Commissioning Policy
Individual Funding Request

Knee Replacement Surgery (including Partial and Total Knee Replacement with or without Patella Replacement or Resurfacing)
Criteria Based Access Policy
Date Adopted: 4th November 2016
Version: 1617.1

Individual Funding Request Team - A partnership between Bristol, North Somerset and South Gloucestershire Clinical Commissioning Groups Commissioning Group
## Document Control

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<tr>
<td>Authors job title(s)</td>
<td>IFR Manager</td>
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<tr>
<td>Document status</td>
<td>v1617.1</td>
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<tr>
<td>Supersedes</td>
<td>Referral of Adults with Osteoarthritis for a Knee Surgeon Opinion 1516.1</td>
</tr>
<tr>
<td>Clinical approval</td>
<td>May 2016</td>
</tr>
<tr>
<td>Discussion and Approval by Clinical Policy Review Group (CPRG)</td>
<td>13&lt;sup&gt;th&lt;/sup&gt; July 2016</td>
</tr>
<tr>
<td>Discussion and Approval by CCG Board</td>
<td>27&lt;sup&gt;th&lt;/sup&gt; September 2016</td>
</tr>
<tr>
<td>Date of Adoption:</td>
<td>4&lt;sup&gt;th&lt;/sup&gt; November 2016</td>
</tr>
<tr>
<td>Publication/issue date</td>
<td>4&lt;sup&gt;th&lt;/sup&gt; November 2016</td>
</tr>
<tr>
<td>Review date</td>
<td>November 2019</td>
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Knee Replacement Surgery (Including Partial and Total Knee Replacement with or without Patella Replacement or Resurfacing)

Policy Statement Date of Adoption: 4th November 2016
Knee replacement surgery is not routinely funded by the CCG and is subject to this restricted policy. This includes partial or total knee replacements with or without a patella replacement or resurfacing.

General Principles

Funding approval will 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 will not be given.

1. All patients must be referred for an initial assessment, and where appropriate conservative management, to commissioned intermediate musculoskeletal services. Musculoskeletal services will assess a patient’s suitability for surgery including: reference to this policy, manage patients conservatively when possible and where appropriate refer patients to secondary care for further management of their condition.

Bristol Patients – Musculoskeletal Assessment and Treatment Service (MATS) and Spinal Service
North Somerset Patients – The Musculoskeletal Interface Service
South Gloucestershire Patients - Clinical/Spinal Assessment & Treatment Service

2. For patients who do not qualify for a referral to secondary care or do not wish to be assessed by musculoskeletal services, individual funding approval must be secured by primary care prior to referring patients seeking advice and/or corrective surgery in secondary care. Referring patients to secondary care without 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.

3. On limited occasions, the CCG may approve funding for a further assessment in secondary care 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.

4. Where funding approval is given by the Individual Funding Request Panel, it will be available for a specified period of time, normally one year.
5. Funding approval will only be given where there is evidence that the treatment requested is effective and the patient has the potential to benefit from the proposed treatment. Where it is demonstrated that patients have previously been provided with the treatment with limited or diminishing benefit, funding approval is unlikely to be agreed.

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 further prior to seeking surgery. In addition, the risks of surgery are significantly increased. (Thelwall, 2015)

7. Patients who are smokers should be referred to smoking cessation services in order to reduce the risk of surgery and improve healing. (Loof S., 2014)

8. Bristol, North Somerset and South Gloucestershire CCG’s support the use of Oxford Knee Score (Isis Innovation) in the assessment of patients with osteoarthritis of the knee. Requests to approve surgery for patients with scores of 30 or more (out of a possible score of 48, where a lower score indicates worse symptoms) would not normally be expected without further clinical evidence clearly demonstrating the need for surgery earlier for the patient.

9. Patients’ (and carers’ as appropriate) expectations of surgery, and the likely degree of additional benefit that may be obtained from surgery compared with continuing conservative management, must have been discussed in primary/intermediate care. Patients must have been given an opportunity in primary/intermediate care to complete the Decision Aid tool on knee replacements: http://sdm.rightcare.nhs.uk/pda/, http://sdm.rightcare.nhs.uk/pda/osteoarthritis-of-the-knee/

Background

Reducing Inappropriate Referrals
This policy sets out when it is appropriate to manage patients conservatively in primary care and when to refer for further assessment and management.

Diagnosing Osteoarthritis

NICE recommend that a diagnosis of osteoarthritis may possibly be made if the patient has the following symptoms:

- 45 years of age or older, and
- has joint pain that gets worse the more they use their joints, and
- has no stiffness in their joints in the morning, or stiffness that lasts no longer than 30 minutes.

Appropriate imaging such as X-Rays can be used to support diagnosis.

Total or partial 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.
Other conditions that cause knee damage and potentially lead to a knee replacement surgery may include:

- rheumatoid arthritis,
- haemophilia,
- gout and
- knee injury.

NICE have produced a clinical guideline CG177 on care and management of patients of OA and recommends that patients diagnosed with this condition should be “holistically” or conservatively managed (NICE, 2014). This includes:

- access to appropriate information and education including self-management techniques,
- activity and exercise,
- interventions to achieve weight loss if the person is overweight or obese,
- pain relief with oral analgesics, topical treatments and/or Nonsteroidal anti-inflammatory drugs (NSAIDS) and highly selective COX-2 inhibitors.

NICE also report that Intra-articular corticosteroid injections should be considered as an adjunct to core treatments. Intra-articular Hyaluronan injections are not commissioned for the treatment of knee pain or OA.

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.

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).

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)** – both sides of the knee joint are replaced and the back of the knee cap may also be replaced
- **partial (half) knee replacement (PKR)** – only one side of the joint is replaced
- **TKR with replacement or resurfaced patella** – where there is evidence of tricompartmental OA with involvement in the patellofemoral compartment (formed by the kneecap and femur) then surgeons may seek to undertake a patellar replacement or resurfacing in conjunction with the TKR or PKR.
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 between thirty minutes to an 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

Clinician’s Guide: When and Where to Refer?

<table>
<thead>
<tr>
<th>Pain</th>
<th>Functional Impairment</th>
<th>Minor</th>
<th>Moderate</th>
<th>Severe</th>
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<tr>
<td>Slight</td>
<td></td>
<td>Manage Conservatively in Primary Care – do not refer without funding approval</td>
<td>Manage Conservatively in Primary Care – do not refer without funding approval</td>
<td>Consider a referral to MSK for further conservative management and advice. MSK to manage conservatively</td>
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<tr>
<td>Moderate</td>
<td></td>
<td>Manage Conservatively in Primary Care – do not refer without funding approval</td>
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<tr>
<td>Intense</td>
<td></td>
<td>Consider a referral to MSK for further conservative management and advice. MSK to manage conservatively</td>
<td>MSK Review and where appropriate referral to Secondary Care</td>
<td>MSK Review and where appropriate referral to Secondary Care</td>
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<tr>
<td>Severe</td>
<td></td>
<td>Consider a referral to MSK for further conservative management and advice. MSK to manage conservatively</td>
<td>MSK Review and where appropriate referral to Secondary Care</td>
<td>Consider referral immediately if risk of losing mobility</td>
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Risks (NHS Choices, 2015)

Knee replacement surgery will normally be carried out under a general anaesthetic. Anaesthetics are extremely safe, but carry a risk of minor side effects such as sickness and confusion (usually temporary). There is also a slight risk of serious complications. The risk of death in a healthy person having routine surgery is very small. Death occurs in around one in every 100,000 general anaesthetics given. The risk is higher if you are older or have other health conditions, such as heart or lung disease.

As with any operation, knee replacement surgery has risks and complications as well as benefits. Complications occur in about one in 20 cases, but most are minor and can be successfully treated. Possible complications include:

- **Infection of the wound** – this will usually be treated with antibiotics, but occasionally the wound can become deeply infected and require further surgery. In rare cases it may require replacement of the artificial knee joint

- **Unexpected bleeding into the knee joint, ligament, artery or nerve damage in the area around the knee joint, blood clots or deep vein thrombosis (DVT)** – clots may form in the leg veins as a result of reduced movement in the leg during the first few weeks after surgery. They can be prevented by using special support stockings, starting to walk or exercise soon after surgery, and by using anticoagulant medicines

- **Fracture in the bone around the artificial joint during or after surgery** – treatment will depend on the location and extent of the fracture

- **Excess bone forming around the artificial knee joint and restricting movement of the knee** – further surgery may be able to remove this and restore movement

- **Excess scar tissue forming and restricting movement of the knee** – further surgery may be able to remove this and restore movement

- **The kneecap becoming dislocated** – surgery can usually repair this

- **Numbness in the area around the wound scar**

- **Allergic reaction** – you may have an allergic reaction to the bone cement if this is used in your procedure

In some cases, the new knee joint may not be completely stable and further surgery may be needed to correct it.

**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.
Policy - Criteria to Access Treatment- CRITERIA BASED ACCESS

Funding approval for surgical treatment will only be provided by the CCG for patients meeting criteria set out below.

1) The patient has been assessed (including paper based triage where appropriate) by Musculoskeletal Services and diagnosed as suffering from end-stage osteoarthritis suitable for referral for consideration of surgery,

AND

2) The patient has fully engaged with conservative measures for a period of at least six months (clearly detailed throughout the patient’s primary care record or via Musculoskeletal Services’ clinic letters), as detailed within this policy, and this has failed to improve the symptoms of the patient,

AND

3) The patient:
   a) Is suffering from intense or severe persistent pain with moderate or severe functional impairment when compared to the classification system on the previous page.
   OR
   b) Has significant instability of the knee joint with significant functional impairment,
   OR
   c) Has radiological features of severe disease with moderate functional impairments;
   OR
   d) Has radiological features of moderate disease with significant functional impairment or instability of the knee joint and is suffering from.

Significant functional impairment is defined by the BNSSG Health Community as:
   - Symptoms preventing the patient fulfilling routine work or educational responsibilities
   - Symptoms preventing the patient carrying out routine domestic or carer activities

OR

4) The patient has severe persistent pain that is causing severe functional impairment* which is compromising their mobility to such an extent that they are in immediate danger of losing their independence and joint replacement would relieve this, and conservative management as set out in this policy is contra-indicated.

OR

5) The patient is at risk of destruction of their joint of such severity that delaying surgical correction would increase the technical difficulties of the procedure.
**Commissioned Prosthesis**
The CCG will only fund standard prostheses conforming with 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).

**Kneecap resurfacing or replacement**
Where patients have evidence of tri-compartmental OA affecting the kneecap, resurfacing or replacement of the patella can be proposed. However, the long-term results are still unclear with a recent meta-analysis showing the difference of absolute risk of reoperation between resurfacing and non-resurfacing being only 4% implying that in order to prevent one reoperation one would have to resurface 25 patellae. (Fu Y, 2011).

**Kneecap resurfacing or replacement – Commissioned procedure** (Monitor and NHS England, 2016). Tri- compartmental knee surgery under the HRG code “HB21C Major Knee Procedures for Non-Trauma, Category 2, without CC” is the routinely commissioned surgery for patients requiring patellar resurfacing or replacement and funding approval for this procedure is not normally needed where patients meet the criteria within this policy.

Tri- compartmental knee surgery under the HRG code “HR05Z Reconstruction Procedures Category 2” is not routinely funded and clinicians should apply for individual funding approval setting out why the patient is unable to access the commissioned treatment and how they will benefit over and above all other patients for whom this treatment is also not available.

**Exclusions:**

**Patient-specific Custom Knee Prosthesis**
This is a more recent advance in knee replacement surgery. A guide is created using magnetic resonance imaging (MRI) scans. This helps to create the best fitting technique for each individual patient's implant. However, there is limited evidence that these benefit patients more than standard prostheses therefore custom knee prosthesis are not routinely funded.

**Hyaluronan Acid Injections**
Intra-articular Hyaluronan injections are not commissioned for the treatment of knee pain or OA.

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**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).

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.
Individual cases will be reviewed at the CCG’s Individual Funding Request Panel upon receipt of a completed application form from the patient’s GP, consultant or clinician. Applications cannot be considered from patients personally.

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 0800 073 0907 or 0117 947 4477.

**Connected Policies:**

**Knee Arthroscopy:** Clinician’s should refer to the intervention specific policy.

This policy has been developed with the aid of the following references:


