

**KNEE REPLACEMENT SURGERY**  
**(Total Knee Replacement with or without Patella Resurfacing and**  
**Patello-Femoral Joint Replacement)**  
**CRITERIA BASED ACCESS (CBA) POLICY**

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Application Form	IFR Generic application form for outside of criteria with evidence of clinical exceptionality

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**VERSION CONTROL**

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**DOCUMENT CHANGE HISTORY**

<b>Version</b>	<b>Date</b>	<b>Comments</b>
1617.v1	September 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

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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 CCG's Individual Funding Request (IFR) Panel by submission of an IFR application
- 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 care without them meeting the criteria or funding approval having been 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 CCG 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 meets 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 CCG does not commission surgery for cosmetic purposes alone
- 1.8 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
- 1.9 Patients with an elevated BMI of 30 or more are likely to receive fewer benefits from surgery and should be encouraged to lose weight further prior to seeking surgery. In addition, the risks of surgery are significantly increased (Thelwall, 2015)
- 1.10 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 CCG and is subject to this restricted policy

- 2.2 A Clinicians Guide of When and Where to Refer (Appendix 2 page 10 )
- 2.3 GPs establish patient compliance to the criteria, with the compliance being confirmed in the Orthopaedic Assessment Services
- 2.4 Ensure all patients receive appropriate Core interventions (item 2.16) before referral to Orthopaedic Assessment Services and secondary care/surgery
- 2.5 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
- 2.6 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
- 2.6.1 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 CCG are not liable for payment
- 2.8 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

### **Diagnosis**

- 2.9 Diagnose osteoarthritis clinically **without investigations** if a person: is 45 years or over and has activity-related joint pain and has either no morning joint-related stiffness or morning joint stiffness that lasts no longer than 30 minutes

**End-stage arthritis** can be defined as:

- 2.10 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**

- NICE guidance cg177**
- 2.11 NICE have produced a clinical guideline CG177 on care and management of patients with OA and recommends that patients diagnosed with this condition should be “holistically” or conservatively managed (NICE , 2014) <https://www.nice.org.uk/guidance/cg177/resources/osteoarthritis-care-and-management-pdf-35109757272517>

**CRITERIA**

- 2.12 All patients referred on to a surgical provider must have confirmation and evidence of compliance with criteria from the Orthopaedic Assessment Services
- 2.13 Patients must have been given an opportunity in primary/intermediate care to complete the Decision Aid tool
- 2.14 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** (item 2.16) and this has failed to improve the symptoms for the patient **AND**
- 2.15 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)

**Conservative measures to include;**

- 2.16 Agreed individualised self-management strategies, weight reduction where appropriate, particularly when the patient has a BMI greater than 30 <https://www.nice.org.uk/guidance/cg189/resources/obesity-identification-assessment-and-management-pdf-35109821097925>
- 2.17 Use of self-management rehabilitation programmes such as Escape-Pain <http://www.escape-pain.org/>
- 2.18 Positive appropriately targeted behavioural changes, such as exercise, use of suitable footwear and pacing
- 2.19 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
- 2.20 Pain relief with oral analgesics, topical treatments and / or Nonsteroidal anti-inflammatory drugs (NSAIDS) and highly selective COX-2 inhibitors
- 2.21 NICE also report that Intra-articular corticosteroid injections should be considered as an adjunct to core treatments

## **Knee replacement surgery with or without a patellar resurfacing**

2.22 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 patients 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

### **Knee Prostheses Commissioned**

2.23 The CCG 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)

### **Knee Prostheses Not Commissioned**

2.24 The provision of specialist custom knee prosthesis is not routinely commissioned and surgical Clinicians would need to apply for Individual Funding approval 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

## **3 BACKGROUND**

### **3.1 Diagnosing Osteoarthritis**

Diagnose osteoarthritis clinically without investigations if a person:

- is 45 or over **and**
- has activity-related joint pain **and**
- has either no morning joint-related stiffness or morning joint stiffness that lasts no longer than 30minutes

3.2 Appropriate imaging such as X-rays should not be requested if the diagnosis can be made without them

3.3 Total knee replacement can be performed for a number of 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

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

- rheumatoid arthritis
- haemophilia
- gout
- knee injury

- 3.5 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
- 3.6 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 )
- 3.7 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)
- 3.8 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
- 3.9 **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 INDIVIDUAL FUNDING REQUEST APPLICATION PROCESS**

- 4.1 Patients who are not eligible for treatment under this policy may be considered on an individual basis where the orthopaedic service and/or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy
- 4.2 Completion of a **Generic IFR Application Form** by the **Orthopaedic Assessment Service and/or Consultant** may be put forward
- 4.3 Applications cannot be considered from patients personally
- 4.4 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 IFRP. This will reassure the Panel that the patient has a reasonable expectation of the outcome of the application and its context
- 4.5 IFR applications are reviewed and considered for clinical exceptionality. For

further information on 'clinical exceptionality' please refer to the NHS England IFR policy  
<https://www.england.nhs.uk/wp-content/uploads/2017/11/comm-policy-individual-funding-requests.pdf>

- 4.6 An application put forward for consideration must demonstrate 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 Clinical Commissioning Group, Freepost RRKL-XKSC-ACSG, Yeovil, Somerset, BA22 8HR or **Email us:**  
[somccg.pals@nhs.net](mailto:somccg.pals@nhs.net)

## 6 REFERENCES

The following sources have been considered when drafting this policy:

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## **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**

<b>Pain</b>	<b>Functional Impairment</b>	<b>Minor</b>	<b>Moderate</b>	<b>Severe</b>
<b>Slight</b>		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
<b>Moderate</b>		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
<b>Intense</b>		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
<b>Severe</b>		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