NHS
Norfolk and Waveney
Integrated Care Board

Norfolk and Waveney ICB

Individual Funding Requests Policy

Document Control Sheet

This document can only be considered valid when viewed via the ICB's intranet. If this document is printed into hard copy or saved to another location, you must check that the version number on your copy matches that of the one online.

Approved documents are valid for use after their approval date and remain in force beyond any expiry of their review date until a new version is available.

Name of document	**Individual Funding Request Policy**
Version	5.4
Date of this version	October 2025
Produced by	Norfolk & Waveney ICB Individual Funding Request Panel
What is it for?	The policy defines the structured process to assess whether a patient with exceptional clinical circumstances should receive a treatment that is not normally funded by the NHS
Evidence base	This policy is based on NHS England » Commissioning policy: Individual funding requests and has also been compared with neighbouring ICB's IFR policy
Who is it aimed at and which settings?	The policy is aimed at clinicians and general public
Consultation	NW ICB Clinical Stewards, Public Health Consultant, NW Medicines Optimisation
Impact Assessment:	See below
Other relevant approved documents	N/A
References:	NHS England Guidance
Monitoring and Evaluation	Policy will be reviewed 2 yearly
Training and competences	Policy has been reviewed NW ICB Clinical Stewards, and Consultant in Public Health Medicine
Reviewed by:	CTPOG Sept 25
Approved by:	Commissioning & Performance Committee
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Signed:	CPC
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Contact for Review:	IFR Manager

Version Control

Revision History	Summary of changes	Author(s)	Version Number
June 2019	Annual Update	NW CCG IFR Panel	5.0
November 2022	Revised copy – approved at PCMMWG Dec 2022 subject to minor changes	NWICB IFR Panel	5.1
May 2023	Revised copy – incorporating changes recommended in Dec 22 Clarification on urgent clinical decisions. Clarity on the definition of a device	NWICB IFR Panel	5.2
April 2024	Revised copy – reference and links NWICB IFR Panel to Knowledge Anglia website amended	NWICB IFR Panel	5.3
October 2025	Revised policy – to reflect amalgamation of IFR panels. Reference links updated	NWICB IFR Panel	5.4

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Contents

1.INTRODUCTION

Norfolk & Waveney ICB (N&W ICB) 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 N&W ICB have a duty to manage them to a robust process.

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 N&W 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 N&W 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 N&W 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.

2.MONITORING & REVIEW

This policy will be reviewed every 2 years by the IFR panel, or sooner if necessary due to guidance/legislative change(s).

3.EQUALITY

N&W ICB have a duty to have regard to the need to reduce health inequalities in accessing health services and the health outcomes achieved as outlined in the Health and Social Care Act 2012. N&W ICB are committed to ensuring equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), marriage and civil partnership, pregnancy and maternity, race, religion or belief or sexual orientation. In carrying out its functions, N&W ICB will have due regard of the Equality Act 2010, the NHS Constitution and the Human Rights Act 1998.
In reviewing this document, as a minimum, the following questions were considered:

- Are the aims of this document clear?
- Are responsibilities clearly identified?
- Has the document been reviewed to ascertain any potential discrimination?
- Are there any specific groups impacted upon?
- Is this impact positive or negative?
- Could any impact constitute unlawful discrimination?
- Are communication proposals adequate?
- Does training need to be given? If so, is this planned?

Adverse impact has been considered for age, disability, gender, race/ethnic origin, religion/belief/sexual orientation. The ICB have satisfied themselves that the document is non-discriminatory. Please also see detailed Equality Impact Assessment

4.INFORMATION GOVERNANCE

N&W 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 N&W ICB or other trusted organisations legitimately acting on behalf of the N&W 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 N&W ICB 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 ICSs
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 N&W ICB reporting processes

5.CLINICAL EXCEPTIONALITY

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. These grounds must be set out on the form provided by N&W ICB 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.

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

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, N&W ICB 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 N&W 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.

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 which is relatively rare. If a GP feels that an IFR for an individual case is appropriate, expert advice should be sought as appropriate. It is for the same reason that patients cannot apply for their own funding, and an appropriate NHS clinician can apply on the patient's behalf if, in their professional opinion it is appropriate to do so.

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.

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. It is the responsibility of the requesting clinician to submit what is required in a timely manner to avoid delays in patient care.

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.

Funding Duration

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

Specialised Treatments

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

6.POLICY

6.0.Clinical Threshold Policy Group

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 NW 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.

6.1.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.

6.2.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 website and disseminated to appropriate Providers and stakeholders. (Clinical Threshold Policy Implementation SOP) see appendix 1

6.3. 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

7.ROLES & RESPONSIBILITIES

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

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 N&W 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 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 (nwknowledgenow.nhs.uk) or via email request nw.ifr@nhs.net. The completed IFR form should be submitted using the agreed template. Handwritten pro-forma's 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 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.

7.1. 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).

7.2. Individual Funding Request Process N&W ICB

N&W ICB will ensure the following;

N&W ICB will appoint a chair for the IFR Panel.

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

7.3. IFR Re-consideration Panel

Where the IFR Panel has declined a request or has approved treatment subject to conditions, the patient shall be entitled to ask that the decision of the IFR Panel be re-considered. Requests for re-consideration must be submitted within 6 months of 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.

Re-consideration would be considered on one of the following grounds only;

- That further evidence can be provided by the referring clinician and is duly submitted;

  and/or

- It was in the clinician's opinion a decision which no reasonable IFR Panel would have reached.

7.4. IFR Appeals Panel

Where all relevant information was available to the IFR Panel when the decision was made, but the referring clinician remains dissatisfied with the decision, the referring clinician may request that the case is reviewed by an Appeals Panel. Submission for a case to appeal must be submitted within 6 months of notification of reconsideration decision.

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 appeals process remains the responsibility of the N&W ICB.

Appeals process would be considered on one of the following grounds only;

- Due process was not followed;

Or

- The IFR panel failed to give a clear rationale for its decision.

The IFR Team will arrange for either an IFR Re-consideration or IFR Appeals Panel to be set up following receipt of a formal request, within the appropriate timeframes and guidelines.

8.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. 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 N&W 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 N&W ICB normal policies. In such circumstances the N&W 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 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 N&W 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, or the Executive Medical Director of the N&W ICB.

- The clinical lead will as far as possible within the constraints of the urgent situation, follow the policy set out above in making the decision. The clinical lead 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 lead 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 N& W 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.Q&A SECTION

9.0. What is a service development?

A service development is any aspect of healthcare which the N&W 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 N&W ICB will be subject to screening by the IFR Panel and N&W 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 N&W 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 N&W ICB Planned Care Clinical Transformation Programme Oversight Group (CTPOG). 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.

9.1. 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.

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

The N&W 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 N&W 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 5 or more patients in the population served by N&W ICB. Upon receipt of the fifth 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 N&W 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 N&W 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 N&W 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 N&W 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 N&W ICB policy in place that describes the availability of the requested intervention and the patient (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

9.3. What are non-clinical factors?

The N&W 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 N&W 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.

9.4. 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 N&W 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 N&W 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.

9.5. 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.

9.6. 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.

9.7. What happens with IFRs which have passed triage?

An exceptionality request can be made in relation to a medical condition where the N&W ICB have a Commissioning Policy but the patient's clinical circumstances or the requested treatment falls

outside the N&W 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 shall be entitled to approve funding if the patient has exceptional clinical circumstances. In considering whether to fund a patient on grounds of exceptional clinical circumstances, in this situation, the IFR Panel will act as follows:

- 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.

The IFR Panel shall be entitled to approve funding an experimental treatment for patients with rare clinical conditions or clinical circumstances.

In considering whether 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
- 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 the request is a service development or trial.

9.8. 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.

9.9.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 N&W 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, 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 N&W 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.

9.10. How does the IFR Panel approve requests?

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 N&W 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 N&W 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 N&W 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.

9.11. 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.

9.12. 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 N&W 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 N&W 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 N&W 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.

9.13. 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.

9.14. Can the IFR Panel decision be appealed against?

Where all the relevant information was available to the IFR Panel when the decision was made, but the referring clinician remains dissatisfied with the decision, they may request that it be reviewed by an IFR Appeals Panel on one of the following grounds only:

a) Due process was not followed
OR
b) The IFR Panel failed to give a clear rationale for its decision

In the case of failure to follow due process or an inadequate rationale for the IFR Panel decision, the referring clinician may request an IFR Appeals Panel review by making a formal request in writing to the IFR Administrator within 6 months of the date of the IFR Panel's decision.

The IFR Administrator will arrange for an IFR Appeals Panel to be set up. This will normally be the next available IFR Drugs Panel.

The IFR Appeals Panel will review the process followed by the IFR Panel. The IFR Appeals Panel will reach a decision within 30 working days of the IFR Administrator referring the case to them.

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

In the event that the IFR Appeals Panel considers that 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 shall uphold the patient's appeal and shall refer the case for reconsideration by the IFR Panel.

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

The IFR Appeals Panel will set out its decision and the reasons for it as soon as practicable in writing via e-mail or letter to the IFR Panel and the referring clinician. It is the responsibility of the referring clinician to 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.

9.15. 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 N&W ICB website and is accessible to all.

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 N&W 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.

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 & Waveney 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).	
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).
N/A

Step 5: Full Impact Assessment Process
Step 5a: Consultation Log
Where are the consultation records stored? Records are held by IFR

Step 5a: Consultation Log	Step 5a: Consultation Log	Step 5a: Consultation Log	Step 5a: Consultation Log
NW ICB local systems			

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

Step 7: Public availability of reports / result

Clinical Threshold Policies and IFR - Knowledge NoW