

MEDICAL POLICY

POLICY TITLE	LOWER LIMB PROSTHESES
POLICY NUMBER	MP 6.042

CLINICAL BENEFIT	<input type="checkbox"/> MINIMIZE SAFETY RISK OR CONCERN. <input type="checkbox"/> MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. <input type="checkbox"/> ASSURE APPROPRIATE LEVEL OF CARE. <input type="checkbox"/> ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. <input checked="" type="checkbox"/> ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. <input type="checkbox"/> ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	4/1/2026

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

MEDICAL POLICY

POLICY TITLE	LOWER LIMB PROSTHESES
POLICY NUMBER	MP 6.042

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

MEDICAL POLICY

POLICY TITLE	LOWER LIMB PROSTHESES
POLICY NUMBER	MP 6.042

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.

L2221, L5969, L5973

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

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**

MEDICAL POLICY

POLICY TITLE	LOWER LIMB PROSTHESES
POLICY NUMBER	MP 6.042

- 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.

L5827, 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**

MEDICAL POLICY

POLICY TITLE	LOWER LIMB PROSTHESES
POLICY NUMBER	MP 6.042

- 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, L5657, 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

MEDICAL POLICY

POLICY TITLE	LOWER LIMB PROSTHESES
POLICY NUMBER	MP 6.042

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 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.

Policy Guidelines

Functional Levels

MEDICAL POLICY

POLICY TITLE	LOWER LIMB PROSTHESES
POLICY NUMBER	MP 6.042

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

MEDICAL POLICY

POLICY TITLE	LOWER LIMB PROSTHESES
POLICY NUMBER	MP 6.042

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.

MEDICAL POLICY

POLICY TITLE	LOWER LIMB PROSTHESES
POLICY NUMBER	MP 6.042

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

PRODUCT VARIATIONS

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations. 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>.

DESCRIPTION/BACKGROUND

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

MEDICAL POLICY

POLICY TITLE	LOWER LIMB PROSTHESES
POLICY NUMBER	MP 6.042

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 (i.e., 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

MEDICAL POLICY

POLICY TITLE	LOWER LIMB PROSTHESES
POLICY NUMBER	MP 6.042

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.

RATIONALE

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 users 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

MEDICAL POLICY

POLICY TITLE	LOWER LIMB PROSTHESES
POLICY NUMBER	MP 6.042

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.

DEFINITIONS

N/A

DISCLAIMER

Capital Blue Cross' medical policies are used to determine coverage for specific medical technologies, procedures, equipment, and services. These medical policies do not constitute medical advice and are subject to change as permitted by law or applicable clinical evidence from independent treatment guidelines. Treating providers are solely responsible for medical advice and treatment of members. These policies are not a guarantee of coverage or payment. Payment of claims is subject to a determination regarding the member's benefit program and eligibility on the date of service, and a determination that the services are medically necessary

MEDICAL POLICY

POLICY TITLE	LOWER LIMB PROSTHESES
POLICY NUMBER	MP 6.042

and appropriate. Final processing of a claim is based upon the terms of contract that applies to the members' benefit program, including benefit limitations and exclusions. If a provider or a member has a question concerning this medical policy, please contact Capital Blue Cross' Provider Services or Member Services.

CODING INFORMATION

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.

Investigational; therefore, not covered:

Procedure Codes							
L2221	L5969	L5973					

Medically necessary and therefore covered:

Procedure Codes							
L2006	L5000	L5010	L5020	L5050	L5060	L5100	L5105
L5150	L5160	L5200	L5210	L5220	L5230	L5250	L5270
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	L5824	L5726	L5728
L5780	L5781	L5782	L5783	L5785	L5790	L5795	L5810
L5811	L5812	L5814	L5816	L5818	L5822	L5824	L5826

MEDICAL POLICY

POLICY TITLE	LOWER LIMB PROSTHESES
POLICY NUMBER	MP 6.042

Procedure Codes							
L5828	L5830	L5840	L5841	L5845	L5848	L5850	L5855
L5856	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	L5657					

REFERENCES

1. Alimusaj M, Fradet L, Braatz F, et al. Kinematics and kinetics with an adaptive ankle foot system during stair ambulation of transtibial amputees. *Gait Posture*. Oct 2009; 30(3):356-363. PMID 19616436
2. Au S, Berniker M, Herr H. Powered ankle-foot prosthesis to assist level-ground and stair-descent gaits. *Neural Netw*. May 2008; 21(4):654-666. PMID 18499394
3. Bellmann M, Schmalz T, Ludwigs E, et al. Immediate effects of a new microprocessor-controlled prosthetic knee joint: a comparative biomechanical evaluation. *Arch Phys Med Rehabil*. Mar 2012; 93(3):541-549. PMID 22373937
4. Berry D. Microprocessor prosthetic knees. *Phys Med Rehabil Clin N Am*. Feb 2006; 17(1):91-113, vii. PMID 16517347
5. Burnfield JM, Eberly VJ, Gronely JK, et al. Impact of stance phase microprocessor-controlled knee prosthesis on ramp negotiation and community walking function in K2 level transfemoral amputees. *Prosthet Orthot Int*. Mar 2012; 36(1):95-104. PMID 22223685
6. Centers for Medicare and Medicaid Services. Local Coverage Determination (LCD): Lower Limb Prostheses (L33787); Accessed June 15, 2022.
7. Darter BJ, Wilken JM. Energetic consequences of using a prosthesis with adaptive ankle motion during slope walking in persons with a transtibial amputation. *Prosthet Orthot Int*. Feb 2014; 38(1):5-11. PMID 23525888
8. Datta D, Heller B, Howitt J. A comparative evaluation of oxygen consumption and gait pattern in amputees using Intelligent Prostheses and conventionally damped knee swing-phase control. *Clin Rehabil*. Jun 2005; 19(4):398-403. PMID 15929508
9. Datta D, Howitt J. Conventional versus microchip controlled pneumatic swing phase control for trans-femoral amputees: user's verdict. *Prosthet Orthot Int*. Aug 1998; 22(2):129-135. PMID 9747997
10. Delussu AS, Brunelli S, Paradisi F, et al. Assessment of the effects of carbon fiber and bionic foot during overground and treadmill walking in transtibial amputees. *Gait Posture*. Sep 2013; 38(4):876-882. PMID 23702342

MEDICAL POLICY

POLICY TITLE	LOWER LIMB PROSTHESES
POLICY NUMBER	MP 6.042

11. Department of Veterans Affairs. *VA Prosthetics and Sensory Aids*. 2006; Accessed June 15, 2022.
12. Eberly VJ, Mulroy SJ, Gronley JK, et al. *Impact of a stance phase microprocessor-controlled knee prosthesis on level walking in lower functioning individuals with a transfemoral amputation*. *Prosthet Orthot Int*. Dec 2014; 38(6):447-455. PMID 24135259
13. Ferris AE, Aldridge JM, Rabago CA, et al. *Evaluation of a powered ankle-foot prosthetic system during walking*. *Arch Phys Med Rehabil*. Nov 2012; 93(11):1911-1918. PMID 22732369
14. Flynn K. *Short Report: Computerized lower limb prosthesis (VA Technology Assessment Program)*. No. 2. 2000; Accessed June 15, 2022.
15. Fradet L, Alimusaj M, Braatz F, et al. *Biomechanical analysis of ramp ambulation of transtibial amputees with an adaptive ankle foot system*. *Gait Posture*. Jun 2010; 32(2):191-198. PMID 20457526
16. Gailey RS, Gaunaud I, Agrawal V, et al. *Application of self-report and performance-based outcome measures to determine functional differences between four categories of prosthetic feet*. *J Rehabil Res Dev*. 2012; 49(4):597-612. PMID 22773262
17. Hafner BJ, Smith DG. *Differences in function and safety between Medicare Functional Classification Level-2 and -3 transfemoral amputees and influence of prosthetic knee joint control*. *J Rehabil Res Dev*. 2009; 46(3):417-433. PMID 19675993
18. Hafner BJ, Willingham LL, Buell NC, et al. *Evaluation of function, performance, and preference as transfemoral amputees transition from mechanical to microprocessor control of the prosthetic knee*. *Arch Phys Med Rehabil*. Feb 2007; 88(2):207-217. PMID 17270519
19. Herr HM, Grabowski AM. *Bionic ankle-foot prosthesis normalizes walking gait for persons with leg amputation*. *Proc Biol Sci*. Feb 7 2012; 279(1728):457-464. PMID 21752817
20. Highsmith MJ, Kahle JT, Bongiorno DR, et al. *Safety, energy efficiency, and cost efficacy of the C-Leg for transfemoral amputees: A review of the literature*. *Prosthet Orthot Int*. Dec 2010; 34(4):362-377. PMID 20969495
21. Highsmith MJ, Kahle JT, Miro RM, et al. *Ramp descent performance with the C-Leg and interrater reliability of the Hill Assessment Index*. *Prosthet Orthot Int*. Oct 2013; 37(5):362-368. PMID 23327837
22. Hofstad C, Linde H, Limbeek J, et al. *Prescription of prosthetic ankle-foot mechanisms after lower limb amputation*. *Cochrane Database Syst Rev*. 2004(1):CD003978. PMID 14974050
23. Howard CL, Wallace C, Perry B, et al. *Comparison of mobility and user satisfaction between a microprocessor knee and a standard prosthetic knee: a summary of seven single-subject trials*. *Int J Rehabil Res*. Mar 2018; 41(1):63-73. PMID 29293160
24. Johansson JL, Sherrill DM, Riley PO, et al. *A clinical comparison of variable-damping and mechanically passive prosthetic knee devices*. *Am J Phys Med Rehabil*. Aug 2005; 84(8):563-575. PMID 16034225
25. Kaufman KR, Levine JA, Brey RH, et al. *Energy expenditure and activity of transfemoral amputees using mechanical and microprocessor-controlled prosthetic knees*. *Arch Phys Med Rehabil*. Jul 2008; 89(7):1380-1385. PMID 18586142
26. Kaufman KR, Levine JA, Brey RH, et al. *Gait and balance of transfemoral amputees using passive mechanical and microprocessor-controlled prosthetic knees*. *Gait Posture*. Oct 2007; 26(4):489-493. PMID 17869114

MEDICAL POLICY

POLICY TITLE	LOWER LIMB PROSTHESES
POLICY NUMBER	MP 6.042

27. Kaufman, KK, Bernhardt, KK, Symms, KK. *Functional assessment and satisfaction of transfemoral amputees with low mobility (FASTK2): A clinical trial of microprocessor-controlled vs. non-microprocessor-controlled knees.* *Clin Biomech (Bristol, Avon)*, 2018 Aug 5; 58:116-122. PMID 30077128
28. Kirker S, Keymer S, Talbot J, et al. *An assessment of the intelligent knee prosthesis.* *Clin Rehabil.* Aug 1996; 10(3):267-273. PMID
29. Klute GK, Berge JS, Orendurff MS, et al. *Prosthetic intervention effects on activity of lower-extremity amputees.* *Arch Phys Med Rehabil.* May 2006; 87(5):717-722. PMID 16635636
30. LCD for Lower Limb Prostheses (L11464).
31. Mancinelli C, Patrilli BL, Tropea P, et al. *Comparing a passive-elastic and a powered prosthesis in transtibial amputees.* *Conf Proc IEEE Eng Med Biol Soc.* Aug 2011; 2011:8255-8258. PMID 22256259
32. Orendurff MS, Segal AD, Klute GK, et al. *Gait efficiency using the C-Leg.* *J Rehabil Res Dev.* Mar-Apr 2006; 43(2):239-246. PMID 16847790
33. Prinsen EC, Nederhand MJ, Olsman J, et al. *Influence of a user-adaptive prosthetic knee on quality of life, balance confidence, and measures of mobility: a randomised cross-over trial.* *Clin Rehabil.* Jun 2015; 29(6):581-591. PMID 25288047
34. Theeven P, Hemmen B, Rings F, et al. *Functional added value of microprocessor-controlled knee joints in daily life performance of Medicare Functional Classification Level-2 amputees.* *J Rehabil Med.* Oct 2011; 43(10):906-915. PMID 21947182
35. Theeven PJ, Hemmen B, Geers RP, et al. *Influence of advanced prosthetic knee joints on perceived performance and everyday life activity level of low-functional persons with a transfemoral amputation or knee disarticulation.* *J Rehabil Med.* May 2012; 44(5):454-461. PMID 22549656
36. VHA Prosthetic Clinical Management Program (PCMP). *Clinical practice recommendations: microprocessor knees, 2004.* See: Berry D. *Microprocessor prosthetic knees.* *Phys Med Rehabil Clin N Am.* 2006; 17:91-113. PMID
37. Webster JB, Crunkhorn A, Sall J et al. *Clinical Practice Guidelines for the Rehabilitation of Lower Limb Amputation: An Update from the Department of Veterans Affairs and Department of Defense.* *Am J Phys Med Rehabil.* 2019 Sep; 98(9). PMID 31419214
38. Williams RM, Turner AP, Orendurff M, et al. *Does having a computerized prosthetic knee influence cognitive performance during amputee walking?* *Arch Phys Med Rehabil.* Jul 2006; 87(7):989-994. PMID 16813788
39. Thomas-Pohl M, Villa C, Davot J, et al. *Microprocessor prosthetic ankles: comparative biomechanical evaluation of people with transtibial traumatic amputation during standing on level ground and slope.* *Disabil Rehabil Assist Technol.* Jan 2021; 16(1): 17-26. PMID 31535903
40. Colas-Ribas C, Martinet N, Audat G, et al. *Effects of a microprocessor-controlled ankle-foot unit on energy expenditure, quality of life, and postural stability in persons with transtibial amputation: An unblinded, randomized, controlled, cross-over study.* *Prosthet Orthot Int.* Dec 01 2022; 46(6): 541-548. PMID 36515900

MEDICAL POLICY

POLICY TITLE	LOWER LIMB PROSTHESES
POLICY NUMBER	MP 6.042

POLICY HISTORY

MP 6.042	01/01/2020 Administrative Update. New 2020 CPT code L2006 added to policy.
	04/23/2020 Consensus Review. Policy statement unchanged. References and Background updated. Coding reviewed and tables added at the bottom of the policy, no new codes added.
	09/22/2021 Administrative Update. New code K1022 added. Effective 10/01/2021.
	06/22/2022 Consensus Review. Policy statement unchanged. Updated FEP, references. Coding reviewed.
	06/07/2023 Consensus Review. Policy statement unchanged. Updated references. Coding reviewed.
	09/08/2023 Administrative Update. Added code L5991, eff 10/01/2023.
	12/12/2023 Administrative Update. Added codes L5615 and L5926. Deleted code K0122. Eff 01/01/2024.
	03/15/2024 Administrative Update. Added codes L5783 and L5841 as MN. Eff 04/01/2024.
	10/16/2024 Minor Review. Policy intent unchanged, editorial updates, coding and references reviewed and updated.
	03/12/2025 Administrative Update. Added code L5827. Effective 04/01/2025.
	09/09/2025 Administrative update. Added L5657. Eff 10/01/2025.
	03/13/2026 Administrative update. Added L2221. Eff 04/01/2026.

Health care benefit programs issued or administered by Capital Blue Cross and/or its subsidiaries, Capital Advantage Insurance Company[®], Capital Advantage Assurance Company[®] and Keystone Health Plan[®] Central. Independent licensees of the BlueCross BlueShield Association. Communications issued by Capital Blue Cross in its capacity as administrator of programs and provider relations for all companies.