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NHS Somerset

KNEE REPLACEMENT SURGERY

(Total Knee Replacement with/without Patella Resurfacing and Patella-Femoral Joint Replacement)

CRITERIA BASED ACCESS (CBA) POLICY

Version:	2425.V4
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Application Form	EBI Generic application form if appropriate to apply

KNEE REPLACEMENT SURGERY
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VERSION CONTROL

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DOCUMENT CHANGE HISTORY		
Version	**Date**	**Comments**
1617.v1	Sept 2016	Draft version
1617.v2a	July 2017	Amend wording within clinician guidance under moderate pain. Removed the word partial & unicompartmental as commissioned by NHS England
1819.v3	February 2019	PALs info update, SFI removal, template update, CEC amendment to include wording 'orthopaedic assessment services and/or consultant' to complete an IFR application form
1819.v3	February 2020	Amendment from IFR to EBI & inclusion bilateral pathway
1920.v3a	December 2021	3-year review, amendment to Decision Aid tools, no clinical amendments
2122.v3b	July 2022	Amendment from SCCG to NHS Somerset ICB. New PALS email address
2223.3c	November 2022	Inclusion of NICE guidelines ng226
2223.3d	January 2023	Amendment to Diagnosis of OA and NSAIDS
2223.V3e	November 2023	Minor wording amendments removal repeated wording NSAIDs, amend primary/community/secondary & inclusion of Exceptions 2.3.1. Updated NICE obesity link & ICB Website wording under point 4
2324.v3f	July 2024	Amendment to website link and clinical exceptionality wording on 4.6

2425.v3g	October 2024	3-year review and wording amendments to general principles and EBI pathway. Removal of wording not relating to criteria.

Equality Impact Assessment (EIA) Form Date:	September 2016 N/A as of January 2019
Quality Impact Assessment QIA. Date:	January 2019
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1 GENERAL PRINCIPLES (CBA)

1.1 Treatment should only be given in line with these general principles.

1.2 Clinicians should assess their patients against the criteria within this policy AND ENSURE that compliance to the policy criteria is met by the patient PRIOR TO a referral to treatment or surgery

1.3 Treatment should ONLY be undertaken where there is evidence that the treatment requested is effective and the patient has the potential to benefit from the proposed treatment

1.4 The ICB may approve funding for an ASSESSMENT ONLY to enable the Clinician to obtain further clinical evidence to help determine compliance to policy criteria by the patient.

In such cases, patients should be made aware that an assessment DOES NOT mean that they will automatically receive the treatment or surgery. The patient should be advised that, to effectively manage patient safety and ensure efficacy of the treatment/ surgery for the patient, they will only receive treatment or surgery if they meet policy criteria

1.5 Patients MUST CONSENT to receiving treatment/ surgery prior to treatment being undertaken

1.6 This policy does not apply to patients with suspected malignancy who should continue to be referred under the NHS '2 week wait pathway' rules for assessment and testing as appropriate

1.7 Patients with an elevated BMI of 30 or more MAY experience more post-surgical complications including post-surgical wound infection and should be encouraged to lose weight further prior to seeking surgery

https://www.sciencedirect.com/science/article/pii/S1198743X15007193 (Thelwall, 2015)

1.8 Patients who are smokers should be referred to smoking cessation services to reduce the risk of surgery and improve healing

1.9 Where patients are unable to meet the specific treatment criteria set out in this policy, funding approval MAY be sought by submission of a Generic EBI application form to the Evidence Based Interventions (EBI) team on grounds of 'clinical exceptionality'

2 POLICY CRITERIA BASED ACCESS (CBA)

2.1 Knee replacement surgery with or without a patellar resurfacing including referral for surgical assessment of osteoarthritis is **not routinely funded** by the ICB

2.2 Patients who are not eligible for treatment under this policy, please refer to section 4 EVIDENCE BASED INTERVENTIONS APPLICATION PROCESS on how to apply for funding with evidence of clinical exceptionality

2.3 All patients must be given the opportunity in primary/community/ secondary care to engage in discussions on the NHS treatment using recent patient decision aids and user guides

2.4 GPs should establish patient compliance to policy criteria prior to referring patients for an orthopaedic assessment. Compliance to policy criteria MUST be confirmed by the Orthopaedic Assessment Service and/or secondary care prior to surgery

2.5 GPs MUST ensure all patients receive appropriate Core interventions prior to referral to Orthopaedic Assessment Services

2.6 Weight loss should be maximised prior to referral to Orthopaedic Assessment Services https://www.nice.org.uk/guidance/cg189/resources/obesity-identification-assessment-and-management-pdf-35109821097925

2.7 All patients referred on to a surgical provider must have confirmation and evidence of compliance with criteria from the Orthopaedic Assessment services otherwise THE ICB ARE NOT LIABLE FOR PAYMENT

Note. for 'A Clinicians Guide of When and Where to Refer' see Appendix 2 page 10)

2.8 **Conservative Measures** MUST INCLUDE all the following – as recommended by NICE:

a) All patients referred on to a surgical provider must have confirmation and evidence of compliance with criteria from the Orthopaedic Assessment services

b) All patients must be given the opportunity in primary/community/ secondary care to engage in discussions on the NHS treatment using recent patient decision aids and user guides

c) Patients MUST have fully engaged with conservative measures for at least **6 months,** and this has failed to improve the symptoms for the patient

d) The patient is suffering from intense or severe persistent pain with moderate or severe functional impairment (Appendix 1 page 9 - Classification of Pain Level and Functional Impairment)

e) Agreed individualised self-management strategies have been agreed with the patient, including weight reduction where appropriate for patients with a BMI greater than 30 [Overview | Obesity: identification, assessment and management | Guidance | NICE]

f) Self-management has been undertaken by the patient, such as:
- activity modification (avoidance of impact and excessive exercise)
- use of suitable footwear and
- pacing

Non-pharmacological management has been undertaken such as:
- biomechanical interventions
- physiotherapy (*Note:* physiotherapy is ineffective in bone-on-bone osteoarthritis)
- weight bearing exercise to improve local muscle strength
- low impact general aerobic exercise to improve aerobic fitness

g) Management with topical NSAIDs or if ineffective oral NSAID (unless contra-indicated) at the lowest effective dose for the shortest possible time with PPI gastroprotection. Do not routinely offer paracetamol or weak opioids unless:
- they are only used infrequently for short-term pain relief **and**
- all other pharmacological treatments are contraindicated, not tolerated or ineffective
- DO NOT offer glucosamine or strong opioids

Note. NICE also report that Intra-articular corticosteroid injections should be considered as an adjunct to core treatments

2.8.1 Exceptions

The requirement to undergo conservative management does not apply for Immediate / Urgent Referral to Orthopaedic Assessment Services in respect of:

- Evidence of infection in the knee joint
- Conditions (such as AVN-avascular necrosis) leading to a rapid deterioration in the joint where delay to treatment would be unreasonable

2.9 Knee replacement surgery with or without a patellar resurfacing

Knee replacement surgery with or without a patellar resurfacing including referral for surgical assessment of osteoarthritis is routinely commissioned without the need for 6 months conservative treatment for patients with;

Severe persistent pain and severe functional impairment (refer to Appendix 1 page 9 - Classification of Pain Level and Functional Impairment) which is compromising a patient’s mobility to such an extent that they are in immediate danger of losing their independence and joint replacement would relieve this

At risk of destruction of their joint of such severity that delaying surgical correction would increase the technical difficulties of the procedure

2.10 **Knee Prostheses Commissioned**

The ICB will only fund standard prostheses conforming to NICE guidelines and that are Orthopaedic Data Evaluation Panel [ODEP] 10A rated, on a trajectory to achieve this rating, or within an ODEP-approved multicentre research trial. (Orthopaedic Data Evaluation Panel)

2.12 **Knee Prostheses Not Commissioned**

The provision of specialist custom knee prosthesis is not routinely commissioned, and surgical Clinicians would need to apply for funding approval through the EBI Service in such circumstances

Setting out why it is proposed to use a custom device and why they are unable to treat with the standard commissioned prosthesis

2.13 **Bilateral Knee Replacement Surgery Pathway**

A GP referral for a knee replacement on one side only MAY become a 'Bilateral Knee Replacement' if the secondary care clinician determines when seeing the patient, that the other side also meets the criteria of Somerset ICB's Knee Replacement CBA policy

Note. The medical notes MUST document how the policy criteria have been met for the second side

3 EVIDENCE BASED INTERVENTIONS APPLICATION PROCESS

3.1 Patients who are not eligible for surgery under this policy may be considered for surgery on an individual basis where the 'CLINICIAN BEST PLACED' believes exceptional circumstances exist that warrant deviation from the rule of this policy

'THE CLINICIAN BEST PLACED' is deemed to be the GP or Consultant undertaking a medical assessment and/or a diagnostic test/s to determine the health condition of the patient

3.2 Completion of a **Generic EBI Funding Application Form** must be sent to the EBI team by the 'clinician best placed' on behalf of the patient

Note. applications CANNOT be considered from patients personally

3.3 Only electronically completed EBI applications emailed to the EBI Team will be accepted

3.4 It is expected that clinicians will have ensured that the patient, on behalf of whom they are forwarding the funding application, has given their consent to the application and are made aware of the due process for receiving a decision on the application within the stated timescale

3.5 Generic EBI Funding Applications are considered against '**clinical exceptionality'**. To eliminate discrimination for patients, social, environmental, workplace, and non-clinical personal factors CANNOT be taken into consideration.

For further information on 'clinical exceptionality' please refer to the NHS Somerset ICB EBI webpage Evidence Based Interventions - NHS Somerset ICB and click on the section titled **Generic EBI Pathway**

3.6 Where appropriate photographic supporting evidence can be forwarded with the application form

4 ACCESS TO POLICY

4.1 If you would like further copies of this policy or need it in another format, such as Braille or another language, please contact the Patient Advice and Liaison Service on Telephone number: 08000 851067

4.2 **Or write to us**: NHS Somerset ICB, Freepost RRKL-XKSC-ACSG, Yeovil, Somerset, BA22 8HR or **Email** us: somicb.pals@nhs.net

5 REFERENCES

The following sources have been considered when drafting this policy:

5.1 Fu Y, W. G. (2011). Patellar resurfacing in total knee arthroplasty for osteoarthritis: a meta-analysis. European Society of Sports Traumatology, Knee Surgery & Arthroscopy

5.2 Isis Innovation. (n.d.). Oxford Knee Score - Threshold for knee replacement. Retrieved 05 19, 2016, from www.orthopaedicscores.com: http://www.orthopaedicscore.com/scorepages/oxford_knee_score.html

5.3 Leyland, K. M.-P.-A. (April 2016). Obesity and the Relative Risk of Knee Replacement Surgery in Patients with Knee Osteoarthritis: A Prospective Cohort Study. Arthritis & rheumatology (Hoboken, N.J.), vol. 68, no. 4, p. 817-825

5.4 National Joint Registry. (n.d.). Joint Replacements. Retrieved 05 18, 2016, from NJR Centre: https://www.njrcentre.org.uk/?s=joint+replacement https://www.njrcentre.org.uk/patients/knee-replacement/

5.5 NICE (2022, February). Osteoarthritis in over 16s: diagnosis and management NG226. Retrieved from NICE: https://www.nice.org.uk/guidance/ng226

5.6 NICE. (n.d.). Mini-incision surgery for total knee replacement. Retrieved May 18, 2016, from NICE: https://www.nice.org.uk/guidance/ipg345

5.7 Orthopaedic Data Evaluation Panel (n.d.). http://www.odep.org.uk/products.aspx?typeid=3 Retrieved May 18, 2016, from Orthopaedic Data Evaluation Panel: http://www.odep.org.uk/Home.aspx

5.8 Thelwall, S. P. (2015). Impact of obesity on the risk of wound infection following surgery: results from a nationwide perspective multicentre cohort study in England. Clinical microbiology and infection: the official publication of the European Society of Clinical Microbiology and Infectious Diseases, vol. 21, no. 11, p. 1008.e1

5.9 https://www.nice.org.uk/guidance/cg189/resources/obesity-identification-assessment-and-management-pdf-35109821097925

5.10 NICE guideline IPG 345 https://www.nice.org.uk/guidance/ipg345

5.11 NICE guideline NG226 https://www.nice.org.uk/guidance/ng226/evidence

5.12 Knee OA decision aid https://www.england.nhs.uk/wp-content/uploads/2022/07/Making-a-decision-about-knee-osteoarthritis.pdf

Appendix 1

Classification of Pain Level and Functional Impairment

This guide below is produced to support all clinicians and patients in classifying the pain and/or impairment suffered due to their condition in order to judge whether it is the appropriate time to refer a patient to secondary care.

Pain Levels:

Slight

- Sporadic pain.
- Pain when climbing/descending stairs.
- Allows daily activities to be carried out (those requiring great physical activity may be limited).
- Medication, aspirin, paracetamol or NSAIDs to control pain with no/few side effects.

Moderate

- Occasional pain.
- Pain when walking on level surfaces (half an hour or standing).
- Some limitation of daily activities.
- Medication, aspirin, paracetamol or NSAIDs to control with no/few side effects.

Intense

- Pain of almost continuous nature.
- Pain when walking short distances on level surfaces or standing for less than half an hour.
- Daily activities significantly limited.
- Continuous use of NSAIDs for treatment to take effect.
- Requires the sporadic use of support systems walking stick, crutches).

Severe

- Continuous pain.
- Pain when resting.
- Daily activities significantly limited constantly.
- Continuous use of analgesics - narcotics/NSAIDs with adverse effects or no response.
- Requires more constant use of support systems (walking stick, crutches).

Functional Impairment

Minor

- Functional capacity adequate to conduct normal activities and self-care
- Walking capacity of more than one hour
- No aids needed

Moderate

- Functional capacity adequate to perform only a few or none of the normal activities and self-care
- Walking capacity of about one-half hour
- Aids such as a cane are needed

Severe

- Largely or wholly incapacitated
- Walking capacity of less than half hour or unable to walk or bedridden
- Aids such as a cane, a walker or a wheelchair are required

Appendix 2

Clinician's Guide: When and Where to Refer

Pain	Functional Impairment	Minor	Moderate	Severe
Slight		Manage Conservatively in Primary Care – do not refer without funding approval	Manage Conservatively in Primary Care – do not refer without funding approval	Consider a referral to MSK for further conservative management and advice MSK to manage conservatively
Moderate		Manage Conservatively in Primary Care – do not refer without funding approval	Manage conservatively in Primary Care for 3 months prior to referral to MSK if no improvement	Consider a referral to MSK for further conservative management and advice MSK to manage conservatively
Intense		Consider a referral to MSK for further conservative management and advice MSK to manage conservatively	MSK Review and where appropriate referral to Secondary Care	MSK Review and where appropriate referral to Secondary Care
Severe		Consider a referral to MSK for further conservative management and advice MSK to manage conservatively	MSK Review and where appropriate referral to Secondary Care	Consider referral immediately if risk of losing mobility