Prevea360 Health Plan Utilization Management Policy

Title: **MICROPROCESSOR CONTROLLED KNEE PROSTHESES, WITH OR WITHOUT POLYCENTRIC, THREE-DIMENSIONAL ENDOSKELETAL HIP JOINT SYSTEM MP9638**

Effective Date: **May 1, 2024**

This policy was developed with input from specialists in orthopedics and physical/rehabilitation medicine and endorsed by the Medical Policy Committee.

PURPOSE

To promote consistency between utilization management reviewers by providing the criteria that determines the medical necessity.

BACKGROUND

Definitions

A. **Prosthesis** is an artificial substitute or replacement of a part of the body. Examples include but are not limited to joints (e.g., hip or knee), limbs (i.e., arm or leg), teeth, eyes, or facial bones. Prosthetics are designed for functional or cosmetic reasons, or both. A prosthesis may be removable (e.g., leg or arm) or permanently implanted (e.g., artificial knee or hip).

B. **Standard knee prosthetic** is defined by Medica as a fluid, pneumatically controlled mechanical device using a hydraulic damping cylinder. Standard devices are designed so that the person varies walking speed by consciously matching the movement of the shin portion of the prosthesis to the movement of the upper leg.

C. **Microprocessor-controlled knee prostheses** are based on scientific gait analyses and biomechanical studies which detect step time and alter knee extension levels to suit walking speed by using a computerized sensor to detect when the knee is fully extended. The prosthetist sets gait parameters which the computer automatically selects and applies according to the real-time pace of ambulation. The microprocessor then adjusts the swing phase of the gait automatically in an attempt to produce a more natural gait within patterns of varying walking or running speeds.

   Advanced microprocessor models contain multiple sensors which gather and calculate data on various parameters such as amount of vertical load, ankle movement, and knee joint movement. The attempt is to mimic a more natural leg function while providing stability and gait fluidity when traversing uneven terrains and/or during sports activities. Examples of microprocessor-controlled prosthetic knee systems include, but are not limited to:

   1. C-Leg® , C-Leg® Compact, and Genium™ Bionic Prosthetic System (Otto Bock Orthopedic Industry, Minneapolis MN)
   2. Intelligent Prosthesis, Intelligent Prosthesis Plus, and The Adaptime (Endolite North America, Centerville OH)
   3. Ossur Rheo Knee (Ossur-Flexfoot, Aliso Viejo CA)
   4. Plié 2.0 (Freedom Innovations, LLC.).

D. **Polycentric, three-dimensional (3-D) endoskeletal hip joint system** is a spring-hydraulic prosthetic hip joint system. It is designed to store energy generated during the stance phase of ambulation to be transferred to the swing phase, helping to compensate for lacking hip muscles and to reduce the amount of energy needed for walking. The system produces a three-dimensional hip movement to facilitate a symmetrical and natural gait. The system also helps reduce the risk of falls, improves sitting posture, and reduces oblique pelvic positioning.

   An example of a polycentric, three-dimensional hip joint system is the Helix-3D / 7E10 Hip Joint System (Otto Bock Orthopedic Industry, Minneapolis MN). The Helix-3D / 7E10 Hip Joint System (Otto Bock Orthopedic Industry, Minneapolis MN) can only be used in combination with the C-Leg microprocessor-controlled knee prosthesis.

E. **Functional ambulation levels**:

   1. **Level 0** – Lacks ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance quality of life or mobility
   2. **Level 1** – Has ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence (typical of the limited and unlimited household ambulator).

3. **Level 2** – Has ability or potential to ambulate with the ability to traverse low level environmental barriers such as curbs, stairs, or uneven surfaces (typical of the limited community ambulator).
4. **Level 3** – Has ability or potential for ambulation at variable cadence (typical of the community ambulatory who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion).
5. **Level 4** – Has ability or potential for prosthetic ambulation that exceeds basic ambulation skills such as those exhibiting high impact, stress, or energy levels (typical of the prosthetic demands of a child, active adult, or athlete).

F. **Skeletal maturity** occurs when bone growth ceases after puberty and refers to demonstration of fusion of skeletal bones. Females reach skeletal maturity at approximately 16 years of age, while males reach skeletal maturity around 18 years of age. Radiographs of either the knee or of the hand and wrist with subsequent mathematical calculations are often used when exact measurement of skeletal maturity is warranted.

BENEFIT CONSIDERATIONS

1. Prior authorization **is required** for microprocessor controlled knee prostheses with or without polycentric, three-dimensional, endoskeletal hip joint system. Please see the prior authorization list for product specific prior authorization requirements.
2. Coverage may vary according to the terms of the member's plan document.
3. Coverage issues related to repair or replacement of a covered prosthetic are addressed in the member's plan document.
4. Use of microprocessor controlled knee prosthesis in the home, employment, or community setting solely for basic ambulation, including limited stair climbing, is not covered.
5. If the Medical Necessity Criteria and Benefit Considerations are met, Medica will authorize benefits within the limits in the member's plan document.
6. If it appears that the Medical Necessity Criteria and Benefit Considerations are not met, the individual's case will be reviewed by the medical director or an external reviewer. Practitioners are advised of the appeal process in their Provider Administrative Manual.

MEDICAL NECESSITY CRITERIA

I. Indications for Microprocessor Knee Prosthesis

Microprocessor knee prosthesis is considered medically necessary when documentation in the medical records indicates that **all of the following** criteria are met:

A. The member:

1. Sustained a trans-femoral or knee disarticulation amputation

2. Has reached skeletal maturity
3. Displays functional ambulation level 3 or above
4. Displays adequate cognitive ability to master gait sequencing or care requirements of the higher level of technology
5. Has adequate cardiovascular, musculoskeletal, and neuromuscular reserve to allow for faster than normal walking pace
6. Has a need for daily long distance ambulation at variable rates (greater than 400 yards)
7. Has a need for regular ambulation on uneven terrain or for regular use on stairs
8. Is being fitted by a prosthetist experienced in fitting a microprocessor controlled knee prosthesis.

II. Indications for Microprocessor Knee Prosthesis with Polycentric 3-D Hip Joint System

Microprocessor knee prosthesis with polycentric 3-D hip joint system is considered medically necessary when documentation in the medical records indicates that **all of the following** criteria are met:

A. The member:

1. Meets all indications for a microprocessor-controlled knee prosthesis outlined above (I.A.1-8)
2. Currently utilizes a microprocessor-controlled knee or is being fitted for a microprocessor-controlled knee at the time of 3-D hip joint system fitting
3. Has sustained either a hip disarticulation amputation or a hemipelvectomy
4. Is being fitted by a prosthetist experienced in fitting both a microprocessor controlled knee prosthesis and a 3-D polycentric hip joint system.

CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

- For Medicare members, refer to the following, as applicable at: https://www.cms.gov/medicare-coverage-database/new-search/search.aspx

WISCONSIN BADGERCARE PLUS

- For members with State of Wisconsin BadgerCare Plus review Forward Health website for coverage and prior authorization requirements. (Forward Health WI Portal)

DOCUMENT HISTORY

Original Effective Date	Created April 19, 2023
MPC Endorsement Date(s)	04/19/2023, 04/17/2024
Administrative Updates	04/17/2024

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Pre-04/2016 MPC:

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