

## Clinical Policy Advisory Group (CPAG)

### CLINICAL & GOVERNANCE POLICIES UPDATED PROCEDURES OF LIMITED CLINICAL VALUE 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 Procedures of Limited Clinical Value (PLCV) policy is to clarify the commissioning intentions of the Integrated Care Board (ICB). The ICB will only fund treatment for clinically effective interventions that are then delivered to the appropriate cohort of patients. When updating Clinical Policies CPAG undertakes Stakeholder engagement with Specialists/Consultants/Clinicians.

Clinical Policy	Key Changes
<a href="#">Bunion (Hallux Valgus) Correction Surgery Policy</a> (Full routine review)	<p>NHS Derby and Derbyshire ICB, in line with its principles for procedures of limited clinical value has deemed that the surgical correction of bunions should not routinely be commissioned unless the criteria within the policy are met.</p> <p>The following minor amendments have been made to the policy:</p> <ul style="list-style-type: none"> <li>• Policy name updated to Bunion (Hallux Valgus) Correction Surgery Policy</li> <li>• Prior Approval form and Blueteq form have been updated to reflect the minor amendments to the policy</li> <li>• Addition of 'Guide to Bunion Surgery BOFAS' under section 4, 'Useful Resources'</li> </ul> <p>There has been no publication of new substantial evidence that is significant and robust since the policy was last reviewed in June 2020 that would warrant a change in the policy.</p> <p>With the exception of <a href="#">NICE CKS: Bunions</a> (last revised in August 2021), the references used within the policy have not been updated since the policy was last reviewed. There were no major changes to clinical recommendations that would necessitate a change to the policy.</p> <p><u>Summary of policy and management</u></p> <p>A bunion, also known as hallux valgus is a deformity of the big toe, where the toe tilts over towards the smaller toes and a bony lump appears on the inside of the foot. Occasionally a soft fluid swelling can also form over the bony lump.</p> <p>The pressure of the shoe over the bony bulge can cause discomfort and/or pain and can lead to blisters or infection. Furthermore, poorly fitting shoes or shoes that have an excessively high heel can worsen the deformity.</p> <p>The management of bunions includes wearing low-heeled, wide shoes, with a soft sole, as well as non-surgical treatments that help alleviate symptoms. Such treatments include oral analgesia, bunion pads and orthoses. Where these measures are not effective, the deformity and pain is worsening and is causing significant disruption to lifestyle the person can be referred for the consideration of surgery.</p> <p>Bunion surgery can help relieve pain and improve the alignment of the toe in 85%–90% of people. However, there is no guarantee that the foot will be perfectly straight or pain-free after surgery. Bunion surgery also carries a risk of complications, such as infection, joint stiffness, transfer pain (pain under the ball of the foot), hallux varus (overcorrection), bunion recurrence, damage to the nerves, and continued long-term pain.</p>
Governance Policy	Key Changes
<a href="#">Interventional Procedures Guidance (IPG) Policy</a> (Partial review)	<p>NHS 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 routinely be funded unless:</p> <ul style="list-style-type: none"> <li>• the NICE IPG states 'use with standard arrangements for clinical governance, consent and audit' <b>OR</b>,</li> <li>• the NICE MTG states 'the case for adoption within the NHS as described is supported by the evidence' <b>OR</b>,</li> <li>• the NICE DTG makes a recommendation as an option for use <b>OR</b>,</li> <li>• the NICE MIB has evaluated the innovation <b>OR</b>,</li> <li>• the NICE HTE has made a recommendation for use while evidence is being generated</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• the provider has submitted a robust, evidenced based business case to the commissioner and this has been subsequently approved</li> </ul> <p>The following amendments have been made to the policy:</p> <ul style="list-style-type: none"> <li>• the addition of Health Technology Evaluations (HTEs) for Early Value Assessments (EVAs) prompted a change to the policy (see below for detail)</li> <li>• the renaming of the IPG MTG, DG, MIB outputs policy to reflect the broader NICE programme areas</li> </ul> <p>The National Institute for Health and Care Excellence (NICE) produces several types of guidance documents including:</p> <ul style="list-style-type: none"> <li>• Cancer service guidance</li> <li>• Clinical guidelines*</li> <li>• Diagnostics guidance</li> <li>• Interventional procedures guidance</li> <li>• Medical technologies guidance</li> <li>• Public health guidance</li> <li>• Technology appraisals guidance</li> <li>• Quality standards</li> </ul>

	<p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>The purpose of the policy is to ensure that Derby and Derbyshire ICB have a consistent approach in considering and implementing IPGs, MTGs, DGs, MIBs and HTEs.</p>
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### MISCELLANEOUS INFORMATION

Statement	Summary
<a href="#">Injections for Nonspecific Low Back Pain without Sciatica including Spinal Fusion for Low Back Pain – Activity Data</a>	<p>Following the removal of Prior Approval CPAG undertook a review of activity.</p> <p>Business Intelligence (BI) produced a comparable dataset which showed that there had been a reduction in elective activity since Covid-19 started in March 2020. The level of activity has remained stable since 2021-2022, and it appears to be average when compared with national data.</p> <p>As activity has remained stable and there has been no increase in activity or any concerns raised, there is no requirement to re-instate Prior Approval.</p>
<a href="#">CPAG Terms of Reference &amp; Stakeholder Map</a> (Full routine review)	<p>CPAG Terms of Reference (ToR) and Stakeholder Map have been reviewed and updated to reflect changes in CPAG membership/infrastructure across the wider ICS as the system matures.</p> <p>The following amendments have been made to the Terms of Reference:</p> <ul style="list-style-type: none"> <li>• Corporate Ethical Framework Policy has been referenced within the CPAG ToR</li> <li>• Reference to the quadruple aim has been added</li> <li>• Management of Conflict of Interests section has been expanded</li> <li>• Reference has been added regarding the democratic election of the Chair</li> </ul> <p>The following amendments have been made to the Stakeholder Map:</p> <ul style="list-style-type: none"> <li>• 'Public Health England' amended to 'UKHSA' (UK Health Security Agency) and 'OHID' (Office for Health Improvement and Disparities)</li> <li>• Connection from 'PLCV' (Procedures of Limited Clinical Value) to 'PHSCC' (Population Health and Strategic Commissioning Committee) has been removed</li> <li>• Reference to the 'Clinical Policy Working Group' has been removed.</li> </ul>
<a href="#">IFR Panel Terms of Reference</a> (Full routine review)	<p>IFR Terms of Reference (ToR) has been updated to include reference to the DDICB Ethical Framework Policy.</p> <p>The Ethical Framework Policy underpins all ICB decision-making made at a population level which includes Individual Funding Requests (IFRs).</p>
<a href="#">Individual Funding Requests (IFR) Screening Cases</a>	<p>CPAG reviewed the IFR Screening cases for March 2023 and are assured that no areas for service development have been identified.</p>

### NICE INTERVENTIONS, DIAGNOSTICS, MEDICAL AND HEALTH TECHNOLOGIES AND INNOVATION PROGRAMMES

The DDICB does not commission and will not fund any procedure or technology assessed by NICE under their IPG, MTG, DTG, MIB or HTE programmes unless:

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

The following NICE programme outputs were noted by the group for the month of March 2023:

IPG/MTG/DTG/HTE/MIB	Description	Outcome
IPG753	<a href="#">Endoluminal gastroplication for gastro-oesophageal reflux disease</a>	NICE recommends further research, DDICB do not commission
IPG754	<a href="#">Percutaneous transluminal renal sympathetic denervation for resistant hypertension</a>	NICE recommends special arrangements, DDICB do not commission
HTE4	<p><a href="#">CaRi-Heart for predicting cardiac risk in suspected coronary artery disease: early value assessment</a></p> <p>1.1 CaRi-Heart is not recommended for use in the NHS while further evidence is generated. It should only be used in research to predict cardiac risk in people with suspected coronary artery disease (CAD), while treatment strategies to reduce coronary inflammation and cardiac death are identified.</p> <p>1.2 Further research is recommended (see the <a href="#">section on further research</a>) on:</p> <ul style="list-style-type: none"> <li>• how clinical outcomes might change for people with</li> </ul>	<p>NICE does not recommend (1.1), DDICB do not commission</p> <p>NICE recommends further research (1.2), DDICB do not commission</p>

	<p>suspected CAD who have had CaRi-Heart testing and appropriate treatment</p> <ul style="list-style-type: none"> <li>• how CaRi-Heart results affect clinical decision making compared with UK standard clinical practice</li> <li>• the costs to the NHS of using CaRi-Heart</li> <li>• how well CaRi Heart predicts cardiac risk to validate it in a UK population; in particular, data should be generated in the following groups: women, people from different ethnic backgrounds, and people who do not have CAD identified on CT coronary angiography (CTCA).</li> </ul>	
HTE5	<a href="#">ProKnow cloud-based system for radiotherapy data storage, communication and management: early value assessment</a>	NICE recommends standard arrangements – not commissioned without the provider submitting a robust, evidenced based business case to the commissioner and subsequent approval
HTE6	<a href="#">Genedrive MT-RNR1 ID Kit for detecting a genetic variant to guide antibiotic use and prevent hearing loss in babies: early value assessment</a>	NICE recommends standard arrangements – not commissioned without the provider submitting a robust, evidenced based business case to the commissioner and subsequent approval
MIB318	<a href="#">QbTest for the assessment of attention deficit hyperactivity disorder (ADHD)</a>	Not commissioned without the provider submitting a robust, evidenced based business case to the commissioner and subsequent approval
MIB319	<a href="#">BPMpathway for rehabilitation support in joint replacement surgery</a>	
MIB320	<a href="#">Macimorelin for diagnosing growth hormone deficiency</a>	

Our ICB continues to monitor and implement IPGs with our main providers.