Humana.

Medicaid Medical Coverage Policy

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Description

A prosthesis or prosthetic is an artificial device that replaces a missing body part. Examples of prostheses include arms, breasts, ears, feet, hands, legs and maxillofacial (jaw and face).

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

The prosthetic foot has several basic functions; it provides a stable weight-bearing surface, absorbs shock, replaces lost muscle function and biomechanics of the foot, replicates the anatomic joints of the ankle and foot and restores appearance. Multiaxial prosthetic feet permit movements in any direction: plantar flexion, dorsiflexion, inversion, eversion and a slight amount of rotation around a vertical axis. Multiaxial feet are appropriate for those who ambulate on uneven terrain, such as community ambulators and active adults or athletes.

The **solid ankle cushion heel** (SACH) consists of a rigid keel covered by semi-noncompressible foam and a synthetic rubber heel wedge. The cushion heel compresses when weight is applied, allowing the forefoot to approach the floor. The amount of simulated plantar flexion depends on the relative softness of the heel

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material and weight of the amputee. Because the keel is rigid, the SACH foot does not provide dorsiflexion; this makes its usefulness on uneven surfaces limited.

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

Upper limb prostheses are classified into the following categories:

- **Body powered** utilizes a body harness and cable system to provide functional manipulation. Voluntary movement of the shoulder and/or limb stump extends the cable system and transmits force to the device to control hand, forearm and elbow movement.
- **Hybrid** is a combination of body powered and myoelectric components and may be used for high-level amputations (at or above the elbow). Hybrid systems allow control of 2 joints at once.
- **Myoelectric** uses muscle activity from the residual limb for control of joint movement. Electromyographic signals from the limb stump are detected by surface electrodes, amplified and then processed by a controller to drive battery powered motors that move the hand, wrist and elbow. These devices operate on rechargeable batteries and require no external cables or harnesses.
- **Passive** is the lightest and serves mostly a cosmetic purpose as it does not restore any function and must be repositioned manually, typically by moving it with the opposite arm.

An **adjustable click prosthesis** (eg, BOA, RevoFit, RevoFit 2) is a self-adjustable prosthetic socket. The click reel consists of an adjustable dial, strong lightweight laces and lace guides. The dial incorporates a gearing mechanism that advances the lace and moveable portions. Turning the click reel engages the lacing system that adjusts predetermined areas of the socket custom to each individual's needs. It purportedly allows for control of compression and expansion to manage residual limb volume fluctuation and ease of donning and doffing. **(Refer to Coverage Limitations section)**

An **enhanced dexterity prosthetic arm** (eg, Life Under Kinetic Evolution [LUKE] Arm) is an upper limb prosthesis that was developed to restore function in those individuals who have lost all or part of their upper limb. It is primarily controlled by a micro-electromechanical system that is operated through an inertial measurement unit (IMU), which is located in a sensor that is attached to or embedded in the individual's shoe. By lifting the foot in various directions, it purportedly commands the motion of the prosthesis.¹⁹ (Refer to Coverage Limitations section)

A **multiarticulating**, **myoelectric hand prosthetic** (eg, bebionic, iLimb, Michelangelo, Vincent) functions by individually powering all 5 digits to grasp by conforming to the objects shape and fluctuating the grip strength. Devices vary in function and options including, but not limited to, the ability to be controlled by a mobile device app, conductive tips for mobile device use, multiple wrist options and skin colored silicone

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glove covers (eg, Livingskin). The prosthetic is described as anthropomorphic (human like) in its appearance and shape.

An **osseointegrated prosthesis** for the rehabilitation of amputees (OPRA), is an osseointegration device, also referred to as osseoanchored device (bone anchored) intended for skeletally mature individuals (bone growth is complete) who have transfemoral amputation due to trauma or cancer.²⁰

A **partial hand myoelectric prosthetic** (eg, ProDigits) replaces the function of one or more missing fingers because of a partial hand amputation. It is intended for use for an amputation at a transmetacarpal (part of the hand but not the wrist itself) level or higher. **(Refer to Coverage Limitations section)**

Coverage Determination

Humana members may be eligible under the Plan for **medically necessary prosthesis devices and supplies** to restore the previous level of function in order to perform normal activities of daily living (ADL). In addition, the following specific criteria must be met:

<u>Eye</u>

Humana members may be eligible under the Plan for an **eye prosthesis (V2623)** due to absence of an eye from a congenital defect, disease, injury or surgical removal.

Facial (including ears)

Humana members may be eligible under the Plan for a **facial prosthesis (21086, 21088, L8044, L8048)** for loss or absence of facial tissue due to a congenital defect, disease, injury or surgery.

<u>Hip</u>

Humana members may be eligible under the Plan for a **pneumatic or hydraulic polycentric hip joint (L5961)** for a <u>functional level</u> of 3 or above.

Residual Limb Volume Management/Moisture Evacuation

Humana members may be eligible under the Plan for **residual limb volume management and moisture evacuation system (eg, Vacuum Assisted Socket System [VASS]) (L5781, L5782)** when the following criteria are met:

• Absence of contraindications;

AND one of the following:

- Diabetes or occlusive arterial disease; OR
- Excessive residual limb hyperemia from prior socket use; OR
- Excessive skin hyperhidrosis from prior socket use that has not responded to treatment (eg, over-thecounter [OTC] and prescription antiperspirant, sheath or sock under liner); **OR**

- Failure of other socket-suspension systems (eg, mechanical, passive suction) to provide secure fit that cannot be resolved by adjustments; **OR**
- Multiple falls in transtibial amputees; **OR**
- Nonhealing skin ulcerations on stump; OR
- Volume fluctuations of limb up to 2 cm in circumference

Osseointegrated Prosthesis for the Rehabilitation of Amputees (OPRA)

Humana members may be eligible under the Plan for **osseointegrated prosthesis for the rehabilitation of amputees (OPRA) (L5991)** when the following criteria (<u>FDA-approved indications</u>)¹⁹ are met:

- Absence of <u>contraindications</u>; AND
- 22 to 65 years of age; AND
- Transfemoral amputation due to trauma or cancer and rehabilitation problems with or cannot use a conventional socket prosthesis with one or more of the following:
 - o Extensive area of skin grafting; OR
 - o Pain; OR
 - o Recurrent skin infections and ulcerations in the socket contact area; OR
 - o Restricted mobility; OR
 - Short stump preventing the use of socket prosthesis; OR
 - Socket retention problems due to excessive perspiration; OR
 - Soft tissue scarring; OR
 - Volume fluctuation in the stump

Accessories

Humana members may be eligible under the Plan for **stump stockings and harnesses (including replacements)** when they are essential to the effective use of the artificial limb.

Humana members may be eligible under the Plan for **prosthetic sheaths/socks**, including a gel cushion layer.

Prosthetic Shoe

Humana members may be eligible under the Plan for a **prosthetic shoe (L3250)** for a partial foot amputation when the prosthetic shoe is an integral part of a covered lower limb prosthesis.

UPPER EXTREMITY

Body Powered

Humana members may be eligible under the Plan for a **body powered upper extremity prosthesis and lock mechanism (L6646, L6647)** when adjustable positions, such as abduction, adduction, flexion and multipositional locking are required to meet the functional needs of performing normal ADLs.

Myoelectric including Hybrid

Humana members may be eligible under the Plan for a **myoelectric upper extremity prosthesis and hand prosthesis** when **ALL** of the following criteria are met:

- Absence of a comorbidity that could interfere with maintaining function of the prosthesis (eg, neuromuscular disease); **AND**
- Amputation or missing limb at the wrist or above (eg, forearm or elbow); AND
- Remaining musculature of the arm contains the minimum microvolt threshold to allow operation of the prosthesis; **AND**
- Standard body powered prosthesis is insufficient to meet the functional needs to perform normal ADLs; **AND**
- Sufficient cognitive and neurological function to operate the prosthesis effectively

Testicular

Humana members may be eligible under the Plan for a **testicular prosthesis (54660)** for congenitally absent testes or testes that are surgically removed due to disease (eg, cancer) or injury.

Prosthesis Repair and Replacement

Humana members may be eligible under the Plan for **repair (L7510, L7520)** of a prosthesis, if not covered by the manufacturer when the following criteria are met:

- Change in the individual's physical condition causing the device to become nonfunctional; OR
- Normal wear and tear renders the device nonfunctional, and the repair will make the device usable

Humana members may be eligible under the Plan for **replacement (L8049)** of a prosthesis, if not covered by the manufacturer **AND** replacement cost is less than the repair cost, when the following criteria are met:

- Change in the individual's physical condition causing the device to become nonfunctional and nonrepairable; **OR**
- Normal wear and tear renders the device nonfunctional and nonrepairable

Humana members may be eligible under the Plan for **replacement of sockets or socket inserts** if there is documentation of functional and/or physiological need (eg, changes in the residual limb; functional need changes; or irreparable damage or wear/tear due to individual's weight or prosthetic demands of very active amputees).

Coverage Limitations

Humana members may **NOT** be eligible under the Plan for a **prosthesis, component or related service** for any indications other than those listed above including, but may not be limited to, the following:

PROSTHETIC/DEVICE	COMMENTS/COVERAGE INSTRUCTIONS
Breast	
Breast prosthesis, custom fabricated (L8035)	Not medically necessary
Nipple prosthesis, custom fabricated (L8033)	
Breast prosthesis, not otherwise specified (L8039)	A review of the current medical literature shows
	that the evidence is insufficient to determine
	that these devices are standard medical
	treatment. There is an absence of current,
	widely-used treatment guidelines or acceptable
	clinical literature examining benefit and long-
	term clinical outcomes establishing the value of
	these devices in clinical management because
	prosthesis
Dunlicate/Renair/Renlacement	prostnesis.
Duplication or ungrade of a functional prosthosis	Not modically pocossary
Duplicate prosthesis repair (17510 17520)	Not medically necessary
Duplicate prostnesis, replacement (18049)	Duplicate prosthetic devices with the same
	function are generally considered not medically
	necessary and therefore the repair or
	replacement of a duplicate prosthetic device or
	its parts or components would also be
	considered not medically necessary.
Prosthesis repair (L7510, L7520)	Repair or replacement of a prosthetic device or
Prosthesis replacement (L8049)	its parts or components for appearance, comfort,
	convenience or due to individual abuse, misuse
	or neglect is considered not medically necessary
Lower Limb	1
Lower limb prosthesis	A lower limb prosthesis for a <u>functional level</u> of 0
	is not medically necessary because the individual
	does not have the ability or potential to
	ampulate or transfer safely with or without

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PROSTHETIC/DEVICE	COMMENTS/COVERAGE INSTRUCTIONS
	assistance and a prosthesis does not enhance
	their quality of life or mobility
Microprocessor controlled ankle foot system (L5973)	Not medically necessary
	A review of the current medical literature shows
	that the evidence is insufficient to determine
	that these devices are standard medical
	treatment. There is an absence of current,
	widely-used treatment guidelines or acceptable
	clinical literature examining benefit and long-
	these devices in clinical management
Liser adjustable heal height feature (IE000)	Net medically recordery
Oser-adjustable neel neight leature (L5990)	Not medically necessary
	A review of the current medical literature shows
	that the evidence is insufficient to determine
	that these devices are standard medical
	treatment. There is an absence of current.
	widely-used treatment guidelines or acceptable
	clinical literature examining benefit and long-
	term clinical outcomes establishing the value of
	these devices in clinical management.
Miscellaneous	
Prosthetic donning sleeve (L7600)	Devices are designed to facilitate easier donning
	of a prosthetic and are not medically necessary
Prosthetics used for activities other than normal daily	Prosthetics used for activities other than normal
living (L5999) (eg, Genium X3)	daily living, including sporting activities (eg,
	skiing) and water prosthesis/water submersible
	(designed to be used for showering, swimming)
	are not medically necessary
	A review of the current medical literature shows
	that there is no evidence to determine that
	these devices are standard medical treatment.
	There is an absence of current, widely-used
	treatment guidelines or acceptable clinical
	literature examining benefit and long-term
	clinical outcomes establishing the value of these
	devices in clinical management.
Test sockets, diagnostic (L5618, L5620, L5622, L5624,	More than 2 diagnostic test sockets per
L5626, L5628)	individual prosthesis at the same time are not
	medically necessary
Test sockets, immediate (L5618, L5620, L5622, L5624,	

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PROSTHETIC/DEVICE	COMMENTS/COVERAGE INSTRUCTIONS
L5626, L5628)	Test sockets for an immediate prosthesis are not
	medically necessary
Upper Limb	
Adjustable click prosthesis (L5999, L7499) (eg, BOA, RevoEit, RevoEit 2)	Experimental and Investigational
	A review of the current medical literature shows
	that there is no evidence to determine that
	these devices are standard medical treatment.
	There is an absence of current, widely-used
	treatment guidelines or acceptable clinical
	literature examining benefit and long-term
	clinical outcomes establishing the value of these
	devices in clinical management.
Enhanced dexterity prosthetic arm (L7499) (Life Under Kinetic Evolution [LUKE] Arm)	Experimental and Investigational
	A review of the current medical literature shows
	that there is no evidence to determine that
	these devices are standard medical treatment.
	There is an absence of current, widely-used
	treatment guidelines or acceptable clinical
	literature examining benefit and long-term
	clinical outcomes establishing the value of these
	devices in clinical management.
Gloves for an upper extremity prosthesis (L6890,	Humana members may NOT be eligible under
L6895)	the Plan for procedures performed for cosmetic
	purposes (to improve or change appearance or
	self-esteem)
	This type of glove does not affect the function of
	the prosthesis customization includes matching
	color, skin, hair and wrinkles and is therefore
	considered cosmetic and not medically
	necessary
Myoelectric partial hand prosthesis (L6026) (eg.	Experimental and Investigational
ProDigits)	
	A review of the current medical literature shows
	that there is no evidence to determine that
	these devices are standard medical treatment.
	There is an absence of current, widely-used
	treatment guidelines or acceptable clinical
	literature examining benefit and long-term
	clinical outcomes establishing the value of these
	devices in clinical management.

Residual Limb Volume Management/Moisture Evacuation

Humana members may **NOT** be eligible under the Plan for **residual limb volume management and moisture evacuation system (eg, Vacuum Assisted Socket System [VASS]) (L5781, L5782)** for any of the following contraindications:

- Individual is receiving dialysis; OR
- Individual is unable to operate the system; OR
- Individual is undergoing interim fittings; OR
- Neuroma preventing individual from being able to bear pressure on the residual limb

This is considered experimental/investigational as it is not identified as widely used and generally accepted for the proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language.

Osseointegrated Prosthesis for the Rehabilitation of Amputees (OPRA)

Humana members may **NOT** be eligible under the Plan for **osseointegrated prosthesis for the rehabilitation of amputees (OPRA) (L5991)** if any of the following contraindications¹⁹ are present:

- Atypical skeletal anatomy with the following:
 - o Conditions which are not amenable to device insertion such as deformities, fracture, infection; OR
 - Development anomalies; OR
 - Skeletal dimensions outside defined interval; OR
- Body weight is higher than 220 pounds including the prosthesis; OR
- Individual is pregnant; OR
- Individual is unable to comply with treatment and follow up requirements; OR
- Individual with one of the following concurrent conditions:
 - Active infection or dormant bacteria; OR
 - Diabetic mellitus with complications; OR
 - o Metabolic bone disease and/or metastatic lesions in the residual femur; OR
 - Neuropathy or neuropathic disease and severe phantom pain; OR
 - Severe peripheral vascular disease; OR
 - Skin disorders involving the residual extremity; OR
- Less than 2 mm of remaining cortex bone available around the implant, if implanted; OR
- Osteoporosis; OR
- Skeletal growth is not complete (completed skeletal growth is defined through the finding of generally closed epiphyseal zones on X-ray)

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This is considered experimental/investigational as it is not identified as widely used and generally accepted for the proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language.

Humana members may **NOT** be eligible under the Plan for **upper limb osseointegrated prosthesis for the rehabilitation of amputees (OPRA) system (24999, L7499)** as this device is not FDA-approved.

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
21086	Impression and custom preparation; auricular prosthesis	
21088	Impression and custom preparation; facial prosthesis	
24999	Unlisted procedure, humerus or elbow	
54660	Insertion of testicular prosthesis (separate procedure)	
CPT [®] Category III Code(s)	Description	Comments
No code(s) ic	lentified	
HCPCS Code(s)	Description	Comments
L3250	Orthopedic footwear, custom molded shoe, removable inner mold, prosthetic shoe, 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	
L5781	Addition to lower limb prosthesis, vacuum pump, residual limb volume management and moisture evacuation system	
L5782	Addition to lower limb prosthesis, vacuum pump, residual limb volume management and moisture evacuation system, heavy-duty	
L5961	Addition, endoskeletal system, polycentric hip joint, pneumatic or hydraulic control, rotation control, with or without flexion and/or extension control	

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L5973	Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, includes power source	
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	
L6026	Transcarpal/metacarpal or partial hand disarticulation prosthesis, external power, self-suspended, inner socket with removable forearm section, electrodes and cables, two batteries, charger, myoelectric control of terminal device, excludes terminal device(s)	
L6646	Upper extremity addition, shoulder joint, multipositional locking, flexion, adjustable abduction friction control, for use with body powered or external powered system	
L6647	Upper extremity addition, shoulder lock mechanism, body powered actuator	
L6890	Addition to upper extremity prosthesis, glove for terminal device, any material, prefabricated, includes fitting and adjustment	
L6895	Addition to upper extremity prosthesis, glove for terminal device, any material, custom fabricated	
L7499	Upper extremity prosthesis, not otherwise specified	
L7510	Repair of prosthetic device, repair or replace minor parts	
L7520	Repair prosthetic device, labor component, per 15 minutes	
L7600	Prosthetic donning sleeve, any material, each	
L8033	Nipple prosthesis, custom fabricated, reusable, any material, any type, each	
L8035	Custom breast prosthesis, post mastectomy, molded to patient model	
L8039	Breast prosthesis, not otherwise specified	
L8044	Hemi-facial prosthesis, provided by a nonphysician	
L8048	Unspecified maxillofacial prosthesis, by report, provided by a nonphysician	
L8049	Repair or modification of maxillofacial prosthesis, labor component, 15 minute increments, provided by a nonphysician	
V2623	Prosthetic eye, plastic, custom	

References

- 1. Agency for Healthcare Research and Quality (AHRQ). Comparative Effectiveness Review (ARCHIVED). Lower limb prosthesis: measurement instruments, comparison of components effects by subgroups, and long-term outcomes. <u>https://www.ahrq.gov</u>. Published September 2018.
- 2. Centers for Medicare & Medicaid Services (CMS). Health Technology Assessment. Lower limb prosthetic workgroup consensus document. <u>https://www.cms.gov</u>. Published September 2017.
- 3. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD). Prosthetic shoe (280.10). <u>https://www.cms.gov</u>.
- 4. ClinicalKey. Nelson F. Prosthetics and orthotics. In: Nelson F. A *Manual of Orthopedic Terminology*. 9th ed. Elsevier; 2022:197-215. <u>https://www.clinicalkey.com</u>.
- ClinicalKey. Rosenblatt NJ, Ehrhardt T. The effect of vacuum assisted socket suspension on prospective, community-based falls by users of lower limb prostheses. *Gait Posture*. 2017;55:100-103. <u>https://www.clinicalkey.com</u>.
- 6. ECRI Institute. Clinical Evidence Assessment. Microprocessor-controlled knee prosthesis use in amputee with limited community ambulation. <u>https://www.ecri.org</u>. Published September 26, 2022.
- 7. ECRI Institute. Clinical Evidence Assessment. OPRA osseointegrated implant system (Integrum AB) for lower-limb amputees. <u>https://www.ecri.org</u>. Published May 19, 2022.
- 8. ECRI Institute. Health Technology Forecast. Enhanced-dexterity prosthetic arm (LUKE arm) to restore natural arm functions after amputations. <u>https://www.ecri.org</u>. Published July 6, 2010. Updated September 15, 2017.
- 9. Hansen C, Godfrey B, Wixom J, McFadden M. Incidence, severity, and impact of hyperhidrosis in people with lower-limb amputation. *J Rehabil Res Dev*. 2015;52(1):31–40. https://www.rehab.research.va.gov.
- 10. Hayes, Inc. Clinical Research Response. Osseointegrated prosthetic implants for lower leg amputation. <u>https://evidence.hayesinc.com</u>. Published September 14, 2022.
- 11. Hayes, Inc. Evolving Evidence Review. OPRA implant system (Integrum Inc.) in patients with transfemoral amputation. <u>https://evidence.hayesinc.com</u>. Published February 15, 2023. Updated March 31, 2024.
- 12. Hayes, Inc. Evolving Evidence Review. Passive microprocessor prosthetic ankles in patients with transtibial amputation. <u>https://evidence.hayesinc.com</u>. Published December 21, 2021. Updated October 23, 2023.
- Hayes, Inc. Evolving Evidence Review. Powered microprocessor prosthetic ankles in patients with transtibial amputation. <u>https://evidence.hayesinc.com</u>. Published February 23, 2022. Updated April 12, 2024.

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- 14. Hayes, Inc. Health Technology Assessment. LUKE arm (Mobius Bionics LLC) for upper extremity amputation. <u>https://evidence.hayesinc.com</u>. Published November 29, 2021. Updated October 23, 2023.
- 15. Hayes, Inc. Health Technology Brief. C-leg prostheses (Otto Bock Healthcare LP) for patients with above-knee amputation. <u>https://evidence.hayesinc.com</u>. Published January 30, 2013. Updated January 12, 2015.
- 16. Rink C, Wernke M, Powell H, et al. Elevated vacuum suspension preserves residual-limb skin health in people with lower-limb amputation: Randomized clinical trial. *J Rehabil Res Dev.* 2017;53(6):1121-1132. <u>https://www.rehab.research.va.gov</u>.
- 17. US Department of Veterans Affairs (VA). VA/DoD clinical practice guideline for rehabilitation on individuals with lower limb amputation. <u>https://www.va.gov</u>. Published 2017.
- 18. US Department of Veterans Affairs (VA). VA/DoD clinical practice guideline for the management of upper extremity amputation rehabilitation. <u>https://www.va.gov</u>. Published 2022.
- US Food & Drug Administration (FDA). Summary of safety and effectiveness data: Osseoanchored prostheses for the rehabilitation of amputees (OPRA). <u>https://www.fda.gov</u> Published December 18, 2020.

Appendix

Appendix A

Lower Extremity Prosthesis Functional Level Criteria^{1,2}

Functional Level	Current and/or Potential Activity Level
0	Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility.
1	Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence; typical of the limited and unlimited household ambulator.
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.
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.
4	Has the ability or potential for prosthetic ambulation that exceeds the basic ambulation skills, exhibiting high impact, stress or energy levels; typical of the prosthetic demands of the child, active adult or athlete.

Change Summary

01/07/2025 New Policy.