I. POLICY

Mechanical (non-myoelectric non- microprocessor) prosthetics

Upper Extremity or Lower Extremity mechanical prosthetics may be considered medically necessary and appropriate when:

- They are used to replace absent limbs; and
- They are prescribed by a physician; and
- There is sufficient clinical documentation of functional need for the technologic or design features of a given type of prosthetic; and
- For Lower Extremity Prosthetics: In addition to the above criteria, the prosthetic device is appropriate to the patient’s level of prosthetic ambulation. (See levels listed below in the definitions section).

Fitting, necessary adjustments, and repairs of prosthetic devices which replace all or part of an absent limb may be considered medically necessary.

Replacement of medically necessary prosthetic devices or parts may be considered medically necessary if it is determined that the replacement device or part is required due to any of the following (for sockets see below):

- A change in the physiological condition of the patient; or
- An irreparable change in the condition of the device or in a part of the device; or
- The condition of the device, or the part of the device, requires repairs and the cost of the repairs would be more than 60 percent of the cost of a replacement device, or of the part being replaced.
Lower Extremity prostheses are considered not medically necessary if the patient has no ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance the quality of life or mobility (functional level of 0).

Sockets
A flex socket may be considered medically necessary for above knee amputations resulting in a short residual limb.

A flexible inner socket with rigid outer frame is considered medically necessary only for above the knee amputations (see background).

Socket replacements may be considered medically necessary for problems including, but not limited to, changes in the residual limb, functional need changes, surgical revision of the residual limb, or irreparable damage or wear and tear (see below).

The following documentation must be included when requesting a socket replacement:

- Detailed history and documentation of socket fit issues including current socket style; and repetitive office visits to evaluate and modify the socket;
- Interventions attempted at multiple visits, including various pads added within the socket and/or addition sock plys and/or socket grinding if too small;
- Functional need changes (e.g., weight gain or loss, neuropathy, decreased balance, etc.);
- Changes in residual limb (e.g., circumferential limb measurements, when the socket was initially made and current, other anatomical changes);
- Documentation of irreparable damage or wear/tear.
- Specific documentation of the need for replacement of non-socket components, including new shaped material, as these are separate components from the socket itself.

Replacement of non-socket components is considered not medically necessary when a socket replacement is necessary but there is no irreparable change in non-socket components.

The following sockets are considered not medically necessary:

- A test socket for an immediate post-operative prosthesis (IPOP).
- More than 2 test (diagnostic) sockets for an individual prosthesis without documentation in the medical record that justifies the need.
- More than two of the same socket inserts per individual prosthesis at the same time.
- A flex socket or flexible inner socket for below knee amputations without specific documentation of rationale (see background).
- Air cushion sockets.
- Vacuum-assisted socket systems (e.g. VASS™) as there are less intensive alternative methods at least as likely to produce equivalent functional results (see Background).

**Accessories/Components**

High activity frames and acrylic resin may be considered **medically necessary** only with documentation of planned regular heavy lifting or heavy work requiring these heavy-duty, extra strength components.

Accessories such as stockings for residual limbs, harnesses, etc. may be considered **medically necessary** when these appliances aid in or are essential to the effective use of the prosthetic limb.

Definitive prosthetics, except foot components prescribed less than three months after an amputation are considered **not medically necessary**.

**Cross-reference:**
- MP-6.042 Microprocessor Controlled Prostheses for the Lower Limb
- MP-6.052 Myoelectric Prosthetic Components for the Upper Limb

**II. PRODUCT VARIATIONS**

This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

BlueJourney HMO* BlueJourney PPO* FEP PPO**

* Refer to DME MAC A (Noridian) LCD, L33787 Lower Limb Prostheses.

**The FEP program dictates that all drugs, devices or biological products approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational. Therefore, FDA-approved drugs, devices or biological products may be assessed on the basis of medical necessity.

**III. DESCRIPTION/BACKGROUND**

A prosthetic limb is an artificial device that is used as a replacement of an absent limb (arm, hand, leg, foot or any portion of an arm, hand, leg or foot).
Post-operative recovery and wound healing after a limb amputation can take from 4 to 8 weeks. Once the recovery is complete and optimal wound healing has occurred, an individual may be fitted with a temporary prosthesis. This will allow for continued shrinkage of the residual limb and participation in rehabilitative therapies until the fitting of a definitive or “permanent” prosthesis. This temporary prosthesis usually includes the most basic components without cosmetic coverings, except that a higher function definitive foot may be utilized from the beginning to enhance ambulation training and is transferred to the definitive prosthesis. Fitting of the definitive prosthesis usually occurs after 3-6 months and is contingent upon the individual’s tolerance of wearing the temporary prosthesis and no further significant changes in residual limb volume.

A socket is the portion of the prosthesis that fits around the residual limb and to which prosthetic components are attached. Test sockets are used to determine the optimal interface between the patient's skin at the residual limb and the artificial material of the prosthesis. Several test sockets may be required as the dimensions of the residual limb stabilize following amputation and as the musculature changes over time. Sockets with a locking pin connection are easier and faster to don, and have some greater attachment reliability than suction sockets. These suspension-locking mechanisms require a special residual limb gel liner, and require a triangular shaped socket to prevent spinning on the residual limb. A small number of residual limbs cannot tolerate this triangular shape. Vacuum is not an issue with a locking pin suspension system. The patient wears a gel liner on his limb that has a crew-like pin protruding off the end. The patient slides his residual limb with liner donned into the socket and the pin engages into a lock that is incorporated in the bottom of the prosthetic socket. Some socket designs feature a flexible inner socket combined with external frame and/or strapping. Holes cut in the outer frame allow muscle or boney prominences to “flex” outward during weight bearing, reducing pressure. The use of flexible inner sockets with rigid outer frame can improve large muscle contraction and improve comfort and functional seated posture (allowing thigh flattening) in above the knee amputations. They can also allow longer useful life of prostheses for growing children. These are almost never needed with transtibial (below the knee) amputations.

A common problem with the residual limb and socket attachment is that there is a large amount of rubbing between the residual limb and socket. As in temporary/preparatory prosthetics, when the residual limb loses volume (shrinks) for whatever reason, application of various combinations of sock ply (thickness) over the gel locking liner takes up the space within the socket. Signs of improper fit may be residual limb pain or skin breakdown, or inner-upper thigh discomfort, as the limb is no longer firmly suspended within the socket. The prosthetist may add various pads within the socket to take up space, but generally the use of socks will suffice. Socket components may require replacement if there is a significant change in residual limb size (usually with change in body weight of ten [10] pounds or more, or limb circumference change of one-half inch or more) resulting in a poor socket fit that cannot be remedied by increasing sock ply or adding pads.

Non-electronic prosthetic components have a normal useful life of approximately five years. Prosthetic components usually have a warranty from the manufacturer for 24 to 36 months.
Depending on the rate of skeletal growth, a child may need a new prosthesis every twelve to eighteen months and adolescents may require replacement of prosthetic components approximately every three years. Fitting the initial socket with a thicker elastomeric liner may increase the life of the socket. The thickness of the liner can be decreased as growth occurs. Replacing the pylons can lengthen a prosthesis that otherwise still fits and functions.

**The Vacuum Assisted Socket System (VASS™)**

The Vacuum Assisted Socket System (VASS™) is a specialized socket enhancement system that includes a total surface bearing socket, urethane interface/liner, sealing sleeves and a vacuum pump/shock absorber. The goals of the VASS™ system are to control volume fluctuation of the residual limb, reduce forces to the limb, and to improve both suspension and proprioception without restricting vascular flow. Anecdotal evidence indicates potential improvement with using this advanced technology, which also has a shorter useful life, in very specific cases. These cases would have clear documentation of significant residual limb volume changes through the day, or supra-physiologic perspiration causing skin breakdown or follicular inflammation, and meticulous skin care and sock management and all other prosthetic set-ups have been tried and failed. Perspiration effects on socket suction and skin irritation can normally be managed by drying of the skin throughout the day. A suction-expulsion valve suspension system should be trialed initially, rather than considering transitioning a patient from a locking-pin directly to a VASS system.

**IV. RATIONALE**

**Flex Sockets**

There is no literature support for efficacy in patients with below knee amputations. For the above knee amputee it is occasionally necessary when there is difficulty with bony prominences or significant muscle mass. There are no new published peer-reviewed studies indicating any additional information.

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

VASS (Otto Bock Harmony Vacuum-Assisted Socket System, Otto Bock HealthCare; Minneapolis, MN) is a technology that is described as helping to control volume fluctuation in the residual limbs of lower-extremity amputees, reducing forces to the limbs, and improving both suspension and proprioception without restricting vascular flow. The device creates an elevated vacuum between the liner and the socket wall which promotes natural fluid exchange that
regulates volume fluctuation in the residual limb, reduces forces to the residual limb, and increases suspension and proprioception.

Maintaining limb volume can help preserve the fit of the socket. A polyurethane liner is applied 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 which facilitates perspiration evaporation within the socket and minimizes friction during movement. The vacuum provides greater control of the prosthesis and decreases shearing forces to the skin and tissue. Although patient selection criteria have not been firmly established, the device may be proposed for individuals with non-healing skin ulcerations located on the residual limb when other socket systems have failed. The manufacturer describes enhanced linkage from the vacuum between the liner and the socket wall decreases weight and facilitates a more functional gait.

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

Another study utilized bioimpedance analysis to measure the residual limb fluid volume of 7 transtibial amputee subjects using elevated vacuum sockets and non-elevated vacuum sockets. Fluid volume changes were assessed during sessions with the subjects sitting, standing, and walking. In general, fluid volume losses during 3- or 5-min walks and losses over the course of the 30-min test session were less for elevated vacuum than for suction. Numerous variables, including the time of day that data were collected, soft tissue consistency, socket-to-limb size and shape differences, and subject health, may have affected the results and had an equal or greater effect on limb fluid volume in comparison to elevated vacuum systems. Researchers will need to consider these variables in the study design of future studies on the effects of elevated vacuum on residual limb volume.

This series of case studies on seven subjects showed that some subjects showed less decrease (or more increase) in limb fluid volume using sockets with elevated vacuum compared with suction sockets or lock-and-pin suspension sockets, while others did not. Some measures of limb fluid volume changed consistently, while others did not. A number of variables may affect limb fluid volume change. When designing future research studies, researchers need to consider these variables in study design, particularly when comparing elevated vacuum to another socket design.
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. There is no more recent update.

**Summary**

The peer-reviewed medical literature does not indicate any new studies demonstrating an improvement in clinical outcomes either by an improvement in function or a reduction in disability. Other than non-controlled case studies, the literature does not demonstrate this type of efficacy. The most recent study by Klute did not demonstrate patient preference or significant functional improvement with this type of system.

**V. Definitions**

**Accessories/Components** are the materials and equipment needed to ensure the comfort and functioning of a prosthetic device.

**Proprioception** is the mechanism involved in the self-regulation of posture and movement through stimuli originating in the receptors imbedded in the joints, tendons, muscles, and labyrinth.

**Basic Activities of Daily Living** include and are limited to walking in the home, eating, bathing, dressing, and homemaking.

**Functional Level Classification (Lower Extremity Prostheses):**

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

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

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

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

**Permanent Prosthesis** is an artificial limb used by amputees whose residual limb has matured and the amputee has satisfactorily completed the temporary limb phase. The socket and components are manufactured to provide lasting durability and proper cosmetic appearance.3

**Preparatory Prosthesis** is the first limb a new amputee will wear. It consists of a plaster/fiberglass cast (applied during or shortly after surgery) and basic components which easily are removed. It controls swelling and protects the residual limb, while allowing minimal (standing, touchdown weight bearing) ambulation.3

**VI. Benefit Variations**

The existence of this medical policy does not mean that this service is a covered benefit under the member’s contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member’s individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member’s benefit information or contact Capital for benefit information.

**VII. Disclaimer**

Capital’s medical policies are developed to assist in administering a member’s benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member’s benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

**VIII. Coding Information**

*Specific coding does not apply to this policy.*
IX. REFERENCES


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X. Policy History

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