Clinical Policy: Prosthetics

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Public Statement

Effective Date:

a) This policy will apply to all services performed on or after the above revision date which will become the new effective date.
b) For all services referred to in this policy that were performed before the revision date, contact customer service for the rules that would apply.

1) Lower extremity prosthetics require preauthorization. A member must be motivated to ambulate and must meet the specific criteria set forth below.
2) Prosthetic devices and prosthetic services are covered in compliance with applicable state law.
   a) Prosthetic devices for athletics, recreation, bathing, or showering are covered. Medical necessity for these prosthetics shall be deemed by the treating or prescribing provider in compliance with Arkansas law.
3) QualChoice does not cover replacement of a prosthetic device or associated prosthetic services more frequently than one (1) time every three (3) years unless medically necessary. However, QualChoice will replace or repair a prosthetic device if necessary due to anatomical changes or normal use, for example, in the case that the rapid growth of a child means that a prosthetic device of a different size is appropriate.
4) Repair of prosthetic devices, if necessary due to anatomical changes or normal use is covered.
5) Repair or replacement of prosthetic devices for damage caused by misuse or neglect is not covered.

Medical Statement

Prosthesis for recreation, athletics, bathing or showering:
Medical necessity for these devices is deemed by the treating or referring physician, provided the device is prescribed by a licensed Doctor of Medicine, Doctor of osteopathy or Doctor of podiatric medicine and provided by a Doctor of medicine, osteopathy, or podiatric medicine, or an orthotist or prosthetist licensed in the state of Arkansas.

Foot Prosthesis:

- A solid ankle-cushion heel (SACH) foot is considered medically necessary for persons whose functional level is 1* or above.

- An external keel SACH foot or single axis ankle/foot is considered medically necessary for persons whose functional level is 1* or above.
- A flexible-keel foot or multi-axial ankle/foot is considered medically necessary for persons whose functional level is 2* or above.
- A flex foot system, energy storing foot, multi-axial ankle/foot, dynamic response foot with multi-axial ankle, shank foot system with vertical-loaded pylon or flex-walk system or equal is considered medically necessary for persons whose functional level is 3* or above.
- A user-adjustable heel height feature is considered not medically necessary.

Note: Foot covers are included in the reimbursement for a prosthetic foot component and are not separately payable.

Knee Prosthesis:

- A fluid or pneumatic knee is considered medically necessary for persons whose functional level is 3* or above.
- A single axis constant friction knee and other basic knee systems are considered medically necessary for persons whose functional level is 1* or above.
- A high-activity knee control frame is considered medically necessary for members whose function level is 4*.

Ankle Prosthesis:

- An axial rotation unit is considered medically necessary for persons whose functional level is 2* or above.

Hip Prosthesis:

- A pneumatic or hydraulic polycentric hip joint is considered medically necessary for members whose functional level is 3* or above.

Sockets:

- Test (diagnostic) sockets for immediate post-surgical or early-fitted prostheses are considered not medically necessary.
- Two test (diagnostic) sockets for an individual prosthetic are considered medically necessary. Additional documentation of medical necessity is required for more than 2 test sockets.
- No more than 2 of the same socket inserts per individual prosthesis at the same time are considered medically necessary.
- Socket replacements are considered medically necessary if there is adequate documentation of functional and/or physiological need, including but is not limited to: changes in the residual limb; functional need changes; or irreparable damage or wear/tear due to excessive weight or prosthetic demands of very active amputees.

Accessories:

- Stump stockings and harnesses (including replacements) are considered medically necessary when they are essential to the effective use of the artificial limb.
- Prosthetic sheaths/socks, including a gel cushion layer (prosthetic gel stockings; 6 in 6 months) are considered medically necessary.
- Prosthetic seals/gaskets, for use with prosthetic socket insert, are considered medically necessary.
- A prosthetic donning sleeve is considered not medically necessary.

Microprocessor-Controlled Lower Limb Prostheses:

QualChoice considers microprocessor-controlled leg prostheses (e.g., Otto Bock C-Leg; Otto-Bock Genium Bionic Prosthetic System (Otto Bock HealthCare, Minneapolis, MN), Intelligent Prosthesis (Endoliete North America, Centerville, OH), and Ossur Rheo Knee (Ossur-Flexfoot, Aliso Viejo, CA)) medically necessary in otherwise healthy, active community ambulating adults (18 years of age or older) (functional level 3* or above) with a knee disarticulation amputation or a trans-femoral amputation from a non-vascular cause (usually trauma or tumor) for whom this prosthesis can be fitted and programmed by a qualified prosthetist trained to do so.

Addition to lower extremity prosthesis, Endoskeletal knee-shin system, powered and programmable flexion/extension assist control includes any type of motor(s) is only considered medically necessary when the member meets all of the criteria below:

I. Has a microprocessor (swing and stance phase type) controlled (electronic) knee; *and*

II. K3 functional level only; *and*

III. Weight greater than 110 lbs. and less than 275 lbs.; *and*

IV. Has a documented comorbidity of the spine and/or sound limb affecting hip extension and/or quadriceps function that impairs K-3 level function with the use of a microprocessor-controlled knee alone; *and*

V. Is able to make use of a product that requires daily charging; *and*

VI. Is able to understand and respond to error alerts and alarms indicating problems with the function of the unit.

Note:

With the exception of items described by specific HCPCS codes, there should be no separate billing and there is no separate payment for a component or feature of a microprocessor-controlled knee, including but not limited to real time gait analysis, continuous gait assessment, or electronically controlled static stance regulator.

QualChoice considers microprocessor-controlled leg prostheses (e.g., Otto Bock C-Leg, Otto-Bock Genium Bionic Prosthetic System, Intelligent Prosthesis, and Ossur Rheo Knee)

experimental and investigational for gait management in spinal cord injury because of insufficient evidence in the peer-reviewed literature.

Prosthetic Shoe:

QualChoice considers a prosthetic shoe medically necessary for a partial foot amputation when the prosthetic shoe is an integral part of a covered basic lower limb prosthetic device.

QualChoice considers microprocessor-controlled ankle-foot prostheses (e.g., PowerFoot BiOM, iWalk, Bedford, MA; Proprio Foot, Ossur, and Aliso Viejo, CA) experimental and investigational because there is inadequate evidence of their effectiveness.

QualChoice considers the Ossur Symbiotic Leg experimental and investigational because its clinical value has not been established.

***Note:** Clinical assessments of a member's rehabilitation potential should be based on the functional classification levels listed in the table below.

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 ambulatory.
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 ambulatory.
Level 3:	Has the ability or potential for ambulation with variable cadence. Typical of the community ambulatory 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.

Limits

1) Prostheses have no proven value for persons whose potential functional level is 0.*
2) Examples of devices that would not be covered include but is not limited to the following examples:
   a) Dispensing of an enhanced prosthetic for a patient who has an adequate and serviceable prosthetic already in his/her possession.
   b) Devices designed to provide enhanced functionality above that needed to restore function.

c) Services or equipment that are more costly when QualChoice determines that less costly, equally effective services or equipment are available.

3) Powered Lower Limb Prosthesis:

QualChoice considers powered lower limb prosthesis (e.g., Power Knee, Ossur, Foothill Ranch, and CA) experimental and investigational because there is inadequate evidence of their effectiveness.

4) Robotic Lower Body Exoskeleton Suits:

QualChoice considers robotic lower body exoskeleton suits (e.g., the ReWalk, Argo Medical Technologies Ltd, Marlborough, MA) experimental and investigational because there is inadequate evidence of their effectiveness.

5) QualChoice considers the C-Leg Protector experimental and investigational because its clinical value has not been established.

6) Codes for ultra-light materials may only be covered when materials such as carbon fiber, fiberglass, Kevlar, or other advanced composite lamination materials are used in the fabrication of a socket for Endoskeletal prosthesis. They are not covered for ultralight materials used in other components of prosthesis.

Background

1) A ”prosthetic device” is defined by Arkansas law as:
   i) An external device that is intended to replace an absent external body part for the purpose of restoring physiological function or cosmesis to a patient; and
   ii) Custom-designed, fabricated, assembled, fitted, or adjusted for the patient using the device prior to or concurrent with the delivery of the device to the patient.
2) Does not include:
   i) An artificial eye
   ii) An artificial ear
   iii) A dental appliance
   iv) A cosmetic device such as artificial eyelashes or wigs
   v) A device used exclusively for athletic purposes
   vi) An artificial facial device
   vii) Any other device that does not have a significant impact on the neuromuscular, musculoskeletal, or neuromusculoskeletal functions of the body.

Reference

Arkansas Code Annotated § 23-99-403 et seq.

Application to Products

This policy applies to all health plans and products administered by QualChoice, both those insured by QualChoice and those that are self-funded by the sponsoring employer, unless there is indication in this policy otherwise or a stated exclusion in your medical plan booklet. Consult the individual plan sponsor Summary Plan Description (SPD) for self-insured plans or the

specific Evidence of Coverage (EOC) or Certificate of Coverage (COC) for those plans or products insured by QualChoice. In the event of a discrepancy between this policy and a self-insured customer's SPD or the specific QualChoice EOC or COC, the SPD, EOC, or COC, as applicable, will prevail. State and federal mandates will be followed as they apply.

Changes: QualChoice reserves the right to alter, amend, change or supplement benefit interpretations as needed.