MEDICAL POLICY

POLICY TITLE	LOWER LIMB PROSTHESES
POLICY NUMBER	MP6.042

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☐ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☒ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**4/1/2024**

I. POLICY

Preparatory Prostheses

Preparatory lower limb prostheses may be considered **medically necessary** for a new or revised amputation when ALL of the following criteria are met:

- The preparatory prosthesis is provided after the surgical incision has healed; **and**
- The preparatory prosthesis is prescribed by an eligible professional provider (i.e., physician with training and expertise in the functional evaluation of individuals with amputations) and fitted/made by an orthotist or prosthetist.

L5500, L5505, L5510, L5520, L5530, L5535, L5540, L5560, L5570, L5580, L5585, L5590, L5595, L5600

Preparatory lower limb prostheses are complete and all-inclusive; consequently, further components, add-ons, upgrades, adjustments, modifications, or substitutions of components, etc., are considered **not medically necessary**.

Definitive Prostheses

Definitive- initial lower limb prostheses may be considered **medically necessary** when ALL of the following criteria are met:

- The definitive prosthesis is provided to an individual whose surgical incision is stable (healed) and will be participating in a rehabilitation program appropriate for the individual's expected functional level is one (1) to four (4); **and**
- The individual has had an in-person medical evaluation with the ordering physician to establish their overall functional capabilities

L5050, L5060, L5100, L5105, L5150, L5160, L5210, L5220, L5230, L5250, L5270, L5280, L5301, L5312, L5321, L5331, L5341

All other uses of definitive prostheses not described above will be denied as **not medically necessary** as there is insufficient evidence to support a general conclusion supporting the health outcomes or benefits associated with this item.

Microprocessor System

A microprocessor-controlled knee may be considered **medically necessary** in amputees who meet the following requirements:

- There is a demonstrated need for long distance ambulation at variable rates (use of the limb in the home or for basic community ambulation is not sufficient to justify provision of the computerized limb over standard limb applications) OR demonstrated patient need for regular ambulation on uneven terrain or for regular use on stairs (use of the limb for limited stair climbing in the home or employment environment is not sufficient evidence for prescription of this device over standard prosthetic application); **and**
- The physical and cognitive ability, as well as including adequate cardiovascular and pulmonary reserve, for ambulation at faster than normal walking speed; **and**
- Individual's functional level is three (3) or above; **and**
- The patient's medical record must provide clear documentation of the patient's history, current condition, and expected functional ability to support the need for the technologic or design feature of the microprocessor-controlled knee (This information must be retained in the physician's or prosthetist's files, and be available upon request.).

L2006, L5828, L5845, L5848, L5856, L5857, L5858, L5859, L5920, L5930, L5950, L5976, L5979, L5980, L5981, L5987

A microprocessor-controlled knee which does not meet the criteria described above will be denied as **not medically necessary** as there is insufficient evidence to support a general conclusion supporting the health outcomes or benefits associated with this item.

Feet and Ankles

One (1) foot/ankle prosthetic may be considered **medically necessary** when a definitive prosthesis meets the above criteria, and the foot/ankle is appropriate for the individual's functional level as indicated below:

- A partial foot prosthesis may be considered medically necessary for individuals whose functional level is one (1) or above.

L5000, L5010, L5020

- An external-keel solid ankle cushion heel (SACH) foot or single-axis ankle/foot may be considered medically necessary for individuals whose functional level is one (1) or above.

L5970, L5974

- A flexible-keel foot or multi-axial ankle/foot may be considered medically necessary for individuals whose functional level is two (2) or above.

L5972, L5978, L5982, L5984, L5986

- An energy-storing foot, dynamic response with multi-axial ankle, flex-foot system, flex-walk system or equal, or shank system with vertical loading pylon may be considered medically necessary for individuals whose functional level is three (3) or above. (Also part of a microprocessor- controlled prosthesis)

L5976

A foot and ankle prosthesis which does not meet the criteria described above will be denied as **not medically necessary** as there is insufficient evidence to support a general conclusion supporting the health outcomes or benefits associated with this item.

Power-Assist Ankle-Foot Prosthetic Systems

Powered ankle or foot prostheses are considered **investigational** as there is insufficient evidence to support a general conclusion supporting the health outcomes or benefits associated with this item.

L5969, L5973

A power-assist ankle-foot prosthetic system which does not meet the criteria described above will be denied as **not medically necessary** as there is insufficient evidence to support a general conclusion supporting the health outcomes or benefits associated with this item.

Knees

Prosthetic knees may be considered **medically necessary**, when a definitive prosthesis meets the above criteria, and the type is based upon the functional needs of the individual as indicated below:

- A single axis constant friction knee and other basic knee systems may be considered medically necessary for individuals whose functional level is one (1) or above.

L5611, L5616, L5710, L5711, L5712, L5714, L5716, L5718, L5810, L5811, L5812, L5816, L5818

- A fluid, pneumatic or electronic knee may be considered medically necessary for individuals whose functional level is three (3) or above.

L5610, L5613, L5614, L5814, L5822, L5824, L5826, L5830, L5840

A knee prosthetic which does not meet the criteria described above will be denied as **not medically necessary** as there is insufficient evidence to support a general conclusion supporting the health outcomes or benefits associated with this item.

Powered and Programmable Flexion/Extension Assist-Control Prosthetic Knees

POLICY TITLE	LOWER LIMB PROSTHESES
POLICY NUMBER	MP6.042

Powered and programmable endoskeletal knee-shin system with flexion-extension assist (addition to lower extremity) may be considered medically necessary when ALL of the following criteria are met (Also part of a microprocessor- controlled prosthesis):

- The individual has a microprocessor (swing and stance phase type) controlled (electronic) knee; **and**
- Individual's functional level is three (3), as indicated by modifier K3 (the device is not intended for high impact activity, sports, excessive loading or heavy duty use); and
- Weight is between 110 lbs and 275 lbs; **and**
- Has a documented comorbidity of the spine and/or sound limb affecting hip extension and/or quadriceps function that impairs K-3 level function with the use of a microprocessor-controlled knee alone; **and**
- Is able to make use of a product that requires daily charging; **and**
- Is able to understand and respond to error alerts and alarms indicating problems with the function of the unit.

L5841, L5856, L5859

A powered and programmable endoskeletal knee-shin system with flexion-extension assist which does not meet the criteria described above will be denied as **not medically necessary** as there is insufficient evidence to support a general conclusion supporting the health outcomes or benefits associated with this item.

Hips

A pneumatic or hydraulic polycentric hip joint may be considered **medically necessary** when a definitive prosthesis meets the above criteria, and for individuals whose functional level is three (3) or above.

L5961

A prosthetic hip is considered **not medically necessary** in individuals who do not meet these criteria as there is insufficient evidence to support a general conclusion supporting the health outcomes or benefits associated with this item.

Sockets and Socket Inserts

One (1) socket per individual definitive prosthesis may be considered **medically necessary** when the prosthesis meets above criteria.

Two (2) test (diagnostic) sockets for an individual definitive prosthesis may be considered **medically necessary** when the prosthesis meets above criteria.

More than two (2) of the same socket inserts per individual prosthesis at the same time is considered **not medically necessary**.

One (1) custom fabricated socket insert may be considered **medically necessary** when the prosthesis meets the above criteria and the ALL of the following:

- Non-custom socket inserts are unable to provide an adequate interface between the residual limb and socket; **and**
- A different type of non-custom insert will not compensate for the irregular contours of the limb.

Socket replacements are **medically necessary** if there is adequate documentation of functional and/or physiological need. Some situations include but are not limited to changes in the residual limb; functional need changes; or irreparable damage or wear/tear due to excessive beneficiary weight or prosthetic demands of very active amputees.

L5200, L5321, L5618, L5620, L5622, L5624, L5626, L5628, L5629, L5630, L5631, L5632, L5634, L5636, L5638, L5639, L5640, L5642, L5643, L5644, L5645, L5646, L5648, L5649, L5650, L5651, L5653, L5654, L5655, L5656, L5658, L5661, L5665, L5668, L5673, L5679, L5681, L5683, L5700, L5701, L5702, L5703, L5704

Prosthetic sockets and inserts which do not meet the criteria described above will be denied as **not medically necessary** as there is insufficient evidence to support a general conclusion supporting the health outcomes or benefits associated with this item.

Suspension Systems

Mechanical

Mechanical suspension systems including, belts, sleeves, straps, socket design features, and pin-locking mechanisms may be considered **medically necessary** when the prosthesis meets the above criteria, and the individual's functional level is at least one (1).

L5666, L5670, L5671, L5672

Suction

Passive suction systems including, belts, sleeves, straps, socket design features, may be considered **medically necessary** when the prosthesis meets above criteria, and the individual's functional level is at least two (2).

L5647, L5652

Vacuum Suspension System

Vacuum suspension systems (e.g., vacuum-assisted socket system [VASS™]) may be considered **medically necessary** to control residual limb volume when there is contraindication to or failure of other socket-suspension systems (e.g., mechanical, passive suction) to adequately secure the limb to the prosthesis; and the individual's functional level is at least a three (3).

L5781, L5782, L5783

A suspension system is considered **not medically necessary** in individuals who do not meet these criteria as there is insufficient evidence to support a conclusion supporting the health outcomes or benefits associated with this item.

Additions and Accessories

Accessories such as sheaths, joints, lacers, belts, covers, socks, etc. may be considered **medically necessary** when these appliances aid in or are essential to the effective use of the prosthetic limb. Additions should be billed on the same claim as the base procedure when supplied at the same time as the base procedure.

L5615	L5617	L5637	L5676	L5677	L5678	L5680	L5682	L5684	L5685	L5686
L5688	L5690	L5692	L5694	L5695	L5696	L5697	L5698	L5699	L5705	L5706
L5707	L5722	L5724	L5726	L5728	L5780	L5785	L5790	L5795	L5850	L5855
L5910	L5925	L5926	L5940	L5960	L5962	L5964	L5966	L5968	L5971	L5975
L5985	L5988	L5990	L7367	L7368	L7600	L7700	L8400	L8410	L8417	L8420
L8430	L8440	L8460	L8470	L8480						

Adjustments

Adjustments and/or modifications to the prosthesis required by wear and tear or due to a change in individual's condition (such as growth in a child) or to improve the function are considered **medically necessary**.

Repairs

Repairs necessary to make the prosthetic functional are **medically necessary**. The expense for repairs may not exceed the estimated expense of purchasing another prosthesis.

L7510, L7520

Replacement

A replacement prosthesis including additions and accessories are medically necessary only if the previous prosthesis is no longer functional or there is documentation of irreparable damage. Requests for upgrades/ newer technology will be reviewed for medical necessity.

Pediatric Lower Limb Prostheses

Pediatric lower limb prostheses may be considered **medically necessary** for congenital and acquired pediatric limb deficiencies.

A child is eligible for prosthetics when they are able to stand on their own (approximately 9-12 months of age).

Components must be evaluated for age-appropriateness, considering comfort, weight, durability, and function.

A new socket and other prosthetic modifications are necessary at least once a year for children between the ages of birth to 18 years to allow for normal growth and development.

Pediatric lower limb prostheses which does not meet the criteria described above will be denied as **not medically necessary** as there is insufficient evidence to support a general conclusion supporting the health outcomes or benefits associated with this item.

Policy Guidelines

Functional Levels

Level 0 - Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility

Level 1 - Has the 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.

Level 2 - Has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulator.

Level 3 - Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.

Level 4 - Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

PATIENT SELECTION AND IDENTIFICATION

Amputees should be evaluated by an independent qualified professional to determine the most appropriate prosthetic components and control mechanism. A trial period may be indicated to evaluate the tolerability and efficacy of the prosthesis in a real-life setting. Decisions about the potential benefits of microprocessor-knees involve multiple factors including activity levels, as well as the patient's physical and cognitive ability. A patient's need for daily ambulation of at least 400 continuous yards, daily and frequent ambulation at variable cadence or on uneven terrain (e.g., gravel, grass, curbs), and daily and frequent use of ramps and/or stairs (especially stair descent) should be considered as part of the decision. Typically, daily and frequent need of two or more of these activities would be needed to show benefit.

For patients in whom the potential benefits of the microprocessor knees are uncertain, patients may first be fitted with a standard prosthesis to determine their level of function with the standard device.

The following are guidelines from the Veterans Health Administration Prosthetic Clinical Management Program Clinical Practice Recommendations for Microprocessor Knees (Berry, 2000).

A. Contraindications for use of the microprocessor knee should include the following:

- Any condition that prevents socket fitting, such as a complicated wound or intractable pain which precludes socket wear.

- Inability to tolerate the weight of the prosthesis.
- Medicare level K 0—no ability or potential to ambulate or transfer.
- Medicare level K 1—limited ability to transfer or ambulate on level ground at fixed cadence.
- Medicare level K 2—limited community ambulator that does not have the cardiovascular reserve, strength, and balance to improve stability in stance to permit increased independence, less risk of falls, and potential to advance to a less-restrictive walking device.
- Inability to use swing and stance features of the knee unit.
- Poor balance or ataxia that limits ambulation.
- Significant hip flexion contracture (over 20 degrees).
- Significant deformity of remaining limb that would impair ability to stride.
- Limited cardiovascular and/or pulmonary reserve or profound weakness.
- Limited cognitive ability to understand gait sequencing or care requirements.
- Long distance or competitive running.
- Falls outside of recommended weight or height guidelines of manufacturer.
- Specific environmental factors—such as excessive moisture or dust, or inability to charge the prosthesis.
- Extremely rural conditions where maintenance ability is limited.

B. Indications for use of the microprocessor knee should include the following:

- Adequate cardiovascular and pulmonary reserve to ambulate at variable cadence.
- Adequate strength and balance in stride to activate the knee unit.
- Should not exceed the weight or height restrictions of the device.
- Adequate cognitive ability to master technology and gait requirements of the device.
- Hemi-pelvectomy through knee-disarticulation level of amputation, including bilateral; lower extremity amputees are candidates if they meet functional criteria as listed.
- The individual is an active walker and requires a device that reduces energy consumption to permit longer distances with less fatigue.
- Daily activities or job tasks that do not permit full focus of concentration on knee control and stability—such as uneven terrain, ramps, curbs, stairs, repetitive lifting, and/or carrying.
- Medicare level K 2—limited community ambulator, but only if improved stability in stance permits increased independence, less risk of falls, and potential to advance to a less restrictive walking device, and patient has cardiovascular reserve, strength, and balance to use the prosthesis. The microprocessor enables fine-tuning and adjustment of the hydraulic mechanism to accommodate the unique motor skills and demands of the functional level K2 ambulator.
- Medicare level K 3—unlimited community ambulator.
- Medicare level K 4—active adult, athlete who has the need to function as a K 3 level in daily activities.
- Potential to lessen back pain by providing more secure stance control, using less muscle control to keep knee stable.
- Potential to unload and decrease stress on remaining limb.
- Potential to return to an active lifestyle.

C. Physical and Functional Fitting Criteria for New Amputees:
- New amputees may be considered if they meet certain criteria as outlined above.
- Premorbid and current functional assessment important determinant.
- Requires stable wound and ability to fit socket.
- Immediate postoperative fit is possible.
- Must have potential to return to active lifestyle.

Cross-References:

MP 6.018 Prosthetics and Accessories
MP 6.028 Foot Orthotics and Other Podiatric Appliances
MP 6.062 Ankle-Foot and Knee-Ankle-Foot Orthoses

II. PRODUCT VARIATIONS

TOP

This policy is only applicable to certain programs and products administered by Capital BlueCross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:

https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies .

III. DESCRIPTION/BACKGROUND

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Lower Extremity Prosthetics

More than 100 different prosthetic ankle-foot and knee designs are currently available. The choice of the most appropriate design may depend on the patient's underlying activity level. For example, the requirements of a prosthetic knee in an elderly, largely homebound individual will differ from those of a younger, active person. Key elements of a prosthetic knee design involve providing stability during both the stance and swing phase of the gait. Prosthetic knees vary in their ability to alter the cadence of the gait, or the ability to walk on rough or uneven surfaces. In contrast to more simple prostheses, which are designed to function optimally at one walking cadence, fluid and hydraulic-controlled devices are designed to allow amputees to vary their walking speed by matching the movement of the shin portion of the prosthesis to the movement of the upper leg. For example, the rate at which the knee flexes after "toe-off" and then extends before heel strike depends in part on the mechanical characteristics of the prosthetic knee joint. If the resistance to flexion and extension of the joint does not vary with gait speed, the prosthetic knee extends too quickly or too slowly relative to the heel strike if the cadence is altered. When properly controlled, hydraulic or pneumatic swing-phase controls allow the prosthetist to set a pace adjusted to the individual amputee, from very slow to a race-walking pace. Hydraulic prostheses are heavier than other options and require gait training; for these reasons, these prostheses are prescribed for athletic or fit individuals. Other design features include multiple

centers of rotation, referred to as “polycentric knees.” The mechanical complexity of these devices allows engineers to optimize selected stance and swing-phase features.

Microprocessor-Controlled Prosthetic Knees
Microprocessor-controlled prosthetic knees have been developed, including the Intelligent Prosthesis (Blatchford, England); the Adaptive (Endolite, Basingstoke, Hampshire, UK); the Rheo Knee® (Össur, Iceland); the C-Leg®, Genium™ Bionic Prosthetic System, and the X2 and X3 prostheses (Otto Bock Orthopedic Industry, Minneapolis, MN); and Seattle Power Knees (3 models include Single Axis, 4-bar, and Fusion, from Seattle Systems). These devices are equipped with a sensor that detects when the knee is in full extension and adjusts the swing phase automatically, permitting a more natural walking pattern of varying speeds. The prosthetist can specify several different optimal adjustments that the computer later selects and applies according to the pace of ambulation. Also, these devices (with the exception of the Intelligent Prosthesis use microprocessor control in both the swing and stance phases of gait. (The C-Leg Compact provides only stance control.) By improving stance control, such devices may provide increased safety, stability, and function; for example, the sensors are designed to recognize a stumble and stiffen the knee, thus avoiding a fall. Other potential benefits of microprocessor-controlled knee prostheses are improved ability to navigate stairs, slopes, and uneven terrain and reduction in energy expenditure and concentration required for ambulation. In 1999, the C-Leg was cleared for marketing by the Food and Drug Administration (FDA) through the 510(k) process (K991590). Next-generation devices such as the Genium Bionic Prosthetic system and the X2 and X3 prostheses use additional environmental input (e.g., gyroscope and accelerometer) and more sophisticated processing that is intended to create more natural movement. One improvement in function is step-over-step stair and ramp ascent. They also allow the user to walk and run forward and backward. The X3 is a more rugged version of the X2 that can be used in water, sand, and mud. The X2 and X3 were developed by Otto Bock as part of the Military Amputee Research Program.

Powered Knee Prostheses
The Power Knee™ (Össur, Iceland), which is designed to replace muscle activity of the quadriceps, uses artificial proprioception with sensors similar to the Proprio Foot to anticipate and respond with the appropriate movement required for the next step. The Power Knee is currently in the initial launch phase in the United States.

Microprocessor-Controlled Ankle-Foot Prostheses
Microprocessor-controlled ankle-foot prostheses are being developed for transtibial amputees. These include the Proprio Foot® (Össur), the iPED (developed by Martin Bionics, Oklahoma City, OK, and licensed to College Park Industries, Warren, MI), and the Elan Foot (Endolite). With sensors in the feet that determine the direction and speed of the foot’s movement, a microprocessor controls the flexion angle of the ankle, allowing the foot to lift during the swing phase and potentially adjust to changes in force, speed, and terrain during the step phase. This technology is designed to make ambulation more efficient and prevent falls in patients ranging from the young active amputee to the elderly diabetic patient. The Proprio Foot® and Elan Foot are microprocessor-controlled foot prostheses that are commercially available at this time and are considered class I devices that are exempt from 510(k) marketing clearance. Information on

the Össur website indicates the use of the Proprio Foot® for low- to moderate-impact for transtibial amputees who are classified as level K3 (ie, community ambulatory, with the ability or potential for ambulation with variable cadence).

Powered Ankle-Foot Prostheses
In development are lower-limb prostheses that also replace muscle activity to bend and straighten the prosthetic joint. For example, the PowerFoot BiOM® (developed at the Massachusetts Institute of Technology and licensed to iWalk) is a myoelectric prosthesis for transtibial amputees that uses muscle activity from the remaining limb for the control of ankle movement (see evidence review 1.04.04 for a description of myoelectric technology). This prosthesis is designed to propel the foot forward as it pushes off the ground during the gait cycle, which in addition to improving efficiency, has the potential to reduce hip and back problems arising from an unnatural gait with use of a passive prosthesis. This technology is limited by the size and the weight required for a motor and batteries in the prosthesis.

Regulatory Status
According to the manufacturers, microprocessor-controlled prostheses are considered a class I device by the U.S. Food and Drug Administration (FDA) and is exempt from 510(k) requirements. This classification does not require submission of clinical data regarding efficacy but only notification of FDA prior to marketing. FDA product codes: ISW, KFX.

IV. RATIONALE

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Microprocessor-Controlled Knee

The literature consists of a number of small within-subject comparisons of microprocessor-controlled knees with non-microprocessor-controlled knee joints. Studies of prostheses with microprocessor knees in Medicare-level K3 and K4 amputees have shown objective improvements in function on some outcome measures and strong patient preference for the microprocessor-controlled prosthetic knees. The evidence in Medicare level K2 ambulators suggests that a prosthesis with stance control only can improve activities that require balance and improve walking in this population. Only 1 biomechanical study of the next-generation Genium prosthesis was identified. One small study found little difference in performance between the Rheo Knee II and the userâ€™s own non-microprocessor-controlled knee.

Microprocessor-Controlled Ankle-Foot Prostheses
Several small studies have been reported with microprocessor-controlled prostheses for transtibial amputees. The evidence to date is insufficient to support an improvement in functional outcomes when compared with the same device in the off-mode or compared with ESR prostheses. Larger, higher quality studies are needed to determine the impact of these devices on health outcomes with greater certainty.

Powered Ankle-Foot Prostheses
Several small studies have been reported with powered ankle-foot prostheses for transtibial amputees. The evidence to date is insufficient to support an improvement in functional outcomes.

Summary of Evidence
For individuals who have a transfemoral amputation who receive a prosthesis with a microprocessor-controlled knee, the evidence includes a number of small within-subject comparisons of microprocessor-controlled knees vs hydraulic knee joints. Relevant outcomes are functional outcomes, health status measures, and quality of life. For K3- and K4-level amputees, studies have shown an objective improvement in function on some outcome measures and a strong patient preference for microprocessor-controlled prosthetic knees. Benefits include a more normal gait, an increase in stability, a decrease in falls, and a decrease in the cognitive burden associated with monitoring the prosthesis. For these reasons, a microprocessor-controlled knee may provide incremental benefit for these individuals. Those considered most likely to benefit from these prostheses have both the potential and need for frequent ambulation at variable cadence, on uneven terrain, or on stairs. The potential to achieve a high functional level with a microprocessor-controlled knee includes having the appropriate physical and cognitive ability to use the advanced technology. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Note that the evidence does not permit conclusions on the effect of a microprocessor-controlled prosthesis on health outcomes in limited community ambulators or on the effect of a next-generation microprocessor-controlled prosthesis on health outcomes.

For individuals who have a transfemoral amputation who receive a prosthesis with a powered knee, the evidence includes limited data. Relevant outcomes are functional outcomes, health status measures, and quality of life. The limited evidence available to date does not support an improvement in functional outcomes with a powered knee prostheses compared with standard prostheses. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have a tibial amputation who receive a prosthesis with a microprocessor-controlled ankle-foot, the evidence includes limited data. Relevant outcomes are functional outcomes, health status measures, and quality of life. The limited evidence available to date does not support an improvement in functional outcomes with microprocessor-controlled ankle-foot prostheses compared with standard prostheses. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have a tibial amputation who receive a prosthesis with a powered ankle-foot, the evidence includes no data. Relevant outcomes are functional outcomes, health status measures, and quality of life. The evidence is insufficient to determine the effects of the technology on health outcomes.

PRACTICE GUIDELINES AND POSITION STATEMENTS

The Veteran's Affairs Prosthetic and Sensory Aids Strategic Healthcare Group established a Prosthetic Clinical Management Program to coordinate the development of clinical practice recommendations for prosthetic prescriptive practices. A subgroup of the Pre-Post National Amputation Workgroup met in 2004 to define patient selection and identification criteria for microprocessor-prosthetic knees. Their proposal was based on recommendations arising from the 2003 Microprocessor Prosthetic Knee Forum. The resulting Department of Veterans Affairs clinical practice recommendations for microprocessor knees are listed in the Appendix.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

Durable medical equipment regional carriers are responsible for creating coverage policies for Medicare regarding durable medical equipment. There is no specific coverage policy on microprocessor-controlled knee prosthesis, in part because there is no specific HCPCS code describing this prosthesis. However, the durable medical equipment regional carriers document has noted that a determination of medical necessity for certain components/additions to the prosthesis is based on the patient's potential functional abilities. Potential functional ability is based on the reasonable expectations of the prosthetist and treating physician, considering factors including, but not limited to the following:

a. the patient's past history, AND
b. the patient's current condition including the status of the residual limb and the nature of other medical problems, AND
c. the patient's desire to ambulate.

The document also has provided the following classification of rehabilitation potential:

Level 0. Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility.

Level 1. Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulatory.

Level 2. Has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulatory.

Level 3. Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.

Level 4. Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demand of the child, active adult, or athlete.

ONGOING AND UNPUBLISHED CLINICAL TRIALS

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary if Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03204513	Impact of Powered Knee-Ankle Prosthesis Leg on Everyday Community Mobility and Social Interaction	15	Apr 2021
Unpublished			
NCT02864693	Comparative Effectiveness of Microprocessor Controlled and Carbon Fiber Energy Storing and Returning Prosthetic Feet in Persons With Unilateral Transtibial Amputation	30	Apr 2018

NCT: national clinical trial.

V. DEFINITIONS

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N/A

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Not medically necessary; therefore, not covered:

Procedure Codes							
L5969	L5973						

Medically necessary and therefore covered:

Procedure Codes							
L2006	L5000	L5010	L5020	L5050	L5060	L5100	L5105
L5150	L5160	L5200	L5210	L5220	L5230	L5250	L527-
L5280	L5301	L5312	L5321	L5331	L5341	L5500	L5505
L5510	L5520	L5530	L5535	L5540	L5560	L5570	L5580
L5585	L5590	L5595	L5600	L5610	L5611	L5613	
L5615	L5616	L5617	L5618	L5620	L5622	L5624	L5626
L5628	L5629	L5630	L5631	L5632	L5634	L5636	L5637
L5638	L5639	L5640	L5642	L5643	L5644	L5645	L5646
L5647	L5648	L5649	L5650	L5651	L5652	L5653	L5654
L5655	L5656	L5658	L5661	L5665	L5666	L5668	L5670
L5671	L5672	L5673	L5676	L5677	L5678	L5679	L5680
L5681	L5682	L5683	L5684	L5685	L5686	L5688	L5690
L5692	L5694	L5695	L5696	L5697	L5698	L5699	L5700
L5701	L5702	L5703	L5704	L5705	L5706	L5707	L5710
L5711	L5712	L5714	L5716	L5718	L5722	L5724	L5726
L5728	L5780	L5781	L5782	L5785	L5790	L5795	L5810
L5811	L5812	L5814	L5816	L5818	L5822	L5824	L5826
L5828	L5830	L5840	L5845	L5848	L5850	L5855	L5856

Procedure Codes							
L5857	L5858	L5859	L5910	L5920	L5925	L5926	L5930
L5940	L5950	L5960	L5961	L5962	L5964	L5966	L5968
L5970	L5971	L5972	L5974	L5975	L5976	L5978	L5979
L5980	L5981	L5982	L5984	L5985	L5986	L5987	L5988
L5990	L5991	L7367	L7368	L7510	L7520	L7600	L7700
L8400	L8410	L8417	L8420	L8430	L8440	L8460	L8470
L8480	L5783	L5841					

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X. POLICY HISTORY

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MP 6.036	**CAC 4/27/04**
MP 6.042	**CAC 6/28/05**
	CAC 6/27/06
	CAC 6/26/07 *(policy # change)*
	CAC 5/27/08
	CAC 5/26/09
	CAC 5/25/10 Minor revision. Background and policy criteria revised regarding myoelectric prosthetic components for the upper limb. For lower limb prosthetics, the powered knee and the microprocessor-controlled or powered foot were changed from not medically necessary to investigational. Policy order revised for clarity.
	CAC 4/26/11 Consensus
	CAC 8/28/12 Adopt BCBSA. By adopting BCBSA, the following criteria were removed from the policy to include: mechanical (non-myoelectric) prosthetics; sockets, accessories and components, and microprocessor prosthetics for the upper limb (criteria moved to MP-6.052 Microprocessor-Controlled Prostheses for the Upper Limb). The revised policy statements clarify that use in the home or basic community ambulation or employment environment is not sufficient evidence for prescription of this device over standard prosthetic application. The FEP variation was revised. Note policy title was changed to Microprocessor-Controlled Prostheses of the Lower Limb. Codes updated 8/7/12.
	01/03/2013- 2013 New codes added
	CAC 7/30/13 Consensus. No change to policy statements. Added policy guidelines from BCBSA policy. No coding changes.
	12/20/2013- New 2014 Code updates made.
	CAC 3/25/14 Consensus review. References updated. Rationale added. Clarification statement added that a microprocessor-controlled knee is considered not medically necessary in individuals who do not meet these criteria. No coding changes.
	CAC 3/24/15 Consensus review. No changes to the policy statements. References and rationale updated**.** Codes reviewed.
	11/2/15 Administrative change. LCD number changed from L11464 to L33787 due to NHIC update to ICD-10.
	CAC 3/29/16 Consensus review. No changes to the policy statements. Rationale and references updated. Coding reviewed.
	Administrative change 7/15/16. DME jurisdiction A carrier change from NHIC to Noridian.
	Admin update 1/1/17: Product variation section reformatted.

POLICY TITLE	LOWER LIMB PROSTHESES
POLICY NUMBER	MP6.042

	CAC 5/23/17 Consensus review. Policy statements unchanged. Description/Background, Rationale and Reference sections updated. Coding reviewed.
	1/1/18 Admin Update: Medicare variations removed from Commercial Policies.
	2/06/18 Minor revision. The investigational policy statement regarding a microprocessor-controlled or powered "foot" device has been further defined as "ankle-foot," the position remains investigational. Added the standard investigational statement to the first investigational position. Appendix added. Description/Background, Rationale and Reference sections updated. Coding updated.
	5/2/18 Minor Revision. Updated policy to include direction for all lower extremity prosthetics with coding in policy statements. References added and updated.
	3/22/19 Consensus review. No changes to policy statements. Rational revised. References updated.
	01/01/20 Coding update. New 2020 CPT code L2006 added to policy.
	4/23/20 Consensus review. Policy statement unchanged. References and Background updated. Coding reviewed and tables added at the bottom of the policy, no new codes added.
	9/22/21 Admin Update: New code K1022 added. Effective 10-1-21.
	6/22/2022 Consensus review. Policy statement unchanged. Updated FEP, references. Coding reviewed.
	6/7/2023 Consensus review. Policy statement unchanged. Updated references. Coding reviewed.
	9/8/2023 Admin Update. Added code L5991, eff 10/1/2023.
	12/12/2023 Admin Update. Added codes L5615 and L5926. Deleted code K0122. Eff 1/1/2024.
	3/15/2024 Admin Update. Added codes L5783 and L5841 as MN. Eff 4/1/2024.

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