



Clinical Commissioning Policy: Microprocessor Controlled Prosthetic Knees

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Complex Disability Equipment-Prosthetics**

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Policy Statement

NHS England will routinely commission in accordance with the criteria outlined in this document.

In creating this policy NHS England has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

This policy document outlines the arrangements for funding of this treatment for the population in England.

Equality Statement

Throughout the production of this document, due regard has been given to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited in under the Equality Act 2010) and those who do not share it.

Plain Language Summary

A prosthetic knee joint forms part of a lower limb walking prosthesis to be used by people with a lower limb loss at or above the level of the knee. Limb loss at these levels is commonly a result of vascular disease with or without diabetes. Other reasons for limb loss include traumatic injuries, treatment of malignant disease, infections, complications of musculoskeletal conditions, and congenital limb deficiency. The service aims to maximise the mobility, function, independence and quality of life working in collaboration with the individual patient. This is achieved through a patient-centred rehabilitation program under the supervision of a specialist multidisciplinary team. One aspect of the rehabilitation program is the provision of prostheses (artificial limbs), which includes a prosthetic knee joint in the case of above knee limb loss.

This policy regulates the NHS provision of a specific category of prosthetic knee components (Microprocessor Controlled Prosthetic Knees). The policy is based on published scientific research evidence, which assessed the benefits and outcomes of using these components. The policy is intended as guidance for the Rehabilitation Multidisciplinary Teams in order to ensure appropriate patient selection and highlight the prescribing pathway. The policy outlines a unified approach to patient care at a national level and is aimed to improve the level of services available to patients with limb loss in England.

1. Introduction

Microprocessor Controlled Knees (MPKs) are a category of prosthetic knee components, gaining increased popularity in recent years. They can be a vital, necessary and important component to improve rehabilitation outcomes and quality of life. An expanding body of research highlights the main benefits and improved outcomes, which in selected cases, would justify the associated short and long term cost implications. Advantages include reduced falls and improved falls management, improved stumble recover, improved stability and controlled sitting and standing, improved gait symmetry, improved and controlled step over step descent, different modes for different activities and an ability to manage obstacles more easily.

NHS Provision of MPKs was only available through exceptional funding applications resulting in significant variations at the national level in the absence of an agreed prescribing policy. This policy aims to create a unified, evidence-based approach to prescribing MPKs and improve the quality of limb loss rehabilitation at a national level.

2. Definitions

- **A Microprocessor Knee:** An artificial knee joint which includes a battery-powered, built-in, programmable computer that continuously controls both swing and stance phase based on real time data of the user's gait. The microprocessor knee components covered by this policy are:
 - Orion Knee (Endolite)
 - The Rheo Knee (Ossur)
 - The C-leg (Ottobock)
 - Plie Knee (Freedom Innovations)
- **Functional Loss in the Contralateral Limb:** This is defined as an amputation on the contralateral side at an ankle disarticulation level or above. However, a partial foot amputation might be considered under this definition if it affects balance and control of one leg stance. A well-fitted comfortable socket must be provided on the contralateral side in order to proceed with MPK provision under this definition. This also includes complex fractures, soft tissue injuries and nerve injuries affecting function of the contralateral limb.
- **Loss of Function in Multiple Limbs:** The loss of function in multiple limbs (including an upper limb), affecting ability to use walking aids or to protect oneself in case of a fall.
- **Stubby Prostheses:** A stubby is an above or through knee prosthesis that does not include a prosthetic knee joint. Stubby prostheses are provided to bilateral transfemoral or through knee patients and usually are made short to lower the amputee's centre of gravity. Their main benefits are to reduce the likelihood and the impact of falls, in addition to reduce the energy requirements of walking.

- **SIGAM Mobility Grade:** The SIGAM (Special Interest Group in Amputee Medicine) scale is a simple yet fully validated scale of Disability Mobility Grades. It measures function of lower limb amputees fitted with a functional or cosmetic prosthesis in terms of mobility. It was developed from the Harold Wood/Stanmore Mobility Grades to improve accuracy of grade allocation. It includes a benchmark distance of 50 meters and uses a questionnaire and algorithm with grades from A (non limb user) to F (normal or near normal walking).
- **K Activity Levels:** A 5-level functional classification system related to the functional abilities of patients with lower-limb loss. It ranges from K0 (no mobility) to K4 (High activity, with high impact stress on the prosthesis).

- **A Trial of a Microprocessor Knee:** Includes 3 dimensions:

1 Outcome measures

Performed first on existing prosthetic limb(s) when the patient collects trial limbs, and then again at the end of the trial with the trial limb(s). Outcome measures should include a variety of measures related to impairment, mobility/activity, participation and emotional including both patient reported and objective measures.

Suggested outcome measures include: Prosthesis Evaluation Questionnaire (PEQ), self reported frequency of stumbles and falls (over the past 6 months), patient diary to record changes, timed walking tests (indoors and outdoors with heart rate monitor to measure Physiological Cost Index), L test, gait lab analysis, TUG, LCI 5, AMP PRO, The Tinetti's balance assessment tool, (RNLI) Reintegration to Normal Living Index, Canadian Occupational Performance Measure (COPM), Goal Attainment Scale (GAS), Hospital Anxiety and Depression Scale (HAD Scale), ABC UK and video evidence of gait and improved performance of functional tasks relevant to the patient's agreed goals.

2 Fitting and initial setup

The knee unit must be used in conjunction with intended and approved components and set in the optimal alignment. A well fitting socket is essential for the success of the trial, and a new socket and in some cases a new prosthesis might be required for the purposes of the trial.

Bench and static alignment followed by dynamic alignment (outdoors if possible with obstacles/ inclines). It is essential this is followed by initial gait training by a physiotherapist.

3 Trial

The duration of the trial should be a minimum of 4 weeks but a longer trial is recommended depending on the patients intended and agreed goals and the manufacturer/supplier conditions. Patients will be allowed to take the trial prosthesis/eses home and use it in their own environment.

3. Aim and objectives

This policy aims to:

- Improve patient choice of prosthetic componentry
- Improve rehabilitation outcomes, safety and quality of life for patients with limb loss at or above the level of the knee
- Define the eligibility criteria, indications and contraindications for prescribing MPK to Transfemoral amputees

To outline the prescribing process starting from patient selection, goal setting, trial period, provision of MPK if clinically appropriate following a successful trial and future review.

4. Epidemiology and needs assessment

MPKs can be suitable for patients with an amputation requiring prosthetic replacement of the knee joint i.e at the knee disarticulation level and higher. This may include transfemoral amputations, hip disarticulations and hemi pelvectomy amputations. The incidence of the highest amputations is relatively small however transfemoral amputations can account for around 40% of total referrals to a prosthetic centre (NASDAB 2007). In England in 2010 there were 4346 amputees referred for limb fitting, 1575 (36%) were transfemoral (Limbless statistics 2010).

These amputations can be caused by trauma, malignancy and infection, however the main cause of amputation in this population is dysvascularity, leading to 73% of transfemoral amputations in 2007. The population also tends to be older with 64% of transfemoral amputees over the age of 65 (NASBAB 2007).

Due to the high incidence of co-morbidities within this patient group not all amputees are fitted with a prosthesis and for those who are fitted, limb abandonment can be a possible outcome as the patient is unable to overcome the challenges of prosthetic use.

Currently this patient group are fitted with mechanical knee joints which can be classified by the complexity of their function during stance or swing phases. This style of prosthetic knee has been used for many years within the NHS.

With the introduction of MPKs came the ability to utilise microprocessor analysis and control over both swing and stance phases. This offered the ability to adjust to the requirements of the prosthetic user in real time and can allow the knee to learn about the patients walking characteristics over time.

An analysis of prevalence of established amputees who according to the proposed policy may benefit from a prescription change and a subsequent trial of a MPK, was undertaken at a medium sized service centre in England. The service centre has a caseload of 1218 patients with 1062 of those having lower limb amputations.

346 (33%) of existing patients had an amputation at, or higher than the knee disarticulation level. (75% are Transfemoral Amputations, 17% Knee Disarticulation Amputations, 2% Hip Disarticulation amputations, 0.3% Hemi pelvectomy and 6%

bilateral amputations).

Of these patients, 146 would have met the policy criteria to undergo a trial with an MPK. This figure represents 12% of the centres entire caseload.

An analysis of incidence of new patients who may be suitable for a microprocessor knee was also carried out at the same medium sized service centre in England. All referrals to the centre were assessed against the proposed criteria. The centre received 120 new referrals in 2012, 64% of those losing their limb due to vascular disease. 36% of referrals could have been considered for MPK (i.e knee disarticulation level or higher). According to the proposed policy 2.5% of referrals received in 2012 could have trialled a MPK following their primary assessment.

At the national level, there were 4077 new lower limb referrals in England in 2007. Using the same percentage of those who were suitable for a trial with a MPK according to the medium centre analysis (2.5% of referrals), we predict 102 new patients would be suitable to go through a trial with a MPK annually in England. Some of those patients might not qualify for provision depending on the outcome of the trial.

It is very difficult to make predictions regarding established amputees due to the lack of national statistics regarding active lower limb prosthetic users. However, our analysis shows the percentage of those who might qualify for a trial of a MPK would be 12% of the existing caseload of centres.

5. Evidence base

Research evidence in relation to MPKs has been limited by the general constraints of research in a rehabilitation setting. Due to practical and ethical issues, fully randomised, blinded studies are difficult to conducted (for example, a physiotherapist needs to know the details of the prosthetic prescription in order to provide appropriate therapy, which makes blinding impossible). However, several systematic reviews of observational studies have investigated key clinical and governance aspects such as energy efficiency, cost effectiveness, impact on quality of life and patient satisfaction.

A literature review of systematic reviews which reported clinical efficacy of MPK was undertaken which identified 2 studies (Highgate et al. 2010 and Sawers and Hafner et al. 2013).

Study characteristics of the two systematic reviews are as follows:

1. Highgate et al. (2010)

- included both uni- and bilateral transfemoral amputees
- included studies with Otto Bock C-leg only
- included studies reporting safety, energy efficiency during gait and cost effectiveness
- study limitations:
 - included case reports or observational studies with small sample sizes
 - not fully inclusive of all studied aspects of the C-Leg as compared

to other knees

- amputees of dysvascular etiology were not represented at levels commensurate with estimates from epidemiologic studies
- numerous variables were not controlled or standardized across included studies (examples include functional level and its rating, accommodation time, control knees, methodologies and selection of outcome measures).

2. Sawers and Hafner et al. (2013)

- included patients with unilateral transfemoral or knee disarticulation of lower limb.
- included studies with any MKP commercially available
- included studies reporting 9 outcomes (metabolic energy expenditure, activity, cognitive demand, gait mechanics, environmental obstacle negotiation, safety, preference and satisfaction, economics, and health and quality of life)
- study limitations:
 - excluded individuals with bilateral transfemoral lower limbs loss (TFLL) and those with more proximal levels of lower limbs loss (LLL).
 - conclusions are based on published literature on a small subset of those prosthetic knees that are commercially available and it is derived predominantly from outcomes related to two specific models (i.e., Compact C-Leg and SmartIP).

Summary of evidence on safety:

60 percent of individuals with above knee amputations have reported at least one fall in the past month or year in retrospective surveys¹⁸. Mechanistic studies of individuals' biomechanical responses to physical perturbations while wearing both swing and stance MPKs and non-MPKs similarly show improvements in standing and walking balance while using MPKs¹⁸. Highgate et al (2010) identified 7 studies reporting on safety outcomes. Authors considered them to have low methodologic quality and have a moderate risk of bias. Only one study had a large sample size of 368 patients, all others had samples between 1-19. Statistical significance of results was achieved in 5/7 studies. In the included studies the following outcomes were reported:

- reduction in frequency of stumbles ranged between 19-31% (n=3 studies)
- decrease in number of stumbles 59% (n=1 low level study)
- decreased number of falls 64% (n=1 study)
- decrease in the frequency of falls 80% in K2 (n=1 study)

Sawers and Hafner et al. (2013) reported the below findings in terms of safety:

- there is low level evidence suggesting the use of swing and stance MPKs results in decreased number of subject-reported stumbles and falls when compared with use of NMPKs among individuals with unilateral TFLL (n=1

low quality study)

- there is insufficient evidence suggesting the use of swing and stance MPKs results in decreased subject-reported frustration with falling when compared with use of NMPKs among individuals with unilateral TFL (n= 2 low quality studies)
- there is moderate evidence suggesting the use of swing and stance MPKs results in increased subject-reported confidence while walking when compared with use of NMPKs among individuals with unilateral TFL (n= 1 moderate quality study and n= 3 low quality studies)

Summary of evidence on cost effectiveness:

Highsmith et al (2010) identified 3 observational studies- One study used a cost-consequence economic evaluation and the other two used cost utility in Swedish, Italian and Dutch settings with sample size ranging 20-100. All three studies concluded that the C-Leg was a societally cost-effective prosthetic knee option.

The initial MPK acquisition costs are significantly greater than the non MPK. However some studies included analysis of expenses beyond the prosthetic prescription, including medical visits, pharmaceutical prescriptions, hospitalizations, transportation, home modifications, housekeeping assistance, and productivity losses¹⁸. For example, the Italian study by Gerzeli et al²⁶ reported mean intervention costs of €18,616 (\$22,348) and €3,600 (\$4,328) for the MPK and non MPK prostheses, respectively. However, after considering all societal costs related to intervention maintenance, medical services, transportation, caregiving, and productivity losses for the 50 subjects enrolled in each group in the study, mean costs were €66,669 (\$80,162) and €66,927 (\$80,473), respectively. The largest societal cost differences in the reviewed literature were attributed to the category of productivity losses^{26,28}. Larger productivity losses were noted with non MPK users than MPK users, suggesting that MPKs may be more effective at allowing users to return to work. Thus, the available evidence indicated that total costs for prosthetic rehabilitation from a societal perspective were equivalent between swing and stance MPKs and non MPKs¹⁸. The incremental cost per QALY varied from €3,218 (\$4,132)²⁷ to €35,971 (\$43,251)²⁶ when considering only prosthesis cost. However, when including societal costs, there is a reported cost savings of €614 (\$738) per QALY with the prescription and use of a swing and stance MPK²⁶.

Sawers and Harner (2012) reported the below findings in terms of cost-effectiveness (P.S, two of the studies included were also considered in Highgate et al (2010):

- there is moderate evidence that prescription of swing and stance MPKs results in increased prosthesis acquisition costs compared with NMPKs among individuals with unilateral TFL (n=2 moderate quality study and n= 1 low quality study)
- there is moderate evidence that prescription of swing and stance MPKs results in equivalent total costs of prosthetic rehabilitation compared with NMPKs among individuals with unilateral TFL(n=2 moderate quality study)

Based on the above evidence, it would appear that the prescription and use of swing and stance MPKs might be considered a cost-effective technology and, despite initially being more expensive, would appear to be an effective alternative

for re-establishing a life that is both of higher quality and longer duration¹⁸.

Summary of evidence on environmental obstacle negotiation:

Evidence derived from a systematic review by Sawers and Hafner 2013¹⁸ revealed that the negotiation of uneven terrain by individuals with above knee amputation is significantly improved with the use of swing and stance MPKs compared to non MPKs. Three publications reported a significant decrease in the time needed to complete the obstacle course when using the swing and stance MPK than when using the non MPK, while a fourth reported a non significant decrease in time associated with the task. MacKenzie et al reported that as few as 43.5 percent of individuals with TF amputation describe being able to independently perform this activity²⁹. Evidence obtained suggests that the use of swing and stance MPKs results in significantly improved stair descent compared with the use of non MPKs¹⁸. Significant improvements in speed and pattern of hill decent were also reported in the same review.

Summary of evidence on energy efficiency:

Highgate et al (2010) identified 8 studies reporting on outcomes on energy efficiency. Authors considered all but one of them to have low methodologic quality and have a moderate risk of bias. Sample size ranged between 1-15. In the included studies the following outcomes were reported:

- 6–7% increased energy efficiency at medium and slow walking speeds (p50.05) (n=1 study)
- 184% reduction of normal oxygen (n=1 study)
- increased energy efficiency at typical (6.4%) and fast (7%) pace walking (p50.05) (n=1 study)
- increased energy expenditure: Total daily (8%) Physical activity (6%), (p_0.04) (n=1 study)
- 20.2% Reduced post-activity heart rate (n=1 study)

Sawers and Hafner (2013) reported the below findings in terms of energy efficiency:

- There is moderate level of evidence that the use of swing and stance MPKs results in equivalent O2 cost (at self-selected, slow, and fast speeds) compared with use of NMPKs among individuals with unilateral TFLL (n=1 moderate quality study and n= 2 low quality studies).
- Use of swing and stance MPKs results in decreased O2 rate (at self-selected walking speed) compared with use of NMPKs among individuals with unilateral TFLL (n= 3 low quality studies).
- Use of swing-only MPKs results in equivalent O2 rate (at self-selected, slow, and fast speeds) compared with use of NMPKs among individuals with unilateral TFLL(n= 3 low quality studies).

Overall, there is a general agreement and evidence supporting improved safety, reduced falls and improved stumble control when compared with non-MPKs. Majority of the current evidence of MPKs is based on studies with low methodological quality and evaluating C-leg in unilateral limb loss.

A reduction of the energy requirements of walking is reported with some papers

showing an increase in activity as a result. Weaker evidence from smaller studies have reported reduced forces on the contralateral limb, which is assumed to reduce the long-term wear and tear effects leading to joint osteoarthritis.

Although many published papers provide evidence of cost effectiveness over the patients expected life, cost effectiveness analysis studies are generally country specific, and need to factor-in the national medical, social and care costs. There are unfortunately no published studies that analyse long term cost effectiveness within the health economy specifics of the UK. However, studies from other European countries such as Italy and the Netherlands reported a long term reduction in medical and care costs.

6. Rationale behind the policy statement

Amputation is a lifelong condition with significant implications on patients, their families and society as a whole. Improvements in prosthetic outcomes and functional abilities are expected to translate to long-term reduction in health care costs and care needs. This policy is based on the reported strong evidence in relation to the outcome of using a MPK compared to a non-MPK. The main outcomes are improved safety, reduced falls and reduced energy requirements of walking. Other outcomes that were taken into account include improved patient satisfaction, improved quality of life, improved activity, and reduced wear and tear in the contralateral limb. Patient selection was focused on those who need to use a MPK to reduce risk, improve independence and quality of life or reduce care needs. However, we recognise that other outcomes such as improved well being, improved confidence and high patient satisfaction add extra weight to justify provision. Increased physical activity will have a beneficial effect on weight, cardiovascular risk factors and diabetes.

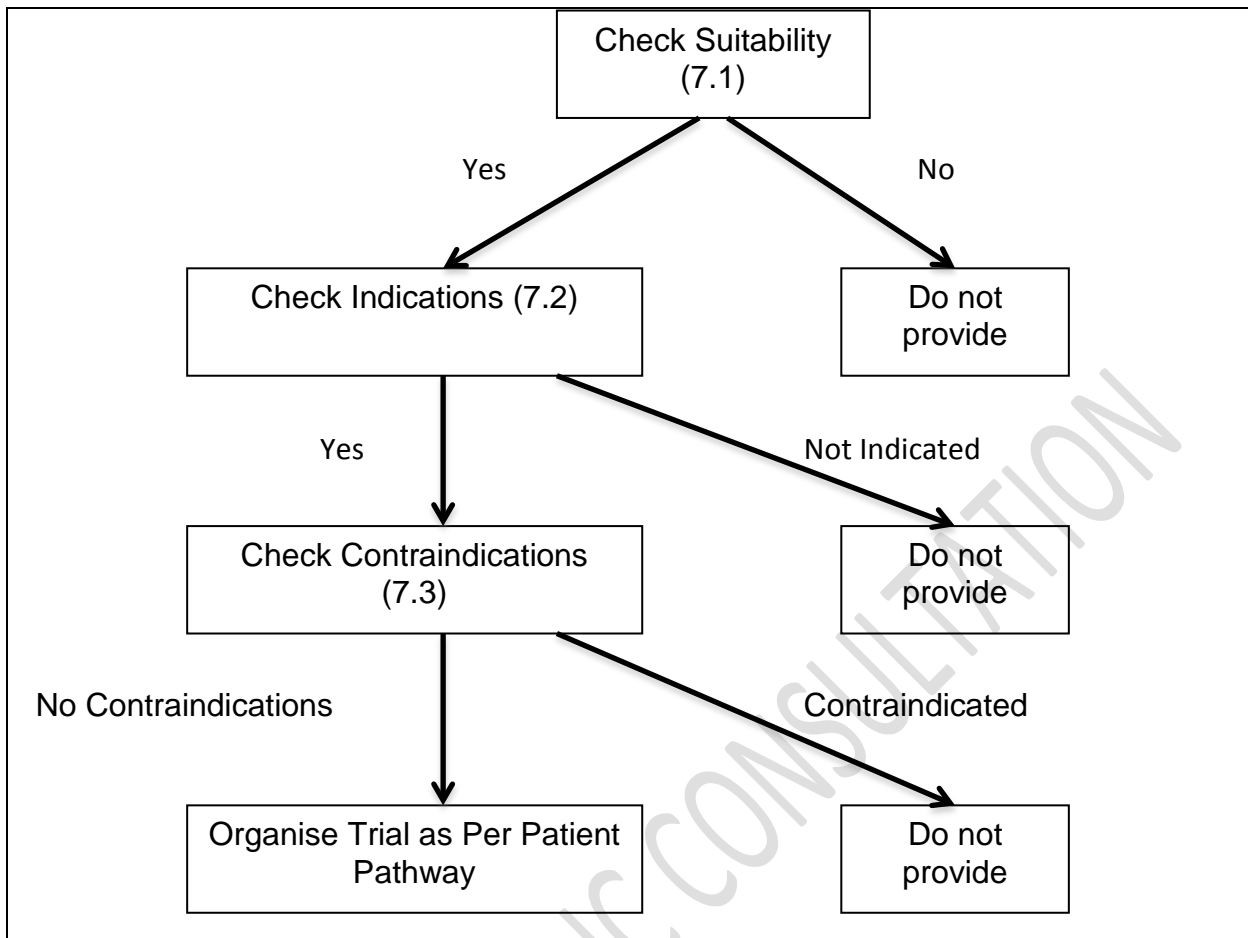
A major limiting factor is the lack of UK-based cost effectiveness studies, and consequently, studies from other European countries had to be considered for supporting evidence.

7. Criteria for commissioning

Criteria for commissioning MKPs are based on the evidence on their clinical efficacy and cost effectiveness summarised in section 5 and agreed prescribing guidelines by multidisciplinary teams representing nine Prosthetic Rehabilitation Centres in the South East England region developed using a Delphi technique (Sedki and Fisher 2014)- see Figure 1.

A patient to be eligible for an MKP, will be eligible for an MPK if they meet the criteria in 7.1 and 7.2. Patients with contraindications listed in 7.3 will not be eligible for an MPK.

Figure 1



7.1 Suitability to be considered for prescribing a MPK

The patient needs to meet atleast one criteria in 7.1.1, 7.1.2 and 7.1.3 and all criteria in 7.1.4 in order to qualify for consideration for an MPK

7.1.1 Activity level:

- Unilateral amputee K3 or K4 – patient is an active walker with a free knee
- Bilateral amputee K2, patient is able to walk with a free knee. However, the minority of bilateral trans-femoral amputees who may be able to achieve independent mobility may only be able to do so with the stability and function of MPKs. Therefore, bilateral trans-femoral amputees who walk with stubbies might be suitable without having to walk with a free non-microprocessor knee.

7.1.2 Mobility level

- SIGAM D or above

7.2.3 Amputation level

- Unilateral Trans-femoral
- Hip disarticulation

- Knee disarticulation
- Bilateral lower limb amputee (A major amputation on the contralateral side at or higher than mid-foot level, or functional loss on the contralateral side as per definition)

7.2.4 Patient must demonstrate

- Commitment to prosthetic rehabilitation through active participation with the therapy team.
- Adequate strength and balance to be able to activate the knee unit
- Requirement of MPK as the main day to day prosthesis
- Cognitive reasoning to master control, operation and care of the device
- sufficient cardiovascular abilities to meet the fitness demands of ambulating outdoors with free knee

7.2 Indications

Patients must meet all criteria in 7.2.1, 7.2.2 or 7.2.1

7.2.1 Unilateral Amputees (K3 level, SIGAM D)

To be considered for an MPK prescription, the user should have a comfortable, well-fitting, well-aligned prosthesis that includes a non-MPK and be able to walk out doors with a free knee. In this case an MPK would be indicated if the patient presented with:

- Clinical presentation of unstable gait evidenced as history of frequent falls, stumbles or near misses (e.g. due to contra-lateral limb impairment or amputation). A trial is required to prove reduced risk of falls
- When the risk of injury from a fall is very high due to a co-existing medical condition (e.g. upper limb joint replacements, inability to protect head in case of a fall due to upper limb impairment, increased risk of fracture). A trial is required to prove reduced risk of injury

7.2.2 Bilateral Transfemoral / Knee Disarticulation Amputees (K2 or above, SIGAM D)

Prescription of MPKs to this patient group is limited to prosthetic users who are able to independently mobilise with Stubbies (see definition), and who have sufficient balance and muscle control to progress on to achieve independent mobility with full length articulating prostheses during rehabilitation.

These patients should initially start mobilising with Stubbies in order to gain strength, balance, improve hip range and allow assessment of rehabilitation potential by the clinical team. A long period of rehabilitation may be required before moving on to use full-length prostheses with prosthetic knees. Full integration of the stubbies into the patient's day to day life should be achieved prior to considering articulated prostheses. In these cases, a direct transition to prostheses with MPKs might be required.

7.2.3 Bone Anchored Prosthesis Techniques

These techniques include Intraosseous Transcutaneous Amputation Prosthesis (ITAP) / Osseointegration. An MPK is indicated when a non-MPK would not allow the patient to mobilise at their full potential, or when an MPK is essential to avoid potential fractures around the implant as a result of a fall.

The absolute need to match manufacturing specifications or to avoid invalidating warranty when other components dictate the choice of knee component. In these cases, the indication to prescribe a MPK is directly linked to the indications for prescribing that other component.

7.3 Contra-indications

- Limited cognitive ability to understand operating and care requirements
- K4 activities, except when the manufacturer specifically states suitability for K4 activities (mainly activities that include running), as most manufacturers of MPKs would not recommend use for K4 activities
- Low activity level – amputee with no or limited ability or potential to ambulate on level ground at fixed cadence
- Patient’s weight or height falls out of manufacturer’s recommendations
- Aggressive environments such as excessive moisture or dust, very warm or cold weather, mechanical vibrations, strong magnetic fields
- Water related activities
- Not enough space to fit the MPK (built on length available) or where cosmetic appearance will be an issue for the user
- Failure to achieve good socket fit or comfort
- Unilateral amputee with low mobility (SIGAM A-C)
- Patient not able to tolerate weight of unit
- Inability to regularly charge batteries
- Extremely rural conditions where maintenance and charging resources are limited
- Significant hip flexion contracture preventing correct knee alignment and MPKs activation as per manufacturer’s recommendations. A hip fixed flexion of 30 or above is unlikely to be suitable for MPK prescription
- User’s inability to commit to regular maintenance as recommended by manufacturer

8. Patient pathway

More advanced prosthetic components such as MPKs were not funded routinely under previous commissioning agreements with the PCTs (Primary Care Trusts). The rehabilitation MDT (usually at a Service Centre) would submit an application for exceptional funding to the relevant PCT. The lack of an agreed national patient pathway resulted in a wide variation in the contents of these applications especially in the selection criteria, indications, use of outcome measures, the details of MPK trials and supporting research evidence. Funding for Prosthetic Services moved to NHS England in April 2013 and this is hoped to eliminate the previous post-code lottery and to agree a clear and unified approach to MPK provision. This policy supports equality of and ease of access to MPKs to all patients who meet the

criteria set out within the policy regardless of what centre a patient may attend. Therefore appropriate referral mechanisms should be in place to provide for appropriate access and opportunity thereby supporting improved service quality and patients outcomes.

The suggested patient pathway is as follows:

Patient Selection: Suitable patients are selected by a full multidisciplinary specialist rehabilitation team according to the outlined suitability criteria in this policy. Patients may also approach the team to be considered for a trial and prescription according to the policy. The majority of cases are expected to be patients who have been provided with a non-MPK although some new primary amputees could be considered if a non MPK was unsuitable for their needs.

Full Clinical Assessment: This includes full history taking and physical examination, with an assessment of the patient's current personal, current daily activities and needs including all social, vocational and occupational aspects. The indication/ indications for prescribing the MPK should be clearly highlighted and the team must rule out any possible contra-indications to prescribing a MPK.

Goal Setting: This is a patient centred process that takes into account the patient's abilities, needs and aspirations. It is essential to outline clear SMART rehabilitation goals to be achieved from the prescription (Specific, Measurable, Attainable, Realistic and Timely). The MDT must consider all the possible available knee components (including non MPK) that might facilitate achieving these goals.

Trial: Once the decision is made that the patient is suitable to be prescribed a MPK, a trial period with a MPK is organised in liaison with the manufacturer. The details of the trial are outlined under the definitions section.

Outcome Measures: Ideally, the outcome measures should be assessed with the existing non MPK component just prior to commencing the trial with a MPK. The same outcomes are repeated at the end of the trial for comparison. A meaningful functional change should be clearly detected. The outcome should be sustainable and strongly relevant to the patient's daily life (i.e. not related to a rare or a one-off task). A video recording of gait while performing tasks relevant to the agreed goals is strongly recommended as evidence of improvement.

Provision: This is agreed at an MDT meeting that includes the patient at or after the end of the trial period. Further gait training must be provided to maximise functional gains based on the agreed rehabilitation goals. Patients are informed about their responsibility in relation to the care of the MPK, maintenance, warranty and restrictions. This forms a treatment contract with the MDT which is reviewed when a replacement knee is required.

Reviews: Follow-ups should be arranged at 6 monthly intervals in the first year, and at least annually after that stage. At follow-up, the initial goals are reviewed to ensure the patient continues to benefit fully from using the MPK. An individual personal/functional/social, vocational or occupational changes might affect the patient's suitability to use a MPK, and any prescription should be reviewed/changed in such cases. Is information should be available for auditing both the implementation of the policy and the service provision.

Manufacturer's recommendations and warranty details might necessitate follow-ups at pre-defined stages and compliance with these details (both by the MDT and the

patient) is essential. It is the responsibility of both service providers and patients are responsible to commit to regular maintenance as recommended by the manufacturer.

9. Governance arrangements

- Provision of MPKs is limited to components that comply with EU safety, health and environmental requirements by having a CE marking.
- It is important that both clinicians and users adhere to safety guidelines as specified by manufacturers, service centres and relevant national guidelines. This is outlined through a treatment contract between the MD team and the user when the MPK is provided.
- Appropriate training and CPD should be supported to ensure clinicians obtain the required skills related to the fitting, maintenance and rehabilitation of users of MPKs
- All prescriptions should be recorded and the specific indication(s) for prescribing the MPK should be clarified by clinicians. This information should be made available to NHS England for the purpose of conducting regular audit.
- The implementation of the policy and the outcomes of this implementation should both be audited and the data made available to NHS England (see section 11).

10. Mechanism for funding

Microprocessor Controlled Knees are a type of prosthetic component and will be provided through Specialist Rehabilitation Service Centres. Prosthetic services in England will be funded through Specialised Commissioning by NHS England. Due to the expected volume of prescriptions being higher than 5 annually, the current commercially available types of Microprocessor Controlled Knees would not normally qualify to be funded through Individual Funding Requests.

It is recognised that once this policy is adopted, there may be an initial large number of patients who would meet the prescribing criteria for MPKs. These are established trans-femoral who needed to use a MPK but were not provided with one due to the limitations of the old system of provision. Once this initial need is met, the number of MPK units provided annually will drop to match the incidence of new cases of amputees.

11. Audit requirements

Mandatory compliance by all service centres with National Microprocessor Controlled Prosthetic Knees Policy, including 100% provision of required data. Outcomes related to the implementation of this policy, functional mobility, disability,

participation, goal achievement in addition to those specified in the CQUINS for amputee rehabilitation/prosthetics should be audited.

Data regarding patient numbers, demographics, levels of amputation, aetiology and providing centres should be collected at a national level and made available for analysis by NHS England. This data will be essential to inform future updates of this policy.

12. Documents which have informed this policy

Government

- National Service Framework for long-term conditions (2005)
- Dr Andrew Murrison MD, MP 'A Better Deal for Military Amputees', 2011
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13. Links to other policies

This policy follows the principles set out in the ethical framework that govern the commissioning of NHS healthcare and those policies dealing with the approach to experimental treatments and processes for the management of individual funding requests (IFR).

National Service Specification: Complex Disability Equipment-Prosthetic Specialised

Services for People of All Ages with Limb Loss
CQUINS for Amputee Rehabilitation/Prosthetics
National Service Framework for long-term conditions (2005)

14. Date of review

This policy will be reviewed in April 2016 unless data received indicates that the proposed review date should be brought forward or delayed. Audit data collected during the implementation of this policy should be used to inform the review. The current policy aims to provide MPKs to those who absolutely need to use them. It is hoped that the indications could be expanded in the future to include all prosthetic users who would benefit from using MPKs.

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