NHS
Norfolk and Suffolk
Integrated Care Board

NHS Norfolk and Suffolk Integrated Care Board

Experimental and Unproven Treatments Policy

1. Version Control

Version	Date	Author and Role	Detail of Change
0.1	01/03/2026	CPDG, IFR, Med Ops	Initial draft
1.0	01/04/2026	Board	Approved

Policy Owner: N&S Clinical Policy Development Group

Responsible Committee: Quality Committee

2. Next Review Date

The date this policy is due for review is*:* 1 March 2028

3. Contents

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Appendices

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. Cross Reference to Other Policies

5.1. NICE

6. Scope

6.1. This policy applies to any patient for whom Norfolk & Suffolk ICB is the responsible commissioner. It does **not** apply to services commissioned directly by NHS England (e.g., specialised services), nor to trials and costs managed through national schemes unless explicitly stated.

6.2. This policy deals with the funding of experimental treatments only. It does not cover primary research into novel treatments.

6.3. Treatments which are judged to be experimental or not to be of proven effectiveness will not be routinely funded.

7. Exceptionality

7.1. Norfolk & Suffolk ICB will consider requests for experimental & unproven treatments, ensuring that decisions are lawful, equitable, evidence based and affordable within finite resources. Treatments that are considered experimental, investigational or without a robust evidence base of clinical and cost-effectiveness will not routinely be commissioned. For patients who do not meet existing policy criteria, or where a treatment is not routinely funded, an application may be made to the Individual Funding Request (IFR) panel if the treating clinician believes there are clinically exceptional circumstances that distinguish the individual from the wider patient cohort. Any request must include sufficient, high-quality evidence demonstrating a reasonable likelihood of clinical effectiveness and cost effectiveness for that particular patient's circumstances. Where such evidence is lacking, the ICB will not support funding.

7.2. IFR policy and procedure documents can be found on Knowledge NoW. Individual Funding Requests - Knowledge NoW

8. Policy Principles

8.1. **Core services first:** Experimental/unproven interventions are lower priority than proven care given finite resources.

Evidence based: Commissioning decisions rely on publicly available, high quality evidence; where evidence is weak/uncertain, routine funding will not be supported.

Consistency & fairness: IFR is reserved for genuine clinical exceptionality; similar patients should be treated similarly.

No retrospective assumption: Treatment started without prior ICB approval is at the provider's risk (except as per urgent IFR process).

Transparency & audit: Decisions documented; outcomes and spend monitored.

9. What is an Experimental Treatment

9.1. **Experimental and/or Unproven Treatment**

A treatment for which there is no established body of robust evidence of clinical effectiveness and/or safety for the indication in question. Those funding health services seek to provide as comprehensive a healthcare service as possible across all patient groups and across the entire patient pathway, within an overriding legal obligation to stay within the financial budget allocated to them. Given that demand for healthcare will always exceed the resources available to fund treatment, it is justifiable to give the funding of experimental treatments a lower priority than funding the provision of core services and treatments of proven benefit.

9.2. Criteria for considering a treatment as experimental include:

- Novel/rare/unknown with insufficient authoritative evidence
- The treatment is still undergoing clinical trials for the indication in question.
- There are no relevant articles published in the peer-reviewed journals available on the treatment for the indication in question.
- The treatment does not have approval from the relevant government body.
- The treatment does not conform to usual clinical practice in the view of the majority of medical practitioners in the relevant field.
- The treatment is being used in a way other than that previously studied or that for which it has been granted approval by the relevant government body.
- The treatment is rarely used, novel, or unknown and there is a lack of authoritative evidence of safety and efficacy.

From the position of those funding healthcare, two other criteria can be added:

- The evidence is not yet available for public scrutiny.
- The decision maker does not have confidence in the evidence base that has been presented (which refers to the interpretation of the evidence).

10. Excess Treatment Costs (ETCs) in research

10.1. Funding of Excess Treatment Costs in research for National Institute for Health Research (NIHR) supported studies is managed via a national management model for England introduced by NHS England in 2018. Funding of ETCs for studies eligible for payment through this process fall outside the scope of this policy. Further information can be found at the dedicated National Institute for Health Research page: Policies and guidelines | NIHR

10.2. ETCs for studies that are not NIHR supported or fall outside the scope of the national model for England will not be routinely funded by Norfolk & Suffolk ICB. When there is good reason for considering requests, these will be managed through Norfolk & Suffolk ICB individual funding request policy and process.

11. Commercially funded trials

11.1. Norfolk & Suffolk ICB position is that where a clinical trial of a treatment has been initiated and sponsored by a manufacturer of pharmaceuticals or medical devices, or by some other commercial organisation, responsibility for funding on-going access to the treatment rests with those parties. Norfolk & Suffolk ICB will not assume funding post-trial unless formally pre-agreed.

11.2. **Non-commercial NIHR- supported funded Trials**

NS ICB may consider ongoing access only where:

- The trial is wholly non-commercial, NIHR supported; and
- A written pre-agreement exists with the ICB before the trial starts; and
- The trial demonstrates clinical benefit, and the supervising clinician confirms ongoing clinical appropriateness; and
- Funding remains affordable within ICB priorities

Treatment will be funded only for as long as the patient's supervising clinician agrees that the treatment is clinically appropriate, and that the treatment is meeting the identified clinical outcomes.

Norfolk & Suffolk ICB expects that all research organisations planning a trial.

- define and agree the arrangements for funding the treatment after the end of the trial for those patients where the trial has shown a

clinical benefit. This is in line with the ethical approval requirements of the Health Research Authority (HRA) for clinical trials https://www.hra.nhs.uk/

Ensure patients participating in a trial are made fully aware of the arrangements for when the trial concludes as part of the process of giving their consent to participate in the trial. This includes making patients aware of whether or in what circumstances they can expect to continue to receive treatment after the end of the trial, in line with the HRA guidance http://www.hra-decisiontools.org.uk/consent/content-sheet-involved.html on the information to be provided to participants taking part in a research.

Where commissioning responsibility for a patient on a clinical trial transfers to Norfolk & Suffolk ICB from another NHS commissioner, and there is written evidence of an agreement to fund on-going treatment costs (after completion of the trial) by the previous NHS commissioner, Norfolk & Suffolk ICB will fund those commitments made by the patient's previous NHS commissioner. This only applies to non-commercial trials supported by the NIHR.

The provider of the trial treatment and the clinician should take care to ensure that participants in a trial do not assume that Norfolk & Suffolk ICB will or might fund ongoing treatment once the trial has completed, unless Norfolk & Suffolk ICB has given a prior written commitment to provide such funding which would apply to that participant.

All requests for on-going funding following a clinical trial shall be made via the IFR process before the trial commences.

11.3. **Funding Excess Treatment Costs (ETCs) - for studies that are not NIHR supported or fall outside the scope of the national model for England**

NHS Treatment Costs, including Excess Treatment Costs are the responsibility of commissioners and are expected to be met through the normal commissioning process Attributing the costs of health and social care research - GOV.UK (April 2024). In practice, for NIHR supported research, this process is managed through the NHS England national management model.

Given a high proportion of research in the UK is supported via the NIHR and will be eligible for payment of ETCs through the national system, requests to fund ETC that fall outside the scope of this system not expected to commonly arise.

When determining whether to fund ETCs it is important to establish what the status of a trial is, who has sponsored it and which bodies contribute to funding the trial.

Those commissioning health care may be asked to explicitly fund trials in two ways:

1. A request to support a trial by funding a number of patients or any qualifying patient to enter the trial. In these instances, the request should be treated as a service development. If it is a very large trial with considerable budgetary consequence, it is more likely that prioritisation should be through the annual commissioning process.

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.*

2. A request to support a single patient to enter a trial. This request should be managed under the organisation's individual funding request policy and process.

The most common situation in which commissioners find themselves is as the recipients of requests to fund on-going treatment once the trial has ended. This is addressed in 3.1 above.

12. Novel or uncertain treatments including unlicensed drugs or drugs used outside their licensed indications (off label)

12.1. This section also applies to novel or uncertain use of devices outside their approved indications. (See also section 4 Clinical Trials and Unlicensed Investigational Drugs).

East of England (EoE) Clinical Commissioners will not pay for any treatment that is 'novel or uncertain'.

Novel or uncertain treatments that clinicians consider necessary for the treatment of patients, outside of approved research trials, should be managed through provider's internal governance processes, e.g. Drugs and Therapeutics Committees and research governance systems, and should be funded from within existing provider income streams, including activity and research income, rather than through Individual Funding Requests (IFRs).

Use of excluded drugs or devices for off-label indications will not be funded unless the specific unlicensed indication or off label use has been approved for use via the ICB's medicines and finance governance processes, e.g. via a business case and/or formulary submission.

Funding for novel or uncertain treatments and new, rarely used, unlicensed and/or investigational drugs, outside of a research trial, will remain the responsibility of the provider. Where it is considered that there is a sufficient evidence base for such use to be considered for routine management of patients, a business case and/or formulary submission must be submitted in advance, to the provider's coordinating commissioner to take through local due process, including financial planning and prioritisation processes that take account of the views of all the commissioners involved in a collaborative contract agreement. It should be noted that such service development reviews may take a considerable period of time; in the interim, patients for whom such treatments are judged clinically appropriate by their consultant should be managed and funded by the provider.

12.2. **Treatment initiated under the Early Access to medicines scheme (EAMS)**

EoE Commissioners will not automatically fund treatment initiated under the Early Access to Medicines Scheme (EAMS) on licencing of that drug, unless it is subject to a positive NICE TA. In the absence of a relevant positive NICE TA, providers are required to submit a local business case and/or formulary submission for consideration through the commissioner's local medicines governance and finance processes. Where routine funding is not approved, responsibility for ongoing funding rests with the manufacturer as set out in the exit strategy agreed with the MHRA as part of the EAMS arrangements

12.3. **Treatment initiated under expanded access schemes**

Expanded access schemes include "free of charge" medicines schemes, "zero risk" schemes or very discounted or significantly discounted schemes.

A free of charge medicines scheme is defined as an arrangement where a UK licensed or unlicensed medicine is provided free of charge (or at a price so low that they are effectively free of charge) by the pharmaceutical company to an individual patient or an identified cohort of patients.

A "zero risk" scheme is where the cost of the treatment is refunded to the provider if treatment goals are not achieved.

In line with NHSE recommendations, EoE commissioners do not support free of charge or expanded access schemes and will not automatically fund treatment initiated under any such scheme. This includes, but is not limited to:

free of charge stock supplied to providers for use in anticipation of a positive NICE TA

zero risk schemes where their use would undermine existing patient pathways very or significantly discounted schemes.

Providers wishing to sign up to any expanded access scheme are required to consult and discuss the implications of this with their local ICB commissioner. In the event that a provider has agreed to an expanded access scheme for a drug or technology which then receives a negative NICE TA, the responsibility for funding ongoing treatment if it remains of

benefit to an individual patient will reside with the initiating provider trust, unless a suitable ongoing zero risk funding arrangement can be agreed with the relevant manufacturer or commercial organisation.

12.4. **Assessing Requests to Fund**

Requests to fund ongoing treatment following a clinical trial, or to fund Excess Treatment Costs for studies that fall outside of the scope for payment through the national system will be assessed against the following criteria:

The potential strategic importance of the treatment. This requires a judgment to be made on whether the trial will address key national priorities for the health issues for a particular patient group or programme area (e.g., cancer, cardiovascular disease).

The status of the clinical trial including whether or not the trial is supported by the NIHR and other relevant professional and research bodies.

The quality of the trial and whether or not it is reasonably expected to generate the sort of information needed to enable those funding healthcare to reach a view on the clinical

effectiveness and cost effectiveness of the treatment. Specialist advice may need to be sought on the methodology to be adopted within any trial.

- Ownership of the data. Trials which do not guarantee that the data will be made available to public authorities and research communities for independent evaluation will not be considered for funding
- Affordability and priority when compared to competing unmet needs

In all circumstances where funding is granted, the Provider must keep a record of acceptance to ensure pick-up funding is honoured, either for an individual patient or for the trial.

13. Use of an Existing Treatment Experimentally for rare Clinical Circumstances – (outside the context of a clinical trial)

13.1. Norfolk & Suffolk ICB will give consideration to supporting an existing treatment in an experimental context for rare clinical situations provided that the clinician making the application is able to demonstrate that running a good quality clinical trial for the treatment in the clinical situation in question is impossible.

It is important for decision-makers to distinguish between those instances where trials are either impossible or improbable and those where the research community and industry have not prioritised a trial.

This type of request will be considered under Norfolk & Suffolk ICB individual funding request policy and process.

In assessing these cases Norfolk & Suffolk ICB will make a decision having regard to the following factors:

- the biological plausibility of benefit based on other evidence
- the potential benefit and risks of the treatment
- an estimate of cost of the treatment and the anticipated value for money
- the priority of the patient's needs compared to other competing needs and unfunded developments.

The clinician will be expected to provide as much information as possible about the treatment, relevant research upon which the claim for biological plausibility of the treatment is based, and costs, as well as clinically relevant information on the patient. In addition, the clinician will identify the clinical markers and clinical outcomes that will be monitored to assess treatment response.

The options for consideration by Norfolk & Suffolk ICB in these instances are, in principle;

- Not to Fund
- Fund on the condition that the patient enters a properly conducted *'n of 1'* trial. In practice this would be challenging due to the need for expert advice and support on design, set-up, management and analysis of such a trial, as well as additional funding considerations.
- Fund a trial of treatment but make ongoing treatment subject to the demonstration of clinical benefit for the individual patient using criteria agreed in advance with the clinical team.
- Fund with no evaluation requirements, although an outcomes report should be requested from the clinician

In all instances, contribution to any relevant clinical database or population registry which is operating will be an additional condition before Norfolk & Suffolk ICB gives approval to funding for the treatment

14. Funding potentially important treatments but where there is minimal evidence and / or concerns remain about the value of the treatment

14.1. **Treatments for which there is minimal evidence of effectiveness and no current research options**

Very rarely do those funding healthcare services may consider an experimental treatment so important that they wish to see a publicly funded

trial established. In the first instance, advice should be sought from the National Institute of Health Research https://www.nihr.ac.uk/partners-and-industry/charities/identify-research-needs.htm whereby topics of interest for research can be raised. Norfolk & Suffolk ICB may, however, consider initiating (and possibly funding) the whole trial themselves. Expert advice on design and development of trials, and applying for funding will, in this instance need to be sought.

14.2. **Treatments for which there are adequate trials, and which have demonstrated effectiveness but for which concerns remain over the true value of the treatment**

It is possible to have a situation where treatment is supported by reasonably good trials, but important questions remain about the treatment and how best to implement. In these instances, the requirement for ongoing evaluation is legitimate.

Issues that might result in Norfolk & Suffolk ICB feeling that a treatment should only be made available if there is ongoing evaluation include but are not limited to:

- Where concerns remain about the nature of the benefit and/or risks
- Where a treatment's true place in management has yet to be established
- Where there is potential for significant variation in clinical practice (which might otherwise be difficult to control).
- Where it is not known how best to deliver the treatment (e.g. dose, frequency, sequencing, concurrent treatment, duration of treatment)
- Where there is a good chance that real-life effects and/or costs may differ from those seen in clinical trials because of difference in context, patient mix, treatment delivery, service provision etc.

Decision-makers should, therefore, be able to apply conditions when funding treatments in this category.

15. Equality Statement

15.1. The Norfolk & Suffolk Integrated Care Board (Norfolk & Suffolk ICB) and the Clinical Policy Development Group (CPDG) are committed to ensuring equality of access and non-discrimination as enshrined in the Health and Social Care act 2012. In carrying out its functions, the CPDG will have due regard to the different needs of protected equality groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. An inequalities Impact Assessment (EHIA) will be maintained for this policy and reviewed as part of the clinical policy development review programme.

15.2 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.

15.3 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.

15.4 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.

15.5 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.

16. Clinical Governance Statement

16.1. It is important that the implementation of this policy is seen as an opportunity to encourage team working and cooperation between commissioners, primary and secondary care providers. Service Providers will be expected to collect and provide audit data on request as part of a professionally led clinical review and audit cycle.

17. Glossary

TERM	DEFINITION
Annual commissioning round	The *annual commissioning round* is the process by which major funding decisions are taken, including the allocation of new money coming into the NHS. This involves a complex process of prioritisation which involves a series of decisions. This process occurs during the months of October to March for the following financial year.
Clinical Effectiveness	C*linical effectiveness* is a measure of how well a healthcare intervention achieves the pre-defined clinical outcomes of interest in a real-life population under real life conditions.
Clinical Trial	*A clinical trial* is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioral treatments, process-of-care changes, preventive care, etc. The ethical framework for conducting trials of medicinal products is set out in the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended). It includes, but does not refer exclusively to, randomised control trials. All research in the NHS, including Clinical Trials must adhere to the UK Policy Framework for Health and Social Care Research, 2017 DHSC https://www.hra.nhs.uk/planning-and-

	improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/
Cost Effectiveness	*Cost effectiveness analysis* is a method for assessing or measuring the reasonably anticipated benefits and clinical effectiveness of a particular expenditure. In the health setting this will be the cost of a particular healthcare intervention together with any other costs of delivering the healthcare intervention. Cost effectiveness analysis requires an examination of expenditure to determine whether the money spent could have been used more effectively (and ideally - whether the resulting benefits could have been attained through less financial outlay).
Effectiveness - General	*Effectiveness* means the degree to which pre-defined objectives are achieved and the extent to which targeted problems are resolved.
Effectiveness - Clinical	C*linical effectiveness* is a measure of the extent to which a treatment achieves pre- defined clinical outcomes in a target patient population.
Efficacious	A treatment is *efficacious* where it has been shown to have an effect in a carefully controlled and optimal environment. However, it is not always possible to have confidence that data from trials which suggest that treatments will be efficacious will translate into clinically meaningful health gain and more specifically the health gain of interest. This is the difference between disease-oriented outcomes and patient oriented outcomes. For example, a treatment might have demonstrated a change in some physiological factor which is used as a proxy measure for increased life expectancy, but this relationship might not be borne out in reality.
Experimental and unproven treatments	Experimental and/or Unproven Treatment A treatment for which there is no established body of robust evidence of clinical effectiveness and/or safety for the indication in question. Indicators include: • Treatment still in clinical trials (including medicines yet to complete Phase III for the indication). • No relevant peer reviewed evidence available. • No marketing or relevant regulatory approval for the indication. • Use outside usual clinical practice or outside approved/previously studied parameters. • Novel/rare/unknown with insufficient authoritative evidence. • Evidence not publicly available or insufficiently reliable for commissioning decision.
Healthcare intervention	A *healthcare intervention* means any form of healthcare treatment which is applied to meet a healthcare need.
NHS commissioned care	*NHS commissioned care* is healthcare which is routinely funded by the patient's responsible commissioner. Norfolk & Suffolk ICB has policies which define the elements of healthcare it is and is not prepared to commission for defined groups of patients.
NICE	National Institution for Health Care and Excellence
NICE's	*NICE's Guidance on Interventional Procedures* are a form of NHS Guidance. They aim to provide information about the safety of

Guidance on Interventional Procedures	new interventional procedures. They are not covered by NHS Directions.
Priority setting	*Priority setting* is the task of determining the priority to be assigned to a service, a service development, a policy variation or an individual patient at a given point in time. Prioritisation is needed because the need and demands for healthcare are greater than the resources available.
Service Development	A proposal to routinely fund a healthcare intervention for a defined group (cohort) of patients—outside the IFR route—and which requires predictable recurrent funding.
Statutory Guidance	*Statutory Guidance* is written Guidance which is issued by the Secretary of State or a body authorised by the Secretary of State (or by another part of government which is directly relevant for the relevant decision-making process). NHS bodies are required to have regard to statutory guidance in their decision making. Statutory Guidance is intended to assist public authorities in the exercise of their statutory duties. It suggests steps which might be taken; factors which could be taken into account and procedures which could be followed to deliver specified steps of administration, or policy delivery. NHS bodies are entitled to depart from statutory guidance if they have a good reason to do so. However: **The NHS body should always record that it has considered statutory guidance as part of its decision-making processes, and** The NHS body should always record the reason or reasons why it has departed from the course of action recommended in the Guidance.
Treatment	*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
Treatment – Costs	*Treatment costs*, in the context of clinical trials, are the patient care costs which would continue to be incurred by the NHS if the service in question continued to be provided after the clinical trial had ceased.
Treatment Costs – Excess	*Excess treatment costs* are incurred where patient care is provided, which differs from the standard treatment, in that it is either an experimental treatment or a service in a different location from where it would normally be delivered. The difference between the total Treatment Costs and the cost of the standard treatment (if any) constitutes the *excess treatment costs*
Trial of Treatment	A t*rial of treatment* refers to a situation where a clinician has exposed a patient to a treatment for the purpose of assessing whether or not the patient is likely to benefit from longer term treatment

18. References

UK Policy Framework for Health and Social Care Research, DHSC, 2017
https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

Saving and Improving Lives: The future of UK Clinical Research Delivery, 2021
https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

Collaborative Commissioning Policy: Ethical Framework for priority setting and resource allocation.

Collaborative Commissioning Policy: On-going access to treatment following the completion of industry sponsored clinical trials or funding

Collaborative Commissioning Policy: On-going access to treatment following the completion of a trial explicitly funded by the Clinical Commissioning Group.

Collaborative Commissioning Policy: On-going access to treatment following the completion of non-commercially funded clinical trials covered by Department of Health Guidance HSG (97) 32. Attributing the costs of health and social care research (Acord), Department of Health and Social Care, 2012
https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research

Collaborative Commissioning Policy: On-going access to treatment following 'a trial of treatment' which has not been sanctioned by the Clinical Commissioning Group for a treatment which is not routinely funded or has not been formally assessed and prioritised.

Department of Health letter, Requirements to support research in the NHS, Gateway number 12153, July 2009.
http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_102098.pdf

Department of Health: HSG(97)32:Responsibilities for meeting Patient Care Costs associated with Research and Development in the NHS.
http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Researchanddevelopment/A-Z/DH_4016456

Department of Health, The NHS Constitution for England, July 2015,
https://www.gov.uk/government/publications/the-nhs-constitution-for-england

Department of Health and Social Care, Excess treatment costs Guidance on the national management model for England, September 2021
NHS England » Excess treatment costs: Guidance on the national management model for England

National Institute for Health and Care Excellence https://www.nice.org.uk

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).

The Norfolk & Waveney ICB clinical threshold policy sets out guidance and information for clinicians for Experimental & Unproven Treatments

This policy outlines how Norfolk & Waveney ICB makes funding decisions for:

- Experimental/unproven treatments
- Access to treatment following clinical trials
- Excess treatment costs
- Use of existing treatments in rare clinical circumstances

The policy emphasises evidence-based commissioning, affordability, prioritisation, and the role of the IFR process.

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	Implications
A Age	• Older adults may have multiple comorbidities and may be excluded from clinical trials; therefore, they may

	disproportionately rely on experimental/unusual treatment pathways. • Children with rare diseases often fall into the “experimental treatment” category due to limited evidence; strict criteria could disadvantage them. IFR route allows case-by-case assessment, including “clinically exceptional circumstances.” and takes into consideration rare clinical situations. No impact identified
B Disability	• People with disabilities (especially learning disabilities, severe mental illness or neurodivergence) may struggle to navigate complex consent processes or IFR pathways. • Those with rare genetic or progressive conditions may disproportionately require experimental treatments. IFR route allows case-by-case assessment, including “clinically exceptional circumstances.” and takes into consideration rare clinical situations. No impact identified
C Gender reassignment	No direct impact identified
D Marriage and Civil Partnership	No direct impact identified
E Pregnancy and maternity	Pregnant people are often excluded from clinical trials, experimental treatments may be deemed too high rick No direct impact identified
F Race	Some communities are under represented in clinical trials meaning that some trials may lack evidence for certain ethnic groups. No direct impact identified

G Religion or belief	No direct impact identified
H Sex	No direct impact identified
I Sexual orientation	No direct impact identified
J Other issues	No direct 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"?

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).

This clinical threshold policy has been reviewed and harmonised to ensure consistent application across the newly formed Norfolk and Suffolk Integrated Care Board (N&S ICB). While the policy was previously approved within the legacy organisations, this harmonised version takes effect and is valid for use from 1 April 2026.

Step 5: Full Impact Assessment Process

Step 5a: Consultation Log

Where are the consultation records stored? All records remain with N&S ICB CPDG

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) Potential issues or impacts (positive and negative)

No impact identified

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

No impact identified

Step 6: Monitoring and review arrangements

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

N&S CPDG have a programme of policy review. This policy will be reviewed as part of this rolling programme or if there is new clinical evidence or a judicial review.

What is the timetable for monitoring (with dates)?

N/A

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

N/A

Step 7: Public availability of reports / result

This policy will be available to view via Knowledge NoW