Microprocessor-Controlled Prostheses for the Lower Limb

Policy # 00426
Original Effective Date: 07/16/2014
Current Effective Date: 07/01/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Myoelectric Prosthetic Components for the Upper Limb is addressed separately in medical policy 00443

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider a microprocessor-controlled knee in individuals with transfemoral amputation who meet the following requirements to be **eligible for coverage:****

Patient Selection Criteria
Coverage eligibility will be considered when all of the following criteria are met:

- Individual has a functional K-Level 3 or above (see Policy Guidelines); AND
- Demonstrated need for daily long distance ambulation at variable rates (generally 400 continuous yards or greater; use of the limb in the home or for basic community ambulation is not sufficient to justify provision of the computerized limb over standard limb applications) OR demonstrated individual need for daily and frequent ambulation on uneven terrain or for regular use on stairs (use of the limb for limited stair climbing in the home or employment environment is not sufficient evidence for prescription of this device over standard prosthetic application); AND
- Physical ability, including adequate cardiovascular and pulmonary reserve, for ambulation at faster than normal walking speed; AND
- Adequate cognitive ability to master use and care requirements for the technology.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers a powered knee to be **investigational.***

Policy # 00426
Original Effective Date: 07/16/2014
Current Effective Date: 07/01/2025

Based on review of available data, the Company considers a microprocessor-controlled or powered ankle-foot to be **investigational.***

Based on review of available data, the Company considers a microprocessor-controlled knee in individuals who do not meet these criteria. to be **investigational.***

Policy Guidelines

Amputees should be evaluated by an independent, qualified professional to determine the most appropriate prosthetic components and control mechanism. A trial period may be indicated to evaluate the tolerability and efficacy of the prosthesis in a real-life setting. Decisions about the potential benefits of microprocessor knees involve multiple factors including activity levels and the individual's physical and cognitive ability. An individual's need for daily ambulation of at least 400 continuous yards, daily and frequent ambulation at variable cadence or on uneven terrain (eg, gravel, grass, curbs), and daily and frequent use of ramps and/or stairs (especially stair descent) should be considered as part of the decision. Typically, the daily and frequent need of 2 or more of these activities would be needed to show benefit.

Individual Selection and Identification

For individuals in whom the potential benefits of the microprocessor knees are uncertain, individuals may first be fitted with a standard prosthesis to determine their level of function with the standard device.

Medicare Functional Classification Levels (K levels)

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

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

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

Level 3: Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.

Level 4: Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

The following are guidelines from the Veterans Health Administration Prosthetic Clinical Management Program Clinical Practice Recommendations for Microprocessor Knees.

A. Contraindications for the use of the microprocessor knee should include the following:
- Any condition that prevents socket fitting, such as a complicated wound or intractable pain which precludes socket wear
- Inability to tolerate the weight of the prosthesis
- Medicare level K0-no ability or potential to ambulate or transfer
- Medicare level K1-limited ability to transfer or ambulate on level ground at fixed cadence
- Medicare level K2-limited community ambulator who does not have the cardiovascular reserve, strength, and balance to improve stability in stance to permit increased independence, less risk of falls, and potential to advance to a less restrictive walking device
- Inability to use swing and stance features of the knee unit
- Poor balance or ataxia that limits ambulation
- Significant hip flexion contracture (>20°)
- Significant deformity of remaining limb that would impair the ability to stride
- Limited cardiovascular and/or pulmonary reserve or profound weakness
- Limited cognitive ability to understand gait sequencing or care requirements
- Long-distance or competitive running
- Falls outside of recommended weight or height guidelines of the manufacturer
- Specific environmental factors such as excessive moisture or dust, or inability to charge the prosthesis
- Extremely rural conditions where maintenance ability is limited.

B. Indications for the use of the microprocessor knee should include the following:
- Adequate cardiovascular and pulmonary reserve to ambulate at variable cadence
- Adequate strength and balance in stride to activate the knee unit
- Should not exceed the weight or height restrictions of the device
- Adequate cognitive ability to master technology and gait requirements of the device
- Hemi-pelvectomy through knee-disarticulation level of amputation, including bilateral; lower-extremity amputees are candidates if they meet functional criteria as listed
- The individual is an active walker and requires a device that reduces energy consumption to permit longer distances with less fatigue
- Daily activities or job tasks that do not permit full focus of concentration on knee control and stability-such as uneven terrain, ramps, curbs, stairs, repetitive lifting, and/or carrying
- Medicare level K2-limited community ambulator, but only if improved stability in stance permits increased independence, less risk of falls, and potential to advance to a less restrictive walking device, and the individual has the cardiovascular reserve, strength, and balance to use the prosthesis. The microprocessor enables fine-tuning and adjustment of the hydraulic mechanism to accommodate the unique motor skills and demands of the functional level K2 ambulator.

- Medicare level K3-unlimited community ambulator
- Medicare level K4-active adult athlete who needs to function as a K3 level in daily activities
- Potential to lessen back pain by providing more secure stance control, using less muscle control to keep the knee stable
- Potential to unload and decrease stress on remaining limb
- Potential to return to an active lifestyle.

C. Physical and Functional Fitting Criteria for New Amputees:
- New amputees may be considered if they meet certain criteria as outlined above
- Premorbid and current functional assessment important determinant
- Requires stable wound and ability to fit the socket
- Immediate postoperative fit is possible
- Must have potential to return to an active lifestyle

Background/Overview

Lower-Extremity Prosthetics

More than 100 different prosthetic ankle-foot and knee designs are currently available. The choice of the most appropriate design may depend on the patient's underlying activity level. For example, the requirements of a prosthetic knee in an elderly, largely homebound individual will differ from those of a younger, active person. Key elements of prosthetic knee design involve providing stability during both the stance and swing phase of the gait. Prosthetic knees vary in their ability to alter the cadence of the gait, or the ability to walk on rough or uneven surfaces. In contrast to more simple prostheses, which are designed to function optimally at 1 walking cadence, fluid and hydraulic-controlled devices are designed to allow amputees to vary their walking speed by matching the movement of the shin portion of the prosthesis to the movement of the upper leg. For example, the rate at which the knee flexes after "toe-off" and then extends before heel strike depends in part on the mechanical characteristics of the prosthetic knee joint. If the resistance to flexion and extension of the joint does not vary with gait speed, the prosthetic knee extends too quickly or too slowly relative to the heel strike if the cadence is altered. When properly controlled, hydraulic or pneumatic swing-phase controls allow the prosthetist to set a pace adjusted to the individual amputee, from very slow to a race-walking pace. Hydraulic prostheses are heavier than other options and require gait training; for these reasons, these prostheses are prescribed for athletic or fit individuals. Other design features include multiple centers of rotation, referred to as "polycentric knees." The mechanical complexity of these devices allows engineers to optimize selected stance and swing-phase features.

Microprocessor-controlled prosthetic knees have been developed, including the Intelligent Prosthesis (Blatchford); the Adaptive (Endolite); the Rheo Knee®‡ (Össur); the C-Leg®‡, Genium™‡ Bionic Prosthetic System, and the X2 and X3 prostheses (Otto Bock Orthopedic Industry); and Seattle Power Knees (3 models include Single Axis, 4-bar, and Fusion, from Seattle Systems). These devices are equipped with a sensor that detects when the knee is in full extension and adjusts the

swing phase automatically, permitting a more natural walking pattern of varying speeds. The prosthetist can specify several different optimal adjustments that the computer later selects and applies according to the pace of ambulation. Also, these devices (except the Intelligent Prosthesis) use microprocessor control in both the swing and stance phases of gait. (The C-Leg Compact provides only stance control.) By improving stance control, such devices may provide increased safety, stability, and function. For example, the sensors are designed to recognize a stumble and stiffen the knee, thus avoiding a fall. Other potential benefits of microprocessor-controlled knee prostheses are improved ability to navigate stairs, slopes, and uneven terrain and reduction in energy expenditure and concentration required for ambulation. In 1999, the C-Leg was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process (K991590). Next-generation devices such as the Genium Bionic Prosthetic system and the X2 and X3 prostheses use additional environmental input (eg, gyroscope and accelerometer) and more sophisticated processing that is intended to create more natural movement. One improvement in function is step-over-step stair and ramp ascent. They also allow the user to walk and run forward and backward. The X3 (Genium X3) is a more rugged version of the X2 that can be used in water, sand, and mud. The X2 and X3 were developed by Otto Bock as part of the Military Amputee Research Program.

In 2000, the Veterans Administration Technology Assessment Program issued a report on computerized lower-limb prostheses. This report offered the following observations and conclusions:

- Energy requirements of ambulation (vs. requirements with conventional prostheses) are decreased at walking speeds slower or faster than the amputee's customary speed but do not differ significantly at customary speeds.
- Results on the potentially improved ability to negotiate uneven terrain, stairs, or inclines are mixed. Such benefits, however, could be particularly important to meeting existing deficits in the reintegration of amputees to normal living, particularly those related to decreased recreational opportunities.
- Users' perceptions of the microprocessor-controlled prosthesis are favorable. Where such decisions are recorded or reported, most study participants choose not to return to their conventional prosthesis or to keep these only as a backup to acute problems with the computerized one.
- Users' perceptions may be particularly important for evaluating a lower-limb prosthesis, given the magnitude of the loss involved, along with the associated difficulty of designing and collecting objective measures of recovery or rehabilitation. However resilient the human organism or psyche, loss of a limb is unlikely to be fully compensated. A difference between prostheses sufficient to be perceived as distinctly positive to the amputee may represent the difference between coping and a level of function recognizably closer to the preamputation level.

The Power Knee™‡ (Össur), which is designed to replace muscle activity of the quadriceps, uses artificial proprioception with sensors similar to the Proprio Foot to anticipate and respond with the appropriate movement required for the next step.

Microprocessor-controlled ankle-foot prostheses have been developed for transtibial amputees. These include the Proprio Foot®‡ (Össur), the iPED (developed by Martin Bionics and licensed to College Park Industries), Meridium (Ottobock), Freedom Kinnex 2.0 (Proteor), and the Elan (Blatchford). With sensors in the feet that determine the direction and speed of the foot's movement, a microprocessor controls the flexion angle of the ankle, allowing the foot to lift during the swing phase and potentially adjust to changes in force, speed, and terrain during the step phase. This technology is designed to make ambulation more efficient and prevent falls in patients ranging from the young, active amputee to the elderly, diabetic patient. The Proprio Foot®‡ and Elan are microprocessor-controlled foot prostheses that are commercially available at this time and are considered class I devices that are exempt from 510(k) marketing clearance. Information on the Össur website indicates the use of the Proprio Foot®‡ for low- to moderate-impact for transtibial amputees who are classified as level K3 (ie, community ambulatory, with the ability or potential for ambulation with variable cadence).

In development are lower-limb prostheses that also replace muscle activity to bend and straighten the prosthetic joint. For example, the PowerFoot BiOM®‡ (developed at the Massachusetts Institute of Technology and licensed to iWalk) is a myoelectric prosthesis for transtibial amputees that uses muscle activity from the remaining limb for the control of ankle movement. This prosthesis is designed to propel the foot forward as it pushes off the ground during the gait cycle, which in addition to improving efficiency, has the potential to reduce hip and back problems arising from an unnatural gait with use of a passive prosthesis. This technology is limited by the size and the weight required for a motor and batteries in the prosthesis. Empower (Ottobock) is a commercially available powered ankle-foot prosthesis.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

According to the manufacturers, microprocessor-controlled prostheses are considered a class I device by the FDA and are exempt from 510(k) requirements. This classification does not require submission of clinical data regarding efficacy but only notification of FDA prior to marketing. FDA product codes: ISW, KFX.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

Microprocessor-controlled prostheses use feedback from sensors to adjust joint movement on a real-time as-needed basis. Active joint control is intended to improve safety and function, particularly for patients who can maneuver on uneven terrain and with variable gait.

Summary of Evidence
For individuals who have a transfemoral amputation who receive a prosthesis with a microprocessor-controlled knee, the evidence includes a number of within-subject comparisons of microprocessor-controlled knees versus non-microprocessor-controlled knee joints and systematic reviews of these studies. Relevant outcomes are functional outcomes, health status measures, and quality of life. For K3- and K4-level amputees, studies have shown an objective improvement in function on some outcome measures, particularly for hill and ramp descent, and strong patient preference for microprocessor-controlled prosthetic knees. Benefits include a more normal gait, increased stability, and a decrease in falls. The evidence in Medicare level K2 ambulators suggests that a prosthesis with stance control only can improve activities that require balance and improve walking in this population. For these reasons, a microprocessor-controlled knee may provide incremental benefit for these individuals. The potential to achieve a higher functional level with a microprocessor-controlled knee includes having the appropriate physical and cognitive ability to use the advanced technology. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have a transfemoral amputation who receive a prosthesis with a powered knee, the evidence includes no data. Relevant outcomes are functional outcomes, health status measures, and quality of life. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have a tibial amputation who receive a prosthesis with a microprocessor-controlled ankle-foot, the evidence includes limited data. Relevant outcomes are functional outcomes, health status measures, and quality of life. The limited evidence available to date does not support an improvement in functional outcomes using microprocessor-controlled ankle-foot prostheses compared with standard prostheses although quality of life improvements were noted in 1 small study. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have a tibial amputation who receive a prosthesis with a powered ankle-foot, the evidence includes limited data. Relevant outcomes are functional outcomes, health status measures, and quality of life. The limited evidence available to date does not support an improvement in functional outcomes using powered ankle-foot prostheses compared with standard prostheses. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in ‘Supplemental Information’ if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

U.S Department of Veterans Affairs/Department of Defense
In 2024, the updated Veterans Affairs/Department of Defense (VA/DoD) Clinical Practice Guideline for Rehabilitation of Individuals with Lower Limb Amputation made the following recommendations (Table 1).

Table 1. VA/DoD Clinical Practice Recommendations for Lower Limb Amputation

Recommendation	Strength
For prosthetic ambulators, we suggest prescribing microprocessor knee units over non-microprocessor knee units for reducing falls, optimizing functional mobility, and improving patient satisfaction.	Weak for
For prosthetic ambulators, there is insufficient evidence to prescribe any specific energy storing and return (ESAR) or microprocessor foot and ankle component over another.	Neither for nor against
For prosthetic ambulators, we suggest energy storing and return (ESAR) or microprocessor-controlled foot and ankle components over solid ankle cushioned heel (SACH) feet to improve ambulation and patient satisfaction	Weak for

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03204513	Impact of Powered Knee-Ankle Prosthesis Leg on Everyday Community Mobility and Social Interaction	15	Dec 2024
NCT04630457	Safety and Effectiveness of Electronically Controlled Prosthetic Ankle in Patients With Transtibial Amputation	42	Dec 2024

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT04784429	Assessing Outcomes With Microprocessor Knee Utilization in a K2 Population (ASCENT K2)	107	Dec 2026
Unpublished			
NCT04112901	Activity, Mobility, Social Functioning, Mental Health and Quality of Life Outcomes in Limited Mobility Transfemoral and Knee Disarticulation Amputees Using Microprocessor-Controlled Knees or Non-Microprocessor Controlled Knees in the United Kingdom: A Cohort Study	330	May 2020
NCT05267639	Clinical Outcomes With Passive MPKs vs. Powered Prosthetic Knees	13	Aug 2024

NCT: national clinical trial.

References

1. Flynn K. Short Report: Computerized lower limb prosthesis (VA Technology Assessment Program). No. 2. Boston, MA: Veterans Health Administration; 2000.
2. Thibaut A, Beaudart C, Maertens DE Noordhout B, et al. Impact of microprocessor prosthetic knee on mobility and quality of life in patients with lower limb amputation: a systematic review of the literature. Eur J Phys Rehabil Med. Jun 2022; 58(3): 452-461. PMID 35148043
3. Hahn A, Bueschges S, Prager M, et al. The effect of microprocessor controlled exo-prosthetic knees on limited community ambulators: systematic review and meta-analysis. Disabil Rehabil. Dec 2022; 44(24): 7349-7367. PMID 34694952
4. Morgan SJ, Friedly JL, Nelson IK, et al. The effects of microprocessor prosthetic knee use in early rehabilitation: A pilot randomized controlled trial. PM R. Feb 02 2025. PMID 39895150
5. Theeven P, Hemmen B, Rings F, et al. Functional added value of microprocessor-controlled knee joints in daily life performance of Medicare Functional Classification Level-2 amputees. J Rehabil Med. Oct 2011; 43(10): 906-15. PMID 21947182
6. Theeven PJ, Hemmen B, Geers RP, et al. Influence of advanced prosthetic knee joints on perceived performance and everyday life activity level of low-functional persons with a transfemoral amputation or knee disarticulation. J Rehabil Med. May 2012; 44(5): 454-61. PMID 22549656
7. Burnfield JM, Eberly VJ, Gronely JK, et al. Impact of stance phase microprocessor-controlled knee prosthesis on ramp negotiation and community walking function in K2 level transfemoral amputees. Prosthet Orthot Int. Mar 2012; 36(1): 95-104. PMID 22223685
8. Orendurff MS, Segal AD, Klute GK, et al. Gait efficiency using the C-Leg. J Rehabil Res Dev. 2006; 43(2): 239-46. PMID 16847790
9. Klute GK, Berge JS, Orendurff MS, et al. Prosthetic intervention effects on activity of lower-extremity amputees. Arch Phys Med Rehabil. May 2006; 87(5): 717-22. PMID 16635636

10. Williams RM, Turner AP, Orendurff M, et al. Does having a computerized prosthetic knee influence cognitive performance during amputee walking?. Arch Phys Med Rehabil. Jul 2006; 87(7): 989-94. PMID 16813788
11. Hafner BJ, Smith DG. Differences in function and safety between Medicare Functional Classification Level-2 and -3 transfemoral amputees and influence of prosthetic knee joint control. J Rehabil Res Dev. 2009; 46(3): 417-33. PMID 19675993
12. Highsmith MJ, Kahle JT, Miro RM, et al. Ramp descent performance with the C-Leg and interrater reliability of the Hill Assessment Index. Prosthet Orthot Int. Oct 2013; 37(5): 362-8. PMID 23327837
13. Howard CL, Wallace C, Perry B, et al. Comparison of mobility and user satisfaction between a microprocessor knee and a standard prosthetic knee: a summary of seven single-subject trials. Int J Rehabil Res. Mar 2018; 41(1): 63-73. PMID 29293160
14. Hafner BJ, Willingham LL, Buell NC, et al. Evaluation of function, performance, and preference as transfemoral amputees transition from mechanical to microprocessor control of the prosthetic knee. Arch Phys Med Rehabil. Feb 2007; 88(2): 207-17. PMID 17270519
15. Kaufman KR, Bernhardt KA, Symms K. Functional assessment and satisfaction of transfemoral amputees with low mobility (FASTK2): A clinical trial of microprocessor-controlled vs. non-microprocessor-controlled knees. Clin Biomech (Bristol). Oct 2018; 58: 116-122. PMID 30077128
16. Kaufman KR, Levine JA, Brey RH, et al. Gait and balance of transfemoral amputees using passive mechanical and microprocessor-controlled prosthetic knees. Gait Posture. Oct 2007; 26(4): 489-93. PMID 17869114
17. Kaufman KR, Levine JA, Brey RH, et al. Energy expenditure and activity of transfemoral amputees using mechanical and microprocessor-controlled prosthetic knees. Arch Phys Med Rehabil. Jul 2008; 89(7): 1380-5. PMID 18586142
18. Johansson JL, Sherrill DM, Riley PO, et al. A clinical comparison of variable-damping and mechanically passive prosthetic knee devices. Am J Phys Med Rehabil. Aug 2005; 84(8): 563-75. PMID 16034225
19. Carse B, Scott H, Brady L, et al. Evaluation of gait outcomes for individuals with established unilateral transfemoral amputation following the provision of microprocessor controlled knees in the context of a clinical service. Prosthet Orthot Int. Jun 01 2021; 45(3): 254-261. PMID 34016870
20. Alzeer AM, Bhaskar Raj N, Shahine EM, et al. Impacts of Microprocessor-Controlled Versus Non-microprocessor-Controlled Prosthetic Knee Joints Among Transfemoral Amputees on Functional Outcomes: A Comparative Study. Cureus. Apr 2022; 14(4): e24331. PMID 35607529
21. Hofstad C, Linde H, Limbeek J, et al. Prescription of prosthetic ankle-foot mechanisms after lower limb amputation. Cochrane Database Syst Rev. 2004; 2004(1): CD003978. PMID 14974050
22. Alimusaj M, Fradet L, Braatz F, et al. Kinematics and kinetics with an adaptive ankle foot system during stair ambulation of transtibial amputees. Gait Posture. Oct 2009; 30(3): 356-63. PMID 19616436

23. Fradet L, Alimusaj M, Braatz F, et al. Biomechanical analysis of ramp ambulation of transtibial amputees with an adaptive ankle foot system. Gait Posture. Jun 2010; 32(2): 191-8. PMID 20457526
24. Darter BJ, Wilken JM. Energetic consequences of using a prosthesis with adaptive ankle motion during slope walking in persons with a transtibial amputation. Prosthet Orthot Int. Feb 2014; 38(1): 5-11. PMID 23525888
25. Gailey RS, Gaunaurd I, Agrawal V, et al. Application of self-report and performance-based outcome measures to determine functional differences between four categories of prosthetic feet. J Rehabil Res Dev. 2012; 49(4): 597-612. PMID 22773262
26. Delussu AS, Brunelli S, Paradisi F, et al. Assessment of the effects of carbon fiber and bionic foot during overground and treadmill walking in transtibial amputees. Gait Posture. Sep 2013; 38(4): 876-82. PMID 23702342
27. Thomas-Pohl M, Villa C, Davot J, et al. Microprocessor prosthetic ankles: comparative biomechanical evaluation of people with transtibial traumatic amputation during standing on level ground and slope. Disabil Rehabil Assist Technol. Jan 2021; 16(1): 17-26. PMID 31535903
28. Colas-Ribas C, Martinet N, Audat G, et al. Effects of a microprocessor-controlled ankle-foot unit on energy expenditure, quality of life, and postural stability in persons with transtibial amputation: An unblinded, randomized, controlled, cross-over study. Prosthet Orthot Int. Dec 01 2022; 46(6): 541-548. PMID 36515900
29. Au S, Berniker M, Herr H. Powered ankle-foot prosthesis to assist level-ground and stair-descent gaits. Neural Netw. May 2008; 21(4): 654-66. PMID 18499394
30. Ferris AE, Aldridge JM, Rábago CA, et al. Evaluation of a powered ankle-foot prosthetic system during walking. Arch Phys Med Rehabil. Nov 2012; 93(11): 1911-8. PMID 22732369
31. Herr HM, Grabowski AM. Bionic ankle-foot prosthesis normalizes walking gait for persons with leg amputation. Proc Biol Sci. Feb 07 2012; 279(1728): 457-64. PMID 21752817
32. Mancinelli C, Patritti BL, Tropea P, et al. Comparing a passive-elastic and a powered prosthesis in transtibial amputees. Annu Int Conf IEEE Eng Med Biol Soc. 2011; 2011: 8255-8. PMID 22256259
33. Cacciola CE, Kannenberg A, Hibler KD, Howell J. Impact of a Powered Prosthetic Ankle-Foot Component on Musculoskeletal Pain in Individuals with Transtibial Amputation: A Real-World Cross-Sectional Study with Concurrent and Recalled Pain and Functional Ratings. J Prosthet Orthot. 2022. doi: 10.1097/JPO.0000000000000442.
34. VA/DOD Clinical Practice Guideline, Work Group. VA/DOD Clinical Practice Guideline for Rehabilitation of Individuals With Lower Limb Amputation. U.S. Government Printing Office; 2024:2-162. https://www.healthquality.va.gov/guidelines/Rehab/amp/LLA-CPG_2024-Guideline_final_20250110.pdf

Policy History

Original Effective Date: 07/16/2014
Current Effective Date: 07/01/2025
07/10/2014 Medical Policy Committee review
07/16/2014 Medical Policy Implementation Committee approval. New policy.
08/06/2015 Medical Policy Committee review

08/19/2015	Medical Policy Implementation Committee approval. No change to coverage.
08/04/2016	Medical Policy Committee review
08/17/2016	Medical Policy Implementation Committee approval. No change to coverage.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
08/03/2017	Medical Policy Committee review
08/23/2017	Medical Policy Implementation Committee approval. No change to coverage.
08/09/2018	Medical Policy Committee review
08/15/2018	Medical Policy Implementation Committee approval. Added policy guidelines. And added "ankle-foot" to investigational statement.
08/01/2019	Medical Policy Committee review
08/14/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/06/2020	Medical Policy Committee review
08/12/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/03/2021	Medical Policy Committee review
06/09/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/02/2022	Medical Policy Committee review
06/08/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/12/2022	Coding update
06/01/2023	Medical Policy Committee review
06/14/2023	Medical Policy Implementation Committee approval. Based on review of available data, the Company considers a microprocessor-controlled knee in individuals who do not meet these criteria. to be investigational. This statement was changed from Not medically necessary to investigational. "Individual has a functional K-Level 3 or above" was added to patient selection criteria. Criteria clarified.
12/12/2023	Coding update
06/06/2024	Medical Policy Committee review
06/12/2024	Medical Policy Implementation Committee approval. No change to coverage.
03/25/2025	Coding update
06/05/2025	Medical Policy Committee review
06/11/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged. Examples of microprocessor-controlled knee, power knee, microprocessor-controlled ankle-foot prostheses and power foot added to background to assist in reviews of the policy.

Next Scheduled Review Date: 06/2026

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2024 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character

identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Louisiana Blue Medical Policy Coverage Guidelines is with Louisiana Blue and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Louisiana Blue Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Louisiana Blue Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No codes
HCPCS	L5615, L5827, L5856, L5857, L5858, L5859, L5930, L5969, L5973
ICD-10 Diagnosis	All related Diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

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

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.