Overview

This Coverage Policy addresses prosthetic devices. Prosthetic devices are defined as fabricated items designed as replacements for missing or non-functioning body parts which are surgically implanted (internal surgical prostheses) or worn as an anatomic supplement (external or non-surgical prostheses).

The policy statements below provide medical necessity criteria, including functional level requirements where applicable, and coding information for the following:

- **General Criteria for any Prosthetic Device**
- **External Facial Prosthetic Device**
- **Upper Limb Prosthetic Device (Myoelectric)**
- **Lower Limb Prosthetic Device (Microprocessor-controlled, Powered-microprocessor controlled, Vacuum Suspension System)**
- **Repair and Replacement**

For information regarding medical necessity criteria for any other prosthetic device please reference the applicable Cigna Medical Coverage Policy:

- **Breast Reconstruction Following Mastectomy or Lumpectomy**
- **Intraocular Lens Implant**
- **Male Sexual Dysfunction Treatment: Non-Pharmacogenic**
- **Treatment of Gender Dysphoria**
Coverage Policy

Coverage for prosthetic devices varies across plans. Please refer to the customer's benefit plan document to determine benefit availability and the terms and conditions of coverage.

Microprocessor-controlled/computer-controlled/myoelectric devices are considered a type of power enhancement/controlled device.

GENERAL CRITERIA FOR A PROSTHETIC DEVICE

Functional Levels
Medical necessity for a lower limb prosthetic appliance is based on an individual's functional ability. Functional ability is based on the following classification 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.

The following prosthetic devices are considered medically necessary when used to replace a missing or nonfunctional body part and when applicable medical necessity criteria listed below is met (Please note: prior authorization requirements may apply):

- External facial (e.g., nose, ear, midfacial, orbital, upper facial, hemifacial)
- Eye prosthesis (e.g., internal ocular, scleral shell)
- Lower extremity (e.g., foot, ankle, above/below knee)
- Upper extremity (e.g., finger, hand, wrist, above/below elbow, shoulder)
- Terminal devices, such as hands or hooks

Accessories to a prosthetic device are considered medically necessary when the accessory is required for the effective use of the prosthesis.

Not Medically Necessary
The following prosthetic devices are each 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
- consumable supplies for the care of prosthetic device (e.g., cosmetics, creams, cleansers, skin barrier wipes)
- prosthetic devices or additions/components not required for participation in normal activities of daily living, including those that are chiefly for convenience, for participation in recreational activities, or that otherwise exceed the medical needs of the individual (e.g., back-up/duplicate prosthetic devices, waterproof leg prosthesis [e.g., Water Leg, used for showering, swimming])
**IRIS PROSHESIS**

An iris prosthesis (HCPCS code C1839) for the treatment of full or partial aniridia is considered experimental, investigational or unproven.

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**EXTERNAL FACIAL PROSTHESIS**

An external facial prosthesis (HCPCS code L8040, L8041, L8042, L8043, L8044, L8045, L8046, L8047 and L8048) is considered medically necessary when the prosthesis is prescribed to compensate for the loss or absence of facial tissue as a result of disease, injury, surgery or congenital defect.

A duplicate external facial prosthesis is considered a convenience item and is considered not medically necessary.

Each of the following supplies related to the care of, and/or application or removal of, an external facial prosthesis is a consumable item specifically excluded under most benefit plans and considered not medically necessary:

- cosmetics
- skin creams
- skin cleansers
- adhesives
- adhesive remover
- skin barrier wipes
- tape

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**UPPER LIMB: MYOELECTRIC PROSTHETIC DEVICE**

If a benefit is available for an upper limb myoelectric device the following medical necessity criteria apply.

An upper limb myoelectric prosthetic device is considered medically necessary for an individual with an amputation or congenital absence of a portion of an arm (e.g., hand, forearm, elbow) when ALL of the following criteria are met:

- The individual has sufficient cognitive ability to successfully utilize a myoelectric prosthetic device.
- The remaining musculature of the arm(s) contains the minimum microvolt threshold to allow operation of a myoelectric prosthetic device.
- A standard body-powered prosthetic device cannot be used or is insufficient to meet the functional needs of the individual in performing activities of daily living

An upper limb sensor and myoelectric controlled prosthetic device with simultaneous multiple degrees of freedom (e.g., LUKE [Life Under Kinetic Evolution] Arm) is considered experimental, investigational or unproven.

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**LOWER LIMB: MECHANICAL (NON-POWERED, NON MICROPROCESSOR)**

The following lower limb additions and/or components are considered medically necessary when the individual is functional level 3 or greater and medical necessity criteria has been met for the base device:

- A flex-walk system or equal, all lower extremity prosthesis (HCPCS code L5981)
- a single axis, fluid swing and stance phase control (HCPCS L5828)
- a fluid stance extension, dampening feature, with or without adjustability (HCPCS L5848)
An adjustable stance flexion feature (HCPCS L5845) is considered medically necessary when the individual is functional level 1 or greater and medical necessity criteria has been met for the base device.

A high activity knee control frame (HCPCS code L5930) is considered medically necessary for an individual who is functional level 4 and medical necessity criteria has been met for the base device.

**LOWER LIMB MICROPROCESSOR-CONTROLLED PROSTHETIC DEVICE**

If a benefit is available for a microprocessor-controlled/computer-controlled lower limb prosthetic, the following medical necessity criteria apply.

Any of the following microprocessor-controlled prosthetics, including additions/components that are required for the effective use of the device (and consistent with the user’s functional level), are considered medically necessary when the individual is functional level 3 or greater:

- a microprocessor-controlled ankle-foot prosthetic (HCPCS code L5973) for a transtibial amputee (below-the-knee)
- a microprocessor-controlled knee prosthetic (HCPCS code L5856, L5857, L5858) for a knee disarticulation amputee or a transfemoral amputee (above-the-knee)
- a combination microprocessor-controlled prosthetic/system (e.g., SYMBIONIC® LEG 3, LiNX®), when a microprocessor-controlled prosthetic knee alone is inadequate to meet the functional needs of the individual (e.g., continued knee/foot instability due to environmental/anatomical barriers)

A microprocessor-controlled prosthetic is considered experimental, investigational or unproven for any other indication.

An osseointegrated/osseoanchored lower limb prosthetic device is considered experimental, investigational or unproven.

**LOWER LIMB: POWERED MICROPROCESSOR-CONTROLLED PROSTHETIC DEVICE**

If a benefit is available for a powered or power-enhanced lower limb prosthetic, the following medical necessity criteria apply.

An endoskeletal knee-shin system (addition to a lower limb device) with powered and programmable flexion/extension assist control, including any type of motor(s) (HCPCS code L5859) (e.g., Össur Power Knee™) is considered medically necessary when ALL of the following criteria have been met:

- Individual has a swing and stance phase type microprocessor controlled (electronic) knee (HCPCS L5856)
- Is K3 functional level only*
- 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

*Note: Coverage of this device is limited to individuals who are Functional Level 3; the device is not intended for high impact activity, sports, excessive loading, or heavy duty use.

The following powered prosthetic devices are each considered experimental, investigational or unproven:

- a microprocessor-controlled ankle foot prosthetic with power assist (e.g., BiOM® Ankle, emPOWER™ Ankle [HCPCS L5973, L5969])
- a powered lower limb prosthetic for any other indication

**LOWER LIMB: VACUUM SUSPENSION SYSTEM**
A vacuum suspension system (e.g., vacuum-assisted socket system [VASS™]) (HCPCS code L5781, L5782) is 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.

REPAIR AND REPLACEMENT
Repair and/or replacement of a medically necessary prosthetic device is considered medically necessary for EITHER of the following indications:

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

General Background

PROSTHETIC DEVICE
A prosthesis is an artificial device used to replace a nonfunctioning or missing body part and is intended to restore normal function.

The following services and items are typically included in the allowance for a prosthetic device:

- the evaluation and fitting of the prosthesis
- the cost of base component parts and labor, as described in HCPCS base codes
- the repairs due to normal wear and tear during the 90-day period following the date of 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 underlying tissue or the patient’s functional ability

Prosthetic devices are secured or retained in place by harnesses or belts, by suction, or using anatomical structures; some devices such as facial prosthetics are held in place with the use of a skin adhesive. Additionally, devices may be held in place by implants, such as bone integrated titanium implants.

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.

IRIS PROSTHESIS
An iris prosthesis is an implanted device recommended for treatment of partial or complete aniridia. Aniridia is absence of the iris and may be associated with visual conditions such as glare, photophobia, glaucoma and/or cataract formation. The prosthetic iris device is made out of foldable medical grade silicone which is then custom-sized and colored for each individual. The iris prosthetic is implanted surgically through a small incision, it is then unfolded, the edges are smoothed out and it is then held in place by anatomical structure of the eye or using sutures. The device allegedly reduces sensitivity to light while improving the appearance of the eye in those with a missing or damaged iris.

The CustomFlex™ Artificial Iris (Clinical Research Consultants, Inc, Cinn. OH) received premarket approval (P170039) by the U.S. Food and Drug Administration (FDA) in December of 2017 as an artificial iris intended for use in children and adults for the treatment of full or partial aniridia resulting from congenital aniridia, acquired defects, or other conditions associated with full or partial aniridia. The FDA is requiring a post approval study to evaluate long term safety outcomes up to three years postoperatively for adults and five years for pediatrics.

There is little evidence in the peer-reviewed scientific literature evaluating use of this device. Hayes published a search and summary report in January 2019 and concluded the evidence was insufficient to evaluate safety and
efficacy of the device for treatment of aniridia. Evidence reviewed by Hayes included two prospective uncontrolled studies, two retrospective uncontrolled studies, four case series, and a surgical technique review.

**EXTERNAL FACIAL PROSTHESIS**

External facial prostheses are used to replace lost or absent facial tissue that is the result of disease, injury, surgery or a congenital defect or they may be considered an alternative to reconstructive surgery. An external device is usually made from silicone materials and requires frequent removal and cleaning while a surgically implanted prosthetic device is typically removed and cleaned less often. The function of the external prosthesis is to protect exposed tissues, cover exposed cavities, and restore physical appearance.

Common types of external facial prostheses include the following:

- **auricular (ear)** - restores all or part of the ear, function includes directing sound into the auditory canal; supporting eyeglasses and acting as a hearing aide if required.
- **nasal (nose)** - restores all or part of the nose and may include the nasal septum; functions to direct airflow to the nasopharynx and may also provide support for eyeglasses
- **midfacial (nose and adjacent tissues)** - restores part or all of the nose and significant adjacent facial tissue/structures, does not include the orbit or any intraoral maxillary prosthesis; adjacent facial tissue/structures include one or more of the following: soft tissue of the cheek, upper lip, or forehead.
- **orbital (orbit/eyelids)** - restores the eyelids and the hard and soft tissue of the orbit, may include the eyebrow; functions to house the artificial eye, does not include the ocular prosthesis
- **upper facial (orbit and adjacent tissues)** - restores the orbit, plus significant adjacent facial tissue/structures, does not include the nose, any intraoral maxillary prosthesis or ocular prosthesis; adjacent facial tissue/structures include soft tissue of the cheek(s) or forehead.
- **hemifacial (nose, orbit and adjacent tissues)** - restores part or all of the nose, the orbit, and significant adjacent facial tissue/structures, does not include any intraoral maxillary prosthesis or ocular prosthesis.
- **partial facial prosthesis** - restores a portion of the face, does not specifically involve the nose, orbit or ear
- **nasal septal prosthesis** - prosthesis that occludes a hole in the nasal septum, does not include superficial nasal tissue

Prosthetic devices may be secured or retained in place by anatomical structures; however, in most cases the device is held in place with the use of a skin adhesive. Additionally, some devices may be held in place by implants, such as bone integrated titanium implants. The method chosen to secure the device and the type of device are usually dependent upon factors such as the degree of deformity, the person's ability to handle maintenance routines, the individual's occupation and lifestyle, and the availability of assistance when needed.

Skin care products (e.g., cosmetics, creams, and cleansers) related to care of the prosthesis, and the application and/or removal of the device are considered personal care items.

**UPPER LIMB: Myoelectric Prosthetic Device**

The conventional prosthetic appliance for replacement of an upper extremity, either below or above the elbow, is a body-powered prosthesis with a terminal hand or hook device. A myoelectric device functions by means of electrical impulses and operates on rechargeable batteries requiring external cables or harnesses. It is a prosthetic device used as an alternative to a passive or conventional body-powered device which enables an amputee to adjust the force of his/her grip and an ability to both open and close the hand voluntarily. Myoelectric devices may be recommended for amputees who are unable to use body-powered devices or who require improved grip function/motion for performance of daily activities. Adults or children with above- or below-the-elbow amputations may use the device effectively, although as a child grows the prosthesis may require multiple socket replacements for proper fit and function.

A hybrid prosthesis is a device that uses a combination of myoelectric and body-powered technology to enhance the amputee's overall functionality, depending on the level and location of amputation. A hybrid device is indicated for high level amputations, (i.e., at or above the elbow) and consists of a body-powered device to control shoulder and elbow movement and a myoelectric device to control hand and wrist motion, allowing control of two joints at one time.
Literature Review
Results of studies published in the peer-reviewed scientific literature evaluating the impact of these devices on clinical outcomes are mixed (Egermann, et al., 2009; Pylatiuk, et al., 2007; Biddess and Chau, 2007; Crandall and Tomhave, 2002; Edelstein and Berger, 1993; Stein and Walley, 1983). Evidence is primarily in the form of small case series and does not provide strong conclusions to support the use of these devices for improving quality of life, although some authors have reported greater function and range of motion among subjects using the device (Crandall, Tomhave, 2002; Stein and Walley, 1983). Edelstein and Berger (1993) reported that activities such as donning socks, cutting paper and applying bandages were performed more rapidly with a myoelectric device when compared to a body-powered device, although performance with both devices was rated poorer than normal quality. In general, the reported outcomes are subjective and include patient acceptance and reasons for disuse; little data regarding functional status and direct comparisons to body-powered devices or passive devices are available. Patient selection criteria are not clearly defined, however despite these and other confounding variables, the published literature tends to support some clinical benefits from the use of a myoelectric prosthesis when compared to a conventional passive or body-powered device.

Areas of development for powered upper limb prosthetic devices include devices that function using implantable sensors, reinnervation of muscle fibers to allow fine movement control as well as sensory feedback and multiple simultaneous degrees of freedom. The LUKE (Life Under Kinetic Evolution) Arm (Mobius Bionics, LLC) is an upper limb prosthesis that has been developed to restore function in individuals who have lost all or part of their upper limb and that has multiple powered joints and grip patterns and is capable of multiple simultaneous degrees of freedom, controlled using EMG signals. In addition to the EMG electrodes, the LUKE Arm contains a combination of mechanisms, including switches, movement sensors, and force sensors. The primary control resides with inertial measurement sensors on top of the feet. The micro-electromechanical control system is operated through an inertial measurement unit (IMU), which is located in a sensor that is attached to or embedded in the individual’s shoe. The user commands motion of the prosthesis by moving the foot in various directions. The device is available for transradial, transhumeral or shoulder amputation. Evidence in the peer reviewed literature is insufficient to support safety and efficacy of these emerging-type of devices. Within a Hayes report published in 2018 and updated in 2019, the authors concluded “the very-low-quality body of evidence is insufficient to draw conclusions regarding the efficacy and safety of the LUKE arm. The limited evidence does not suggest consistent improvement on measures of function or performance with the LUKE arm compared with existing prostheses and lacks adequate follow-up to compensate for the potential patient learning curve associated with the new prosthesis.”(Hayes, 2019). Hayes noted the evidence reviewed included only two 2 pretest/posttest studies with internal controls; one was a Veterans’ Affair (VA) study to optimize the arm system (optimization study) and the second a VA home study of an advanced upper limb prosthesis.

LOWER LIMB PROSTHETIC DEVICE
Prior to being fitted with a lower limb 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.

Lower limb prosthetic devices may be preparatory or permanent. A preparatory device 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. A permanent prosthesis is 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.

Components and/or additions to a 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 may also be considered medically necessary devices. Accessories that are not necessary for the effective use of the device are considered not medically necessary. While some prosthetic manufacturers offer devices with waterproof features, including...
devices that are submergible (e.g., Water Leg, [Standard Cyborg, SF, CA] [used for showering, swimming], Genium X3 [Ottobock, US], [a waterproof microprocessor-controlled knee prosthetic device]), when used for recreational purposes these prosthetic accessories/devices are considered a convenience item and not medically necessary.

**Osseointegrated Prosthesis**

Additionally, more advanced technological systems using multiple sensors to send messages back to a microchip regarding changes in walking patterns and osseointerected prosthetic devices for lower limbs are being investigated. These devices represent emerging technologies and are undergoing clinical trials evaluating performance, safety, and durability. In contrast to the standard of care socket-suspended prosthesis, an osseointegrated prosthetic device consists of a fixture and abutment screw that is surgically implanted into bone. After healing and various stages of rehabilitation the fixture is then attached to a prosthesis. One such device, the OPRA™ Implant System (Integrum AB, Sweden), has received FDA approval as a humanitarian device for prosthetic use. According to the manufacturer the system consists of three parts; an anchoring element (the Fixture) and a skin penetrating connection (the Abutment), and a securing titanium screw (the Abutment Screw). FDA labeling indicates the intended use is for patients who have transfemoral amputation due to trauma or cancer and who have rehabilitation problems with, or cannot use, a conventional socket prosthesis. The OPRA device is intended for skeletally mature patients. According to Hayes, evidence in the peer reviewed scientific literature evaluating this technology is insufficient to support safety and efficacy (Hayes, 2018). A systematic review published in 2018 by Kunutsor and colleagues evaluating the safety and efficacy of osseointegrated prostheses included a total of 22 eligible articles; 13 of the studies were unique. The average sample size of the studies included ranged from 11 to 100 participants, none of the studies were RCTs. The reported outcomes of all studies supported improvement in functional outcomes (walking ability, prosthetic use and mobility), and satisfaction and quality of life following osseointegration, compared with their preoperative status or when using a conventional socket prosthesis. Infection rates varied from 1% to 77%, with the majority of infections described as low-grade soft tissue or superficial infections related to the skin–implant interface. Infections were treated effectively with antibiotics. According to the authors none of the studies reported additional amputation or death as a result of osseointegration and they concluded osseointegration following limb amputation improved prosthetic use, comfort when sitting, walking ability, mobility, gait, and quality of life. However, use of such devices is associated with an increased risk of soft tissue infection.

In 2017 the Canadian Agency for Drugs and Technologies in Health (CADTH) published a systematic review to evaluate the evidence for osseointegrated prosthetic devices for lower limb amputation. After reviewing seven studies that met inclusion criteria, the authors concluded the quality of evidence is generally low, and while some evidence suggests there is improvement in quality of life, function, and mobility after implantation there is concern regarding high rates of infection, and the design of and materials used affecting safety and efficacy. Overall, the authors reported the available evidence suggests that careful attention should be given to patient selection, implant selection, and residual limb skin integration, as well as surgical and rehabilitation protocols, to optimize outcomes and reduce adverse event rates.

**LOWER LIMB: Microprocessor-controlled Device**

**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®, 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 symmetrical 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). Some evidence supports both reduced hip moment and metabolic requirements particularly at faster speeds. 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® (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 who are classified as level K3 (i.e., community ambulatory, with the ability or potential for ambulation with variable cadence); it is not suitable for sport and high impact activities.

**Literature Review:** 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 (Struchkov, Buckley, 2016; DeLussu, et al., 2013; Agrawal, et al., 2013; Darter and Wilkin, 2013; Fradet, et al., 2010; Alimusaj et al., 2009; Wolf, et al., 2009). Although limited, the evidence does demonstrate some clinical advantages for use compared to conventional ankle foot prostheses for individuals who are functional level 3 or greater.

**Combination Microprocessor-controlled Knee-Ankle/Foot Prosthetic:** Combination microprocessor prosthetics are available integrating both a microprocessor knee and the ankle/foot device (e.g., SYMBIONIC® LEG 3 [Ossur, Iceland]; LINX® [Endolite]). One device, the SYMBIONIC® LEG 3 is a prosthesis that combines a microprocessor knee with a powered microprocessor ankle with proactive ankle flexion. The device purportedly has a more powerful knee actuator and new kinematic sensors for improved stability, increased support with stance flexion, and more rapid, and consistent swing extension. For a transfemoral amputee, combining both types of prosthetic devices theoretically enables a more natural and symmetrical gait when ambulating, decreasing energy expenditure, and offering increased stability. The device is intended for use by individuals who are Functional Level 3 or 4. The LINX® [Endolite]) prosthetic system is intended for individuals who are Functional Level 3 or greater; according to the manufacturer this system is an integrated prosthetic utilizing a microprocessor-controlled system in addition to sensors and actuators which simultaneously controls the knee and foot.

**Technology Assessment:** 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 C-Leg microprocessor-controlled prosthetic met CTAF criteria for safety, effectiveness, and improvement in health outcomes for a subset of individuals.
In a more recent report evaluating the C-Leg prosthesis for individuals with above-knee amputee, Hayes, Inc. concluded the available studies provided preliminary evidence that compared with mechanical prostheses the C-Leg prosthesis improves the mobility of selected unilateral transfemoral amputees (Hayes, 2015).

**Professional Societies/Organizations:** Although there are no recent updates, the United States Department of Veterans Affairs (VA, 2000), the Washington State Department of Labor and Industries (2002) and the Workers Compensation Board of British Columbia (2003, updated 2009) previously evaluated the clinical utility of microprocessor-controlled prosthetics. Within these publications the authors acknowledge, although not robust, there is some evidence to support a microprocessor knee improves function and/or is equivalent to a non-microprocessor device and supports use for some individuals.

**LOWER LIMB: Powered Microprocessor-controlled Prosthetic Device**

**Powered Knee:** Powered prosthetic devices that use signals from muscle activity in the remaining limb to bend and straighten the device remain 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). In comparison to a passive prosthetic knee, including a microprocessor device, the manufacturer suggests a power knee offers advantages such as powered extension with standing, controlled resistance with descending, and active flexion and extension during walking. The device controls the transition from a bent knee to an extended knee, at heel strike supports the individual’s full body weight, and can help lift above-knee amputees out of a chair to a standing position. It is suggested the device helps to maintain walking speeds, assists with upward motion (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. The device is compatible with a variety of dynamic flex-foot feet, must be re-charged daily and is not intended for high impact activity, sports, excessive loading or heavy duty use.

According to criteria outlined in the Centers for Medicare and Medicaid Services Local Coverage Determination, the following individuals may benefit from the use of a power knee-ankle device:

- the individual has a microprocessor (swing and stance phase type (L5856) controlled (electronic) knee
- is K3 functional level only
- 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
- is able to make use of a product that requires daily charging
- is able to understand and respond to error alerts and alarms indicating problems with the function of the unit.

**Powered Foot-ankle:** Similar to the powered knee device, powered foot-ankle prosthetic devices (HCPCS L5973 and L5969) are currently under investigation. Two such devices are the BiOM® Ankle and emPOWER™ Ankle, (BionX Medical Technologies, [previously iWalk, Inc., Bedford, MA). The BiOM 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 and is intended for amputees that are functional level 3 or 4. According to the manufacturer, the emPOWER™ Ankle is a more recent generation of the BiOM® Ankle.

**Literature Review:** The available evidence in the published scientific literature consists mainly of preliminary studies evaluating device design and biomechanics with few comparative trials available. While some authors have reported on performance such as kinematic measures, improved energy costs, and biomechanical analysis (Simon, et al., 2016; Ingraham, et al., 2016; Gates, et al, 2013; Aldridge, et al., 2013) with the use of a powered prosthetic device (ankle/foot or knee), 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. There is a paucity of published evidence evaluating ankle/foot powered devices (Rabago, et al., 2016; Esposito, et al., 2016; Takahashi, et al., 2013; Grabowski, DeAndrea, 2013; Herr, Grabowski, 2012). Until clinical trials are conducted to confirm the safety, efficacy and overall clinical utility of the powered ankle/foot device compared with other conventional or microprocessor prostheses, improvement in net health outcomes has yet to be determined.

Appendix 1 – Lower Limb Prosthetic “Device to Coding” Crosswalk

Please note, coding may vary according to manufacturer. This list is for informational purposes, it DOES NOT indicate coverage/non-coverage of a device.

<table>
<thead>
<tr>
<th>Device Name</th>
<th>Brief Description</th>
<th>Manufacturer</th>
<th>Code(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allux</td>
<td>Microprocessor-controlled knee</td>
<td>Nabtesco</td>
<td>L5613, L5845, L5848, L5856</td>
</tr>
<tr>
<td>BiOM Foot</td>
<td>Microprocessor-controlled ankle foot (power)</td>
<td>BionX Medical</td>
<td>L5969, L5973</td>
</tr>
<tr>
<td>C-Leg</td>
<td>Microprocessor-controlled knee</td>
<td>Otto Bock</td>
<td>L5856, L5848, L5845, L5828</td>
</tr>
<tr>
<td>C-Leg Compact</td>
<td>Microprocessor-controlled knee</td>
<td>Otto Bock</td>
<td>L5858, L5828, L5848</td>
</tr>
<tr>
<td>Élan Foot</td>
<td>Microprocessor-controlled ankle foot</td>
<td>Endolite</td>
<td>L5973</td>
</tr>
<tr>
<td>EmPOWER™</td>
<td>Microprocessor-controlled ankle foot (power)</td>
<td>BionX Medical</td>
<td>L5969, L5973</td>
</tr>
<tr>
<td>Genium</td>
<td>Microprocessor-controlled knee</td>
<td>Otto Bock</td>
<td>L5999, L5999, L5999, L5848, L5828, L5850, and L5930</td>
</tr>
<tr>
<td>Genium X2, Genium X3</td>
<td>Microprocessor-controlled knee (X3 is water proof)</td>
<td>Otto Bock</td>
<td>L5999</td>
</tr>
<tr>
<td>IP +</td>
<td>Microprocessor-controlled knee</td>
<td>Endolite</td>
<td>L5857, L5830, L5616, L5845</td>
</tr>
<tr>
<td>Kinnex Foot</td>
<td>Microprocessor ankle/foot (waterproof)</td>
<td>Freedom Innovations</td>
<td>L5973</td>
</tr>
<tr>
<td>LINX®</td>
<td>Combination microprocessor-controlled knee and foot; additionally has sensors and actuators</td>
<td>Endolite</td>
<td>L5856, L5848, L5845, L5828, L5830, L5973</td>
</tr>
<tr>
<td>Meridium Foot</td>
<td>Microprocessor-controlled ankle foot</td>
<td>Otto Bock</td>
<td>L5999</td>
</tr>
<tr>
<td>Orion</td>
<td>Microprocessor-controlled knee</td>
<td>Endolite</td>
<td>L5856, L5848, L5845, L5828, L5830</td>
</tr>
<tr>
<td>Össur Power Knee</td>
<td>Motor powered knee</td>
<td>Össur</td>
<td>L5859, L5856, L5828, L5848, L5845</td>
</tr>
<tr>
<td>Plié 3</td>
<td>Microprocessor-controlled knee (submersible)</td>
<td>Freedom Innovation</td>
<td>L5856, L5848, L5845, L5828</td>
</tr>
<tr>
<td>Proprio Foot®</td>
<td>Microprocessor-controlled ankle foot</td>
<td>Össur</td>
<td>L5973</td>
</tr>
<tr>
<td>Raize Foot</td>
<td>Microprocessor foot (does not have the power ankle)</td>
<td>Fillauer</td>
<td>L5973</td>
</tr>
</tbody>
</table>
Rheo | Microprocessor-controlled knee | Össur | L5856, L5848, L5845, L5828
---|---|---|---
Rheo XC | Microprocessor-controlled knee (supports rehabilitation to full recovery) | Össur | L5856, L5848, L5845, L5828
SYMBIONIC® LEG 3 | Combination microprocessor-controlled knee and ankle with proactive ankle flexion | Össur | L5856, L5848, L5845, L5828, L5973

**LOWER LIMB: Vacuum Suspension System**

Suspension systems for lower limb prostheses keep the prosthesis in place, ensuring a good fit between the socket and residual limb. The intended function is to provide a connection that reduces rotational and shearing forces which can result in skin breakdown as well provide for balance and steady gait. Various types of suspension systems are available and include those that are primarily mechanical or suction-type systems. Mechanical systems involve the use of belts, straps, or sleeves, for example, to attach the device to the residual limb (L5666, L5670-L5672). Suction-type systems function by way of a negative pressure created between the socket and insert/liner. These devices can be passive (air escapes while donning via a one-way valve) or active (suction pump evacuates the air). Passive systems involve the use of a soft liner, a one-way valve and a donning sleeve. A liner is placed over the limb, the limb is placed in the socket and the force of one’s body weight upon standing expels excess air through the valve creating a seal. With active suction devices the sleeve creates a seal around the edge of the socket and a pump and exhaust remove the excess air between the socket and the liner to ensure a secure fit.

Various vacuum suction-type devices (mechanical or electrical) are available and include the Vacuum-Assisted Socket System (VASS™) (Otto Bock Harmony Vacuum-Assisted Socket System, Otto Bock HealthCare; Minneapolis, MN), the eVAC® (Smith, Global), and the LimbLogic™ VS prosthetic vacuum suspension system (Mount Sterling, Ohio). Each device is a vacuum suction-type suspension system 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. Although patient selection criteria have not been firmly established, the device has been proposed for individuals with non-healing skin ulcerations located on the stump and/or when other socket systems have failed to provide a secure fit.

Evidence in the published, peer-reviewed scientific literature evaluating suspension systems, in particular vacuum suction–type suspension systems is limited. Much of the published literature is in the form of feasibility trials, case reports, and uncontrolled case series involving small populations. Reported outcomes are mixed, are short term, lack high statistical power and cannot be generalized. The results of one 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.

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.

The published evidence does not provide strong support of clinical utility for this technology compared to conventional socket-suspension systems for the general population and clinical effectiveness has not been firmly established. The choice of a suspension system is determined by factors such as activity level, residual stump shape, age, and health status. There is some evidence in the published literature to support vacuum systems decrease limb volume fluctuations, can improve socket fit, reduce inside movement for some individuals, as well as improve comfort and satisfaction (Gholizadeh, et al., 2016). While additional long term studies and higher
quality data would be helpful for evaluating an active suction-type vacuum suspension system, for individuals where other types of suspension systems have failed to provide a secure fit or are contraindicated, a vacuum suction-type suspension system may be considered an effective alternative.

Centers for Medicare & Medicaid Services (CMS)
- National Coverage Determinations (NCD): No NCD found.
- Local Coverage Determination (LCD): Multiple LCDs found. Refer to the LCD table of contents link in the reference section.

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.

IRIS PROSTHESIS
Experimental/Investigational/Unproven

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1839</td>
<td>Iris prosthesis</td>
</tr>
</tbody>
</table>

EXTERNAL FACIAL PROSTHESIS
Considered Medically Necessary when criteria in the applicable policy statements listed above are met and only when coverage is available under the plan for the specific device/component/item.

Nasal Prosthesis
Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>21087</td>
<td>Impression and custom preparation; nasal prosthesis</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L8040</td>
<td>Nasal prosthesis, provided by a non-physician</td>
</tr>
<tr>
<td>L8047</td>
<td>Nasal septal prosthesis, provided by a non-physician</td>
</tr>
</tbody>
</table>

Orbit Prosthesis
Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>21077</td>
<td>Impression and custom preparation; orbital prosthesis</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L8042</td>
<td>Orbital prosthesis, provided by a non-physician</td>
</tr>
</tbody>
</table>

Ear Prosthesis
Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>21086</td>
<td>Impression and custom preparation; auricular prosthesis</td>
</tr>
</tbody>
</table>
**Facial Prosthesis**

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>21088</td>
<td>Impression and custom preparation; facial prosthesis</td>
</tr>
</tbody>
</table>

**Maxillofacial Prosthesis, External**

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L8048</td>
<td>Unspecified maxillofacial prosthesis, by report, provided by a non-physician</td>
</tr>
</tbody>
</table>

Considered not medically necessary when used to report non-covered consumable supplies outlined in the coverage policy:

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A4364</td>
<td>Adhesive, liquid or equal, any type, per ounce</td>
</tr>
<tr>
<td>A4450</td>
<td>Tape, non-waterproof, per 18 square inches</td>
</tr>
<tr>
<td>A4452</td>
<td>Tape, waterproof, per 18 square inches</td>
</tr>
<tr>
<td>A4455</td>
<td>Adhesive remover or solvent (for tape, cement or other adhesive), per ounce</td>
</tr>
<tr>
<td>A4456</td>
<td>Adhesive remover, wipes, any type, each</td>
</tr>
<tr>
<td>L9900</td>
<td>Orthotic and prosthetic supply, accessory, and/or service component of another HCPCS “L” code</td>
</tr>
</tbody>
</table>

**UPPER LIMB ADDITIONS/COMPONENTS**

Additional Components/Features of Non Myoelectric Prosthetic Device:

Considered medically necessary when used to report a medically necessary component or addition to an upper limb prosthetic device in the absence of a specific code:

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L6646</td>
<td>Upper extremity addition, shoulder joint, multipositional locking, flexion, adjustable abduction friction control, for use with body powered or external powered system</td>
</tr>
<tr>
<td>L6647</td>
<td>Upper extremity addition, shoulder lock mechanism, body powered actuator</td>
</tr>
<tr>
<td>L7499†</td>
<td>Upper extremity prosthesis, not otherwise specified</td>
</tr>
</tbody>
</table>

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

**UPPER LIMB: MYOELECTRIC PROSTHETIC DEVICE**
Considered Medically Necessary when criteria in the applicable policy statements listed above are met and only when coverage is available under the plan for the specific device/component/item:

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L6026</td>
<td>Transcarpal/metacarpal or partial hand disarticulation prosthesis, external power, self-suspended, inner socket with removable forearm section, electrodes and cables, two batteries, charger, myoelectric control of terminal device, excludes terminal device(s)</td>
</tr>
<tr>
<td>L6611</td>
<td>Addition to upper extremity prosthesis, external powered, additional switch, any type</td>
</tr>
<tr>
<td>L6638</td>
<td>Upper extremity addition to prosthesis, electric locking feature, only for use with manually powered elbow</td>
</tr>
<tr>
<td>L6646</td>
<td>Upper extremity addition, shoulder joint, multipositional locking, flexion, adjustable abduction friction control, for use with body powered or external powered system</td>
</tr>
<tr>
<td>L6647</td>
<td>Upper extremity addition, shoulder lock mechanism, body powered actuator</td>
</tr>
<tr>
<td>L6648</td>
<td>Upper extremity addition, shoulder lock mechanism, external powered actuator</td>
</tr>
<tr>
<td>L6715</td>
<td>Terminal device, multiple articulating digit, includes motor(s), initial issue or replacement</td>
</tr>
<tr>
<td>L6880</td>
<td>Electric hand, switch, or myoelectric controlled, independently articulating digits, any grasp pattern or combination of grasp patterns, includes motor(s)</td>
</tr>
<tr>
<td>L6881</td>
<td>Automatic grasp feature, addition to upper limb electric prosthetic terminal device</td>
</tr>
<tr>
<td>L6882</td>
<td>Microprocessor control feature, addition to upper limb prosthetic terminal device</td>
</tr>
<tr>
<td>L6920</td>
<td>Wrist disarticulation, external power, self-suspended inner socket, removable forearm shell, Otto Bock or equal, switch, cables, two batteries and one charger, switch control of terminal device</td>
</tr>
<tr>
<td>L6925</td>
<td>Wrist disarticulation, external power, self-suspended inner socket, removable forearm shell, Otto Bock or equal, electrodes, cables, two batteries and one charger, myoelectronic control of terminal device</td>
</tr>
<tr>
<td>L6930</td>
<td>Below elbow, external power, self-suspended inner socket, removable forearm shell, Otto Bock or equal switch, cables, two batteries and one charger, switch control of terminal device</td>
</tr>
<tr>
<td>L6935</td>
<td>Below elbow, external power, self-suspended inner socket, removable forearm shell, Otto Bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device</td>
</tr>
<tr>
<td>L6940</td>
<td>Elbow disarticulation, external power, molded inner socket, removable humeral shell, outside locking hinges, forearm, Otto Bock or equal switch, cables, two batteries and one charger, switch control of terminal device</td>
</tr>
<tr>
<td>L6945</td>
<td>Elbow disarticulation, external power, molded inner socket, removable humeral shell, outside locking hinges, forearm, Otto Bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device</td>
</tr>
<tr>
<td>L6950</td>
<td>Above elbow, external power, molded inner socket, removable humeral shell, internal locking elbow, forearm, Otto Bock or equal switch, cables, two batteries and one charger, switch control of terminal device</td>
</tr>
<tr>
<td>L6955</td>
<td>Above elbow, external power, molded inner socket, removable humeral shell, internal locking elbow, forearm, Otto Bock or equal electrodes, cables, two batteries and one charger, myoelectric control of terminal device</td>
</tr>
<tr>
<td>L6960</td>
<td>Shoulder disarticulation, external power, molded inner socket, removable shoulder shell, shoulder bulkhead, humeral section, mechanical elbow, forearm, Otto Bock or equal switch, cables, two batteries and one charger, switch control of terminal device</td>
</tr>
<tr>
<td>L6965</td>
<td>Shoulder disarticulation, external power, molded inner socket, removable shoulder shell, shoulder bulkhead, humeral section, mechanical elbow, forearm, Otto Bock or equal electrodes, cables, two batteries and one charger, myoelectric control of terminal device</td>
</tr>
<tr>
<td>L6970</td>
<td>Interscapular-thoracic, external power, molded inner socket, removable shoulder shell, shoulder bulkhead, humeral section, mechanical elbow, forearm, Otto Bock or equal switch, cables, two batteries and one charger, switch control of terminal device</td>
</tr>
<tr>
<td>L6975</td>
<td>Interscapular-thoracic, external power, molded inner socket, removable shoulder shell, shoulder bulkhead, humeral section, mechanical elbow, forearm, Otto Bock or equal electrodes, cables, two batteries and one charger, myoelectric control of terminal device</td>
</tr>
<tr>
<td>HCPCS Codes</td>
<td>Description</td>
</tr>
<tr>
<td>-------------</td>
<td>-------------</td>
</tr>
<tr>
<td>L7007</td>
<td>Electric hand, switch or myoelectric controlled, adult</td>
</tr>
<tr>
<td>L7008</td>
<td>Electric hand, switch or myoelectric controlled, pediatric</td>
</tr>
<tr>
<td>L7009</td>
<td>Electric hook, switch or myoelectric controlled, adult</td>
</tr>
<tr>
<td>L7040</td>
<td>Prehensile actuator, switch controlled</td>
</tr>
<tr>
<td>L7045</td>
<td>Electric hook, switch or myoelectric controlled, pediatric</td>
</tr>
<tr>
<td>L7170</td>
<td>Electronic elbow, Hosmer or equal, switch controlled</td>
</tr>
<tr>
<td>L7180</td>
<td>Electronic elbow, microprocessor sequential control of elbow and terminal device</td>
</tr>
<tr>
<td>L7181</td>
<td>Electronic elbow, microprocessor simultaneous control of elbow and terminal device</td>
</tr>
<tr>
<td>L7185</td>
<td>Electronic elbow, adolescent, Variety Village or equal, switch controlled</td>
</tr>
<tr>
<td>L7186</td>
<td>Electronic elbow, child, Variety Village or equal, switch controlled</td>
</tr>
<tr>
<td>L7190</td>
<td>Electronic elbow, adolescent, Variety Village or equal, myoelectronically controlled</td>
</tr>
<tr>
<td>L7191</td>
<td>Electronic elbow, child, Variety Village or equal, myoelectronically controlled</td>
</tr>
<tr>
<td>L7259</td>
<td>Electronic wrist rotator, any type</td>
</tr>
<tr>
<td>L7499</td>
<td>Upper extremity prosthesis, not otherwise specified</td>
</tr>
</tbody>
</table>

†Note: Considered Medically Necessary when used to report components and/or additions to an upper limb prosthetic myoelectric device, if coverage for a myoelectric prosthetic device is available, and when medical necessity criteria are met.

Experimental/ Investigational/ Unproven when used to report an upper limb sensor and myoelectric controlled prosthetic device with simultaneous multiple degrees of freedom (e.g., LUKE [Life Under Kinetic Evolution] Arm)

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L7499</td>
<td>Upper extremity prosthesis, not otherwise specified</td>
</tr>
</tbody>
</table>

LOWER LIMB: MECHANICAL (NON-POWERED, NON MICROPROCESSOR)
Considered medically necessary when used to report a component or addition to a lower limb prosthetic device when criteria in the applicable policy statements listed above are met and when coverage is available under the plan for the specific device/component/item:

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L5828†</td>
<td>Addition, endoskeletal knee-shin system, single axis, fluid swing and stance phase control</td>
</tr>
<tr>
<td>L5845††</td>
<td>Addition, endoskeletal knee-shin system, stance flexion feature, adjustable</td>
</tr>
<tr>
<td>L5848†</td>
<td>Addition to endoskeletal, knee-shin system, fluid stance extension, dampening feature, with or without adjustability</td>
</tr>
<tr>
<td>L5930†††</td>
<td>Addition, endoskeletal system, high activity knee control frame</td>
</tr>
<tr>
<td>L5981†</td>
<td>All lower extremity prostheses, flex-walk system or equal</td>
</tr>
<tr>
<td>L5999††††</td>
<td>Lower extremity prosthesis, not otherwise specified</td>
</tr>
</tbody>
</table>

†Note: Considered medically necessary for functional level 3 or above when medical necessity criteria has been met for the base device.

††Note: Considered medically necessary for functional level 1 or above when medical necessity criteria has been met for the base device.

†††Note: Requires K-4 functional level and when medical necessity criteria has been met for the base device.

††††Note: Considered medically necessary when used to report a medically necessary component or addition to a lower limb prosthetic device in the absence of a more specific code and when medical necessity criteria has been met for the base device.

LOWER LIMB MICROPROCESSOR-CONTROLLED PROSTHETIC DEVICES
Considered Medically Necessary when criteria in the applicable policy statements listed above are met and when benefits are available under the plan for a microprocessor-controlled prosthetic:

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L5856</td>
<td>Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type</td>
</tr>
<tr>
<td>L5857</td>
<td>Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing phase only, includes electronic sensor(s), any type</td>
</tr>
<tr>
<td>L5858</td>
<td>Addition to lower extremity prosthesis, endoskeletal knee shin system, microprocessor control feature, stance phase only, includes electronic sensor(s), any type</td>
</tr>
<tr>
<td>L5973</td>
<td>Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, includes power source</td>
</tr>
</tbody>
</table>

**Additional Components/Features of Microprocessor-Controlled Prosthetic Devices:**

Considered Medically Necessary when criteria in the applicable policy statements listed above are met and when benefits are available under the plan for a microprocessor-controlled prosthetic:

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

†Note: L5930 requires K-4 functional level.

‡‡Note: Covered when used to report a medically necessary component/feature or addition to a lower limb prosthetic microprocessor-controlled device in the absence of a specific code.

**LOWER LIMB: POWERED MICROPROCESSOR-CONTROLLED PROSTHETIC DEVICES**

Considered Medically Necessary and when benefits are available for a power-controlled or power-assisted lower limb knee device (e.g., Ossur Power Knee):

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L5859 †</td>
<td>Addition to lower extremity prosthesis, endoskeletal knee-shin system, powered and programmable flexion/extension assist control, includes any type motor(s)</td>
</tr>
</tbody>
</table>

†Note: L5859 requires K-3 functional level; the device is not intended for high impact activity, sports, excessive loading or heavy duty use.

**Microprocessor-Controlled Ankle Foot Prosthetic with Power Assist (e.g., BiOM® Ankle, emPOWER™ Ankle)**

Experimental/Investigational/Unproven:
HCPCS Codes | Description
---|---
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 when reported in addition to a non-covered power-controlled (L5859, L5973) or power-assisted (L5969) prosthetic device:

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L5828</td>
<td>Addition, endoskeletal knee-shin system, single axis, fluid swing and stance phase control</td>
</tr>
<tr>
<td>L5845</td>
<td>Addition, endoskeletal knee-shin system, stance flexion feature, adjustable</td>
</tr>
<tr>
<td>L5848</td>
<td>Addition to endoskeletal knee-shin system, fluid stance extension, dampening feature, with or without adjustability</td>
</tr>
<tr>
<td>L5856</td>
<td>Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type</td>
</tr>
<tr>
<td>L5969</td>
<td>Addition, endoskeletal ankle-foot or ankle system, power assist, includes any type motor(s)</td>
</tr>
</tbody>
</table>

LOWER LIMB: VACUUM SUSPENSION SYSTEM

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L5781</td>
<td>Addition to lower limb prosthesis, vacuum pump, residual limb volume management and moisture evacuation system</td>
</tr>
<tr>
<td>L5782</td>
<td>Addition to lower limb prosthesis, vacuum pump, residual limb volume management and moisture evacuation system, heavy duty</td>
</tr>
</tbody>
</table>

REPAIR AND REPLACEMENT

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L7510</td>
<td>Repair of prosthetic device, repair or replace minor parts</td>
</tr>
<tr>
<td>L7520</td>
<td>Repair prosthetic device, labor component, per 15 minutes</td>
</tr>
<tr>
<td>L8049</td>
<td>Repair or modification of maxillofacial prosthesis, labor component, 15 minute increments, provided by a non-physician</td>
</tr>
</tbody>
</table>


References


18. Centers for Medicare and Medicaid Services (CMS) Local Coverage Determination. Lower Limb Prosthesis (L33787). Revision effective date 10/1/2018. Available at URL address:


55. Hayes, Inc. Health Technology Brief. The available studies provide preliminary evidence that, compared with mechanical prostheses, the C-Leg prosthesis improves the mobility of selected unilateral transfemoral amputees. Lansdale, PA: Hayes, Inc. Published Jan 30, 2013; reviewed Jan 12, 2015, archived March 2016.


