Derby and Derbyshire
Integrated Care Board

DERBY AND DERBYSHIRE ICB CLINICAL POLICY ADVISORY GROUP
POLICY SPECIFICATION 2025-26 Version 5

Intentions of the policy specification

The policy specification is part of the healthcare services contract that commissioners (ICBs) have with provider organisations. This document outlines the role and responsibilities of our providers in ensuring a transparent and collaborative approach to the safe and effective commissioning of procedures, seamless care of patients between NHS organisations and ensuring high quality treatment.

The document is updated annually for changes in process and best practice. It is then presented to the Clinical Policy Advisory Group (CPAG), which includes representatives from both commissioner, including contracting, and provider organisations across Derbyshire. This ensures that its requirements are fair, transparent and reasonable. Once agreed and ratified by CPAG, the policies can be included as part of the contract policy requirements for the 2025-26 contract year.

- Derby and Derbyshire Integrated Care Board (DDICB) have a portfolio of clinical policies for clinical procedures. The most current, ratified policies can be found on http://www.derbyshiremedicinesmanagement.nhs.uk/clinical-policies-home.
- These are the commissioning requirements of DDICB and should be followed by all providers where there are contractual arrangements.
- Only procedures, devices and technologies with indications for use that are the responsibility of ICBs, and which have been through the ICB due governance process and received a positive funding decision should be commissioned.

Clinical Policies

DDICB clinical policies include Evidence Based Intervention (EBI) policies and Cosmetic Policies, DDICB has a process with appropriate governance for the managed introduction of NICE Interventions, diagnostics, medical and health technologies and innovation programmes, such as Interventional Procedures Guidance (IPG). See DDICB Interventional Procedures Guidance Policy. Procedures and services commissioned by NHS England are not included in this policy specification.

Evidence Based Interventions (EBI) Local Policies

- EBI research evidence shows that some interventions are not clinically effective or only effective when they are performed in specific circumstances. The NHS has a responsibility to make sure it is using its limited resources to maximise health benefits and outcomes for patients The purpose of the EBI policies is to clarify the ICB's intentions to only fund treatments for clinically effective interventions when delivered to the appropriate cohort of patients, and to provide value for money in the use of public resources.

- Only patients meeting the DDICB policy's eligibility criteria should be referred for the procedure/service. If a patient has not had a full diagnosis (relating to EBI local policy areas only), the referring GP is able to refer for an opinion.
- Medical emergencies and "red flags" are excluded from the NHS DDICB Clinical Policies and Position Statements.
- DDICB is currently developing a set of benchmarking tools to assure policy compliance.

Prior Approval Schemes

- Currently there are no DDICB Prior Approvals schemes in operation for Evidence Based Interventions. The previous scheme ceased operation in March 2024[1].
- The NHS National Standard Contract allows Prior Approval Schemes to be notified to a provider via its Co-ordinating Commissioner and sets out the terms of applicability of any ICB schemes for prior approval or for the restriction of procedures of limited clinical value. The NHS standard contract can be found at - https://www.england.nhs.uk/nhs-standard-contract/25-26/
- In the event of significant outliers or variation to agreement DDICB may require providers to undertake assurance through mechanisms such as clinical audit, deep dives etc.
- Where variation is unwarranted DDICB reserves the right for ongoing challenge with providers.
- In the event of a provider not providing sufficient assurance DDICB may introduce a Prior Approval Scheme. Ideally schemes will be introduced prior to the start of the contract year. Schemes can be amended, and new Schemes introduced in-year with one month's notice and new schemes are then applicable to all patients referred after the effective date. The ICB will endeavour to keep in-year changes to a minimum to reduce the administrative burden on providers in implementing scheme changes. The ICB will review the cost-effectiveness of any Prior approval arrangements prior to implementation to ensure that it can be demonstrated that this will result in a net overall saving to the local NHS. All providers are required to register and comply with the data collection required for EBI procedures

Evidence-Based Interventions Programme

- DDICB generally aligns to the recommendations of the National Evidence Based Interventions (EBI) programme with local variations. Providers are advised to consult DDICB clinical policy website for current polices.
- EBI is part of the NHS standard contract which is mandated by NHS England for use by commissioners for all contract for healthcare services other than primary care. It should be noted that EBI recommendations are guidance and not a statutory requirement. In addition to specific policies for interventions DDICB has produced an Overarching Position Statement which covers EBI that are considered pathways and provides details of the system assurance for these interventions. A link is available here: - Overarching_Position_Statement_for_EBI.pdf

Cosmetic Policies

- The collection of DDICB cosmetic policies cover both primary and secondary care healthcare professionals when advising and referring patients, and by providers when considering the treatment options for patients.
- These policies have been developed and evolved around the evidence-base available, for example the British Association of Plastic, Reconstructive and Aesthetic Surgeons (BAPRAS), literature reviews and local consultant engagement.
- Providers will be expected to comply with the criteria within the cosmetic policies.

[1] Clinical_Policies_Operating_Framework.pdf(Accessed 29/04/25)

NICE Interventions, Diagnostics, Medical and Health Technologies and Innovation Programme Policy

- Policy and Commissioning Statements can be found on the DDICB Clinical Policies website: http://www.derbyshiremedicinesmanagement.nhs.uk/clinical-policies-home/clinical-policies/ipg
- DDICB has no statutory duty to fund the use of the procedures or technologies assessed under the National Institute for Health and Clinical Excellence (NICE).
- DDICB has deemed the use of any procedure or technology assessed by NICE under their IPG, MTG, DTG, MIB or HTE programmes should **not normally be funded** unless:
  - the NICE IPG states 'use with standard arrangements for clinical governance, consent and audit' **OR**,
  - the NICE MTG states 'the case for adoption within the NHS as described is supported by the evidence' **OR**,
  - the NICE DTG makes a recommendation as an option for use **OR**,
  - the NICE MIB* has evaluated the innovation **OR,**
  - the NICE HTE has made a recommendation for use while evidence is being generated
    AND
  - the provider has submitted a robust, evidenced based business case to the commissioner and this has been subsequently approved.
- The following exemption has been agreed to the requirements of a business case - For procedures that that have previously been assessed under the NICE IPG programme that have since been accepted as established practice with good governance of introduction and safe operating practice. (CPAG acknowledge that when procedures become established clinical practice the providers internal governance will provide the operating model and the assurance for adoption. This includes any increase in activity/cost that has been accounted for in the horizon scanning, planning considerations and prioritisation process and subsequently agreed with the commissioner)

  **from April 2023 Nice will no longer produce or maintain Medtech Innovation Briefings (MIBs) on behalf of NHS England*

- It was agreed, that from, 12th December 2019 any new standard IPGs/normal arrangements will require a business case to be submitted to DDICB Clinical Policy Advisory Group for agreement - Template is available at http://www.derbyshiremedicinesmanagement.nhs.uk/clinical-policies-home/clinical-policies/ipg

For the remaining NICE IPG categories, 'Special arrangements', 'Procedures which are recommended only to be carried out in the context of formal research studies approved by a research ethics committee' and 'Procedures which should not be used in the NHS', **DDICB does not commission these and will not fund them under any circumstances**. If a provider does carries out activity at its own risk, DDICB requires a description of their internal governance process for approving procedures for assurance.
NICE suggest the following governance arrangements:

NICE IPG category	Suggested Governance Arrangement
Special arrangements	This recommendation means there are uncertainties about if the procedure is safe and effective. We also recommend special arrangements if there are known risks of serious harm that need to be carefully explained to the patient before they make a decision. It emphasises the need for informed consent, both from the patient (or carer) and from senior medical staff, such as the clinical governance lead in their trust. Clinicians using the procedure should also collect data, for example by audit or research.
Research only	This means that the procedure should only be carried out in the context of formal research studies, as approved by a research ethics committee.

	We make this recommendation if the procedure is still considered to be experimental or because there are uncertainties that need to be resolved.
Do not use	We make this recommendation if the evidence suggests that the procedure doesn't work well, or if there are unacceptable safety risks

MedTech Funding Mandate

The MedTech Funding Mandate is a NHS Long Term Plan commitment to get selected NICE approved cost-saving devices, diagnostics and digital products to NHS patients more quickly. It consists of a mandatory policy document ensuring ICB funding for selected products, so healthcare providers can make these available to NHS patients. It is implemented within the NHS and supported by the Health Innovation Network (HIN).

- The role of CPAG will be to act as a single point of entry for the ICB to provide assurance that internal governance has been undertaken and a systemwide implementation plan exists ensuring that investments align with the systems goals and result in tangible benefits for patients and healthcare providers. Responsibility for the implementation of any systemwide plan sits with the provider and is not a role undertaken by CPAG.
- For assurance purposes a checklist document has been produced to support system wide engagement, to review each technology and provide a rationale for adoption or non-adoption.
- All items listed in the table are covered by the MedTech Funding Mandate which are excluded from NHSPS prices which allows them to be reimbursed at cost via a pass-through payment approach. Funding for the products should not be included in aligned payment and incentive fixed elements. However, the fixed element should include funding for implementation costs. For further details please see: www.england.nhs.uk/aac/what-we-do/how-can-the-aac-help-me/the-medtech-funding-mandate/
- The impact on financial processes/risks will be an additional cost to the ICB, as this has not been accounted for although through the planning round, the ICB may agree with Joined Up Care Derbyshire (JUCD) providers to include in the block element.
- Health Innovation Networks (HINS) can advise providers on how to access this funding. Details are available at https://healthinnovation-em.org.uk/

Product	NICE Guidance
HeartFlow	www.nice.org.uk/guidance/mtg32
SecurAcath	www.nice.org.uk/guidance/mtg34
GammaCore	www.nice.org.uk/guidance/mtg46
Placental growth factor (PIGF)-based tests	www.nice.org.uk/guidance/dg49
UroLift	www.nice.org.uk/guidance/mtg58
GreenLight XPS	www.nice.org.uk/guidance/mtg29
Rezum	www.nice.org.uk/guidance/mtg49
PLASMA system	www.nice.org.uk/guidance/mtg53
XprESS multi-sinus dilation system	www.nice.org.uk/guidance/mtg30
Thopaz+ portable digital system	www.nice.org.uk/guidance/mtg37
Spectra Optia*	www.nice.org.uk/guidance/mtg28
AposHealth for Knee Arthritis	https://www.nice.org.uk/guidance/mtg76

*Specta Optia is part of the Specialist Haemoglobinopathy Service and covered by Specialised Commissioning

- All current technologies will continue to be funded on a cumulative basis
- See DDICB Clinical Policies website https://www.derbyshiremedicinesmanagement.nhs.uk/clinical-policies-home/goverance/medtech-funding-mandate

NICE Early Value Assessment (EVA)

NICE has launched an Early Value Assessment (EVA) programme for its MedTech outputs. The objective is to offer rapid assessment of digital products devices and diagnostics for clinical effectiveness and value for money which will enable services and patients to be able to benefit sooner. Through Early Value Assessment, commissioners will be assured they are choosing products that offer real potential value while further evidence is being developed.

DDICB Policy on NICE Outputs remains current i.e. all other technologies not covered by the MedTech Funding Mandate are not commissioned and require the submission and subsequent approval of a business case as per the Interventional Procedure Policy.

Innovations and Technology Payments

- NHS ICBs have no statutory duty to fund the **additional costs** associated with access schemes such as the implementation of NHS England's Innovation and Technology Payment Innovations. The Derbyshire Clinical Policy Advisory Group has confirmed that the ICB does not commission and will not fund any additional costs associated with innovations assessed by either of the previous schemes: - NHS England launched the Innovation and Technology Tariff (ITT) - Innovation and Technology Payment (ITP) - Evidence Generation Fund (EGF), unless the provider has submitted a robust evidence-based business case to the commissioner, and this has been subsequently approved.

Governance Policies

- Derby and Derbyshire Healthcare Professionals should adhere to the procedures that are not commissioned or commissioned with restrictions by DDICB. DDICB requests Healthcare Professionals working within the ICBs boundaries to respect the intentions of the commissioner as expressed in the policies described above.
- The DDICB Defining the Boundaries between NHS and Private Healthcare Policy is in place to outline criteria for NHS continuation of funding for treatment that has been commenced privately. The requirements set out in this policy specification apply to private providers of healthcare where patients treated privately transfer into the NHS. Patients moving into the NHS setting will be treated the same way as any other NHS patient.

Clinical Policy Review Process

- DDICB clinical policies are usually reviewed every 3 years or earlier where there is new significant evidence that warrants the need for a clinical review or if the procedure/service commissioned is unsafe.
- The clinical review of a policy is a two-step process, which involves the review of literature and the engagement of stakeholders. Stakeholder feedback and the literature review are then presented to the clinically led CPAG.
- CPAG is a strategic, local decision-making committee, with responsibility for promoting appropriate, safe, rational and cost-effective clinical policies to be used across Derby & Derbyshire. CPAG reports to the Strategic Commissioning and Integration Committee (SCIC) of the ICB which is a Non-Executive Member led subcommittee of the ICB Board. CPAG will make decisions, updates, and amendments to clinical policy for the ICB under delegated authority of SCIC. CPAG meetings occur monthly, and membership is listed within CPAG's Terms of Reference, which can be found on the DDICB Clinical Policies website:
  https://www.derbyshiremedicinesmanagement.nhs.uk/assets/Clinical-Policies/CPAG/CPAG_TOR/CPAG_Terms_of_Reference.pdf

Stakeholder Engagement

- CPAG membership is outlined in the CPAG Terms of Reference, including clinicians and Public Health representatives. It is also supported by a Stakeholder Engagement map.
- The review process for stakeholder engagement for the review of existing policies, can be found by clicking on the following link on the DDICB Clinical policies website:
- https://icm.derbyshiremedicinesmanagement.nhs.uk/assets/Clinical-Policies/CPAG/Stakeholder-Engagement-Process/Stakeholder_Engagement_Process_for_Review_of_Clinical_Policies.pdf

Individual Funding Request (IFR)

- IFR is a process that is in place for considering individual requests for fundings where a service, intervention or treatment falls outside of existing service provision.
- DDICB will only consider funding in response to an IFR if satisfied that the case meets the following criteria:
  - There is a DDICB clinical Commissioning policy and/or other mandatory/statutory guidance in place and it can be demonstrated that the patients is in a different clinical condition or stage when compared to the typical patient population with the same condition and (if relevant) at the same stage of progression and is likely to receive material additional clinical benefit from treatment that would not be plausible for any typical patient
  - There is not a relevant DDICB clinical commissioning policy and/or other mandatory/statutory guidance in place for the management of the patient's condition and the clinical presentation is so unusual that they could not be considered to be part of a defined group of patients in the same or similar clinical circumstances.
  - There is not a relevant DDICB clinical commissioning policy and/or other mandatory/statutory guidance in place for the management of the patient's condition and there is evidence to suggest that the Incidence and Prevalence criteria set out in the IFR policy is met

- NHS clinicians should complete an IFR form if they consider that the patient's clinical situation is so different to other patients with the same condition that it is appropriate that they should have different treatments compared to other patients with the same condition.
- The IFR Policy, Standard Operating Procedures and ToR can be on the DDICB Clinical Policies website: http://www.derbyshiremedicinesmanagement.nhs.uk/clinical-policies-home/goverance-policies.
- The DDICB IFR policy should be read in conjunction with the Experimental and Unproven treatment policy