Lower Extremity Prosthetics

Policy Number: 2025T0645H
Effective Date: April 1, 2025

➲ Instructions for Use

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Application

UnitedHealthcare Commercial

This Medical Policy applies to UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans in all states except for Colorado.

Coverage Rationale

➲ See Benefit Considerations

A lower extremity prosthetic for amputations is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment, Prosthetics, Lower Extremity.

Click here to view the InterQual® criteria.

A bone anchored percutaneous limb Prosthesis [e.g., Osseoanchored Prostheses for the Rehabilitation of Amputees (OPRA) Implant System] is unproven and not medically necessary due to insufficient evidence of efficacy.

An endoskeletal knee-shin system with microprocessor control feature (swing/stance phase) is unproven and not medically necessary due to insufficient evidence of efficacy for the following:

- Amputee with functional classification status of K1 or K2; and
- One of the following:
  - Transfemoral [above knee (AK)] amputation (includes knee disarticulation); or
  - Hip disarticulation or hemipelvectomy

A combined microprocessor-controlled ankle foot system with power assist is unproven and not medically necessary due to insufficient evidence of efficacy for the following:

- Transfemoral [above knee (AK)] amputation (includes knee disarticulation)
- Transtibial [below knee (BK)] amputation
- Hip disarticulation or hemipelvectomy

Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to the protocol titled Medical Records Documentation Used for Reviews.

Definitions

Activities of Daily Living (ADLs): Basic tasks people need to do to function and interact such as bathing, grooming, dressing, toilet use, eating, and physical ambulation (Mlinac and Feng, 2016, Edemekong et al., 2022).

Instrumental Activities of Daily Living (IADLs): A higher cognitive and complex activity related to independent living such as shopping, transportation, meal preparation, housecleaning, managing finances and managing medications (Mlinac and Feng, 2016, Edemekong et al., 2022).

CMS Modifiers/Medicare Functional Classification Level (MFCL): A clinical assessment of member rehabilitation potential must be based on the following classification levels:

- **Modifier K0 (MFLC-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.
- **Modifier K1 (MFLC-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.
- **Modifier K2 (MFLC-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.
- **Modifier K3 (MFLC-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.
- **Modifier K4 (MFLC-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. [CMS Health Care Procedures Coding System (HCPCS)/Theevan et al. (2011)]

Microprocessor Controlled Ankle Foot Prosthesis: (e.g., Proprio Foot) Is able to actively change the ankle angle and to identify sloping gradients and ascent or descent of stairs as the result of microprocessor-control and sensor technology.

Microprocessor Controlled Lower Limb Prostheses: Microprocessor controlled knees offer dynamic control through sensors in the Device. Microprocessor controlled knees attempt to simulate normal biological knee function by offering variable resistance control to the swing or stance phases of the gait cycle. The swing-rate adjustments allow the knee to respond to rapid changes in cadence. Microprocessor controlled knee flexion enhances the stumble recovery capability. Prosthetic knees such as the microprocessor-controlled knee that focus on better control of flexion abilities without reducing stability have the potential to improve gait pattern, wearer confidence, and safety of ambulation. Available devices include but are not limited to Otto-Bock C-Leg device®, the Ossur RheoKnee® or the Endolite Intelligent Prosthesis®.

Modifier: A two-position code that is added to the end of a code to clarify the services being billed [CMS Health Care Procedures Coding System (HCPCS)]. K0 through K4 are HCPCS level II Modifiers.

Myoelectric Prosthetic: A prosthetic device operated by battery-powered electric motors that are activated through electrodes by the myoelectric potentials provided by muscles (Medical Dictionary).

Prosthesis: A man-made substitute for a missing body part (American Cancer Society®).

Prosthetist: A healthcare professional who makes and fits artificial limbs (prostheses) for people with disabilities. This includes artificial legs and arms for people who have had amputations due to conditions such as cancer, diabetes, or injury (John Hopkins Medicine).

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
L5000	Partial foot, shoe insert with longitudinal arch, toe filler
L5010	Partial foot, molded socket, ankle height, with toe filler
L5050	Ankle, Symes, molded socket, SACH foot
L5060	Ankle, Symes, metal frame, molded leather socket, articulated ankle/foot (SACH)
L5100	Below knee (BK), molded socket, shin, SACH foot
L5105	Below knee (BK), plastic socket, joints and thigh lacer, SACH foot
L5150	Knee disarticulation (or through knee), molded socket, external knee joints, shin, SACH foot
L5160	Knee disarticulation (or through knee), molded socket, bent knee configuration, external knee joints, shin, SACH foot
L5200	Above knee (AK), molded socket, single axis constant friction knee, shin, SACH foot
L5210	Above knee (AK), short prosthesis, no knee joint (stubbies), with foot blocks, no ankle joints, each
L5220	Above knee (AK), short prosthesis, no knee joint (stubbies), with articulated ankle/foot, dynamically aligned, each
L5230	Above knee (AK), 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 (BK), 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 (AK), 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 postsurgical or early fitting, application of initial rigid dressing, including fitting, alignment, suspension, and one cast change, below knee (BK)
L5410	Immediate postsurgical or early fitting, application of initial rigid dressing, including fitting, alignment and suspension, below knee (BK), each additional cast change and realignment
L5420	Immediate postsurgical or early fitting, application of initial rigid dressing, including fitting, alignment and suspension and one cast change 'ak' or knee disarticulation
L5430	Immediate postsurgical or early fitting, application of initial rigid dressing, including fitting, alignment and supension, above knee (AK) or knee disarticulation, each additional cast change and realignment
L5450	Immediate postsurgical or early fitting, application of non-weight bearing rigid dressing, below knee (BK)
L5460	Immediate postsurgical or early fitting, application of non-weight bearing rigid dressing, above knee (AK)

CPT Code	Description
L5500	Initial, below knee (BK) PTB type socket, nonalignable system, pylon, no cover, SACH foot, plaster socket, direct formed
L5505	Initial, above knee (AK), knee disarticulation, ischial level socket, non-alignable system, pylon, no cover, SACH foot, plaster socket, direct formed
L5510	Preparatory, below knee (BK) PTB type socket, nonalignable system, pylon, no cover, SACH foot, plaster socket, molded to model
L5520	Preparatory, below knee (BK) PTB type socket, nonalignable system, pylon, no cover, SACH foot, thermoplastic or equal, direct formed
L5530	Preparatory, below knee (BK) PTB type socket, nonalignable system, pylon, no cover, SACH foot, thermoplastic or equal, molded to model
L5535	Preparatory, below knee (BK) PTB type socket, nonalignable system, no cover, SACH foot, prefabricated, adjustable open-end socket
L5540	Preparatory, below knee (BK) PTB type socket, nonalignable system, pylon, no cover, SACH foot, laminated socket, molded to model
L5560	Preparatory, above knee (AK)- knee disarticulation, ischial level socket, nonalignable system, pylon, no cover, SACH foot, plaster socket, molded to model
L5570	Preparatory, above knee (AK) - knee disarticulation, ischial level socket, nonalignable system, pylon, no cover, SACH foot, thermoplastic or equal, direct formed
L5580	Preparatory, above knee (AK) - knee disarticulation ischial level socket, nonalignable system, pylon, no cover, SACH foot, thermoplastic or equal, molded to model
L5585	Preparatory, above knee (AK) - knee disarticulation, ischial level socket, nonalignable system, pylon, no cover, SACH foot, prefabricated adjustable open-end socket
L5590	Preparatory, above knee (AK) - knee disarticulation ischial level socket, nonalignable 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 (AK), hydracadence system
L5611	Addition to lower extremity, endoskeletal system, above knee (AK), knee disarticulation, four-bar linkage, with friction swing phase control
L5613	Addition to lower extremity, endoskeletal system, above knee (AK), knee disarticulation, four-bar linkage, with hydraulic swing phase control
L5614	Addition to lower extremity, exoskeletal system, above knee (AK), knee disarticulation, four-bar linkage, with pneumatic swing phase control
L5615	Addition, endoskeletal knee-shin system, 4 bar linkage or multiaxial, fluid swing and stance phase control
L5616	Addition to lower extremity, endoskeletal system, above knee (AK), universal multiplex system, friction swing phase control
L5617	Addition to lower extremity, quick change self-aligning unit, above knee (AK) or below knee (BK), each
L5618	Addition to lower extremity, test socket, Symes
L5620	Addition to lower extremity, test socket, below knee (BK)
L5622	Addition to lower extremity, test socket, knee disarticulation
L5624	Addition to lower extremity, test socket, above knee (AK)
L5626	Addition to lower extremity, test socket, hip disarticulation
L5628	Addition to lower extremity, test socket, hemipelvectomy
L5629	Addition to lower extremity, below knee (BK), acrylic socket
L5630	Addition to lower extremity, Symes type, expandable wall socket
L5631	Addition to lower extremity, above knee (AK) or knee disarticulation, acrylic socket

CPT Code	Description
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 (BK), total contact
L5638	Addition to lower extremity, below knee (BK), leather socket
L5639	Addition to lower extremity, below knee (BK), wood socket
L5640	Addition to lower extremity, knee disarticulation, leather socket
L5642	Addition to lower extremity, above knee (AK), leather socket
L5643	Addition to lower extremity, hip disarticulation, flexible inner socket, external frame
L5644	Addition to lower extremity, above knee (AK), wood socket
L5645	Addition to lower extremity, below knee (BK), flexible inner socket, external frame
L5646	Addition to lower extremity, below knee (BK), air, fluid, gel or equal, cushion socket
L5647	Addition to lower extremity, below knee (BK) suction socket
L5648	Addition to lower extremity, above knee (AK), air, fluid, gel or equal, cushion socket
L5649	Addition to lower extremity, ischial containment/narrow M-L socket
L5650	Additions to lower extremity, total contact, above knee (AK) or knee disarticulation socket
L5651	Addition to lower extremity, above knee (AK), flexible inner socket, external frame
L5652	Addition to lower extremity, suction suspension, above knee (AK) 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 (BK) (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 (AK) (kemblo, pelite, aliplast, plastazote or equal)
L5661	Addition to lower extremity, socket insert, multidurometer Symes
L5665	Addition to lower extremity, socket insert, multidurometer, below knee (BK)
L5666	Addition to lower extremity, below knee (BK), cuff suspension
L5668	Addition to lower extremity, below knee (BK), molded distal cushion
L5670	Addition to lower extremity, below knee (BK), molded supracondylar suspension (PTS or similar)
L5671	Addition to lower extremity, below knee (BK)/above knee (AK) suspension locking mechanism (shuttle, lanyard or equal), excludes socket insert
L5672	Addition to lower extremity, below knee (BK), removable medial brim suspension
L5673	Addition to lower extremity, below knee (BK)/above knee (AK), 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 (BK), knee joints, single axis, pair
L5677	Additions to lower extremity, below knee (BK), knee joints, polycentric, pair
L5678	Additions to lower extremity, below knee (BK), joint covers, pair
L5679	Addition to lower extremity, below knee (BK)/above knee (AK), 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 (BK), thigh lacer, nonmolded
L5681	Addition to lower extremity, below knee (BK)/above knee (AK), custom fabricated socket insert for congenital or atypical traumatic amputee, silicone gel, elastomeric or equal, for use with or without locking mechanism, initial only (for other than initial, use code L5673 or L5679)
L5682	Addition to lower extremity, below knee (BK), thigh lacer, gluteal/ischial, molded

CPT Code	Description
L5683	Addition to lower extremity, below knee (BK)/above knee (AK), custom fabricated socket insert for other than congenital or atypical traumatic amputee, silicone gel, elastomeric or equal, for use with or without locking mechanism, initial only (for other than initial, use code l5673 or l5679)
L5684	Addition to lower extremity, below knee (BK), fork strap
L5685	Addition to lower extremity prosthesis, below knee (BK), suspension/sealing sleeve, with or without valve, any material, each
L5686	Addition to lower extremity, below knee (BK), back check (extension control)
L5688	Addition to lower extremity, below knee (BK), waist belt, webbing
L5690	Addition to lower extremity, below knee (BK), waist belt, padded and lined
L5692	Addition to lower extremity, above knee (AK), pelvic control belt, light
L5694	Addition to lower extremity, above knee (AK), pelvic control belt, padded and lined
L5695	Addition to lower extremity, above knee (AK), pelvic control, sleeve suspension, neoprene or equal, each
L5696	Addition to lower extremity, above knee (AK) or knee disarticulation, pelvic joint
L5697	Addition to lower extremity, above knee (AK) or knee disarticulation, pelvic band
L5698	Addition to lower extremity, above knee (AK) or knee disarticulation, Silesian bandage
L5699	All lower extremity prostheses, shoulder harness
L5700	Replacement, socket, below knee (BK), molded to patient model
L5701	Replacement, socket, above knee (AK)/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 (SACH) foot, replacement only
L5704	Custom shaped protective cover, below knee (BK)
L5705	Custom shaped protective cover, above knee (AK)
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	Additions 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
L5785	Addition, exoskeletal system, below knee (BK), ultra-light material (titanium, carbon fiber or equal)
L5790	Addition, exoskeletal system, above knee (AK), 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)

CPT Code	Description
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
L5827	Endoskeletal knee-shin system, single axis, electromechanical swing and stance phase control, with or without shock absorption and stance extension damping
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, 4-bar linkage or 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 (AK) or hip disarticulation, knee extension assist
L5855	Addition, endoskeletal system, hip disarticulation, mechanical hip extension assist
L5856	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type
L5857	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing phase only, includes electronic sensor(s), any type
L5858	Addition to lower extremity prosthesis, endoskeletal knee shin system, microprocessor control feature, stance phase only, includes electronic sensor(s), any type
L5859	Addition to lower extremity prosthesis, endoskeletal knee-shin system, powered and programmable flexion/extension assist control, includes any type motor(s)
L5910	Addition, endoskeletal system, below knee (BK), alignable system
L5920	Addition, endoskeletal system, above knee (AK) or hip disarticulation, alignable system
L5925	Addition, endoskeletal system, above knee (AK), knee disarticulation or hip disarticulation, manual lock
L5926	Addition to lower extremity prosthesis, endoskeletal, knee disarticulation, above knee, hip disarticulation, positional rotation unit, any type
L5930	Addition, endoskeletal system, high activity knee control frame
L5940	Addition, endoskeletal system, below knee (BK), ultra-light material (titanium, carbon fiber or equal)
L5950	Addition, endoskeletal system, above knee (AK), ultra-light material (titanium, carbon fiber or equal)
L5960	Addition, endoskeletal system, hip disarticulation, ultra-light material (titanium, carbon fiber or equal)
L5961	Addition, endoskeletal system, polycentric hip joint, pneumatic or hydraulic control, rotation control, with or without flexion and/or extension control
L5962	Addition, endoskeletal system, below knee (BK), flexible protective outer surface covering system
L5964	Addition, endoskeletal system, above knee (AK), 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
L5969	Addition, endoskeletal ankle-foot or ankle system, power assist, includes any type motor(s)
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, foot, flexible keel
L5973	Endoskeletal ankle foot system, microprocessor-controlled feature, dorsiflexion and/or plantar flexion control, includes power source

CPT Code	Description
L5974	All lower extremity prostheses, foot, single axis ankle/foot
L5975	All lower extremity prosthesis, 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 prosthesis, 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 prosthesis, axial rotation unit, with or without adjustability
L5985	All endoskeletal lower extremity prostheses, dynamic prosthetic pylon
L5986	All lower extremity prostheses, multiaxial rotation unit (MCP or equal)
L5987	All lower extremity prosthesis, 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
L5991	Addition to lower extremity prostheses, osseointegrated external prosthetic connector
L5999	Lower extremity prosthesis, not otherwise specified
L7367	Lithium-ion battery, rechargeable, replacement
L7368	Lithium-ion battery charger, replacement only
L7600	Prosthetic donning sleeve, any material, each
L7700	Gasket or seal, for use with prosthetic socket insert, any type, each
L8400	Prosthetic sheath, below knee (BK), each
L8410	Prosthetic sheath, above knee (AK), each
L8417	Prosthetic sheath/sock, including a gel cushion layer, below knee (BK) or above knee (AK), each
L8420	Prosthetic sock, multiple ply, below knee (BK), each
L8430	Prosthetic sock, multiple ply, above knee (AK), each
L8440	Prosthetic shrinker, below knee (BK), each
L8460	Prosthetic shrinker, above knee (AK), each
L8470	Prosthetic sock, single ply, fitting, below knee (BK), each
L8480	Prosthetic sock, single ply, fitting, above knee (AK), each

Description of Services

A Prosthesis is an artificial device used to replace all or part a missing body part and is intended to restore normal function. Meier and Melton (2014) identify the most common levels of amputations for the lower limb are the transtibial (TT) (below knee, BK) and the transfemoral (TF) (above knee, AK).The Prosthesis is a tool that helps the single-limb amputee gain functional independence. Ideally, lower limb amputees should be able to accomplish things such as ambulation with Prosthesis on level and uneven surfaces, stairs, ramps, and curbs, independent with dressing and return to work with or without modifications.

Benefit Considerations

Prosthetic Devices

An initial or replacement prosthetic device is a covered health care service when all of the following criteria are met:

- The prosthetic device replaces a limb or a body part, limited to:
  - Artificial arms, legs, feet, and hands

  and
- The prosthetic device is medically necessary, as defined in the member's specific benefit plan document; and
- The prosthetic device is not subject to a coverage exclusion in the member's specific benefit plan document

Benefits are provided only for external prosthetic devices and do not include any device that is fully implanted into the body. Internal prosthetics are a covered health care service for which benefits are available under the applicable medical/surgical covered health care service categories in the certificate.

If more than one prosthetic device can meet the member's functional needs, benefits are available only for the prosthetic device that meets the minimum specifications for the member's needs. If the member purchases a prosthetic device that exceeds these minimum specifications, payment will only be the amount that would have paid for the prosthetic that meets the minimum specifications, and the member will be responsible for paying any difference in cost.

Exclusions and Limitations

- Devices used as safety items or to help performance in sports-related activities
- Repair or replacement of prosthetic devices due to misuse, malicious damage, or gross neglect or to replace lost or stolen items

Clinical Evidence

Bone Anchored Percutaneous Limb Prostheses

The available clinical evidence is insufficient to conclude that the OPRA Implant System is effective and safe due to the limited low-quality evidence and high rates of infection and mechanical complications reported in the studies.

A Hayes Evolving Evidence Review (2023, updated 2024) completed a systematic search of the literature and found three studies (two with overlapping patient populations) with no clear support for use of the Osseoanchored Prostheses for the Rehabilitation of Amputees (OPRA) Implant System (Integrum Inc.) in patients with transfemoral (above the knee) amputation (TFA). Hayes found that two of the studies were of poor quality and the third was of very poor quality and that, although OPRA fixture survival was reasonably high across studies, the rate of revisions was very high in all three studies as it was above 85% in two of the studies with 10- and 15-year follow up. The report indicates there were high rates of infection (including osteomyelitis) with many requiring debridement, and one of the studies also reported an average of 3.3 mechanical complications per 10 person-years that required hardware replacement. The 2024 update identified one additional study; however, after their review of the abstract, Hayes concluded that there was no change to their previous no or unclear level of support for OPRA in patients with TFA.

Ranaldi et al. (2023) conducted a two-center, retrospective, cross-sectional comparative study of gait parameters in participants fitted with transfemoral bone-anchored prostheses (BAPs) using a total of 14 gait parameters. Two control arms included eight able-bodied participants arm (54 ±9 years, 1.75 ±0.07 m, 76 ±7 kg) and nine participants fitted with transfemoral socket-suspended prostheses (SSPs) arm (59 ±9 years, 1.73 ±0.07 m, 80 ±16 kg). The intervention arm included nine participants fitted with transfemoral bone-anchored prostheses arm (51 ±13 years, 1.78 ±0.09 m, 87.3 ±16.1 kg). Comparisons were performed for two spatio-temporal, three spatial and nine temporal gait parameters. The cadence and speed of walking were 107 ±6 steps/min and 1.23 ±0.19 m/s for the able-bodied participants arm, 88 ±7 steps/min and 0.87 ±0.17 m/s for the socket-suspended prosthesis arm, and 96 ±6 steps/min and 1.03 ±0.17 m/s for bone-anchored prosthesis arm, respectively. Able-bodied participants and bone-anchored prosthesis arms were comparable in age, height, and body mass index as well as cadence and speed of walking, but the able-bodied participant arm showed a swing phase 31% shorter. Bone-anchored and socket-suspended prostheses arms were comparable for age, height, mass, and body mass index as well as cadence and speed of walking, but the bone-anchored prosthesis arm showed a step width and duration of double support in seconds 65% and 41% shorter, respectively. The authors concluded that bone-anchored and socket-suspended prostheses restored equally well the gait parameters at a self-selected speed. This benchmark data provides new insights into the walking ability of individuals using transfemoral bionics bone-anchored prostheses. Limitations include small sample size (17) and the fitting of prosthetic components. Participants in BAP and SSP arms were fitted with a mismatch of knees and ankle/foot prosthetic component models although the ratio of knees with and without microprocessor-controlled was the same. Further research is needed to determine the clinical relevance of these findings.

In a 2022 ECRI clinical assessment, the evidence is inconclusive for the OPRA (Osseointegrated Prostheses for the Rehabilitation of Amputees) Implant System. The OPRA is a bone anchored percutaneous limb prosthesis intended for skeletally mature patients with transfemoral amputations due to trauma or cancer. Evidence from two systematic reviews, two before and after studies and two case series is limited and of low quality. The studies report that while OPRA restores mobility and improves the patient's quality of life (QOL), serious complications, such as infection and implant loosening, have been frequently reported and thus the risk-benefit balance remains unclear.

Sinclair et al. (2022) evaluated the safety and efficacy of the percutaneous osseointegrated prosthesis (POP) in ten unilateral transfemoral amputees. This single center, prospective study was conducted with FDA Investigational Device Exemption (IDE) and Institutional Review Board approval. A two-staged surgical protocol was used; the first surgery included resection of the residual femur to accommodate the length of the device and prosthetic components, and the second surgery addressed attachment of the percutaneous post. Rehabilitation started with physical therapy postop day one and then continued with supervised sessions twice a week for a minimum of at least 10 days. DEXA scans and radiography were performed to observe the bone response to the device and determine its safety. Functional use of the device was assessed by timing participants while they put the device on and off, evaluation of distance walked over a 6-minute timeframe and collection of patient-reported outcomes on the Questionnaire for Persons with a Transfemoral Amputation (Q-TFA). Adverse events (AEs) included one device loosening and needed removal at 5 weeks; a second device was removed at approximately 7 months due to a periprosthetic fracture after a non-device-related fall; a third patient was treated for postoperative infection not related to the device implant; and other various minor AEs included musculoskeletal pain, stoma irritation and a loose outer adaptor bolt for three patients. The authors concluded that the POP offers a promising alternative for transfemoral amputees who have dissatisfaction with socket prostheses. Limitations included small sample size, two of ten participants were lost to follow-up due to device removal, lack of female participants and limited number of surgeons in the single center where the study took place.

Hagberg et al. (2022) conducted a nonrandomized, prospective cohort study including participants with transfemoral amputations (TFAs) treated between 1999 and 2007 with the Osseointegrated Prosthesis for the Rehabilitation of Amputees (OPRA) system (n = 51). A total of 28 men/23 women; mean age at amputation: 32 years old; mean age at treatment: 44 years old in a single university hospital were followed for ten years. Patient-reported outcomes (PROs) included the Questionnaire for Persons with a Transfemoral Amputation (Q-TFA, four scores 0-100) and the Short Form 36 Health Survey (SF-36, ten scores 0-100) and were answered before treatment and until the ten-year follow-up after treatment. Analyses of differences in PRO scores were conducted using Wilcoxon's signed rank test. The implant survival and revision-free rates with respect to adverse events (implant revision, mechanical complications, and deep infections) were presented as Kaplan-Meier graphs with 95% confidence intervals (CIs). The incidences of events per ten and five person-years were calculated. Spearman's correlation analysis was used for analyses of associations between adverse events. PROs showed mean improvements between baseline and the ten-year follow-up regarding all Q-TFA scores: the prosthetic use score (+36), prosthetic mobility score (+18), problem score (-28) and global score (+38) (all $p < 0.001$), and the SF-36 physical functioning score (+26, $p < 0.001$) and physical component score (+6, $p < 0.01$). No PROs showed a statistical deterioration. Over the ten years, 12 patients were lost (one lost to follow-up, one dropped out of the study, two died, and eight had implants removed (four before five years and four between five and ten years). At ten years, the revision-free survival rates were 83% (CI: 69%-91%), 65% (CI: 49%-77%) and 17% (CI: 7%-29%) for implant revision, deep infection, and mechanical complications, respectively. Mechanical complications, 3.9 per 10 person-years (CI: 2.2-5.1) constituted the most common serious adverse event and were more common during the last five years than during the first five years ($p < 0.001$). No significant difference in the incidence of deep infections was observed between the earlier and the later five-year periods: 0.3 per 5 person-years (CI: 0.1-0.5) vs. 0.3 per person-years (CI: 0.1-0.5) ($p = 0.740$). Correlation analyses between the earlier and later five years revealed a positive association between deep infections and implant removal (0.57, $p < 0.001$) and between mechanical complications and adverse events (0.65, $p < 0.001$). The authors concluded that improved PROs were demonstrated ten years after the introduction of a novel principle for bone anchorage of amputation prostheses. However, the authors stated an increasing rate of mechanical complications is of concern. Limitations in the OPRA study design include the lack of a comparable control group with socket-suspended prostheses, the relatively small number of patients included, the mixture of patients having both unilateral and bilateral TFAs and the absence of systematically registered prosthetic device details (i.e., type of prosthetic knee and foot components). Finally, this ten-year follow-up did not include details about other complications commonly reported among individuals living for decades with a lower-limb amputation, such as low back pain, phantom limb pain, falls, and arthrosis in the lower extremity. Further research is needed to determine the clinical relevance of these findings.

In a cohort study of 111 participants, Hagberg et al. (2020) reported on device and patient outcomes for unilateral transfemoral amputees treated with a bone-anchored, transcutaneous prosthesis. The patients were treated for the first time with the Osseointegrated Prostheses for the Rehabilitation of Amputees (OPRA) implant system, and all consented to a longitudinal follow-up that occurred over 18 years. Treatment consisted of a two-stage surgery approach followed by a rehabilitation protocol. The primary outcome was to describe patient reported outcome measures (PROMs) which were captured using the questionnaire for Persons with Transfemoral Amputation (Q-TFA); the secondary outcome was to relate the mechanical failures to the demographic data, activity level, and PROMs. The authors found at two, five, seven, and ten years, respectively, the Q-TFA scores demonstrated far more prosthetic use, improved mobility, and fewer problems. The authors discovered 55% of patients had at least one mechanical complication, almost 20% of patients had six or more complication events, and approximately 40% of patients had repeated episodes of fractures. These drawbacks were contributed to a higher prosthetic activity level with more demanding physical activities. It was concluded that over a 15-year period, the fixture remained stable and was able to transfer loads to an artificial limb anchored to the

fixture via the abutment. Limitations included lack of control group, missing data due to 15-year follow-up, lack of investigation into the mechanical failures, and lack of association between patient outcome, mechanical complications, and infection.

Brånemark et al. (2019) conducted a nonrandomized study on fifty-one transfemoral amputees that were treated with the OPRA implant system. Inclusion criteria consisted of patients with issues related to using a conventional socket-suspended prosthesis, the inability to use a prosthesis, or not using one at all. Exclusion criteria consisted of amputation due to severe peripheral vascular disease (PVD) and/or diabetes mellitus (DM), skin diseases on the amputated limb, pregnancy, and current treatment with systemic corticosteroids, chemotherapeutic agents, or other drugs that could adversely affect the treatment. The implant system consists of three main components (the fixture, the abutment, and the external prosthesis) and involves two separate surgeries separated by 6 months and followed by a rehabilitation program. Clinical examination for safety assessment was completed at 3, 6, 12, and 24 months. The Transfemoral Amputation (Q-TFA) and the Short Form 36 (SF-36) Health Survey were given to the participants before the first surgery and again at one year, two year and 5 years following the second surgery. From the original fifty-one patients, only forty made it through to five years for analysis. Adverse events were numerous and included 34 patients with multiple superficial skin infections, 14 deep infections on eleven patients, and 43 mechanical complications in fifteen patients which resulted in replacement of the damaged abutment and/or the abutment screw. Details of prosthetic use demonstrated 29 out of 42 participants used their prostheses on a daily basis for at least 13 hours; at five years, it was 28 out of 40 that showed continued use of at least 13 hours. The authors found at the 5-year mark, patients demonstrated a continuous cumulative fixture (bone anchorage) survival rate of 92%, but the increased number of mechanical complications and the increase in deep infections was troublesome; further research and investigation regarding this is warranted. Limitations included small sample size, four patients withdrew from the study, three patients were lost to follow-up and the adverse outcomes were numerous.

Microprocessor Controlled Knee Prostheses

Although there is ample clinical literature to support the efficacy of microprocessor knees with community ambulators [Medicare functional classification level (MFCL) K3], there is insufficient evidence to support suitability of microprocessor knees for patients with lower functional classification levels.

Klenow et al. (2024) conducted a randomized controlled trial (RCT) to evaluate the feasibility and effectiveness of enhancements to the Genium™/Genium X3™ microprocessor-controlled prosthetic knee (MPK). Twenty-six subjects (n = 26) were enrolled. Enhancements to the Genium™/Genium X3™ MPK included an updated ruleset, hydraulics, and new bilateral parameter presets was made to improve safety while stumbling and the smoothness of gait for all users while also improving the experience of bilateral users. A convenience sample of MPK users was recruited from two sites in the USA in two phases. Assessments included the L-Test of Functional Mobility, Activity-specific Balance Confidence Scale, Prosthetic Limb User Survey of Mobility, a study-specific questionnaire, and the Comparative Activities of Daily Living (ADL) Questionnaire. Statistical significance of extracted data was tested with the Wilcoxon Rank-Sum Test for independent data and Wilcoxon Signed-Rank for paired data with an a priori significance level of $p < 0.05$. Unilateral subjects were age-matched to the group of bilateral subjects for between-groups and within-groups analyses. Stumble frequency reduced 85% from 16.0 ±39.7 to 2.4 ±2.3 ($p = 0.008$) between baseline and final assessment overall. The bilateral group reported 50% ($p = 0.009$) and 57% ($p = 0.009$) greater relative improvement in patient-reported ease and safety, respectively, of completing ADLs compared to the unilateral group. The unilateral group reported residual limb pain and low back pain reduced from 2.3 to 1.4 ($p = 0.020$) and 3.8 to 1.8 ($p = 0.027$), respectively, whereas the bilateral group did not. Enhancements resulted in substantial reductions in stumbles, residual limb pain, and back pain overall. These reductions were driven by the unilateral group who also showed improvements in comfort, exertion, and concentration while walking. The enhancements to the knee likely reduced some gait asymmetry for unilateral users. Improvements in patient-reported ease and safety of completing ADLs were shown overall and were driven by the bilateral group. The authors concluded that further improvement in patient experience is achievable through innovation in MPK technology even for patients who appear to be functioning well. This RCT has limitations. Sample size was based on stated needs of the product developers and not on a sample size calculation which is typically done in RCTs. Therefore, the overall sample of users with transfemoral amputation (TFA) (n = 25) and smaller sub-sample of bilateral subjects (n = 9) may have resulted in the study being underpowered. Further, users of the Genium™ and Genium X3™ are usually MFCL K3 or higher and typically walk well, so there is not much room for improvement in functional performance which was evident in the baseline scores. While the mixed sample was necessary to determine the efficacy of this update, the heterogeneity somewhat limits the generalizability of aggregate findings for either group since they are clinically different. A limitation of the Comparative ADL-Q is its direct comparison of recalled and concurrent experience which inherently introduces a bias. The experience with the existing prosthesis is recalled over an extended period whereas the experience with the experimental prosthesis is concurrent. Recalled ratings are often less accurate than concurrent ratings since the latter is fresh in the subjects' minds. This may also have affected the final question in the ABC regarding confidence walking on icy sidewalks because the baseline assessments occurred in spring and summer whereas final assessments occurred in

winter. In this case the baseline assessment would be recalled and final assessment concurrent. This was the item of greatest improvement in the ABC, improving 46.9%–60.8%. Lack of randomization or a crossover component also increases bias. An additional limitation was the use of the SSQ and ADL-Q in this study since the clinical meaning of unvalidated measures is obscure. Further research is needed to determine the clinical relevance of these findings.

A study conducted by Tacca et al. (2024) on participants with unilateral transtibial amputation (TTA) using 1) a passive-elastic prosthesis exhibiting lower positive affected leg trailing work (AL-trail W-pos) and a greater magnitude of negative unaffected leg leading work (UL-lead W-neg) during walking than non-amputees, which may increase joint pain and osteoarthritis risk in the unaffected leg. And 2) participants with TTA using a stance-phase powered prosthesis (e.g., BiOM, Ottobock, Duderstadt, Germany) walking with increased AL-trail W-pos and potentially decreased magnitude of UL-lead W-neg compared to a passive-elastic prosthesis. Using linear mixed effects models to determine the effects of stiffness category and power settings on AL-trail W-pos, UL-lead W-neg, and effective foot length ratio (EFLR), the authors hypothesized that decreased stiffness and increased power would increase AL-trail W-pos, not change and decrease UL-lead W-neg magnitude, and decrease and not change prosthesis EFLR, respectively. The BiOM device includes a passive-elastic prosthesis with a manufacturer-recommended stiffness category and can be tuned to different power settings, which may change AL-trail W-pos, UL-lead W-neg, and the prosthesis effective foot length ratio (EFLR). Thirteen people with TTA walked using 16 different prosthetic stiffness category and power settings on a level treadmill at 0.75-1.75 m/s. The authors found there was no significant effect of stiffness category on AL-trail W-pos, but increased stiffness reduced UL-lead W-neg magnitude, perhaps due to a 0.02 increase in prosthesis EFLR compared to the least stiff category. Furthermore, the authors found that use of the BiOM with 10% and 20% greater than recommended power increased AL-trail W-pos and decreased UL-lead W-neg magnitude at 0.75-1.00 m/s. However, prosthetic power setting depended on walking speed so that use of the BiOM increased UL-lead W-neg magnitude at 1.50-1.75 m/s compared to a passive-elastic prosthesis. The authors concluded the results suggest that at 0.75-1.00 m/s, prosthetists should utilize the BiOM attached to a passive-elastic prosthesis with an increased stiffness category and power settings up to 20% greater than recommended based on biological ankle values. This prosthetic configuration can allow people with unilateral transtibial amputation to increase AL-trail W-pos and minimize UL-lead W-neg magnitude, which could reduce joint pain and osteoarthritis risk in the unaffected leg and potentially lower the metabolic cost of walking. This study has limitations. For each prosthetic configuration, participants walked for at least three minutes on the treadmill at 1.25 m/s before any data were collected, but the accommodation period may not have been long enough for the participants to adapt to each prosthetic configuration. Future studies should determine the effects of different prosthetic stiffness and power configurations on joint mechanics of the prosthetic ankle compared to the biological ankle. The small study population limits the validity of the conclusions of this study. Well designed, comparative studies with larger patient populations are needed to further describe safety and clinical outcomes.

Alzeer et al. (2022) assessed the impact of using a microprocessor-controlled prosthetic knee (MCPK) and compared it to a non-microprocessor-controlled prosthetic knee (NMCPK) in 76 adult unilateral transfemoral amputees. In this hospital-based comparative study, the participants were put into one of two groups: 38 were part of the MCPK group and the other 38 were put into the NMCPK group. Inclusion criteria consisted of participants aged 18-60 years old, medically stable, able to perform outdoor ambulation at a mobility level of K3 and K4, and intact cognition. Outcomes were measured by self-reporting responses via the Prosthetic Evaluation Questionnaire (PEQ), which consisted of scores for ambulation (AM), appearance (AP), frustration (FR), perceived response (PR), residual limb health (RL), social burden (SB), sounds (SO), utility (UT), and quality of life (QoL). Data results suggest the MCPK prostheses improved gait, daily activities, and overall positive experience in transfemoral amputee. The authors found participants with MCPK experienced higher prosthetic satisfaction, improved QoL and body image, and greater well-being when compared to those with NMCPK. Limitations of this study included a homogeneous population, self-reporting data, and a modified PEQ scale with inability to compare results to other PEQ scales. Future studies with larger sample sizes are warranted to check the efficacies of different MCPK types.

Jayaraman et al. (2021) conducted a 13-month longitudinal crossover randomized clinical trial that included 10 individuals with unilateral transfemoral amputation due to vascular conditions designated as Medicare functional classification level (MFCL) K2 to evaluate gait performance and safety with a microprocessor-controlled knee (MPK). Participants were randomized to one of two groups, either an intervention with a MPK with a standardized 1M10 foot or with then non-microprocessor-controlled knee (NMPK) with a standardized 1M10 foot. Inclusion criteria were dysvascular or diabetic unilateral transfemoral amputation; at least 6 months or more post-prosthetic fitting; currently using an NMPK appropriate foot; and household or limited ambulator post-amputation (MFCL K1 or K2 level). Exclusion criteria were individuals with amputation secondary to trauma, cancer, or congenital causes; skin ulcers or lesions on the residual limb that may prevent fitting the prosthesis or from physical activity; and visual impairments or cognitive deficits that may impair ability to give informed consent or follow simple instructions during the study. Clinical outcomes and self-reported outcomes were collected at the end of 6-month interventions. Some limitations of this study include small sample size, the mean age of study participants is 63 ±9 years [which is relatively young when compared to the typical age range (70–75 years) of

transfemoral amputation due to vascular complications in the United States], consideration of comorbidities, and the use of assistance devices in the home. The authors concluded that individuals with transfemoral amputation from dysvascular conditions at a MFCL K2 designation benefited from using an MPK with appropriate foot in gait speed, balance, self-reported mobility and fall safety.

A systematic review and meta-analysis were conducted by Hahn et al. (2021) to update a previous 2014 analysis of benefits in safety, performance-based, and patient-reported outcomes the use of microprocess-controlled prosthetic knees (MPKs) in limited community ambulators. The investigators searched Medline, Cochrane Library, CINAHL Complete, EMBASE, and Google Scholar and found 13 research projects (n = 704 participants classified as limited community ambulators). Two reviewers independently rated relevant publications for their methodological quality. According to the investigators, limitations of this analysis include the challenge of effective blinding to meet the formal criteria of high-quality research, some studies suffered high attrition that limit generalizability but may also reflect the challenge of natural progression of underlying conditions (e.g., vascular disease, diabetes) over longer observation periods, all studies reported some outcomes did not improve as expected, and the vast variety of parameters characterizing clinical outcomes. The investigators of this review are also noted as employed by a manufacture of MPKs. The authors concluded that the review suggests that limited community ambulators may experience reduced fall, fear of falling, and risk of falling, and improve mobility but indicate further research to study specific needs and characteristics of this population should be considered.

Deems-Dluhy et al. (2021) evaluated the potential of the microprocessor swing and stance-controlled knee-ankle-foot orthosis (MPO) on improving balance, functional mobility, and quality of life (QOL) in 18 individuals with lower-extremity impairments as compared to a stance-control-orthosis (SCO) and conventional knee-ankle-foot orthosis (KAFO) over 30 days of use. Assessments were done at baseline with the participants own device and again after training and use of each of the study devices. Performance-based outcome measures included walking endurance, gait speed, balance, functional sit to stand and outdoor ambulation; patient reported outcome measures included the Modified Falls Efficacy Scale (mFES) and the Orthotic and Prosthetic User's Survey (OPUS). Clinic visits included reports of any falls and adverse events. The results identified several performance-based measures improved significantly from baseline scores to post testing scores with the participants that wore the C-Brace but not with the SCO. In addition, the ability to descend hills measured by hill assessment index showed the MPO group performed better and were able to walk significantly farther. The authors found improvements in both static and dynamic balance, gait speed, walking endurance, stair descent, and self-reported falls while using the MPO but not the SCO. Limitations included small sample size, inability to blind participants due to device type and short time frame of study.

Mileusnic et al. (2021) conducted a systematic review to evaluate the effect of the Genium knee on ambulation, mobility, activities of daily living (ADLs) and quality of life compared to standard MPKs. A search was conducted using PubMed, Cinahl and Cochrane Database of Systematic Reviews and returned 12 publications. Six publications contained randomized control cross-over design, five publications before-and-after design and one study used a cross-sectional design. Participant sample sizes ranged from 10 to 25 patients and follow up was anywhere from two days to three months. The overall quality of evidence was moderate to high except for one article. Data was gathered on how the Genium was assessed for walking, ramps and stairs. The authors found that while mobility and functional levels were both significantly improved and there were positive effects on the performance and safety of ADLs, it is unclear if the results can be generalized beyond community ambulators with a transfemoral amputation. Limitations included absence of blinding in all studies, short acclimation period for the patient with the prosthetic and small sample sizes.

Stevens and Wurdeman (2019) published clinical recommendations on prosthetic knee selection for unilateral amputees at the knee and transfemoral level. The following are the proposed recommendations:

- Fluid knee benefits and indications: knees with hydraulic or pneumatic swing resistance are indicated for active walkers, permitting increased walking comfort, speed, and symmetry.
- Microprocessor knee benefits when compared with non-microprocessor knees:
    - With respect to self-report indices and measures, microprocessor knees are indicated to reduce stumbles, falls, and associated frustrations as well as the cognitive demands of ambulation.
    - With respect to self-report indices and measures, microprocessor knees are indicated to increase confidence while walking, self-reported mobility, satisfaction, well-being, and quality of life.
    - With respect to physical performance indices and measures, microprocessor knees are indicated to increase self-selected walking speed, walking speed on uneven terrain, and metabolic efficiency during gait.
- Microprocessor knee equivalence: given the comparable values observed with the use of microprocessor and non-microprocessor knees with regard to daily step counts, temporal and spatial gait symmetry, self-reported general health, and total costs of prosthetic rehabilitation, these parameters may not be primary indications in prosthetic knee joint selection.

- Microprocessor knees for limited community ambulators: among limited community ambulators, microprocessor knees are indicated to enable increases in level ground walking speed and walking speed on uneven terrain while substantially reducing uncontrolled falls and increasing both measured and perceived balance.

Kaufman et al. (2018, included in the Hahn et al. (2021) systematic review above) conducted a prospective non-randomized cross-over clinical trial with repetition to evaluate if limited community ambulators would benefit from a microprocessor-controlled knee (MPK). The aim of the study was to compare functional efficacy, patient satisfaction, and safety of MPK vs NMPK. The study included 50 unilateral transfemoral amputees (TFA) with a mean age of 69 (range 55-93) and a MFCL of K2 (n = 48) or K3 (n = 2) that were tested with current non-microprocessor knee (NMPK), then tested with a MPK after 10 weeks of acclimation. Participants were then retested with their original mechanical NMPK after 4 weeks of re-acclimation. Participants were excluded if on dialysis, contained a history of acute or chronic residual limb skin breakdown or had a prosthetic socket adjustment within the previous 90 days. Participants self-assessed on nine validated scales for ambulation, appearance, frustration, perceived response, residual limb health, social burden, sounds, utility, and well-being. Limitations of the study include safety data is directly linked to the ability to accurately monitor falls, increased burden on participants, use of recall that is limited by the extent of memory decay over time or under or over estimation, and intervention bias. A number of subjects (n = 21) did not complete the final data capture. The authors concluded that this trial confirmed that MPK use to patients with a TFA and MFCL K2 results in improved function in the free-living environment, a reduction in fall and improved patient satisfaction.

The Agency for Healthcare Research and Quality (AHRQ) conducted an effectiveness review (2018) on Lower Limb Prostheses (LLP) (Balk et al., 2018). A literature search was conducted in PubMed®, both the Cochrane Central Trials Registry and Cochrane Database of Systematic Reviews, Embase®, and CINAHL®/PsycINFO® databases and identified 77 articles for review; 52 articles addressed key questions (KQ) 1-3, fifteen articles addressed KQ 4, one article addressed KQ 6, nine articles addressed KQ 7, and no articles were found for KQ 5.

- What assessment techniques used to measure functional ability of adults with major lower limb amputation have been evaluated in the published literature?
- What prediction tools used to predict functional outcomes in adults with major lower limb amputation have been evaluated in the published literature?
- What functional outcome measurement tools used to assess adults who use an LLP have been evaluated in the published literature?
- In adults who use a lower limb prosthesis, how do ambulatory, functional, and patient-centered outcomes with different prosthesis components vary based on study participant characteristics?
- How do study participants' pre prescription expectations of ambulation align with their functional outcomes?
- What is the level of patient satisfaction with the process of accessing an LLP?
  At 6 months, 1 year, and 5 years after receipt of an LLP, (accounting for intervening mortality, subsequent surgeries, or injuries) what percentage of individuals maintain ambulation, continue to use their prosthesis as intended, have abandoned their prosthesis or have encountered major problems?

The following key findings were found:

- Since many specific measures can be used for at all stages of evaluation of function for amputees, it is difficult to effectively make the distinction between assessment techniques, prediction tools, and outcome measures.
- Among the 50 instruments found to assess the psychometric properties, 41 had evidence of test validity, 35 had evidence of reliability, and 28 had evidence of both test validity and reliability.
- 14 studies were found that compared LLP components along with provided data to compare differences in effect among different subgroups, however, most studies were small, underpowered, nonrandomized, reported only participant-level data, and did not evaluate heterogeneity of treatment effect. In addition, most of these studies evaluated knee components and most included younger men at K2 or K3 level, with unilateral transfemoral amputations with traumatic etiologies; only one study addressed a mean age greater than 65 years.
- No evidence was found that addressed how study participants' pre prescription expectations of ambulation aligned with their functional outcomes.
- As far as long-term follow-up, eight studies with at least 100 participants were found that addressed follow-up of at least 6 months after prescribed LLP, but only one of these studies was conducted in the United States and most (including the U.S. study) were published more than 10 years ago. There is insufficient or low evidence:
  - Regarding failure to maintain bipedal ambulation.
  - Regarding use of prostheses only for transfers.
  - Regarding reasons why LLP amputees have poor outcomes in terms of their prostheses use.
  - Regarding rationale of amputees and why they have abandoned use of their prostheses at 1 year.

Limitations of this review included that most studies were observational, evaluated only a limited set of patient characteristics lacking heterogeneity, and most long-term studies were conducted outside the U.S. which addressed a different healthcare system. Future research should include robust studies including amputation level and etiology, baseline K level or equivalent, living situation, and other participant functional status.

Kannenberg et al. (2014, included in Hahn et. al. (2021) systematic review above) conducted a systematic review on behalf of the manufacturer to evaluate if there is support that limited community ambulators (Medicare Functional Classification Level [MFCL]-2) may benefit from using a microprocessor-controlled prosthetic knee (MPK) in safety, performance-based function and mobility, and perceived function and satisfaction. The investigators searched the Medline, EMBASE, PsychInfo, Cochrane Library, CINAHL, DARE, Cirrie, OTseeker, PEDro, and RECAL Legacy for terms related to MPKs and individuals with a unilateral transfemoral amputation (TFA) and MFCL-2 mobility grade. Two reviewers independently screened studies, extracted data, and assessed for relevance. Of 986 articles screened, 3 studies were eligible for final inclusion for safety outcomes (n = 27 with MFCL-2 mobility grade); 6 studies for performance-based function and mobility outcomes (n = 57 with MFCL-2 mobility grade); 5 articles on perceived function and satisfaction (n = 57 with MFCL-2 mobility grade). The authors concluded that the results of this systematic review of clinical trials of individuals with a unilateral TFA on interventions with MPKs suggest MPK use may significantly reduce uncontrolled falls by up to 80% and significant improved fall risk. Performance-based outcome measures suggest individuals with MFCL-2 mobility grade may be able to walk about 14% - 25% faster on level ground, be around 20% quicker on uneven surfaces and descend a slop almost 30% faster when using an MPK. Trial fitting may be used to determine whether or not individuals with TFA and MFCL-2 mobility grade benefit from MPK use is also suggested by this systematic review. According to the authors, limitations of this systematic review was that the results of the studies were derived with low to moderate methodological quality in a limited number of patients, trial fittings with different types of MPKs and that the criteria for appraising success or failure of the trial fitting have been suggested. The authors indicate that the current general and ambiguous definitions of the MFCLs are a challenge and that an evidence-based and unambiguous quantifiable functional classification would help better define patient groups for clinical research.

Theeven et al. (2011) conducted a randomized cross-over trial on 41 participants to assess the effects of using a microprocessor-controlled prosthetic knee joint on the functional performance of ADLs in persons with a unilateral above-knee or knee disarticulation limb loss above knee(AK) leg amputation, classified as Medicare Functional Classification Level-2 (MFCL-2). The patients were tested in 3 different prosthetic knee joint conditions: 1) with their current mechanically controlled knee joint or manual locking knee, 2) with a knee joint featuring a microprocessor-controlled stance and swing phase (MPK-A), and 3) with a knee joint featuring a microprocessor-controlled stance phase (MPK-B). Baseline data was collected for the mechanically controlled knee joint condition and then performance using both MPK devices was compared to the use of the patient's mechanically controlled knee. After 13 participants dropped out, MPKs were randomly assigned to the remaining 28 participants by a blinded assessor. The test circuit utilized consisted of 11 circuit stations, where the participants were tested on 17 simulated daily activities. For each activity the performance time was recorded, and with the visual analogue scale (VAS), participants rated the perceived level of difficulty for each circuit station; 0 was deemed very easy to 100 which was considered very difficult. At the end of the study the participants were asked which type of knee joint they preferred in daily life. The authors found some participants preferred and benefited from the MPK-A, some participants preferred and benefited from the MPK-B and one patient preferred their own mechanically controlled prosthesis. These results illustrate a singular prosthesis may not be the best choice for an entire group of amputees; utilization of tests such as the ADAPT help to personalize the choice for the patient since each individual responds differently to a specific prosthesis.

Powered Microprocessor Prosthetic Ankles

There is insufficient evidence in the clinical literature demonstrating support for the use of powered microprocessor prosthetic ankles (MPAs) for transtibial amputations.

Herrin et al. (2024) conducted a comparison study with the goal of identifying performance-based metrics capable of distinguishing between good (as determined by a clinician) from poor gait quality in participants using a powered prosthetic foot. The authors studied eight different metrics of gait quality associated with use of a research-grade powered prosthetic foot in seven individuals with transtibial amputation during treadmill walking. The authors compared clinically tuned and untuned conditions. Study participants were aged between 18 and 69 years, at least 12 months post-transtibial amputation, classified as a K3–K4 walker, capable of walking with a prosthesis without assistive devices, and not using a solid ankle, cushion heel (SACH) foot as clinically prescribed. The participants were excluded if they met any of the following criteria: presence of dementia or inability to give informed consent, significant loss of hip, knee, or ankle joint motion, history of dizziness and/or balance problems, and currently pregnant. Differences between the tuned and untuned conditions were reflected in ankle power, both the vertical and anterior-posterior impulse symmetry indices, limb-force alignment, and positive ankle work, with improvements seen in all metrics during use of the tuned prosthesis. The authors concluded that all these metrics relate to the timing of force generation during walking which is information not directly

accessible to a prosthetist during a typical tuning process. This work indicates that relevant, real-time biomechanical data provided to the prosthetist through the future provision of wearable sensors may enhance and improve future clinical tuning procedures associated with powered prostheses as well as their long-term outcomes. This study was uncontrolled and unblinded and had inadequate sample size. Well designed, comparative studies with larger patient populations are needed to further describe safety and clinical outcomes.

Rogers-Bradley et al. (2024) performed a comparison study evaluating the kinematics and kinetics of walking with a microprocessor-controlled, variable-stiffness ankle-foot prosthesis (VSA) (945 g) compared to a standard low-mass passive prosthesis (Ottobock Taleo, 463 g) with seven study participants having unilateral transtibial amputation (TTA). By modulating prosthesis stiffness under computer control across walking speeds, the authors demonstrate that there exists a stiffness that increases prosthetic-side energy return, peak power, and center-of-mass push-of work and decreases contralateral limb peak ground reaction force compared to the standard passive prosthesis across all evaluated walking speeds. The authors noted an increase in center-of-mass push-of work of 26.1%, 26.2%, 29.6% and 29.9% at 0.75 m/s, 1.0 m/s, 1.25 m/s, and 1.5 m/s, respectively, and a decrease in contralateral limb ground reaction force of 3.1%, 3.9%, and 3.2% at 1.0 m/s, 1.25 m/s, and 1.5 m/s, respectively. The authors concluded that this study demonstrates the potential for a quasi-passive microprocessor-controlled variable-stiffness prosthesis to increase push-of power and energy return during gait at a range of walking speeds compared to a passive device of a fixed stiffness. This study has limitations. Most experimental conditions were performed with the VSA, which may have inadvertently allowed the participants additional adaptation time for the VSA compared to the Taleo. This effect was anticipated to be minimal because all study participants use energy storage and return (ESR) prostheses as their daily prosthetic but warrants further investigation. Additional potential study limitations include the evaluation of walking at four discrete treadmill speeds, which may not fully capture the performance of the Taleo at participants' preferred walking speeds. However, the range of evaluated speeds was selected to encompass typical self-selected walking speeds for people with TTA. The small study population limits the validity of the conclusion of this study. Well designed, comparative studies with larger patient populations are needed to further describe safety and clinical outcomes.

An evolving evidence review from Hayes (2022, updated 2024) focused specifically on the evidence to support the use of powered MPAs for transtibial amputations. Hayes reviewed the full text of three studies (two poor quality and one very poor quality) that suggested that powered MPAs may increase walking speed and improve perceived social burden of wearing the prosthesis relative to nonpowered prostheses; however, their findings were not consistent across studies and the follow-up was short. There were no systematic reviews identified nor were there any relevant professional guidelines identified. This review included the Kim (2021) study below. In their annual updates, Hayes found one newly published study in 2023 and in 2024 which did not change their current level of minimal support for powered MPAs, and Hayes did not find any new/updated systematic reviews or clinical practice guidelines.

Kannenberg et al. (2022) conducted a pragmatic, exploratory cross-sectional study to determine whether anecdotal reports on reduced musculoskeletal pain and improved patient-reported mobility were isolated occurrences or reflect a common experience in powered prosthetic ankle-foot (PwrAF) users. Two hundred and fifty individuals with transtibial amputation (TTA) who had been fitted a PwrAF in the past were invited to an online survey on average sound knee, amputated side knee, and low-back pain assessed with numerical pain rating scales (NPRS), the PROMIS Pain Interference scale, and the PLUS-M for patient-reported mobility in the free-living environment. Subjects rated their current foot and recalled the ratings for their previous foot. Recalled scores were adjusted for recall bias by clinically meaningful amounts following published recommendations. Statistical comparisons were performed using Wilcoxon's signed rank test. Forty-six subjects, all male, with unilateral TTA provided data suitable for analysis. Eighteen individuals (39%) were current PwrAF users, whereas 28 subjects (61%) had reverted to a passive foot. After adjustment for recall bias, current PwrAF users reported less sound knee pain than they recalled for use of a passive foot (-0.5 NPRS, $p = 0.036$). Current PwrAF users who recalled sound knee pain ≥ 4 NPRS with a passive foot reported improvements in sound knee pain (-2.5 NPRS, $p = 0.038$) and amputated side knee pain (-3 NPRS, $p = 0.042$). Current PwrAF users also reported improvements in patient-reported mobility (+4.6 points PLUS-M, $p = 0.016$). Individuals who had abandoned the PwrAF did not recall any differences between the feet. The authors concluded that current PwrAF users reported significant and clinically meaningful improvements in patient-reported prosthetic mobility as well as sound knee and amputated side knee pain compared to recalled mobility and pain with passive feet used previously. However, a substantial proportion of individuals who had been fitted such a foot in the past did not recall improvements and had reverted to passive feet. The identification of individuals with unilateral TTA who are likely to benefit from a PwrAF remains a clinical challenge and requires further research. This study has limitations. First, it used recall for pain and prosthetic mobility for prosthetic feet that subjects had used in the past and compared them to ratings for the currently used prosthetic foot. Subjects are known to tend to overrate past pain and physical function as compared to current ratings taken in the past. The risk of recall bias in this study was addressed by adjusting the recalled ratings by clinically meaningful amounts following recommendations in the literature. In addition, these recall adjustments were only performed if they resulted in a disadvantage for the PwrAF by narrowing the differences to the passive feet. A second

limitation is the current inability to define predictive characteristics of responders to the PwrAF. Thus, the study could only survey a sample whose majority had not benefitted from using the PwrAF. A third limitation of this study is that no information was available on other factors that may have had an impact on musculoskeletal pain associated with prosthesis use, such as prosthetic alignment or concurrent medical treatments, such as physical therapy. Future research should assess musculoskeletal pain prospectively with current ratings of the studied devices and consider potential confounding factors. Third of the 250 potential subjects asked to participate in the survey, only 52 (20.8%) responded, all of them male and 80% with traumatic amputations. It is unknown whether the results are representative for the entire population and may also be transferable to female individuals, subjects with other amputation etiologies, or whether the sample was overly skewed toward individuals who did not benefit from the PwrAF. The findings of this study need to be validated by well-designed studies. Further investigation is needed before clinical usefulness of this procedure is proven.

Thomas-Pohl et al. (2021) investigated the relevance of microprocessor prosthetic ankles (MPAs) on six participants with transtibial amputation that currently wear an energy storing and returning (ESR) foot; the ability to stand on both level and inclined surfaces was evaluated. The study evaluated three MPAs: ElanVR Endolite (MPA1), MeridiumVR Ottobock (MPA2), ProprioFootVR Ossur (MPA3). All participants completed the simplified Activities-Specific Balance Confidence scale (ABC) questionnaire and underwent balance and mobility tests [the Berg Balance (BBS) scale, and the 2-min walk test (2MWT)]. Instrumental analysis was completed by furnishing the subjects in reflective markers and performance of several walking tasks; lower limb angular position and moment, Centre of Pressure (CoP) position, Ground Reaction Forces (GRF) and functional scores were collected stationary, on level ground and at 12% inclined slope. The authors concluded that increased ankle mobility is associated with better posture and slope balance and that the benefits of wearing MPAs had a direct relation to their design. Limitations included small sample size and lack of comparison group.

Kim et al. (2021) Twelve individuals with unilateral transtibial amputations (TTA) participated in a randomized clinical trial comparing unpowered prosthesis against the BiOM powered prosthesis. 7 people were randomly assigned to the powered prosthesis group and the other 5 were part of the unpowered prosthesis group; 10 participants completed the full study. Inclusion criteria for the participants consisted of patients aged 21years or older and had a unilateral TTA with prosthetic use for at least six months. The authors collected data on metabolic costs, walking speeds in-lab and in daily life, step count, step count away from home, perceived mobility, and preference between powered and unpowered prostheses. Participants completed the Prosthesis Evaluation Questionnaire (PEQ) which captured their mobility experience and quality of life. The authors concluded there was no significance between the two groups; wearing the powered prosthesis did not significantly decrease metabolic costs, increase physical activity or walking speed, or increase the individual's perceived mobility. Yet participants with the powered prosthesis reported they felt they could walk faster and with more ease but did complain about the battery life and weight of the prosthesis. Limitations included small sample size, lab environment assessments which contributed to the absence of real-world situations, and inaccurate data for the power operated device due to dead battery. Future studies with larger cohorts are warranted.

Kaluf et al. (2020) examined the differences in patient reported balance, mobility, socket comfort, and preference between a fixed-ankle energy-storing-and-returning (ESAR) foot and an MPA. 23 participants at a K3 level with unilateral transtibial amputation (UTA) were randomly assigned into two groups. Group AB received the MPA to use during the first 4-week period and Group BA received the ESAR foot; both groups then switched. A certified prosthetist performed all the fitting and alignment of each participant's prosthetic. At each visit, participants filled out patient reported outcome measures (PROM) which included the Activities Specific Balance Confidence Scale (ABC), Prosthesis Evaluation Questionnaire–Mobility Subscale (PEQ-MS), and Prosthetic Limb User Survey of Mobility (PLUS-M), Socket Comfort Score (SCS). At the end of study, each subject was interviewed by the research prosthetist and asked what they liked and disliked about both devices, and which would be their choice for their daily prosthetic. The authors found the MPA showed significantly better patient reported outcomes when it came to walking and standing on sloped surfaces. Limitations included small sample size, male gender participants only and participants with K3 level functioning or higher. Future studies should examine type of ankle-foot system and type of socket suspension, physical therapy training, comparison groups along with including patients with lower classification levels.

Struchkov and Buckley (2016) studied nine unilateral trans-tibial amputees to determine whether use of a microprocessor-controlled passive-articulating (MPC) hydraulic ankle–foot device improved the gait biomechanics when compared to conventional ankle–foot mechanisms. Out of the nine participants, which were all classified as K3 users, 4 of them used an Elan, 4 an Echelon VT and one a Re-flex Rotate; all were familiarized with using an articulating ankle–foot device. The ramp used was custom made with a 5-degree incline and 2.8 m long/1 m wide walking surface. The participants completed trials at two speeds walking down the ramp with both active and inactive MPC and the comparable elastic foot device. Residual limb kinematics, joint moments/powers and prosthetic foot power absorption/return were compared across all ankle types using analysis of variance (ANOVA). The authors found that use of a MPC hydraulic foot reduced the biomechanical compensations used to walk down slopes. Limitations included small sample size, lack of comparison group, and limited education and use for the non-hydraulic foot may have skewed certain values/results.

Clinical Practice Guidelines

Department of Veterans Affairs(VA)/Department of Defense (DoD)

In a 2017 Clinical Practice Guideline for Rehabilitation of Individuals with Lower Limb Amputation, the following is recommended:

- Assessment of behavioral health and psychosocial functioning at every phase of amputation management and rehabilitation. (Weak recommendation)
- Institute rehabilitation training interventions, using both open and closed chain exercises and progressive resistance to improve gait, mobility, strength, cardiovascular fitness, and activities of daily living performance in order to maximize function. (Strong recommendation)
- Microprocessor knee units over non-microprocessor knee units for ambulation to reduce risk of falls and maximize patient satisfaction. There is insufficient evidence to recommend for or against any particular socket design, prosthetic foot categories, and suspensions and interfaces. (Weak recommendation)
- Use of valid, reliable, and responsive functional outcome measures, including, but not limited to, the Comprehensive High-level Activity Mobility Predictor, Amputee Mobility Predictor, 10-meter walk test, and 6-minute walk test. (Strong recommendation)

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Prosthetic devices and components are classified by the FDA as Class I medical devices. Class I devices have the least amount of regulatory control; manufacturers of these devices are exempt from the premarket notification procedures and are not required to provide safety and effectiveness data prior to marketing. Examples of these devices include “ankle, foot, hip, knee, and socket components; mechanical or powered hand, hook, wrist unit, elbow joint, and shoulder joint components; and cable and prosthesis suction valves.” Additional information is available at: https://www.fda.gov/medical-devices. (Accessed October 22, 2024)

The OPRA™ Implant System is an Osseoanchored Prostheses for the Rehabilitation of Amputees (OPRA) device and composed of parts that allow a prosthesis to attach directly to the femur (thigh bone). The device was granted FDA premarket approval on December 18, 2020. Additional information is available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P190009. (Accessed October 22, 2024)

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Policy History/Revision Information

Date	Summary of Changes
04/01/2025	**Applicable Codes** • Updated list of applicable HCPCS codes to reflect quarterly edits; added L5827 **Supporting Information** • Archived previous policy version 2025T0645G

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.