KNEE REPLACEMENT SURGERY

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

CRITERIA BASED ACCESS (CBA) POLICY

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Application Form	EBI Generic application form if appropriate to apply

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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	PAL's 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

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

1.1 Treatment should only be given in line with these general principles. Where patients are unable to meet these principles, in addition to the specific treatment criteria set out in this policy, funding approval may be sought from the ICB Evidence Based Interventions Service (EBI) by submission of an EBI application form

1.2 Clinicians should assess their patients against the criteria within this policy prior to a referral and/or treatment

1.3 Treatment should only be undertaken where the criteria have been met and there is evidence that the treatment requested is effective and the patient has the potential to benefit from the proposed treatment. Where the patient has previously been provided with the treatment with limited or diminishing benefit, it is unlikely that they will qualify for further treatment

1.4 Referring patients to secondary / community care without them meeting the criteria or funding approval not secured not only incurs significant costs in out-patient appointments for patients that may not qualify for surgery, but inappropriately raises the patient's expectation of treatment

1.5 On limited occasions, the ICB may approve funding for an assessment only in order to confirm or obtain evidence demonstrating whether a patient meets the criteria for funding. In such cases, patients should be made aware that the assessment does not mean that they will be provided with surgery and surgery will only be provided where it can be demonstrated that the patients meet the criteria to access treatment in this policy

1.6 Patients should be advised being referred does not confirm that they will receive treatment or surgery for a condition as a consent discussion will need to be undertaken with a clinician prior to treatment

1.7 The policy does not apply to patients with suspected malignancy who should continue to be referred under 2 week wait pathway rules for assessment and testing as appropriate

1.8 Patients with an elevated BMI of 30 or more may experience more post-surgical complications including post-surgical wound infection so should be encouraged to lose weight further prior to seeking surgery. https://www.sciencedirect.com/science/article/pii/S1198743X15007193 (Thelwall, 2015)

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

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 and is subject to this restricted policy

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

a) A Clinicians Guide of When and Where to Refer (Appendix 2 page 11)

b) GPs establish patient compliance to the criteria, with the compliance being confirmed in the Orthopaedic Assessment Services

c) Ensure all patients receive appropriate conservative interventions (Point 2.3) before referral to the Orthopaedic Assessment Services/Secondary Care or for surgery

d) Offer advice on the following core treatments to all people with clinical osteoarthritis:
- Access to appropriate information
- Activity and exercise
- Interventions to achieve weight loss if the person is overweight or obese

e) Patients with an elevated BMI of 30 or more are likely to receive fewer benefits from surgery and should be encouraged to lose weight prior to seeking surgery. In addition, the risks of surgery are significantly increased

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

f) 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

g) The Orthopaedic Assessment Services will assess a patient's suitability for a referral to secondary care for surgery including:
- reference to this policy
- manage patients conservatively when possible
- where appropriate refer patients to secondary care for further management of their condition

2.2 **Diagnosis of Osteoarthritis**

a) Diagnose osteoarthritis clinically **without investigations** if a person is 45 years or over and has activity-related joint pain

NICE (TA 304) recommend that a diagnosis of Osteoarthritis may possibly be made if the patient has the following symptoms, but not limited to:

- 45 years of age or older **AND**
- Joint pain gets worse the more they use their joints
- Has no stiffness in their joints in the morning, or stiffness that lasts no longer than 30 minutes
- Is diagnosed clinically and usually does not need imaging to confirm the diagnosis
- Management should be guided by symptoms and physical function
- The core treatments for the condition are therapeutic exercise and weight management (if appropriate), along with information and support

Imaging

- Do not routinely use imaging for follow-up or to guide non-surgical management of osteoarthritis
- Imaging can be useful if atypical features are present that could suggest an alternative or additional diagnosis, such as other inflammatory forms of arthritis (for example, rheumatoid arthritis) and malignancy.
- Imaging is important for confirming the severity of structural joint changes when planning or considering surgery. However, in most cases, imaging should not be needed for managing osteoarthritis because it does not guide how the condition will respond to treatment.

b) **End-stage arthritis** can be defined as: The point where progressive wearing down of the articular cartilage results in bone-on-bone grinding down of the joint surface. The patient with **end-stage arthritis** has pain combined with a loss of function and mobility, **which severely limits normal activity**

c) **NICE guidelines NG226**
NICE have produced a clinical guideline NG226 on care and management of patients with OA and recommends that patients diagnosed with this condition should be “holistically” or conservatively managed (NICE , 2022) https://www.nice.org.uk/guidance/ng226

2.3 **CRITERIA**

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) The Patient has end stage Osteoarthritis suitable for referral for consideration of surgery and has fully engaged with conservative measures for at least **6 months** (Point 2.3) and this has failed to improve the symptoms for the patient **AND**

d) The patient is suffering from intense or severe persistent pain with moderate or severe functional impairment (Appendix 1 page 10 - Classification of Pain Level and Functional Impairment)

2.4 **Conservative measures to include:**

a) Agreed individualised self-management strategies, weight reduction where appropriate, particularly when the patient has a BMI greater than 30 Overview | Obesity: identification, assessment and management | Guidance | NICE

b) Use of self-management rehabilitation programmes such as Escape-Pain http://www.escape-pain.org/

c) Positive appropriately targeted behavioural changes, such as exercise, use of suitable footwear and pacing

d) Giving accurate verbal and written information to all people with osteoarthritis to enhance understanding of the condition and its management, and to counter misconceptions, such as that it inevitably progresses and cannot be treated. Ensure that information sharing is an ongoing, integral part of the management plan rather than a single event at time of presentation

e) 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

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

2.4.1 **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

2.5 **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 10 - 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

2.6 **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)

2.7 **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

2.8 **Bilateral Knee Replacement Surgery Pathway**

If the original GP referral is for only one side and the secondary care clinician determines when seeing the patient that the other side also meets the criteria of Somerset ICB Knee Replacement CBA policy, then the provider may undertake the procedure on the second side without returning the patient to either the Orthopaedic Assessment Service or the GP. The medical notes must clearly document how the criteria have been met for the second side

3 BACKGROUND

3.1 Total knee replacement can be performed for several conditions, but it is most often performed for patients with osteoarthritis of the knee. Osteoarthritis [OA] of the knee presents with joint pain, deformity, stiffness, a reduced range of movement and sometimes giving way

3.2 Other conditions that cause knee damage and potentially lead to a knee replacement surgery may include:

- rheumatoid arthritis
- gout
- haemophilia
- knee injury

3.3 The usual indications for a knee replacement are pain and disability with accompanying radiological changes. Occasionally knee replacements are done to manage a progressive deformity/instability

3.4 Any co-morbidity, including obesity should be managed to their optimum level prior to referral. Although obesity has been shown to increase the need for knee replacement surgery by 100%, particularly younger patients, weight reduction strategies could potentially reduce the need for knee replacement surgery by 31% among patients with knee OA (Leyland, April 2016)

3.5 What does surgery or treatment involve:
The main types of surgery carried out, depending on the condition of the knee, are:

- Total Knee Replacement (TKR) with or without patellar resurfacing
- Knee Replacement (PKR / UKR) which may refer to the medial or the lateral compartment
- Patello-Femoral Joint Replacement (PFJR)

3.6 How long will a replacement knee last:
Wear and tear through everyday use means a replacement knee will not last forever. However, for most people it will last at least 15-20 years, especially if cared for properly and not put under too much strain

3.7 **NATIONAL JOINT REGISTRY**
In line with NICE guideline IPG 345, (NICE) where patients consent, Surgeons should submit details on all patients undergoing mini-incision surgery for total knee replacement to the National Joint Registry (National Joint Registry)

4 EVIDENCE BASED INTERVENTIONS APPLICATION PROCESS

4.1 Patients who are not eligible for treatment under this policy may be considered on an individual basis where their GP or Consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy

4.2 Completion of a **Generic EBI Application Form** by a patient's GP or Consultant is required

4.3 Applications cannot be considered from patients personally

4.4 Only electronically completed EBI applications will be accepted to the EBI Service

4.5 It is expected that clinicians will have ensured that the patient, on behalf of who they are forwarding the application for, is appropriately informed about the existing policies prior to an application to the EBI service. This will reassure the service that the patient has a reasonable expectation of the outcome of the application and its context

4.6 EBI applications are reviewed and considered against clinical exceptionality

For further information on 'clinical exceptionality' please refer to the NHS Somerset ICB website and input into the 'Search this website' box clinical exceptionality. Click on the link to access the full NHS description of clinical exceptionality

Social, Emotional and Environmental factors *i.e., income, housing, environmental pollution, access to services, family, friends, ethnicity, life experiences etc.* CANNOT be considered with an application

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

4.8 An application put forward for consideration must demonstrated some unusual or unique clinical factor about the patient that suggests they are exceptional as defined below:

- Significantly different to the general population of patients with the condition in question

- Likely to gain significantly more benefit from the intervention than might be expected from the average patient with the condition

5 ACCESS TO POLICY

5.1 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

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

6 REFERENCES

The following sources have been considered when drafting this policy:

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6.8 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
6.9 https://www.nice.org.uk/guidance/cg189/resources/obesity-identification-assessment-and-management-pdf-35109821097925
6.10 NICE guideline IPG 345 https://www.nice.org.uk/guidance/ipg345
6.11 NICE guideline NG226 https://www.nice.org.uk/guidance/ng226/evidence
6.12 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