NHS
Lincolnshire
Integrated Care Board

# NHS Lincolnshire Integrated Care Board (ICB)

# Individual Funding Requests (IFR) Commissioning Policy

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# 1.0 Introduction

1.1. This policy applies to the NHS Lincolnshire Integrated Care Board, hereafter referred to as 'the ICB'. ICBs were established under the Health and Care Act 2022 (NHS Act 2006 as amended) Health and Care Act 2022 (legislation.gov.uk) has the function of arranging for the provision of services for the purposes of the health service in England in accordance with this Act.

1.2. The NHS exists to serve the needs of all of its patients and NHS Lincolnshire ICB (the ICB) has a statutory responsibility for commissioning services including medicines and other treatments for the population it serves within available resources and by prioritising between competing demands. As part of these duties, there is a need to commission services which are evidence based, cost effective, improve health outcomes, reduce health inequalities, and represent value for money.

1.3. The ICB also has a statutory duty financially to break even, as detailed in the NHS Act 2006, Section 223GC: 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 of their population, and to commission appropriate care to meet the clinical needs of individual patients.

1.4. 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 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.'*
- *'You have the right to receive the vaccinations that the Joint Committee on Vaccination and Immunisation recommends that you should receive under an NHS-provided national immunisation programme.'*

1.5. 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.

1.6. The ICB does not expect to make significant decisions about funding outside the process that is routinely used and in particular does not expect to commit significant new resources in year to the introduction of new healthcare technologies (including drugs, surgical procedures, public health programmes), since to do so risks ad hoc decision making and can destabilise previously identified priorities.

1.7. 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. The fact that the ICB is not meeting a healthcare need due to resource constraints is an inevitable fact of life in the NHS and not indicate that the ICB is breaching its statutory obligations.

1.8. 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 specified treatment is not in the ICB policy or does not meet the criteria set out in the policy

1.9. The NHS Evidence Based Interventions programme NHS England » Evidence-Based Interventions Programme identifies the difference between groups of procedures which are not routinely commissioned as:

- **Category 1** – treatments with no or very limited evidence for effectiveness. Not routinely funded unless the patient is considered clinically exceptional following a successful IFR

- **Category 2** – treatments that are more effective in groups of patients that meet clinical criteria where the health benefit is greater than the risks. Funded when the patient meets specified clinical criteria (Prior Approval), but not otherwise funded unless a patient is considered clinically exceptional following a successful IFR

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 Individual Funding Requests Panel. In considering an individual case the IFR Panel will apply the ICB Commissioning Principles for decision-making set out in Section 6 and the underpinning policies of the ICB.

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# 2.0 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
- Inform health professionals about the policy in operation and how to request restricted treatments or the options available following individual decisions to decline a request for a restricted treatment
- Ensure decisions are made in a fair, open, transparent and consistent manner
- Provide a firm and robust background in which requests can be judged, 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. This process is also applied to Prior Approval requests governed by the Prior Approval policy.

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 clinical evidence and in accordance with the ICB commissioning principles.

2.5. Personal Health Budgets (PHB), Continuing Healthcare (CHC) for adults, Children's Continuing Care (CCC) and Mental Health medicines/treatment 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.

# 3.0 Scope

3.1. This policy applies to:

- All employees of the ICB, any staff who are seconded to the ICB
- Contract and agency staff and any other individual working on ICB premises
- Employees of the ICB, who are seconded to the IFR team, contract and agency staff together with other staff who contribute to the IFR process
- All referring clinicians in primary, secondary, independent sector treatment centres and tertiary care
- Those treatments and services subject to ICB commissioning but are not routinely funded by the ICB and funding needs to be considered on an individual basis, such as interventions not supported by (National Institute for Health and Care Excellence) NICE

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 IFRs relevant to policies or specialised services they commission.

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# 4.0 Definitions

| Term | Definition |
|---|---|
| **Cost Effectiveness** | The cost effectiveness of a treatment or intervention is the ration of its cost to a relevant and accepted clinical measure of its benefit. Cost effectiveness is concerned with gaining maximum health impact for the resource used on a treatment. |
| **Clinical Effectiveness** | 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. |
| **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.<br>This is where there is no relevant clinical commissioning policy, NICE Technology Appraisal (TA) guidance or Highly Specialised Technology (HST) Appraisal guidance in place 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 e.g., the number of new cases of a disease in a defined population within a specified period of time. The intervention for a particular condition at the same stage of progression of that condition is expected to be initiated for **two or fewer** patients per million population per year.<br>Prevalence e.g., the number of cases of a disease in a defined population at a point in time. The total number of patients on the intervention for a particular condition at the same stage of progression of that condition **is less than 10 patients per million** population at any one time. |
| **Defining Exceptionality** | This is where there is a clinical commissioning policy, NICE Technology Appraisal (TA) guidance or Highly Specialised Technology (HST) Appraisal guidance that governs whether to fund or not fund the treatment for the patient's condition, and a clinician can demonstrate that their patient is in a different clinical condition when compared to the typical patient population with the same condition and (if relevant) at the same stage of progression, and because of that difference their patient is likely to receive material additional clinical benefit from treatment that would not be plausible for any typical patient. |
| **IFR Panel** | This is the Individual Funding Request Panel that represents the ICB and have been authorised to make decisions on its behalf relating to 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. |

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# 5.0 Roles and Responsibilities

| Role | Responsibility |
|---|---|
| **Arden & GEM CSU IFR team** | In order to carry out its functions, the ICB has commissioned NHS Arden & Greater East Midlands Commissioning Support Unit (Arden & GEM CSU) to administer the IFR process. Arden & GEM CSU is not a statutory body and the ICB remains the responsible organisation to decide whether or not an IFR application will be granted. The ICB is responsible for the fulfilment of its legal obligations and its duties and responsibilities to its own patient population as set out in the Health and Care Act 2022 (NHS Act 2006 as amended) Health and Care Act 2022 (legislation.gov.uk). |
| **Chief Nurse/Deputy Director of Nursing** | Has delegated responsibility to ensure this policy is applied and adhered to. Deputy Director of Nursing 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. |
| **Designated Officer** | This role is undertaken by a Consultant in Public Health. |
| **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. |
| **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 to determine whether the request under consideration is exceptional and should therefore have access to that treatment funded by the NHS. |
| **IFR Review Panel** | The 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. |
| **Pharmacy Advisors** | Provide specialist pharmaceutical support and advice concerning drug IFR cases to the IFR team and IFR Panel. Provides specialist input on IFR drug cases including efficacy, safety, cost and cost effectiveness. |
| **Public Health** | Provide Public Health support and independent advice to the IFR team and IFR Panel. Their role is to give public health advice in relation to clinical appropriateness, clinical effectiveness and cost effectiveness of a treatment. They also perform systematic reviews of the literature and perform individual case reviews based on clinical evidence. Public Health support currently sits with Lincolnshire County Council. |

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# 6.0 ICB Commissioning Principles that underpin IFR decision-making

6.1. It is important that the ICB ensures a consistent approach is used to guide the allocation of its resources in both population based and individual commissioning decisions.

6.2. A principle based decision-making process supports the strategic planning and the effective use of resources within the ICB. All ICB decisions need to be made in accordance with these principles.

6.3. The principles that the ICB seeks to support are:

- The ICB requires clear evidence of clinical effectiveness before NHS resources are invested in the treatment
- The ICB requires clear evidence of cost effectiveness before NHS resources are invested in the treatment
- The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor
- The ICB will consider the extent to which the individual or patient group will gain a benefit from the treatment
- The ICB will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
- The ICB will consider all relevant national standards and take into account all proper and authoritative guidance
- Where a treatment is approved, the ICB will respect patient choice as to where a treatment is delivered

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

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

6.5. The ICB considers all lives of all patients to be of equal value and in making decisions about funding treatments will seek not to discriminate on the grounds of age, gender, 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.

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# 7.0 Policy Guidance

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

## Introduction of New Drugs and Technologies

7.2. With the exception of NICE Technology Appraisals, the ICB will not introduce new drugs/technologies on 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 destabilise 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 ICB. 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)

7.3. Drugs and technologies that are approved as the result of a NICE TA need to be implemented within 3 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

7.3. The ICB policy is that treatments not currently included in established care pathways (as identified for example in the Schedules to the service agreements with acute care providers) or identified for funding through the commissioning process are not routinely funded. For a number of these interventions the ICB has published specific policy statements setting out restrictions on access based on evidence of effectiveness or relative priority for funding.

7.4. Policy development is an on-going process and future policy on further treatments, in response to NICE Guidance/Guidelines, health technology assessments etc. will be produced and published.

## Treatments not covered by ICB Commissioning Policies

7.5. Specific groups of patients may not be covered by ICB Commissioning Policy including:

- Patients with conditions for which the ICB does not have an agreed policy, including patients with rare conditions and whose proposed treatment is outside agreed service agreements

- Patients with conditions for which the ICB does have an agreed policy but who may have exceptional clinical circumstances which lead to their clinician seeking a treatment that is not routinely available

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

7.7. The role of the IFR Panel is to make decisions on individual cases. It cannot be used as a means of 'creeping implementation' for new technologies. Consideration therefore needs to be given as to the likelihood of other patients having the same clinical need who could also benefit from the proposed treatment. If there are or are likely to be other patients then, properly considered, the request is for a service development and not an individual application. Where a decision may affect other patients, the application should be considered as a service development and not through the IFR process.

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

## Requests to continue funding for patients coming off drugs trials

7.9. The ICB does not expect to provide funding for patients to continue medication/treatment commenced as part of a clinical trial. In line with the Medicines for Human Use (Clinical Trials) Regulations 2004 The Medicines for Human Use (Clinical Trials) Regulations 2004 (legislation.gov.uk) and the Declaration of Helsinki WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects – WMA – The World Medical Association 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' or by others (including patients)

7.10. On occasions, a request is received where a provider trust has commenced an unfunded treatment prior to asking for or receiving confirmation that the ICB will approve funding. Evidence that the patient is responding to the treatment is then presented as part of the case for ICB funding.

7.11. The provider'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 in these circumstances.

7.12. In considering a request for funding the ICB will apply the criteria set out in this policy as it would for any other request and accords no special privileges because the unfunded drug was given by a provider trust.

7.13. The ICB policy is that, unless a decision has been taken to approve routine funding for a treatment, the treatment will only be commissioned for an individual patient if the clinician is able to demonstrate that the patient has exceptional clinical circumstances. The fact that a patient has responded to a drug or other treatment in a manner which was anticipated for a proportion of patients who are commenced on the treatment is unlikely to be sufficient to demonstrate exceptional clinical circumstances.

7.14. Where such an application is approved on the basis of the clinician demonstrating that the patient has exceptional clinical circumstances (as defined in this policy), the ICB will not accept responsibility for the costs of any treatment provided by the provider prior to authorisation being given by the ICB.

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

7.16. There are occasions where the initial stages of an unfunded treatment have been funded privately by the patient. The ICB will consider any information submitted on behalf of a patient in support of their case that the patient has exceptional clinical circumstances.

7.17. This may include evidence derived from treatment that has been purchased privately and used by the patient. However, this potentially opens the way for a limited group of patients who can afford to fund a treatment that the ICB does not usually fund to be able to demonstrate benefit by virtue of access to private care and then submit this as a reason to justify NHS funding for the treatment in their particular case.

7.18. This is a potentially inequitable approach and, in order to ensure that the ICB does not act in an inequitable manner, the issue of exceptional clinical circumstances will therefore continue to be the criteria applied by the IFR process. Accordingly, the ICB adopts no presumption in favour of continuing treatment which has been previously paid for privately by the patient. As stated above, evidence that a treatment works as anticipated for a proportion of patients in the patient's clinical circumstances is unlikely to provide evidence of exceptionality.

## Requests to continue funding of care commenced privately e.g., reverting to NHS care

7.19. Patients who are having private treatment have a right to revert to NHS funded treatment at any point during their care. However, if they wish to exercise this right, the ICB will expect their care to be transferred to local pathways.

7.20. Funding for the individual to continue care in a private facility, or to transfer to an NHS provider with which a clinical 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., for patients who move

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

## Second Opinions

7.22. 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 IFR processes)

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

### Treatment in another country

7.24. Requests for NHS funded treatment in European Union (EU) country or Switzerland, Norway, Iceland or Liechtenstein will be considered by NHS England in accordance with the current processes for accessing treatment via the S2 route The Planned Treatment (S2 funding) route - NHS (www.nhs.uk) The EU Directive route has ended in the UK. However, there are some legacy arrangements The EU Directive route - NHS (www.nhs.uk) NHS England will liaise with the ICB's IFR team for information regarding the patient's entitlement to seek treatment abroad.

# 8.0 Defining Exceptionality and an Individual Patient Exceptionality

### Exceptionality

8.1. The words 'exceptional', 'exceptionality' and 'exceptional clinical circumstances' bear their natural meanings as defined in Oxford English Dictionary. In addition, the NHS Confederation (2008) defined exceptionality as follows:

- Exceptionality is essentially an equity issue that is best expressed by the question 'on what grounds can funding be justified for this patient when others from the same patient group are not being funded?'

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

8.3. In order to be able to consider whether a patient has exceptional clinical circumstances the IFR Panel may find it helpful to focus on the following issues:

- Are there any clinical features of the patient's case which make the patient significantly different to the general population of patients with the condition in question at the same stage of progression of the condition?

- Would the patient be likely to gain significantly more clinical benefit from the requested intervention than might be normally expected for the general population of patients with the condition at the same stage of the progression of the condition?

8.4. The implications of this approach are that if a patient can be seen to be part of a group of patients for whom a treatment is not made available by the ICB under the ICB's existing policies, then exceptionality for this individual patient is unlikely to be demonstrable. In this case, the appropriate process for obtaining funding for the requested treatment will be for the ICB to change its policy. Such a change must happen through the ICB's commissioning process (which will require the development of a business case and for the treatment to be prioritised against other developments) or through the ICB agreeing to make a change to its policy outside the commissioning process. Once the change is made it will apply to all similar patients. However, the IFR process is not the procedure for the ICB to make such policy changes.

8.5. The ICB is required to achieve financial balance each year and therefore has a default policy of not funding a treatment where no specific policy exists to approve funding for the treatment. If the ICB has not previously been asked to fund an intervention that has the potential to affect a number of patients, the application should be made by clinicians for the ICB to consider the intervention through the ICB's commissioning process and not by way of an IFR application.

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

## An Individual Patient

8.7. For the purposes of this policy, an individual patient is determined by reviewing the incidence and prevalence of the requested intervention for a particular condition at the same stage of progression of that condition. If the ICB has no policy for the intervention being requested for a particular condition, then the IFR panel can only consider the request if both the incidence and prevalence criteria (see 8.11. and 8.12.) are met or the patient has exceptional clinical circumstances compared to the cohort of patients (however small) with the presenting condition.

8.8. 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.

8.9. 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.

8.10. 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.

8.11. **Incidence:** e.g., the number of new cases of a disease in a defined population within a specified period of time. The intervention for a particular condition at the same stage of progression of that condition is expected to be initiated for two or fewer patients per million population per year.

8.12. **Prevalence:** e.g., the number of cases of a disease in a defined population at a point in time. The total number of patients on the intervention for a particular condition at the same stage of progression of that condition is less than 10 patients per million population at any one time.

# 9.0 The Process for managing IFRs and Prior Approval Requests

## Who can submit an IFR and Prior Approval Request?

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 treatment request form/Prior Approval request is **fully** 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 a request for funding as a clinical sponsor is required. On receipt of a submission the following processes should be followed.

## Administration and Reporting

9.2. Requests for funding are received via secure email and Blueteq, the IFR database, (where the referring clinician inputs the request directly into Blueteq). Upon receipt of an email request, an automatic acknowledgement message is generated to the referrer.

9.3. All appropriate email requests are logged on Blueteq by a member of the IFR team. The patient information for all requests (via Blueteq and email) are checked against the NHS summary care record to ensure the correct patient data is documented.

9.4. For each request logged, a unique reference number is generated. All relevant documentation, communications (via email and/or telephone) and decisions will be fully recorded and held on the Blueteq patient case file in chronological order.

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

9.6. All national and local policies regarding confidentiality, retention and destruction of records will be adhered to. The IFR Manager undertakes an audit of a randomly selected IFR and prior approval cases and produces an annual report of all activity within the IFR team which is submitted to the ICB.

## Timescale for managing a IFR and Prior Approval Request

9.7. All IFRs progressed to the IFR Panel will normally be managed to conclusion within 40 working days from the date of receipt to conclusion – when the IFR Panel decision letter is emailed (securely) to the referring clinician. This timescale may be exceeded where there is a delay in receiving any required additional information, in order that the request can be appropriately and fully considered.

9.8. All Prior Approval requests will normally be managed to conclusion within 10 working days from the date of receipt to the decision being sent (via secure email) to the referring clinician. This timescale may be exceeded where there is a delay in receiving any required additional information, in order that the request can be appropriately and fully considered. In cases where additional information is required, the IFR team will request this is returned within 15 working days. If the information is not received within this timescale, the request is withdrawn and the referring clinician notified via email. This is a local timescale and not mandatory.

## Initial Handling of a Prior Approval and IFR

9.9. All requests for funding (IFRs and Prior Approvals) are initially dealt with and screened by the screening pair (the IFR Officer and IFR Manager), following this, the IFR team will then 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 advice is required, the IFR Manager/Officer will review requests with Lincolnshire County Council's Public Health Directorate.

9.10. Clinically urgent IFRs submitted by a referring clinician will be managed under the 'Identifying Urgent IFR cases' process (see 9.24. and Appendix C).

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 screening pair, then the request will be progressed as a Prior Approval and an outcome decision will be sent via email to the referrer within 10 working days of the date of the initial request. 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 the application of SLAs and/or current commissioning policies is inappropriate, then it may be that an IFR form (see Appendix E) will need to be submitted, if the request has not been submitted on an IFR form. However, this will be determined at initial triage on a case-by-case basis, and not fundamentally the rule.

9.13. A copy of the Guidance Notes for submission of an IFR form should be included (see Appendix F). If a clinician wishes to discuss the IFR process they can contact the IFR team via email at agcsu.ifrlincs@nhs.net .

9.14. In cases where the referring clinician has submitted an IFR form, following the initial screening, the IFR team will acknowledge via email advising of the action that will/has been undertaken within 5 working days.

## Submission of an Individual Funding Request Form (IFR)

9.15. Any healthcare professional involved in the clinical care of a patient can submit an IFR. An IFR form will need to be completed for every request. The completion of an IFR 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 patients' 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.

9.16. Each section of the IFR form needs to be completed **in full** in order for the request to progress. Any IFR form which is incomplete will be returned to the referring clinician and the application will not progress any further until a fully completed form has been resubmitted.

## Triage of a Prior Approval and an IFR form

9.17. The IFR form or prior approval will be triaged by the screening pair (the IFR Manager and the IFR Officer). For complex prior approval cases and all IFR forms submitted, the triage process will consist of the IFR Manager/Officer together with a Public Health Consultant, nominated by the Director of Public Health. For IFRs (excluding urgent IFRs), the triage process will involve the completion of the 'IFR Triage Decision Support Framework' document (See Appendix L). Any IFR to be progressed to the IFR Panel will be anonymised and forwarded to a different Public Health Consultant for review and to obtain their clinical advice (which is then forwarded to the IFR Panel). If the IFR form is not fully completed the IFR Manager/Officer will email the form back to the referring clinician requesting this is fully completed. Once this has been returned, the IFR form will be forwarded to a Public Health Consultant for clinical advice.

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

- Determine whether an existing commissioning policy or SLA covers the treatment request
- Interpret the ICB's definitions of exceptionality and/or individuality in the context of the clinical information that is provided

The pair will be able to consider four options:

- Approve the request if it is covered by an existing commissioning policy or SLA
- Signpost clinicians to specialised commissioning services, where required
- Refuse the request without reference to the IFR Panel (see 9.20.)
- Refer the request to the IFR Panel

9.19. The criteria used to triage an IFR form is whether there is an arguable case of exceptionality and/or individuality in the context of the clinical information that is provided.

9.20. An IFR will not be progressed following the triage stage if:

- The requested treatment arises in relation to a medical condition where there is an ICB policy and:
  a. The requested treatment criteria are not met within the policy, 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. On the evidence presented the requested intervention for that particular condition may affect other patients in the ICB population, as defined in this policy (see An Individual Patient – 8.7.) and
  b. There is no arguable case to evidence exceptional clinical circumstances, which will normally be determined by comparing this patient to a cohort of patients (however small) with the presenting condition (see Exceptionality – 8.1.). These requests should be reviewed as a potential service/commissioning policy development.

9.21. If an IFR 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 to an outcome and therefore no decision-making processes have been undertaken. However, the patient does have the right to make a complaint, in line with the ICB's Complaints Policy.

9.22. 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 referring clinician may submit a new IFR form for consideration.

9.23. If a prior approval request is declined, an outcome letter will be sent to the referring clinician explaining the rationale for the decision and outlining the options that are available, which are:

- Accept the decision
- Submit further information creating a new application
- Submit a Request for a Review of the decision
- Submit an Exceptionality Request

## Identifying Urgent IFR 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. 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 (see Appendix C).

9.27. Where an urgent IFR consideration is required, the IFR Panel will follow the procedure set out in this policy (see Appendix C). 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.

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## 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 a six-monthly 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 in person.

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 the clinical advice provided by Public Health.

## Membership of the IFR Panel

9.31. NHS Lincolnshire ICB has an IFR Panel (see Terms of Reference – Appendix I). The IFR Panel considers all cases referred to them by the Screening Pair.

9.32. The members of the IFR Panel should together have the necessary skills and expertise in order to make effective, fair and rational decisions by considering all the clinical evidence provided by the referring clinician. The key competencies and experience required within the Panel are:

- Ability to understand and interpret the clinical information regarding the individual case and place it in the context of a wider clinical population
- Ability to understand and interpret clinical and cost effectiveness data (critical appraisal skills)
- A lay/societal perspective
- Ability to understand and advise on the broader commissioning policy implications for the ICB including consideration of the intervention in the ICB's commissioning process

9.33. The core panel will consist of:

1. Director of Public Health or nominated deputy, as agreed by the ICB
2. IFR Lead – who is an ICB clinical representative or nominated deputy, as agreed by the ICB
3. IFR Chair – who is an ICB/GP clinical representative , as agreed by the ICB
4. Lay representative

9.34. The IFR Panel will only be quorate if all of the above four core members are present.

9.35. In attendance:

- Other individuals with specific expertise/skills may also be included on the IFR Panel e.g., pharmacist or commissioning manager, in order to ensure effective and robust decision-making
- IFR Manager to support facilitation of the meeting and the IFR Officer to record the decisions of the IFR Panel

9.36. The IFR Manager/Officer will present anonymised IFR cases to the IFR Panel members prior to the meeting via email, in order to allow sufficient time for IFR Panel members to review each case in advance of the IFR Panel meeting.

9.37. IFR Panel decisions are reached by consensus, with one of the following outcomes:
- Approved
- Declined
- Deferred for further information

9.38. 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

9.39. If any of the members, observer/s, or attendee/s 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 IFR Chair will be responsible for determining how any declarations will be dealt with.

## Purpose of the IFR Panel & Decision-Making Framework

9.40. 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.

9.41. The IFR Panel shall only be entitled to approve IFRs where each of the following conditions detailed in **A. B.** and **C.** are met:

**A.** Either

1. The clinician makes an IFR for treatment in connection with a patient's presenting medical condition for which the ICB has no policy criteria

AND

- Where the clinician has demonstrated that the patient represents exceptionality as 'An Individual Patient' (see 8.01. and 8.7.)

**OR**

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

AND

- Where the clinician has demonstrated that the patient has exceptional clinical circumstances (see 8.1.)

**OR**

3. 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 (see 8.1.). This option would arise if the patient was not 'An Individual Patient' (see 8.7.)

**B.** There is sufficient evidence to show that, for the individual 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 of the IFR 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

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

9.43. The IFR Panel shall determine, based upon the evidence provided to the panel, whether the patient has demonstrated exceptional clinical circumstances. The evidence must demonstrate for the individual patient that the proposed treatment is likely to be clinically effective and that the patient's clinical circumstances are asserted to be exceptional.

9.44. 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

9.45. 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 that application of the rule of rescue would form the basis for treatment, funding will be declined.

## The likely clinical outcomes of the Proposed Treatment

9.46. The referring clinician shall:

- Describe the anticipated clinical outcomes for the individual patient of the proposed treatment and the degree of confidence of the referring clinician that the outcomes will be delivered for this particular patient
- Refer to and preferably include copies of any clinical research material which supports, questions or undermines the case that is being made that the treatment is likely to be clinically effective in the case of the individual patient

9.47. 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.

9.48. The IFR Panel is not required to accept the views expressed by the referring clinician concerning the likely clinical outcomes for the individual patient of the proposed treatment but is entitled to reach its own views on:

- The likely clinical outcomes for the individual patient of the proposed treatment

  **AND**

- The quality of the evidence to support that decision and/or the degree of confidence that the IFR Panel has about the likelihood of the proposed treatment delivering the proposed clinical outcomes for the individual patient

## The Costs of the Proposed Treatment

9.49. 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 they are able to, on the information provided, apply the ICB's policy principles on cost effectiveness (see 6.0.) 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 in line with the ICB's service development processes.

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 G). The draft notes of the IFR Panel meeting, will be forwarded to the IFR Chair for agreement prior to uploading to the database (Blueteq). 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 IFR Panel Chair to the referring clinician, informing them of the outcome of the IFR Panel meeting with the rationale for the IFR Panel's decision. The outcome letter (and Decision Framework Document) are sent to the IFR Chair for agreement prior to the outcome letter being communicated to the referring clinician via email.

9.57. The outcome letter will inform the referring clinician that they are responsible for advising the patient/guardian or carer of the IFR Panel's decision. The IFR team will aim to inform referring clinicians of the outcome decision (by letter via email) within 5 working days of the IFR Panel decision.

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### Reconsideration of funding request

9.58. New or further information:

- If the referring clinician believes there is significant new or further relevant clinical information that was not originally provided at the time of the request, which they believe would have an impact on the decision, then they may submit a new request in its entirety, and it will be considered as a new application.
- IFRs previously declined, which are then re-submitted with new/further information, will be triaged with the IFR Manager/Officer together with a Public Health Consultant
- For IFRs – If it is deemed that there is new clinical information, and there is a case for exceptionality, the request will be referred to the next IFR Panel meeting
- For Prior Approvals – If it is deemed that there is new clinical information, the request will be considered as a new application
- If it is deemed that there is no new clinical information provided and there is no case for exceptionality, then the referring clinician will be informed (by letter via email) that the case will not be progressed, and the referring clinician will be informed

9.59 Request for Review:

- This must be submitted to the IFR Manager/Officer within 20 working days of the date of the IFR Panel outcome letter/Prior Approval outcome letter. The Designated Officer will review the case to determine whether there is a debatable case for consideration, or not (see 10.0.)

- A Request for Review **can only** be submitted by the referring clinician, who needs to explain the reasons why they consider the decision taken by the IFR Panel/Screening pair was either procedurally improper and/or misunderstood the medical evidence and/or was, in his or her opinion, a decision which no reasonable IFR panel/Screening pair could have reached

# 10.0 The process for managing a Request for Review

### How the decision on the treatment request is communicated

The outcome of the funding request is communicated to the referring clinician via email, informing them of the criteria which was applied to the treatment request and the reason the request was declined. It is the responsibility of the referring clinician to communicate the outcome to the patient. A Request for Review **can only** be submitted by the referring clinician. The form for completion (Appendix H) and guidance notes (Appendix K) can be obtained by emailing the IFR team at agcsu.ifrlincs@nhs.net

### Grounds for submission of a Request for Review – IFR & Prior Approval

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 (see Appendix D):

- The IFR Panel/Screening pair failed to follow due process and, as a result, the decision reached was different to the one that would be reached if due process had been followed, and/or
- The IFR Panel/Screening pair did not take into account, or weigh appropriately, all relevant evidence submitted at the time of the request

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## Initial Consideration of a Request for Review prior to the Review Panel

10.2. 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 should be submitted in its entirety, which will be considered as a new application.

10.3. The Request for Review will initially be considered by the ICB Designated Officer not involved in the original funding request application:

**No arguable case:**

- If the Designated Officer determines there is no arguable case to support the Request for Review, 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 of a new IFR, if there is new information, see 10.7). The referring clinician is responsible for advising the patient/guardian or carer of the IFR Panel's/Screening Pair decision.

**Arguable case:**

- If the Designated Officer considers that there is an arguable case to support the Request for Review, the case will be referred to the next scheduled Review Panel meeting for consideration and the referring clinician will be informed of this outcome.

## Membership of the Review Panel

10.4. The ICB will have a Review Panel (see Terms of Reference – Appendix J). The Review Panel will consist of the following three members:

- Non-executive Director/Lay Representative of the ICB
- ICB Chief Executive or their nominated deputy
- Director of Public Health or nominated Public Health representative

10.5. None of these members should have been involved in the case prior to the Review Panel. The panel will only be quorate if all three members are in attendance and decisions will be reached by consensus. 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.

10.6. 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

10.7. The purpose of the review process is to provide the referring clinician with the opportunity to have the funding request reviewed if they do not agree with the decision. The grounds for submission of a Request for Review are detailed above in 10.1.

10.8. The Review Panel will determine whether the original decision is valid in terms of process followed, the evidence/factors considered and the criteria applied. This relates to both IFRs and Prior Approvals. The Review Panel **will not** consider new information.

10.9. In deciding the outcome of a review, the Review Panel will consider whether:

- The process followed by the IFR Panel (for IFRs)/Screening pair (for Prior Approvals) was consistent with that detailed in the IFR Policy

**AND**

- The outcome decision reached by the IFR Panel/Screening pair:
    - 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 IFR Panel/Screening pair acted in good faith
    - Was a decision which a reasonable IFR Panel/Screening pair was entitled to reach

## Documentation considered at the Review Panel

10.10. The Review Panel will only consider the following written documentation:

- The original IFR form/Prior Approval request submitted to the ICB
- The IFR/Prior Approval 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 in their Request for Review

## Possible decisions of the Review Panel

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

- To uphold the decision reached by the IFR Panel/Screening Pair, or
- Refer the case to the IFR Panel with detailed points for consideration

10.12. In the event that the Review Panel consider that either:

- The process followed was inconsistent with that detailed in the IFR Policy; or
- The decision may not have been consistent with the ICB Commissioning Principles; or
- The IFR Panel/Screening pair may not have taken into account and weighed all the relevant evidence; or
- The IFR Panel/Screening pair may have taken into account irrelevant factors; or
- The IFR Panel/Screening pair did not act in good faith; or
- The IFR Panel/Screening pair may have reached a decision which a reasonable IFR panel/Screening pair was not entitled to reach

10.13. 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 may be approved by the IFR Panel when it considers the case.

10.14. If the Review Panel considers that, notwithstanding their decision on the procedure adopted by the IFR Panel/Screening pair, there is no arguable case that the decision would have been different; the Review Panel shall uphold the decision of the IFR Panel/Screening pair.

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## Outcome of the Review Panel

10.15. The outcome of the Review Panel will be either to uphold the decision of the IFR Panel/Screening pair or to refer the case back to the IFR Panel for consideration.

10.16. 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 Review Panel decision. Reasons given should only refer to the IFR policy, as this is the basis on which the original decision is made. The referring clinician is responsible for communicating the outcome to the patient/guardian or carer and the available options.

10.17. If the Review Panel uphold the IFR Panel/Screening pair original decline decision, the remaining options are:

- 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 by the IFR Panel

  or

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

10.18. If the Review Panel determines that the IFR Panel should consider the case, the funding request will be referred to the next IFR Panel meeting.

10.19. 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 of 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.

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# 11.0 Equality and Diversity Statement

11.1. NHS Lincolnshire 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.

# 12.0 Communication, Monitoring and Review

12.1. The IFR process will be monitored and reviewed 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.

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. 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 agcsu.ifrlincs@nhs.net

# 13.0 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 the IFR and Review Panel should undergo mandatory induction training. This will cover both the legal and ethical framework for IFR decision making, commissioning processes, 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.

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# 14.0 Interaction with Other Policies

14.1. The following policies should be read in conjunction with this policy:

- NHS Lincolnshire ICB Prior Approval Policy current policy in force NHS Lincolnshire ICB - CG 003 - Prior Approval Policy
- NHS Lincolnshire ICB Complaints Policy, current policy in force Documents Library - Lincolnshire ICB

# 15.0 Anti-Fraud, Bribery and Corruption

15.01 The ICB has a responsibility to ensure that all staff are made aware of their duties and responsibilities arising from the Bribery Act 2010. Under the Bribery Act 2010 there are four criminal offences:

- Bribing or offering to bribe another person (Section 1)
- Requesting, agreeing to receive or accepting a bribe (Section 2)
- Bribing, or offering to bribe, a foreign public official (Section 6)
- Failing to prevent bribery (Section 7)

15.02 These offences can be committed directly or by and through a third person and, in many cases, it does not matter whether the person knows or believes that the performance of the function or activity is improper.

15.03 It should be noted that there need not be any actual giving and receiving for financial or other advantage to be gained, to commit an offence.

15.04 All individuals should be aware that in committing an act of bribery they may be subject to a penalty of up to ten years imprisonment, an unlimited fine, or both. They may also expose the organisation to a conviction punishable with an unlimited fine because the organisation may be liable where a person associated with it commits an act of bribery.

15.05 Individuals should also be aware that a breach of this Act renders them liable to disciplinary action by the ICB, whether or not the breach leads to prosecution. Where a material breach is found to have occurred, the likely sanction will be loss of employment and pension rights.

15.06 To raise any suspicions of bribery and/or corruption please contact the Local Counter Fraud Specialist (LCFS) Audit Yorkshire - Home

15.07. Alternatively, contact the NHS counter fraud reporting line on 0800 028 40 60 between 8am – 6pm Monday – Friday or report online at Report NHS Fraud | Home | NHSCFA

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# 16.0 References

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


- Supporting rational local decision-making about medicines and treatments (2015)
  Available from: Developing and updating local formularies (nice.org.uk)

- Improving Access to medicines for NHS patients (2008)
  Available from: prof-richards-report.pdf (publishing.service.gov.uk)

- Priority setting: managing individual funding requests. (2008)
  Available from: 75683-02-08 PRIO 3 MAN FUNDS (nhsconfed.org)

- NHS Confederation. Priority setting: an overview (2008)
  Available from: 75128-09-07 (nhsconfed.org)

- NHS Confederation. Priority setting: managing new treatments (2008)
  Available from: 75508-01-08 text (nhsconfed.org)

- NHS Confederation. Priority setting: managing individual funding requests (2008)
  Available from: 75683-02-08 PRIO 3 MAN FUNDS (nhsconfed.org)

- NHS Confederation. Priority setting: legal considerations (20082)
  Available from: 75690-02-08 LEGAL CONS text (nhsconfed.org)

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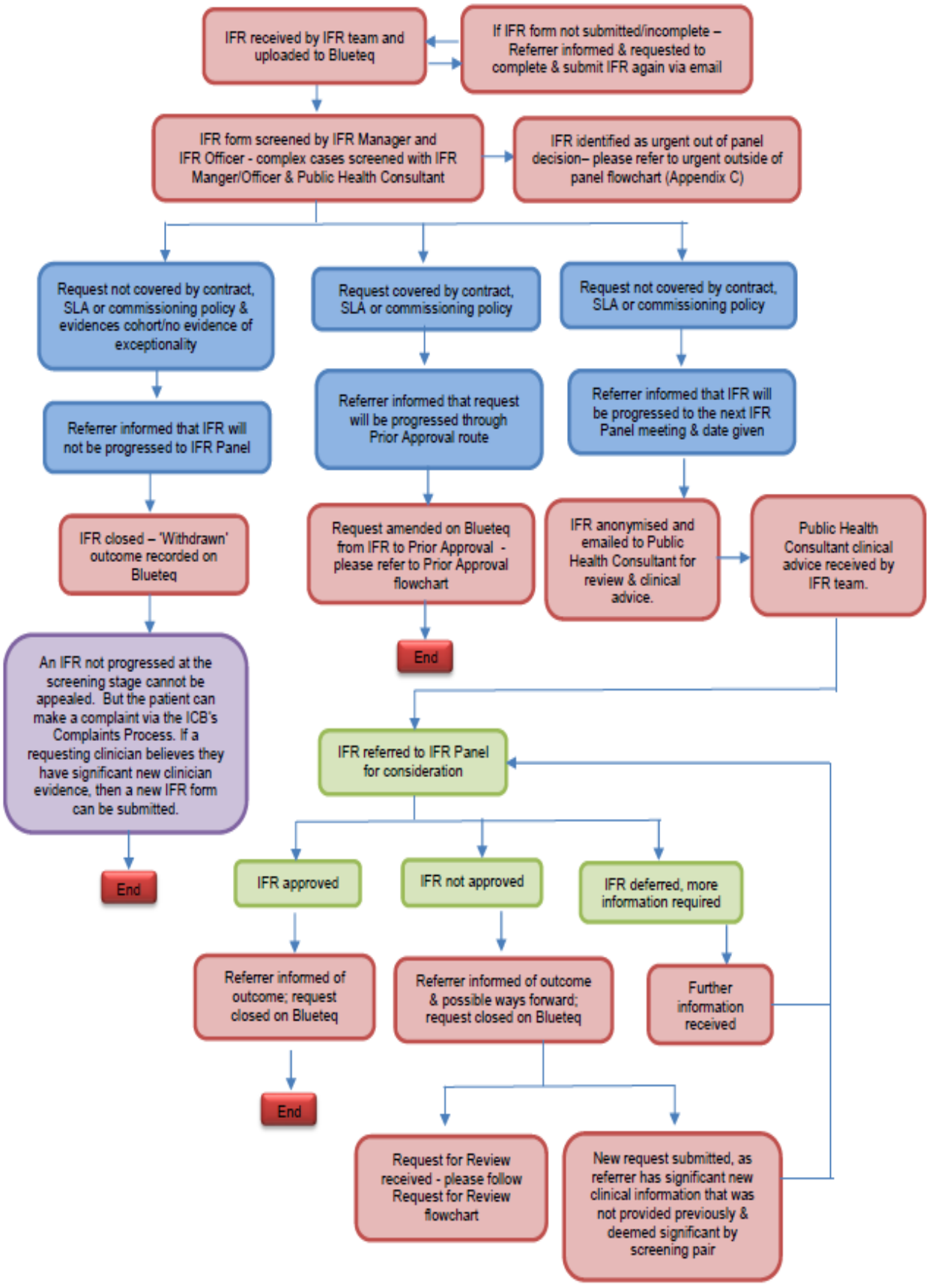
## Appendix A: Flowchart of IFR process – Routine cases



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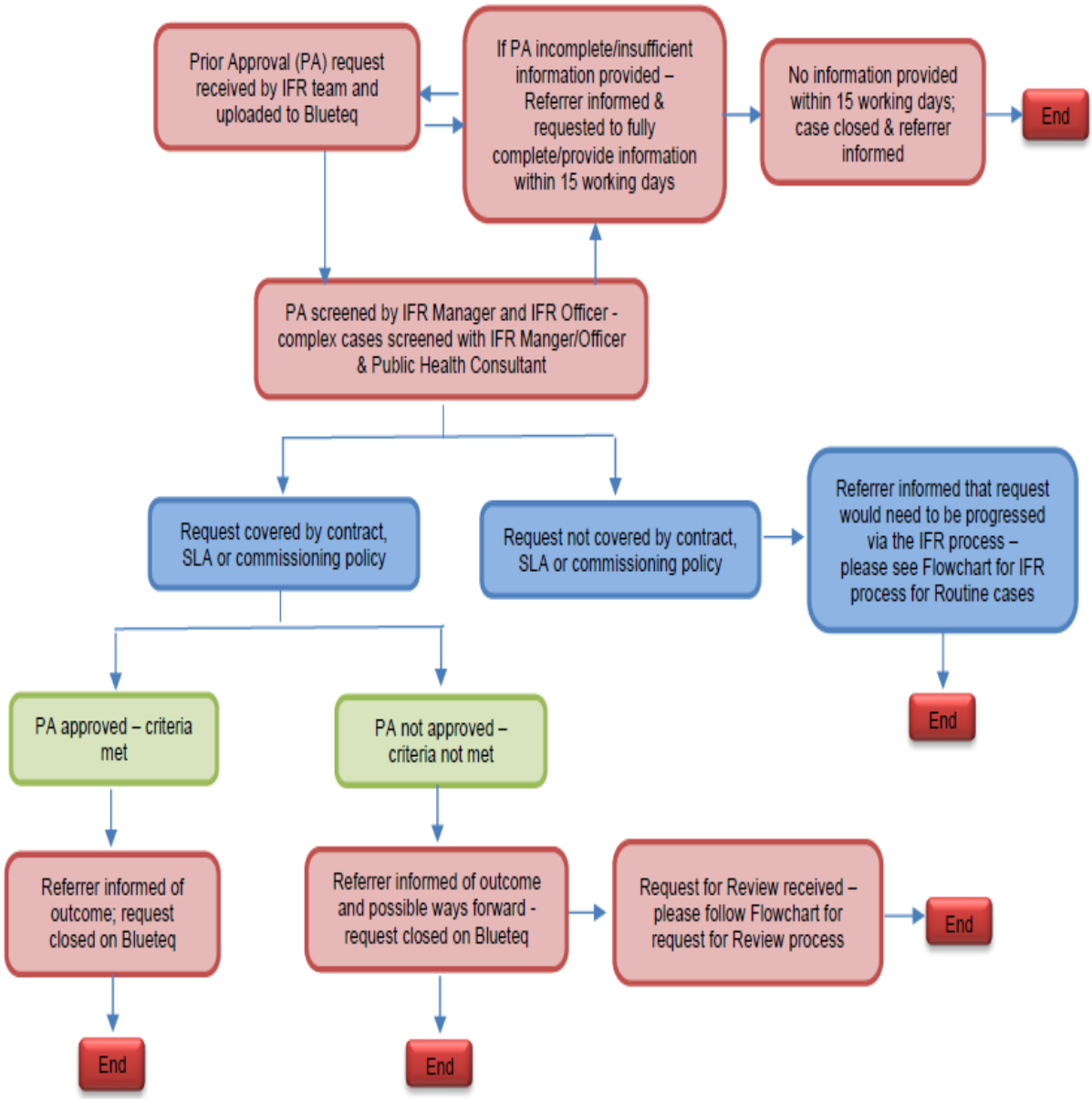
## Appendix B: Flowchart of Prior Approval process



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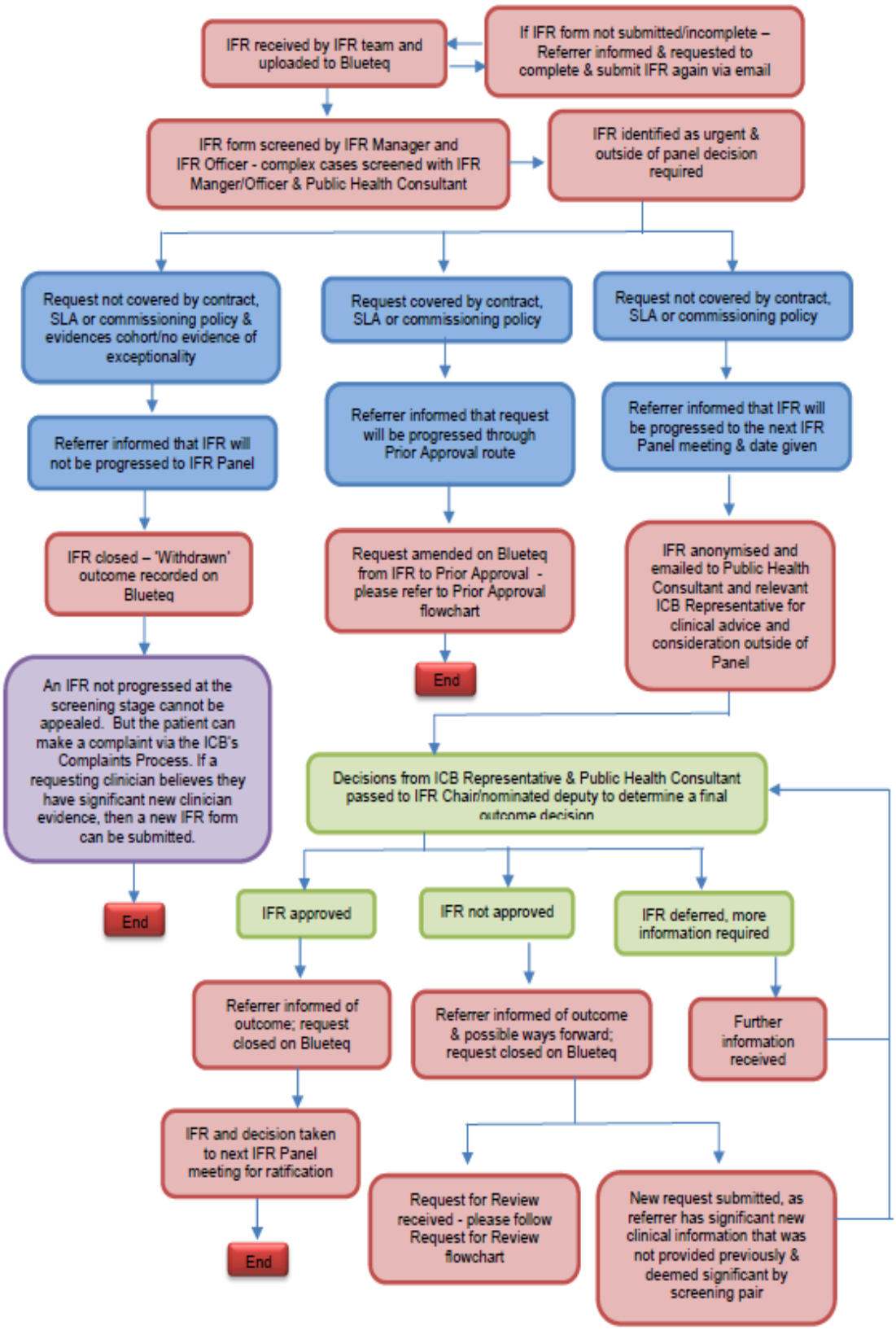
## Appendix C: Flowchart of IFR process – Urgent IFR outside of IFR Panel



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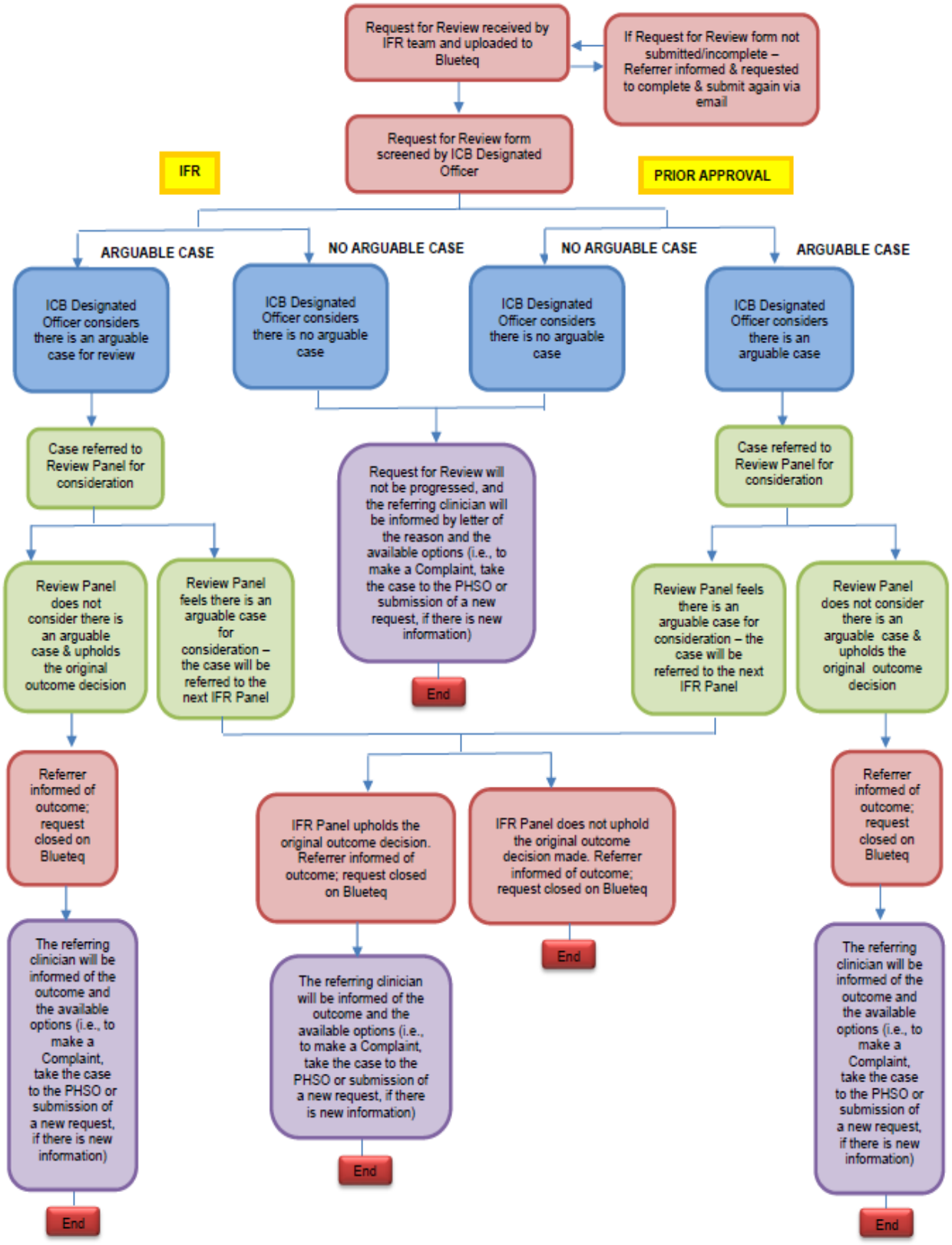
## Appendix D: Flowchart of Request for Review process



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## Appendix E: Individual Funding Request Form

Arden&GEM
Health and social care systems support

NHS
Arden and
Greater East Midlands
Commissioning Support Unit

**INDIVIDUAL FUNDING TREATMENT REQUEST FORM**

Please complete this form for all individual funding requests and send electronically to agcsu.ifrlincs@nhs.net adhering to confidentiality guidelines.

**Please ensure the form fully completed & legible, ensuring that all relevant clinical information is included. Incomplete forms will not be accepted.**

**1. PATIENT PERSONAL DETAILS**

Patient Name:

Date of Birth:

NHS Number:

GP Name & Practice Details:

Please note that all personal information will be removed prior to the consideration by the Individual Funding Request process.

**2. TREATMENT REQUESTED**

**3. DIAGNOSIS**

**4. DETAILS OF REQUESTER** (include referring clinician. Contact details in the event of query or need for clarification)

Name: Designation:

Trust/Surgery:

Contact 'phone number:

Secure email or postal address for correspondence:

Provider Trust Clinical Director Support:

(Signature of Clinical Director)

Provider Trust approval (please indicate as appropriate).

| | | |
|---|---|---|
| DTC..... | YES | NO |
| Ethics..... | YES | NO |
| MDT..... | YES | NO |

Date to DTC / MDT/Ethics:

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

**5. CONSENT** I confirm that this Individual Funding Request has been discussed in full with the patient and it would / would not be appropriate (please delete as necessary) for the patient to be copied into all correspondence*.

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

Signature of Requester: Date:

* Please note, NHS Lincolnshire Integrated Care Board (the ICB) is under obligation to let the patient know the outcome of all IFR applications. Where the patient has requested the IFR submission, it is good practice to ask the patient if they wish to be copied into other correspondence between the clinician and the ICB. Where the patient has not made the request, the patient should be copied into other correspondence between the clinician and the ICB unless it is clinically inappropriate to do so.

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.

**6. CLINICAL BACKGROUND**

Outline the clinical situation. Please include:

- Previous therapies tried and current treatment including intolerance and response
- Current performance status/symptoms
- Anticipated prognosis if treatment requested is not funded (include what treatment will be given to the patient)

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

**7. 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? (Please refer to the ICB definition of what constitutes an exceptional case.) If so, please give your reasons.**

**8. 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?** (Please refer to the ICB definition of what constitutes an individual case.)

**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?** |

| |
|---|
| **11. 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.**<br><br>**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 in this individual case 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? (The 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.** |

## 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? |
|---|
| |

## E. OTHER

| 20. Clinicians are required to disclose all material facts to the ICBs as part of this process. Are there any other comments/considerations that are appropriate to bring to the attention of the IFR team? |
|---|
| |

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## Appendix F: IFR process – Guidance notes for clinicians

Arden&GEM
Health and social care systems support

NHS
Arden and
Greater East Midlands
Commissioning Support Unit

### NHS Lincolnshire Integrated Care Board (ICB)

### Guidance notes for clinicians on the Individual Funding Request (IFR) process

#### 1. How to decide whether to make an IFR

The criteria on who is eligible to be considered as an IFR are clarified within NHS Lincolnshire ICB's (the ICB) IFR policy and these principles will be is applied consistently. The key consideration is whether the treatment being requested for the individual patient will meet the definition for '*exceptional clinical circumstances*' as set out in the ICB's IFR 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 the 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', the clinician must demonstrate that the patient is 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, the clinician must show that the patient is clinically exceptional from others in the group of patients with the same condition/stage of the disease and has clinical features which mean that they will derive much more benefit from the treatment being requested.

#### 3. Why only clinical features are taken into account

The ICB must make decisions fairly about funding treatments and not on the basis of age, gender, race, religion, lifestyle, occupation, family status (including responsibility for caring for others) social position, financial status etc.

#### 4. How to make an IFR

Any healthcare professional involved in the clinical care of the patient can submit an IFR. The completion of the IFR form ensures that the same level of relevant information is provided by every clinician for every IFR, regardless of the nature of intervention/treatment requested or the patients' 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.

Each section of the IFR form needs to be completed IN FULL comprehensively and accurately, along with any relevant research papers, by the referring clinician to avoid delays in reaching a decision. Any IFR form which is incomplete will be returned to the referring clinician and the application will not be progressed any further until a fully completed form has been resubmitted. Please contact the IFR team via email for a copy of an IFR form: aqcsu.ifrlincs@nhs.net

All IFRs progressed to the IFR Panel will normally be managed within a timescale of 40 working days from the date of receipt to the IFR Panel decision letter being sent (via secure email) to the referring clinician.

## 5. The IFR decision making process

The IFR form will be triaged by the screening pair (the IFR Manager and the IFR Officer). For complex cases, the triage process will consist of the IFR Manager/Officer together with a Public Health Consultant, nominated by the Director of Public Health, in line with the IFR policy.

If there is no evidence of exceptional circumstances, often because the patient is clearly part of a definable cohort, then the IFR is not progressed to the IFR Panel. If it is felt at the triage stage that there is potential evidence of exceptionality, then the case will be forwarded to the ICB's IFR Panel for consideration.

The patient/carer/guardian/representative and referring clinician are not entitled to attend the IFR Panel. The IFR Panel will only consider the written evidence that has been submitted, so it is very important that all the evidence is included.

The core membership of the IFR Panel consists of:

- A Director of Public Health or nominated deputy
- The IFR Lead – who is an ICB clinical representative/nominated deputy
- The IFR Chair – who is an ICB/GP clinical representative, and
- A Lay representative

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

## 6. Communication of the IFR Panel's decision

Following initial triage of the IFR form, the IFR team 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, the referring clinician will be informed when the next IFR Panel 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.

## 7. Process for making an appeal against the IFR Panel's decision

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, as follows:

- The IFR Panel/Screening pair failed to follow due process and, as a result, the decision reached was different to the one that would be reached if due process had been followed, and/or

- The IFR Panel/Screening pair did not take into account, or weigh appropriately, all relevant evidence submitted at the time of the request

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## Appendix G: IFR Panel – Decision Framework Document



### NHS LINCOLNSHIRE ICB - IFR PANEL MEETING

### DECISION FRAMEWORK DOCUMENT

| | |
|---|---|
| IFR Panel Date | |
| Reference | |
| Background to requested treatment | |
| Cost of requested treatment | |
| IFR Panel Discussion | |
| IFR Panel Outcome Decision | |

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## Appendix H: Request for Review form

Arden&GEM
Health and social care systems support

NHS
Arden and
Greater East Midlands
Commissioning Support Unit

### INDIVIDUAL FUNDING REQUEST & PRIOR APPROVAL REQUEST

### REQUEST FOR REVIEW FORM

| | | | |
|---|---|---|---|
| IFR TEAM REF. | | | |
| TREATMENT REQUESTED | | | |
| FULL NAME | | | |
| DATE OF BIRTH | | NHS NO. | |

**GROUNDS FOR REQUEST FOR REVIEW:** *(please indicate as appropriate)*

| | |
|---|---|
| The correct process was not followed, in line with the IFR Commissioning policy and as a result, the decision reached was different to the one that would be reached if the correct process had been followed. | ☐ |
| All relevant evidence submitted at the time of the request was not appropriately considered. | ☐ |

**RELEVANT INFORMATION TO SUPPORT REQUEST FOR REVIEW:** *(Please detail below, or within enclosed letter)*

| |
|---|
| |

**Please return the completed form to via email to:** agcsu.ifrlincs@nhs.net

Any queries, please contact the IFR team via email: agcsu.ifrlincs@nhs.net or telephone: 01522 857788

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## Appendix I: Individual Funding Request (IFR) Panel –Terms of reference

Arden&GEM
Health and social care systems support

NHS
Arden and
Greater East Midlands
Commissioning Support Unit

### NHS Lincolnshire Integrated Care Board (ICB)

### Individual Funding Request (IFR) Panel – Terms of Reference

#### 1. Membership & Quorum

The Individual Funding Request (IFR) Panel will have a core membership of:

- Director of Public Health or nominated deputy, as agreed by the ICB
- IFR Lead – who is an ICB clinical representative or nominated deputy, as agreed by the ICB
- IFR Chair – who is an ICB/GP clinical representative , as agreed by the ICB
- Lay representative

The IFR Panel will only be quorate if all of the above four core members are present.

In attendance:

- Other individuals with specific expertise/skills may also be included on the IFR Panel e.g., pharmacist or commissioning manager, in order to ensure effective and robust decision-making
- IFR Manager to support facilitation of the meeting and the IFR Officer to record the decisions of the IFR Panel

If any of the IFR Panel members, any observer/s, or attendee/s 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 IFR Chair will be responsible for determining how any declarations will be dealt with.

In instances whereby the timescale of the next IFR Panel is deemed too far in advance, the decision-making process involves consideration outside of IFR Panel, determined by:

- IFR Panel Chair or nominated deputy
- ICB Representative and
- Public Health Consultant

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.

#### 2. Purpose

The purpose of the IFR Panel is to consider IFRs for commissioned and funded treatment. Each individual funding request will be processed in line with the ICB's IFR policy, ensuring each IFR is considered in a fair and transparent way, with decisions based on the available clinical evidence and the ICB commissioning principles.

#### 3. Frequency of meetings

The IFR Panel will normally be held on a monthly basis, although urgent IFRs can be considered between meetings. 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. 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.

## 4. Voting Rights

IFR Panel members will seek to reach decisions by consensus where possible, but if a consensus cannot be achieved, decisions will be taken by a majority vote with each IFR Panel member present having an equal vote. If the IFR Panel is equally split, then the IFR Chair will have an additional casting vote.

## 5. Documentation

All requests for funding are received via secure email. Upon receipt of this email, an automatic acknowledgement message is generated to the referrer. All appropriate requests are logged onto the IFR database (Blueteq) by a member of the IFR team and the patient information is checked against the NHS summary care record to ensure the correct patient data is documented. For each request logged, a unique reference number is generated. All relevant documentation, communications (via email and/or telephone) and decisions will be fully recorded and held on the Blueteq patient case file in chronological order. It is the responsibility of the IFR Manager/Officer to manage all requests received to conclusion. All IFRs are anonymised before consideration by the IFR Panel. All clinical documentation with the IFR form is made available to the IFR Panel, together with the advice provided by the Public Health Consultant.

## 6. Authority

The IFR Panel has delegated authority to make decisions in respect of IFR cases on behalf of the ICB. It is not the IFR Panel's role to make/amend commissioning policy for the ICB.

## 7. Accountability, Reporting & Monitoring

The IFR Manager/Officer will record the decision of the IFR Panel on the Decision Framework Document. The draft notes of the IFR Panel meeting are forwarded to the IFR Chair for agreement prior to uploading to the database. The agreed Decision Framework notes will form the basis of the minutes the IFR Panel meeting, together with the IFR Panel members attendance and any other business. The minutes of the IFR Panel meeting are approved by the IFR Panel at the next IFR Panel meeting.

All national and local policies regarding confidentiality, retention and destruction of records will be adhered to. The IFR Manager undertakes an audit of a randomly selected IFR and prior approval cases and produces an annual report of all activity within the IFR team, which is submitted to the ICB Governing Body.

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## Appendix J: Request for Review Panel –Terms of reference

Arden&GEM
Health and social care systems support

NHS
Arden and
Greater East Midlands
Commissioning Support Unit

### NHS Lincolnshire Integrated Care Board (ICB)

### Review Panel – Terms of reference

#### 1. Membership & Quorum

The Review Panel will have a core membership of:

- Non-executive Lay Member of the ICB
- ICB Representative/Accountable Officer or nominated deputy
- Director of Public Health or nominated Public Health representative

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

#### 2. Purpose

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. 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 **and**
- The decision reached by the IFR Panel:
    - Was consistent with the ICB Commissioning Principles:
    - Had taken into account and weighed all the relevant evidence; or had not taken into account irrelevant factors
    - Indicates that members of the IFR Panel acted in good faith
    - Was a decision which a reasonable IFR Panel was entitled to reach

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

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

In the event that the Review Panel consider that either:

- The decision may not have been consistent with the ICB Commissioning Principles; or
- The IFR Panel may not have taken into account and weighed all the relevant evidence; or
- The IFR Panel may have taken into account irrelevant factors; or
- The IFR Panel may have reached a decision which a reasonable IFR panel was not entitled to reach

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 may be approved by the IFR Panel when it reconsiders the case. 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.

## 3. Frequency of meetings

The Review Panel will normally be held on a monthly basis, although urgent cases can be considered between meetings. 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 Review Panel meeting. Any administrative delay on the part of the referring clinician will not be considered as urgent and the application will be considered at the next scheduled Review Panel.

## 4. Voting Rights

The Review Panel members will seek to reach a decision by consensus. If this is not possible a decision will be made by a vote with each member having one vote.

## 5. Documentation

All requests for funding are received via secure email. Upon receipt of this email, an automatic acknowledgement message is generated to the referrer. All appropriate requests are logged onto the IFR database (Blueteq) by a member of the IFR team and the patient information is checked against the NHS summary care record to ensure the correct patient data is documented. For each request logged, a unique reference number is generated. All relevant documentation, communications (via email and/or telephone) and decisions will be fully recorded and held on the Blueteq patient case file in chronological order. It is the responsibility of the IFR Manager/Officer to manage all requests received to conclusion. All requests are anonymised before consideration by the Review Panel. The Review Panel will only consider the following documentation:

- The original IFR form/original Prior Approval request
- The IFR/Prior Approval process records in handling the request
- The IFR Panel records, including the Decision Framework Document and any additional supporting information considered by the IFR Panel
- The grounds submitted by the referring clinician in their Request for Review

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

## 6. Authority

The Review Panel has delegated authority to review decisions in respect of funding request cases on behalf of the ICB. It is not the Review Panel's role to reach a decision on funding requests or make/amend commissioning policy for the ICB.

## 7. Accountability, Reporting & Monitoring

The IFR Manager/Officer will record the decision of the Review Panel on the Decision Framework Document. The draft notes of the Review Panel meeting are forwarded to the Review Chair for agreement prior to uploading to the database. The agreed Decision Framework notes will form the basis of the minutes the Review Panel meeting, together with the Review Panel members attendance and any other business. The minutes of the Review Panel meeting are approved by the Review Panel at the next Review Panel meeting.

All national and local policies regarding confidentiality, retention and destruction of records will be adhered to. The IFR Manager undertakes an audit of a randomly selected IFR and prior approval cases and produces an annual report of all activity within the IFR team, which is submitted to the ICB Governing Body.

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## Appendix K: Request for Review process – Guidance notes for clinicians

Arden&GEM
Health and social care systems support

NHS
Arden and
Greater East Midlands
Commissioning Support Unit

### NHS Lincolnshire Integrated Care Board (ICB)

### Guidance notes for clinicians on the Request for Review process

#### 1. How the decision on the treatment request is communicated

The outcome of the funding request is communicated to the referring clinician, informing them of the criteria that applied to the treatment request and the reason why the request was declined. It is the responsibility to communicate the outcome of any funding request to the patient. A Request for Review **can only** be submitted by the referring clinician, and the form for completion can be obtained by emailing the IFR team aqcsu.ifrlincs@nhs.net

#### 2. Grounds for submission of a Request for Review – IFR & Prior Approval

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, as follows:

- The IFR Panel/Screening pair failed to follow due process and, as a result, the decision reached was different to the one that would be reached if due process had been followed, and/or
- The IFR Panel/Screening pair did not take into account, or weigh appropriately, all relevant evidence submitted at the time of the request

#### 3. Initial Consideration of a Request for Review prior to the Review Panel

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 should be submitted in its entirety, which will be considered as a new application.

The Request for Review for an IFR 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 there is no arguable case to support the Request for Review, 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 of a new IFR, if there is new information.) The referring clinician is responsible for advising the patient/guardian or carer of the IFR Panel's/Screening Pair decision.
- **Arguable case:**
  - If the Designated Officer considers that there is an arguable case to support the Request for Review, the case will be referred to the next scheduled Review Panel meeting for consideration and the referring clinician will be informed of this outcome.

## 4. Membership of the Review Panel

The ICB will have a Review Panel. The Review Panel will consist of the following three members:

- Non-executive Lay Member of the ICB
- ICB Representative/Accountable Officer or nominated deputy
- Director of Public Health or nominated Public Health representative

None of these members should have been involved in the case prior to the Review Panel. The Review 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 Review Panel e.g., pharmacist, commissioning manager, GP Representative, in order to ensure effective and robust decision making.

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

## 5. Purpose of the Review Panel

The purpose of the review process is to provide the referring clinician with the opportunity to have the funding request reviewed if they do not agree with the decision. The grounds for submission of a Request for Review are detailed above in point 2.

The Review Panel will determine whether the original decision is valid in terms of process followed, the evidence/factors considered and the criteria applied. This relates to both IFRs and Prior Approvals. The Review Panel **will not** consider new information.

In deciding the outcome of a review, the Review Panel will consider whether:

- The process followed by the IFR Panel (for IFRs)/Screening pair (for Prior Approvals) was consistent with that detailed in the IFR Policy

  **AND**

- The outcome decision reached by the IFR Panel/Screening pair:

  - 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 IFR Panel/Screening pair acted in good faith
  - Was a decision which a reasonable IFR Panel/Screening pair was entitled to reach

## 6. Documentation considered at the Review Panel

The Review Panel will only consider the following written documentation:

- The original IFR form/Prior Approval request submitted to the ICB
- The IFR/Prior Approval process records in handling the request
- The IFR Panel records, including the Decision Framework Document and any additional supporting information considered by the IFR Panel
- The grounds submitted by the referring clinician in their Request for Review

## 7. Possible decisions of the Review Panel

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

- To uphold the decision reached by the IFR Panel/Screening Pair, or
- Refer the case to the IFR Panel with detailed points for consideration

In the event that the Review Panel consider that either:

- The process followed was inconsistent with that detailed in the IFR Policy; or
- The decision may not have been consistent with ICB Commissioning Principles; or
- The IFR Panel/Screening pair may not have taken into account and weighed all the relevant evidence; or
- The IFR Panel/Screening pair may have taken into account irrelevant factors; or
- The IFR Panel/Screening pair did not act in good faith; or
- The IFR Panel/Screening pair may have reached a decision which a reasonable IFR Panel/Screening pair was not entitled to reach

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 may be approved by the IFR Panel when it considers the case.

If the Review Panel considers that, notwithstanding their decision on the procedure adopted by the IFR Panel/Screening pair, there is no arguable case that the decision would have been different; the Review Panel shall uphold the decision of the IFR Panel/Screening pair.

## 8. Outcome of the Review Panel

The outcome of the Review Panel will be either to uphold the decision of the IFR Panel/Screening pair or to refer the case back to the IFR Panel for reconsideration.

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 Review Panel decision. Reasons given should only refer to the IFR policy, as this is the basis on which the original decision is made. The referring clinician shall advise the patient/guardian or carer of the outcome and the available options.

If the Review Panel uphold the IFR Panel/Screening pair original decline decision, the remaining options are:

- 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 by the IFR Panel, or
- To take the case to the Parliamentary Health Service Ombudsman (PHSO)

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

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 of 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.

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## Appendix L: IFR Triage Decision Support Framework Document

Arden&GEM
Health and social care systems support

NHS
Arden and
Greater East Midlands
Commissioning Support Unit

### INDIVIDUAL FUNDING REQUEST TRIAGE
### DECISION SUPPORT FRAMEWORK DOCUMENT

| | |
|---|---|
| **IFR Screening Date** | |
| **Reference** | |
| **Clinical condition** | |
| **Treatment Requested** | |
| **Urgent Y/N** | |

| | Questions | Answer: Yes / No/ Unclear / N/A | | | | Comments |
|---|---|---|---|---|---|---|
| | | Y | N | U | N /A | |
| 1. | Is the treatment requested within the ICB's commissioning remit? | | | | | |
| 2. | Is there an ICB policy criteria for the treatment requested? | | | | | |
| 3. | If yes, does the patient meet the ICB policy criteria? | | | | | |
| 4. | Is there a NICE TA or other relevant clinical guidance for the treatment requested? | | | | | |
| 5. | If yes, does the patient meet the recommendations within the NICE TA or other relevant guidance? | | | | | |
| 5. | If this is a drug, is it licensed for the requested clinical condition? | | | | | |
| 6. | If the drug is licensed, is the dosage/frequency within the recommended NICE TA or other relevant guidance? | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| 7. | Have there been previous IFR submissions to the ICB for this treatment? | | | | | |
| 8. | Is the patient potentially part of a definable cohort? | | | | | |
| 9. | Is this a rare presentation of a more common condition? | | | | | |
| 10. | Is the supporting evidence provided by the referrer relevant to the treatment requested? | | | | | |
| 11. | Does the requested treatment appear to be experimental and /or unproven? | | | | | |
| 12. | Are there sufficient grounds for considering this patient to be clinically exceptional and likely to derive greater benefit than others in the same clinical circumstances? | | | | | |
| 13. | Based on the information provided, is there sufficient information to progress the IFR to the IFR Panel, ie is there an arguable case of exceptionality? | | | | | |
| **14.** | **Overall Summary:** *including rational for decision* | | | | | |
| 15. | **Screening outcome:** | | | | | |
| | Progress to IFR Panel | | | | | |
| | Pending, awaiting further information from referrer | | | | | |
| | Not progressed to IFR Panel | | | | | |
| | Refer to IFR panel sufficient information for panel – please attach evidence review for panel papers | | | | | |
| | Refer to IFR panel - reconsideration | | | | | |

| | | |
|---|---|---|
| | Refer to IFR panel sufficient information for panel – please attach evidence review for panel papers | |
| | Refer to IFR panel - reconsideration | |

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# Equality Impact Assessment form – Project details

| | |
|---|---|
| **Project Name:** | **Individual Funding Requests Commissioning policy** |
| **EA Author:** | **Samantha Jones** |
| **Team:** | **Quality & Nursing** |
| **Date completed:** | **May 2025** |
| **Version:** | **2.4** |

| **What is the aim of the project/proposal?** |
|---|
| The Individual Funding Requests (IFR) Commissioning policy document has been reviewed as part of its 2-year review process, as detailed within the policy, and therefore requires an Equality Impact Assessment. The policy sets out to make explicit the process by which IFRs are submitted, assessed, and responded to. As the statutory body responsible for NHS spend and performance within the Lincolnshire system, it is imperative that NHS Lincolnshire Integrated Care Board seeks to maximise value for money and the number of patients treated within a sustainable financial envelope. This means only evidence-based, clinically effective services will be commissioned. |

| **Who will be affected by this work? e.g., staff, patients, service users, partner organisations etc.** |
|---|
| The IFR Commissioning policy applies to all staff members, including Governing Body Members and practice representatives, involved in the ICB's policy-making processes, whether permanent, temporary or contracted-in (either as an individual or through a third-party supplier). The IFR Commissioning policy is for the attention of:<br>• All clinicians submitting IFRs<br>• All employees undertaking commissioning and related financial decision making<br>• All staff members involved in the ICB's policy-making processes<br>• For reference, for all employees not directly involved in any of the above activities |

**Stage 1, Scoping point**

**Is a full Equality Impact Analysis required for this project?**

**You should consider whether a full EIA is required, referring to the relevant guidance for information and guidance on making this decision.**

**It is important this decision is made with an open mind and correctly, advice should be sought from the EIHR team if you are unsure.**

| | | | | | |
|---|---|---|---|---|---|
| **Yes** | ☑ | Proceed to the full Equality Impact Analysis form | **No** | ☐ | Explain why further analysis is not required. |

*If no, explain below why further EIA is not required.*
*E.g. 'This report is for information only' or 'The decision has not been made by the ICB' or 'The decision will not have any impact on patients or staff'. Very few decisions affect all groups equally and this is not a rationale for not completing an EIA.*

If, at an initial stage, further information is needed to complete a section, this should be recorded and updated in subsequent versions of the EIA. An EIA is a developing document, if you need further information for any section then this should be recorded in the relevant section in the form and dated.

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# Equality Impact Analysis Form

**1. Evidence used**

*To demonstrate that the decision made has been informed you should include examples of the information used to determine the impact and complete the EIA.*

*Examples are likely to include:*

- ***Population Data -** e.g., demographic profile (Census),*
- ***Service Activity Data e**.g., profile of patients using a service*
- ***Consultation and Involvement findings -** e.g., any engagement with service users, local community, specific groups.*
- ***Research -** e.g., good practice guidelines, service evaluations, literature reviews, reports*
- ***Participant knowledge -** e.g., experiences of working with different or population groups, experiences of service users in other service areas / localities*

The policy sets out the principles and procedures of IFRs and Prior Approvals, to make explicit the process by which these are submitted, assessed, and responded to.

The document makes explicit the position and process of IFRs for the NHS in Lincolnshire about which treatments will, or will not be, commissioned by providers and the criteria and thresholds to be applied, as well as the processes and procedures for Prior Approvals. The Policy is a tool to enable the ICB to support clinicians in requesting/applying for IFRs and Prior approvals should be read in conjunction with the Prior Approval Criteria's Policy.

The policy applies to all clinicians who serve the whole population which has the following demographic profile:

Lincolnshire is a largely rural county with an ageing population with 23% of residents over the age of 65. The diversity of the population has increased in recent years as a result of new and emerging communities, which is primarily made up of Eastern European communities. Levels of deprivation vary across the county, which has an influence on health and wellbeing needs. The general pattern is that the urban centres and coastal strip show higher levels of deprivation than other parts of the county.

The Equality Impact Assessment (EIA) process requires completion of a Quality Impact Assessment (QIA). Completion of the QIA Initial Screening Tool ensured there was consideration of the impact of the policy on patient safety, patient experience, patient choice and access to services, be it positive, neutral, or adverse.

NHS Lincolnshire ICB aims to design and implement services, policies and measures that are fair and equitable. As part of its development, this policy and its impact on staff, patients and the public have been reviewed in line with NHS Lincolnshire ICB's legal equality duties. Equality aspects have been considered so that no-one is adversely affected by the policy.

In carrying out its functions, NHS Lincolnshire ICB is committed to having due regard to Section 149 of the Equality Act 2010 (the Public Sector Equality Duty). This applies to all the activities for which NHS Lincolnshire ICB is responsible, whether internal or on behalf of customers, including policy development, implementation, review, and evaluation. There will be the ability to monitor the demographics of the patients referred to the prior approval process, and the outcome of their referral. This will ensure that there are no inequalities of access to procedures that sit within the prior approval process.

**2. Impact of decision**

*In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should include any identified health inequalities which exist in relation to this work.*

*As part of these considerations, you should include how the ICB will be meeting the requirements of the public sector equality duty (PSED):*

*"In exercising their functions, public authorities must have due regard to the need to:*

- *Eliminate unlawful discrimination, harassment and victimisation.*
- *Advance equality of opportunity between people sharing a protected characteristic and others.*
- *Foster good relations between people sharing a protected characteristic and others."*

*Before completing this section, you should ensure you can suitably answer the following:*

*What is the equality profile of the population i.e. service users/patients and/or workforce that is intended to benefit from the activity/project?*

*(By collecting and analysing demographic data of protected characteristics relating to patients/service users and/or workforce, within the geographical area concerned, the ICB will be able to identify the groups that may be adversely affected at a greater proportion to others).*

**2.1 Age**

*Describe age-related impact and evidence. This can include safeguarding, consent, and welfare issues.*

The IFR policy 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. The policy will work to ensure that no age-related adverse impact is experienced.

**2.2 Disability**

*Describe disability-related impact and evidence. This can include attitudinal, physical, communication and social barriers as well as mental health/learning disabilities, cognitive impairments.*

The IFR policy 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 has not adverse impact on disabled people.

Consideration may need to be given around providing information to support understanding of the process to specific individuals who may have accessibility requirement – implementation of the Accessible Information Standard will be considered in these circumstances supporting those who may require information in different formats in relation to them with sensory and neurodiversity requirements.

| |
|---|
| **2.3 Gender reassignment (including transgender)**<br>*Describe any impact and evidence in relation to transgender people. This can include issues such as privacy of data and harassment.* |
| The IFR policy 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 on people who may have gone through or going through transition. |
| **2.4 Marriage and civil partnership**<br>*Describe any impact and evidence in relation to marriage and civil partnership. This can include working arrangements, part time working and caring responsibilities.* |
| The IFR policy 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. |
| **2.5 Pregnancy and maternity**<br>*Describe any impact and evidence in relation to Pregnancy and Maternity. This can include working arrangements, part time working and caring responsibilities.?* |
| The IFR policy 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 pregnancy and maternity. |
| **2.6 Race**<br>*Describe race-related impact and evidence. This can include information on different ethnic groups, Roma gypsies, Irish travellers, nationalities, cultures, and language barriers.* |
| The IFR policy 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. Consideration may need to be given around providing information to support understanding of the process to specific individuals who have little or no English. |
| **2.7 Religion or belief**<br>*Describe any impact and evidence in relation to religion, belief or no belief on service delivery or patient experience. This can include dietary needs, consent and end of life issues.* |
| The IFR policy 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. Consideration may need to be given around providing information to support understanding of the process to specific individuals who have little or no English. |
| **2.8 Sex**<br>*Describe any impact and evidence in relation to men and women. This could include access to services and employment.* |
| The IFR policy 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 on whether a person is male or female or has gone through or is going through transition as in point 2.3 above. |

| **2.9 Sexual orientation**<br>*Describe any impact and evidence in relation to heterosexual people as well as lesbian, gay and bisexual people. This could include access to services and employment, attitudinal and social barriers.* |
|---|
| The IFR policy 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. |
| **2.10 Carers**<br>*Describe any impact and evidence in relation to part-time working, shift-patterns, general caring responsibilities. (Not a legal requirement but a ICB priority and best practice)* |
| The IFR policy 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 including providing relevant information to carers of those patients so that they are fully aware of the process. |
| **2.11 Other disadvantaged groups**<br>*Describe any impact and evidence in relation to groups experiencing disadvantage and barriers to access and outcomes. This can include socio-economic status, resident status (migrants, asylum seekers), homeless people, looked after children, single parent households, victims of domestic abuse, victims of drug/alcohol abuse. This list is not finite. This supports the ICB in meeting its legal duties to identify and reduce health inequalities.* |
| The IFR policy 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, irrespective of age, disability, race, religion and belief, gender, sexual orientation, or other disadvantaged groups. The decision-making processes set out in the prior approval policy are not impacted by socio-economic status. No patients would be disadvantaged by this policy by their socio-economic status, as the policy ensures that only evidence-based, clinically effective services will be commissioned regardless of socio-economic status. |

| **3. Human rights**<br>*The principles are Fairness, Respect, Equality, Dignity and Autonomy.* | | | | |
|---|---|---|---|---|
| **Will the proposal impact on human rights?** | Yes | ☐ | No | ☑ |
| **Are any actions required to ensure patients' or staff human rights are protected?** | Yes | ☐ | No | ☑ |
| **If so, what actions are needed?** *Please explain below.* | | | | |
| | | | | |

**4. Health Inequalities.**

*The Health and Social Care Act 2012 established the first specific legal duties on ICBs to have regard to the need to reduce inequalities between patients in **access** to, and **outcomes** from, healthcare services and in securing that services are provided in an integrated way. These duties had legal effect from 1st April 2013.*

*The duties require that ICBs properly and seriously takes into account inequalities when making decisions or exercising functions, and has evidence of compliance with the duties, whilst also assessing how well commissioned providers have discharged their legal duties on health inequalities.*

**4.1 What evidence have you considered to determine what health inequalities exist in relation to your work?**

*This can include local and national research, surveys, reports, research interviews, focus groups, pilot activity evaluations or other equality analyses. If there are gaps in evidence, state what you will do to mitigate them.*

*This may be different or similar to that which has informed the EIA.*

In addition to the health inequality risks related to people with protected characteristics, health inequalities specific to Lincolnshire's demography were considered in the development of this policy. The QIA process reviewed the policy against quality criteria that are subject to local health inequalities. For example, patient & staff experience, clinical effectiveness, and patient safety quality domains were rated as having neutral, positive, or adverse impacts.

**4.2 What is the potential impact of your work on health inequalities?**

*Can you demonstrate through evidenced based consideration how the health outcomes, experience and access to health care services differ across the population group and in different geographical locations that your work applies to?*

*If you feel that the project will not impact / be relevant to Health Inequalities, please give a rationale.*

The IFR policy ensures that only evidence-based, clinically effective services will be commissioned. The prior approval policy document sets out to make explicit the position of the ICB about which treatments will or will not be commissioned from providers and the criteria and thresholds to be applied. The guidance in the policy applies irrespective of population groups and geographical locations (within Lincolnshire). Health outcomes, patient experience and access to services will not be impacted on by this policy.

**4.3 How can you make sure that your work has the best chance of reducing health inequalities?**

NHS Lincolnshire ICB aims to design and implement services, policies and measures that are fair and equitable. As part of its development, the IFR policy and its impact on staff, patients and the public have been reviewed in line with NHS Lincolnshire ICB's legal equality duties.

In carrying out its functions, NHS Lincolnshire ICB is committed to having due regard to Section 149 of the Equality Act 2010 (the Public Sector Equality Duty). This applies to all the activities for which NHS Lincolnshire ICB is responsible, whether internal or on behalf of customers, including policy development, implementation, and review.

The Health and Social Care Act 2012 places specific legal duties on ICBs to have regard for the need to reduce inequalities between patients in access to, and outcomes from, healthcare services and in securing that services are provided in an integrated way.

**5. Engagement/consultation**

*What engagement is planned or has already been done to support this project?*

*It is expected that the ICB will have carried out a level of engagement with those affected, whether formal or informal. This should be focused on the groups most affected and as per the guidance document published by NHSE: Working in partnership with people and communities: statutory guidance*

| Engagement activity | With whom? *e.g., protected characteristic/group/community* | Date |
|---|---|---|
| | | |

*Please summarise below the key finding / feedback from your engagement activity and how this will shape the policy/service decisions e.g., patient told us, so we will… (If a supporting document is available, please provide it or a link to the document)*

This is not a new process, but a policy update review only, therefore, no new consultation or engagement initiated. However, the IFR policy is based on both legal and nationally mandated evidence-based documents (e.g., NICE Guidance), public consultation has taken place on these documents at a national level.

**6. Mitigations and changes**

*If you have identified mitigations or changes, summarise them below, e.g., restricting prescribing over the counter medication. It was identified that some patient groups require high volumes of regular prescribing of paracetamol, this needs to remain under medical supervision for patient safety, therefore an exception is provided for this group which has resolved the issue.*

*Are these vital to the project continuing?*

None identified

**7. Is further work required to complete this EIA?**

*Please state below what work is required and to what section e.g., additional consultation or engagement is required to fully understand the impact on a particular protected group (e.g., disability)*

| Work needed | Section | When | Date completed |
|---|---|---|---|
| | | | |

**8. Development of the Equality Impact Analysis**

*If the EIA has been updated from a previous version, please summarise the changes made and the rationale for the change, e.g., Additional information may have been received – examples can include consultation feedback, service Activity data*

| Version | Change and Rationale | Version Date |
|---|---|---|
| *e.g., Version 0.1* | *The impact on wheelchair users identified additional blue badge spaces are required on site to improve access for this group.* | *26 September 2017* |
| Version 1.0 | Policy updated to reflect the organisational change to the Lincolnshire Integrated Care Board (ICB) | 06 February 2023 |
| Version 2.0 | Policy reviewed in line with 2-year review process, as detailed in the policy. | May 2025 |
| | | |

| **9. Final Sign off**<br>*Completed EIA forms must be signed off by the completing manager. They will be reviewed as part of the decision-making process. Service lines should maintain an up-to-date log of all EIAs.* | | | |
|---|---|---|---|
| **Version approved:** | Version 2.4 | | |
| | | **Name** | **Date** |
| **Signature of responsible officer** | | Samantha Jones | May 2025 |
| **Which committee will be considering the findings and sign off the EA?** | | Clinical Policies Sub-group committee | May 2025 |
| **Minute number** *(to be inserted following presentation to committee)* | | | |

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# Stage One - Quality Impact Assessment Initial Screening Tool

The QIA Initial Screening Tool is required for all projects to identify the project's impact on quality, be it positive, neutral, or adverse. Five quality domains are thereby defined in the Initial Screening Tool, against which risks must be assessed and scored (see Appendix B for instructions on scoring).

For each quality domain in the Initial Screening Tool, highlight the proposal's impact on quality as either positive (P), neutral (N) or adverse (A). For **neutral** and **adverse** impacts, add a score for consequence (C) and likelihood (L) (Appendix B). Multiply the consequence and likelihood scores and record that number as the total score (T), then enter yes or no regarding need for a Stage 2 QIA for any domains with scores of 8 or greater. Calculate and record the total score of all domains. Complete an Equality Impact Assessment (EIA) and the EIA section on the QIA screening tool.

| **Quality Impact Assessment - Initial Screening Tool** | | Instructions:<br>• Answer Positive, Neutral or Adverse (P, N or A) against each quality domain<br>• If Neutral or Adverse, insert a Consequence (C) and Likelihood (L) score, multiply the scores, and insert the total score in the Total (T) column<br>• Add a brief description of the potential impact and mitigating actions<br>• Insert Y (yes) indicating need for a Stage 2 QIA for any domains with scores of 8 or greater<br>• Record the total score of all domains<br>• Complete an Equality Impact Assessment (EIA) and the EIA section on the QIA screening tool | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Quality Domain** | **Impact Question**<br>Could the proposal impact on any of the following? | **P/ N/ A** | **C** | **L** | **T** | **Brief description of potential impact** | **Mitigation strategy and monitoring arrangements** | **Stage 2 QIA? Y/N** |
| **Duty of Quality** | • The duty to safeguard children and vulnerable adults<br>• The duty to promote equality – https://bit.ly/3v85CNs<br>• The functions of other services within the organisation<br>• The clinical effectiveness of services<br>• Patients' and public experiences of services<br>• Compliance with NHS constitution's core principles - https://bit.ly/37vzY4k<br>Any other factors related to the duty to uphold and improve quality | A | 2 | 3 | 6 | Some patients will experience dissatisfaction as they may not receive NHS funded treatment procedures they perceive to be required. Formal complaints from patients who do not receive their requested procedure. | The IFR policy sets out the process for clinicians where treatment procedures which are not commissioned may be applied for. This policy ensures decisions for Funding requests are considered in line with the both the IFR policy and Prior Approval criteria's Policy. | N |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Patient Safety** | • Avoidable harm; clinical/environmental/other<br>• Infection prevention and control practices, systems, statutory expectations and acceptable standards<br>• Referral to treatment times<br>• Safeguarding Adults, Young People & Children – see https://bit.ly/3jeY3ih<br>• Workforce levels and competencies<br>Any other risk indicators relevant to patient safety. | N | 1 | 3 | 3 | Patients may experience emotional distress or have a personal financial impact because of not receiving perceived required treatment procedures. They may seek to access the procedures through independently funded streams which may be from providers who are not regulated resulting in them potentially sourcing unsafe treatments. | The IFR policy has been developed to ensure that only evidence-based, clinically effective services may be requested and may be commissioned. Patients in Lincolnshire will not have their access to essential care and treatment limited by this policy. There is no impact on patient safety because of not funding treatments that have poor or unproven clinical or cost effectiveness or where there is the availability of more appropriate treatment alternatives. | N |
| **Patient / Staff Experience** | • Informed choice, autonomy, and involvement<br>• Access to services<br>• Dignity, respect, compassion, and consent<br>• Patients' satisfaction with services<br>• Complaints and redress<br>Any other risk indicators relevant to patient experience: | N | 1 | 3 | 3 | Patients may perceive that they do not have access to services they require. They may not be able to make some decisions about their care if the procedure they are requesting is not routinely commissioned and needs prior approval | NHS Lincolnshire ICB aims to design and implement services, policies and measures that are fair and equitable. As part of its development, the IFR policy and its impact on staff, patients and the public have been reviewed in line with NHS Lincolnshire ICB's legal equality duties. The policy has been designed to ensure equality aspects are considered so that no-one is adversely affected by the policy. Staff/clinicians are supported with making decisions about procedures through the processes described in the policy | N |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | which provide appropriate guidance to staff. Patients would have the right to complain about decision outcomes in line with the ICB complaints policy. | |
| **Clinical effective-ness** | • Evidence based practice & standards<br>• Clinical outcomes<br>• Clinical leadership and engagement<br>Any other risk indicators relevant to clinical effectiveness: | P | N/A | N/A | N/A | Positive impact as the policy highlights the need for robust processes where procedures are not evidenced to be clinically effective. The policy clearly outlines the need for procedures to have an evidence base of clinical and cost effectiveness through the IFR process. | N/A | N |
| **Non-clinical/ operational impact** | • Impact on cost effectiveness<br>• Impact on infrastructure<br>• Impact on staff satisfaction and welfare<br>• Impact on the public perception of the organisation<br>• Social value impact<br>• Relationships with partner organisations | P | N/A | N/A | N/A | Positive impact as the policy highlights the need for thorough consideration and robust processes where procedures are not evidenced to be cost effective. The policy has a positive impact on the system infrastructure through best use of resources; this positively impacts on patient flow through the system by prioritising resources for those in most clinical need. This has a positive impact on the public perception of the organisation, through demonstration of equity of access. | N/A | N |
| | | **Total overall score =** | | | | **12** | | |

| EQUALITY | An Equality Impact Assessment must also be undertaken | | |
|---|---|---|---|
| **Name of person completing the Equality Impact Assessment:** | **Samantha Jones** | **Date: May 2025** | **Signature: Samantha Jones** |
| **Position:** | **Deputy Director of Nursing & Quality** | | |