the patient of the outcome.

8. How will my patient be informed of whether the request has been approved?

All correspondence on the outcome at each stage of the IFR process will be copied to their GP. The rationale for the decision will be included at each stage of the process. It is the responsibility of the referring clinician to inform the patient of the outcome.

9. Can either the patient, or a clinician involved in their care, attend the panel?

No. The panel will only consider the written evidence that has been submitted so it is very important that all the evidence is presented in your treatment request form.

10. Can I or my patient appeal against the ICB decision?

There is no right to appeal against the decision at the 'screening' stage although it is possible to complain under the ICBs Complaints Policy. However, this will not overturn the decision of the screening stage but will examine whether the policy was properly followed. If the ICB panel does not approve your request you, or your patient, are entitled to ask for a review of the process that was undertaken by the ICB. The Review Panel will decide if the ICB followed the correct procedures and the ICB Panel reached a decision that was rational and based on all the evidence that was presented.

11. What can I do if my patient is not exceptional e.g., represents a group of patients in similar clinical circumstances?

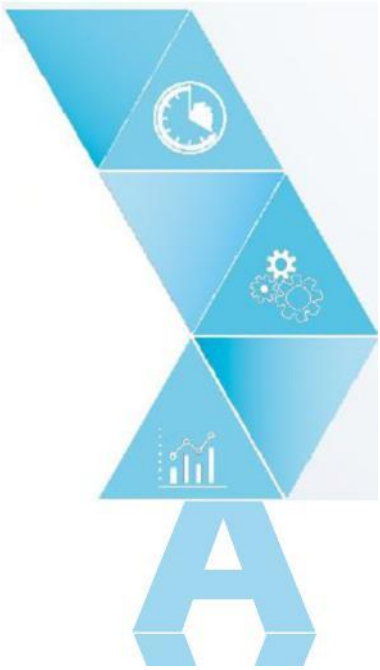
If you disagree with an existing policy, then you can try to change it, but this cannot be achieved through the IFR process. If the treatment or services is covered by NHS England Prescribed Specialised Services, you should contact the area team responsible for managing IFRs england.ifr@nhs.net for all other services an treatments you should contact your directorate management team for discussion with the relevant ICB.

Please note that it would be unusual to introduce a new development in year as each year resources are already committed through an annual round of prioritisation. Hence new developments will usually require reallocation of resources from existing services.

Information updated June 2024

Nottingham and Nottinghamshire

Integrated Care Board



Individual funding requests

a guide for patients

As medical technology advances, a large number of new treatments become available every year –

including drugs, medical devices and new surgical techniques.

Some of these are introduced into the NHS in response to guidance from the National Institute for Health and Care Excellence (NICE), while others are brought in after NHS England has evaluated them and found that they are both clinically effective and that they offer the best value for patients and taxpayers.

The NICE website has more information on their guidance: www.nice.org.uk

In some cases, it may be possible to fund a treatment for an individual patient outside of the process described above. This is called an individual funding request (or IFR).

NHS Nottingham and Nottinghamshire (NN) Integrated Care Board (ICB) commissions (or buys) high quality clinical care for its population. The treatments funded by NN ICB are those regarded as safe, effective and evidence based, giving the best value to patients in terms of health outcomes. However, NN ICB has a limited budget, it is inevitable that decisions need to be made about which healthcare treatments to commission for our local population.

What is an individual funding request?

An individual funding request can be made by the clinician treating you if they believe that because your clinical circumstances are exceptional, you may receive benefit from a treatment or service that isn't routinely offered by the NHS.

Why are some treatments not routinely offered by the NHS?

There may be some cases where a treatment is not available because there is limited evidence for how well it works or because it is very high cost and doesn't offer good value for money for taxpayers and the NHS.

When can an individual funding request be made?

An individual funding request can be made for a treatment that is not routinely offered by the NHS:

- when your clinician believes that your clinical circumstances are clearly different to other patients with the same condition, and
- when there is a reason why you would respond differently to other patients - and therefore gain more clinical benefit from the treatment.

In the application, your clinician will need to explain why your clinical circumstances are different and show all available clinical evidence for why they believe you would benefit more from the treatment than other patients with the same condition. They will also explain to you why they believe that a treatment that is not routinely offered by the NHS is the best treatment option for you.

Patients understand their symptoms better than anyone and may be very well informed on their condition. If you're aware of a treatment that you think may help you, discuss it with your clinician who can advise you if an individual funding request would be appropriate. If there are likely to be other patients with similar clinical circumstances who might benefit from the treatment in a similar way, your clinician can request that NHS NN ICB consider introducing it as a routine treatment. If it is approved, the clinician can then make the treatment available to you.

Does the individual funding request process take into account any other patient circumstances apart from clinical exceptionality?

Every person has the same rights to treatment under the NHS no matter what their social, family or other circumstances are. For this reason, it's important that non-clinical factors are not considered in IFR decision-making. For example, factors such as the effect of a treatment on a patient's ability to work or study, care for dependants, or meet financial commitments can't be considered as

part of the IFR process. The decision is based on clinical circumstances only, which ensures the IFR process is fair, equitable and non-discriminatory.

Who can make an individual funding request?

If your GP or Consultant agrees that a treatment would be of benefit to you, and that there are no alternative treatments or services available for your condition, they can then make a request to the NN ICB on your behalf but only if they consider your individual circumstances are exceptional.

Requests are made on a form which asks questions that allow your GP or Consultant to describe your personal clinical circumstances, how they think the treatment will specifically benefit you, the evidence that it is both safe and effective, the cost of the treatment and how commonly your condition occurs in the community

Who considers the application?

Your application will first go through a screening process by NHS NN ICB a Public Health Consultant and a Clinical member of the ICB to make sure all relevant information has been submitted and the application meets the criteria for an individual funding request.

If the screening team agrees that there are grounds to consider your request as exceptional, your case will be considered by the ICBs IFR Panel within 40 working days of the screening decision, unless the clinical circumstances indicate that a quicker decision is needed.

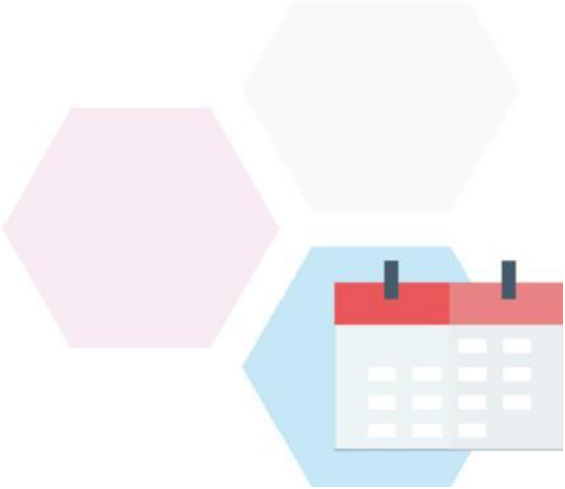
The panel is made up of health professionals, NN ICB managers who consider the request against an agreed set of criteria to ensure the decision-making is fair, consistent and transparent.

The panel reviews whether the treatment is likely to be beneficial and is safe (known as 'clinical effectiveness'), how much it will cost to achieve the health benefit that is predicted (known as 'cost effectiveness') and the cost of the treatment in relation to the total ICB budget for providing health care (known as 'affordability').

Your personal details will be kept confidential.

NHS NN ICB will let your clinician know the outcome of the funding request and you will also be sent a letter to notify you of the decision.

If your application is unsuccessful, your clinician will discuss with you the reasons for the decision and what other treatment options may be available.



How long will an application take?

As long as all the required information is submitted, it usually takes 40 working days from receiving an application to a decision, but it can often be sooner. Urgent cases can be processed more quickly if needed.

How can I find out how my application is progressing?

NHS NN ICB will keep in contact with your clinician during the application process and let them know how the application is progressing and if there are any delays. You should therefore speak to your clinician in the first instance.

If you feel your application hasn't been considered within the timelines set out above, you can get in touch with NHS NN ICB Patient Experience Team. Contact details are below.

Telephone: **0115 8839570**

Email: **nnicb-nn.patientexperience@nhs.net**

Post: **NHS NN ICB, Sir John Robinson House, Arnold, NG5 6DA**

Please ensure you provide your full name, address and date of birth. Your request will be passed to the Individual Funding Request team who will respond as soon as possible.

What do I do if I disagree with the decision?

If the IFR panel hasn't supported funding for a requested treatment, or if it has approved a treatment subject to conditions and you don't agree, in the first instance you should speak to your GP or consultant. You and your GP or Consultant can ask for a review of the IFR Panel's decision on the following grounds:

- The IFR Panel failed to follow due process and, as a result, the decision reached by the panel was different from the one that would be reached if due process had been followed.

- The IFR Panel did not take into account, or weigh appropriately, all the relevant evidence when making its decision.

The request for a review must be made in writing to the Chief Executive of the ICB within 20 working days of the date of the IFR Panel's decision letter. The ICB may accept requests outside this time limit if there are good reasons for the delay.

If the NN ICB does accept the grounds put forward then a Review Panel will be convened. To ensure a fair process, all reviews are considered by different people from those who made the original IFR decision.

If the NN ICB does not accept the grounds put forward for a review, a letter will be sent to the referring GP or Consultant explaining the reasons.

The Review Panel will not consider new clinical evidence. If new evidence becomes available your GP or Consultant should make a new Individual Funding Request submission.

The Review Panel cannot overturn the IFR Panel decision. However, if the Review Panel decides that the decision was not reached correctly then it can instruct the Individual Funding Request Review Panel to reconsider your case.

The review can be requested if you and your clinician think that the process hasn't been followed correctly and must be made within 28 days of when you were informed of the decision.

If your situation changes or more clinical evidence becomes available about the effectiveness of your treatment your clinician may also be able to submit additional information which will be considered.

This information can be made available in alternative formats, such as easy read or large print, and may be available in alternative languages, upon request. Please contact nnicb-nn.ifrteam@nhs.net

APPENDIX D: Decision Framework Template

NHS
Nottingham and Nottinghamshire

Date Request Received: **IFR Panel Meeting:** **Patient No:**

Funding Request for Consideration:

DECISION FRAMEWORK DOCUMENT FOR INDIVIDUAL FUNDING REQUEST PANEL

STRICTLY PRIVATE & CONFIDENTIAL

All attendees should be aware of the ICB's participation in the Freedom of Information Act. The minutes and papers from this meeting could be published on the Publication Scheme and be made available to the referring clinician and patient.

Notes of Guidance:

1. A copy of this form is to be provided to each panel member for each person in respect of whom an application is being considered
2. The copies will, at the end of the meeting, be collected and retained by the Individual Funding Request Officer
3. The Framework will be used to inform the letter to be written by the Chair of the IFR Panel

Panel Members
Intervention Requested
Documents pertaining to the case
Brief background to intervention requested

No	Points for consideration	Discussion notes	Decision
	Individual Need for Care		**Yes/No**
1	Does the ICB have a policy to cover the treatment which is made available to patients with the medical condition of the patient? Did the panel reach the view that the patient had demonstrated exceptional clinical circumstances in this individual case?		**NB: If the ICB has a policy for the condition in question and the patient has not demonstrated exceptional clinical circumstances, the IFR Panel are required to turn down the application.**
	Evidence of effectiveness: Clinical / Cost		
2	Does the panel consider that there is robust evidence of the clinical effectiveness of this drug/intervention?		
3	Is there robust evidence that this drug/intervention has been or will be effective in this individual case and that they will gain significantly greater clinical benefit than other patients with the same clinical condition and stage of disease?		
4	Does the panel consider that there is enough evidence to make a decision regarding the cost effectiveness of this drug/intervention? (NICE, Appraisals) and does that evidence indicate the treatment requested will be cost-effective in this individual case?		

No	Affordability	Discussion notes	Decision
5	What are the absolute costs involved in funding this treatment, in relation to the overall resources of the ICB for health care?		
	Equity/ Needs of the Community		
6	What will the anticipated impact be on the rest of the patient population should this treatment be funded? ***Will we be setting a precedent?***		
7	Will it be equitable to the wider population to fund this treatment after consideration of the clinical needs of this patient? ***Equal Access for Equal Need?***		
	Other factors		
8	Are there any other factors which were considered relevant by the Panel?		

RETURN THIS FORM TO THE PANEL ADMINISTRATOR AFTER THE MEETING

	SUMMARY		
	Funding Approved:	**Any conditions / review mechanisms required. Outcome measures to be monitored and date of review.**	
	Funding Denied	**Reasons**	

APPENDIX E

Individual Funding Request Panel - Terms of Reference

1. Purpose	The Individual Funding Request (IFR) Panel exists to consider funding requests for individuals who seek NHS commissioned services outside established commissioning policies in line with the IFR process, as set out within NHS Nottingham and Nottinghamshire ICB's IFR Policy. This may either be a request for funding treatment where there is no commissioning policy, or where the medical condition is not included in a current policy or does not meet the criteria set out in the policy. The Panel will ensure that requests are considered in a fair and transparent way, with decisions based on the best available evidence and the ICB's commissioning principles. NOTE: It is not the role of the IFR Panel to make commissioning policy decisions on behalf of the Nottingham and Nottinghamshire ICB.
2. Status	The IFR Panel is established in accordance with the ICB's IFR Policy and has delegated authority to make financial decisions in respect of the funding of individual cases on behalf of NHS Nottingham and Nottinghamshire ICB.
3. Duties	a) Make decisions in relation to IFR requests in line with the ICB's IFR Policy. When making decision the Panel will ensure that: i) Appropriate evidence is available to demonstrate clinical and cost effectiveness, including consideration of benchmarking information where available; ii) Checks are made against the manual for prescribed specialised services to determine commissioning responsibility; and iii) Ensure that the patient had demonstrated exceptional or individual clinical circumstances. b) Agree monitoring parameters for each of the individual cases that are approved and receive subsequent update reports regarding patients' responses. c) Consider quarterly summaries of all requests received to evaluate implementation of the IFR process, including the consistency of decision-making, to consider any improvements that can be made d) Oversee the identification and management of risks relating to the Panel's remit. e) Contribute to the review of the Policy.

4. Membership	The IFR Panel will comprise of the following: a) IFR Manager Chair b) Public Health Consultant c) Chief Nurse or Deputy Nurse d) Senior Finance Officer e) Three GP Advisors f) The IFR Officer will routinely attend meetings of the Panel and other individuals with specific expertise and skills may also attend meetings of the Panel (e.g. pharmacist, commissioning manager, health economist) to support effective and robust decision-making.
5. Chair and Deputy	The Chair is the Individual Funding Request Manager Deputy Chair is the Assistant Director of Nursing and Quality The panel members will determine the chair and deputy chair for the panel, they will each serve for a period of 2 years.
6. Quorum	The IFR Panel will be quorate with a minimum of five members, to include the chair or deputy chair, Chief Nurse or deputy, Public Health Consultant one GP Advisor and Finance. To ensure that the quorum can be maintained, Panel members are able nominate a suitable deputy to attend a meeting of the Panel that they are unable to attend to speak and vote on their behalf. Panel members are responsible for fully briefing their nominated deputies and for informing the secretariat so that the quorum can be maintained. If any Panel member has been disqualified from participating in the discussion and/or decision-making for an item on the agenda, by reason of a declaration of a conflict of interest, then that individual shall no longer count towards the quorum. For the sake of clarity, no person can act in more than one capacity when determining the quorum.

7. Decision-making Arrangements	Panel members will seek to reach decisions by consensus where possible. If a consensus agreement cannot be reached, then a vote of members will be required. Each member will be entitled to one vote and decisions will be made by simple majority. If an equal number of votes are for and against a request, then the chair of the panel will have a second and casting vote. A Decision Framework Document will be completed for every IFR Request considered by the Panel. The completed Decision Framework Document, together with details of members present, will form the record of an individual case. On occasion, the Panel may be required to take urgent decisions. An urgent decision is one where the requirement for the decision to be made arises between the scheduled monthly meetings of the Panel and in relation to which a decision must be made prior to the next scheduled meeting. The Panel members may meet either in person or virtually to take an urgent decision. The decision-making arrangements as described above apply for urgent decisions, and the quorum (as described in section 6) must be adhered to. A minute of the discussion (including those performed virtually) and decision will be taken by the secretary to the Panel and will be reported to the next meeting of the Panel for formal ratification.
8. Frequency of Meetings	Meetings of the IFR Panel will be scheduled on a monthly basis and held at least quarterly. Every effort will be made to provide between 5 and 10 calendar days' notice in instances where meetings are stood down due to there being no cases to consider. On occasion it may be necessary to hold "virtual" panel meetings to consider any urgent funding request. This may be via an MS Teams meeting for by way of completion of the IFR Panel Decision Framework by each IFR Panel member via email. Meetings of the Panel, other than those regularly scheduled above, shall be summoned by the secretary to the Panel at the request of the Chair.

9. Secretariat and Conduct of Business	Secretariat support will be provided to IFR Panel to ensure the day-to-day work of the Panel is proceeding satisfactorily. Agendas and supporting papers will be circulated no later than five calendar days in advance of meetings and will be distributed by the secretary to the Panel. Any items to be placed on the agenda are to be sent to the secretary no later than seven calendar days in advance of the meeting. Items which miss the deadline for inclusion on the agenda may be added on receipt of permission from the Chair. The Panel agenda will be agreed with the Chair prior to the meeting.
10. Minutes of Meetings	Minutes will be taken at all meetings and presented according to the corporate style. The minutes will be ratified by agreement of the IFR Panel, either at the following meeting or virtually via email. In instances where minutes are agreed virtually, then they will be reported to the next meeting of the Panel for formal ratification.
11. Conflicts of Interest Management	In advance of any meeting of the IFR Panel, consideration will be given as to whether conflicts of interest are likely to arise in relation to any agenda item and how they should be managed. This may include steps to be taken prior to the meeting, such as ensuring that supporting papers for a particular agenda item are not sent to conflicted individuals. At the beginning of each Panel meeting, members and attendees will be required to declare any interests that relate specifically to a particular issue under consideration. If the existence of an interest becomes apparent during a meeting, then this must be declared at the point at which it arises. Any such declarations will be formally recorded in the minutes for the meeting. The Chair of the Panel will determine how declared interests should be managed, which is likely to involve one the following actions: a) Requiring the individual to withdraw from the meeting for that part of the discussion if the conflict could be seen as detrimental to the Panel's decision-making arrangements. b) Allowing the individual to participate in the discussion, but not the decision-making process. c) Allowing full participation in discussion and the decision-making process, as the potential conflict is not perceived to be material or detrimental to the Panel's decision-making arrangements.

12. Reporting Responsibilities and Review of Panel Effectiveness	An annual report will be presented to the Strategic Planning and Integration Committee to provide assurance that NHS Nottingham and Nottinghamshire ICB's IFR Policy is being appropriately and effectively implemented. The work of the IFR Panel will form part of this reporting. Only brief details of the number of cases considered and outcomes will be reported to the Strategic Planning and Integration Committee, due to low numbers and the high chance of identification of patients. The Panel will conduct an annual review of its effectiveness to consider how well bit is discharging its delegated responsibilities, as set out in these terms of reference.
13. Review of Terms of Reference	These terms of reference will be formally reviewed on an annual basis but may be amended at any time in order to adapt to any national guidance as and when issued.
14. Training	All members of the IFR Panel must undergo mandatory induction training organised by the Individual Funding Request Manager on behalf of NHS Nottingham and Nottinghamshire ICB. This will cover both the legal and ethical framework for IFR decision-making, the ICB's commissioning processes and structures, and the technical aspects of 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. Electronic records will be kept of all training completed.

Issue Date:	**Status:**	**Version:**	**Review Date:**
1 June 2024	FINAL	2.0	1 July 2025

APPENDIX F

NHS Nottingham and Nottinghamshire ICB IFR Process Map

1. Submit Request

- Clinician fills in IFR documentation IFR-Form-June-2024
- Sign off by Trust Clinical Director and Chief Pharmacist (for drugs)
- Submit IFR application to: nnicb-nn.ifrteam@nhs.net

2. Received by NHS NN ICB

- Application given unique blueteq reference number by NHS NN ICB
- Acknowledgment sent to clinician, GP and patient

3. Screening

- Pre-Screening
  - Checks include:
    - Does the treatment or medicine fall NHS NN ICB's responsibility (eg: not that of NHS England)?
    - Is there already a relevant policy / contract in place?
    - Has the applicant supplied all relevant information?
    - Have they submitted relevant evidence?
- Screening Group
  - Screening with IFR Manager, Public Health Consultant and ICB Clinical Member
- Sufficient info: Progress to IFR panel
- Application rejected: does not progress to IFR panel
  - Clinician, patient and GP notified

Can be sent back for more info

4. IFR Panel

- IFR Panel assessment
  - Assessed for:
    - A. Clinical exceptionality
    - B. Clinical effectiveness
    - C. Appropriate use of NHS
- Final decision

5. Decision

- Successful IFR application
  - Funding approved for treatment
    - Clinician, patient and GP informed
- IFR application rejected
  - Clinician, patient and GP informed

Can be sent back for more info

NHS Nottingham and Nottinghamshire Integrated Care Board

Review of process

- Can request review of IFR final decision process against decision-making criteria
- IFR Panel review
- Outcome communicated to clinician, patient and GP