NHS
Cheshire and Merseyside

Clinical Commissioning Policy

CMICB_Clin094
Patient-specific unicompartmental knee replacement

Category 1 Interventions – Not routinely commissioned

Contents

Last Reviewed: March 2024

This policy statement will be reviewed 5 years from the date of the last review unless new evidence or technology is available sooner.

1. Policy statement

1.1 Where MCAS services are in place the patient needs to be seen in a Musculoskeletal Clinical Assessment (MCAS) service before referral to a consultant.

1.2 Patient specific implants for use in unicompartmental knee arthroplasty is not routinely commissioned.

2. Exclusions

2.1 None.

3. Core Eligibility Criteria

3.1 There are several circumstances where a patient may meet a 'core eligibility criterion' which means they are eligible to be referred for this procedure or treatment, regardless of whether they meet the policy statement criteria, or the procedure or treatment is not routinely commissioned.

3.2 These core clinical eligibility criteria are as follows:

- Any patient who needs 'urgent' treatment will always be treated.
- All NICE Technology Appraisals Guidance (TAG), for patients that meet all the eligible criteria listed in a NICE TAG will receive treatment.
- In cancer care (including but not limited to skin, head and neck, breast and sarcoma) any lesion that has features suspicious of malignancy, must be referred to an appropriate specialist for urgent assessment under the 2-week rule.
  NOTE: Funding for all solid and haematological cancers are now the responsibility of NHS England.
- Reconstructive surgery post cancer or trauma including burns.
- Congenital deformities: Operations on congenital anomalies of the face and skull are usually routinely commissioned by the NHS. Some conditions are considered highly specialised and are commissioned in the UK through the National Specialised Commissioning Advisory Group (NSCAG). As the incidence of some cranio-facial congenital anomalies is small and the treatment complex, specialised teams, working in designated centres and subject to national audit, should carry out such procedures.
- Tissue degenerative conditions requiring reconstruction and/or restoring function e.g. leg ulcers, dehisced surgical wounds, necrotising fasciitis.
- For patients expressing gender incongruence, further information can be also be found in the current ICB gender incongruence policy and within the NHS England gender services programme - https://www.england.nhs.uk/commissioning/spec-services/npc-crg/gender-dysphoria-clinical-programme/

4. Rationale behind the policy statement

4.1 Although unicompartmental knee arthroplasty can provide faster recovery with fewer complications, the revision rate is around 3 times higher compared to a total knee arthroplasty. As a result, many surgeons do not perform this technique at all or do so in very small numbers. The evidence for customised implants using MRI is inadequate according to NICE who recommend that this technique should only be used in the context of research.

5. Summary of evidence review and references

5.1 Knee osteoarthritis, one of the most common conditions which affects the knee, is a clinical syndrome in which cartilage progressively breaks down with eventual loss and destruction. It is caused by abnormal wearing of the cartilage and reduction of the zones where the synovial fluid lubricates the joint and feeds the cartilage.[1] Unicompartmental knee arthroplasty dates back to the 1950s.[2] This involves replacing the missing (load) bearing surface of one compartment of the knee (either the medial or lateral compartment) with an implant which then allows the patient to bear more weight on the resurfaced compartment.[1] Conservative treatments include medication to relieve pain and inflammation, physiotherapy, prescribed exercises and/or corticosteroid injections.[3]

5.2 The lifetime risk of developing knee osteoarthritis is 50% with half of these cases diagnosed by the age of 55 years. Although severe arthritis can be limited to one compartment and thus is treatable with unicompartmental knee arthroplasty, total knee arthroplasty may also be employed.[4] The main advantages of the unicompartmental procedure are reduced tissue resection and blood loss, low morbidity and mortality, reduced post-operative pain and improved functional outcomes with faster post-operative rehabilitation.

5.3 Customisation of the knee implant is a relatively new development and this involves reproducing the patient's individual anatomy and joint morphology. Following radiographic assessment and MRI imaging of the knee, individualised 3D printed cutting guides for both the femur and tibia are produced for every case. The current literature regarding personalised components is relatively scarce because this is an emerging concept.[5] In addition, of the 50 most influential articles on general unicompartmental knee arthroplasty, most were regarded as "low level" and there is a need for future research.[2]

5.4 In terms of efficacy, evidence suggests that although unicompartmental knee arthroplasty provides faster recovery, fewer complications and better function than total arthroplasty, the revision rate for unicompartmental arthroplasty is 3 times higher. More specifically, a structured evaluation of one type of device (the medial Oxford unicompartmental knee arthroplasty) observed a 7% revision rate at 10 years. The most common reasons for revision were lateral disease progression (1.4%), aseptic loosening (1.3%), bearing dislocation (0.58%), pain (0.57%) and infection (0.47%).[6]

5.5 As a result of the high revision rate, many surgeons either don't perform this technique at all or in small numbers, [7] the technique is considered to be highly specialised. [8] It has been suggested that should surgeons perform substantially more unicompartmental procedures, the revision rate might be improved. A systematic review and meta-analysis confirmed higher post-operative complications with total knee arthroplasty but lower revision rates. Further research was needed to assess long-term survivorship to better evaluate these procedures.[9] The evidence for customised implants using MRI has been found to be inadequate by NICE and this technique, therefore, should only be used in the context of research.[3]

5.6 In summary, knee arthroplasty (replacement) is most likely performed in patients affected by osteoarthritis. This is one of the most common conditions affecting the knee and is due to progressive breakdown of cartilage. Unicompartmental knee arthroplasty involves replacement of specific components of the knee by an implant. The alternative is replacement of the whole of the knee joint (total knee arthroplasty).

5.7 However, although unicompartmental knee arthroplasty can provide faster recovery with fewer complications, the revision rate is around 3 times higher compared to a total knee arthroplasty. As a result, many surgeons do not perform this technique at all or do so in very small numbers. The evidence for customised implants using MRI is inadequate according to NICE who recommend that this technique should only be used in the context of research.

5.8 In conclusion, unicompartmental knee arthroplasty with its low procedure rates and high revision rates is regarded as a specialist technique. Set against this background, the evidence for patient specific implants to be used for this procedure is not very compelling.

REFERENCES

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6. Advice and Guidance

6.1 Aim and Objectives

- This policy aims to ensure a common set of criteria for treatments and procedures across the region. This is intended to reduce variation of access to NHS services in different areas and allow fair and equitable treatment for all patients.

- This policy relates to the commissioning of interventions which optimise clinical effectiveness and represent value for money.

- This document is part of a suite of policies which the Integrated Care Board (ICB) uses to drive its commissioning of healthcare. Each policy is a separate public document in its own right but should be considered alongside all the other policies in the suite as well as the core principles outlined.

- At the time of publication, the evidence presented per procedure/treatment was the most current available.

- The main objective for having healthcare commissioning policies is to ensure that:
  - Patients receive appropriate health treatments
  - Treatments with no or a very limited evidence base are not used; and
  - Treatments with minimal health gain are restricted.

- Owing to the nature of clinical commissioning policies, it is necessary to refer to the biological sex of patients on occasion. When the terms 'men' and 'women' are used in this document (unless otherwise specified), this refers to biological sex. It is acknowledged that this may not necessarily be the gender to which individual patients identify.

6.2 Core Principles

- Commissioning decisions by ICB Commissioners are made in accordance with the commissioning principles set out as follows:

  - Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment.
  - Commissioners require clear evidence of cost effectiveness before NHS resources are invested in the treatment.
  - Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment.
  - Commissioners will balance the needs of an individual patient against the benefit which could be gained by alternative investment possibilities to meet the needs of the community.
  - Commissioners will consider all relevant national standards and consider all proper and authoritative guidance.
  - Where a treatment is approved Commissioners will respect patient choice as to where a treatment is delivered, in accordance with the 'NHS Choice' framework.
  - Commissioning decisions will give 'due regard' to promote equality and uphold human rights. Decision making will follow robust procedures to ensure that decisions are fair and are made within legislative frameworks.

6.3 Individual Funding Requests (Clinical Exceptionality Funding)

- If any patients are excluded from this policy, for whatever reason, the clinician has the option to make an application for clinical exceptionality. However, the clinician must make a robust case to the Panel to confirm their patient is distinct from all the other patients who might be excluded from the designated policy.

- The ICB will consider clinical exceptions to this policy in accordance with the Individual Funding Request (IFR) Governance Framework consisting of: IFR Decision Making Policy; and IFR Management Policy available on the C&M ICB website: https://www.cheshireandmerseyside.nhs.uk/your-health/individual-funding-requests-ifr/

6.4 Cosmetic Surgery

- Cosmetic surgery is often carried out to change a person's appearance to achieve what a person perceives to be a more desirable look.

- Cosmetic surgery/treatments are regarded as procedures of low clinical priority and therefore not routinely commissioned by the ICB Commissioner.

- A summary of Cosmetic Surgery is provided by NHS Choices. Weblink: http://www.nhs.uk/conditions/Cosmetic-surgery/Pages/Introduction.aspx and http://www.nhs.uk/Conditions/Cosmetic-surgery/Pages/Procedures.aspx

6.5 Diagnostic Procedures

- Diagnostic procedures to be performed with the sole purpose of determining whether or not a restricted procedure is feasible should not be carried out unless the eligibility criteria are met, or approval has been given by the ICB or GP (as set out in the approval process

of the patients responsible ICB) or as agreed by the IFR Panel as a clinically exceptional case.

- Where a General Practitioner/Optometrist/Dentist requests only an opinion the patient should not be placed on a waiting list or treated, but the opinion given and the patient returned to the care of the General Practitioner/Optometrist/Dentist, in order for them to make a decision on future treatment.

6.6 **Clinical Trials**

- The ICB will not fund continuation of treatment commenced as part of a clinical trial. This is in line with the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Declaration of Helsinki which stipulates that the responsibility for ensuring a clear exit strategy from a trial, and that those benefiting from treatment will have ongoing access to it, lies with those conducting the trial. This responsibility lies with the trial initiators indefinitely.

7. Monitoring and Review

7.1 This policy remains in force until it is superseded by a revised policy or by mandatory NICE guidance or other national directive relating to this intervention, or to alternative treatments for the same condition.

7.2 This policy can only be considered valid when viewed via the ICB website or ICB staff intranet. If this document is printed into hard copy or saved to another location, you must check that the version number on your copy matches that of the one published.

7.3 This policy may be subject to continued monitoring using a mix of the following approaches:
- Prior approval process
- Post activity monitoring through routine data
- Post activity monitoring through case note audits

7.4 This policy will be kept under regular review, to ensure that it reflects developments in the evidence base regarding effectiveness and value.

8. Quality and Equality Analysis

8.1 Quality and Equality Impact Analyses have been undertaken for this policy at the time of its review.

9. Clinical Coding

9.1 **Office of Population Censuses and Surveys (OPCS)**

In primary position
W55.1 Primary prosthetic interposition arthroplasty of joint

In combination with
Z84.5 Tibiofemoral joint or
Z84.6 Knee joint

9.2 **International classification of diseases (ICD-10)**

None

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Document Control

Ref:	CMICB_Clin094 – Patient-specific unicompartmental knee replacement
Version:	1
Supersedes:	Previous Clinical Commissioning Group (CCG) Policies
Author (inc Job Title):	Consultant in Public Health, NHS Midlands and Lancashire
Ratified by: **(Name of responsible Committee)**	ICB Board
Cross reference to other Policies/Guidance	N/A
Date Ratified:	March 2024
Date Published and where (Intranet or Website):	March 2024 - (Website)
Review date:	March 2029
Target audience:	All Cheshire & Merseyside ICB staff and provider organisations

Version History
Version 1 – March 2024 – Policy ratified by NHS Cheshire & Merseyside ICB