NHS
Cheshire and Merseyside

Clinical Commissioning Policy

Total Knee Arthroplasty, patient specific instrumentation/implants

Category 1 Intervention - Not routinely commissioned -

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Purpose	This document is part of a suite of policies that the Integrated Care Board (ICB) uses to drive its commissioning of healthcare. Each policy in that suite is a separate public document in its own right but will be applied with reference to other policies in that suite.
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1. Introduction

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

1.2 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 in Appendix 1.

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

2. Purpose

2.1 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.

3. Policy statement

3.1 Patient specific instrumentation to produce patient specific implants for total knee arthroplasty are not routinely commissioned.

4. Exclusions

4.1 None

5. Rationale

5.1 Current published data (based on many systematic reviews) suggest that patient specific instrumentation used to develop personalised knee implants offer no advantage or disadvantage in comparison to conventional methods.

5.2 Therefore, the intervention offers no particular advantage at a much-increased cost and is not routinely commissioned unless further information is published.

6. Underpinning evidence

6.1 The primary objective of total knee arthroplasty (replacement) is to restore normal biomechanics to the patient's deformed knee and involves restoration of normal alignment, rotation, joint line height and soft tissue balancing which ultimately bring the knee back to its pre-arthritic parameters.[1] A malalignment of as little as 3° in the coronal plane can result in accelerated prosthesis wear, increased revision rate and poorer quality of life.

6.2 Overall, around 20%-25% of patients are dissatisfied with the clinical outcome of their total knee arthroplasty as they suffer from persistent pain, instability, recurrent effusion and limited knee function which often leads to revision arthroplasty. Most revisions are due to aseptic loosening, instability, and patellofemoral disorders which are known to be affected by the size or positioning of the implant.[2,3]

6.3 Conventional "off-the-shelf" knee implants were developed on the basis of measurements taken from a defined standard population. Using modern imaging and implant fabrication techniques, it is now possible to produce patient-specific instrumentation and implants which are more likely to fit the individual patient's knee- joint morphology.[2] The instrumentation is based on computed tomography (CT) or magnetic resonance imaging (MRI) and sometimes combined with radiographs of the lower extremity.

6.4 The imaging is then used by manufacturers to develop 3–dimensional models of the patient's anatomy which are further used to produce disposable pinning or cutting blocks to help the surgeon reproduce the surgical plan during the intervention.[3] It has been suggested that this technique reduces the risk of infection, DVT and minimises blood loss [1] and is increasingly being used.[4]

6.5 Between 2014 – 2017, several systematic reviews and meta-analyses have been published which are generally not supportive of Patient Specific Instrumentation (PSI) in total knee arthroplasty. Various authors have made the following concluding statements:

- "PSI isn't superior to standard technology" [5],
- "Although PSI improves the accuracy of alignment, the differences were minimal and by themselves not a substantial justification for routine use" [3],
- "PSI has not consistently been shown to be cost-effective or to offer any clinical benefit with regard to functional scores assessed" [6],
- "PSI does not result in clinically meaningful improvement in alignment, fewer outliers or better early patient-reported outcome measures. Efficiency is improved but PSI doesn't reduce operation time" [7] ,
- "Current literature is insufficient to address whether there is a benefit of PSI in total knee arthroplasty in terms of improvement in functional outcomes" [8] ,
- "Based on the current literature, more prospective studies are necessary to evaluate the routine use of PSI in total knee arthroplasty" [9] ,
- "Limited available literature does not clearly support any improvement of post-operative pain, activity function when compared to traditional instrumentation" [10] ,
- "PSI does not improve the accuracy of alignment of the components compared to conventional instrumentation" [11]

6.6 A review published in 2019 acknowledged that most publications do not claim a significant increase in PSI accuracy, neither do they say that accuracy is worse. Further studies are required to more thoroughly assess the advantages and disadvantages of this "promising" technology. [12] The most recent systematic review (2021) concluded that the effective overall superiority of PSI has yet to be proven in long-term studies. [2]

6.7 The Cochrane database of systematic reviews published (in 2017) a protocol intended to assess the potential benefits and possible harms of patient specific cutting guides versus conventional instruments for total knee arthroplasty.[13] It should be emphasised that this is a protocol for a systematic review and the timetable for publication is unknown.

6.8 In summary, the majority of total knee arthroplasties (replacements) are currently performed using "off-the-shelf" prosthetic joints. Patient Specific Instrumentation (PSI) utilises CT or MRI scanning to create individualised tools which are then used to create or cut highly specific implants on a patient-by-patient basis.

6.9 The evidence suggests that PSI prostheses may improve some but not all knee-angle measurements. As with all knee prostheses, the objective is to obtain an implant which closely mimics the knee in its pre-arthritic state. Current data (based on many systematic reviews and meta-analyses) suggest that the PSI devices offer no advantage or disadvantage in comparison to conventional methods.

6.10 Based on current evidence, and until the Cochrane database publishes its systematic review, it is recommended that PSI knee arthroplasty should not be routinely commissioned.

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7. Force

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.

8. Coding

8.1 **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. Monitoring And Review

9.1 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

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

10. Quality and Equality Analysis

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

Appendix 1 - Core Objectives and Principles

Objectives

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.

Principles

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.

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.

Core Eligibility Criteria

There are a number of circumstances where a patient may meet a 'core eligibility criterion' which means they are eligible to be referred for the procedures and treatments listed, regardless of whether they meet the criteria; or the procedure or treatment is not routinely commissioned.

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 wishing to undergo Gender reassignment, this is the responsibility of NHS England and patients should be referred to a Gender Identity Clinic (GIC) as outlined in the Interim NHS England Gender Dysphoria Protocol and Guideline 2013/14.

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

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.

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.

Clinical Exceptionality

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.