Norfolk and Suffolk
Integrated Care Board

NHS Norfolk and Suffolk Integrated Care Board

Individual Funding Requests Policy

1. Version Control

Version	Date	Author and Role	Detail of Change
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Policy Owner: Ruth Spencer, Individual Funding Request Manager

Responsible Committee: Quality Committee

2. Next Review Date

The date this policy is due for review is*:* 01 April 2028

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4. Statement of Overarching Principles

4.1. All Policies, Procedures, Guidelines and Protocols of the Norfolk and Suffolk Integrated Care Board (ICB) are formulated to comply with the overarching requirements of legislation, policies or other standards relating to equality and diversity

5. Introduction

Norfolk & Suffolk ICB (NSICB) wish to operate a policy for decision making in respect of Individual Funding Requests (IFR). This document sets out the operating policy.

Like any other organisation, the NHS has limited resources, and NS ICB have a duty to manage them to a robust process. This policy applies to any patient for whom the NHS Norfolk and Suffolk ICB is the Responsible Commissioner for that person or needs medical treatment where the ICB is the responsible Commissioner for the provision of that medical treatment as part of NHS care.

Clinicians, on behalf of their patients, are entitled to make an individual IFR application to the IFR Panel for treatment to be funded by the NS ICB that is not normally commissioned under defined conditions, namely;

The request does not constitute a service development

AND

The patient is suffering from a medical condition for which the NS ICB have a policy but where the patient's particular clinical circumstances fall outside the criteria set out in the existing commissioning policy – this is a request for exceptional funding

OR

The patient is suffering from a medical condition, or requesting a treatment, for which the NS ICB have no related clinical threshold policy –this is a request for individual funding

OR

The patient has a rare clinical circumstance, rendering it impossible to carry out clinical trials, and for whom the clinician wishes to use an existing treatment on an experimental basis – this is a request for individual funding.

This policy outlines the conditions and the criteria which are used for decision making when considering IFR requests and applies to any person for those treatments for whom the ICB is the responsible commissioner for NHS care.

The ICB NS IFR Panel cannot consider any request for indications or therapies commissioned by NHS England (See https://www.england.nhs.uk/commissioning/spec-services/key-docs / for a list of the prescribed specialised services documents) Applications for these should be made direct to NHS England.

6. Scope

The NS ICB IFR Panel have a formal process to review IFR submissions and will make a decision to fund a request based purely on patients' 'clinical exceptionality'

To be able to consider funding requests for treatment there should be evidence provided within the application to show how the patient would meet both criteria of clinical exceptionality. The requesting clinician should therefore provide evidence to show how 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

7. Cross Reference to Other Policies

7.1. This policy is based on [NHS England » Commissioning policy: Individual funding requests] and has also been compared with neighbouring ICB's IFR policy

8. Clinical Exceptionality

The policy of the ICB is that there is no requirement for the Panel to carry out its own investigations about the patient's circumstances in order to try to find a ground upon which the patient may be considered to be exceptional nor to make assumptions in favour of the patient if one or more matters are not made clear within the application.

Therefore, if a clear case of exceptionality is not made out by the paperwork placed before the IFR- Panel, the panel would be entitled to turn down the application. The responsibility is on the clinical applicant to set out the grounds clearly for the panel on which it is said that the patient is exceptional.

The grounds will usually arise out of exceptional clinical manifestations of the medical condition, as compared to the general population of patients with the same medical condition as the patient. An exceptionality request can be made in relation to a medical condition where the ICB has a Commissioning Policy or a formal Commissioning Position, but the patient's clinical circumstances or the requested treatment falls outside that ICB Policy or Position. These grounds must be set out on the form provided by NSICB and should clearly set out any factors which the clinician invites the panel to consider as constituting a case of exceptional clinical circumstances.

Exceptional in IFR terms means a person to whom the general rule should not apply.

This implies that there is likely to be something about their clinical situation which was not considered when formulating the general rule. Very few patients have clinical circumstances which are genuinely
exceptional.

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

When making their decision, the NS IFR Panel is required to restrict itself to considering only the patient's presenting medical condition and the likely benefits which have been demonstrated by the evidence to be likely to accrue to the patient from the proposed treatment.

If a patient's clinical condition matches the 'accepted indicators' for a treatment that is not funded, their circumstances are not by definition, exceptional.

The IFR Panel will use the information provided by the requester to compare the patient to other patients with the same presenting medical condition at the same stage of progression. Specifically, the panel may consider, based upon the evidence provided to it, whether or not the patient has demonstrated exceptional clinical circumstances which lead the panel to believe that the patient would benefit significantly more from the treatment than the other patients not meeting funding criteria.

9.1 Identification Bias

The IFR Panel shall take care to avoid identification bias, often called the "rule of rescue". This can be described as the imperative people feel to rescue identifiable individuals facing avoidable death or a preference for identifiable over statistical lives[1].In plain terms this means; supporting intensive effort to prolong life (when prognosis appears poor and death unavoidable) and when there is little research evidence to support treatment options (e.g. in relapsed/refractory stages of disease). The fact that a patient has exhausted all NHS treatment options available for a particular condition is unlikely, of itself, to be sufficient to demonstrate exceptional circumstances. Equally, the fact that the patient is refractory to existing treatments where a recognised proportion of patients with the same presenting medical condition at this stage are, to a greater or lesser extent, refractory to existing treatments is unlikely, of itself, to be sufficient to demonstrate exceptional circumstances.

9.2 Funding of Experimental Treatments

This patient group represents a distinct group of exceptions and so are assessed in line with the ICB commissioning policy on experimental and unproven treatments.

In the absence of such a policy, the IFR panel shall be entitled to approve funding an experimental treatment for patients with rare clinical conditions or clinical circumstances.

In considering whether or not to agree to fund the treatment the IFR Panel's consideration shall include the following factors:

- The potential benefit and risks of the treatment
- The biological plausibility of anticipated benefit for the patient based on evidence of this treatment in other similar disease states
- Value for money
- Affordability and priority compared to other competing needs and unfunded developments
- Where the request is in respect of more than one patient or it is clear from the nature of the request that there is likely to be more than one patient, then the IFR panel should consider whether or not the request is a service development or trial

9.3 Clinical Exceptionality – Non-Clinical & Social Factors

The IFR process considers clinical information only. Non-clinical and social factors have to be disregarded for this purpose in order for the IFR Panel to be confident of dealing in a fair manner in comparable cases. If these factors were to be included in the decision-making process, NSICB could not be assured that it was being fair and equitable to other patients who cannot access such treatment and whose non-clinical and social factors would be the same or similar.

Consideration of social factors would also be contrary to NS ICB policy of non-discrimination in the provision of medical treatment. If, for example, treatment was to be provided on the grounds that this would enable an individual to stay in paid work, this would potentially discriminate in favour of those working compared to those not working. These are value judgements which the IFR Panel should not make.

9.4 A Good use of NHS Resources

Applications must be made by appropriate NHS treating clinicians. This is likely to be the patients' treating NHS doctor but may be an NHS therapist or other NHS healthcare professional applying appropriately within their scope of expertise. It is expected that the majority of IFRs will be submitted by secondary/tertiary care clinicians rather than primary care clinicians. It may not be uncommon for a GP to submit an IFR request. However, an IFR should be based on clinical exceptionality. If a GP feels that an IFR for an individual case is appropriate, expert advice should be sought, and included in the application, as appropriate. Patients cannot apply for their own funding, but an appropriate NHS clinician can apply on the patient's behalf if, in their professional opinion it is appropriate to do so.

Requesting clinicians are expected to submit a full and complete application form and all necessary supporting evidence. Should the IFR administration team require further information, it will be requested from the requesting clinician only, and the request will not be considered until the necessary information has been received. It is the responsibility of the requesting clinician to submit what is required in a timely manner to avoid delays in patient care. Where there is insufficient information submitted for the panel to make an informed decision the requesting clinician will be notified and the case closed until supporting information is made available.

The requesting clinician will be expected to explain why they consider the treatment for which funding has been applied for will be a good use of NHS resources.

This criterion is only applied where the panel has already concluded that the criteria of clinical exceptionality and clinical effectiveness have been met. Against this criterion the Panel balances the degree of benefit likely to be obtained for the patient from funding the treatment against cost. Having regard to the evidence submitted and the analysis they have carried out when considering clinical exceptionality and clinical effectiveness, Panel members will consider the nature and extent of the benefit the patient is likely to gain from the treatment, the certainty or otherwise of the anticipated outcome from the treatment and the opportunity costs for funding the treatment.

This means considering, for example, how significant a benefit is likely to be gained for the patient, and for how long that benefit will last. These factors need to be balanced against the cost of the treatment and the impact on other patients of withdrawing funding from other areas in order to fulfil the IFR. This reflects the fact that the only way to provide the funding for treatment under IFR, i.e. outside commissioned clinical policies which are developed through the structured prioritisation process, is to divert resources away from current services.

9.5 Funding Duration

Funding is valid whilst the patient remains registered with a GP within NS ICB area. This general rule is in line with NHS England guidance Who Pays? NHS England » Who Pays?

9.6 Specialised Treatments

NS ICB wants the best for its patients. It is important that when a patient reaches a stage in their treatment pathway that requires a specialist intervention, NS ICB would expect our patients to be referred to an officially designated, accredited centre (usually commissioned by NHSE) to ensure high quality care. NS ICB will not support specialised treatment at undesignated, non-accredited centres.

Requests for patients covered by NHS England's responsibilities should be sent directly to NHS England. If such requests are sent to the address above, the requesting clinician will be informed that they will need to submit a request to NHS England via mailto:england.ifr@nhs.net

It is not within the IFR Panel's remit to consider applications which have been refused by NHS England.

9.7 Urgent Requests

Where an IFR request is marked as urgent, the IFR Panel, will aim to make a decision within 5 working days of receipt. This working day period discounts any working days where the IFR team are awaiting information sought from the requesting clinician. At any point in the IFR process, the IFR team can ask for further information to clarify the request. If the requester does not provide a response to the IFR team within 3 working days the request will be closed and the requester

informed. Such a request can be reopened on submission of the additional information.

An urgent request is one which requires urgent consideration and decision because the patient faces a substantial risk of death or significant harm if a decision is not made before the next scheduled meeting of the IFR Panel. If the referring clinician considers that treatment cannot be delayed and decides to treat immediately then the cost of such treatment is incurred at the risk of the Provider.

The NS ICB recognise that there will be occasions when an urgent decision needs to be made to consider approving funding for treatment for an individual patient outside the NS ICB normal policies. In such circumstances the NS ICB recognise that an urgent decision may have to be made before a panel can be convened. The following provisions apply to such a situation.

- Urgency under this policy cannot arise as the result of a failure by the Clinical Team to expeditiously seek funding through the appropriate route and/or where the patient's legitimate expectations have been raised by a commitment being given by the provider trust to provide a specific treatment to the patient, will **not** lead to the circumstances being considered as urgent under this policy. In such circumstances the NS ICB expect the provider trust to proceed with treatment and for the provider to fund the treatment.

- In situations of clinical urgency, the decision will be made by a nominated clinical member of the panel, with the support of the Executive Medical Director of the NS ICB. In the absence of the Executive Medical Director, the deputy Medical Director of the ICB can make this decision.

- The clinical member will as far as possible within the constraints of the urgent situation, follow the policy set out above in making the decision. The clinical member shall consider the nature and severity of the patient's clinical condition and the time period within which the decision needs to be taken. As much information about both the patient's illness and the treatment should be provided as is feasible in the time available and this shall be considered for funding in accordance with relevant existing commissioning policies.

- The clinical member shall be entitled to reach the view that the decision is not of sufficient urgency or of sufficient importance that a decision needs to be made outside of the usual process.

- The IFR administrative team will submit anonymised urgent requests via e-mail to NS ICB IFR panel members.

- The IFR Panel will aim to make a decision within 5 working days of receipt of the request. Trusts should treat all urgent and life-threatening situations based on the clinical need.

- Urgent requests will also be discussed at the next available panel meeting and a record added to the minutes.

9.8 Approval

Complete IFR requests are reviewed by the NSICB IFR panel which includes senior clinicians and a consultant in Public Health medicine. The IFR panel review submitted clinical evidence relevant NICE guidance, existing clinical policies and pathways and evidence of exceptionality. The panel makes one of the following decisions:

Approve funding

The IFR Panel shall be entitled to approve requests for funding for treatment for individual patients where all the following conditions are met:

- The IFR Panel is satisfied that there is no cohort of similar patients. If there is a cohort of similar patients the IFR Panel shall decline to make a decision because the application is required to be treated as a request for a service development. (The IFR Panel will continue to have the right to make decisions on any further similar applications for funding whilst a policy is in the process of being produced.)

- The request does not constitute a service development.

- The patient is suffering from a medical condition for which the NS ICB has a policy but where the patient's particular clinical circumstances fall outside the criteria set out in the existing commissioning policy for funding the requested treatment.

- The patient is suffering from a medical condition, or requesting a treatment, for which the NS ICB has no policy.

- The patient has a rare clinical circumstance, this rendering it impossible to carry out clinical trials, and for whom the clinician wishes to use an existing treatment on an experimental basis.
- Exceptional circumstances apply where there is sufficient evidence to show that, for the individual patient, the proposed treatment is likely to be clinically and cost effective or that the clinical trial has sufficient merit to warrant NHS funding.

The IFR Panel is not required to accept the views expressed by the patient or the clinical team concerning the likely outcomes for the individual patient of the proposed treatment, but it 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 presented to support the request 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 IFR Panel may make such approval contingent on the fulfilment of such conditions as it considers fit.

Very occasionally an individual funding request presents a new issue which needs a substantial piece of work before the NS ICB can reach a conclusion upon its position. This may include wide consultation. Where this occurs the IFR Panel may adjourn a decision on an individual case until that work has been completed.

Decline Funding – where the request does not meet the criteria outlined in this policy.

Request further information where there is insufficient information presented to enable the Panel to reach a decision.

The IFR administration team will provide the requesting clinician with a written outcome of the decision within 5 working days. The decision letter will clearly document the rationale for the decision. The requesting clinician will be responsible for informing the patient.

9.9 Review of the Decision

In any case, where further relevant information becomes available which has not been considered by the NS IFR Panel, the referring clinician may ask the NS IFR Panel to reconsider the case specifically in the light of this further information

Requests for re-consideration for drugs IFR must be submitted within 30 working days of panel decision, and for non-drugs cases must be submitted within 6 months of panel decision. The referring clinician must clearly outline the reasons for the re-consideration and/or the clinician requesting the re-consideration must submit new clinical evidence to the panel.

9.10 Appeal of the Decision

Where the NS IFR Panel has refused to support funding for a requested treatment or has approved the treatment subject to conditions, the patient shall be entitled to ask that the decision of the NS IFR Panel be reviewed by appeal. All requests for appeal must be supported by the senior treating clinician in writing to the Chair of the NS IFR Panel within 30 working days (i.e. 6 weeks) for IFR drugs cases and within 6 months (non-drugs) of the date of the NS IFR Panel's decision. The clinician must clearly outline the reasons as to why the decision taken by the NS IFR panel was:

- procedurally improper and/or
- that it misunderstood the medical evidence and/or
- was in the clinician's opinion a decision which no reasonable IFR panel would have reached.

The NS IFR Panel Chair will consider the clinician's request and refer the case to the NS IFR Panel Administrator to convene an appeal panel and reach a decision within 30 working days of receipt of the appeal.

The IFR Appeal Panel is part of the corporate governance process of the ICB. The role of the IFR Appeal Panel is to determine whether the NS IFR Panel has followed the ICB procedures, has properly considered the evidence presented to it and has come to a reasonable decision upon the evidence.

The IFR Appeal Panel shall consider whether:

- The process followed by the NS IFR Panel was consistent with the operational policy of the ICB
- The decision reached by the NS IFR Panel:
- was taken following a process which was consistent with the policies of the ICB
- had taken into account and weighed all the relevant evidence
- had not taken into account irrelevant factors
- indicated that the members of the panel acted in good faith
- was a decision which a reasonable IFR panel was entitled to reach.

If the IFR Appeal Panel considers that there was no reasonable prospect of the NS IFR Panel coming to a different decision, then the IFR Appeal Panel shall uphold the decision notwithstanding the procedural error.

However, if the IFR Appeal Panel considers that there was a reasonable prospect that NS IFR Panel may have come to a different decision if the NS IFR Panel had not made the procedural error, the IFR Appeal Panel shall require the NS IFR Panel to reconsider the decision.

The IFR Appeal Panel shall not have power to authorise funding for the requested treatment but shall have the right to make recommendations to the NS IFR Panel and/or to request one of the Officers authorised to take urgent decisions to consider exercising that power.

Should the referring clinician or patient remain dissatisfied with the IFR Review Panel decision, either of them may pursue the matter through the NHS Complaints Procedure.

9. Related ICB Governance and Policies

9.1. Clinical Threshold policies

The Clinical Policy Development Group is to support effective commissioning by developing clinical threshold policies based on the best available evidence, in an open and transparent process. These policies support NS ICB to prioritise resource allocation for treatments based on evidence of clinical effectiveness, safety, cost effectiveness and affordability, to ensure finite resources are managed to optimise health outcomes for the local population.

9.2. Consultation Process

All affected Providers, Primary Care and other appropriate stakeholders will be given the opportunity to engage in the policy development process via the Clinical Policy Development Group. The Clinical Policy Development Group will consider all feedback received and where appropriate, are willing to make amendments as suggested.

9.3. Clinical Thresholds

Once the procedures and thresholds for any new or existing phase are decided the Clinical Thresholds Policy will be amended, uploaded on to Knowledge NoW (or appropriate successor website) and disseminated to appropriate Providers and stakeholders. (Clinical Threshold Policy Implementation SOP) see appendix 1

9.4. Area Prescribing Committee (NS APC) (TAG /IMOC or equivalent)

The NS APC has a responsibility to promote rational, evidence-based, high quality, best-value medicines optimisation across Norfolk and Suffolk to ensure equity of access to medicines for all residents. The remit is to provide oversight and direction to deliver a shared medicines optimisation agenda for improving population health, preventing ill health, reducing health inequality, and promoting physical and mental health and wellbeing across Norfolk and Suffolk. It provides a system-wide collective clinical leadership approach to medicines optimisation and clinical decision making ensuring a best value approach across the ICS including; acute and mental health services, Primary Care Networks and Community Services There is also consideration of other health-system costs to support and facilitate service redesign.

The NS APC commission NICE approved treatments; adopting NICE Technology Appraisals (TAs) within the mandated timeframe, make local commissioning recommendations considering regional and national guidance, in ways that are clear, consistent, and defensible, using the NHS 'Ethical & Commissioning Principles' Framework and local decision-making criteria

9.5. Knowledge NoW

The IFR policy can be found on the Knowledge NoW website available for downloading here IFR Policy . The IFR form is available via primary care clinical systems, or Knowledge NoW, IFR Form . This website is subject to change with the evolution of the new NSICB.

10. Roles and Responsibilities

10.1. Individual Funding Request Process – Providers, Including General Practice

The voting members of the panel are clinically experienced professionals who have undertaken robust IFR training. This enables them to evaluate each request on a consistent and evidenced based manner, considering biological plausibility, clinical effectiveness, and financial sustainability.

Providers, including General Practice, are to ensure the following:

The Clinical Thresholds Policy, IFR form and other associated documentation is shared and communicated internally with all relevant staff to ensure compliance with the Policy.

Clinicians will take the NS ICB, clinical threshold policies into account in the advice and guidance given to patients prior to making the decision to request an IFR. The IFR process is discussed with the patient in clinic to ensure the patient understands the process regarding funding requirements and consent to share information. A patient information leaflet explaining the IFR process can be located via the link below and should be given to the patient to assist with this discussion.

Information for Patients - Knowledge NoW

An IFR form must be completed electronically, by the relevant supporting clinician for the patient. The request forms are available on Ardens, the Knowledge NoW website at; Referral Forms - Knowledge NoW (NSknowledgenow.nhs.uk) although this website may be subject to change with the evolution of the new NSICB, or via email request nw.ifr@nhs.net. The completed IFR form should be submitted using the agreed template. Handwritten pro-formas cannot be accepted and will be returned to the requesting clinician.

The IFR form must be completed to indicate patient consent, where patient consent has not been declared or clearly marked the incomplete proforma will be returned to the requesting clinician

Once a request has been submitted for funding, the clinician will respond to queries and/or requests for further information in a timely manner.

Funding requests reviewed by the IFR Panel will result in a formal outcome letter sent to the requesting clinician. This letter will include the rationale for the decision, and any relevant instructions or follow-up actions. Where applicable, the panel may request a clinical update of the patient's progress to support further consideration.

All communication with the patient is the responsibility of the requesting clinician. The requesting clinician is responsible for informing the patient of the ultimate decision.

The IFR- Panel cannot consider any request for indications or therapies commissioned by NHS England (See NHS England 'The Manual' for a list of the prescribed specialised services)https://www.england.nhs.uk/commissioning/spec-services/key-docs/ Applications should be made direct to NHS England.

Requests for patients covered by NHS England's responsibilities should be sent directly to NHS England. If such requests are sent to the address above, the requesting clinician will be informed that they will need to submit a request to NHS England via mailto:england.ifr@nhs.net

It is not within the IFR- Panel's remit to consider applications which have been refused by NHS England.

If an IFR is returned to the referring clinician approved, the patient should be referred or listed for the requested procedure and the relevant authorisation number recorded by the hospital / other provider, according to their local policies and procedures.

If an IFR is declined, it will be returned to the referring clinician, the patient should not be referred or listed for the procedure.

10.2. Individual Funding Request Process

Please see table below of the IFR process. In summary;

- IFR Panels will be administered by IFR administration team.
- IFR Panels will be held on a monthly basis.

Stage	Time Frame
Acknowledgement Letter sent to referring Clinician.	IFR administration to complete within **5 working days** of receipt.
Admin Triage – To ascertain if further information is required.	Administrate within **15 working days** of receipt.
Panel papers circulated to panel members.	Administrate within **5 working days** of monthly panel meeting.
Decision communicated to referring clinician.	Administrate within **5 working days** after panel.
Urgent Requests.	IFR panel members to provide a decision. Administrate within **5 working days**.
If any further information requested by IFR team, fails to be submitted the IFR case will be lapsed and referrer will be notified with the option to re-submit.	Cases to be processed within **40 working days** of receipt

The IFR Team will process requests from receipt to decision letter within 40 working days (this timeframe will be subject to any requested information awaited from the referrer/clinician/patient).

10.3. Individual Funding Request Process NS ICB

NS ICB will ensure the following;

NS ICB will appoint a lay chair for the IFR Panel.

NS ICB will ensure there are clinical representatives at each IFR Panel meeting. The NS ICB representatives will have delegated authority to make decisions on behalf of NS ICB.

The Lay-Chair of the IFR Panel has delegated responsibility to approve funding requests up to a maximum of £50,000 per case after approval by the IFR Panel. Responsibility for approving requests for funding over £50,000 per case has been delegated to the Chief Executive Officer or Director of Finance after recommendation by the IFR Panel and subsequent approval of the Executive Medical Director or their deputy.

For a panel meeting to be quorate, there is a requirement for three medically qualified members of the panel to be present. This may include a medically qualified Consultant in Public Health.

11. Q&A Section

11.1. What is a service development?

A service development is any aspect of healthcare which the NS ICB has not historically agreed to fund, and which will require additional and predictable recurrent funding.

Some funding requests may fall within the Experimental and Unproven Treatments Policy the policy is available Experimental and Unproven Treatments Policy

All individual funding requests submitted to NS ICB will be subject to screening by the IFR Panel and NS ICB to determine whether the request represents a service development. Service developments include, but are not restricted to:

- New services
- New treatments including medicines, surgical procedures and medical devices.
- Developments to existing treatments including medicines, surgical procedures and medical devices.
- New diagnostic tests and investigations.
- Requests to alter existing policy (called a policy variation). The proposed change could involve adding in an indication for treatment, expanding access to a different patient sub-group or lowering the threshold for treatment.

- Requests to fund a number of patients to enter a clinical trial and the commissioning of a clinical trial are considered as service developments in this context as they represent a need for additional investment in a specific service area.

Where there is an identified service development, or an identified gap in commissioning service, the IFR panel will advise the NS ICB Clinical Policy Development Group (CPDG). This will then be recorded onto CPDG action log for further review. New or amended clinical threshold policies instigated from CPDG, will then be presented at NS ICB Scheduled Care board (or relevant successor meeting) for final ratification.

A request for a treatment should be classified as a request for a service development if there are likely to be a cohort of similar patients who are:

- In the same or similar clinical circumstances as the requesting patient whose clinical condition means that they could make a like request (regardless as to whether such a request has been made)

AND

- Who could reasonably be expected to benefit from the requested treatment to the same or a similar degree.

It is common for clinicians to request an individual funding request for a patient where the request is properly analysed, the first patient of a group of patients wanting a particular treatment. Any individual funding request which is representative of this group represents a service development. As such it is difficult to envisage circumstances in which the patient can properly be classified to have exceptional clinical circumstances. Accordingly, the individual funding request route is usually an inappropriate route to seek funding for such treatments as they constitute service developments.

11.2. What is a "cohort of similar patients"?

A cohort of similar patients for the purposes of this policy has been defined as the number of requests received or likely to be received per year which will require consideration of a commissioning policy. In these circumstances, the IFR route to funding may only be considered if the patient is clinically exceptional to the cohort.

11.3. When should consideration of a commissioning policy be given?

The NS ICB have set the level at which cases will require consideration of a commissioning policy. Once this number of requests is met, the IFR route to funding may only be considered if the patient is clinically exceptional to the cohort.

The NS ICB will consider the development of a clinical commissioning policy where:

- The numbers of patients for whom the treatment will be requested per year is likely to be for drugs IFR 2 or more patients in the population served by NS ICB and for non-drugs IFR 5 or more patients in the population served

by NS ICB. Upon receipt of the trigger request for funding a business case/clinical commissioning policy will be requested. (The IFR Panel will continue to have the right to make decisions on any further similar applications for funding whilst a policy is in the process of being produced.) **OR**

- The cost of funding the requested treatment for an individual is likely to result in expenditure to the NS ICB in excess of £50,000.

If the number of patients for whom the treatment is requested is likely to be below 5 per year, the IFR Panel will consider the request for funding.

The IFR Panel is not entitled to make policy decisions for NS ICB. It follows that where a request has been classified as a service development for a cohort of patients, the IFR Panel is not the correct body to make a decision about funding the request. In such circumstances the individual funding request should not and will not be presented to the IFR Panel but will be dealt with in the same way as other requests for a service development through NS ICB due processes (the IFR Panel will continue to have the right to make decisions on further similar applications whilst a policy is in the process of being developed).

Where an IFR has been classified as a service development for a cohort of patients, the options open to the IFR Panel include:

- To refuse funding and request the provider prioritises the service development internally within the provider organisation that made the request and, if supported, to invite the provider to submit a business case as part of the annual commissioning round for the requested service development.
- To refuse funding and initiate an assessment of the clinical importance of the service development within the NS ICB with a view to developing a policy and determining its priority for funding in the next financial year
- To refer the request for funding for immediate workup of the service development as a potential candidate for in year service development.

In practice, all requests for funding for an individual patient have been called Individual Funding Requests (IFRs) but these sub-categories of request should be recognised.

The broad types of request that may be received are;

- Representing a service development for a cohort of patients
- On grounds of clinical exceptionality where there are commissioning arrangements in place
- On grounds of rarity and no commissioning arrangements exist.
- For a new intervention or for use of an intervention for a new indication, where no commissioning arrangements exist.

There can be no exhaustive definition of the conditions which are likely to come within the definition of an exceptional individual case. The word ‘exception’ means;

‘a person, thing or case to which the general rule is not applicable’.

To meet the definition of ‘exceptional clinical circumstances’ there must be a NS ICB policy in place that describes the availability of the requested intervention and the patient must be (or their clinician 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

11.4. What are non-clinical factors?

The NS ICB do not discriminate on grounds of social factors (for example, but not limited to: age, gender, ethnicity, employment status, parental status, marital status, religious/cultural factors). Social factors will not be taken into account in determining whether exceptionality has been established.

The NS ICB will seek to commission treatment based on the presenting clinical condition of the patient and not based on the patient’s non-clinical circumstances.

In reaching a decision as to whether a patient’s circumstances are exceptional, the panel is required to follow the principles that non-clinical factors including social value judgements about the underlying medical condition or the patient’s circumstances are not relevant.

Clinicians are asked to bear this policy in mind and not refer to non-clinical factors to seek to support the application for individual funding.

11.5. How do you prove the patient’s circumstances are exceptional?

The responsibility is on the clinical applicant to set out the grounds clearly for the panel on which it is said that this patient is exceptional.

The grounds will usually arise out of exceptional clinical manifestations of the medical condition, as compared to the general population of patients with the medical condition which the patient has. These grounds must be set out on the form provided by the NS ICB and should clearly set out any factors which the clinician invites the panel to consider as constituting a case of exceptional clinical circumstances. If a clear case as to why the patient’s clinical circumstances are said to be exceptional is not made out, then the panel can do no other than refuse the application.

The panel recognises that the patient’s referring clinician and the patient together are usually in the best position to provide information about the patient’s clinical condition as compared to a subset of patients with that condition.

The referring clinician is advised to set out the evidence in detail because the panel will contain a range of individuals with a variety of skills and experiences but may well not contain clinicians of that speciality. The NS ICB therefore requires the referring clinician, as part of their duty of care to the patient, to explain why the patient's clinical circumstances are said to be exceptional.

There may be cases where clinicians and/or patients seek to rely on multiple grounds to show their case is exceptional. In such cases the panel should look at each factor individually to determine;

(a) whether the factor was capable of making the case exceptional and
(b) whether it did in fact make the patient's case exceptional

The panel may conclude, for example, that a factor was incapable of supporting a case of exceptionality and should therefore be ignored. That is a judgment within the discretion of the panel.

If the panel is of the view that none of the individual factors on their own make the patient's clinical circumstance exceptional, the panel should then look at the combined effect of those factors which are, in the panel's judgement, capable of supporting a possible finding of exceptionality. The panel should consider whether, in the round, these combined factors demonstrate that the patient's clinical circumstances are exceptional. In reaching that decision the panel should remind itself of the difference between individual distinct circumstances and exceptional clinical circumstances.

11.6. What is rarity in an IFR?

The assessment of these funding requests should be distinguished from requests on the grounds of exceptionality.

A set of criteria need to be applied when a patient's medical condition is so rare or their condition is so unusual that the clinician wishes to use an existing treatment in an experimental way. This exception does not routinely apply to rare disorders or small subgroups of patients within a more common disorder because here it would be normal to have a trial involving sufficient patients formally to evaluate the proposed treatment in a trial.

Experimental-Unproven-Treatments-Policy.docx

In assessing these cases the panel should consider the following;

- Can this treatment be studied properly using any other established method? If so then funding should be refused.
- Is the treatment likely to be clinically effective?
- In addition, the usual considerations are included. Whether the treatment is cost effective, and what is this patient's priority compared to patients whose care has not been funded.

11.7. What is Triage?

Requests are subject to a triage process to determine whether the request has sufficient clinical and other information for the individual funding request to be considered fully by the IFR Panel.

All requests will be triaged prior to presenting at the IFR Panel. Triage will consider the information provided in the request against any relevant commissioning policies and make recommendations for the panel to consider. Recommendations include;

- Approved
- Declined
- Further clinical debate required at panel

Sometimes, triage will determine that more information is required to progress the request and the referrer will be contacted.

11.8. What happens with IFRs which have passed triage?

An exceptionality request can be made in relation to a medical condition where the NS ICB have a Commissioning Policy but the patient's clinical circumstances or the requested treatment falls outside the NS ICB Policy. These exceptionality requests should be completed by the clinician with reference to the relevant generic and/or treatment specific commissioning policy.

The IFR Panel will use the information provided by the requester to compare the patient to other patients with the same presenting medical condition at the same stage of progression. Specifically, the panel may consider, based upon the evidence provided to it, whether the patient has demonstrated exceptional clinical circumstances which lead the panel to believe that the patient would benefit significantly more from the treatment than the other patients not meeting funding criteria. When making their decision, the IFR Panel is required to restrict itself to considering only the patient's presenting medical condition and the likely benefits which have been demonstrated by the evidence to be likely to accrue to the patient from the proposed treatment.

The IFR Panel shall seek to make decisions in accordance with the NHS ethical framework & principles, including the requirement to have due regard to the obligations of the Equality Act 2010 save where a difference in treatment is based on objectively justifiable factors and is a justified and proportionate response to the needs of different groups of patients.

The IFR Panel shall seek to make decisions in accordance with the 1998 Human Rights Act.

The IFR Panel will not make decisions for treatments available to individual patients, or other clinically similar patients, on the basis of non-clinical factors.

11.9. What happens if an IFR is Urgent?

An IFR request is considered *urgent* when the patient could face a serious risk of death or significant harm if a funding decision is not made before the next scheduled IFR Panel meeting. The IFR Panel aims to make a decision within 5 working days of receiving the urgent request If the clinician feels the patient must be treated immediately, they may go ahead —
but the provider takes on the financial risk if funding is later declined.

A situation is **not** considered urgent if:

- the clinical team did not request funding promptly, or
- the patient has been given unrealistic expectations about treatment before funding was agreed.

In these situations, the provider is expected to treat and fund the care themselves.

Urgent decisions are made by:

- a nominated clinical member of the IFR Panel, and
- the Executive Medical Director (or the Deputy Medical Director if needed).

This is done when waiting for a full panel meeting would risk harm.

They may decide that the case does **not** require a fast-track decision and can wait for the usual IFR Panel process.
All urgent approvals or rejections are reviewed at the next scheduled panel meeting, and a record is added to the minutes.

11.10. Retrospective payments for funding?

Individual Funding Requests will not be accepted where the request is for retrospective funding e.g. requests from clinicians or providers made after a period of care has commenced or request from patients for reimbursement of the costs of a treatment which has been purchased privately.

Treatments that are undertaken, without funding approval or agreement, will be at the risk of the provider.

11.11. What information is submitted to the IFR Panel?

All applications must be accompanied by written support and evidence provided by the clinical team treating the patient. It is the clinician's responsibility to ensure that the appropriate information is provided to the NS ICB according to the type of request being made, in a timely fashion consistent with the urgency of the request. If relevant information is not submitted, then the referring clinician will bear responsibility for any delay that this causes.

All clinical teams submitting IFR requests must be aware that information that is immaterial to the decision will not be considered by the IFR Panel. This may include information about non-clinical factors relating to the patient or information which does not have a direct connection to the patient's clinical circumstances.

An electronic request form must be completed by the referring clinician. The request forms are available via primary care clinical systems, or Knowledge NoW (or successor website), IFR Form

Requests for patients covered by NHS England's responsibilities should be sent directly to them.

If further information is required to prepare the case for consideration by the IFR Panel this may delay presentation to the IFR Panel. All required information from the provider hospital trust/clinician must be sent to the IFR Administrator at least 10 working days before the scheduled date of the IFR Panel at which the case is to be considered.

All applications must be accompanied by written support and evidence provided by the clinical team treating the patient explaining:

- Whether the request for funding is an individual request or an exceptional request.
- The clinical circumstance of the patient. The clinical team is required to present a full report to the IFR Panel which sets out a comprehensive and balanced clinical picture of the history and present state of the patient's medical condition, the nature of the treatment requested and the anticipated benefits of the treatment.
- The planned treatment and the expected benefits and risks of treatment. The clinical team shall describe the anticipated clinical outcomes for the individual patient of the proposed treatment and the degree of confidence of the clinical team that the outcomes will be delivered for this particular patient.
- The evidence on which the clinical opinion is based. The clinician shall refer to, and 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.
- The clinical team shall set out the full attributable costs of and connected to the treatment.
- Whether or not there are likely to be similar patients either within the NS ICB or across the region. For exceptionality requests the clinician must also provide the case for treating this patient and no other apparently similar patients.

11.12. What are the possible outcomes from an IFR request?

The IFR Team will advise relevant applicants of the outcome of their application within 10 working days of the Panel meeting (although in reality, this is usually sooner.)

11.13. Approval

Where treatment requested meets the criteria outlined in the NS IFR Panel Policy.

11.14. Approval with conditions

Where an IFR Team will require an update on the clinical outcome of treatment from the requesting clinician in order to determine whether it has resulted in the anticipated level of benefit to the patient, an appropriate review date will be determined by the NS IR Panel and recorded. An outcomes reporting form will be provided to the requesting clinician with the decision letter. This information is essential when processing requests for continuation of treatment. Provider Trusts and their clinicians are required to comply with such requests for information on the outcomes of treatment for their patients, in compliance with the NS IFR Panel policy. Funding continuation is a condition on this being provided.

11.15. Decline

The NS IFR panel may decline funding on of two grounds:

That there is insufficient information presented to enable the Panel to reach a decision.

The NS IFR Panel may wish to seek further information to clarify specific issues relating to the case. Where this is the case the NS IFR Panel Chair will clearly outline the action to be taken. Any advice received will be shared with the requester at the same time that the IFR outcome is communicated.

That the request does not meet the criteria outlined in the IFR-Drugs Panel policy.

A written response will be sent to the clinician explaining the reason for the decision and outlining the options that are available. The responsibility for explaining the reasons for the decision and answering any questions which the patient may have about the request or their clinical options will lie with the requesting clinician. This is because the clinician will have the full details of the reasons for the decision. The clinician should contact the patient in order to discuss the outcome.

11.16. How are IFR Panel decisions communicated?

The referring clinician making the request will be informed of the IFR Panel’s decision as soon as practicable via email within 5 working days. Patient confidentiality will be maintained at all times.

11.17. Will the IFR Panel give reasons as to why a decision has been made?

The NHS Constitution requires NHS organisations to make decisions ‘rationally following a proper consideration of the evidence’ and be clear about the reasons for their decisions. The NS ICB will give reasons for its decisions.

The purpose of a duty to give reasons is to tell the patient in general terms why the NS ICB reached the decision it did and the factors that it considered in reaching the decision.

Where a public body is required to give reasons for its decision, it is required to give reasons which are proper, adequate, and intelligible and enable the person affected to know why they have been approved or declined. These can be expressed in a few sentences, but they need to go into sufficient detail so that the patient knows that the main aspects of their case have been properly considered.

Whether the NS ICB IFR Panel has or has not discharged the duty to give reasons will all depend on the individual circumstances. There will be simple cases where a single sentence is sufficient and there will be more complex cases where a full paragraph or two is needed to explain the thinking of the IFR Panel, and the rationale for the panel's decision.

The duty will usually mean that the decision letter should explain:

- Whether the panel reached the view that the patient did or did not demonstrate exceptional clinical circumstances, and the basis for that decision. If the panel felt that the patient's clinical circumstances were broadly in line with the clinical circumstances of those in the cohort of other patients in the same clinical condition, then this should be stated.

- If the patient put forward specific factors which were said to support his or her claim to be in exceptional clinical circumstances, the letter should explain (by reference to the main factors) why the panel did not consider that these amounted to exceptional clinical circumstances.

11.18. Can the IFR Panel decision be reviewed?

Where the IFR Panel has declined a request or has approved the treatment subject to conditions, the patient shall be entitled to ask that the decision of the IFR Panel be reviewed. All requests for a review must be supported by the senior treating clinician in writing to the IFR Administrator within 6 months from the date of notification of the date of the IFR Panel's decision. The clinician must clearly outline the reasons as to why a review is requested. It will be either;

- That further evidence can be provided by the referrer and is duly submitted; and/or
- It was in the clinician's opinion a decision which no reasonable IFR Panel would have reached.

The IFR Administrator will prepare the additionally submitted evidence for discussion at the next available panel meeting. The IFR Panel will then review its initial decision based on any additional information received. The result of the review will be communicated to the referring clinician who must then notify the patient of the panel's decision.

Should the referring clinician or patient remain dissatisfied with the IFR Panel decision, the matter may be pursued through the NHS Complaints Procedure. This can be done by contacting: Nwicb.contactus@nhs.net or by telephone 01603 595857.

11.19. What is an Appeals Panel and why would it be used?

The appeals process remains the responsibility of the NS ICB.

The IFR Appeal Panel is part of the corporate governance process of the ICB. The role of the IFR Appeals Panel is to determine whether the IFR Panel has followed its own policy and procedures, has properly considered the evidence presented to it and has come to a reasonable decision upon the evidence.

An appeals panel would consist of a designated chairperson supported by a minimum of two other clinical panel members, who were not previously part of the IFR decision making of the particular case in question.

The IFR Appeals Panel considers whether the IFR Panel has:

Failed in a material way to follow its own procedures; and/or

Failed in a material way properly to consider the evidence presented to it (e.g. by taking account of an immaterial fact or by failing to take account of a material fact); and/or

Failed to give a clear rationale for its decision;

The IFR Appeals Panel may uphold the patient's appeal and refer the case for reconsideration by the IFR Panel.

The IFR Appeals Panel does not have power to authorise funding for the requested treatment but will make recommendations to the IFR Panel.

The IFR Appeals Panel will inform the NS IFR panel and referring clinician of it's decision and the reasons for it as soon as practicable in writing via e-mail or letter. The referring clinician will notify the patient in a timely manner of the IFR Appeals Panel decision.

Should the referring clinician or patient remain dissatisfied with the IFR Appeals Panel decision, the matter may be pursued through the NHS Complaints Procedure. This can be done by contacting: Nwicb.contactus@nhs.net or telephone: 01603 595857.

11.20. Decisions on Funding

The IFR panel is committed to ensuring that decision making is transparent, fair and equitable. At all times, decision to fund treatments will be based upon both national and local guidance. Where there is no guidance available, or to be ratified, the panel will make decisions based upon rational and supporting evidence submitted to support the IFR application.

The standard policy is available on NS ICB website and is accessible to all.

12. Glossary

Appeal refers to the process where the referring clinician can request that the IFR Panel decision is assessed, either on the basis that due process was not followed by the IFR Panel or that the IFR Panel failed to give a clear rationale for its decision.

Clinical circumstances means a full history of the patient's medical condition, a full description of the patient's present medical condition and as comprehensive an assessment of the patient's future medical condition and prognosis as the Clinical Team treating the patient is able to provide.

Cohort of similar patients for the purposes of this policy has been defined as the number of requests received or likely to be received per year which will require consideration of a commissioning policy.

Device in the context of this non-drug policy is something that isn't prescribable on NHS primary care prescription (FP10) or via hospital electronic prescribing (EPMA) and is for the treatment of a specific condition and provided under medical supervision. Items that are not medicines but are prescribable by the above methods are in the scope of the drugs IFR policy.

Exceptional clinical circumstances refers to a patient who has clinical circumstances which, taken as a whole, are outside the range of clinical circumstances presented by a patient within the normal population of patients with the same medical condition and at the same stage of progression as the patient.

IFR Panel is the committee of NS ICB clinicians who have been given authority to make individual funding request decisions on its behalf in line with the legal duties of ICBs set out in The Health & Social Care Act 2012.

Individual funding request is a request received from a clinician which seeks funding for a single identified patient for a specific treatment.

Integrated Care Board is a statutory organisation responsible for purchasing health and care services for patients.

NHS Constitution refers to the established principles and values of the NHS in England.

NICE refers to the National Institute for Health & Care Excellence. They provide national guidance and advice to improve health and social care.

Policy refers to a written document determining whether or not a particular treatment is commissioned.

Policy variation occurs when an existing policy is changed. When there is a proposal which would result in increased access to a treatment (for example by lowering the threshold for treatment or adding a new indication for treatment) the policy variation is a service development and will be treated as such.

Rarity refers to a patient whose medical condition is so rare, or their condition is so unusual that the clinician wishes to use an existing treatment in an experimental way.

Review refers to the process where the referring clinician can request the IFR Panel decision is reviewed, either on the basis that further evidence can be provided in support of the IFR or that the decision, in the clinician's opinion, was one which no reasonable IFR Panel would have reached.

Service Development refers to any aspect of healthcare which the ICB has not historically agreed to fund, and which will require additional and predictable recurrent funding.

Social factors are, for example, (but not limited to) age, gender, ethnicity, employment status, parental status, marital status, religious/cultural factors.

Treatment means any form of healthcare intervention which has been proposed by a clinician and is proposed to be administered as part of NHS commissioned and funded healthcare.

Triage is a process to determine whether the request has sufficient clinical and other information in order for it to be fully considered by the IFR Panel.

Urgent request requires urgent consideration and a decision because the patient faces a substantial risk of death or significant harm.

13. Information Governance

NS ICB are the statutory body responsible for funding decisions. The individual funding request form and any other supporting information supplied may therefore be shared with the NS ICB or other trusted organisations legitimately acting on behalf of the NS ICB.

In applying this policy, the ICB will have due regard for the Data Protection Act 2018 and the requirement to process personal data fairly and lawfully and in accordance with the data protection principles. Data Subject Rights and freedoms will be respected, and measures will be in place to enable employees to exercise those rights. Appropriate technical and organisational measures will be designed and implemented to ensure an appropriate level of security is applied to the processing of personal information. Employees will have access to a Data Protection Officer for advice in relation to the processing of their personal information and data protection issues.

When an IFR has been submitted for patients who are aged 25 years or younger, the patient record will be shared securely with NSICB Children and Young Peoples Service for the following purposes:

- To ensure that there is a consistent and transparent process to each funding request
- Requests are reviewed by the appropriate funding panel

- Identification of safeguarding concerns
- Enable response to complaints, FOI requests
- Identify specific care needs within adolescent health care by having oversight of requests for funding of treatments

Further Information regarding Child & Young Peoples Services can be found via the following link: [Children and Young People - Norfolk and Waveney ICS]

IFR panel meeting minutes, will not be made available in the public domain. Personal information may be retained only for the purposes of the IFR application and, in some cases, may be used for invoicing and payment reconciliation. Patient's medical records may be used for the purposes of quality audit which will be completed by a health professional. Anonymised information may also be shared as part of the NS ICB reporting processes

14. Equality Statement

1.1 This Policy will operate alongside the ICBs Equal Opportunities, Diversity at Work Policy, and Equality Delivery System. The ICB values the diversity of its employees, volunteers and people who are entitled to our services, irrespective of their race, disability, age, gender including sexual orientation, religion or belief, status, or grade.

1.2 The ICB assures employees, volunteers and people entitled to our services are treated fairly, equally and with respect and dignity. The ICB will challenge discriminatory attitudes and provide rules and standards of behaviour.

1.3 The use of this Policy will not discriminate directly or indirectly on the grounds of race, gender, sexual orientation, ethnic or national origin, religion, culture, disability, age, membership of a trade union or staff organisation or political affiliation.

1.4 The ICB will monitor the use of this Policy, as far as it is able, and take action if it appears that it is has a disproportionate effect.

Appendix 1 EQUALITY IMPACT ASSESSMENT

Step 1: Aims and purpose of the proposal / policy being assessed (This should reflect what the policy is intending to achieve and how it seeks to achieve, it is this intention that the assessment seeks to measure, consider who benefits and how and who doesn't and why, also consider the impact of associated aims).

Norfolk & Suffolk ICB clinical threshold policy for sets out the structured process to assess whether a patient with exceptional clinical circumstances should receive a treatment that is not normally funded by the NHS.

Funding decisions are based on clinical effectiveness, and whether the treatment represents a good use of NHS resources.
The policy outlines what constitutes clinical exceptionality meaning that the patient differs significantly from others with the same condition in a way that justifies different treatment.
The policy provides transparency and accountability ensuring that funding decisions are made consistently across regions and are subject to review and appeal processes, promoting fairness and public trust.
The policy defines who can submit requests, how panels are formed, and how decisions are documented and communicated.

In applying this policy, all clinicians and those involved in making decisions affecting patient care will pay due regard to the need to eliminate unlawful discrimination, harassment, victimisation, etc., and will advance equality of opportunity and foster good relations between people who share a protected characteristic and those who do not. In particular, due regard will be paid in relation to the following characteristics protected by the Equality Act 2010: age, disability, sex, gender reassignment, marriage or civil partnership, pregnancy and maternity, race, religion or belief and sexual orientation.

Step 2: Screening process for relevance to equality & diversity issues. Does this proposal / policy have any equality & diversity relevance in the following areas? (This should be considered in relation to the formulation and application of the policy. As far as possible engagement with the relevant staff network groups should take place to identify any potential areas of relevance).

Characteristic	Implication
A Age	No impact identified
B Disability	No impact identified
C Gender reassignment	No impact identified
D Marriage and Civil Partnership	No impact identified
E Pregnancy and maternity	No impact identified
F Race	No impact identified
G Religion or belief	No impact identified

H Sex	No impact identified
I Sexual orientation	No impact identified
J Other issues	No impact identified

Step 3: If you have answered, "Yes", to any of the protected characteristic boxes in Step 2, a full impact assessment is required

Are any of the protected characteristic boxes in Step 2 marked "Yes"? No

Step 4: Examination of available information (sources can include but are not restricted to – ESR data; MI relating to Recruitment /Employee Relations/Attrition; Industry best practice; legal overview; research articles; matters arising from judgements tested during consultation; consider four-fifths rule to assess difference).

Not applicable

Step 5: Full Impact Assessment Process

Step 5a: Consultation Log

Where are the consultation records stored? Records are held by IFR, NS ICB local systems

Date of consultation	Method	Who was consulted	What was the outcome
N/A	N/A	N/A	N/A

Step 5b: EIA Action Plan: Workforce Impacts (internal). Potential issues or impacts (positive and negative)

None Identified

Step 5c: EIA Action Plan: Service Delivery Impacts (external). Potential issues or impacts (positive and negative)

None Identified

Step 6: Monitoring and review arrangements

How will the implementation of the proposal / policy be monitored, and by whom?

Policy is available to access via Knowledge NoW website to health professionals and the general public. Changes to legislation or feedback that relates to the policy may warrant a further review.

What is the timetable for monitoring (with dates)?

The policy will be scheduled for review October 2027

Is there a plan to undertake an evaluation of this policy (with dates)?

The policy will be scheduled for review October 2027

Step 7: Public availability of reports / result

Clinical Threshold Policies and IFR - Knowledge NoW