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PRICING DATA ANALYSIS AND CODING (PDAC)

PALMETTO GBA®
A CELERIAN GROUP COMPANY

August 16, 2024

KIMBERLY HANSON
OTTO BOCK HEALTHCARE
11809 DOMAIN DR FLOOR 400
AUSTIN, TX 78758

Document Control Number (DCN): 24150047000011

Manufacturer Name	Product Name	Model Number	Assigned HCPCS Code(s)
OTTO BOCK HEALTHCARE	C-LEG MICROPROCESSOR CONTROLLED KNEE JOINT	3C98-X-Y	L5828+L5845+L5848+L5856+L5850+L5925
OTTO BOCK HEALTHCARE	C-LEG MICROPROCESSOR CONTROLLED KNEE JOINT	3C88-X-Y	L5828+L5845+L5848+L5856+L5850+L5925

Dear KIMBERLY HANSON,

The Pricing, Data Analysis, and Coding (PDAC) Contractor has reviewed the product(s) listed above and has approved the listed Healthcare Common Procedure Coding System (HCPCS) code(s) for billing the four Durable Medical Equipment Medicare Administrative Contractors (DME MACs).

The PDAC Contractor provides coding assistance to manufacturers to ensure proper coding of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS). The PDAC publishes coding decisions based on the coding guidelines established by the Local Coverage Determinations (LCDs) and associated Policy Articles and any related Advisory Articles established by the DME MACs. All products submitted to the PDAC for a coding verification review are examined by coders and professionals following a formal, standardized process.

Based on this review and application of DME MAC policy, the HCPCS code(s) listed below

should be used when billing the DME MACs:

L5828 ADDITION, ENDOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, FLUID SWING AND STANCE 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

L5856 ADDITION TO LOWER EXTREMITY PROSTHESIS, ENDOSKELETAL KNEE-SHIN SYSTEM, MICROPROCESSOR CONTROL FEATURE, SWING AND STANCE PHASE, INCLUDES ELECTRONIC SENSOR(S), ANY TYPE

L5850 ADDITION, ENDOSKELETAL SYSTEM, ABOVE KNEE OR HIP DISARTICULATION, KNEE EXTENSION ASSIST

L5925 ADDITION, ENDOSKELETAL SYSTEM, ABOVE KNEE, KNEE DISARTICULATION OR HIP DISARTICULATION, MANUAL LOCK

If you disagree with this decision, you may request a reconsideration within 45 calendar days of the Coding Verification letter's date and provide evidence to substantiate a reconsideration of PDAC's original coding determination. To request a reconsideration, complete the Reconsideration Request form located on the PDAC website at www.dmepdac.com. If your request for a reconsideration of PDAC’s coding determination is made after the 45 calendar day time frame, it will require a new application and documentation to support the request.

It is the responsibility of manufacturers and distributors to notify the PDAC immediately of any changes involving their products, as listed on the Product Classification List (PCL) on the Durable Medical Equipment Coding System (DMECS). Further information for requesting updates to the PCL can be found on the PDAC website at www.dmepdac.com. It is also the responsibility of manufacturers and distributors to assure their websites and product marketing materials accurately reflect the product reviewed by the PDAC and the coding decision assigned.

An assignment of the HCPCS code(s) to product(s) is not an approval or endorsement of the product(s) by Medicare or Palmetto GBA; nor does it imply or guarantee claim reimbursement or coverage.

If you have questions, please contact the PDAC HCPCS Helpline at (877) 735-1326 during the

hours of 9:30 a.m. to 5:00 p.m. ET, Monday through Friday. You may also visit our website to chat with one of our representatives or select the Contact Us button at the top of the page for email, FAX or postal mail information.

Sincerely,

Pricing, Data Analysis, and Coding (PDAC)
Palmetto GBA, LLC
www.dmepdac.com

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C-Leg®

Reimbursement Guide

C-Leg Product Information

[1]C-Leg Coding (U.S. only)

The Healthcare Common Procedure Coding System (HCPCS) for prosthetics is an add-on code system. Rather than issuing new HCPCS Level II national codes to describe the various microprocessor knees that came to market, the Alpha-Numeric HCPCS Panel instead issued add-on codes to upgrade the mechanical (non-microprocessor) knee codes.

The following codes are PDAC Verified for C-Leg

L5828[3]	Hydraulic Swing and Stance Phase Knee
L5845	Stance flexion feature
L5848[3]	Hydraulic stance extension feature
L5856[3]	Microprocessor control feature, swing and stance phase, includes sensors

Additional codes describe C-Leg 's new functionality

Verify coverage with your payer

L5850	Knee extension assist
L5925	Manual lock
L5999[2]	Inertial Motion Unit Control Feature for intuitive standing and walking backwards.

Additional codes that might be on a C-Leg claim

L5920	Alignable System (for a complete new prosthesis or when the prosthesis needs to be realigned)
L5950/L5960	Ultralight Material (when added to a socket)

Warranty

The C-Leg 4 has a three-year manufacturer warranty (extendable to six years); Repair costs are covered except for those associated with damages resulting from improper use. Fixed service inspections are not required during the warranty period.

Health Canada Compliance

This device meets the requirements of the Medical Device Regulations (SOR/98-282). It has been classified as a class I medical device according to the classification criteria outlined in schedule 1 of the Medical Device Regulations.

FDA Status

Under FDA's regulations, the C-Leg Microprocessor-Controlled Prosthetic Knee is a Class I device, exempt from the premarket notification [510(k)] requirements. C-Leg prosthetic knee has met all applicable general control requirements which include Establishment Registration (21CFR 807), Medical Device Listing (21 CFR part 807), Quality System Regulation (21CFR part820), Labeling (21CFR part 801), and Medical Device Reporting (21 CFR Part 803). The C-Leg prosthetic knee is listed under external limb prosthetic component; Listing Number is E253231.

Who Can Provide a C-Leg?

The C-Leg is prescribed by a physician and may only be provided by a qualified Prosthetist who has received specific product training. Ottobock employs a team of orthotists and prosthetists to educate practitioners on fabricating and fitting our products. This includes in-person and online training, webinars, and technical bulletins. We also provide Cooperative Care Services for the more challenging fittings, which includes on-site assistance with the fitting in conjunction with product qualification training for the practitioner.

[1] The product/device "Supplier" (defined as an O&P practitioner, O&P patient care facility, or DME supplier) assumes full responsibility for accurate billing of Ottobock products. It is the Supplier's responsibility to determine medical necessity; ensure coverage criteria is met; and submit appropriate HCPCS codes, modifiers, and charges for services/products delivered. It is also recommended that Supplier's contact insurance payer(s) for coding and coverage guidance prior to submitting claims. Ottobock Coding Suggestions and Reimbursement Guides are based on reasonable judgment and are not recommended to replace the Supplier's judgment. These recommendations may be subject to revision based on additional information or alpha-numeric system changes.

[2] It is not recommended to bill L5999 to Medicare for Microprocessor Knees.

[3] Patient must be functional level 3 to use this code.

C-Leg Features and Benefits

Introduced in 1997, the C-Leg® was the first prosthetic knee joint to control and adapt to an individual's complete gait pattern during stance and swing phase using a microprocessor. Today's C-Leg actively controls all aspects of the swing and stance phase with the microprocessor-controlled hydraulics and adapts to the variation in walking speeds. The result is a system that recognizes which phase of gait and situation the patient is in—and adapts in real time. The new functionality of C-Leg includes patented technology which provides intuitive standing function and backward walking recognition and adjustments.

Enhanced Stumble Recovery

Swing flexion resistance: The enhanced stumble recovery feature on the C-Leg 4 takes stability to a new level by actively controlling and adjusting swing flexion resistance while the knee is in the swing extension motion. This ensures that the proper amount of resistance is in place to enable recovery in the event of a stumble.

Varied Cadence

Microprocessor controlled hydraulic swing: The C-Leg's main microprocessor gathers information from the various data sources and processes this information to adjust the knee joint´s functionality in real time, allowing the patient to walk more naturally and vary cadence with the knee adapting more accurately and more quickly than without a microprocessor. Hydraulic swing resistance also provides smooth deceleration when changing walking speed thus reducing the need for compensation.

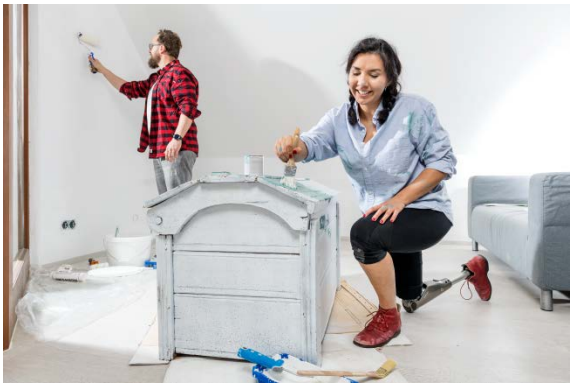
Knee Extension Assist: The knee extension assist is used in promoting knee extension at the beginning of swing phase extension. This function allows the user to walk more efficiently at variable cadence since the spring extension assist mechanically limits the knee flexion at the end range and begins to bring the knee into extension for a more symmetrical gait at faster walking speeds. It also ensures the knee comes to full extension for the beginning of stance phase for a more secure loading condition.

Stairs, Slopes, Ramps, Challenging Terrain

Stance flexion: The C-Leg provides hydraulic resistance against knee flexion (bending) mimicking the eccentric action of the quadriceps muscle. This controlled knee flexion occurs in early stance phase during weight bearing, and also provides shock absorption and reduced impact, thus allowing the patient to securely walk up and down slopes and ramps, negotiate uneven/ challenging terrain, and to descend stairs step over step.

Support for Sitting and Kneeling

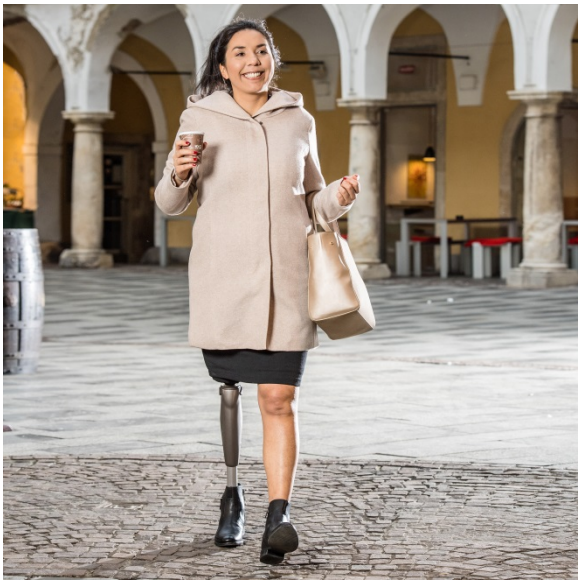
Stance flexion: This feature also allows patients to "ride" the knee (the knee supports patients' weight on flexed knee without buckling and lowers them into desired position) such as when sitting into a chair or kneeling.



C-Leg Features and Benefits

Back-up, Step Away

Inertial Motion Unit (IMU): The patented IMU on the C-Leg provides stability when taking steps backwards/backing-up. Contrast this to traditional microprocessor knees which do not accommodate backward walking, causing the knee to collapse when stepping backward.



Smooth and Natural Gait

Hydraulic stance extension damping: The C-Leg provides microprocessor-controlled progressive resistance in real time during stance extension resulting in a more natural gait. Without this increased resistance the patient would feel a pronounced “snap back” or “jerk” at the knee, and would also present with an unnatural looking gait pattern.

Intuitive Standing

Inertial Motion Unit (IMU): The IMU also allows the patient to intuitively stand on a flexed and stable knee on level, uneven, or inclined surfaces (ramps or hills). With traditional prosthetic knees people with limb loss must use hip extension to stabilize the knee or cognitively ensure that their center of mass stays ahead of their knee axis to prevent unexpected flexing of the prosthetic knee.

Manual Lock: The manual locking feature allows the user to lock the knee in full extension for safer standing or more comfortable standing due to equal weight distribution on the prosthetic and sound sides. The manual lock is activated and deactivated by the patient by three different methods: motion pattern, remote, or via a cellular telephone App.

Activity Reports

The practitioner is able to print out reports including:

1. Average number of steps/day
2. Average walking speed
3. Ranges of different walking speeds/cadences
4. Number of steps on slopes, ramps and stairs
5. Time totals for walking, sitting, standing

Protected Componentry

Weatherproof: The latest version of the C-Leg has IP 67 rating which protects it from damage due to incidental contact with or temporary submersion in fresh water. It is not designed to be routinely submerged or used while showering or swimming. Because the C-Leg 4 is considered weatherproof, the patient does not have to worry while walking in the rain or using it around water.

Protective Covers: C-Leg Protective Covers are used to provide greater defense for protecting the knee unit. These covers are custom designed for this knee unit only, and are able to withstand sudden jolts that may penetrate the knee unit.

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C-Leg Clinical Studies

1. Bellmann M, Köhler TM, Schmalz T. Comparative biomechanical evaluation of two technologically different microprocessor-controlled prosthetic knee joints in safety-relevant daily-life situations. Biomed Tech (Berl). 2018 Dec 12. pii: /j/bmte.ahead-of-print/bmt-2018-0026/bmt-2018-0026.xml. doi: 10.1515/bmt-2018-0026. [Epub ahead of print]. Download

2. Kaufman KR, Bernhardt KA, Symms K. Functional assessment and satisfaction of transfemoral amputees with mobility (FASTK2): A clinical trial of microprocessor-controlled vs. non-microprocessor-controlled knees. Clin Biomech (Bristol, Avon) 2018 Oct;58:116-122. doi: 10.1016/j.clinbiomech.2018.07.012. Epub 2018 Jul 19. Download

3. Thiele J, Schöllig C, Bellmann M, Kraft M. Designs and performance of three new microprocessor-controlled knee joints. Biomed Tech (Berl) 2018 Feb 9. pii: /j/bmte.ahead-of-print/bmt-2017-0053/bmt-2017-0053.xml. doi: 10.1515/bmt-2017-0053. [Epub ahead of print]. Download

4. Cutti AG, Lettieri E, Del Maestro M, Radaelli G, Luchetti M, Verni G, Masella C. Stratified cost-utility analysis of C-Leg versus mechanical knees: Findings from an Italian sample of transfemoral amputees. Prosthet Orthot Int 2017; 41(3): 227-236. [Epub 2016 ahead of print]. Download

5. Hahn A, Lang M. Effects of mobility grade, age, and etiology on functional benefit and safety of subjects evaluated in more than 1200 C-Leg trial fittings in Germany. J Prosthet Orthot 2015; 27(3): 86-95. Download

6. Wong K, Rheinstein J, Stern MA. Benefits for adults with transfemoral amputation and peripheral artery disease using microprocessor compared with nonmicroprocessor prosthetic knees. Arch Phys Med Rehabil 2015; 94 (10): 804-810. Download

7. Kannenberg A, Zacharias B, Pröbsting E: Benefits of microprocessor prosthetic knees to limited community ambulators: A systematic review. J Rehabil Res Dev 2014; 51 (10): 1469-1495. Download

8. Highsmith MJ, Kahle JT, Shepard NT, Kaufman KR: The effect of the C-leg knee prosthesis on sensory dependency and falls during sensory organization testing. Technol Innov 2014; 15: 343-347. Download

9. Thiele J, Westebbe B, Bellmann M, Kraft M: Designs and performance of microprocessor-controlled knee joints. Biomed Tech (Berl) 2014; 59(1): 65-77. Download

10. Eberly VJ. Mulroy SJ, Gronley JK, Perry J, Burnfield JM: Impact of a stance phase microprocessor-controlled knee prosthesis on level walking in lower functioning individuals with transfemoral amputation. Prosth Orthot Int 2014; 38(6): 447-455. Download

11. William D, Beasley E, Shaw A: Investigation of the quality of life of persons with a transfemoral amputation who use a C-leg® prosthetic device. J Prosthet Orthot 2013; 25(3): 100-109. Download

12. Tofts LJ, Hamblin N: C-Leg® improves function and quality of life in an adolescent traumatic transfemoral amputee – a case study. Prosthet Orthot Int 2013; Sep 20 [epub ahead of print]. Download

13. Wolf EJ, Everding VQ, Linberg AA, Czerniecki JM, Gambel, JM: Comparison of the Power Knee and C-Leg during step-up and sit-to-stand tasks. Gait Posture 2013; 38(3): 397-402. Download

14. Wolf EJ, Everding VQ, Linberg AA, Schnall BL, Czerniecki JM, Gambel, JM: Assessment of transfemoral amputees using C-Leg and Power Knee for ascending and descending inclines and steps. J Rehabil Res Dev 2012; 49(6): 831-842. Download

C-Leg Clinical Studies

15. Highsmith MJ, Kahle JT, Miro RM, Mengelkoch, MJ: Ramp descent performance with the C-leg and interrater reliability of the Hill Assessment Index. Prosthet Orthot Int 2013; 37(5): 362-368. Download

16. Wong CK, Benoy S, Blackwell W, Jones S, Rahal R: A comparison of energy expenditure in people with transfemoral amputation using microprocessor and nonmicroprocessor knee prostheses: a systematic review. J Prosthet Orthot 2012; 24(4): 202-208. Download

17. Meier MR, Hansen AH, Gard SA, McFayden AK: Obstacle course: users´ maneuverability and movement efficiency when using Otto Bock C-leg, Otto Bock 3R60, and CaTech SNS prosthetic knee joints. J Rehabil Res Dev 2012; 49(4): 583-596. Download

18. Schaarschmidt M, Lipfert SW, Meier-Gratz C, Scholle H, Seyfarth A. Functional gait asymmetry of unilateral transfemoral amputees. Human Movement Science. 2012;31: 907–917. Download

19. Kaufman KR, Frittoli S, Frigo CA: Gait asymmetry of transfemoral amputees using mechanical and microprocessor controlled prosthetic knees. Clin Biomech 2012; 27 (5): 460-465. Download

20. Bar JB, Wutzke CJ, Threlkeld AJ: Longitudinal gait analysis of a person with a transfemoral amputation using three different prosthetic knee/foot pairs. Physiother Theor Pract 2012; 28(5): 407-411. Download

21. Wong CK, Wilska J, Stern M: Balance, balance confidence, and falls using nonmicroprocessor and microprocessor knee prostheses: a case study after vascular amputation with 12-month follow-up. JPO 2012;24(1): 16-18. Download

22. Theeven PJ, Hemmen B, Geers RP, Smeets RJ, Brink PR, Seelen HA: Influence of advanced prosthetic knee joints on perceived performance and everyday life activity of low-functional persons with a transfemoral amputation or knee disarticulation. J Rehabil Med 2012, 44 (5): 454-461. Download

23. Burnfield JM, Eberly VJ, Gronely JK, Perry J, Yule WJ, Mulroy SJ: Impact of stance phase microprocessor-controlled knee prosthesis on ramp negotiation and community walking function in K2 level transfemoral amputees. Prosthet Orthot Int 2012, 36 (1): 95-104. Download

24. Theeven P, Hemmen B, Rings F, Meys G, Brink P, Smeets R, Seelen H: Functional added value of microprocessor-controlled knee joints in daily life performance of Medicare Functional Classification Level-2 amputees. J Rehabil Med 2011; 43 (10): 906-915. Download

25. Highsmith MJ, Kahle JT, Carey SL, Lura DJ, Dubey RV, Csavina KR, Quillen WS: Kinetic asymmetry in transfemoral amputees while performing sit to stand and stand to sit movements. Gait Posture 2011; 34(1): 86-91. Download

26. Mâaref K, Martinet N, Grumillier C, Ghannouchi S, André JM, Paysant J. Kinematics in the Terminal Swing Phase of Unilateral Transfemoral Amputees: Microprocessor-Controlled Versus Swing-Phase Control Prosthetic Knees. Arch Physl Med Rehabil. 2010; 91(6): 919-925. Download

27. Theeven P, Hemmen B, Stevens C, Ilmer E, Brink P, Seelen H. Feasibility of a new concept for measuring ACTUAL functional performance in daily life of transfemoral amputees. J Rehabil Med 2010; 42: 744–751. Download

C-Leg Clinical Studies

28. Highsmith MJ, Kahle JT, Bongiorni DR, Sutton BS, Groer S, Kaufman KR
Safety, energy efficiency, and cost efficacy of the C-leg for transfemoral amputees. Prosth Orthot Int 2010, 34 (4): 362-377. Download

29. Bellmann M, Schmalz T, Blumentritt S
Comparative biomechanical analysis of current microprocessor-controlled prosthetic knee joints. Arch Phys Med Rehabil 2010, 91(4): 644-652. Download

30. Petersen AO, Comins J, Alkjær T: Assessment of gait symmetry in transfemoral amputees using C-leg compared with 3R60 prosthetic knees. J Prosthet Orthot 2010; 22(2): 106-112. Download

31. Blumentritt S, Schmalz T, Jarasch R: The safety of C-leg: Biomechanical tests. J Prosthet Orthot 2009, 21(1): 2-17. Download

32. 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): 417-434. Download

33. Seelen HAM, Hemmen B, Schmeets AJ, Ament AJHA, Evers SMAA: Costs and consequences of a prosthesis with an electronic stance and swing phase controlled knee joint. Technology and Disability 2009, 21: 25-34. Download

34. Berry D, Olson MD, Larntz K: Perceived stability, function, and satisfaction among transfemoral amputees using microprocessor and non-microprocessor controlled prosthetic knees: a multicenter survey. J Prosthet Orthot 2009, 21 (1): 32-42. Download

35. Kaufman KR, Levine JA, Brey RH, McCrady SK, Padgett DJ, Joyner MJ: Energy Expenditure and Activity Level of Transfemoral Amputees using Passive Mechanical and Microprocessor-controlled Prosthetic Knees. Arch Phys Med Rehabil 2008 (89(7), 1380-1385. Download

36. Gerzeli S, Torbica A, Fattore G: Cost utility analysis of knee prosthesis with complete microprocessor control (C-leg) compared with mechanical technology in trans-femoral amputees. Eur J Health Econ 2009; 10 (1): 47-55. Download

37. Kahle JT, Highsmith MJ, Hubbard SL: Comparison of Non-microprocessor Knee Mechanism versus C-Leg on Prosthesis Evaluation Questionnaire, Stumbles, Falls, Walking Tests, Stair Descent, and Knee Preference; J Rehabil Res Dev 2008; 45 (1): 1-14. Download

38. Brodtkorb TH, Henniksson M, Johanneson-Munk K, Thidell F: Cost-effectiveness of C-leg compared with non-microprocessor-controlled knees: a modeling approach. Arch Phys Med Rehabil 2008 89(1): 24-30. Download

39. Kaufman KR, Levine JA, Brey RH, et al. Gait and Balance of transfemoral amputees using passive mechanical and microprocessor-controlled prosthetic knees. Gait Posture. 2007; 26: 489-493. Download

40. Schmalz T, Blumentritt S, Marx B: Biomechanical Analysis of Stair Ambulation in Lower Limb Amputees. Gait Posture. 2007; 25: 267-278. Download

41. Seymour R, Engbretson B, Kott K, Ordway N, Brooks G, Crannell J, Hickernell E, Wheller K: Comparison between the C-leg(R) microprocessor-controlled prosthetic knee and non-microprocessor control prosthetic knees: A preliminary study of energy expenditure, obstacle course performance, and quality of life survey. Prosthet Orthot Int 2007; 31(1): 51 – 61. Download

42. Hafner BJ, Willingham LL, Buell NC, Allyn KJ, Smith DG: Evaluation of Function, Performance, and Preference as Transfemoral Amputees Transition from Mechanical to Microprocessor Control of the Prosthetic Knee. Arch Phys Med Rehabil 2007; 88(2): 207-17. Download

C-Leg Clinical Studies

43. Bunce DJ, Breakey JW: The Impact of C-Leg on the Physical and Psychological Adjustment to Transfemoral Amputation. J Prosthet Orthot 2007; 19(1): 7-14. Download

44. Segal AD, Orendurff MS, Klute GK, McDowell ML, Pecoraro JA, Shofer J, Czerniecki JM: Kinematic and Kinetic Comparisons of Transfemoral Amputee Gait using C-Leg and Mauch SNS Prosthetic Knees. J Rehabil Res Dev 2006; 43(7): 857-870. Download

45. Klute GK, Berge JS, Orendurff MS, Williams RM, Czerniecki JM: Prosthetic Intervention Effects on Activity of Lower Extremity Amputees. Arch Phys Med Rehabil 2006; 87: 717-722. Download

46. Williams RM, Turner AP, Orendurff M, Segal AD, Klute GK, Pecoraro J, Czerniecki J: Does Having a Computerized Prosthetic Knee Influence Cognitive Performance during Amputee Walking? Arch Phys Med Rehabil 2006; 87: 989-994. Download

47. Orendurff MS, Segal AD, Klute GK, McDowell ML, Pecoraro JA, Czerniecki JM: Gait Efficiency Using the C-Leg. J Rehabil Res Dev 2006; 43(2):239-246. Download

48. Chin T, Machida K, Sawamura S, Shiba R, Oyabu H, Nagakura Y, Takase I, Nakagawa A: Comparison of different microprocessor controlled knee joints on the energy consumption during walking in trans-femoral amputees: intelligent knee prosthesis (IP) vs. C-Leg. Prosthet Orthot Int 2006; 30(1): 73-80. Download

49. Johannson JL, Sherill DM, Riley PO, Bonato P, Herr H: A clinical comparison of variable-damping and mechanically passive prosthetic knee devices. Arch J Phys Med Rehabil 2005, 84 (8): 563-575. Download

50. Swanson E, Stube J, Edman P: Function and body image levels in individuals with transfemoral amputation using the C-leg. JPO 2005, 17 (3): 80-84. Download

51. Perry J, et al: Energy Expenditure and Gait Characteristics of a Bilateral Amputee Walking with C-Leg Prostheses Compared with Stubby and Conventional Articulating Prostheses. Arch Phys Med Rehabil 2004; 85: 1711-1717. Download

52. Schmalz T, Blumentritt S, Jarasch R. Energy Expenditure and Biomechanical Characteristics of Lower Limb Amputee Gait: Influence of Prosthetic Alignment and Different Prosthetic Components. Gait Posture. 2003; 16: 255-263. Download

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Coding Options[1] for Ottobock Microprocessor Knees

January 01, 2020

BASE CODE OPTIONS (select one, not all inclusive)		
KNEE DISARTICULATION	L5312	Knee disarticulation, molded socket, single axis knee, pylon, SACH foot, endoskeletal system.
ABOVE KNEE	L5321	Above knee, molded socket, open end, SACH foot, endoskeletal system, single axis knee.
HIP DISARTICULATION	L5331	Hip disarticulation, Canadian type, molded socket, endoskeletal system, hip joint, single axis knee, SACH foot
HEMIPELVECTOMY	L5341	Hemipelvectomy, Canadian type, molded socket, endoskeletal system, hip joint, single axis knee, SACH foot
SOCKET REPLACEMENT		
KNEE DISARTICULATION	L5701	Replacement socket, above knee/knee disarticulation, including attachment plate, molded to patient model.
ABOVE KNEE	L5701	Replacement socket, above knee/knee disarticulation, including attachment plate, molded to patient model.
HIP DISARTICULATION	L5702	Replacement socket, hip disarticulation, including hip joint, molded to patient model.
SOCKET ADDITIONS (if used)		
Interested in Ottobock Fabrication Services?: Click here		
KNEE DISARTICULATION		
Check Socket	L5622	Test [check] socket, knee disarticulation
Acrylic	L5631	Acrylic Socket, Above knee or Knee disarticulation
ABOVE KNEE		
Check Socket	L5624	Test [check] socket, above knee
Acrylic	L5631	Above knee or Knee disarticulation, acrylic socket
Flex Inner Socket	L5651	Above knee, flexible inner socket, external frame
Suction	L5652	Suction suspension, above knee/knee disarticulation
Alignable	L5920	Above knee or hip disarticulation, alignable system
Total Contact	L5650	Total Contact, above knee or knee disarticulation socket
Ischial Containment	L5649	Ischial containment, narrow M-L socket
Ultralight	L5950	Above knee, Ultralight material (titanium, carbon fiber, or equal)

[1] The product/device "Supplier" (defined as an O&P practitioner, O&P patient care facility, or DME supplier) assumes full responsibility for accurate billing of Ottobock products. It is the Supplier's responsibility to determine medical necessity; ensure coverage criteria is met; and submit appropriate HCPCS codes, modifiers, and charges for services/products delivered. It is also recommended that Supplier's contact insurance payer(s) for coding and coverage guidance prior to submitting claims. Ottobock Coding Suggestions and Reimbursement Guides are based on reasonable judgment and are not recommended to replace the Supplier's judgment. These recommendations may be subject to revision based on additional information or alpha-numeric system changes.

[2] At this time, it is not recommended to bill miscellaneous code L5999 to Medicare for microprocessor knees.

[3] K-Level restrictions may apply to this code. Please check with your payer.

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Coding Options[1] for Ottobock Microprocessor Knees

January 01, 2020

HIP DISARTICULATION		
Check Socket	L5626	Test [check] socket, hip disarticulation
Alignable	L5920	Above knee or hip disarticulation, alignable system
Total Contact	L5650	Total Contact, above knee or knee disarticulation socket
Flex Inner Socket	L5643	Hip disarticulation, flexible inner socket, external frame
Ultralight	L5960	Hip disarticulation, ultralight material (titanium, carbon fiber, or equal)
HEMIPELVECTOMY		
Check Socket	L5628	Test [check] socket, hemipelvectomy
MICROPROCESSOR KNEE OPTIONS (select one)		
C-LEG Pyramid: 3C98-* Threaded 3C88-* see the C-Leg Reimbursement Tool Kit		
Codes PDAC Verified for C-Leg		
MP Control	L5856[3]	Microprocessor control feature, swing and stance phase, incl. sensors
Swing & Stance Ctrl	L5828	Fluid swing and stance phase control
Stance Flexion	L5845	Stance flexion feature, adjustable
Stance Extension	L5848[3]	Fluid stance extension, dampening feature, with or without adjustability
Additional Codes Describe C-Leg's New Functionality (for private payers) (check for coverage)		
Knee Ext Assist	L5850	Knee extension assist
Manual Lock	L5925	Manual Lock
IMU	L5999[2]	Inertial Motion Unit Control Feature: for intuitive standing and walking backwards (see Reimbursement Tool Kit for billing instructions)
Additional Codes that might be on a C-Leg Claim		
Alignable System	L5920	For a complete new prosthesis or when the prosthesis needs to be realigned
Ultralight Material	L5950/60	When added to a socket
Kenevo Pyramid: 3C60 Threaded 3C60=ST see the Kenevo Reimbursement Tool Kit		
Swing & Stance Ctrl	L5828	Fluid swing and stance phase control
Stance Flexion	L5845	Stance flexion feature, adjustable
Stance Extension	L5848[3]	Fluid stance extension, dampening feature, with or without adjustability
Knee Ext Assist	L5850	Knee extension assist
MP Control	L5858[3]	Microprocessor control feature, stance phase, includes sensors
IMU	L5999[2]	Inertial Motion Unit Control feature for intuitive standing and walking backwards. (see Reimbursement Tool Kit for billing instructions)

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[2] At this time, it is not recommended to bill miscellaneous code L5999 to Medicare for microprocessor knees.

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Coding Options[1] for Ottobock Microprocessor Knees

January 01, 2020

GENIUM Pyramid: 3B1-*, Threaded: 3B1-*=ST see the Genium Reimbursement Tool Kit		
MP Control	L5999[2,3]	Autoadaptive microprocessor controlled swing and stance phase, with simulated physiologic rule sets; predicted by multi-modal proprioceptive input.
Obstacles, Stairs	L5999[2]	Loading flexed knee to traverse obstacles and ascend stairs.
Dynamic Stability	L5999[2]	Dynamic stability control all transitional gait (i.e. safe multidirectional movement in confined spaces, stance release on ramps, transition to running, weight compensation for stance release).
Inertial Motion Ctrl	L5999[2]	Inertial Motion Unit Control Feature: for intuitive standing and walking backwards. (see Reimbursement Tool Kit for billing instructions)
Swing and Stance	L5828	Fluid swing and stance phase control
Stance Flexion	L5845	Stance flexion feature, adjustable
Stance Extension	L5848[3]	Fluid stance extension, dampening feature, with or without adjustability
X3[2] Pyramid: 3B5-*, Threaded: 3B5-*=ST See the X3 Reimbursement Tool Kit		
MP Control	L5999[2,3]	3B5-X3 Adaptive Microprocessor-Controlled Swing and Stance Phase prosthetic knee, with Simulated-Physiologic Rule Sets, predicted by Multi-Modal Proprioceptive Input. Features include: Optimized Physiologic Gait, Dynamic Stability Control for all Transitional Gait, Inertial Motion Unit Control Feature for intuitive standing and walking backwards, Loading Flexed Knee to Traverse Obstacles and Stairs; Corrosion Resist with IPX7 Waterproof Rating; Protective Cover, Running Mode and Mute Mode.
Swing and Stance	L5828	Fluid swing and stance phase control
Stance Flexion	L5845	Stance flexion feature, adjustable
Stance Extension	L5848[3]	Fluid stance extension, dampening feature, with or without adjustability
HIP OPTIONS		
7E10 Helix[3D] (C-Leg/Genium/X3)	Base + L5961[3]	Polycentric hip joint, pneumatic or hydraulic control, rotation control, with or without flexion and/or extension. See the Helix Reimbursement Tool Kit
7E9 Single Axis, Hyd (Kenevo/C-Leg)	Base +L5999	Monocentric, Hydraulic Swing and Stance Phase Control, Independently and Individually Adjustable Flexion and Extension Resistance. See the 7E9 Reimbursement Tool Kit
7E7 Single Axis, Int Ext (Kenevo/C-Leg)	Base+ L5855	Mechanical Hip Extension Assist

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Coding Options[1] for Ottobock Microprocessor Knees

January 01, 2020

FOOT OPTIONS (select one)		
1A1-1 Empower (C-Leg, Genium, X3) Note: private pay only	L5973[3] L5969[3]	Ankle-foot system, microprocessor control feature Power Assist (May use L5999 in absence of L5969) See Empower Reimbursement Tool Kit
1A30 Greissinger Plus (Kenevo/C-Leg/Genium)	L5972 L5986[3]	Flexible keel foot Multiaxial rotation unit
1B1 Meridium Foot (C-Leg/Genium/X3)	L5973[3]	Ankle-foot system, microprocessor control feature See Meridium Reimbursement Tool Kit
1C11 Terion K2 (Kenevo)	L5972 L5986[3]	Flexible keel foot Multiaxial rotation unit
1C30 Trias (Kenevo/C-Leg/Genium/X3)	L5981[3] L5986[3]	Flex-walk system Multiaxial rotation unit
1C40 C-Walk (C-Leg/Genium/X3)	L5981[3] L5986[3]	Flex-walk system Multiaxial rotation unit
1C50 Taleo (C-Leg/Genium/X3)	L5980[3] L5986[3]	Flex-foot system Multiaxial rotation unit
1C60 Triton (C-Leg/Genium/X3)	L5980[3] L5986[3]	Flex-foot system Multiaxial rotation unit
1C61 Triton Vertical Shock (C-Leg/Genium/X3)	L5987[3] L5986[3]	Shank foot system with vertical loading pylon Multiaxial Rotation unit
1C62 Triton Harmony (C-Leg/Genium/X3)	L5987[3] L5986[3] L5781	Shank foot system with vertical loading pylon Multiaxial rotation unit Vacuum pump, residual limb volume mgmt. and moisture evacuation See the Harmony Reimbursement Tool Kit
***1C63 Triton LP (low profile)** (C-Leg/Genium/X3)	L5981[3] L5986[3]	Flex-walk system Multiaxial rotation unit
1C64 Triton HD (heavy duty) (C-Leg/Genium/X3)	L5980[3] L5986[3]	Flex-foot system Multiaxial rotation unit
1C68 Triton side flex (C-Leg/Genium/X3)	L5981[3] L5986[3]	Flex-walk system Multiaxial rotation unit
1D10/11 Dynamic Foot (Kenevo/C-Leg)	L5972[3]	Flexible keel foot

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Coding Options[1] for Ottobock Microprocessor Knees

January 01, 2020

1D35 Dynamic Motion (Kenevo/C-Leg/Genium/X3)	L5979[3]	Multiaxial ankle, dynamic response foot
1E56 Axtion (C-Leg/Genium/X3)	L5981[3]	Flex-walk system
1E57 Lo Rider (C-Leg/Genium/X3)	L5981[3]	Flex-walk system
1E95 Challenger* (Genium/X3)	L5987[3]	Shank foot system with vertical loading pylon
1H32, 34, 38, 40 Single Axis (Kenevo)	L5974	Energy Storing Foot
1M10 Adjust (Kenevo/C-Leg/Genium)	L5972[3] L5986[3]	Flexible keel foot Multiaxial rotation unit
1S49, 66, 67, 90, 101-103 (Kenevo)	Incl. Base	Sach Foot
LINERS, SHUTTLE LOCKS, SOCKS OPTIONS (not all inclusive)		
PREFABRICATED LINERS WITH DISTAL CONNECTION		
6Y80 Skeo 6Y85 Skeo Skinguard TF 6Y88 Skeo 3D Skinguard TF	L5673	Custom/Prefabricated socket insert, silicone gel, elastomeric or equal, for use with lock.
PREFABRICATED LINERS WITHOUT DISTAL CONNECTION		
6Y81 ProSil (uncovered) 6Y110 Skeo Sealing Liner 6Y520 Uneo (Uniform) 6Y522 Uneo (Tapered, Uncovered) 6Y523 Uneo (tapered, covered)	L5679	Custom/Prefabricated socket insert, silicone gel, elastomeric or equal, not for use with lock.
CUSTOM LINERS		
6Y416 Shape Plus (Urethane) 6Y417 Shape Plus (replacement)	L5681 L5683	For Initial Liner use: Custom socket insert, for congenital/atypical traumatic amputee, silicone gel, elastomeric or equal, for use with/without lock. OR For Replacement Liner (same mold) use: Custom socket insert, not for congenital/atypical traumatic amputee, silicone gel, elastomeric or equal, for use with/without lock.

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Coding Options[1] for Ottobock Microprocessor Knees

January 01, 2020

SHUTTLE LOCKS		
6A20=10, =20 Shuttle Lock 6A30=10, =20 Shuttle Lock 6A40 MagnoFlex Shuttle Lock 4R160=1, =2 KISS Lanyard System	L5671	Suspension Lock (shuttle, lanyard, or equal)
SOCKS		
453D4, D5, D7 Derma Seal	L8417	Sheath/Sock, including Gel cushion layer.
451F4=20 TF Residual Limb Sock - Nylon	L8410	Sheath, above knee
451F6=20 TF Residual Limb Sock - Cotton	L8430	Sock, multiple ply
PROTECTIVE COVERING (if used)		
See the main product Reimbursement Tool Kits for billing instructions.		
3S26=L44 Cosmetic Foam Cover	L5705	
4X840 Kenevo Protective Cover	L5999[2]	Ottobock 4X840 Kenevo Protector
4X860 + 4P863=* C-Leg Protective Cover + Shield	L5999[2]	Ottobock 4X860=* C-Leg Protective Cover + Shield
4P862 + 4P863=* C-Leg Guard + Shield	L5999[2]	Ottobock 4P862 C-Leg Guard Protective Cover + Shield
4X880 Genium Protective Cover	L5999[2]	Ottobock 4X880 Genium Protective Cover
4X889 SF Genium Protector	L5999[2]	Ottobock 4X889 Genium Protector, high strength, light weight, carbon Prepreg protective cover for the Genium Knee.
4X193-1 X3 Protective Cover	L5999[2]	Ottobock 4X193-1 Protective Cover for the X3 Knee
4X900 X3 Protective Cover	L5999[2]	Ottobock 4X900 Protective Cover for the X3 Knee.
99B16 Soft Touch Stocking	A4467	Above knee, flexible, protective outer surface covering
ADAPTORS (if used)		
4R10=111 Quickchange (Genium/X3)	L5617	Quick change self-aligning unit
4R57 Rotation Adaptor (Kenevo, C-Leg)	L5999	Ottobock 4R57 Rotation Adapter added to lower limb prosthesis to provide rotation for [add medical need]. Email reimbursement911@ottobock.com for assistance.
4R40 Torsion Adapter (Kenevo, C-Leg)	L5984[3]	Axial rotation unit, with or without adjustability

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Coding Options[1] for Ottobock Microprocessor Knees

January 01, 2020

BATTERY/CHARGER (Replacement only) *Contact service department for battery replacement		
4E50 + 757L16 C-Leg Charger and Adapter	L7368	Charger & Adapter for Lithium Ion Battery, replacement only (initial charger included in microprocessor code)
4E60 + 757L16 Genium/X3 Charger and Adapter	L7368	Charger & Adapter for Lithium Ion Battery, replacement only (initial charger included in microprocessor code)
4E70 + 757L16 Kenevo Charger and Adapter	L7368	Charger & Adapter for Lithium Ion Battery, replacement only (initial charger included in microprocessor code)
Li-Ion Battery (CLeg/Genium/X3/Kenevo)	L7367	Lithium Ion Battery, replacement only (initial battery included in microprocessor code)
PYLONS (Replacement only)		
2R57 Tube Adaptor (C-Leg)	L7510	Replace 2R57 Electronic Pylon on Ottobock C-Leg (include model #, original purchase date, reason for replacement, continued medical need & MSRP)
2R67 Tube Adaptor w/ Torsion (C-Leg)	L5984[3] or L7510	(initial claim only) Axial rotation unit, with or without adj. Replace 2R67 Electronic Pylon w/ Torsion on Ottobock C-Leg (include model number, original purchase date, reason for replacement, continued medical need & MSRP)
2R17 AxonTube Adaptor (Kenevo)	L7510	Replace 2R17 Electronic Pylon on Ottobock Kenevo (include model #, original purchase date, reason for replacement, continued medical need & MSRP)
2R19 Axon Tube Adapter (X3)	L7510	Replace 2R19 Electronic Pylon on Ottobock X3 (include model #, original purchase date, reason for replacement, continued medical need & MSRP)
2R20 Axon Tube Adapter (Kenevo/Genium)	L7510	Replace 2R20 Electronic Pylon on Ottobock Genium/Kenevo (include model #, original purchase date, reason for replacement, continued medical need & MSRP)
2R21 Axon Tube Adaptor w/Torsion (Kenevo/Genium)	L5984[3] or L7510	(initial claim only) Axial rotation unit, with or without adjustability Replace 2R21 Electronic Pylon w/Torsion on Ottobock Genium/Kenevo (include model #, original purchase date, reason for replacement, continued medical need & MSRP)

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C-Leg® Microprocessor Knee
Tips for Billing Private Payers

[1] Suggested Coding

The following codes are PDAC Verified for the C-Leg

L5828	SINGLE AXIS, FLUID (HYDRAULIC), SWING AND STANCE PHASE KNEE.
L5845	STANCE FLEXION FEATURE, ADJUSTABLE
L5848	FLUID STANCE EXTENSION DAMPING FEATURE
L5856	MICROPROCESSOR CONTROL FEATURE, SWING AND STANCE PHASE, INCLUDES SENSORS

Additional codes for the new functionality of C-Leg 4

Please check with your payer for coverage of these codes.

L5850	KNEE EXTENSION ASSIST
L5925	MANUAL LOCK
**L5999	ADDITION TO ENDOSKELETAL SYSTEM (OTTOBOCK 3C98 / 3C88 C-LEG), INERTIAL MOTION UNIT CONTROL FEATURE FOR INTUITIVE STANDING AND WALKING BACKWARDS.

Other codes that you might see on a C-Leg claim

L5920	ALIGNABLE SYSTEM (for a new prosthesis/replacement that needs realignment)
L5950/L5960	ULTRALIGHT MATERIAL (TITANIUM, CARBON FIBER, OR EQUAL) (when added to a socket)

**It is not recommended to bill L5999 to Medicare for Microprocessor Knees.

[2] Manufacturer Suggested Retail Price (MSRP)

2020 MSRP for the Inertial Motion Control Unit miscellaneous (NOC) code is $5,000

C-Leg® Microprocessor Knee
Tips for Billing Private Payers

Billing Tips for the C-Leg Miscellaneous code - L5999

Because L5999 is an unlisted (NOC) code, the claim must have additional information to describe the item. This will allow the payer to understand what you are billing for. Most payers require a narrative be added to the claim (e.g. description, manufacturer, name & model#, serial number#, and MSRP). Please check with your software vendor and payer for to confirm narrative placement.

Where to Put the Narrative

[3] Electronic Claim

Notes can be added in 2 places; the 2300 Segment (pertains to the entire claim) and the 2400 Segment (pertains to each line item). Note: Segments are limited to 80 characters each (including spaces).

2300 Segment:

Insert information here about the overall device you are billing for (socket, knee, ankle, foot, etc.)

Example:

TF PROSTHESIS W/SOCKET, 3C98 C-LEG MP KNEE W/IMU, VS PYLON FOOT, CUST LINER, COVER

2400 Segment:

Insert information here about each line item (L5999)

Examples:

ADDITION, INERTIAL MOTION CONTROL FEATURE ON OTTOBOCK 3C98 C-LEG MSRP $5000

[3] Paper Claim

Enter entire narrative on **Line 19** when submitting a hand-written paper claim (CMS-1500). Include the HCFA 1500 line number (1-6) that the L5999 code is located on.

Example:

TF PROSTHESIS W/SOCKET, 3C98 C-LEG, VS PYLON FOOT, CUST LINER, PROTECTIVE COVER; Line 3: L5999 ADDITION, INERTIAL MOTION CONTROL FEATURE (ON OTTOBOCK 3C98 C-LEG) MSRP $ 5,000.

C-Leg® Microprocessor Knee
Tips for Billing Private Payers

[3] Reimbursement Amount

The reimbursement methodology for miscellaneous codes is generally stated in your contract with the payer. Miscellaneous codes are sometimes referred to as Not Otherwise Classified (NOC), Not Otherwise Specified (NOS) or Non-Assigned codes. The most common methodologies are:

- MSRP minus ___%
- Cost plus ___%
- Usual and Customary (average amount that you bill for similar devices)
- Average Regional Amount billed for similar devices
- Lesser of the above

It is highly recommended to carefully review your contract with the payer when providing a miscellaneous coded product. If the information is not in your contract, provider relations may be able to help.

Medical Review

Sometimes codes requiring narratives are sent to Medical Review regardless of proper claim submission. If this happens, you will need to submit all documentation (including proof of medical necessity and reason for replacement) as the claim will likely undergo medical necessity review.

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[2] The manufacturer's suggested retail pricing (MSRP) is a suggested retail price only. Ottobock has provided the suggested MSRP in the event that third-party and/or federal healthcare payers request it for reimbursement purposes. **Con**The practitioner and/or patient care facility is neither obligated nor required to charge the MSRP when submitting billing claims for third-party reimbursement for the product(s).

[3] Joint DME MAC. Local Coverage Article: Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426). Not Otherwise Classified (NOC) BILLING INFORMATION. Updated Aug, 9, 2019. (effective Jan, 1, 2019).

Contact

Ottobock Reimbursement North America
P 800 328 4058 F 800 962 2549
professionals.ottobockus.com
reimbursement911@ottobock.com

ottobock.

Lower Limb Prosthesis Documentation Packet

Lower Limb Prosthesis Documentation Packet

Revised: February, 28 2020

Table of Contents

If you need help:

Contact the Ottobock Reimbursement Team

- Call 800-328-4058 and ask for reimbursement, or
- Email your request to Reimbursement911@Ottobock.com

Ottobock Reimbursement North America
P 800 328 4058 F 800 962 2549
professionals.ottobockus.com
professionals.ottobock.ca
reimbursement911@ottobock.com

Documentation Checklist

Patient Name:

Date:

Completed by:

FROM THE PHYSICIAN

History of Amputation

- ❑ Date and Cause of amputation(s)
- ❑ Affected side(s)
- ❑ Clinical course, interventions & results, prognosis

Physical Examination

- ❑ Height, weight, recent loss/gain
- ❑ Cognitive ability to use & care for new prosthesis
- ❑ Condition of residual limb
- ❑ Cardiopulmonary, Musculoskeletal, Neurological
- ❑ Strength, ROM, gait, balance, coordination

Functional Limitations

- ❑ Limitations caused by current condition/comorbidities
- ❑ Diagnoses causing the symptoms.

Ambulatory assistance

- ❑ Used currently/prior to amputation
- ❑ Situational/temporary?
- ❑ Plan to be free of assistive devices (if applicable).

Functional Level

- ❑ Patient's activities prior to amputation
- ❑ Patient's current activities & impact of the limitations identified above.
- ❑ Desired & potential activities using new prosthesis

Prosthetic Use

- ❑ Past: components tried & result
- ❑ Current: History and condition of each component
- ❑ Reason for replacement

For Repair, Replacement, or Refill

- ❑ Patient continues to use a prosthesis
- ❑ The prosthesis is medically necessary

Desire and Motivation

- ❑ To ambulate and use new prosthesis

Functional State

- ❑ K-Level (based on prior activities, current condition, and motivation to ambulate).
- ❑ Recommendation for new prosthetic components
- ❑ For potential K-level, include explanation & plan to reach desired K-Level & approx. how long it will take

DISPENSING ORDER (RX)

Effective 1/1/20 not required for Medicare

- ❑ Patient's name
- ❑ Date of order (prescription date/date of call)
- ❑ Description of item being dispensed
- ❑ Printed name and signature of physician or person who took the call.
- ❑ Meets your state's requirement for orders

STANDARD WRITTEN ORDER (SWO) –supplier generated

Effective 01/01/2020 – replaces DWO

- ❑ Date of Order: on/prior to the delivery date
- ❑ Narrative description, HCPCS code, HCPCS code narrative, or Brand Name/Model Number.
- ❑ Physician demographics/NPI ok for Medicare
- ❑ Physician's hand written signature, date
- ❑ Quantity & RT/LT
- ❑ Meets your state's requirement for orders
- ❑ Patient name on each page/MBI ok for Medicare

PROSTHETIST'S DOCUMENTATION

Functional Level – should match physician's determination

- ❑ Testing
- ❑ Activities prior to amputation
- ❑ Current Activities
- ❑ Future activities
- ❑ For potential K-Level: explanation for the difference

History of Prosthetic Use Over Time

- ❑ Brand, how long used, result

History of Current Components

- ❑ History of components being replaced (age, condition, result)
- ❑ Description of Labor (casting, modification, time, tools, materials & where applied
- ❑ Reason for Replacement

Recommendation for Type and Brand of Prosthesis

- ❑ Based on physician's recommendation
- ❑ Medical Necessity and Justification for each component

Desire and Motivation

- ❑ To ambulate and use new prosthesis

Additional

- ❑ Chart note for each visit
- ❑ Signature of signee

For Refills (liners, socks, etc)

- ❑ Continued Need: MD note within 12 mo. (or substitute new verbal/written order).
- ❑ Continued Use: Document the refill request and condition of the item being replaced.

PROOF OF DELIVERY

- ❑ Delivery Date
- ❑ Patient's Name
- ❑ Delivery Address
- ❑ Narrative description, HCPCS code, HCPCS code narrative, or Brand Name/Model Number.
- ❑ Signature and Printed name of signee
- ❑ Relationship to patient and reason why patient cannot sign
- ❑ Signature time, if signed on same day as SWO obtained.

❑ BENEFICIARY AUTHORIZATION

❑ ABN IF REQUIRED

Documentation Guide for LL Prosthetics

January 2020

Following is Medicare's criteria for coverage of LL Prosthetics, which also can be found in other medical coverage policies.

Medical Necessity

Medical necessity for prosthetic components or additions to the prosthesis is based on:

1. The patient's past history [activities],
2. The patient's current condition [residual limb and any medical conditions that might affect patient's ability to use the new prosthesis], and
3. Desire to ambulate. [desire to use the new prosthesis and get back to those previous activities]

A lower limb prosthesis is covered when:

4. Prescribed by a physician
5. The member will reach or maintain a defined functional state (Potential K-Level) within a reasonable period of time, and
6. The member is motivated to ambulate

Note: For Medicare all 6 criteria must be documented.

- You should have on file chart notes reflecting the need for the care (e.g. evaluation, treatment plan, history and physical, etc.) from the patient's medical records charted contemporaneously, in other words, when the patient is present.
- To be on the safe side, it is recommended that this information be collected up-front to be sure the physician's documentation supports the claim.
- All documents that support medical necessity must be signed and dated prior to the delivery date.

Item 1: Physician Documentation

Recent physical evaluation (focus should be on the amputation, the prosthesis, and ambulatory difficulties). Elements that should be included:

a. **History of the Amputation**

- Diagnosis/etiology of amputation(s)
- Date and affected side (s)
- Clinical course
- Therapeutic interventions and results
- Prognosis

b. **Physical Examination Relevant to Functional Limitations**

- Height, weight, recent loss/gain
- Cognitive ability to use & care for new prosthesis
- Description of the residual limb (e.g. local and/or phantom pain; wound healing issues; skin irritation, breakdown, infection; limb volume changes or swelling; weight fluctuations; muscle atrophy or contractures; osteoarthritis, or other arthritic conditions of the residual limb joints).
- Cardiopulmonary, musculoskeletal, neurological, arm and leg strength, ROM, gait, balance, coordination

c. **Functional Limitations**

Describe the nature and extent of any functional limitations whether from current condition or comorbidities.

Examples:

- Cardiopulmonary conditions that might limit the patient's capacity [e.g. congestive heart failure (CHF), coronary heart disease (CHD), endocarditis, myocarditis, arrhythmias, peripheral arterial (occlusive) disease (PAD/PAOD), chronic venous insufficiency (CVI) with recurring ulcers, lymphedema].
- Musculoskeletal conditions (e.g. osteoarthritis sound side leg joints, spinal stenosis, severe low back pain, etc.).
- Neurological conditions that cause impairments in gait, balance or coordination (e.g. MS, stroke, SCI, Parkinson's, peripheral nerve lesions, lumbar disc herniation with motor paresis, dementia/Alzheimer's disease, depression, psychiatric disorders/diseases).
- Other comorbidities (e.g. chronic kidney failure, chronic liver failure, cancer with chemotherapy/radiation, general deconditioning).

d. **Ambulatory Assistance** prior to the amputation and/or currently used (e.g. cane, walker, wheelchair, caregiver).

- For non-routine/occasional use, describe the situation when the patient uses the assistive device.
- If this is a temporary situation state in your opinion how long it will take the patient to be back to functioning at the desired level (free of the assistive device).

e. **Define Patient's Functional State:**

Describe patient's functional capabilities in K-Level terms, as they relate to the patient's activities. These should be **real activities**, such as "walking the dog" and related K-level functions that patient encounters (e.g. long-distance ambulation, obstacles, types of terrain, slopes, stairs, ramps, crowds, public transportation).

Functional Levels (K-Levels)

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 *[i.e. patient likely will not be able to ambulate at all].*

Level 1: Has the ability or potential to use prosthesis for transfers or ambulation on level surfaces at fixed cadence *[i.e. patient likely will be able to use the prosthesis within his/her dwelling only].*

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 *[i.e. patient will likely be able to use prosthesis within his/her dwelling and a limited radius in the community].*

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. *[i.e. patient will likely have a prosthetic ability comparable with that of a non-amputated person with no mobility restrictions].*

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.

Following is what must be in the record:

- **Patient's activities prior to amputation.** Identify prior activities in the patient's potential K-Level category.
- **Patient's current activities.** Include the impact of the limitations identified above. Is the patient more limited by his/her medical conditions or by the function of the prosthesis?
- **Activities that patient desires to get back to** (and has the potential for) using the new prosthesis.

Note: If patient was a community ambulator (K3/K4) earlier in life, but not prior to the amputation due to a medical condition (e.g. neuropathy, ulcers, and neuropathic pain) or if patient was never a community ambulator (K3/K4) and now has demonstrated capacity to be one, include why you believe the patient will be a community ambulator with the new prosthesis (e.g. sound limb is asymptomatic, achievements during rehabilitation/physical therapy, diseased limb was the primary cause of the mobility restrictions, etc.).

f. **Document the Current Prosthesis:**

- **Condition of each component** (e.g. socket, knee, pylon, ankle, foot) should be documented.
- **Reasons for replacement** One of the following reasons should be documented for each component being replaced.

  Reasons allowed by most payers:
  - Patient's functional needs have changed
  - Due to physical changes the component no longer fits
  - Device is irreparably worn

  Additional reasons allowed by Medicare
  - Device is lost or damaged beyond repair
  - Cost to repair will be greater than 60% of the cost (Medicare allowable) to purchase a new device.

- **If the patient's condition has changed**, describe why the current prosthesis is no longer appropriate. (e.g. weight gain/loss, decreased stability, etc.)
- **If the device was damaged or lost**, describe the incident.

g. **Previous Prostheses:**
- Document patient's past experience with prosthetic components (what has been tried, and the result).

h. **For a Repair, Replacement or Refill**
- Document that patient continues to use prosthesis.
- And prosthesis is medically necessary.

i. **Desire and Motivation:**
- Document patient's desire to use the new prosthesis.
- Document patient's motivation to ambulate.

j. **Recommendation for the type of new Prosthesis/ Component(s)** and the medical reason for your decision.

- The recommendation should be based on patient's prior activities, current condition, and desire to ambulate (used to determine the K-Level).
- The Brand name of the prosthetic components is not required.
- Important: If the patient has the potential to reach a higher K-level designation in the future, an explanation for the difference is required. Include a treatment plan that will achieve this increase in functional level, and what it will take to get there (e.g. physical therapy, gait training, etc.). For Medicare, the plan should specify in your opinion approximately how long _____ it will take the patient to be functioning at the potential K-Level.

Item 2: Initial Order (Prescription)

- Effective January 1, 2020: For Medicare the initial order is no longer required for orthotics and prosthetics; however, a signed Standard Written Order (SWO) must be obtained prior to billing.
- If an initial order is required by the insurance payer, state, or credentialing agency, the initial order can either be verbal and documented in the patient's chart OR written by the ordering physician.
- It is the supplier's responsibility to ensure compliance with pertinent insurance criteria, credentialing, and state laws.

Elements included on a typical initial order/ prescription when required (best practice):

a. **Patient's name**
b. **Date of order**
   - For written order: use the date of the prescription
   - For verbal order: use the date the call was received
c. **Description of item(s)**
d. **Signature**
   - For written order: Physician's signature and date , printed name and credential
   - For verbal order: Printed name of person taking order, signature, date, time.

New Item 3: Standard Written Order (SWO)

- The SWO replaces the DWO
- The provider may write the SWO; however, the physician must review and sign it.
- An initial order can be used as a SWO if it contains all elements required below.
- The SWO must meet state prescribing, credentialing and/or other applicable laws.

Minimum elements that must be included on a "supplier generated" SWO: Effective Jan. 1, 2020

a. **Order date** New: The SWO must be dated on/prior to the date of delivery
b. **Describe what is being ordered** (list all items, options or additional features that will be separately billed or require an upgraded code).

You may use **one** of the following methods:
- **Narrative description** (AK polycentric knee w/friction)
- **HCPCS** code (L5613),
- **HCPCS code narrative** (Addition to lower extremity, endoskeletal system, above knee, knee disarticulation, 4-bar linkage, with friction swing phase control)
- **Brand name/model number** (4R36 Titan polycentric knee joint)

To avoid confusion, we recommend including brand name and model number for items with multiple HCPCS codes.

c. **Physician's Demographics** printed name, credential, address, phone, NPI Effective January 1, 2020: only the physician's name/National Provider Identifier (NPI) number is required for Medicare.
d. **Quantity** to be dispensed
e. **RT/LT** (recommended)
f. **Physician's signature**
g. **Patient's name** on each page (Effective January 1, 2020: The Medicare Beneficiary Identifier (MBI) may be used in place of patient's name for Medicare)

Item 4: Liners, Socks, Other Non-Consumable Items

- These are treated as a refill and covered under the original order.
- Note: keep in mind that Medicare and other large payers have medically unlikely edits established for liners and socks. Look up your code here.
- Replace only when item is no longer functional and document condition with sufficient detail.
- For documentation requirements, see Item 5.f.

The following items must be included in a liner, sock, or other non-consumable order (information may be included on the SWO).

a. **Patient's name** (Effective January 1, 2020: MBI is allowed in place of name for Medicare)
b. **Order date**
c. **Description of item(s)** being ordered
d. **Quantity** to be dispensed
e. **RT/LT** (recommended)
f. **Patient continues to use the orthosis**
g. **Physician demographics** printed name, credential, address, phone, NPI (Effective January 1, 2020: only physician's name or NPI required for Medicare)
h. **Physician's signature**

Item 5: Prosthetist's Documentation

- Medical records must support that the device is still medically necessary.
- Medicare expects that a lost/damaged item would be reported to some authority (e.g. police, homeowners insurance, etc.) and requires that a copy of that report be available. If patient did not report the accident/loss, you will need a signed statement from the patient describing the incident.

a. **Functional Evaluation** (K-level should match physician's evaluation -see Physician Documentation section)
b.

- **Activities prior to amputation**
  - Activities that patient did in the past and would like to get back to using a new device (e.g. home, work, therapeutic, exercise).
- **Current activities.**
  - Focus on activities that the new prosthesis will allow that the current prosthesis does not.
  - Describe difficulties, such as falls, stumbles, not making it across street before light changes, inability to change speed when needed, etc.
  - How will patient be able to do it better with the new prosthesis?
- **Potential future activities.**
  - If these vary from prior activities, an explanation will be required)

c. **History of Prosthetic Use**
- Your records should have a history of each prosthesis patient has used/trialed in the past.
  - Brand of component
  - How long did patient use it?
  - What was the result?

d. **Current Prosthesis**
- **History of each component being replaced** (age, condition, how did it work out?)
- **Description of the labor involved** (e.g. casting, modification, time, tools used, materials used, where was material applied, etc.)
- **Reason for replacement** (e.g. change in patient's condition, device no longer fits, device does not meet functional needs, item is worn and cannot be repaired. Medicare and some payers also allow replacement when the cost to repair is greater than 60% of the Medicare allowable for a new device or item is lost or damaged beyond repair).

e. **Recommendation for the type and brand of the new prosthesis:**
- Must be based on physician's recommendation
- Include rationale for your decision
- Include medical necessity and justification for each code that will be billed.

f. **Patient's motivation and desire** to use the new prosthesis (and to ambulate for lower extremity)

g. **Document Refill Requests** (e.g. liners, socks, other non-consumable items). This can be a written request from the patient or telephone contact between supplier and patient.

The following elements should be included on the refill request:

- **Patient's name** (or authorized representative and relationship)
- **Date of request** (must be no sooner than 14 calendar days prior to delivery/shipping)
- **Description** of each item requested
- **RT/LT**
- **Quantity and functional condition** of items being replaced

  Note: Shipment/delivery may not occur sooner than 10 calendar days prior to current supply exhausting.

h. **Chart note for each visit with patient** with printed name, credential, signature and date on each note.

i. **Patient's name on each page**.

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Item 6: Proof of Delivery (POD)

- A signature date is no longer required; however, if there is one on the form, it must be the date of service on your claim.

Elements to be included on the POD when device is delivered direct to the patient:

a. **Delivery Date**
b. **Patient's name**
c. **Address** where item is delivered (your office, patient's home, SNF, etc.)
d. **Quantity** delivered for each item
e. **Amputation side** for each item, LT/RT
f. Describe what will be delivered. You may use **one** of the following methods:

   - **Narrative description** (AK polycentric knee w/friction)
   - **HCPCS** code (L5613)
   - **HCPCS code narrative** (Addition to lower extremity, endoskeletal system, above knee, knee disarticulation, 4-bar linkage, with friction swing phase control)
   - **Brand name/model number** (4R36 Titan polycentric knee joint)
   - **Note:** To avoid confusion, we recommend including brand name and model number for items with multiple HCPCS codes.

g. **Signature and printed name** of the patient or designee

   Note: If designee signs, include the designee's relationship to the patient and the reason why patient could not sign. This person cannot have any financial connection to the provider.

Item 7: Beneficiary Authorization

- A new authorization is required anytime a new prosthesis/component(s) is provided. In other words, a new authorization is required anytime a new HCPCS code is billed.
- This authorization should give you:
  - Permission to submit claims on behalf of beneficiary.
  - Permission to pay you directly (assigns the benefits to the provider).
  - Release to authorize the provider to obtain confidential medical information about the beneficiary in order to process the claim.

Example of an Authorization:

- Name of Beneficiary:
- HICN:
- I authorize (supplier)_____ to submit claims to Medicare on my behalf. I request that payment of authorized Medicare benefits be made either to me or on my behalf to (supplier)_____ for any services furnished me by that supplier.
- I authorize any holder of medical information about me to release to (supplier) _____ and/or the Centers for Medicare & Medicaid Services and its agents any information needed to determine these benefits or the benefits payable for related services.
-
- Signature_____
  Date_____

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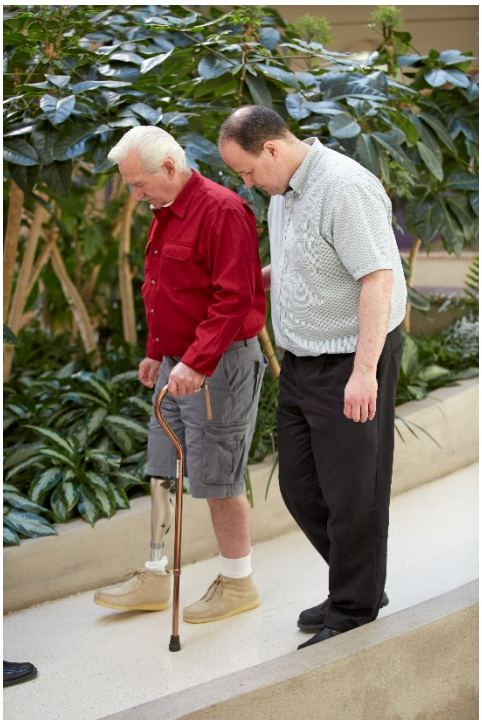
Item 8. Advanced Beneficiary Notice (ABN) if required



- NOTE: Medicare does not allow "blanket" ABN's to be issued. In other words, one cannot give an ABN to every patient, in anticipation that Medicare might deny. ABNs are to be used on a case-by-case basis when there is a clear indication that the device will be denied as not medically necessary/not reasonable and necessary. The most common situation would be when a patient does not meet the criteria for coverage.

- **Examples of when an ABN might be used:**
  - Patient does not meet criteria for coverage as stated in LCD
  - Physician clearly has not provided sufficient documentation to meet Medicare's documentation requirements and there is a high probability that the claim will be denied as not medically necessary.

References: Joint DME MAC Local Coverage Policy L33686 and Policy Articles: A55426 and A52457 effective January 1, 2020; CGS & Noridian Supplier Manuals.

Fax to:		Fax from:	
Company:		Company:	
Phone:	Fax:	Phone:	Fax:
Patient Name:		Date of Birth:	No. Pages:

FAX: Documentation Request for a Lower Limb Prosthesis

This is a request for medical records on the above patient relative to his/her prosthesis.

- **History of Amputation:** Cause, date & side of amputation(s); clinical course, therapeutic interventions & results, prognosis
- **Physical Examination**
  1. Weight, Height, Weight Loss/Gain.
  2. Cognitive ability to use the use and care for the new prosthesis
  3. Condition of residual limb
  4. Cardiopulmonary, musculoskeletal, neurological, strength, ROM, gait, balance, coordination
- **Functional Limitations** Describe nature and extent of any functional limitations, whether from current prosthesis, current condition, or comorbidities (e.g., decreased pulmonary reserve, disabling cardiovascular, neuromuscular, peripheral vascular or musculoskeletal conditions).
- **Ambulatory Assistance Used** prior to the amputation and/or current. Is it routine, situational, temporary? Explain
- **Document Medical Necessity in K-Level Terms:** (see descriptions below)
  1. Patient's activities prior to amputation
  2. Patient's current activities along with any functional limitations as identified above
  3. Activities that patient desires to get back to (and has the potential for) using the new prosthesis.
  4. Describe patient's desire and motivation to ambulate with the new prosthesis
- **Document the condition/status of current prosthesis and reason for replacement of each component.** If worn/broken, describe the condition of each component that needs to be replaced. If patient's physical condition or functional needs have changed, describe why prosthesis/component no longer meets his/her needs.
- **Describe Past Experience with Prostheses/Components** Describe what has been tried in the past and the results.
- **For continuing care (e.g. replacement, repair, or refill)** Document continued medical necessity and continued use.
- **Recommendation for the new components.** Include medical reason for your decision.
- **K-Level.** If the patient has potential to reach a higher K-level designation in the future, include an explanation and treatment plan that will achieve this increase in functional level, and what it will take to get there (e.g. physical therapy, gait training, etc.). The plan should specify in your opinion approximately how long _____ it will take the patient to be functioning at the potential K-Level and address use of the mobility aid if pertinent.
- **Functional Capabilities for Lower Extremity [K-Levels]**

  Level K-0: Does not have the ability/potential to ambulate or transfer safely with/without assistance

  Level K-1: Home Ambulator with ability/potential for transfers or ambulation on level surfaces at fixed cadence.

  Level K-2: Limited Community Ambulator with ability/potential for ambulation and to traverse low level environmental barriers

  Level K-3: Full Community Ambulator with ability/potential for ambulation with variable cadence and to traverse higher level barriers

  Level K-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.

Please FAX the signed and dated Medical Necessity documents to:

_____ at (_____)_____

Documentation Tips

Justifying Functional Level

Following is Medicare's coverage criteria for a lower limb prosthesis, which is also found in many private insurance policies. For Medicare **all** criteria must be documented!

COVERAGE

A lower limb prosthesis is covered when the beneficiary:

1. Will reach or maintain a defined functional state within a reasonable period of time; and
2. Is motivated to ambulate.

FUNCTIONAL LEVELS:

A determination of the medical necessity for certain components/additions to the prosthesis is based on the beneficiary's potential functional abilities. Potential functional ability is based on the reasonable expectations of the prosthetist, and treating physician, considering factors including, but not limited to:

- The beneficiary's past history (including prior prosthetic use if applicable); and
- The beneficiary's current condition including the status of the residual limb and the nature of other medical problems; and
- The beneficiary's desire to ambulate.

CLASSIFICATION LEVELS:

Clinical assessments of beneficiary rehabilitation potential must be based on the following classification levels:

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
Level 1: Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.
Level 2: Has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs or uneven surfaces. Typical of the limited community ambulator.
Level 3: Has the ability or potential for ambulation with variable cadence. Typical of the community ambulatory who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
Level 4: Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

The records must document the beneficiary's current functional capabilities and his/her expected functional potential, including an explanation for the difference, if that is the case. It is recognized, within the functional classification hierarchy, that bilateral amputees often cannot be strictly bound by functional level classifications. However, the records must still document the beneficiary's past history, current condition, and expected functional potential.

Documentation Tips

Justifying Functional Level

For devices with K3 criteria requirements:

Use “K-Level” language in your documentation. Include “real life” daily activities that require ambulation with variable cadence, and describe with great detail the terrain encountered. Include vocational, therapeutic, and exercise activities that demand prosthetic utilization beyond simple (K2 level) locomotion. Describe why patient has the potential or ability to perform each activity and what is involved, such as how far will the patient walk, when will he/she need to change cadence, and types of barriers encountered. If the patient has other functional limitations (e.g. vascular/ cardiovascular disease, cognitive issues, osteoarthritis, etc.), explain why these issues will not limit the patient’s ability to use the device to perform the activities.

Per the Medicare LCD for LL Prosthetics, the following codes are covered for K3 and above:

Feet			
L5973	MP Controlled ankle foot system, dorsiflex and/or plantarflex control	L5976	Energy storing foot (Seattle Carbon Copy II or equal)
L5979	Dynamic response foot with multi-axial ankle	L5980	Flex foot system
L5981	Flex-walk system or equal	L5987	Shank foot system with vertical loading pylon
Knees	**(Endoskeletal Knee Shin System)**		
L5610	Hydracadence system	L5613	Knee disarticulation, 4-bar linkage with hyd swing phase control
L5814	Polycentric, hydraulic swing phase control, mechanical stance phase lock.	L5822	Pneumatic swing, friction stance phase control
L5824	Fluid swing phase control	L5826	Hydraulic swing phase control, with miniature high activity knee frame
L5828	Fluid swing and stance phase control	L5830	Pneumatic/swing phase control
L5840	4-bar linkage or multiaxial, pneumatic swing phase control	L5848	Fluid stance extension, dampening feature
L5856	MP control feature, swing and stance phase	L5857	MP control feature, swing phase only
L5858	MP control feature, stance phase only	L5859	Powered programmable flexion/extension assist control (see LCD for additional criteria)
Hips			
L5961	Polycentric hip joint, pneumatic/hydraulic control, rotation control w/w out flexion and/or extension		

Documentation Tips

Justifying Functional Level

For devices with K2 criteria requirements:

Use “K-Level” language in your documentation. Describe “real life” daily activities detailing the terrain encountered, including low-level environmental barriers that the patient encounters, such as a curb, minimal stairs, or slightly uneven surface. Describe why patient has potential or ability to perform these activities. If patient has other functional limitations (e.g. vascular/cardiovascular disease, cognitive issues, osteoarthritis, etc.), explain why these issues will not limit the patient’s ability to use the new prosthesis to perform the activities.

Per the Medicare LCD for LL Prosthetics, the following codes are covered for K2 and above:

Feet			
L5972	Flexible keel Foot	L5878	Multi-axial ankle/foot
Axial Rotation			
L5984	Axial rotation unit, w/ without adjustability	L5985	Dynamic prosthetic pylon
L5986	Multi-axial rotation unit (MCP or equal)		

Example – Changing from a Mechanical knee to a C-Leg

Daily Activities	**Current Prosthesis/ Component**	**Replacement Prosthesis/ Component**
List daily activities in great detail, including those that require traversing environmental barriers, changes in gait speed, and prosthetic utilization beyond simple locomotion when applicable.	Describe current prosthesis (e.g. technologic design & features).	Describe replacement prosthesis (E.g. technologic design & features).
Activities (e.g. home, work, therapeutic, exercise, and recreational). • Describe setting • Current Responsibilities • Problems with prosthesis • Goals	How does the current prosthesis work for this activity? • Can patient successfully execute the activity? • Any falls or stumbles? • Strain to sound side? • Other issues?	How will the replacement prosthesis solve the problem? • What feature will allow patient to execute the activity? • Or do it better? • Explain why

Medicare Rules for Replacement of Prosthesis or Components Documentation Requirements

January 2020

Correct Prosthesis: The supplier (prosthetist) is responsible to provide the correct prosthesis for the patient. If an incorrect prosthesis is supplied the supplier is obligated to make the situation right (take back the incorrect prosthesis, provide the correct one, and adjust the billing). There is no time limit for this.

Repairs and Adjustments: Repairs and adjustments are covered when necessary to make the prosthesis functional. Repairs and adjustments are covered under the initial order. Manufacturer-Required Maintenance is covered as a repair.

What about the 5-year Useful Lifetime Rule? This rule does not apply to prosthetics. The Social Security Act was amended in 2001 to exclude Prosthetics from the Useful Lifetime Rule, so amputees could get replacements when needed.

What is a Replacement? A replacement is the provision of an identical or nearly identical item. If the prosthesis is different, it is considered a new device and no longer covered under the original order.

Rules for Replacement

1. **Replacement** is covered if the treating physician orders a replacement of the entire prosthesis or a major component (e.g. socket, knee, or foot) and the replacement falls under one of the following **Reasons for Replacement** (documented on the order or in the referring physician's notes).
   a) There is a change in the physiological condition of the beneficiary; or
   b) There is irreparable wear of the prosthesis/component; or
   c) The condition of the prosthesis/component requires repairs, and the cost of such repairs [list price of parts + labor] is greater than 60% of the cost [Medicare allowable] of the replacement prosthesis/component.
2. **Loss or Irreparable damage** without a physician's order
3. **Socket Replacements** are considered for payment if reasonable and necessary due to:
   a) changes in the residual limb; or
   b) functional need changes; or
   c) wear/tear due to excessive patient weight; or
   d) wear/tear due to prosthetic demands of very active amputees; or

Medicare Rules for Replacement of Prosthesis or Components Documentation Requirements

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Tips

1) Take care when describing the current prosthesis in the medical record, so it does not sound like an incorrect prosthesis was provided.
2) Choose one reason (see examples below) for replacing the prosthesis and carefully build a case to support this in the patient's medical record. Explain in great detail why the prosthesis is being replaced. While it is required that the status of the current prosthesis be documented, if the patient's functional need or physiological condition has changed and a different prosthesis is needed, this should be the focus of the documentation.

Documentation Requirements

Reason for Replacement	Documentation Requirement
CHANGE IN PATIENT'S CONDITION PHYSIOLOGICAL OR FUNCTIONAL Replace with Identical or Nearly Identical Device Note: If device is not identical or nearly identical, it is considered a new prosthesis/component. See Documentation Guide in this packet.	Physician: New Standard Written Order (SWO) is required. The reason for replacement can be on the order (SWO) or in the physician's medical record. The reason for replacement in this case would be the change that has occurred in the patient's physiological condition or a change in the patient's functional need. Prosthetist: Document condition of components being replaced, orders, reason for replacement, description of labor involved, and proof of delivery.
IRREPARABLE WEAR/TEAR OF THE DEVICE. Replace with Identical or Nearly Identical Device Note: If device is not identical or nearly identical, it is considered a new prosthesis/component. See Documentation Guide in this packet.	Physician: New Standard Written Order (SWO) is required. The reason for replacement must be on the order (SWO) or in the physician's medical record. The reason for the replacement would be "due to wear/tear (e.g. device cannot be repaired) Prosthetist: Document condition of components being replaced, orders, reason for replacement, description of labor involved, and proof of delivery.

Medicare Rules for Replacement of Prosthesis or Components Documentation Requirements

January 2020

Reason for Replacement	Documentation Requirement
WEAR/TEAR OF THE DEVICE OR COMPONENT; WHEN COST OF REPAIR IS GREATER THAN 60% OF THE COST OF A REPLACEMENT. Replace with Identical or Nearly Identical Device Note: If device is not identical or nearly identical, it is considered a new prosthesis/component. See Documentation Guide in this packet.	Physician: New Standard Written Order (SWO) is required. The reason for replacement must be on the order (SWO) or in the physician's medical record. The reason for the replacement would be "the cost of repair is greater than 60% of the cost of replacement and the reason for wear/tear (device cannot be repaired.) Prosthetist: Document condition of the components being replaced, reason for replacement, a description of labor involved, orders, and proof of delivery. If replacing an MPK, we suggest having on file a quotation demonstrating repair cost will exceed 60% of replacement cost (i.e. 60% of the total allowable for the new codes being billed).
IRREPARABLE DAMAGE DUE TO SPECIFIC ACCIDENT OR NATURAL DISASTER (E.G. FIRE OR FLOOD) **OR** **DEVICE IS LOST OR STOLEN** Replace with exact same device as originally ordered.	Physician: May be replaced under the original order. Prosthetist: Proof of loss or damage through documentation such as a police report, picture, or corroborating statement should be submitted with the claim. Describe in medical record that the prosthesis, as originally ordered, still meets the beneficiary's medical needs. Retain documentation of components being replaced, reason for replacement, description of labor involved, original orders, and proof of delivery.
SOCKET REPLACEMENTS DUE TO: • Changes in residual limb, • Functional need changes, or • Irreparable damage/wear and tear due to excessive beneficiary weight or prosthetic demands of a very active amputee.	Physician: May be replaced under original order. Prosthetist: Reason for replacement, condition of components, original orders, description of labor and proof of delivery. Describe in medical record that the prosthesis, as originally ordered, still meets the beneficiary's medical needs.

Reference: LCA. Standard Documentation for All Claims Submitted to the DME MACs (A55426). [Revised January 1, 2020]

Signature Requirements for Documentation

What is Allowed?

Handwritten, Electronic, and Stamped (only if the signee cannot sign due to a disability)

Handwritten Signatures

- A handwritten signature is a mark or sign for services provided/ordered.
- An illegible signature should be accompanied by a signature log or attestation statement.
- Documentation (other than orders) that lack a signature, require an attestattion.
- Orders (e.g. authorizations for tests, plans of care, and procedures) must be validated with a timely signature. Without a signature, they will not be considered.
- It is not allowed to add late signatures to a medical record (beyond the short delay that occurs during the transcription process).

Signature Dates

Signatures do not need to be dated if there is enough information to determine the date when the service was performed or ordered. Example: entries immediately above or below the signature.

Signature Log/Key

- A signature log accompanies one set of medical records.
- Lists the printed name (and credentials) associated with initials or an illegible signature.
- The signature log can be a separate document (or it can be on the actual page where the initials or illegible signature are used).
- A signature log may be created at any time.
- This may include yourself and/or your office staff.

Example:

Name	Signature	Initial	Date of Signature
John Doe, MD	*John Doe, MD*	*JD*	8/31/2019
A. Prosthetist, CPO	*A. Prosthetist, CPO*	*AP*	8/31/2019
I.M. Manager	*I.M. Manager, Office Manager*	*IMM*	8/31/2019

Signature Requirements for Documentation

Signature Attestation Statement Example

Patient Name: I.M. Patient

Medicare Number: 555555555A

I, John Doe, hereby attest that the medical record entry for July 1, 2019 accurately reflects signatures/notations that I made in my capacity as MD when I treated/diagnosed the above listed Medicare beneficiary. I do hereby attest that this information is true, accurate, and complete to the best of my knowledge and I understand that any falsification, omission or concealment of material fact may subject me to administrative, civil, or criminal liability.

John Doe, MD

Signature

08/12/2019

Date

Note: In order to be a valid attestation, it must be signed by the person who authored the medical record entry. It cannot be a partner in the same group practice or other staff member.

Electronic Signature

Examples of electronic signature notations (not all inclusive):

Electronically signed by	Finalized by
Authenticated by	Signed by
Approved by	Validated by
Completed by	Sealed by

References

DME MAC Joint Publication. Medicare Record Authentications – Tips for Physicians. July 2011
CMS Pub. 100-08, Medicare Program Integrity Manual, Chap. 3-Section 3.3.2.4 (Rev. 751; Issued: 10-20 - 17; Effective 11-20-17; Implementation 11-20-17)
Medicare Learning Network. Complying with Medicare Signature Requirements. ICN 905364. May 2018

Changes to the Medical Record
Amendments, Corrections and Delayed/Late Entries

The CMS Program Integrity Manual, instructs the Medicare Auditors to consider all properly written amendments, corrections and late/delayed entries in patient medical records. This means that the physician can add clarification to the medical record after-the-fact if something was missed when the patient was there; however, there are specific record keeping principles that need to be followed.

"All services provided to beneficiaries are expected to be documented in the medical record at the time they are rendered. Occasionally, certain entries related to services provided are not properly documented. In this event, the documentation will need to be amended, corrected, or entered after rendering the service. When making review determinations the MACs, CERT, Recovery Auditors, SMRC, and ZPICs shall consider all submitted entries that comply with the widely accepted Recordkeeping Principles." (CMS Program Integrity Manual)

What are Recordkeeping Principles?

"Regardless of whether a documentation submission originates from a paper record or an electronic health record, documents submitted to MA, CERT, Recovery Auditors, and UPICs containing amendments, corrections or addenda must:

- Clearly and permanently identify any amendment, correction or delayed entry as such, and
- Clearly indicate the date and author of any amendment, correction or delayed entry, and
- Clearly identify all original content, without deletion" (CGS JC)

Specific Rules for Amendments, Corrections and Late Entries

Late Entries

"A late entry supplies additional information that was omitted from the original entry. The late entry bears the current date, is added as soon as possible, is written only if the person documenting has total recall of the omitted information and signs the late entry." (Noridian JE)

Addendums:

"An addendum is used to provide information that was not available at the time of the original entry. The addendum should also be timely and bear the current date and reason for the addition or clarification of information being added to the medical record and be signed by the person making the addendum." (Noridian JE)

[An example would be a lab test not yet available at the time of the exam.]

Changes to the Medical Record
Amendments, Corrections and Delayed/Late Entries

Corrections:

"Paper Medical Record

- Use a single line strike through so the original content is still readable, and
- The author of the alteration must sign and date the revision.

Electronic Health Records (EHR):

- Distinctly identify any amendment, correction or delayed entry, and
- Provide a reliable means to clearly identify the original content, the modified content, and the date and authorship of each modification of the record." (CGS JC)

What is Considered Falsified Documentation?

"Examples of falsifying records include:

- Creation of new records when records are requested
- Back-dating entries
- Post-dating entries
- Pre-dating entries
- Writing over, or
- Adding to existing documentation (except as described in late entries, addendums and corrections)" (Noridian JE)

References

CMS Program Integrity Manual. 3.3.2.5 Amendments, Corrections and Delayed Entries in Medical Documentation. (Rev. 732; Issued: 07-21-17; Effective: 08-22-17; Implementation: 08-22- 17)

CGS Jurisdiction C. Entries in Medical Records: Amendments, Corrections, and Delayed Entries. (January 19, 2016 – revised 03.21.19)

Noridian JE Part B Medical Review. Documentation Guidelines for Amended Medical Records: Amended Medical Records. (Last Updated Aug 14, 2018)

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