Derby and Derbyshire
Integrated Care Board

CLINICAL POLICY ADVISORY GROUP (CPAG)

Experimental and Unproven Treatments Policy

Statement

NHS Derby and Derbyshire ICB (DDICB) has deemed that the following treatments will not be routinely funded:

- Treatments which are judged to be experimental or not of proven effectiveness unless they are funded in the context of good quality studies

These commissioning intentions will be reviewed periodically. This is to ensure affordability against other services commissioned by the ICB.

1. Background - what is an experimental treatment?

Experimental and unproven treatments are medical treatments or proposed treatments where there is no established body of evidence to how that the treatments are clinically effective. They may include the following:

- The treatment is still undergoing clinical trials and/or is a drug yet to undergo a phase III clinical trial for the indication in question
- The evidence is not available for public scrutiny
- 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 an established 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 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 evidence of safety and efficacy.
- There is some evidence to support a case for clinical effectiveness but the overall quantity and quality of that evidence is such that DDICBdoes not have confidence in the evidence base and/or there is too great a measure of uncertainty over whether the claims made for a treatment can be justified.

2. The Policy

2.1 The policy applies to any patient for whom DDICB is the responsible commissioner.

2.2 Treatments which are judged to be experimental or not be of proven effectiveness will not be routinely funded unless they are funded in the context of good quality studies

2.3 This policy does not cover the research governance requirements of the NHS

2.4 DDICB will endeavour to comply with the 'Department of Health and Social Careletter to the NHS (9 July 2009) (Gateway number 12153) provided that the ICB is satisfied as to affordability and has taken account of competing demands upon its budget.

2.5 DDICB is satisfied itself that the clinical trial is supported by the National Institute for Health and Care Research and other relevant national bodies which are covered by the agreement by the 'Department of Health and Social Care (which are listed in the 'Department of Health and Social Care's Guidance on funding excess treatment costs related to non-commercial research studies and applying for a subvention

2.6 The DDICB will be prepared to consider funding a clinical trial or to sponsor a patient into an existing ongoing trial but funding cannot be guaranteed. The ability of the ICB to support R&D is influenced by:

- Capacity constraints within the ICB's team for those trials that have to be 100% funded by the ICB.
- The research priorities of the clinical community. However desirable a trial, clinical or R&D support, there can be no guarantee that a given evaluation is a research priority for the clinical and R&D community, on whom commissioners are dependent for delivering a trial.
- Financial constraints. Any trial has to be prioritised against competing needs.

2.7 Requests to enter a single patient into a clinical trial will be managed through the Individual Funding Request (IFR) Policy and process. The ICB will give consideration, within its level of commissioning responsibility i.e. not for specialised and rare conditions that are considered the remit of NHS England, to supporting experimental treatment or off label use for applications for rare clinical situations for which good quality clinical trials are considered impossible, considering the best available evidence of clinical efficacy/effectiveness in absence of randomised control trial studies. These will be identified on the basis of:

- the epidemiology of the condition;
- the nature of the intervention;
- the nature of the clinical research community (level of evidence base available)

2.8 Requests to support a number of patients into a single clinical trial will be treated as a proposed service development. The decision to fund may be through an in-year service development route or through the normal annual commissioning round

2.9 When a case has been identified under paragraph 2.7 the ICB will consider the following:

- The potential benefit and risks of the treatment
- The biological plausibility of benefit based on other evidence;
- The priority of the patient's needs and opportunity costs vis-à-vis other competing demands.
- An assessment of cost effectiveness

2.10 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 that will be monitored to assess treatment response.

2.11 When a case has been identified under paragraph 2.7 the funding options which the ICB will consider are:

- Not to fund
- Fund on the condition that the patient enters a properly conducted *'n of 1'* trial – if and when such a unit is available (this is currently not open to NHS commissioners).
- Fund the treatment for a period of time but make ongoing treatment subject to the demonstration of clinical benefit for the individual patient using criteria agreed in advance with the clinical team.

2.12 In all instances contribution to any relevant clinical database or population registry which is operating will be an additional condition of approval of funding for the treatment.

2.13 The ICB is not a research organisation but will be prepared to consider requests to sponsor an individual patient to enter a clinical trial. When such an application is made, the ICB will give consideration to:

- The potential strategic importance of the treatment. This requires a judgment to be made on whether the trial will address key goals and ICB priorities for the programme area.
- The quality of the trial and whether or not it is going to generate the sort of information needed to enable the ICB 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 in the public domain will not be considered for funding.
- Affordability.

2.14 Where an application is made under paragraph 2.13 the clinician will be expected to provide as much information about the patient, the treatment and the trial as possible. A copy of the trial protocol should also be included with the application.

2.15 Very rarely the ICB may consider support for an experimental or unproven treatment which is considered to be so important that the ICB wishes to see a publicly funded trial established. Such trials are a major undertaking and usually require collaborations with other ICBs. As such they are infrequent events.

2.16 If pick-up funding may be required following a trial, details of this potential should be indicated in any application for funding. If the patient is sponsored, a record of acceptance should be kept in the patient notes to ensure pick-up is carried out. This is of particular importance given the constant re-organisation of the commissioning arm of the NHS.

2.17 Primary research into novel treatments will not be funded through this funding source.

3. Key Principles Supporting this Policy

3.1 ICBs have legal responsibility for NHS healthcare budgets and their primary duty is to live within the budget allocated to them.

3.2 ICB commissioners have a responsibility to make rational decisions in determining the way in which they allocate resources and to act fairly between patients.

3.3 Interventions of proven effectiveness should be prioritised above funding research and evaluation.

3.4 The NHS should only invest in treatments which are of proven effectiveness unless it does so in the context of well designed, sufficient powered and properly conducted clinical trials.

3.5 Because the capacity to meet the needs for R&D and service evaluation is insufficient, research has to be prioritised and therefore not all treatments can be investigated.

4. Rationale for Recommendation

- The primary reason for adopting this policy is that it is difficult to justify funding an experimental treatment with outcomes which are either unproven or unclear when many proven interventions and important elements of healthcare remain either unfunded or are not fully accessed by sections of the population.
- In doing so, we recognise that every patient is unique and there will be rare occasions when patients will present with conditions that will not be covered by existing policies.

5. Useful Resources

- NHS Derby & Derbyshire IFR Policy, https://www.derbyshiremedicinesmanagement.nhs.uk/assets/Clinical-Policies/Goverance_Policies/IFR_Policy.pdf
- NHS Derby and Derbyshire ICB Ethical Framework for Decision Making Policy,

https://joinedupcarederbyshire.co.uk/derbyshire-integrated-care-board/
- NHSE: Understanding NHS Jargon - Acronym Buster, https://www.england.nhs.uk/get-involved/resources/involvejargon/

6. References

- EMSCG Commissioning Policy for Experimental and Unproven Treatments 2009, https://webarchive.nationalarchives.gov.uk/ukgwa/20130123174743/http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Actsandbills/DH_064103
- Department of Health & Social Care, The NHS Constitution for England, July 2009, https://webarchive.nationalarchives.gov.uk/ukgwa/+/www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/dh_093419
- The National Prescribing Centre, Supporting rational local decision-making about medicines (and treatments), February 2009, https://webarchive.nationalarchives.gov.uk/ukgwa/20121107151232/http:/www.npc.nhs.uk/local_decision_making/constitution_handbook.php
- NHS Confederation Priority Setting Series, 2008, https://www.nhsconfed.org/publications/priority-setting-overview
- Department of Health & Social Care: HSG(97)32:Responsibilities for meeting Patient Care Costs associated with Research and Development in the NHS. https://webarchive.nationalarchives.gov.uk/ukgwa/20091105221312/http://www.dh.gov.uk/en/Researchanddevelopment/A-Z/DH_4016456
- Department of Health & Social Care letter, Requirements to support research in the NHS, Gateway number 12153, July 2009. https://webarchive.nationalarchives.gov.uk/ukgwa/20130123180315/http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH_102101

7. Appendices

Appendix 1 - Consultation

Consultee	Date
Derbyshire Research Forum	February 2024
DDICB IFR Chairs	February 2024
Public Health, Derbyshire County Council	February 2024
Public Health, Derby City Council	February 2024
Clinical Policy Advisory Group (CPAG)	February 2024

Appendix 2 - Document Update

Document Update	Date Updated
Version 1.0 • Reference to DDCCG updated to DDICB • Department of Health updated to Department of Health and Social Care • National Institute of Health Research updated to National Institute for Health and Care Research • Update to section 4 'Rationale for Recommendation' - second bullet point • NHS Derby and Derbyshire ICB Ethical Framework for Decision Making Policy and NHSE: Understanding NHS Jargon - Acronym Buster added to useful resources • Links to references updated as documents now archived • New consultees added to appendix 1 (February 2024)	February 2024