Derby and Derbyshire
Integrated Care Board

CLINICAL POLICY ADVISORY GROUP (CPAG)

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

Statement

Derby and Derbyshire ICB 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:

1. 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 (including EVA) has made a recommendation for use while evidence is being generated

   AND

2. The provider has submitted a robust, evidenced based business case to the commissioner and this has been subsequently approved.

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

***** *As of the 12th December 2019, the ICB will not challenge any standard/normal IPG's that are already being carried out at our providers prior to this date.*

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

1. Derbyshire Health Optimisation for Surgical Interventions

Any surgical intervention carries a risk, however small, to the patient. These risks are increased in those who are overweight/obese, smoke or have poorly controlled long term conditions. When surgery is planned this is a good opportunity to offer support to patients to stop smoking, reduce their weight and optimise treatment of long term conditions in order to reduce their risks and improve their recovery and other outcomes. This could be achieved by referral to an appropriate lifestyle service for help with obesity and smoking and working with healthcare professionals for management of any long term conditions.

2. Summary

NICE Interventional Procedures Guidance (IPG), Medical Technologies Guidance (MTG), Diagnostics Guidance (DG), MedTech Innovation Bulletin (MIBs) and Health Technology Evaluations (HTE), including early value assessment (EVA) are not mandatory and NHS bodies are entitled to take decisions which do not follow the guidance if they have a good reason to do so.

The Clinical Policy Advisory Group has considered these types of NICE guidance, and agreed that the use of any procedure or technology assessed by NICE under their IPG, MTG, DTG, MIB and HTE programmes are **not normally funded** unless:

a. 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 (including EVA) has made a recommendation for use while evidence is being generated

   AND

b. the provider has submitted a robust, evidenced based business case to the commissioner and this has been subsequently approved

** As of 12th December 2019, the ICB will not challenge any standard/normal IPG's that are already being carried out at our providers prior to this date*

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

(The term 'Challenge' refers to a contractual process between the commissioner and provider)

3. Introduction

The National Institute for Health and Care Excellence (NICE) produces several types of guidance documents including:

- Cancer service guidance
- Clinical guidelines*
- Diagnostics guidance
- Interventional procedures guidance
- Medical technologies guidance
- Public health guidance
- Technology appraisals guidance
- Quality standards

Of these, only technology appraisals guidance (TAs) are legally binding; other guidance, including interventional procedures guidance (IPGs), medical technologies guidance (MTGs), diagnostics guidance (DGs) and Health Technology Evaluations (HTE) are statutory guidance which is intended to assist the NHS in the exercise of its statutory duties.

MIBs are not NICE guidance. They differ in format, contain no judgement on the value of the technology and do not constitute a guidance recommendation.

HTEs are guidance on products that have been assessed using the Early Value Assessment (EVA) approach which includes a recommendation for use while evidence is being generated.

NHS bodies are entitled to take decisions which do not follow guidance (other than TAs) if they have a good reason to do so. The availability of resources and competing priorities can be a valid reason.

The purpose of the policy is to ensure that Derby and Derbyshire ICB (DDICB) have a consistent approach in considering and implementing IPGs, MTGs, DGs, MIBs and HTEs.

** The ICB retains the ability to review and approve the introduction of devices and procedures introduced under this NICE output*

4. Background

NICE have been producing IPGs since 2003 and have, more recently started publishing MTGs (since 2010), DGs (since 2011), MIBs (since 2014), HTEs (since 2023).

4.1 Interventional Procedures Guidance (IPGs)

The remit of the Interventional Procedures programme, as defined by NICE, is to:

… assess the efficacy and safety of interventional procedures, with the aim of protecting patients and helping clinicians, healthcare organisations and the NHS to introduce procedures appropriately. By reviewing evidence, consulting widely, facilitating data collection and analysis, and providing guidance on the efficacy and safety of interventions, the Programme enables clinical innovation to be conducted responsibly.

No interventional procedure is entirely free from risk; the Programme gauges the extent of risks and benefits and makes recommendations in terms of their implications.

To fall within the remit of the IP Programme, a notified interventional procedure must:

1. *involve an incision or a puncture or entry into a body cavity, or the use of ionising, electromagnetic or acoustic energy, and*

2. *be available within the NHS or be about to be used for the first time in the NHS, outside formal research, and*

3. *be either not yet generally considered standard clinical practice, or a standard clinical procedure, the safety or efficacy of which has been called into question by new information and have a CE mark specific for the notified indication if a device is involved.*

The programme's main focus is safety. It considers efficacy but not cost-effectiveness. The recommendations are largely focused on how the treatment should be delivered within the NHS and there are 4 categories:

1. Normal arrangements: NICE has concluded that the evidence for the efficacy and safety of the procedure is deemed adequate and has recommended that clinicians should observe normal arrangements for governance, consent and audit.

2. Special arrangements: NICE has concluded that the procedure needs further evaluation and/or is an emerging technology. Clinicians wishing to use such a procedure are advised to inform their clinical governance lead, make special arrangements for consent and make special arrangements to audit and review their results.

3. Procedures which are recommended only to be carried out in the context of formal research studies approved by a research ethics committee. These are procedures which are still considered experimental.

4. Procedures which should not be used in the NHS. NICE has concluded that the evidence suggests that the procedure has no efficacy and/or poses unacceptable safety risks.

4.2 Medical Technologies Guidance (MTGs)

The remit of the Medical Technologies programme, as defined by NICE, is to:

…identify medical technologies that have the potential to offer substantial benefit to patients and/or to the NHS and are likely to be adopted more consistently and more rapidly if NICE develops guidance on them.

NICE aims to evaluate the case for adoption, with particular emphasis on technologies that when compared with current management may provide more benefits at the same or lower cost or provide the same benefits at a lower cost.

The possible recommendations are:

1. The case for adoption is fully supported - recommended for use.

2. The case for adoption is partially supported - recommended for use in specific circumstances or recommended for use in specific circumstances and recommendation for

development of further evidence.

3. The case for adoption is not currently supported but the technology has potential to provide significant patient or healthcare system benefits - recommended for use in a research context.

4. The case for adoption is not supported and the technology does not have potential to provide significant patient or healthcare system benefits - recommendation highlighting this.

4.3 Diagnostics Guidance (DGs)

DGs evaluate new, innovative diagnostic technologies. They include all types of measurements and tests that are used to evaluate a patient's condition. Diagnostic technologies may be used for various purposes including:

- ruling in or out a specific disease
- general examination looking for clues to the cause of the symptoms
- staging, or additional testing to assess how advanced or severe the disease is
- monitoring a patient over time to determine changes in their condition
- screening tests to look for conditions in patients without signs or symptoms of the specific condition.

NICE takes into account: The broad balance of clinical benefits and costs; the degree of clinical need of patients under consideration; any guidance issued to the NHS by the Secretary of State; the potential for long-term benefits to the NHS of innovation.

Recommendations may have a variety of formats depending on the circumstances:

1. If there is sufficient evidence to demonstrate the technology's cost effectiveness, the Committee makes a recommendation for use of the technology. Recommendations for use of a diagnostic test, or use of a diagnostic test as an option, may be limited to specific circumstances such as: the patient's characteristics, aetiology of the disease, the training and skills of those providing the test, availability of equipment, and the availability of other portions of the care pathway. In some cases, adoption recommendations may be made on the basis that additional research is performed as the technology is adopted.

2. If there is not sufficient evidence to determine the cost effectiveness of the technology, the Committee may make various types of recommendation, such as a recommendation for use only in research or, in particular circumstances, combined with a recommendation for further research. The Committee's recommendations depend on factors such as the quality of the evidence and the degree of risk, both in terms of cost and patient outcomes associated with the use of the technology. The rationale for their recommendations is outlined in the 'considerations' section of the guidance.

3. If there is sufficient evidence to demonstrate the technology is not cost effective, the Committee does not recommend it for use. This recommendation may be for either general or specific circumstances. If, on the basis of expert advice or ongoing research, the Committee considers that the technology has the potential to be of benefit to the NHS in the foreseeable future, it may decide to not recommend the technology for use at the present time instead of a general recommendation against its use.

4. If there is considerable uncertainty about the cost effectiveness of a technology, the Committee may consider issuing a recommendation that highlights the importance of

gaining additional information. The factors it may consider include: the costs and benefits of the additional research; the probability of the research affecting future use; the non-recoverable investment costs of early implementation; the losses in patient benefits from delaying adoption to await research; the probability that the uncertainty will resolve over time; and the impact of adoption recommendations on the feasibility of doing the research.

4.4 MedTech Innovation Briefings (MIBs)*

NICE MIBs are designed to support NHS and social care commissioners and staff who are considering using new medical devices and other medical or diagnostic technologies.

The information provided includes a description of the technology, how it's used and its potential role in the treatment pathway. A MIB also includes a review of relevant published evidence and the likely costs of using the technologies, but they are not NICE guidance and do not make any recommendations on the value of using the technologies.

The briefings will help avoid the need for organisations to produce similar information locally, which in turn will save staff time, effort and resources.

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

4.5 Health Technology Evaluations (HTEs)

NICE HTEs are for products that have been assessed using the Early Value Assessment (EVA) approach.

This approach allows rapid assessment of digital products, devices and diagnostics for clinical effectiveness and value for money to enable to the NHS and patents to be able to benefit from these promising technologies sooner.

Once a technology is recommended for use in the NHS, NICE will develop an evidence generated plan. This will detail the evidence that needs to be gathered while the product is in use. When NICE have the evidence needed, they will make a full recommendation for using the technology.

5. Definitions

Cost effectiveness	Cost effectiveness is an assessment as to whether a healthcare intervention provides value for money. In this document it does not necessarily imply that this is measured using a specific methodology.
NICE's Technology Appraisals	NICE's Technology Appraisals are a specific form of Guidance published by NICE which is covered by NHS Directions issued in 2003. The Directions provide that Integrated Care Boards shall make funding available to patients who meet the criteria set out in the Guidance. This funding should be made available within three months from the date that the Technology Appraisal Guidance has been issued unless an extension has been authorised by the Secretary of State.

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 the 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.

6. Full Details of Policy

This policy applies to any patient in circumstances where Derbyshire ICB is the responsible commissioner for their NHS care.

The Clinical Policy Advisory Group has considered these types of NICE guidance, and agreed that the use of any procedure or technology assessed by NICE under their IPG, MTG, DTG and HTE programmes are **not normally funded** unless:

1. 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

2. the provider has submitted a robust, evidenced based business case to the commissioner and this has been subsequently approved.

** As of 12th December 2019, the ICB will not challenge any standard/normal IPG's that are already being carried out at our providers prior to this date*

If the above criteria are not met but individual patient circumstances require the escalation of their care, providers should refer to the Derby and Derbyshire Individual Funding Request (IFR) policy.

Trusts wishing to undertake research associated with the use of new technologies and interventions, including IPG, MTG, DTG, MIB or HTE technologies, must apply for research funds in the usual way. Clinicians wishing to undertake such procedures should ensure they fulfil the normal requirements for undertaking research.

The following exemption has been agreed to the requirement of a business case –

Exemption - For procedures that have previously been assessed under the NICE IPG, DTG, MTG, HTE and MIB programmes 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 has been accounted for in the horizon scanning, planning considerations and prioritisation process and subsequently agreed with the commissioner e.g. multi ICB pathways such as cancer).

7. Key Principles Supporting this Policy:

- ICBs have legal responsibility for NHS healthcare budgets and working with partner trusts, have a duty to operate within their resource limits.

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

- All NHS commissioned care should be provided as a result of a specific policy or decision to support the proposed treatment. A third party has no mandate to pre- commit resources from ICB budgets unless directed by the Secretary of State.

- The priority for an individual patient or group of patients for funding for NHS commissioned healthcare to meet the healthcare needs of that individual or group of patients must always be assessed against other competing demands and within the resources available.

- The NHS must ensure it demonstrates value for money and appropriate use of NHS funding based on the needs of the population it serves.

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

- The ICB should strive to provide equal treatment in the same clinical circumstance. An ICB should therefore not offer to one patient a treatment which cannot be afforded for all patients in the same clinical circumstance.

8. References/Supporting Documents

East Midlands Specialised Commissioning Group (EMSCG) Commissioning Policy (EMSCGP027V2):
Guidance produced by the National Institute of Health and Clinical Excellence.

NICE Interventional Procedures Guidance: https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-interventional-procedures-guidance (accessed 15/01/25)

NICE Medical Technologies Guidance: https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-medical-technologies-guidance (accessed 15/01/25)

NICE Diagnostics Guidance: https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-diagnostics-guidance (accessed 15/01/25)

NICE Medtech Innovation Briefings: https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-advice/Medtech-innovation-briefings/MIB-faq-document.pdf (accessed 15/01/25)

NICE EVA for Medtech: https://www.nice.org.uk/about/what-we-do/eva-for-medtech (accessed 15/01/25)

9. Monitoring and Review

Monthly monitoring will be undertaken to validate any activity carried out and the ICB will not fund any procedures/treatment without the approval of a business case.

Derby and Derbyshire ICB has deemed that NICE IPGs, MTGs, DGs, MIBs and HTEs should only be funded as per this policy. Continued funding and its commissioning intentions will be reviewed periodically. This is to ensure affordability against other services commissioned by the ICB.

Information about topics can be provided directly to NICE via:

- NICE's interventional procedures notification page (for interventional procedures)
- UK PharmaScan (for medicines)
- HealthTech Connect (for devices, diagnostics and digital health technologies)
- NICE's topic selection team

10. Appendices / Relevant Web Links

A full list of current NICE IPGs, MTGs, DGs and HTEs can be found at:

IPGs - https://www.nice.org.uk/guidance/published?type=ipg
MTGs - https://www.nice.org.uk/guidance/published?type=mtg
DGs - https://www.nice.org.uk/guidance/published?type=dg
MIBs - https://www.nice.org.uk/guidance/published?type=mib
HTEs - https://www.nice.org.uk/guidance/published?ngt=Health+technology+evaluations

Appendix 1 - NICE Interventions, Diagnostics, Medical and Health Technologies and Innovation Programmes Business Case Template

Administration:

Project Name:	
Version:	
Executive Lead:	
Clinical Lead:	
BC Author:	
Date:	
Project/Operational Lead:	

Version Control:

Version	Date issued	Brief Summary of change	Change Owner

This template is used for both Outline Business Case (OBC) and Full Business Case (FBC)

Consultant/Department	
Trust/Clinic details	*Include full contact details*
Name of procedure	
NICE IPG/MTG/DG/HTE number	
Confirm that the IPG/MTG/DG/HTE has been through the trust's internal governance process and has received clinical and management sign-off	*Include minutes of meetings where appropriate.* ***All business cases should include a Quality Impact Assessment (QIA)***
Description	*Provide some background information which will explain why this treatment/diagnostic is required.* ***Procedure must be in line with the relevant NICE guidance***

Estimated no. of patients per annum	
Strategic Context	*Include how this proposal supports NHS wider strategy/organisational direction e.g.* – *Strategic Transformation Plan – Derbyshire Wide* – *ICB Corporate Objectives* – *National Strategy and Policy* – *Local Strategy and Policy*
Case for Change	*State what needs to change supported by reasons and evidence where available e.g.* – *Reference to information sources and what these indicate that this project will help address e.g. Better Care Better Value; JSNA; Network Recommendations; DH directive etc. – prevalence; opportunities etc.* – *National and local issues that the proposal aims to address* – *Stakeholders views - (include sources e.g. feedback from surveys)* – *Objectives and goals of project e.g. quality of patient care* – *financial benefits; workforce etc.* – *Future needs of the population/health and care economy/service – horizon scanning including demographic change and within local and national strategic ambitions* – *Assumptions: state these – what we don't yet know or have had to guess and based on what.* – *Proposed change e.g. overview of new service, new process*
Current available procedure(s)	

Claimed advantage(s) over existing procedure(s) for same indication(s)	*Greater clinical effectiveness compared with current procedures?*
	Increased cost-effectiveness compared with current procedures?
	Anticipated health benefits compared with current procedures?
	Positive impact on health inequalities compared with current procedures?
Evidence for claimed benefits	*Clinical effectiveness – any new evidence not included in the relevant NICE guidance?* *Please attach copies of papers or quote references*
	Cost-effectiveness – is there any evidence that the new procedure will be cost-saving? Is there any other cost-effectiveness evidence (e.g. Costs per Quality Adjusted Life Year (QALY))?
	Health Benefits – is there any evidence for decreased mortality or morbidity, improved quality of life or less impact on activities of daily living?

	Health inequalities – is there any evidence for reduced health inequalities?
Cost implications for commissioning ICB	*EXISTING COSTS* *How many patient activities per annum: First and Follow up outpatients, Elective (length of stay) / Day case, Drug costs (HCD if applicable)* *NEW COSTS* *How does the new Procedure rank against the existing: First and Follow up outpatients, Elective (length of stay) / Day case* *Drug costs (HCD if applicable)* *Assumptions about local growth, repatriation from other hospitals (numbers)?*

Options Appraisal	– *List each of the options available including 'do nothing'.* – *Describe each of the options available* – *State any assumptions that have been made (where information is not available)* – *Set out process and approach taken to review options and select a preferred option (provide a 'ranking' of options if appropriate) e.g. SWOT, cost-benefits appraisal etc.* *For each of the options stated ensure that you include the following:* • ***Risk appraisal*** – *State risks involved and how those risks may be mitigated* – *Traffic light the risks if appropriate in line with ICB's risk register rankings to indicate likelihood of the risk and consequence* • ***Financial appraisal*** – *The financial cost or benefit. Include the investment required and savings to be gained. Also briefly state how these have been calculated (include specific calculations if possible/feasible).* – *This should include stating where costs or savings are recurrent or non-recurrent.* – *Also include the financial year in which costs will be incurred or savings will be made.* • ***Preferred option*** – *Summarise why this is the preferred option specifying factors that have been taken into account in arriving at the preference*

Commercial/Other Consideration	*State other considerations which need to be taken into account e.g.* – *Funding sources* – *Any decommissioning/recommissioning implications* – *Commercial approach i.e. procurement programme/route to market, contracting approach etc.* – *Engagement and consultation with patients and stakeholders* – *Potential impact on local workforce*
Management Arrangements	*Describe how the proposal will be implemented* – *Explain how the benefits/success will be measured* – *Provide a project governance overview* – *State the project management approach and actions required to deliver outcomes* – *What are / are the resources or expertise required (internal and external)?* – *Project hand-off to business-as-usual e.g. ongoing contact management of service* – *Include a high level project plan with timescales and key milestones*
Supporting Information	*Please provide any other information to support your business Case*
Business Case completed by:	Print name:
	Signature:
	Designation:
	Date:

Completed Business Cases should be returned to: ddicb.ifrfundingrequest@nhs.net

Appendix 2 - FAQ IPG

Question	Response
A provider wishes to change established clinical practice for a NICE Interventional Procedure Guidance given standard clinical governance. Does this require approval by CPAG?	Initially changes in Clinical Practice would require approval by Trusts internal governance processes. The ICBs stance on IPGs that were conducted prior to 2019 is affirmed in our 2019 IPG Letter. The NICE Interventions, Diagnostics, Medical and Health Technologies and Innovation Programmes Policy should be read in conjunction with the above letter. A business case is required, if the provider wishes to commence a procedure that has been given 'standard' clinical governance arrangements from the NICE IPG programme not previously carried out prior to Dec 2019.
A provider wishes to make changes to the choice of medical devices/instruments for an established IPGs (as per 2019 IPG Letter). Does this require approval by CPAG?	Changes to devices for approved IPGs undertaken by Trusts (as per 2019 IPG Letter) would not require CPAG approval. Any device change for established procedures (as per 2019 IPG Letter) would require Trusts to approve as per their own governance framework. Providers are able to notify NICE of interventional procedures and medical technologies for assessment through the following link
How do we contact the Clinical Policy Team?	For advice on the NICE Interventions, Diagnostics, Medical and Health Technologies and Innovation Programmes Policy please contact the Clinical Policy Team via email. In the subject line please add FAO of Clinical Policy Team. ddicb.ifrfundingrequest@nhs.net
What is the role of CPAG?	CPAG decisions are based on the responsibility for promoting appropriate, safe, rational and cost-effective clinical policies for commissioning services across Derbyshire. Requests for increased funding should be directed to the appropriate Finance Team.

Appendix 3 - Consultation

Consultee / Engagement	Date
Public Health Consultants (City & County)	January 2025
DDICB Head of Contracting	January 2025
DDICB Director of Delivery	January 2025
DDICB Director of Place and Partnership	January 2025
DDICB Deputy Chief Nurse	January 2025
DDICB Head of Digital & Information Governance	January 2025
DDICB Innovation Lead	January 2025
Chief Pharmacist DHCFT	January 2025
CPAG Provider Leads (UHDBFT & CRHFT)	January 2025
Commercial and NHS Contracts Manager (CRHFT)	January 2025
Head of Contracting and Performance (UHDBFT)	January 2025
Clinical Policy Advisory Group (CPAG)	February 2025

Appendix 4 - Document Update

Document Update	Date Updated
Version 4 • Link to Early Value (EVA) approach added • Link to NICE topic selection team added • Added, from April 2023 NICE will no longer produce or maintain Medtech Innovation Briefings (MIBs) on behalf of NHS England • Aligned legal responsibilities of the ICB to the language of the legislation (s223M of NHS Act 2006)	February 2025