GIG CYMRU NHS WALES

Pwyllgor Gwasanaethau Iechyd Arbenigol Cymru (PGIAC)

Welsh Health Specialised Services Committee (WHSSC)

Specialised Services Commissioning Policy: CP218

Microprocessor Controlled Prosthetic Knees

December 2021

Version 1.0

PARCH - RESPECT

PARTNERIAETH - PARTNERSHIP

GWELLA AC ARLOESI - IMPROVEMENT & INNOVATION

Document information	
Document purpose	Policy
Document name	Microprocessor Controlled Prosthetic Knees
Author	Welsh Health Specialised Services Committee
Publication date	December 2021
Commissioning Team	Neurosciences and Complex Conditions
Target audience	Chief Executives, Medical Directors, Directors of Finance, Chief Pharmacists, Staff in Artificial Limbs and Appliance Services (ALAS), Rehabilitation Consultants, Vascular Surgeons, Trauma and Orthopaedic Surgeons and Limbless Association.
Description	NHS Wales routinely commission this specialised service in accordance with the criteria described in this policy.
Document No	CP128
Review Date	Extended to March 2025

Contents

Policy Statement

Welsh Health Specialised Services Committee (WHSSC) commission microprocessor controlled prosthetic knees (MPK) for people resident in Wales and in accordance with the criteria outlined in this document.

In creating this document WHSSC has reviewed the place of microprocessor controlled prosthetic knees in current clinical practice, and whether existing national evidence-based guidance has shown the treatment to be of benefit to patients (including how any benefit is balanced against possible risks).

Disclaimer

WHSSC assumes that healthcare professionals will use their clinical judgment, knowledge and expertise when deciding whether it is appropriate to apply this policy.

This policy may not be clinically appropriate for use in all situations and does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian, or Local Authority.

WHSSC disclaims any responsibility for damages arising out of the use or non-use of this policy.

1. Introduction

This policy has been developed for the planning and delivery of microprocessor controlled prosthetic knees (MPK) for people resident in Wales. This service will only be commissioned by the Welsh Health Specialised Services Committee (WHSSC) and applies to residents of all seven Health Boards in Wales.

1.1 Plain Language Summary

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 limb or have a congenital absence 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 accident (traumatic injuries)
- treatment of malignant' disease – usually related to cancer
- infections
- complications of muscle and bone illness (musculoskeletal)
- limb deformities from birth (congenital).

MPK's are an artificial knee joint which includes a battery-operated, built in, programmable computer that continuously controls both swing and stance based on real time data of the users gait. 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. MPK's may improve controlled sitting and standing, walking gait symmetry, stair descent, controlled step over step down a slope, reduced energy expenditure, and given different modes for different activities an ability to manage obstacles more easily[1].

1.2 Aims and Objectives

This policy defines the commissioning position of WHSSC on the use of microprocessor controlled prosthetic knees for people resident in Wales.

The objectives of this policy are to:

- ensure commissioning for the use of microprocessor controlled prosthetic knees is evidence based
- ensure equitable access to microprocessor controlled prosthetic knees

[1] NHS England, Clinical Commissioning Policy: Microprocessor Controlled Prosthetic Knees, December 2016

- define criteria for people with limb loss to access treatment
- enhance quality of life for improving patient choice of prosthetic componentry based upon individual need
- help people to recover from the effects of amputation or limb absence, 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.

1.3 Epidemiology

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 people with diabetes. 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[2].

1.4 Current Treatment

The treatment goal for people who have limb loss/absence at or above the knee is to provide the best mobility and function as possible. This should improve their long-term health and quality of life. It should also help with recovery from ill health and injury. This should ensure that people 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 where appropriate, prostheses (artificial limbs), which includes a prosthetic knee joint where there is limb loss above the knee.

[2] NHS England, Clinical Commissioning Policy: Microprocessor Controlled Prosthetic Knees, December 2016

1.5 Proposed Treatment

Microprocessor Controlled Prosthetic Knees (MPK) are a group of knee components that could improve rehabilitation outcomes and quality of life for people with a prostheses and limb loss above the knee. These limbs could improve walking and balance by aiding walking movements in real time, which may reduce falls and accidents caused by a lack of stability that can be experienced with other prosthetic limbs.

This policy has been adapted from existing national evidence based clinical guidance (see section 3).

- 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 to support the MDT in the decision making process.
- 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 Wales.

1.6 What NHS Wales has decided

WHSSC will fund the provision and use of microprocessor controlled prosthetic knees (MPK) for residents of all seven Health Boards in Wales within the criteria set out in section 2.1 of this policy.

1.7 Relationship with other documents

This document should be read in conjunction with the following documents:

- **NHS Wales**
  - All Wales Policy: Making Decisions in Individual Patient Funding requests (IPFR).

- **WHSSC policies and service specifications**
  - Specialised Services Service Specification: CP89 Prosthetic Provision, December 2020
  - Specialised Services Commissioning Policy: CP49 War Veterans – Enhanced Prosthetic Provision, October 2020
  - Specialised Services Service Specification: CP59 All Wales Posture and Mobility Services, April 2017

- **Relevant NHS England policies**
  - Clinical Commissioning Policy: Microprocessor controlled prosthetic knees, December 2016

- **Other relevant national guidance**
  - International Society for Prosthetics and Orthotics: Developing prescribing guidelines for microprocessor controlled prosthetic knees in the South East England (2015) https://journals.sagepub.com/doi/pdf/10.1177/0309364614525801

2. Criteria for Commissioning

The Welsh Health Specialised Services Committee approve funding of microprocessor controlled prosthetic knees (MPK) for people resident in Wales, in line with the criteria identified in this policy.

2.1 Inclusion Criteria

A patient will be eligible for an MPK if they meet the criteria below.

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

- Meet at least **one** criteria in each of:
  - Amputation level (see section 2.1.1)
  - Activity Level (see section 2.1.2)
  - Mobility level (see section 2.1.3).
- Meet **all** criteria of section 2.1.4, patient requirements.
- Have at least **one** of the indications in section 2.1.5, Indications for using an MPK.
- Have **none** of the contra-indications identified in the exclusion criteria in section 2.2.

2.1.1 Amputation level

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

2.1.2 Activity level

- Unilateral amputee who has mobility level K3 or K4 and able to walk with a free prosthetic knee and has the ability or potential for ambulation with variable cadence and traverse environmental barriers as a community ambulator.
- K2 transfemoral/knee disarticulation/hip disarticulation amputee with demonstrable potential to improve to K3 which is later confirmed through a trial with an MPK.
- Bilateral amputee who is able to walk with at least one free prosthetic knee[3].

[3] International Society for Prosthetics and Orthotics Developing prescribing guidelines for microprocessor controlled prosthetic knees in the South East England (2015)

2.1.3 Mobility level

- Special Interest Group in Amputee Medicine (SIGAM) D or above. Able to walk more than 50 metres on level ground.

2.1.4 Patient requirements

Patients need to demonstrate the following:

- 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 ability to master control, operation and care of the device.
- Sufficient cardiovascular abilities to meet the fitness demands of ambulating outdoors with a free knee.

2.1.5 Indications for using a MPK

Patients need to meet **one** of the following criteria:

- The user should have a comfortable, well-fitting socket and be able to walk out doors with a free knee and have the ability or potential for ambulation with variable cadence.
- 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 user's occupation or activities of daily living require different walking speeds, sudden change of directions, managing obstacles where improved control and stability is required over uneven terrain, ramps or curbs.
- Bilateral amputee who is capable of walking and controlling a free prosthetic knee in the presence of clear, realistic, achievable, functional goals. [Those goals should be reviewed following MPK trial.]
- Patients who would require a reduced energy of walking for occupational reasons or to perform essential ADLs. MPK should demonstrate significantly improved function to justify cost.
- Osseointegration patients. Voluntary control knees would not allow the patient to mobilise at their full potential.
- Contralateral limb impairment affecting balance and control in a unilateral amputee who is able to walk outdoors with a free knee.

- Loss of function in multiple limbs (affecting the ability to use walking aids or protect oneself in case of a fall). A trial with an MPK is needed to show improvement[4].

2.2 Exclusion Criteria

Patients with the following contraindications will not be eligible for an MPK.

- 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 (see annex iii).
- 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. Appropriate socket fit is essential for successful utilisation of the prosthesis (whether it includes a mechanical knee or MPK). A good socket fit needs to be achieved in order to proceed with componentry selection[5].
- Low mobility level (SIGAM A-C), which can't be improved through an MPK trial (see annex iii).
- 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.

[4] International Society for Prosthetics and Orthotics Developing prescribing guidelines for microprocessor controlled prosthetic knees in the South East England (2015)
[5] International Society for Prosthetics and Orthotics Developing prescribing guidelines for microprocessor controlled prosthetic knees in the South East England (2015)

2.3 Continuation of Treatment

Healthcare professionals are expected to review a patient's health at regular intervals to ensure they are demonstrating an improvement to their health due to the treatment being given. If no improvement to a patient's health has been recorded then clinical judgement on the continuation of treatment must be made by the treating healthcare professional.

2.4 Acceptance Criteria

The service outlined in this policy is for patients ordinarily resident in Wales, or otherwise the commissioning responsibility of the NHS in Wales. This excludes patients who whilst resident in Wales, are registered with a GP practice in England, but includes patients resident in England who are registered with a GP Practice in Wales.

2.5 Patient Pathway (Annex i)

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:

2.5.1 Patient Selection

Suitable patients are selected for a MPK by a full multidisciplinary specialist rehabilitation team (MDT) according to the inclusion criteria in this policy (section 2.1). Patients may also self-refer to their clinicians to be considered for a trial and prescription according to the policy. The majority of cases are expected to be patients who are known to the service and 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.

2.5.2 Prioritisation

Resources for MPK's are limited, and 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 will therefore be prioritised based on their clinical need.

2.5.3 Full Clinical Assessment

This includes full history taking and physical examination by the patients Prosthetist and specialist Physiotherapist, with an assessment of the patient's current personal 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.

2.5.4 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 need to consider all the possible available knee components (including non MPK) that might facilitate achieving these goals.

2.5.5 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.

Patients are required to trial the MPK for a minimum of 2 weeks, although a trial of up to 4 weeks is recommended, and will depend on the patients intended and agreed goals and the manufacturer/supplier conditions. Patients need to be allowed to take the trial prosthesis home and use it in their own environment. Patient reported outcomes and objective measures should be collected, first on the existing prosthetic limb(s) and then at the end of the trial with the trial MPK. Successful completion of the trial will lead to supply, unsuccessful outcomes will be recorded in the patient's clinical notes[6].

It is important that both clinicians and users adhere to safety guidelines as specified by manufacturers, service centres and relevant national guidelines.

2.5.6 Fitting and initial setup

The knee unit needs to 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) needs to be undertaken. It is essential this is followed by initial gait training by a physiotherapist in combination with the prosthetist.

[6] NHS England, Clinical Commissioning Policy: Microprocessor Controlled Prosthetic Knees, December 2016

2.5.7 Outcome Measures

The outcome measures (included in Annex iii) need to 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.

2.5.8 Provision

This is agreed at an MDT meeting that includes the patient, at or after the end of the trial period. Further gait training should 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 NHS Wales.

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.

2.5.9 Reviews

Follow-up should be arranged at six monthly intervals in the first year, and at least annually thereafter. 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.

2.6 Designated Centre

- Artificial Limb and Appliance Service (ALAS)
  Rookwood Hospital
  18-20 Fairwater Road
  Llandaff
  Cardiff
  CF5 2YN

- Artificial Limb and Appliance Service
  Morriston Hospital
  Swansea
  SA6 6LG

- Artificial Limb and Appliance Service (ALAS)
  Wrexham Maelor Hospital
  Gate 7
  Croesnewydd Road
  Wrexham
  LL13 7NT

These Centres have expertise for all levels of amputation and limb loss (including upper limb, congenital and multiple limb loss), and are able to provide the full range of advice and prosthetic rehabilitation for all levels of upper and lower limb loss including paediatric services.

2.7 Exceptions

If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

If the patient wishes to be referred to a provider outside of the agreed pathway, an IPFR should be submitted.

Further information on making IPFR requests can be found at: Welsh Health Specialised Services Committee (WHSSC) | Individual Patient Funding Requests

2.8 Clinical Outcome and Quality Measures

The Provider must work to written quality standards and provide monitoring information to WHSSC. Providers are expected to submit the following information:

- Service Activity (including the number of Microprocessor Controlled Prosthetic Knees)
- Waiting Times

- Clinical Statistics
- Patient Reported Outcome Measures (PROMS).
- Patient Reported Experience Measures (PREMS).

The Designated Centre should enable the patient's, carer's and advocate's informed participation and to be able to demonstrate this. Provision should be made for patients with communication difficulties.
Mandatory compliance is required by all Designated Centres with this Microprocessor Controlled Prosthetic Knees Policy, including 100% provision of required data.

2.9 Responsibilities

Referrers should:

- inform the patient that this treatment is not routinely funded outside the criteria in this policy,
- Inform the patient that due to the limited amount of funding available in Wales they may have to wait for an extended period of time before receiving their MPK, and
- refer via the agreed pathway

Clinicians considering treatment should:

- discuss all alternative treatments with the patient
- advise the patient of any side effects and risks of the potential treatment
- inform the patient that treatment is not routinely funded outside of the criteria in the policy, and
- confirm that there is contractual agreement with WHSSC for the treatment.

In all other circumstances an IPFR must be submitted.

3. Evidence

WHSSC is committed to regularly reviewing and updating all of its commissioning policies based upon the best available evidence of both clinical and cost effectiveness. The evidence to support the recommendations within the policy are derived and have been directly adapted from the documents listed below. An updated evidence review has been commissioned by WHSSC to inform the next update of this commissioning policy.

3.1 References

- Clinical Commissioning Policy: Microprocessor controlled prosthetic knees (2016)
  https://www.england.nhs.uk/wp-content/uploads/2016/12/clin-comm-pol-16061P.pdf
- International Society for Prosthetics and Orthotics: Developing prescribing guidelines for microprocessor controlled prosthetic knees in the South East England (2015)
  https://journals.sagepub.com/doi/pdf/10.1177/0309364614525801

3.2 Date of Review

This document will be reviewed 12-months post publication to coincide with the completion of the updated WHSSC commissioned evidence review.

If an update is carried out the policy will remain extant until the revised policy is published.

4. Equality Impact and Assessment

The Equality Impact Assessment (EQIA) process has been developed to help promote fair and equal treatment in the delivery of health services. It aims to enable Welsh Health Specialised Services Committee to identify and eliminate detrimental treatment caused by the adverse impact of health service policies upon groups and individuals for reasons of race, gender re-assignment, disability, sex, sexual orientation, age, religion and belief, marriage and civil partnership, pregnancy and maternity and language (Welsh).

This policy has been subjected to an Equality Impact Assessment.

The Assessment demonstrates the policy is robust and there is no potential for discrimination or adverse impact. All opportunities to promote equality have been taken.

5. Putting Things Right:

5.1 Raising a Concern

Whilst every effort has been made to ensure that decisions made under this policy are robust and appropriate for the patient group, it is acknowledged that there may be occasions when the patient or their representative are not happy with decisions made or the treatment provided.

The patient or their representative should be guided by the clinician, or the member of NHS staff with whom the concern is raised, to the appropriate arrangements for management of their concern.

If a patient or their representative is unhappy with the care provided during the treatment or the clinical decision to withdraw treatment provided under this policy, the patient and/or their representative should be guided to the LHB for NHS Putting Things Right. For services provided outside NHS Wales the patient or their representative should be guided to the NHS Trust Concerns Procedure, with a copy of the concern being sent to WHSSC.

5.2 Individual Patient Funding Request (IPFR)

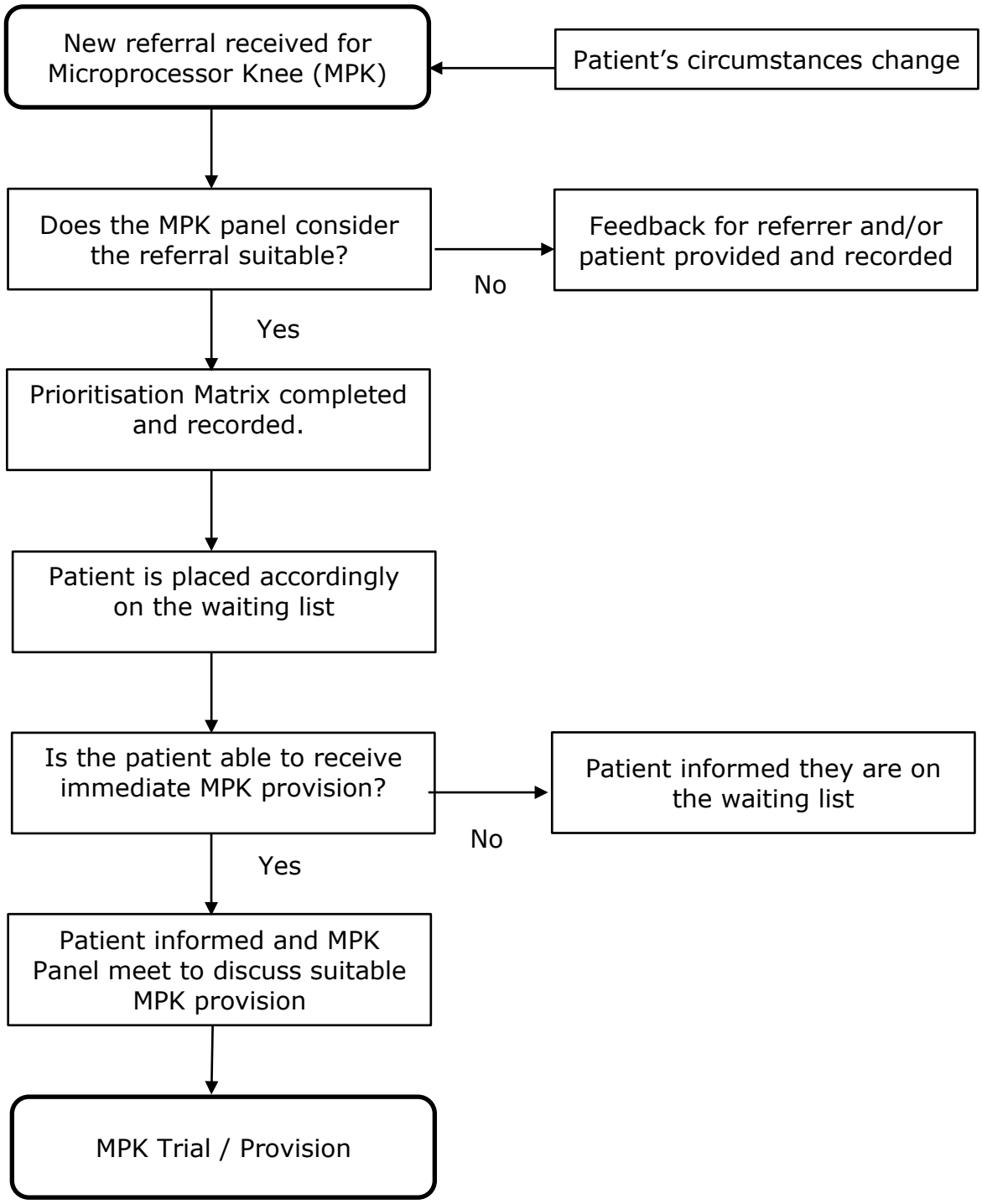
If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

If an IPFR is declined by the Panel, a patient and/or their NHS clinician has the right to request information about how the decision was reached. If the patient and their NHS clinician feel the process has not been followed in accordance with this policy, arrangements can be made for an independent review of the process to be undertaken by the patient's Local Health Board. The ground for the review, which are detailed in the All Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR), must be clearly stated

If the patient wishes to be referred to a provider outside of the agreed pathway, and IPFR should be submitted.

Further information on making IPFR requests can be found at: Welsh Health Specialised Services Committee (WHSSC) | Individual Patient Funding Requests

Annex i Patient Pathway



Annex ii Abbreviations and Glossary

Abbreviations

ADLs Activities of Daily Living

ALAS Artificial Limb and Appliance Service

IPFR Individual Patient Funding Request

KD Knee Disarticulation

MDT Multidisciplinary Team

MPK Microprocessor Knee

PEQ Prosthesis Evaluation Questionnaire

SIGAM Special Interest Group in Amputee Medicine

TAPES Trinity Amputation and Prosthesis Experience Scales

TF Trans femoral

TT Trans Tibial

TUG Timed Up and Go

WHSSC Welsh Health Specialised Services

Glossary

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.

Individual Patient Funding Request (IPFR)

An IPFR is a request to Welsh Health Specialised Services Committee (WHSSC) to fund an intervention, device or treatment for patients that fall outside the range of services and treatments routinely provided across Wales.

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).

K CODES	
GRADE	**DESCRIPTION**
K0	Non-limb wearing or cosmetic use only
K1	Has the ability/potential to use a prosthesis for transfers, or ambulation on a level surface at fixed cadence i.e. household ambulatory
K2	Has the ability/potential to do low kerbs, uneven surfaces and low-level environmental barriers i.e. a community ambulatory
K3	Has the ability/potential for ambulation with variable cadence. The ability to transverse most environmental barriers. Prosthetic utilisation beyond simple locomotion, vocational, therapeutic or exercise ability
K4	Has the ability/potential that exceeds basic ambulation skills. Exhibiting high impact stress or energy levels. Typical of the prosthetic demands of the child, active adult or athlete

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.

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).

SIGAM MOBILITY GRADES	
GRADE	**DESCRIPTION**
A	Limb wearing abandoned or use of cosmetic limb only
B	Therapeutic wearer wears prosthesis only for transfers, to assist nursing, walking with the physical aid of another or during therapy
C	Walks on level ground only, < 50 metres, with or without use of walking aids: a. Frame, b) Crutches, C) 1 Stick/Crutch, D) No Stick
D	Walks outdoors on level ground only & in good weather, > 50 metres, with or without use of walking aids: a. Frame, b)2 Sticks/Crutches, c) 1 Stick/Crutch
E	Walks > 50 metres. Independent of walking aids except occasionally for confidence or to improve confidence in adverse terrain or weather
F	Normal or near normal gait

Welsh Health Specialised Services Committee (WHSSC)

WHSSC is a joint committee of the seven local health boards in Wales. The purpose of WHSSC is to ensure that the population of Wales has fair and equitable access to the full range of Specialised Services and Tertiary Services. WHSSC ensures that specialised services are commissioned from providers that have the appropriate experience and expertise. They ensure that these providers are able to provide a robust, high quality and sustainable services, which are safe for patients and are cost effective for NHS Wales.

Annex iii Outcome measures

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 laboratory analysis, the Trinity Amputation and Prosthesis Experience Scales (TAPES)[7], the Timed Up and Go (TUG), Locomotor Capabilities Index 5 (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. The service will need to agree across the three Centres which of these they will use.

[7] International Society for Prosthetics and Orthotics Developing prescribing guidelines for microprocessor controlled prosthetic knees in the South East England (2015)