NHS
Derby and Derbyshire
Integrated Care Board

DERBY AND DERBYSHIRE ICB CLINCAL POLICY ADVISORY GROUP
POLICY SPECIFICATION 2023-2024 version 3

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 and taken to the Clinical Policy Advisory Group (CPAG), with representation from both commissioner and provider organisations across Derbyshire, to ensure that its requirements are both fair and reasonable. Once agreed and ratified by CPAG the policies can then be included as part of the contract policy requirements for the following contract year.

- Only procedures and devices 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.
- 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 the Derbyshire Medicines Management website: http://www.derbyshiremedicinesmanagement.nhs.uk/clinical-policies-home.
- These are the commissioning requirements of DDICB and should be followed by all providers.

Clinical Policies

DDDICB clinical policies include Procedures of Limited Clinical Value (PLCV) policies, Cosmetic Policies, the National Institute for Health and Care Excellence (NICE) Interventional Procedures Guidance (IPG) Policy and Governance Policies. Procedures and services commissioned by NHS England are not included in this policy specification.

PLCV Policies

- Research evidence shows that some interventions are not clinically effective or only effective when they are performed in specific circumstances. The purpose of the PLCV policies is to clarify the ICB's intentions to only fund treatment for clinically effective interventions when delivered to the appropriate cohort of patients.
- Only patients meeting the policy's eligibility criteria should be referred for the procedure/service. If a patient has not had a full diagnosis (relating to PLCV policy areas only), the referring GP is able to refer for an opinion by using the PLCV Opinion Proforma.
- Where prior approval is stated to be required, this is implemented through a prior approval system operationalised through the E-referral System (E-rS) in primary care and the web-based Blueteq system within secondary care.

- A monthly challenge process is in place for PLCV which raises queries on any procedures which appear they may have been carried out in contravention of the PLCV policies.

Prior Approval Schemes[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/23-24/
- A Prior Approval Scheme will typically set out DDIBC's policy for access to a certain service or treatment - a high-cost drug, for instance, or a treatment of perceived low clinical value. By setting out the clinical criteria or access thresholds in advance, the commissioner enables the provider to offer treatment to patients without needing to seek specific approval from the DDIBB on an individual patient basis. In determining potential Prior Approval Schemes, DDICB will wish to review the evidence base and consider the need for appropriate consultation.
- DDICB will notify the provider of any Prior Approval Schemes before 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.
- All providers are required to register and comply with the data collection required for PLCV procedures (Blueteq)
- Blueteq™ reporting is in place to ensure that the treatment protocol is in line with the published policy statement.
- Additional information can be found here: http://www.derbyshiremedicinesmanagement.nhs.uk/clinical-policies-home
- From one month of the date specified above, DDICB will only reimburse these treatments for patients that have been confirmed as meeting the eligibility criteria via the formal Prior Approval Scheme i.e., Blueteq Treatment will only be funded where the minimum dataset is fully and accurately populated prior to treatment.

Evidence-Based Interventions Guidance

Statutory guidance on evidence-based interventions was initially published in 2018 and was supplemented by further guidance in 2020 covering a second tranche of interventions. EBI is now in its third Phase (List 3) with a further 10 Interventions being published in May 2023. Unlike in previous phases which focused on reduced or stopping tests, treatments and procedures, List 3 takes a more holistic approach and proposes that some interventions should be increased. This is because even with the pressures the NHS is under, following the pandemic, it is right to take a long-term review of a patient's care needs. If a relatively straightforward and low-cost medical intervention can be made now which will alleviate or reduce the need for other potential more expensive interventions further down the line, then we should take this opportunity. Altogether, the three guidance documents, set out the commissioning arrangements which apply to 58 specific treatment interventions.

  - Category 1 Interventions - interventions which should not be routinely commissioned or performed, and for which an IFR, approved in advance by the commissioner, is always required: and
  - Category 2 Interventions - interventions which should only be routinely commissioned or performed when specific criteria are met
- 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.
- DDICB produces Overarching Position Statements which provides details of the system assurance for the interventions contained within EBI. The overarching Position Statements are available at - Evidence-based Interventions programme (derbyshiremedicinesmanagement.nhs.uk)

[1] NHS Standard Contract 2023/24 – Technical Guidance - Paragraph 42.8-13

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 around the evidence-base provided by the British Association of Plastic, Reconstructive and Aesthetic Surgeons (BAPRAS)
- Providers are expected to follow and comply with requests from the Nurse led Cosmetic Referral Assessment Service (RAS)

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

- 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)
- Policy and Commissioning Statements can be found on the DDICB Clinical Policies website: http://www.derbyshiremedicinesmanagement.nhs.uk/clinical-policies-home/clinical-policies/ipg

**Additional Clarification for Standard/Normal Arrangements (this should be read in conjunction with the above bullet points)*

- From, 12th December 2019 any new standard IPGs/normal arrangements will require a business case to be submitted to DDICB Clinical Policies Advisories 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 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 products 2023/24

- All items listed in the table are covered by the MedTech Funding Mandate which are excluded from NHSPS prices. 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/
- It has been decided that no additional technologies will be added to the MedTech funding mandate for 2023/24. Instead, systems are asked to prioritise the appropriate adoption of 2021/22 and 2022/23 technologies where this has not yet occurred.
- Academic Health Science Networks can advise providers on how to access this funding.

Product	Commentary
HeartFlow	Includes HeartFlow analysis only
SecurAcath	Includes SecurAcath device only
GammaCore	www.nice.org.uk/guidance/mtg46
Placental growth factor (PIGF)-based tests	Use with clinical judgement and other diagnostic tests: www.nice.org.uk/guidance/dg23
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

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

- The MedTech Funding Mandate Policy can be found on the DDICB Clinical Policies website http://www.derbyshiremedicinesmanagement.nhs.uk/clinical-policies-home/goverance-policies/innovation-and-technology-payment

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 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 Population Health and Strategic Commissioning Committee (PHSCC)) of the ICB which is a Non-Executive Member led sub committee of the ICB Board. CPAG will make decisions, updates, and amendments to clinical policy for the ICB under delegated authority of PHSCC. CPAG meetings occur monthly, and membership is listed within CPAG's Terms of Reference, which can be found on the DDCCG Clinical Policies Website:
  https://www.derbyshiremedicinesmanagement.nhs.uk/assets/Clinical-Policies/CPAG/CPAG_TOR/CPAG_Terms_of_Reference.pdf

Stakeholder Engagement

- Clinicians are welcomed to be part of the clinical policy review process representing provider Medical Directors and providing individual expertise in their field.
- An email will be sent out from a member of the Clinical Policies Department to stakeholders giving four weeks' notice to respond (option to extend with prior agreement).
- As a prompt, if a response is not received after 3 weeks, a follow up email will be sent and cc'd to provider leads

- CPAG leads for UHDB and CRH, as identified in the CPAG ToR, will be expected to take a role in ensuring the appropriate clinician (for a non-response) have been contacted in a timely manner
- If no response is received after 4 weeks, the CPD team will take this as positive engagement that the stakeholder agrees with the policy as stated in the correspondence.

Individual Funding Request (IFR)

- IFR is a process that is in place for considering funding for individuals who seek NHS commissioned services outside of the established commissioning policies.
- The two main types of funding requests are for treatments for medical conditions where the ICB has no established commissioning policy or for medical conditions or where the ICB does have a commissioning policy for the requested treatment and the criteria set out in the policy is not met.
- NHS clinicians should complete an IFR form if they consider the patient concerned to be significantly different clinically to the group of patients with the condition in question
  AND
  They are likely to gain significantly more clinical benefit than others in the group of patients with the condition in question.
- The complete IFR Policy and ToR can be on the DDICB Clinical Policies website: http://www.derbyshiremedicinesmanagement.nhs.uk/clinical-policies-home/goverance-policies.