



**BlueCross BlueShield
of Alabama**

Name of Policy:

Lower Limb Prostheses

Policy #: 094

Category: Durable Medical Equipment

Latest Review Date: October 2018

Policy Grade: D

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

- 1. The technology must have final approval from the appropriate government regulatory bodies;*
- 2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
- 3. The technology must improve the net health outcome;*
- 4. The technology must be as beneficial as any established alternatives;*
- 5. The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

- 1. In accordance with generally accepted standards of medical practice; and*
- 2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
- 3. Not primarily for the convenience of the patient, physician or other health care provider; and*
- 4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

The definition of prosthesis is an artificial substitute that replaces all or part of a body organ, or replaces all or part of the function of a permanently inoperative, absent, or malfunctioning body part. Lower limb prostheses may include a number of components, such as prosthetic feet, ankles, knees, endoskeletal knee-shin systems, socket insertions and suspensions, lower limb-hip prostheses, and limb-ankle prostheses.

Lower Limb Prosthesis

A lower limb prosthesis is designed to replace portions of the lower extremity to improve function. A prosthetic knee performs several functions: it provides support during the stance phase of ambulation, produces smooth control during the swing phase and maintains unrestricted motion for sitting and kneeling. The prosthetic knee may have a single axis with a simple hinge and a single pivot point or it may have a polycentric axis with multiple centers of rotation, which is more similar to the anatomic human knee. Pylons are the connection between the residual limb and the prosthetic joint.

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)

Knee Prosthetics

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. 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.

Prosthetic Feet

The prosthetic foot also has several basic functions: provides a stable weight-bearing surface, absorbs shock, replaces lost muscle function and biomechanics of the foot, replicates the anatomic joints of the ankle and foot and restores appearance.

Multiaxial prosthetic feet permit movements in any direction: plantar flexion, dorsiflexion, inversion, eversion and a slight amount of rotation around a vertical axis. Multiaxial feet are appropriate for those who ambulate on uneven terrain, such as community ambulators and active adults or athletes.

The solid ankle cushion heel (SACH) consists of a rigid keel covered by semi-noncompressible foam and a synthetic rubber heel wedge. The cushion heel compresses when weight is applied, allowing the forefoot to approach the floor. The amount of simulated plantar flexion depends on the relative softness of the heel material and weight of the amputee. Because the keel is rigid, the SACH foot does not provide dorsiflexion; this makes its usefulness on uneven surfaces limited.

Policy:

Lower limb prosthesis meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage when the following criteria are met:

- **The patient will reach or maintain a defined functional state within a reasonable period of time;**
- **The patient is motivated to ambulate; and**
- **The prosthesis is furnished incident to a physician's services or on a physician's order.**

Determination of medical criteria for coverage for prostheses is also based on the patient's potential functional level (*see Key Points*).

Replacement or repair of prosthetic parts or prosthesis meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage when there is **adequate documentation of functional and/or physiological need** such as, but not limited to; changes in the residual limb, functional need changes, or irreparable damage or wear/tear due to excessive patient weight or prosthetic demands of very active amputees.

Prosthetic Feet

Medical criteria for coverage for selected foot prostheses and components is determined according to potential functional levels (*see Key Points*). Determination of the type of prosthetic foot will be made by the prescribing physician and/or prosthetist based on the functional needs of the patient.

External keel (L5972), SACH foot (L5970) or single axis ankle/foot (L5974) meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage for patients with functional **Level 1 or above** (*see Key Points*).

Flexible-keel foot (L5972) and multiaxial ankle/foot (L5978) meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage for patients with **functional Level 2 or greater** (*see Key Points*).

Flex foot system (L5980), energy storing foot (L5976), multiaxial, dynamic response ankle/foot (L5979), or flex walk system or equal (L5981) or shank foot system with vertical loading pylon (L5987) meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage for patients with **functional Level 3 or above** (*see Key Points*).

Prosthetic Knee

Medical criteria for coverage for selected knee prostheses and components is determined according to potential functional levels (*see Key Points*). Determination of the type of prosthetic knee will be made by the prescribing physician and/or prosthetist based on the functional needs of the patient.

Knee systems L5611, L5616, L5710-L5718, and L5810-L5818 meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage for patients with **functional Level 1 or above** (*see Key Points*).

Fluid and pneumatic knees (L5610, L5613, L5614, L5722-L5780, L5822-L5840) meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage for patients with functional **Level 3 or above** (*see Key Points*).

See Medical Policy #083 for coverage of Microprocessor/ Computerized Knee Prostheses.

Prosthetic Ankle

Axial rotation units (L5982-L5986) meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage for patients with **functional Level 2 or above** (*see Key Points*).

Sockets

Test (diagnostic) sockets for immediate prostheses (L5618-L5628 when used with **L5400-L5460)** **does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **non-covered**. Immediate prostheses **do** meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage.

Test sockets for permanent prostheses meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage.

Blue Cross and Blue Shield of Alabama will **cover no more than two of the same socket inserts (L5654-L5665) per individual prosthesis at the same time.**

Socket replacements meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage when there is **adequate documentation of functional and/or physiological need** such as, but not limited to; changes in the residual limb, functional need changes, or irreparable damage or wear/tear due to excessive patient weight or prosthetic demands of very active amputees.

Lifelike components (i.e., silicone covered prosthesis) **do not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and are considered **cosmetic**. Consideration will be given for reimbursement of a basic component if the basic component meets medical criteria for coverage.

Vacuum Assisted Socket Systems (e.g. VASS™; Otto Bock Harmony® P4 System) **does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational** due to a lack of evidence in the published peer-reviewed literature.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

The most recent literature search for this policy was performed through October 2018.

There are nearly 2 million people living with limb loss in the United States. Among those living with limb loss, the main causes are vascular disease (54%) – including diabetes and peripheral arterial disease – trauma (45%) and cancer (less than 2%). Approximately 185,000 amputations occur in the United States each year. Approximately 70% are lower-limb amputations.

People with lower-limb amputations walk slower and use a less efficient, asymmetrical gait compared to normal subjects with non-pathological gait. The more proximal the amputations, the more exacerbated these differences are.

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

- a) the patient's past history (including prior prosthetic use if applicable);
- b) the patient's current condition including the status of the residual limb and the nature of other medical problems; and
- c) the patient's desire to ambulate.

Clinical assessments of the patient's rehabilitation potential should be based on the following classification levels. Medical records should document the patient's current functional capabilities and his/her expected functional potential, including an explanation for the difference, if that is the case.

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 their quality of life or mobility.
Level 1	Has the ability or potential to use prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.
Level 2	Has the ability or potential for ambulation with the ability to traverse low-level

	environmental barriers such as curbs, stairs or uneven surfaces. Typical of the limited community ambulator.
Level 3	Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
Level 4	Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the active adult.

Vacuum-assisted Socket

A residual limb volume management and moisture evacuation system (e.g., Vacuum Assisted Socket System [VASS]) is a specialized device used with artificial limbs in an attempt to manage residual limb volume fluctuation. The system consists of a liner, suspension sleeve and air evacuation pump. The device creates an elevated vacuum between the liner and the socket wall. The elevated vacuum attempts to promote natural fluid exchange to regulate volume fluctuation in the residual limb, reduce forces to the residual limb and increase suspension and balance.

The Vacuum Assisted Socket System (VASS), developed by Total Environmental Control (TEC), is a specialized device used with artificial limbs to manage residual limb volume fluctuation in amputees. The manufacturer claims that the enhanced linkage from the vacuum between the liner and the socket wall decreases weight and promotes an improved gait.

A polyurethane liner sits directly against the skin, and a suspension sleeve creates a seal between the prosthesis and the residual limb. A Harmony® 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, providing the control of the prosthesis and reducing the shearing forces to the skin and tissue.

Murphy (2014) stated that elevated vacuum systems are a form of suspension that is becoming more often used and seen in the younger population of wearers requiring a continued level of suspension throughout a variety of activities. An elevated vacuum system uses a draw pump to draw air out of the socket pulling air from between the residuum and the inner socket to maintain the tissue against the walls of the socket at a desired level of vacuum within the confines of the socket, thus preventing movement in all directions. The suspension is not for those with inconsistent volume loss requiring frequent sock ply management.

In a randomized controlled study, Trallesi et al (2012) examined the effects of a vacuum-assisted socket system (VASS) in a sample of trans-tibial amputees with wounds or ulcers on the stump and evaluated prosthesis use as a primary outcome. Secondary outcome measures were

mobility with the prosthesis, pain associated with prosthesis use, and wound/ulcer healing. A total of 20 dysvascular trans-tibial amputees suffering from ulcers due to prosthesis use or delayed wound healing post-amputation were enrolled. Participants were separated into 2 groups: the experimental group was trained to use a VASS prosthesis in the presence of open ulcers/wounds on the stump; and the control group was trained to use a standard suction socket system prosthesis following ulcers/wounds healing. The experimental group was trained to use a VASS prosthesis in the presence of open ulcers/wounds on the stump; and the control group was trained to use a standard suction socket system prosthesis following ulcers/wounds healing.

At the end of the 12-week rehabilitation program, all VASS users were able to walk independently with their prosthesis as reflected by a median Locomotor Capability Index (LCI) value of 42, whereas only 5 participants in the control group were able to walk independently with a median LCI value of 21. At the 2-month follow-up, the participants used their VASS prostheses for 62 hours a week (median; range of 0 to 91), which was significantly longer than the control group using the standard prosthesis for 5 hours per week (range of 0 to 56, $p = 0.003$). At the 6-month follow-up, the difference between VASS-users (80, range of 0 to 112 hours a weeks) and control-users (59, range of 0 to 91) was no longer significant ($p = 0.191$). Despite more intense use of the prosthesis, pain and wound healing did not significantly differ between the 2 groups. The authors concluded that these findings showed that the VASS prosthesis allowed early fitting with prompt ambulation recovery without inhibiting wound healing or increasing pain.

Samitier et al (2016) investigated the effect of vacuum-assisted socket system on transtibial amputees' performance-based and perceived balance, transfers, and gait. Subjects were initially assessed using their prosthesis with the regular socket and re-evaluated 4 weeks after fitting including the vacuum-assisted socket system. These researchers evaluated the mobility grade using Medicare Functional Classification Level, Berg Balance Scale, Four Square Step Test, Timed Up and Go Test, the 6-Min Walk Test, the Locomotor Capabilities Index, Satisfaction with Prosthesis (SAT-PRO questionnaire), and Houghton Scale. A total of 16 unilateral transtibial dysvascular amputees, mean age of 65.12 (standard deviation = 10.15) years were included. Using the vacuum-assisted socket system, the patients significantly improved in balance, gait, and transfers: scores of the Berg Balance Scale increased from 45.75 (standard deviation = 6.91) to 49.06 (standard deviation = 5.62) ($p < 0.01$). Four Square Step Test decreased from 18.18 (standard deviation = 3.84) s to 14.97 (3.9) s ($p < 0.01$). Timed Up and Go Test decreased from 14.3 (standard deviation = 3.29) s to 11.56 (2.46) s ($p < 0.01$). The distance walked in the 6-Min Walk Test increased from 288.53 (standard deviation = 59.57) m to 321.38 (standard deviation = 72.81) m ($p < 0.01$). The investigators concluded that vacuum-assisted socket systems are useful for improving balance, gait, and transfers in over 50-year old dysvascular transtibial amputees. Due to the lack of published peer-reviewed literature this socket system is not covered and is considered investigational.

Prosthesis Fitting

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. Pinzur (2003) writes that immediate postoperative prosthetic limb fitting has not gained

wide acceptance due to unacceptable rates of wound complications . Additionally, immediate postoperative or initial prostheses require frequent adjustments and changes, some as frequent as every 7 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 6 weeks to 3 months, depending on response and condition noted by 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.

Summary of Evidence

Appropriate selection of componentry for prosthetic restoration of the amputee is an extremely important and challenging task in view of the variety and complexity of available prosthetic devices and the functional requirements of patients. After prescription and fitting of the device, training is indispensable and should include prosthetic management and functional training with the goal of achieving community reintegration.

Key Words:

Prosthetic leg, prosthetic knee, prosthetic ankle, prosthetic foot, leg prosthesis, foot prosthesis, ankle prosthesis, knee prosthesis, artificial leg, artificial knee, artificial ankle, artificial foot, vacuum assisted socket system, VASS

Approved by Governing Bodies:

Not applicable

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply

FEP contracts: Special benefit consideration may apply. Refer to member's benefit plan.

Coding:

CPT codes:	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
	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, bent knee configuration, external knee
- L5160** Knee disarticulation (or through knee), molded socket, bent knee configuration, external knee
- 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
- L5250** Hip disarticulation, Canadian type; molded socket, hip joint, single axis constant friction knee, shin, SACH foot
- L5270** Hip disarticulation, tilt table type; molded socket, locking hip joint, single axis constant friction knee, shin, SACH foot
- L5280** Hemipelvectomy, Canadian type; molded socket, hip joint, single axis constant friction knee, shin, SACH foot
- L5301** Below knee, molded socket, shin, SACH 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
- L5331** Hip disarticulation, Canadian type; molded socket, endoskeletal system, hip joint, single axis knee, SACH foot
- L5341** Hemipelvectomy, Canadian type; molded socket, endoskeletal system, hip joint, single axis knee, SACH foot
- L5400** Immediate post surgical or early fitting, application of initial rigid dressing, including fitting, alignment and suspension, below knee, each additional cast change and realignment
- L5410** Immediate post surgical or early fitting, application of initial rigid dressing, including fitting, alignment and suspension, below knee, each additional cast change and realignment
- L5420** Immediate post surgical or early fitting, application of initial rigid dressing, including fitting, alignment and suspension and one cast change "AK" or knee disarticulation
- L5430** Immediate post surgical 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 post surgical or early fitting, application of non-weight bearing rigid dressing, above knee
- L5460** Immediate post surgical 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, plaster socket, molded to model
- 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
- L5595** Preparatory, hip disarticulation-hemipelvectomy, pylon, no cover, SACH foot, thermoplastic or equal, molded to patient model
- L5600** Preparatory, hip disarticulation-hemipelvectomy, pylon, no cover, SACH foot, laminated socket, molded to patient model
- L5610** Addition to lower extremity, endoskeletal system, above knee, Hydracadence 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, exoskeletal system, above knee-knee disarticulation, 4-bar 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 knee 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
- L5626** Addition to lower extremity, test socket, hip disarticulation
- L5628** Addition to lower extremity, test socket, hemipelvectomy
- 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
- L5643** Addition to lower extremity, hip disarticulation, flexible inner socket, 184
- 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 cushion socket
- L5647** Addition to lower extremity, below knee, suction socket
- L5648** Addition to lower extremity, above knee, air cushion socket
- L5649** Addition to lower extremity, ischial containment/narrow M-L 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, multi-durometer Symes

- L5665** Addition to lower extremity, socket insert, multi-durometer, 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** Additions to lower extremity, below knee, knee joints, single axis, pair
- L5677** Additions to lower extremity, below knee, knee joints, polycentric, pair
- L5678** Additions 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, non-molded
- 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
- 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
- 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 joint
- 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
- L5702** Replacement, socket, hip disarticulation, including hip joint, molded to patient model
- L5703** Ankle, Symes, molded to patient model, socket without solid ankle cushion heel
- L5704** Custom shaped protective cover, below knee
- L5705** Custom shaped protective cover, above knee
- L5706** Custom shaped protective cover, knee disarticulation
- L5707** Custom shaped protective cover, hip 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/hydra pneumatic swing phase control
- 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
- 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)

- L5795** Addition, exoskeletal system, hip disarticulation, 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** 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 multiaxial, pneumatic swing 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
- L5850** Addition, endoskeletal system, above knee or hip disarticulation, knee extension assist
- L5855** Addition, endoskeletal system, hip disarticulation, mechanical hip extension assist
- L5858** Addition to lower extremity prosthesis, endoskeletal knee shin system, microprocessor control feature, stance phase only, includes electronic sensor(s), any type
- 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)

- L5960** Addition, endoskeletal system, hip disarticulation, 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
- L5966** Addition, endoskeletal system, hip disarticulation, flexible protective outer surface covering system
- L5968** Addition to lower limb prosthesis, multiaxial ankle with swing phase active dorsiflexion feature
- L5970** All lower extremity prostheses, foot, external keel, SACH foot
- L5971** All lower extremity prosthesis, 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, multiaxial ankle/foot
- L5979** All lower extremity prostheses, multiaxial 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
- 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
- L5988** Addition to lower limb prosthesis, vertical shock reducing pylon feature
- L5990** Addition to lower extremity prosthesis, user adjustable heel height
- L5999** Lower extremity prosthesis, not otherwise specified
- L7510** Repair of prosthetic device, repair or replace minor parts
- L7520** Repair prosthetic device, labor component, per 15 minutes
- L7700** Gasket or seal, for use with prosthetic socket insert, any type, each
(Effective 01/01/2018)
- 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

HCPCS modifiers: **K0** Functional Level 0; *see Key Points*
 K1 Functional Level 1; *see Key Points*
 K2 Functional Level 2; *see Key Points*
 K3 Functional Level 3; *see Key Points*
 K4 Functional Level 4; *see Key Points*

References:

1. Alaranta, H., Kinnunen, A., et al. Practical benefits of flex-foot™ in below-knee amputees, *Journal of Prosthetics and Orthotics* 1991, Vol. 3, No. 4, pp. 179-181.
2. Anzel, Stanford H., Perry, Jacquelin, et al. Prosthetic design for dysvascular below-knee amputees, Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Project #A735-RA, www.var.org/prog/94/ch01/pr94020.htm.
3. Anzel, Stanford H., Perry, Jacquelin, et al. Prosthetic foot design for the dysvascular below-knee amputee, Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Project #A735-RA, www.var.org/prog/95/ch01/pr95024.htm.
4. Beil TL, Street GM and covey SJ. Interface pressures during ambulation using suction and vacuum-assisted prosthetic sockets. *Journal of Rehabilitation Research and Development*, November/December 2002, Vol. 39, No. 6, pp. 693-700.
5. Bodeau Valerie S, et al. Lower limb prosthetics, August 27, 2002 www.emedicine.com/pmr/topic175.htm.
6. Centers for Medicare and Medicaid Services (CMS). LCD for lower limb prostheses (L11442). January 2010.
7. Esquenazi, A., Amputation rehabilitation and prosthetic restoration. From surgery to community reintegration, *Disability and Rehabilitation*, 2004; Vol 26, No. 14/15, 831-836.
8. Hafner, B.J., Sanders, J.E., et al. Energy storage and return prostheses: Does patient perception correlate with biomechanical analysis, *Clin Biomech (Bristol, Avon)* June 2002; 17(5): 325-44.
9. Klute, Glenn K., et al. Mechanical properties of prosthetic limbs: Adapting to the patient, *Journal of Rehabilitation Research and Development*, May/June 2001, Vol. 38, No. 3, www.var.org/jour/01/38/3/klute383.htm.
10. Macfarlane, Pamela A., et al. Gait comparisons for below-knee amputees using a flex-foot™ versus a conventional prosthetic foot, *Journal of Prosthetics and Orthotics* 1991, Vol. 3, No. 4, pp. 150-161.
11. Macfarlane, Pamela A., et al. Mechanical gait analysis of transfemoral amputees: SACH foot versus the flex-foot, *Journal of Prosthetics and Orthotics* 1997, Vol. 9, No. 4, pp. 144-151.
12. Macfarlane, Pamela A., et al. Perception of walking difficulty by below-knee amputees using a conventional foot versus the flex-foot, *Journal of Prosthetics and Orthotics* 1991, vol. 3, No. 3, pp. 114-119.

13. Macfarlane, Pamela A., et al. Transfemoral amputee physiological requirements: Comparisons between SACH foot walking and flex-foot [sic] walking, *Journal of Prosthetics and Orthotics* 1997, Vol. 9, No. 4, pp. 138-143.
14. Martin CW; WCB Evidence Based Group. Otto Bock C-leg®: A review of its effectiveness for special care services. Assessment prepared for Workers Compensation Board of British Columbia, Compensation and Rehabilitation Services Division. Vancouver, BC: Workers Compensation Board of British Columbia; November 27, 2003.
15. Menard, Michael R. and Murray, D. Duncan. Subjective and objective analysis of an energy-storing prosthetic foot, *Journal of Prosthetics and Orthotics*, Vol. 1, No. 4, pp. 220-230.
16. Menard, Michael R. et al. Comparative biomechanical analysis of energy-storing prosthetic feet, *Arch Phys Med Rehabil*, May 1992, Vol. 73, pp. 451-458.
17. Murphy D. *Fundamentals of amputation care and prosthetics*. New York, NY: Demos Medical Publishing, LLC; 2014.
18. Pinzur MS. Prosthetic considerations. In: Browner BD, Jupiter JB, Levine AM, Trafton PG, editors. *Skeletal Trauma: Basic Science, Management, and Reconstruction*, 3rd ed. 2003. Chapter 64.
19. Samitier CB, Guirao L, Costea M, et al. The benefits of using a vacuum-assisted socket system to improve balance and gait in elderly transtibial amputees. *Prosthet Orthot Int*. 2016;40(1):83-88.
20. Sherman RA, Casey Jones DE. *The amputees guide to the amputation and recovery process*. Second edition, 1995. Accessed August 14, 2013. Available at URL address: <http://www.fizjoterapeutom.pl/files/13/amputeeguide.pdf>
21. Traballese M, Delussu AS, Fusco A, et al. Residual limb wounds or ulcers heal in transtibial amputees using an active suction socket system. A randomized controlled study. *Eur J Phys Rehabil Med*. 2012;48(4):613-623.
22. www.palmettogba.com/palmetto/LMRPs_DMERC.nsf/9a111459ebdc924685256a76.

Policy History:

- Medical Policy Group, February 2003 (2)
- Medical Policy Administration Committee, February 2003
- Available for comment April 1-May 16, 2003
- Medical Policy Group, July 2004
- Medical Policy Administration Committee, August 2004
- Available for comment August 12-September 25, 2004
- Medical Policy Group, January 2006 (1)
- Medical Policy Group, August 2006 (2)
- Medical Policy Administration Committee, August 2006
- Available for comment August 15-September 28, 2006
- Medical Policy Group, April 2007 (2)
- Medical Policy Administration Committee May 2007
- Available for comment May 8-June 21, 2007
- Medical Policy Group, August 2007 (3)
- Medical Policy Administration Committee, August 2007
- Available for comment September 27-November 13, 2007

Medical Policy Group, February 2009 **(1)**

Medical Policy Group, August 2010 **(1)** Added non-coverage statement for VASS, Key Points

Medical Policy Administration Committee, August 2010

Available for comment August 6-September 4, 20107700

Medical Policy Administration Committee, September 2010

Available for comment September 4-October 18, 2010

Medical Policy Group, October 2010

Medical Policy Group, December 2011(1): 2012 Code updates; Code L5311 was deleted and Code L5312 was added effective January 1, 2012.

Medical Policy Group, February 2015 **(6)**: 2015 Updates – annual review of policy, cleaned up coding section – removing deleted codes and adding new codes; no change to policy statement

Medical Policy Group, December 2017: Annual Coding Update 2017. Added new HCPCS code L7700 to Current Coding.

Medical Policy Group, October 2018 **(6)**: Updates to Description, Key Points and References. No change to policy intent.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.