



# Cigna Medical Coverage Policy

**Subject Prosthetic Devices: Lower Limb (Including Vacuum-Assisted Socket System and Microprocessor/Computer-Controlled Lower Limb Prosthesis)**

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### INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna companies. Coverage Policies are intended to provide guidance in interpreting certain **standard** Cigna benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supersedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of Cigna. Copyright ©2014 Cigna

## Coverage Policy

Coverage for basic lower limb prosthetic devices is subject to the terms, conditions and limitations of the applicable benefit plan's External Prosthetic Appliance and Devices (EPA) or Durable Medical Equipment (DME) benefit and schedule of copayments. In addition, some benefit plans may specifically exclude or limit coverage for certain prosthetic devices. Replacement and/or repair may be limited in some benefit plans. Please refer to the applicable benefit plan document to determine benefit availability and the terms and conditions of coverage. Under many benefit plans, coverage for EPA and DME is limited to the lowest-cost alternative.

Additionally, power enhancements and/or power controls are specifically excluded under many benefit plans. Microprocessor-controlled/computer-controlled devices are considered a type of power enhancement/controlled device, and therefore are not covered under many benefit plans.

Components and/or additions to a lower limb prosthetic device may require a medical necessity determination that takes into account the individual's current functional ability and the expected functional potential as outlined by the prosthetist and ordering physician. Unless specifically prior authorized, documentation supporting medical necessity must accompany claims submitted for prosthetic components and/or additions.

Functional level criteria are defined as follows:

- Level 0:** Does not have the ability or potential to ambulate or transfer safely with or without assistance and prosthesis does not enhance his/her quality of life or mobility.
- Level 1:** Has the ability or potential to use prosthesis for transfers or ambulating on level surfaces at fixed cadence; typical of the limited and unlimited household ambulator.
- Level 2:** Has the ability or potential for ambulating with the ability to traverse environmental barriers such as curbs, stairs or uneven surfaces; typical of the limited community ambulator.
- Level 3:** Has the ability or potential for ambulating 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 ambulating that exceeds basic ambulating skills, exhibiting high impact, stress, or energy levels; typical of the prosthetic demands of the child, active adult, or athlete.

**If coverage for the specific type of lower limb prosthetic device noted is available, the following conditions of coverage apply. Cigna covers a basic lower limb prosthetic device when the individual is motivated to ambulate and functional level 1 or greater. Please note, consideration of coverage may not be limited to the code for the specific anatomical prosthesis listed below as the actual device may incorporate other components/additions as medically necessary depending on the location of amputation. -**

### **FOOT PROSTHESIS**

**Cigna covers ANY of the following foot prostheses as medically necessary when the associated functional level criteria are met:**

- An external-keel SACH foot (HCPCS code L5970) or single-axis ankle/foot (HCPCS code L5974) for functional level 1 or above.
- A flexible-keel foot (HCPCS code L5972) or multi-axial ankle/foot (HCPCS code L5978) for functional level 2 or above.
- An energy-storing foot (HCPCS code L5976), dynamic response with multi-axial ankle (HCPCS code L5979), flex-foot system (HCPCS code L5980), flex-walk system or equal (HCPCS code L5981), or shank system with vertical loading pylon (HCPCS L5987) for functional level 3 or above.

### **KNEE PROSTHESIS**

**Cigna covers ANY of the following knee prostheses as medically necessary when the associated functional level criteria are met:**

- A high activity knee control frame (L5930) for functional level 4.
- A fluid, pneumatic or electronic knee (HCPCS codes L5610, L5613, L5614, L5722–L5780, L5822–L5840, L5848) for functional level 3 or above.
- Other knee systems (HCPCS codes L5611, L5616, L5710–L5718, and L5810–L5818) for functional level 1 or above.

### **ANKLE PROSTHESIS**

**Cigna covers an axial rotation unit (HCPCS codes L5982-L5986) as medically necessary for functional level 2 or above.**

### **MICROPROCESSOR-CONTROLLED KNEE PROSTHESIS**

**If coverage for microprocessor-controlled/computer-controlled lower limb prosthetic devices is available, Cigna covers a microprocessor-controlled/computer-controlled lower limb prosthetic knee (HCPCS code L5856, L5857, L5858) device, including additions/components that are required for the effective use of the device, as medically necessary for an above-the-knee amputee when ALL of the following criteria have been met:**

- Functional level 3 or 4.
- Absence of a significant cardiovascular, neuromuscular or musculoskeletal condition which would be expected to adversely affect use of the device (i.e., a condition that may prohibit a fast walking pace).

- A gait analysis demonstrates the ability to ambulate at a rate faster than baseline using a standard prosthetic application with swing and stance control.
- The individual requires an ambulatory rate/stance control not achievable with a basic lower limb device for use outside of the home on a daily basis.

### **PROSTHETIC SHOE**

**Cigna covers a prosthetic shoe for a partial foot amputation as medically necessary when the prosthetic shoe is an integral part of a covered basic lower limb prosthetic device.**

### **NOT COVERED**

**Cigna does not cover ANY of the following lower limb prosthetic devices because each is considered not medically necessary:**

- a lower limb prosthetic device for functional level 0
- additions/components that are not required for the effective use of the device
- additions/components for an immediate post-surgical, initial or preparatory prosthesis not in accordance with functional level assessment (e.g., protective covers, sockets, ultralite material, energy storing devices such as flex foot systems)
- test (diagnostic) sockets<sup>†</sup> for an immediate post-surgical or early fitted prosthesis

**†NOTE: Up to two test (diagnostic) sockets may be required for accurate fitting of an individual prosthesis. In addition, up to two socket inserts may be required per individual prosthesis at the same time. Requests for additional test sockets and/or socket inserts require documentation supporting medical necessity.**

**Cigna does not cover ANY of the following lower limb prosthetic devices because each is considered experimental, investigational or unproven (this list may not be all-inclusive):**

- microprocessor-controlled ankle foot prosthesis (e.g., Proprio Foot<sup>®</sup> [HCPCS code L5973], élan foot [HCPCS L5999, L5973])
- powered lower limb prosthesis (e.g., Power Knee<sup>™</sup> [HCPCS codes L5859, L5856, L5828, L5848, L5845], BiOM<sup>®</sup> Ankle-Foot System [HCPCS code L5973, L5969])
- residual limb volume management and moisture evacuation system (e.g., vacuum-assisted socket system [VASS<sup>™</sup>]) (HCPCS code L5781, L5782)

### **REPAIR AND REPLACEMENT**

**Cigna covers repair and/or replacement of a medically necessary external prosthetic device under the following circumstances:**

- Repair is covered only when anatomical change or reasonable wear and tear renders the item nonfunctional and the repair will make the equipment usable.
- Replacement is covered only when anatomical change or reasonable wear and tear renders the item nonfunctional and nonrepairable.

**Cigna does not cover repair or replacement if a prosthetic device becomes unusable or nonfunctioning because of individual misuse, abuse or neglect.**

## **General Background**

External prosthetic appliances are devices used to replace the function of a missing body part and are often referred to as prosthetic devices, or prostheses. Lower limb prostheses are used to replace the function of a lower extremity.

Several prosthetic devices are available to replace the function of lower limbs. For amputees with above-knee limb loss, devices have traditionally consisted of single-axis knees and/or hydraulic or pneumatic fluid-controlled therapy devices. These devices provide optimum gait control at usual speed but require additional

compensation when walking slower or faster and also require increased concentration and effort of the amputee. Although a device of this type does produce a limp, the greatest stability is offered with the use of a manual locked knee which locks the prosthesis straight for walking. The manual locked-knee device has a release lever or cable that can be pulled to unlock the joint and allows bending. Prosthetic devices consisting of an ankle and/or foot device are also utilized for below-the-knee amputees.

The clinical application of a microprocessor or computer-control to knee prosthetics has been used and is claimed to be a significant improvement in comparison to conventional, mechanically controlled devices. Some of the computerized knees function by using a computer-regulated valve to adjust the swing phase resistance of the prosthetic cylinders. Another device uses the computer to control swing and stance phase. Additionally, more advanced technological systems using multiple sensors to send messages back to a microchip about changes in walking patterns and myoelectric prostheses for lower limbs are being investigated; myoelectric devices replace muscle activity for bending and extension of the joint.

### **Recovery Stages**

The American Academy of Orthotists and Prosthetists (AAOP) formed the Clinical Standards of Practice (CSOP) on Post-operative Management of the Lower Extremity (2004). The committee defined stages of care extending from the preoperative period to the late stage postoperative rehabilitation. Typically, the postoperative recovery period (including activity recovery, reintegration, prosthetic management and training) lasts from 12–18 months. However, healing of a residual limb is a continuous process and prosthetic readiness is an individualized transition point. In addition to the preoperative, acute postoperative and immediate postacute hospital stages, the following two stages of care were defined:

- Intermediate recovery stage: This stage begins with wound healing and extends 4–6 months from the healing date and involves the use of a preparatory prosthesis or first prosthesis. Often, the most rapid limb volume changes occur during this period as a result of ambulation and prosthetic use. This stage typically ends with stabilization of residual limb size, as defined by consistency of prosthetic fit for several months.
- Transition to stable stage: A period of relative limb stabilization after the immediate recovery stage. This stage was historically marked as a transition from the preparatory prosthesis to the definitive prosthesis, although more recently it has been characterized by a change from a rapidly changing limb to a slower maturation of the limb. While limb volume changes are not as drastic in this stage, the limb may continue to change for 12–18 months after initial healing. Modular systems are frequently encouraged during this stage.

Postoperative rehabilitation should begin as soon as possible. Fitting for the prosthesis may begin once the suture line has completely healed, and swelling is minimized, although in some rare cases (e.g., young patients with traumatic amputations), a temporary prosthesis may be fitted in surgery. Immediate postoperative prosthetic limb fitting has not gained wide acceptance due to unacceptable rates of wound complications (Pinzur, 2003). Additionally, immediate postoperative or initial prostheses require frequent adjustments and changes, some as frequent as every seven to 10 days until the preparatory prosthesis is prescribed.

Residual limb shrinkage and swelling are often controlled in the postoperative recovery phase with the use of various types of dressings. Ace wraps prevent swelling and encourage shrinkage and may be used prior to complete healing of the limb. A rigid dressing, such as a cast, may be used when temporary prosthetic devices are recommended. Other methods to assist in shrinkage and reduction of swelling include the use of compression stockings and stump shrinkers (elastic stockings). The initial shrinkage and shaping of the limb takes approximately six weeks to three months, depending on response and condition (Sherman and Jones, 1995). Care of the residual limb is a lifelong process, and changes in residual stump size may be the result of weight gain, weight loss or swelling.

Prosthetic devices for children are often staged based on the child's developmental readiness. The prosthesis must accommodate growth and other physiological changes. According to AAOP (Cummings and Kapp, 1992), methods that allow for growth and that may increase the lifespan of the prosthesis include the following:

- modification of socket liners
- flexible sockets

- removable sockets (slip or triple wall sockets)
- adding or decreasing sock thickness
- distal pads
- the use of modular systems
- growth oriented suspension systems and modifications

Furthermore, although the prosthetic treatment plan is highly individualized, children require frequent follow-up for growth and typically require new devices every 12–18 months on average, although the actual lifespan of the device depends on the child's rate of skeletal growth.

### **Types of Prosthetic Devices**

Prosthetic devices may be preparatory or permanent. A preparatory device (more common for lower limb amputees) is a prosthesis made soon after an amputation (approximately four weeks) as a temporary method of retraining a person to walk and balance while shrinking the residual limb. Preparatory devices often use transparent diagnostic test sockets and special fitting techniques to accurately fit the prosthesis so problems can be eliminated before it is copied for the permanent prosthesis. The average use of these devices may last for 3–6 months in some cases or until the residual limb has reached its final shape and size. Stabilization of the residual limb is difficult to define; however, AAOP CSOP (2004) suggests that a permanent prosthesis be recommended when an individual has used a prosthetic device full time for a period of six months and when the limb volume has stabilized to a point where the socket fit remains relatively consistent for 2–3 weeks. Once fitted the permanent prosthesis, also referred to as a definitive prosthesis, is classified as a device that meets accepted clinical standards for comfort, fit, function, appearance and durability. In some circumstances, an individual may be fitted only for a permanent device, and fitting should be delayed until the residual limb is fully mature (usually 3–4 months) or until stabilization occurs in the individual's weight and stump circumference (Bodeau, 2002).

When an initial below-knee prosthesis (HCPCS code L5500) or a preparatory below-knee prosthesis (HCPCS codes L5510–L5530, L5540) is provided, prosthetic substitutions and/or additions of procedures and components may be medically necessary in accordance with the functional level assessment, except for HCPCS codes L5629, L5638, L5639, L5646, L5647, L5704, L5785, L5962 and L5980; the latter are not considered medically necessary. When a below-knee preparatory, prefabricated prosthesis (HCPCS code L5535) is provided, prosthetic substitutions and/or additions of procedures may be medically necessary in accordance with the functional level assessment, except for HCPCS codes L5620, L5629, L5645, L5646, L5670, L5676, L5704 and L5962; the latter codes are not considered medically necessary.

When an above-knee initial prosthesis (HCPCS code L5505) or an above-knee preparatory (HCPCS codes L5560–L5580, L5590–L5600) prosthesis is provided, prosthetic substitution and/or additions of procedures and components may be medically necessary in accordance with the functional level assessment, except for HCPCS codes L5610, L5631, L5640, L5642, L5644, L5648, L5705, L5706, L5964, L5980, L5710–L5780 and L5790–L5795; the latter codes are not considered medically necessary. When an above-knee preparatory, prefabricated prosthesis (HCPCS code L5585) is provided, prosthetic substitution and/or additions of procedures and components may be medically necessary in accordance with the functional level assessment, except for HCPCS codes L5624, L5631, L5648, L5651, L5652, L5705, L5706, L5964 and L5966; the latter codes are not considered medically necessary.

### **Functional Classifications**

Prior to being fitted with a prosthetic device, the individual must demonstrate specific functional levels. A functional level is defined as a measurement of the capacity and potential of the individual to accomplish his/her expected post-rehabilitation daily function. The Centers for Medicare and Medicaid Services (CMS) have defined the following functional levels:

- Level 0:** Does not have the ability or potential to ambulate or transfer safely with or without assistance and prosthesis does not enhance his/her quality of life or mobility.
- Level 1:** Has the ability or potential to use prosthesis for transfers or ambulating on level surfaces at fixed cadence; typical of the limited and unlimited household ambulator.
- Level 2:** Has the ability or potential for ambulating with the ability to traverse environmental barriers such as curbs, stairs or uneven surfaces; typical of the limited community ambulator.

- Level 3:** Has the ability or potential for ambulating 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 ambulating that exceeds basic ambulating skills, exhibiting high impact, stress, or energy levels; typical of the prosthetic demands of the child, active adult, or athlete.

Potential functional ability is based on reasonable expectations of the prosthetist and the treating physician that are based on factors including but not limited to:

- the individual's past history (including prior prosthetic use, if applicable)
- the individual's current condition (including status of the residual limb and the nature of other medical problems)
- the individual's desire to ambulate

An individual whose functional level is zero (0) is not considered a candidate for a prosthetic device; the device is considered not medically necessary.

A basic (i.e., conventional) lower limb prosthetic device consists of the following:

- a socket (connection between the residual limb and prosthesis)
- a suspension mechanism (how the socket is attached to the prosthesis)
- a knee joint (provides support during stance, smooth control during swing phase and unrestricted motion for sitting and kneeling)
- a pylon (a tube or shell that attaches the socket to the terminal device) that is either exoskeleton or endoskeleton
- a terminal device (foot)

Components and/or additions to the prosthesis may be medically necessary; the determination of medical necessity is based on the person's functional ability and expected functional potential as defined by the prosthetist and the ordering physician. Additional documentation supporting medical necessity must accompany claims submitted for prosthetic components and/or additions. Customizing prosthetic devices with enhanced features is not medically necessary if activities of daily living can be met with standard devices.

Accessories that are necessary for the effective use of the prosthetic device, such as stump socks and harnesses, may be considered medically necessary devices. Accessories that are not necessary for the effective use of the device are considered not medically necessary.

The following items are typically included in the reimbursement for a prosthetic device:

- evaluation of the residual limb and gait
- fitting of the prosthesis
- cost of base component parts and labor contained in HCPCS base codes
- repairs due to normal wear and tear during the 90 days following delivery
- adjustments of the prosthesis or the prosthetic component made when fitting the prosthesis or component and for 90 days from the date of delivery when the adjustments are not necessitated by changes in the residual limb or the person's functional ability

### **Prosthetic Shoes**

Prosthetic shoes (HCPCS code L3250) may be medically necessary if they are an integral part of the prosthesis for a person with a partial foot amputation. These types of devices are used when all or most of the forefoot is missing and are considered terminal prosthetic devices. The function of a prosthetic shoe is different from that of an orthopedic shoe and supportive foot device, which are used by individuals whose feet, although impaired, are essentially intact. Prosthetic shoes for other conditions are considered not medically necessary.

### **Foot Prostheses**

The basic lower-extremity foot prosthesis consists of the solid-ankle/cushioned-heel (SACH) foot. Other prosthetic feet may be considered medically necessary, based upon functional classification, ability and individual need. The SACH simulates plantar flexion at heel strike by compressing an elastic heel wedge and provides forefoot dorsiflexion by way of a flexible toe section. The device has no moving parts and is frequently indicated for amputees defined as functional level 1, but may be used in level 2 or level 3 amputees. It may also be selected as a preparatory prosthesis. A single-axis foot provides fore-aft movement about an ankle axis limited and cushioned by plantar flexion and dorsiflexion bumpers. It is often used in amputees of functional level 3 and is frequently preferred for above-the-knee amputees because of the increase in knee stability during early stance phase. Multiaxial devices provide inversion-eversion and some degree of transverse rotation in addition to dorsiflexion and plantar flexion. These types of devices are particularly suited for ambulating on uneven terrain and for bilateral amputees. A flexible keel provides dynamic assist at toe-off, helping to propel the leg into swing phase. The flexible keel is often used with a dynamic response that allows the amputee to ambulate at variable cadence. The device deforms during weight-bearing, storing energy and then releasing it during late stance phase, allowing forward movement. The flexible keel is also known as a SAFE (solid-ankle-flexible-endoskeletal) foot. Foot covers are included in the codes for the prosthetic foot component.

Medical necessity for a prosthetic foot is based on the following functional levels:

- An external-keel SACH foot (HCPCS code L5970) or single-axis ankle/foot (HCPCS code L5974) may be medically necessary for an individual whose functional level is 1 or above.
- A flexible-keel foot (HCPCS code L5972) or multi-axial ankle/foot (HCPCS code L5978) may be medically necessary for an individual whose functional level is 2 or above.
- An energy-storing foot (HCPCS code L5976), dynamic response with multi-axial ankle (HCPCS code L5979), a flex-foot system (HCPCS code L5980), flex-walk system or equal (HCPCS code L5981), or shank system with vertical loading pylon (HCPCS L5987) may be medically necessary for an individual whose functional level is 3 or above.

### **Knee Prostheses**

The basic lower-extremity prosthesis includes a single-axis, constant friction knee. This device is a basic knee that acts as a door-and-hinge device, is free-swinging and does not allow stance control. It allows one-speed ambulation and is often used in children. Other prosthetic knees may be medically necessary based upon functional classification, ability and individual need. A hydraulic unit that includes piston cylinders and contains either air (i.e., pneumatic) or fluid (i.e., hydraulic) may be added to the knee device to allow swing control as the amputee speeds up or slows down. Swing control may allow the amputee to walk at variable speeds. It is often used in more active amputees. The polycentric knee, a device with multiple rotational axes, is sometimes referred to as the "four bar" knee. It has four points of rotation connected by a linkage bar. The device is asserted to be very stable in early stance and easy to flex in swing phase.

Medical necessity for a prosthetic knee device is based on the following functional levels:

- A high activity knee control frame (L5930) may be medically necessary for individuals whose functional level is 4.
- Fluid, pneumatic or electronic knees (HCPCS codes L5610, L5613, L5614, L5722–L5780, L5822–L5840, L5848, L5856, L5857, and L5858) may be medically necessary for individuals whose functional level is 3 or above.
- Other knee systems (HCPCS codes L5611, L5616, L5710–L5718, and L5810–L5818) may be medically necessary for individuals whose functional level is 1 or above.

### **Ankle Prostheses**

Axial rotation units (HCPCS codes L5982–L5986) may be medically necessary for individuals whose functional level is 2 or above.

### **Sockets**

The socket is the part of the prosthesis that fits around the residual limb and fits around the liner or socket insert. Test sockets are used prior to permanent sockets to determine correct fitting. Test sockets (e.g., diagnostic sockets) for immediate postsurgical or early-fitted prostheses (HCPCS codes L5400–L5460) are

considered not medically necessary. However, for an individual definitive prosthesis, two test sockets (e.g., diagnostic sockets) may be considered medically necessary in some situations (.e.g., hard-to-fit amputee).

Socket inserts are soft foam contoured to fit around the residual limb. They fit inside the socket in order to provide increased padding and comfort for the residual limb. No more than two of the same socket inserts (L5654–L5665, L5673, L5679, L5681, and L5683) are medically necessary per individual prosthesis at the same time.

Socket replacements may be medically necessary if there is a functional or physiological need, including but not limited to changes in the residual limb, changes in functional need, irreparable damage or wear and tear due to excessive weight or prosthetic demands of very active amputees.

### **Microprocessor-Controlled Prosthetics**

**Microprocessor-controlled Knee:** Microprocessor-controlled knee prosthetics are sensor-equipped devices. The sensor detects when the knee is in full extension and adjusts the swing phases automatically, allowing a more natural pattern of walking at variable speeds (passive powered device). Multiple devices are available that use various degrees of computer technology to enhance the clinical function of the basic mechanical knee design; all microprocessor controlled systems do not have identical features and functions. Some devices have swing only, stance phase only, or swing and stance phase. Some of the devices currently available include but are not limited to the Otto Bock C-Leg<sup>®</sup>, Genium and X2 (Otto Bock HealthCare, Minneapolis, MN), and the Endolite Orion, Intelligent and SmartIP (Endolite North America, Chase A. Blatchford and Sons Ltd., Miamisburg, OH). Another microprocessor device, the X3 (Otto Bock HealthCare, Minneapolis, MN), is waterproof; the device is completely submersible according to the manufacturer. A number of other devices are currently under investigation.

The purported advantages of a microprocessor controlled above-the-knee (AKA) prosthesis include:

- reduced energy expenditure of the amputee
- improved ability to walk on uneven ground
- improved ability to climb and descend stairs
- increased walking distance

**Literature Review:** In the published, peer-reviewed scientific literature, evidence supporting the use of microprocessor-controlled/computer-controlled prostheses comes primarily from small-group case studies with few randomized, case-controlled trials, and few systematic reviews. Of the groups studied clinically, most individuals were in good health and without other medical complications. Evidence in the peer-reviewed, published scientific literature does support reduction in energy consumption and a more normal gait pattern when compared to a standard device (Datta and Howitt, 1998; Datta, et al., 2005; Seymour, et al., 2007; Highsmith, et al., 2010; Aldridge Whitehead, et al., 2014). Although the evidence continues to evolve, there is evidence that supports the effective use of these devices for limited populations (Kaufmann, et al., 2007; Hafner, et al., 2007; Seymour, et al., 2007; Orenduff, et al., 2006; Datta, et al., 2005; Chin, et al., 2003; Datta and Howitt, 1998).

**Microprocessor-controlled Ankle:** In order to enhance the basic mechanical design and mimic the action of a biological ankle researchers have applied microprocessor technology to prosthetic feet (e.g., Proprio Foot, Ossur, élan Foot, Endolite). Stair ambulation is limited in the transtibial amputee as a result of neutral and fixed ankle position. Newer prosthetic ankles which adjust for ankle angle during swing phase and identify sloping gradients and ascent or descent of stairs are under investigation. One microprocessor-controlled ankle foot prosthesis currently available which has received FDA approval is the Proprio Foot<sup>®</sup> (Ossur, ALiso Viejo, CA). The Proprio Foot is a quasi-passive ankle that is able to actively change the ankle angle in the unloaded swing phase as the result of microprocessor-control and sensor technology. The device is passive (without power) while in stance phase. According to the manufacturer the proposed benefits of microprocessor–controlled ankle movements include the ability to identify slopes and stairs, when ascending or descending stairs the device automatically adapts ankle position to enable the next step; allows the user to place both feet behind their knees when rising from a chair; and automatically gives a toe-lift allowing sufficient ground clearance when walking. The device is designed to promote a more symmetrical and balanced gait and is intended for use by transtibial amputees engaging in low to moderate impact activities; it is not suitable for sport and high impact activities.

**Literature Review:** Darter and Wilken (2013) evaluated the impact of the Proprio device on gait performance in a small comparative analysis (n=6). After observing treadmill walking tests of six unilateral transtibial amputees fitted with a Proprio device the authors reported there were no statistical differences noted in metabolic energy expenditure, energy cost for walking, or rate of walking difficulty during level walking or ascent. However, for slope descent there was improvement in energy cost and expenditure with the active Proprio device (compared to an inactivated Proprio device). In 2010 Fradet and colleagues compared the gait of 16 subjects using a Proprio foot device to 16 subjects without gait deficits during ramp ascent and descent. The authors noted reduced knee flexion during ramp ascent on the involved side of the transtibial amputees and increased plantarflexion on the sound side. At ramp descent, increased plantarflexion with use of the adapted mode improved all ankle angle measurements although there was less physiologic kinematics and kinetics. Nonetheless, subjects reported they felt safer and had improved support during the adapted mode with a reduction of stress at the knee joint (Fradet, et al., 2010). Wolf et al. (2009) evaluated socket pressure under different walking conditions (n=12) in subjects fitted with a Proprio Foot. The results of this study suggest that microprocessor-controlled adaptation of the prosthetic ankle angle is a valuable means of modifying joint kinetics and thereby the pressure distribution at the stump. Alimusaj et al. (2009) evaluated the biomechanical effects of dorsiflexion adaptation in transtibial amputees during stair ambulation using the Proprio Foot (n=32). The results of this study demonstrate that use of an adapted ankle resulted in improvements related to knee flexion kinematics and kinetics of the involved side during stance.

Evidence in the published peer-reviewed scientific literature evaluating the use of microprocessor-controlled ankle foot devices is limited and consists mainly of pilot studies and case series involving small sample populations (Agrawal, et al., 2013; Darter and Wilkin, 2013; Fradet, et al., 2010; Alimusaj et al., 2009; Wolf, et al., 2009). While some reported outcomes are encouraging, there is insufficient evidence to support clinical utility beyond that of a conventional device. Additional clinical trials are needed to demonstrate the clinical advantages of the microprocessor-controlled ankle foot device compared to conventional ankle foot prosthesis.

### **Powered Prosthetic Devices**

**Powered Knee:** Powered prosthetic devices that use signals from muscle activity in the remaining limb to bend and straighten the device are currently under investigation. These devices utilize sensors and electronics to process data and control movement and power of the knee. Examples of this type of device include the Power Knee™, manufactured by Ossur (Foothill Ranch, CA). According to the manufacturer, the Power Knee is described as a motorized device which contains a rechargeable battery pack. It is designed to replace muscle activity of the quadriceps muscle and uses artificial proprioception with sensors in order to anticipate and respond with the appropriate movement required for stepping (active powered device). It is suggested the device helps to maintain walking speeds, assists with upward motion which is required for stairs and inclines, and learns and responds to gait patterns. With the initial use of the device a practitioner must program and align the knee. Once programming and alignment are complete, the user needs only to press the power button to use the device.

**Powered Foot:** Similar to the powered knee device, powered foot-ankle prosthetic devices are currently under investigation. One such device is the BiOM® (iWalk, Inc., Bedford, MA). This device (previously referred to as Powerfoot One) uses a combination of processors, sensors, motors, and springs that allow the user a powered push-off with taking steps. Theoretically the device replaces the action of the foot, Achilles tendon and calf muscle to result in a near normalized gait for amputees.

**Literature Review:** Evidence in the peer-reviewed published scientific literature evaluating the safety and efficacy of these devices is lacking. Most of these devices are in the early stages of development. The available evidence in the published scientific literature consists mainly of preliminary studies evaluating device design and small comparative trials. While some authors have reported on performance such as kinematic measures, improved energy costs, and biomechanical analysis (Gates, et al, 2013; Aldridge, et al., 2013) with the use of a powered foot device, these studies involve small sample populations and evaluate short-term outcomes. Regarding the powered knee device, Wolfe et al. (2013) evaluated functional and clinical differences during sit-to-stand and step-up among power knee users (n=5) compared to the microprocessor C-Leg (n=5). The authors noted few differences between users during sit-to-stand and step-up task and no difference with regards to decreased impact on the intact limb. Until clinical trials are conducted to confirm the safety and efficacy of these devices the overall clinical benefit of powered lower extremity prostheses compared with other conventional prostheses is undetermined.

**Professional Societies/Organizations:** The United States Department of Veterans Affairs (VA) (2000) conducted an evidence-based review of computerized lower limb prostheses (the Otto Bock C-Leg and the Intelligent Prosthesis). The VA noted significant potential for selection bias and that less than 3% of the published articles represented structured research and that many of the published articles were descriptive or promotional. Their review of published studies concluded the following:

- Energy requirements of ambulation (compared to requirements with conventional prostheses) are decreased at walking speeds slower or faster than the amputee's customary speed but are not significantly different at customary speeds.
- Results on the potentially improved ability to negotiate uneven stairs or inclines are inconclusive.
- User's perception of the microprocessor-controlled prosthesis was favorable when compared to the conventional device.

The VA prescribing guidelines (2000) for provision of computerized lower extremity prosthetic devices are limited to the following criteria:

- The individual has adequate cardiovascular reserve and cognitive learning ability to master the higher level of technology and to allow for faster than normal walking speed.
- The individual must demonstrate the ability to ambulate at a faster than baseline rate using a standard prosthetic application with a swing and stance control knee.
- The individual has a demonstrated need for long distance ambulation at variable rates (greater than 400 yards) on a daily basis. 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.
- The individual has a demonstrated 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.

The Workers Compensation Board of British Columbia (2003) conducted an evidence-based review of microprocessor-controlled above-knee prosthetic limbs. The panel reviewed three case studies, not published in peer-reviewed journals; four studies published in peer-reviewed journals; systematic reviews conducted by the U.S. Department of Veterans Affairs and the State of Washington Department of Labor and Industries and other literature relevant in evaluating prosthetic knees. The published studies enrolled highly selected sample of amputees who did not have additional medical problems and who were fit and active; variables which may confound results of studies. Despite these and other variables, the board concluded that they would follow the guidelines developed by the U.S. Department of Veterans Affairs for provision of microprocessor-controlled knee prostheses. In 2009 the Evidence Based Practice Group updated the systematic review with no change to position (Edeer, Martin, WorkSafe BC, 2009).

The California Technology Assessment Forum (CTAF) conducted a review of the scientific evidence for the use of microprocessor-controlled prosthetic knees for individuals with trans-femoral amputations (CTAF, 2007). The forum recommended that use of a C-Leg microprocessor-controlled prosthetic knee in otherwise healthy, active K3-K4 community ambulating adults with a trans-femoral amputation from a non-vascular cause for whom this prosthesis can be fit and programmed by a qualified prosthetist trained to do so, meets CTAF criteria for safety, effectiveness and improvement in health outcomes.

In an updated technology assessment the Washington State Department of Labor and Industries (2011) evaluated the current evidence for both microprocessor knee devices and microprocessor feet. A total of 12 studies were reviewed that evaluated outcomes of the knee device in un-controlled or real-life use (n=614); there was insufficient evidence to evaluate the comparative effectiveness, safety, or cost effectiveness of microprocessor-controlled foot devices. Regarding the microprocessor knee the evidence supports improvement or equivalence with microprocessor use compared to non-microprocessor devices in real-life conditions, however the strength of the evidence is low.

### **Vacuum-Assisted Socket System (VASS™)**

VASS (Otto Bock Harmony Vacuum-Assisted Socket System, Otto Bock HealthCare; Minneapolis, MN) is a technology that manufacturers claim helps control volume fluctuation in the residual limbs of lower-extremity amputees, reduces forces to the limbs, and improves both suspension and proprioception without restricting

vascular flow. Maintaining limb volume can help preserve the fit of the socket. A polyurethane liner sits directly against the skin, and a suspension sleeve creates a seal between the prosthesis and the residual limb. A Harmony<sup>®</sup> vacuum pump sits below the socket and evacuates air with each step, ultimately creating a vacuum between the liner and the socket wall. The vacuum facilitates perspiration evaporation within the socket and minimizes friction during movement, thus providing greater control of the prosthesis and reducing shearing forces to the skin and tissue. Although patient selection criteria have not been firmly established, the device may be proposed for individuals with non-healing skin ulcerations located on the stump when other socket systems have failed. L-codes representing the vacuum pump, volume management and moisture evacuation systems are HCPCS codes L5781 and L5782.

Evidence in the published, peer-reviewed scientific literature is insufficient and does not substantiate the effectiveness of the VASS device in maintaining limb volume. Much of the published literature is in the form of feasibility trials, case reports, and uncontrolled case series involving small populations. Reported outcomes are short term, lack high statistical power and cannot be generalized. However, the results of a recently published randomized trial (Traballesi, et al., 2012) demonstrated that following a 12 week rehabilitation program VASS users had better clinical mobility compared to subjects using a conventional prosthesis with a standard suction socket. The authors reported that VASS users used their prosthesis more than the control group and that despite increased use, pain while using the VASS device did not differ significantly compared to the control group at various points of follow-up. The sample size of the trial involved only 20 subjects, three of whom dropped out of the study, and therefore generalization of results to larger populations cannot be made. At present, the published evidence does not support clinical utility for this technology compared to conventional socket systems and overall effectiveness has not been clearly established.

Although there is no recent update, the Washington State Department of Labor and Industries (2003) concluded, after an evaluation conducted by the technology assessment committee of the Otto Bock Vacuum Assisted Socket System (VASS) device, that the published literature does not substantially support the device's effectiveness for maintaining limb volume.

#### **U.S. Food and Drug Administration (FDA)**

Prosthetic devices are subject to regulation by the FDA as medical devices. Prosthetic accessories and limb components are classified by the FDA as Class I devices.

The external assembled lower limb prosthesis is a device that is intended for medical purposes and is a preassembled external artificial limb for the lower extremity. External knee-shank-ankle-foot systems are regulated by the FDA as Class II devices.

**Use Outside of the US:** Although various powered and microprocessor controlled devices are available in countries outside the US such as Europe, Canada, and the United Kingdom, specific guidelines and recommendations for use of these devices is lacking.

#### **Summary**

Several types of lower limb prostheses are available and considered medically necessary when used to replace the function of a lower extremity. Microprocessor-controlled/computer-controlled knee devices have been evaluated and recommended as an alternative to standard basic knee prostheses. Published evidence supports reduced oxygen consumption and improvement in ambulation with the use of these devices. As such, microprocessor controlled knee devices may be considered medically necessary for a specifically defined subset of individuals.

Scientific evidence evaluating the safety and effectiveness of other devices such as the microprocessor-controlled ankle device and powered lower limb prosthetic devices is inadequate to draw conclusions. Additionally, evidence in the published, peer-reviewed scientific literature is insufficient to substantiate the effectiveness of the VASS device in maintaining limb volume. At present there is no supportive data to demonstrate the added clinical value of these technologically advanced prosthetic devices for improving health outcomes in amputees.

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## **Coding/Billing Information**

**Note:** 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

**Covered when medically necessary only when coverage is available under the plan for the specific device/component/item. Benefit exclusions and limitations may apply. Some of the devices listed below are specifically excluded under many plans and therefore generally not covered.**

**Basic lower limb prosthetic device**

<b>HCPCS Codes</b>	<b>Description</b>
L5050	Ankle, Symes, molded socket, SACH foot
L5060	Ankle, Symes, metal frame, molded leather socket, articulated ankle/foot
L5100	Below knee, molded socket, shin, SACH foot
L5105	Below knee, plastic socket, joints and thigh lacer, SACH foot
L5150	Knee disarticulation (or through knee), molded socket, external knee joints, shin, SACH foot
L5160	Knee disarticulation (or through knee), molded socket, bent knee configuration, external knee joints, shin, SACH foot
L5200	Above knee, molded socket, single axis constant friction knee, shin, SACH foot
L5210	Above knee, short prosthesis, no knee joint ("stubbies"), with foot blocks, no ankle joints, each
L5220	Above knee, short prosthesis, no knee joint ("stubbies"), with articulated ankle/foot, dynamically aligned, each
L5230	Above knee, for proximal femoral focal deficiency, constant friction knee, shin, SACH foot
L5301	Below knee, molded socket, shin, each foot, endoskeletal system
L5312	Knee disarticulation (or through knee), molded socket, single axis knee, pylon, SACH foot, endoskeletal system
L5321	Above knee, molded socket, open end, SACH foot, endoskeletal system, single axis knee
L5400	Immediate postsurgical or early fitting, application of initial rigid dressing, including fitting, alignment, suspension, and one cast change, below knee
L5410	Immediate postsurgical or early fitting, application of initial rigid dressing, including fitting, alignment and suspension, below knee, each additional cast change and realignment
L5420	Immediate postsurgical or early fitting, application of initial rigid dressing, including fitting, alignment and suspension and one cast change "AK" or knee disarticulation
L5430	Immediate postsurgical or early fitting, application of initial rigid dressing, including fitting, alignment and suspension, "AK" or knee disarticulation, each additional cast change and realignment
L5450	Immediate postsurgical or early fitting, application of non-weight bearing rigid dressing, below knee
L5460	Immediate postsurgical or early fitting, application of non-weight bearing rigid dressing, above knee
L5500	Initial, below knee "PTB" type socket, non-alignable system, pylon, no cover, SACH foot, plaster socket, direct formed
L5505	Initial, above knee - knee disarticulation, ischial level socket, non-alignable system, pylon, no cover, SACH foot plaster socket, direct formed
L5510	Preparatory, below knee "PTB" type socket, non-alignable system, pylon, no cover, SACH foot, plaster socket, molded to model
L5520	Preparatory, below knee "PTB" type socket, non-alignable system, pylon, no cover, SACH foot, thermoplastic or equal, direct formed
L5530	Preparatory, below knee "PTB" type socket, non-alignable system, pylon, no

	cover, SACH foot, thermoplastic or equal, molded to model
L5535	Preparatory, below knee "PTB" type socket, non-alignable system, pylon, no cover, SACH foot, prefabricated, adjustable open end socket
L5540	Preparatory, below knee "PTB" type socket, non-alignable system, pylon, no cover, SACH foot, laminated socket, molded to model
L5560	Preparatory, above knee - knee disarticulation, ischial level socket, non-alignable system, pylon, no cover, SACH foot, plaster socket, molded to model
L5570	Preparatory, above knee - knee disarticulation, ischial level socket, non-alignable system, pylon, no cover, SACH foot, thermoplastic or equal, direct formed
L5580	Preparatory, above knee - knee disarticulation, ischial level socket, non-alignable system, pylon, no cover, SACH foot, thermoplastic or equal, molded to model
L5585	Preparatory, above knee - knee disarticulation, ischial level socket, non-alignable system, pylon, no cover, SACH foot, prefabricated adjustable open end socket
L5590	Preparatory, above knee - knee disarticulation, ischial level socket, non-alignable system, pylon, no cover, SACH foot, laminated socket, molded to model
L5970	All lower extremity prostheses, foot, external keel, SACH foot
L5971	All lower extremity prostheses, solid ankle cushion heel (SACH) foot, replacement only
L5972	All lower extremity prostheses, flexible keel foot (SAFE, STEN, Bock Dynamic or equal)
L5974	All lower extremity prostheses, foot, single axis ankle/foot
L5975	All lower extremity prostheses, combination single axis ankle and flexible keel foot
L5976	All lower extremity prostheses, energy storing foot (Seattle Carbon Copy II or equal)
L5978	All lower extremity prostheses, foot, multi-axial ankle/foot
L5979	All lower extremity prostheses, multi-axial ankle, dynamic response foot, one piece system
L5980	All lower extremity prostheses, flex-foot system
L5981	All lower extremity prostheses, flex-walk system or equal
L5982	All exoskeletal lower extremity prostheses, axial rotation unit
L5984	All endoskeletal lower extremity prostheses, axial rotation unit, with or without adjustability
L5985	All endoskeletal lower extremity prostheses, dynamic prosthetic pylon
L5986	All lower extremity prostheses, multi-axial rotation unit ("MCP" or equal)
L5987	All lower extremity prostheses, shank foot system with vertical loading pylon
L5999 <sup>†</sup>	Lower extremity prosthesis, not otherwise specified

<sup>†</sup>**Note:** Covered when used to report a medically necessary lower limb prosthetic device in the absence of a specific code.

**Basic Additions to lower limb prosthetic device**

**Covered when medically necessary:**

<b>HCPCS Codes</b>	<b>Description</b>
L5610	Addition to lower extremity, endoskeletal system, above knee, hydraulic system
L5611	Addition to lower extremity, endoskeletal system, above knee - knee disarticulation, 4-bar linkage, with friction swing phase control
L5613	Addition to lower extremity, endoskeletal system, above knee - knee disarticulation, 4-bar linkage, with hydraulic swing phase control
L5614	Addition to lower extremity, endoskeletal system, above knee - knee disarticulation, 4-bar linkage, with pneumatic swing phase control
L5616	Addition to lower extremity, endoskeletal system, above knee, universal

	multiplex system, friction swing phase control
L5617	Addition to lower extremity, quick change self-aligning unit, above or below knee, each
L5618	Addition to lower extremity, test socket, Symes
L5620	Addition to lower extremity, test socket, below knee
L5622	Addition to lower extremity, test socket, knee disarticulation
L5624	Addition to lower extremity, test socket, above knee
L5629	Addition to lower extremity, below knee, acrylic socket
L5630	Addition to lower extremity, Symes type, expandable wall socket
L5631	Addition to lower extremity, above knee or knee disarticulation, acrylic socket
L5632	Addition to lower extremity, Symes type, "PTB" brim design socket
L5634	Addition to lower extremity, Symes type, posterior opening (Canadian) socket
L5636	Addition to lower extremity, Symes type, medial opening socket
L5637	Addition to lower extremity, below knee, total contact
L5638	Addition to lower extremity, below knee, leather socket
L5639	Addition to lower extremity, below knee, wood socket
L5640	Addition to lower extremity, knee disarticulation, leather socket
L5642	Addition to lower extremity, above knee, leather socket
L5644	Addition to lower extremity, above knee, wood socket
L5645	Addition to lower extremity, below knee, flexible inner socket, external frame
L5646	Addition to lower extremity, below knee, air, fluid, gel or equal, cushion socket
L5647	Addition to lower extremity, below knee, suction socket
L5648	Addition to lower extremity, above knee, air, fluid, gel or equal, cushion socket
L5650	Addition to lower extremity, total contact, above knee or knee disarticulation socket
L5651	Addition to lower extremity, above knee, flexible inner socket, external frame
L5652	Addition to lower extremity, suction suspension, above knee or knee disarticulation socket
L5653	Addition to lower extremity, knee disarticulation, expandable wall socket
L5654	Addition to lower extremity, socket insert, Symes (Kemblo, Pelite, Aliplast, Plastazote or equal)
L5655	Addition to lower extremity, socket insert, below knee (Kemblo, Pelite, Aliplast, Plastazote or equal)
L5656	Addition to lower extremity, socket insert, knee disarticulation (Kemblo, Pelite, Aliplast, Plastazote or equal)
L5658	Addition to lower extremity, socket insert, above knee (Kemblo, Pelite, Aliplast, Plastazote or equal)
L5661	Addition to lower extremity, socket insert, multidurometer, Symes
L5665	Addition to lower extremity, socket insert, multidurometer, below knee
L5666	Addition to lower extremity, below knee, cuff suspension
L5668	Addition to lower extremity, below knee, molded distal cushion
L5670	Addition to lower extremity, below knee, molded supracondylar suspension ("PTS" or similar)
L5671	Addition to lower extremity, below knee/above knee suspension locking mechanism (shuttle, lanyard or equal), excludes socket insert
L5672	Addition to lower extremity, below knee, removable medial brim suspension
L5673	Addition to lower extremity, below knee/above knee, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, for use with locking mechanism
L5676	Addition to lower extremity, below knee, knee joints, single axis, pair
L5677	Addition to lower extremity, below knee, knee joints, polycentric, pair
L5678	Addition to lower extremity, below knee joint covers, pair
L5679	Addition to lower extremity, below knee/above knee, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, not for use with locking mechanism
L5680	Addition to lower extremity, below knee, thigh lacer, nonmolded

L5681	Addition to lower extremity, below knee/above knee, custom fabricated socket insert for congenital or atypical traumatic amputee, silicone gel, elastomeric or equal, for use with or without locking mechanism, initial only (for other than initial, use code L5673 or L5679)
L5682	Addition to lower extremity, below knee, thigh lacer, gluteal/ischial, molded
L5683	Addition to lower extremity, below knee/above knee, custom fabricated socket insert for other than congenital or atypical traumatic amputee, silicone gel, elastomeric or equal, for use with or without locking mechanism, initial only (for other than initial, use code L5673 or L5679)
L5684	Addition to lower extremity, below knee, fork strap
L5685	Addition to lower extremity prosthesis, below knee, suspension/sealing sleeve, with or without valve, any material, each
L5686	Addition to lower extremity, below knee, back check (extension control)
L5688	Addition to lower extremity, below knee, waist belt, webbing
L5690	Addition to lower extremity, below knee, waist belt, padded and lined
L5692	Addition to lower extremity, above knee, pelvic control belt, light
L5694	Addition to lower extremity, above knee, pelvic control belt, padded and lined
L5695	Addition to lower extremity, above knee, pelvic control, sleeve suspension, neoprene or equal, each
L5696	Addition to lower extremity, above knee or knee disarticulation, pelvic joint
L5697	Addition to lower extremity, above knee or knee disarticulation, pelvic band
L5698	Addition to lower extremity, above knee or knee disarticulation, Silesian bandage
L5699	All lower extremity prostheses, shoulder harness
L5700	Replacement, socket, below knee, molded to patient model
L5701	Replacement, socket, above knee/knee disarticulation, including attachment plate, molded to patient model
L5703	Ankle, Symes, molded to patient model, socket without solid ankle cushion heel (SACH) foot, replacement only
L5704	Custom shaped protective cover, below knee
L5705	Custom shaped protective cover, above knee
L5706	Custom shaped protective cover, knee disarticulation
L5710	Addition, exoskeletal knee-shin system, single axis, manual lock
L5711	Addition, exoskeletal knee-shin system, single axis, manual lock, ultra-light material
L5712	Addition, exoskeletal knee-shin system, single axis, friction swing and stance phase control (safety knee)
L5714	Addition, exoskeletal knee-shin system, single axis, variable friction swing phase control
L5716	Addition, exoskeletal knee-shin system, polycentric, mechanical stance phase lock
L5718	Addition, exoskeletal knee-shin system, polycentric, friction swing and stance phase control
L5722	Addition, exoskeletal knee-shin system, single axis, pneumatic swing, friction stance phase control
L5724	Addition, exoskeletal knee-shin system, single axis, fluid swing phase control
L5726	Addition, exoskeletal knee-shin system, single axis, external joints, fluid swing phase control
L5728	Addition, exoskeletal knee-shin system, single axis, fluid swing and stance phase control
L5780	Addition, exoskeletal knee-shin system, single axis, pneumatic/hydrapneumatic swing phase control
L5785	Addition, exoskeletal system, below knee, ultra-light material (titanium, carbon fiber or equal)
L5790	Addition, exoskeletal system, above knee, ultra-light material (titanium, carbon fiber or equal)
L5810	Addition, endoskeletal knee-shin system, single axis, manual lock

L5811	Addition, endoskeletal knee-shin system, single axis, manual lock, ultra-light material
L5812	Addition, endoskeletal knee-shin system, single axis, friction swing and stance phase control (safety knee)
L5814	Addition, endoskeletal knee-shin system, polycentric, hydraulic swing phase control, mechanical stance phase lock
L5816	Addition, endoskeletal knee-shin system, polycentric, mechanical stance phase lock
L5818	Addition, endoskeletal knee-shin system, polycentric, friction swing and stance phase control
L5822	Addition, endoskeletal knee-shin system, single axis, pneumatic swing, friction stance phase control
L5824	Addition, endoskeletal knee-shin system, single axis, fluid swing phase control
L5826	Addition, endoskeletal knee-shin system, single axis, hydraulic swing phase control, with miniature high activity frame
L5828 <sup>†</sup>	Addition, endoskeletal knee-shin system, single axis, fluid swing and stance phase control
L5830	Addition, endoskeletal knee-shin system, single axis, pneumatic/swing phase control
L5840	Addition, endoskeletal knee-shin system, 4-bar linkage or multiaxial, pneumatic swing phase control
L5845 <sup>†</sup>	Addition, endoskeletal knee-shin system, stance flexion feature, adjustable
L5848 <sup>†</sup>	Addition to endoskeletal knee shin system, fluid stance extension, dampening feature, with or without adjustability
L5850	Addition, endoskeletal system, above knee or hip disarticulation, knee extension assist
L5910	Addition, endoskeletal system, below knee, alignable system
L5920	Addition, endoskeletal system, above knee or hip disarticulation, alignable system
L5925	Addition, endoskeletal system, above knee, knee disarticulation or hip disarticulation, manual lock
L5930	Addition, endoskeletal system, high activity knee control frame
L5940	Addition, endoskeletal system, below knee, ultra-light material (titanium, carbon fiber or equal)
L5950	Addition, endoskeletal system, above knee, ultra-light material (titanium, carbon fiber or equal)
L5962	Addition, endoskeletal system, below knee, flexible protective outer surface covering system
L5964	Addition, endoskeletal system, above knee, flexible protective outer surface covering system
L5968	Addition to lower limb prosthesis, multiaxial ankle with swing phase active dorsiflexion feature
L5988	Addition to lower limb prosthesis, vertical shock reducing pylon feature
L5990	Addition to lower extremity prosthesis, user adjustable heel height
L5999 <sup>††</sup>	Lower extremity prosthesis, not otherwise specified
L7600	Prosthetic donning sleeve, any material, each
L8400	Prosthetic sheath, below knee, each
L8410	Prosthetic sheath, above knee, each
L8417	Prosthetic sheath/sock, including a gel cushion layer, below knee or above knee, each
L8420	Prosthetic sock, multiple ply, below knee, each
L8430	Prosthetic sock, multiple ply, above knee, each
L8440	Prosthetic shrinker, below knee, each
L8460	Prosthetic shrinker, above knee, each
L8470	Prosthetic sock, single ply, fitting, below knee, each
L8480	Prosthetic sock, single ply, fitting, above knee, each

**†Note:** Covered when medically necessary and when used to report components or additions to a covered lower limb prosthetic device.

**††Note:** Covered when used to report a medically necessary component or addition to a lower limb prosthetic device in the absence of a specific code.

**Microprocessor-controlled prosthesis**

**Covered when medically necessary when benefits are available for a microprocessor-controlled prosthetic:**

<b>HCPCS Codes</b>	<b>Description</b>
L5856 <sup>†</sup>	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type
L5857 <sup>†</sup>	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing phase only, includes electronic sensor(s), any type
L5858 <sup>†</sup>	Addition to lower extremity prosthesis, endoskeletal knee shin system, microprocessor control feature, stance phase only, includes electronic sensor(s), any type

**†Note:** Experimental/Investigational/Unproven/Not Covered when used to report an addition to a powered lower limb prosthetic device.

**Additional components/features of microprocessor-controlled prosthetic devices:**

**Covered when medically necessary when benefits are available for a microprocessor-controlled prosthetic:**

<b>HCPCS Codes</b>	<b>Description</b>
L5925	Addition, endoskeletal system, above knee, knee disarticulation or hip disarticulation, manual lock
L5828	Addition, endoskeletal knee-shin system, single axis, fluid swing and stance phase control
L5845	Addition, endoskeletal knee-shin system, stance flexion feature, adjustable
L5848	Addition to endoskeletal knee-shin system, fluid stance extension, dampening feature, with or without adjustability
L5920	Addition, endoskeletal system, above knee or hip disarticulation, alignable system
L5930	Addition, endoskeletal system, high activity knee control frame
L5950	Addition, endoskeletal system, above knee, ultra-light material (titanium, carbon fiber or equal)
L5999	Lower extremity prosthesis, not otherwise specified

**Powered Lower Limb Prosthesis**

**Experimental/Investigational/Unproven/Not Covered:**

<b>HCPCS Codes</b>	<b>Description</b>
L5828	Addition, endoskeletal knee-shin system, single axis, fluid swing and stance phase control
L5845	Addition, endoskeletal knee-shin system, stance flexion feature, adjustable
L5848	Addition to endoskeletal knee-shin system, fluid stance extension, dampening

	feature, with or without adjustability
L5856	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type
L5859	Addition to lower extremity prosthesis, endoskeletal knee-shin system, powered and programmable flexion/extension assist control, includes any type motor(s)
L5969	Addition, endoskeletal ankle-foot or ankle system, power assist, includes any type motor(s)
L5973	Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, includes power source

**Additional components/features of powered prosthetic devices, including power assist features**

**Experimental/Investigational/Unproven/Not Covered when reported in addition to a non-covered prosthetic device:**

<b>HCPCS Codes</b>	<b>Description</b>
L5828	Addition, endoskeletal knee-shin system, single axis, fluid swing and stance phase control
L5845	Addition, endoskeletal knee-shin system, stance flexion feature, adjustable
L5848	Addition to endoskeletal knee shin system, fluid stance extension, dampening feature, with or without adjustability
L5856	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type
L5859	Addition to lower extremity prosthesis, endoskeletal knee-shin system, powered and programmable flexion/extension assist control, includes any type motor(s)
L5969	Addition, endoskeletal ankle-foot or ankle system, power assist, includes any type motor(s)
L5999	Lower extremity prosthesis, not otherwise specified

**Vacuum-assisted socket system**

**Experimental/Investigational/Unproven/Not Covered:**

<b>HCPCS Codes</b>	<b>Description</b>
L5781	Addition to lower limb prosthesis, vacuum pump, residual limb volume management and moisture evacuation system
L5782	Addition to lower limb prosthesis, vacuum pump, residual limb volume management and moisture evacuation system, heavy duty

**Prosthetic Shoe**

**Covered when medically necessary:**

<b>HCPCS Codes</b>	<b>Description</b>
L3250	Orthopedic footwear, custom molded shoe, removable inner mold, prosthetic shoe, each
L5000	Partial foot, shoe insert with longitudinal arch, toe filler
L5010	Partial foot, molded socket, ankle height, with toe filler
L5020	Partial foot, molded socket, tibial tubercle height, with toe filler

**Repair/replacement**

**Covered when medically necessary:**

<b>HCPCS Codes</b>	<b>Description</b>
L7510	Repair of prosthetic device, repair or replace minor parts
L7520	Repair prosthetic device, labor component, per 15 minutes

**\*Current Procedural Terminology (CPT®) © 2013 American Medical Association: Chicago, IL.**

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