NHS
Cheshire and Merseyside

Clinical Commissioning Policy

CMICB_Clin084
Hip and knee replacement surgery

Category 2 Intervention - Only routinely commissioned when specific criteria are met

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 Joint replacement (arthroplasty) surgery for hip or knee are routinely commissioned if all the following criteria are satisfied:

- Patient's symptoms (pain, stiffness and reduced function) are having a substantial impact on the quality-of-life.

AND

- Symptoms persist despite at least a 3 months' trial of conservative measures (such as medication, prescribed exercises).

AND

- Advice and pre-operative guidance is given in relation to
  - weight loss (if BMI >30 kg/m^2), **AND**
  - smoking cessation, **AND**
  - need to achieve a minimum of 150 minutes per week of aerobic exercise.

AND

- There is radiographic confirmation of diagnosis.

1.3 Patient specific factors such as age, sex, smoking, obesity and comorbidities should not be barriers to referral. The impact of these on surgical outcome should be explained to the patient.

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 This policy statement on joint replacement has been developed in accordance with national guidelines in particular from NICE, the Royal College of Surgeons and other national guidelines.

4.2 There are no restrictions on age, BMI, sex etc. in accordance with a NICE recommendation.

5. Summary of evidence review and references

5.1 Hip and knee replacements are common procedures which are performed due to persistent pain or limitation of function (or both) and which cannot be managed by conservative treatment alone. The leading cause is usually osteoarthritis but could include rheumatoid arthritis, trauma, congenital abnormalities, dysplasia or osteochondritic disease.[1]

5.2 Symptoms of *hip arthritis* include pain and stiffness which limit daily activities such as walking, climbing stairs and performing household tasks. Diagnosis is made on the basis of clinical history, deformity and a reduced range of movement. It has been estimated that up to 8.5 million people in the UK are affected by joint pain (usually attributed to osteoarthritis) and the 2nd most likely cause is rheumatoid arthritis (which affects around 400,000 people in the UK).[2] The Royal College of Surgeons estimate that 450 patients per 100,000 population present to primary care with hip pain each year.[3]

5.3 Similarly, the indications for total knee arthroplasty (replacement) are prolonged symptoms with both supporting clinical and radiological signs. [4] It has also been estimated that up to 20% of adults aged 45 and older have sought treatment for knee osteoarthritis and the lifetime risk of requiring joint replacement is 10%. [5]

5.4 Initial management of hip osteoarthritis involves medication, patient education, exercise therapy and physical activity. It has been shown that such measures can delay surgery for a considerable time. However, in more advanced stages, total hip replacement is one of the most successful and effective treatment options. According to a 2019 meta-analysis, 89.4% of joint replacements will last 15 years, 70% after 20 years and 57.9% after 25 years.[6] Other studies have also shown that hip replacement confers significant improvements in health related quality-of-life across a broad range of health domains.[7]

5.5 Knee replacement is also considered to be highly effective in up to 85% of patients with joint survivals of approximately 95% at 7 years.[5] Knee arthroplasty in the <55 years age group is increasing and a systematic review concluded this is an excellent treatment option for these young osteoarthritic patients who experienced a >50% improvement in functional knee scores with high patient satisfaction and low revision rates (approximately 0.5%).[8] There is some controversy regarding whether a single-stage bilateral knee replacement is better (or worse) compared to staged, unilateral replacement.[9]

5.6 In general, surgical risks for these procedures are small. In one study, 1.51% of patients experienced general complications and 2.35% experienced specific complications (related to the joint) with a mortality of 0.04%.[6] Both knee[5] and hip replacements are thought to be highly cost-effective and the latter has a cost per quality adjusted life year[1] of £1372.[3]

5.7 Of particular note in recent years has been the focus on obesity and how this might impact (or not) on joint replacements. In hip arthroplasty, complications increased by a factor of 4 fold in obese patients and the impact on outcomes was mixed with a few studies showing a detrimental effect whereas most showing no effect.[10] However, a very recent review (2020) found that people were up to 8.5 times more likely to require a hip arthroplasty when very obese (>40 kg/m²) compared to nonobese patients. Although the operation is technically more difficult in this group (infection is the main problem), functional outcomes are comparable to patients with normal BMIs.[11]

5.8 In knee arthroplasty, the impact of obesity is similar to the above. An early review had noted that obesity is a recognised risk factor for developing knee osteoarthritis. In addition, whilst the procedure is technically more challenging, obese patients are at greater risk of perioperative complications and potentially at increased risk of premature joint failure. However, the absolute improvements in outcome are similar in both groups.[12] A 2nd review found that the mean revision rate was higher in obese (BMI >30) patients but this wasn't statistically significant.[13] Interestingly, the evidence to support pre-surgery weight loss in very obese individuals (BMI >40 kg/m²) is lacking.[14]

National guidelines

5.9 The Royal College of surgeons' commissioning guide [3] for hip pain in adults recommends referral for total hip replacement when the following conditions are satisfied:

- Pain is inadequately controlled by medication.
- Functional impairment.
- Narrowing of the joint space on radiograph.
- Quality-of-life is significantly compromised.

5.10 In more detail, guidelines from the German Society for orthopaedic and trauma surgery [6] suggest that total hip replacement may be indicated in the following circumstances:

- Diagnosis confirmed radiologically and clinically (history of pain, morning stiffness, painful internal rotation).
- Significant patient distress.
- 3 months unsuccessful use of medication and other non-pharmacological treatments (patient education, exercise therapy and weight reduction).

5.11 NICE have recommended that the chosen hip prostheses have rates (or projected rates) of revision of 5% or less at 10 years.[2]

5.12 The Royal College of Surgeons' commissioning guide on painful osteoarthritis of the knee recommend referral for surgery when symptoms are not controlled after 3 months of nonoperative treatment. The decision on surgery should account for preoperative levels of

[1] Note: An intervention is considered to be "cost-effective" by NICE when the cost per QALY is <£20,000.

symptoms, capacity to benefit, expectation of the outcome and attitude to the risks. This requires a shared decision making process.[5]

5.13 More generally, in 2016 a review of all guidelines available (at that time) to determine the indication criteria for hip and knee arthroplasties found 6 guidelines and 18 papers out of 3065 references.[15] The review concluded that the criteria developed had been based on limited and low quality evidence. Perhaps, the most authoritative guidance is the NICE guideline (NG 157) on primary joint replacement for hip & knee.[16] This recommends shared decision-making and information specific to the procedure delivered in a format easily understood by patients. Preoperatively, patients should be given advice on exercise therapy (before and after surgery), weight management, diet and smoking cessation although there are no specific recommendations regarding referral criteria for surgery. NICE guideline CG 177 explicitly states that patient specific factors such as age, sex, smoking, obesity and comorbidities should not be barriers to referral for joint surgery.[17] In addition, the Getting It Right First Time (GIRFT) guidance on a hip and knee joint replacement pathway suggests that patients should have received at least 3 months conservative treatment prior to referral.[18]

5.14 In summary, replacement (arthroplasty) procedures for knee and hip joints are very common. Although there are other causes, the majority of cases are caused by osteoarthritis. Symptoms include pain, stiffness and limitation of daily activities.

5.15 Initial management involves medication, patient education, prescribed exercise therapy and modification of physical activity. When these measures fail (after a trial period of 3 – 6 months) and the patient continues to experience problems then surgical joint replacement is a known and effective option.

5.16 National guidelines recommend joint replacement in patients with confirmed diagnoses and who continue to experience significant reductions in quality-of-life despite a trial of conservative measures described above. Over the last few years, the impact of obesity on joint replacement surgery has received some attention in the literature. Certain CCGs have restricted their policy inclusion criteria according to specific BMIs. On balance, the current consensus is that a high BMI increases the surgical risks (usually infection) but the outcomes are the same in obese and non-obese individuals.

5.17 NICE's guidance (NG 157) on joint replacement surgery (2020) doesn't specify a BMI before surgery and neither are their weight restrictions stipulated by the Royal College of Surgeons' hip & knee commissioning guidelines. Shropshire (2019) and North Staffordshire (2018) CCGs specify a maximum BMI of 35 kg/m² in their policies. Greater Manchester CCG's policy (2020/21), the most recently reviewed, does not specify a maximum BMI and this is consistent with NICE guidance which places no limitations on BMI, age, sex, or comorbidities. The current Mersey CCG policy is the same as Cheshire CCG (i.e. a maximum BMI of <40 kg/m² for knee arthroplasty only).

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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)**

a) HIP

Any in primary position

W371 Primary total prosthetic replacement of hip joint using cement
W378 Other specified total prosthetic replacement of hip joint using cement
W379 Unspecified total prosthetic replacement of hip joint using cement
W381 Primary total prosthetic replacement of hip joint not using cement
W388 Other specified total prosthetic replacement of hip joint not using cement
W389 Unspecified total prosthetic replacement of hip joint not using cement
W391 Primary total prosthetic replacement of hip joint NEC
W398 Other specified other total prosthetic replacement of hip joint
W399 Unspecified other total prosthetic replacement of hip joint
W461 Primary prosthetic replacement of head of femur using cement
W468 Other specified prosthetic replacement of head of femur using cement
W469 Unspecified prosthetic replacement of head of femur using cement
W471 Primary prosthetic replacement of head of femur not using cement
W478 Other specified prosthetic replacement of head of femur not using cement
W479 Unspecified prosthetic replacement of head of femur not using cement
W481 Primary prosthetic replacement of head of femur NEC
W488 Other specified other prosthetic replacement of head of femur
W489 Unspecified other prosthetic replacement of head of femur
W93.1 Primary hybrid prosthetic replacement of hip joint using cemented acetabular component
W94.1 Primary hybrid prosthetic replacement of hip joint using cemented femoral component
W95.1 Primary hybrid prosthetic replacement of hip joint using cement NEC

b) KNEE

Any in primary position

W401 Primary total prosthetic replacement of knee joint using cement
W408 Other specified total prosthetic replacement of knee joint using cement
W409 Unspecified total prosthetic replacement of knee joint using cement
W411 Primary total prosthetic replacement of knee joint not using cement
W418 Other specified total prosthetic replacement of knee joint not using cement
W419 Unspecified total prosthetic replacement of knee joint not using cement
W421 Primary total prosthetic replacement of knee joint NEC
W428 Other specified other total prosthetic replacement of knee joint
W429 Unspecified other total prosthetic replacement of knee joint
O18.1 Primary hybrid prosthetic replacement of knee joint using cement

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

None

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