Clinical Commissioning Policy: Microprocessor controlled prosthetic knees

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Clinical Commissioning Policy: Microprocessor controlled prosthetic knees

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Policy Statement

NHS England will commission microprocessor controlled prosthetic limbs 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

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need 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 under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities

Plain Language Summary

About microprocessor controlled prosthetic knees and leg loss

A prosthetic knee joint is part of a lower leg walking 'prosthesis' – sometimes known as an artificial leg or limb. It is used by people who have lost a leg at or above the knee. The loss of this part of the leg is commonly a result of problems with the blood vessels in the leg ('vascular disease').

- These problems may happen with or without diabetes.

Other causes of limb loss include:

- severe injuries caused through an accidents ('traumatic injuries')
- treatment of 'malignant' disease – usually related to cancer
- infections

- complications of muscle and bone illness (‘musculoskeletal’)
- limb deformities from birth (called ‘congenital’).

About the current treatment

The aim is to give people the best mobility and function possible. This should improve long-term health and quality of life. It should also help with recovery from ill health and injury. This should make sure that patients have a positive experience of care and are protected from avoidable harm.

This is achieved through a rehabilitation program which is ‘patient-centred’. It is supervised by a specialist team of different professionals and specialists (‘multi-disciplinary team’). One aspect of the rehabilitation program is giving people prostheses (artificial limbs), which includes a prosthetic knee joint where there is leg loss above the knee.

About the new treatment

This policy relates to the NHS providing a specific type of prosthetic knee called a ‘microprocessor controlled prosthetic knee’. Microprocessor Controlled Prosthetic Knees are a group of knee components that can be a vital, necessary and important component to improve rehabilitation outcomes and quality of life. These limbs improve walking and balance by aiding walking movements in real time and this reduces falls and accidents caused by a lack of stability that can be experienced with other prosthetic limbs.

The policy is based on published scientific research evidence.

- This evidence looked at the benefits and results of using these parts of the prosthesis.
- The policy is to guide the rehabilitation multidisciplinary teams in order.
- It is to make sure the right patients are selected for this prosthesis and highlight the prescribing pathway.
- The policy outlines a unified approach to patient care at a national level. It aims to improve the level of services available to patients with limb loss in England.

What we have decided

NHS England has reviewed the evidence and concludes that there is sufficient evidence to consider supporting routine commissioning of microprocessor limbs.

1 Introduction

Microprocessor Controlled Knees (MPKs) are a category of prosthetic knee components, becoming more widely prescribed in the last 15-20 years. They can be a vital and important component to improve rehabilitation outcomes and quality of life. An ever expanding body of research highlights the main benefits and improved outcomes, which in selected cases, would justify the associated short term cost implications. MPKs provide enhanced stability and stumble recovery, which improves fall management and reduces the incidence of falls. This supports the increases in self-reported improved individual mobility and independence. MPKs also improve controlled sitting and standing, walking gait symmetry, stair decent, controlled step over step descent down a slope, reduced energy expenditure, and given different modes for different activities an ability to manage obstacles more easily. MPKs aid health and well-being and are cost effective in overall health economic terms

NHS Provision of MPKs was previously available through Individual Funding Requests (IFRs) resulting in significant variations in prescription and use at the national level in the absence of an agreed prescribing policy. This policy aims to create an equitable, evidence-based approach to the prescribing of MPKs and improve the quality of limb loss rehabilitation and outcomes 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.

Functional Loss in the Contralateral Limb

Functional loss includes complex fractures, soft tissue injuries and nerve injuries affecting function of the contralateral limb. It also includes amputation on the contralateral side. A well-fitted comfortable socket must be provided on the contralateral side in order to proceed with MPK provision under this definition.

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:

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 functional mobility, participation and goal setting. The chosen outcome measures should include both patient reported and objective measures.

Patient reported and objective measures include Core Outcome Measures which are mandated and Additional Optional Outcome Measures.

Core Outcome Measures

Prosthesis Evaluation Questionnaire (PEQ), self-reported frequency of stumbles and falls (over the past 6 months), patient stumbles and falls diary to record changes, timed walking tests (indoors and outdoors),TUG Timed Up and Go, (RNLI) Reintegration to Normal Living Index, Joint Movement Data

Additional Optional Outcome Measures

L test, gait lab analysis, TUG, LCI 5, AMP PRO, (Physiological Cost Index), the Tinetti's balance assessment tool, 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

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 in combination with the prosthetist.

Trial

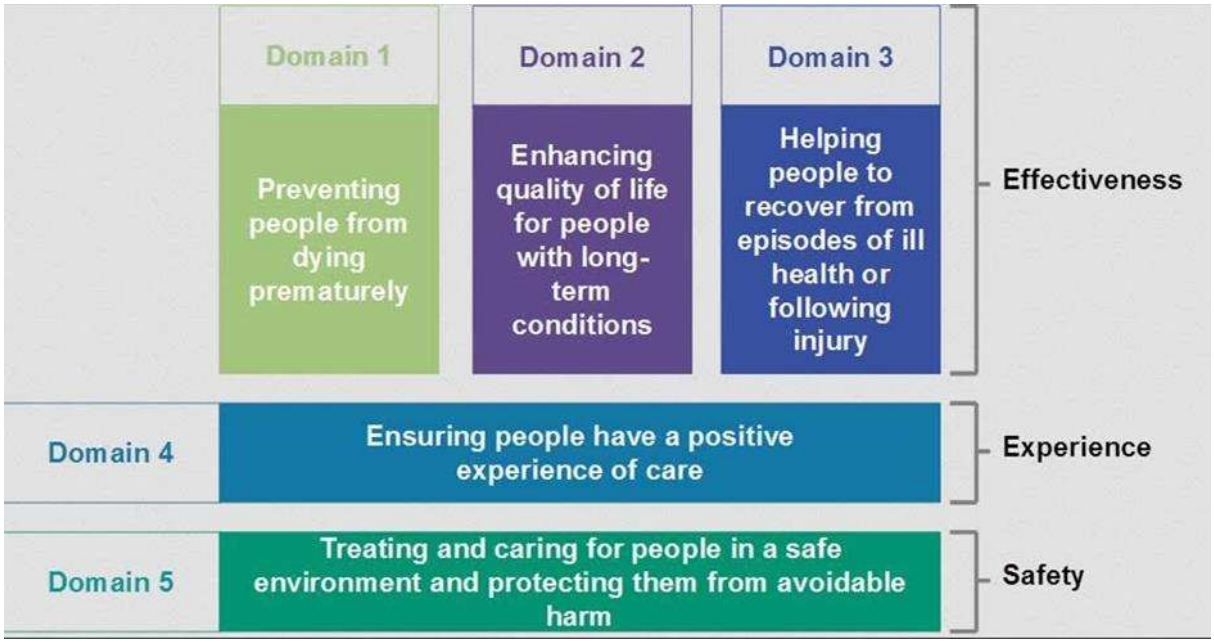
The duration of the trial should be a minimum of 4 weeks but a longer trial is recommended depending on the patients intended and agreed goals and the manufacturer/supplier conditions. Patients must be allowed to take the trial prosthesis/eses home and use it in their own environment.

3 Aims and Objectives

This policy aims to:

- Enhance quality of life by improving patient choice of prosthetic componentry based upon individual need
- Help people recover from the effects of amputation by improving rehabilitation outcomes, safety and quality of life for patients with limb loss at or above the level of the knee
- Ensure a positive experience of care

- 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

It is estimated that 500-1000 patients per million of the UK population have clinically significant peripheral vascular disease. Of these, roughly 1-2% of patients will eventually require a lower limb amputation, though this figure increases to 5% in diabetics. A retrospective review of hospital data in the UK reported that men over the age of 70 account for 69% of all amputations.

In the UK and Europe, diabetes accounts for around 40 to 64% of amputations. Peripheral arterial disease is a primary cause (without diabetes, or non-diabetes) for 18 to 58% of amputations in the UK and European countries. Amputations related to trauma are the primary cause of 2 to 13% of UK and European amputations. Finally, malignant tumours are a primary cause of between 2 to 3% of amputations in the UK and Europe. Infections contribute to anywhere between 4 to 100% of all amputations; however infections are typically preceded by the above conditions. (Johansson et al 2005, Khale et al 2008)

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 controlled and/or blinded studies are difficult to conduct (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 reported outcome measures (PROMS).

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

Studies

Study characteristics of the two systematic reviews are as follows:

Highsmith et al. (2010)

- Included both uni- and bilateral transfemoral amputees
- 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 aetiology 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)

Sawers and Hafner el 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.

Summary of evidence on safety

60% of individuals with above knee amputations have reported at least one fall in the past month or year in retrospective surveys (Sawers and Hafner 2013). 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 MPKs (Sawers and Hafner 2013). Highsmith et al (2010) identified seven 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 el al. (2013) reported the following findings in terms of safety:

- There is low level evidence suggesting that 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 that 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 TFLL (n= 2 low quality studies)
- There is moderate evidence suggesting that 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 TFLL (n= 1 moderate quality study and n= 3 low quality studies)

Summary of evidence on cost effectiveness

Highsmith et al (2010) identified three observational studies- One study used a cost-consequence economic evaluation and the other two used cost utility analyses in Swedish, Italian and Dutch settings with sample sizes ranging between 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 losses (Sawyers and Hafner 2013). For example, the Italian study by Gerzeli et al 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 (Gerzeli et al 2009, Seelen et al 2009). 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 MPKs (Sawers and Hafner 2013). The incremental cost per QALY varied from €3,218 ($4,132)[27] to €35,971 ($43,251) (Gerzeli et al 2009) 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 MPK (Gerzeli et al 2009).

Sawers and Harner (2012) reported the following findings in terms of cost-effectiveness (note that two of the studies included were also considered in Highsmith 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 TFLL (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 TFLL(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 duration (Sawers and Hafner, 2013).

Summary of evidence on environmental obstacle negotiation

Evidence derived from a systematic review by Sawers and Hafner 2013 (Sawers and Hafner 2013) 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 transfemoral amputation describe being able to independently perform this activity (Mackenzie et al 2004). Evidence obtained suggests that the use of swing and stance MPKs results in significantly improved stair descent compared with the use of non MPKs (Sawers and Hafner 2013). Significant improvements in speed and pattern of hill decent were also reported in the same review.

Summary of evidence on energy efficiency

Highsmith et al (2010) identified eight 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 ($p<0.05$) (n=1 study)
- 184% reduction of normal oxygen (n=1 study)
- increased energy efficiency at typical (6.4%) and fast (7%) pace walking ($p<0.05$) (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 following findings in terms of energy efficiency:

- There is moderate level of evidence that the use of swing and stance MPKs results in equivalent O^2 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 O^2 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 O^2 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 in 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.

Summary of Evidence on Clinical Effectiveness and Well Being

Sawers and Hafner (2013) conducted a systematic review to examine whether the use of MPKs, compared with non MPKs, improved outcomes among individuals with unilateral transfemoral limb loss. The authors included 27 studies; there is considerable overlap between the papers included in this review and those included in Highsmith et al.

The authors found low quality evidence to support the effectiveness of MPKs in reducing energy expenditure, increasing self-selected walking speed, increasing walking speed on uneven terrain, and reducing stumbles and falls. They also found moderate evidence to support the effectiveness of MPKs in increasing self-reported mobility and well-being.

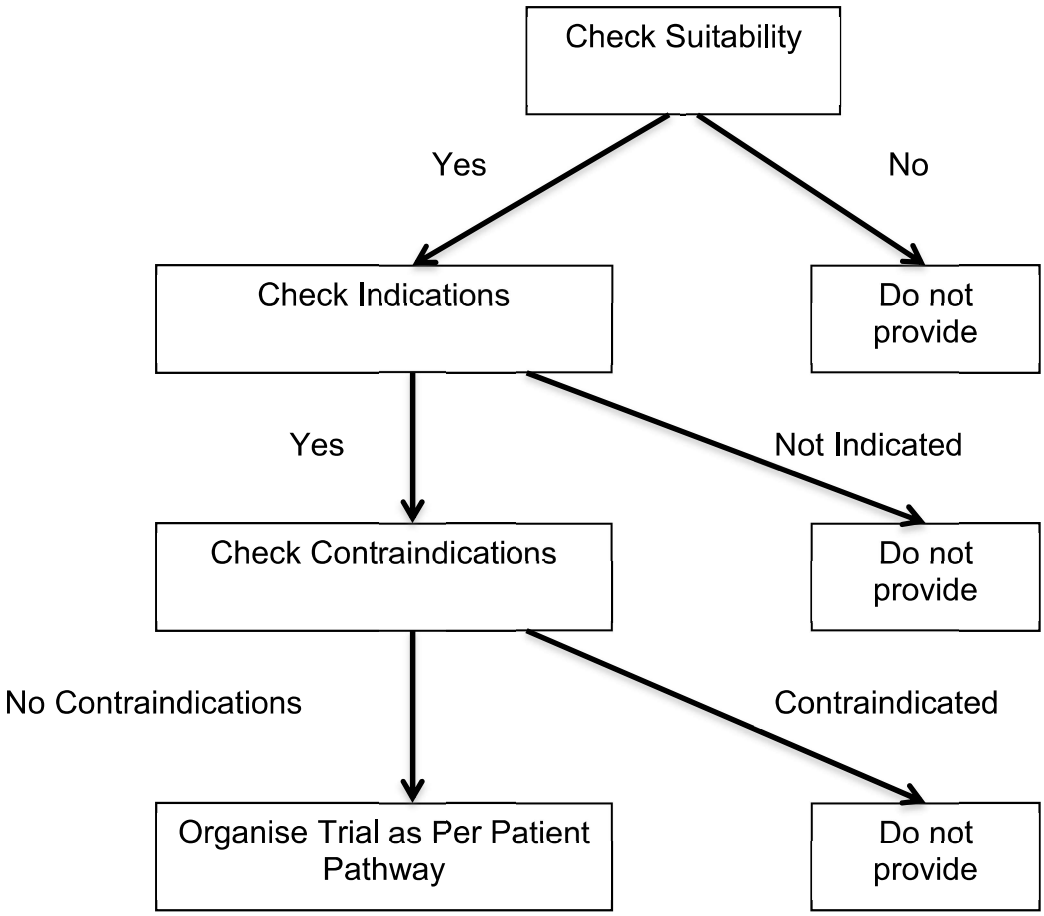
The authors concluded that the results from this review suggest that some evidence exists to inform clinical practice, but that additional research is needed to confirm existing evidence.

6 Criteria for Commissioning

Criteria for commissioning MPKs are based on the evidence of their clinical efficacy and cost effectiveness summarised in section 5 see Figure 1.

A patient will be eligible for an MPK if they meet the criteria below. Patients with contraindications listed below will not be eligible for an MPK.

Figure 1 (Based on criteria outlined below in section 6)



In order to qualify for consideration for an MPK, the patient needs to:

- Meet at least one criteria in each of: 'Amputation level', 'Activity Level' and 'Mobility level'
- Meet all criteria in 'Patient must demonstrate'
- Have at least one of the indications in 'Indications'
- Have none of the contra-indications in 'Contra-indications'.

Amputation level

- Unilateral Trans-femoral
- Hip disarticulation
- Knee disarticulation
- Bilateral lower limb amputee with at least one trans-femoral amputation

Activity level

- K3, patient is able to walk with a free mechanical knee and has the ability or potential for ambulation with variable cadence and traverse environmental barriers as a community ambulator.

Mobility level

- SIGAM D or above. Able to walk more than 50 yards on level ground

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

Patients must meet one of the following criteria:

To be considered for an MPK prescription, the user should have a comfortable, well-fitting socket and be able to walk out doors with a free knee. In this case an MPK would be indicated:

- With a 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.
- When the reduced energy requirements for walking would allow the user to improve mobility and environmental obstacle negotiation.

Contra-indications

- Limited cognitive ability to understand operating and care requirements
- K4 activities (mainly activities that include running as most MPK manufacturers recommend against that), except when the manufacturer specifically states suitability for K4 activities 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
- Water related activities, unless the MPK manufacturer specifically states the MPK is water proof
- 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
- Low mobility level (SIGAM A-C), which can't be improved through an MPK trial
- Patient not able to tolerate weight of unit
- Inability to regularly charge batteries

- 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

7 Patient Pathway

All patients are required to go through the patient pathway described in the policy as a mandatory requirement prior to MPK provision. The 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.

As part of procurement for microprocessor controlled prostheses consideration will be given to how usage can be maximised. Some limbs do have a chip built in that could be used to determine the level of use as it records the joint movement within the device

Prioritisation

Given the limited resources available within NHS centres, it will not be possible for all patients eligible for the prescription of a MPK under this policy to be assessed, trialled and fitted immediately. Patients should be prioritised on clinical need.

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

As set out in Section 3.

The outcome measures must be assessed with the existing non MPK component just prior to commencing the trial with a MPK and must include PROMS. 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. Outcome measures should then be assessed at the one-year follow up review to confirm sustained long-term benefits.

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. The MPK remains the property of NHSE.

In order to satisfy the value for money test, clinicians must prescribe a microprocessor controlled knee at the lowest cost to meet the clinical criteria and achieve the outcomes within the commissioning policy. Centres will be audited to ensure this requirement is implemented.

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 as clinically indicated. This information should be available for auditing both the implementation of the policy and the service provision. The outcomes and further data should comply with the audit requirements of this policy.

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, that they are responsible to commit to regular maintenance as recommended by the manufacturer.

8 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 conduction 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 10)

9 Mechanism for Funding

- Microprocessor Controlled Knees will be provided through Specialised Prosthetic/Amputee Rehabilitation Centres.
- Microprocessor Controlled Knees will be funded as a specialist device with a monthly/quarterly reconciliation.
- A web based system will be used for audit purposes.
- Initially there will be a larger number of patients who meet the prescribing criteria for Microprocessor Controlled Knees as established trans-femoral amputees, whose current limbs are requiring replacement, are assessed.
- Once this initial need is met, the number of Microprocessor Controlled Knees provided annually will drop to match the incidence of new cases of amputees.
- Non submission of monthly data reporting will result in contract penalties.

10 Audit Requirements

Mandatory compliance required by all service centres with this National Microprocessor Controlled Prosthetic Knees Policy, including 100% provision of required data.

Providers are required to demonstrate compliance against the eligibility criteria and indications specified in the policy. Outcomes related to the implementation of this policy should include outcome measures related to functional mobility, participation and goal achievement in addition to those specified in the CQUINS for amputee rehabilitation/prosthetics (see section 2.5.1). These outcome measures should be collected during the trial period, and then at the one-year follow up review to assess the sustained long-term benefits.

The collection of data will be through a web based system using data as set out in Section 6. A training programme for service managers will be developed as part of the implementation of the policy.

Data regarding patient numbers, demographics, levels of amputation, aetiology and providing service 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.

11 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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Multi-Disciplinary Team

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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).

12 Date of Review

This document will be reviewed when information is received which indicates that the policy requires revision.

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