

**LCD - Lower Limb Prostheses (L33787)**

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**Contractor Information**

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
CGS Administrators, LLC	DME MAC	17013 - DME MAC	J-B	Illinois Indiana Kentucky Michigan Minnesota Ohio Wisconsin
CGS Administrators, LLC	DME MAC	18003 - DME MAC	J-C	Alabama Arkansas Colorado Florida Georgia Louisiana Mississippi New Mexico North Carolina Oklahoma Puerto Rico South Carolina Tennessee Texas Virgin Islands Virginia West Virginia
Noridian Healthcare Solutions, LLC	DME MAC	16013 - DME MAC	J-A	Connecticut Delaware District of Columbia Maine Maryland Massachusetts New Hampshire New Jersey New York - Entire State Pennsylvania Rhode Island Vermont

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
Noridian Healthcare Solutions, LLC	DME MAC	19003 - DME MAC	J-D	Alaska American Samoa Arizona California - Entire State Guam Hawaii Idaho Iowa Kansas Missouri - Entire State Montana Nebraska Nevada North Dakota Northern Mariana Islands Oregon South Dakota Utah Washington Wyoming

## LCD Information

### Document Information

**LCD ID**

L33787

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**LCD Title**

Lower Limb Protheseses

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**Proposed LCD in Comment Period**

N/A

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**Source Proposed LCD**

[DL33787](#)

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**Issue****Issue Description**

The proposed LCD proposes modifications to the coverage criteria for microprocessor-controlled prosthetic knees (MPKs) for Medicare Functional Classification Level (MFCL) 2 beneficiaries with lower limb amputations who require a prosthetic knee based on the best available evidence. Additionally, the proposed LCD proposes that the coverage criteria for prosthetic feet be modified to allow coverage of a compatible foot when coverage criteria for an MPK are met. KX, GA, GY, and GZ modifier requirements have also been posed for inclusion, for all codes, to facilitate claims processing and assist in the prevention of improper claims payments.

**Issue - Explanation of Change Between Proposed LCD and Final LCD**

The proposed coverage criteria remain largely the same after the comment period with a few minor revisions as follows: updated the coverage criteria for microprocessor knees to remove the word "all" from the requirement to consider and rule out lower-level knee systems (e.g., knee systems which exclude use of fluid, pneumatic, or microprocessor); and added HCPCS code L5841 to the coverage criteria for fluid and pneumatic knees.

**CMS National Coverage Policy**

N/A

**Coverage Guidance****Coverage Indications, Limitations, and/or Medical Necessity**

For any item to be covered by Medicare, it must: 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding "reasonable and necessary" criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the "reasonable and necessary" criteria contained in this LCD there are other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.

- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the "reasonable and necessary" criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

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 treating practitioner and prosthetist, considering factors including, but not limited to:

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

Clinical assessments of beneficiary rehabilitation potential must be based on the following classification levels (see the FUNCTIONAL LEVEL CHARACTERISTICS section in the LCD related Policy Article for additional details):

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 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 medical records must document the beneficiary's current functional and physical capabilities and their 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.

#### GENERAL:

If a prosthesis is denied as not reasonable and necessary, related additions will also be denied as not reasonable and necessary.

When an initial below knee prosthesis (L5500) or a preparatory below knee prosthesis (L5510, L5520, L5530, L5540) is provided, prosthetic substitutions and/or additions of procedures and components are covered in accordance with the functional level assessment except for codes L5629, L5638, L5639, L5646, L5647, L5704, L5785, L5962, and L5980 which will be denied as not reasonable and necessary. When a below knee preparatory prefabricated prosthesis (L5535) is provided, prosthetic substitutions and/or additions of procedures are covered in accordance with the functional level assessment except for codes L5620, L5629, L5645, L5646, L5670, L5676, L5704, and L5962 which will be denied as not reasonable and necessary.

When an above knee initial prosthesis (L5505) or an above knee preparatory (L5560, L5570, L5580, L5590, L5595, L5600) prosthesis is provided, prosthetic substitution and/or additions of procedures and components are covered in accordance with the functional level assessment except for codes L5610, L5631, L5640, L5642, L5644, L5648, L5705, L5706, L5964, L5980, and L5710, L5711, L5712, L5714, L5716, L5718, L5722, L5724, L5726, L5728, L5780, L5790, L5795 which will be denied as not reasonable and necessary. When an above knee preparatory prefabricated prosthesis (L5585) is provided, prosthetic substitution and/or additions of procedures and components are covered in accordance with the functional level assessment except for codes L5624, L5631, L5648, L5651, L5652, L5705, L5706, L5964, and L5966 which will be denied as not reasonable and necessary.

In the following sections, the determination of coverage for selected prostheses and components with respect to potential functional levels represents the usual case. Exceptions will be considered in an individual case if additional documentation is included which justifies the medical necessity. Prostheses will be denied as not reasonable and necessary if the beneficiary's potential functional level is 0.

#### FEET:

A determination of the type of foot for the prosthesis will be made by the treating practitioner and/or the prosthetist based upon the functional needs of the beneficiary. Basic lower extremity prostheses include a SACH foot. Other prosthetic feet are considered for coverage based upon functional classification.

An external keel SACH foot (L5970) or single axis ankle/foot (L5974) is covered for beneficiaries whose functional level is 1 or above.

A flexible-keel foot (L5972) or multiaxial ankle/foot (L5978) is covered for beneficiaries whose functional level is 2 or above.

A microprocessor-controlled ankle foot system (L5973), energy storing foot (L5976), dynamic response foot with multi-axial ankle (L5979), flex foot system (L5980), flex-walk system or equal (L5981), or shank foot system with vertical loading pylon (L5987) is covered when one of the following criteria is met:

1. The beneficiary's functional level is 3 or above; or,
2. The beneficiary's functional level is 2; and,
  - a. Meets the functional level 2 coverage criteria for a fluid, pneumatic, or electronic/microprocessor control addition for a prosthetic knee; and,

- b. A higher-level (i.e., functional level 3) foot is required for the safe and proper use of the prescribed knee system.

The microprocessor foot or ankle system addition with power assist which includes any type motor (L5969) is not covered because there is insufficient information to demonstrate that the item meets the Medicare standard to be considered reasonable and necessary as per PIM Chapter 13. Claims for L5969 will be denied as not reasonable and necessary.

Coverage is extended only if there is sufficient clinical documentation of functional need for the technologic or design feature of a given type of foot. This information must be retained in the treating practitioner's or prosthetist's files.

A user-adjustable heel height feature (L5990) will be denied as not reasonable and necessary.

#### KNEES:

A determination of the type of knee for the prosthesis will be made by the treating practitioner and/or the prosthetist based upon the functional needs of the beneficiary. Basic lower extremity prostheses include a single axis, constant friction knee. Other prosthetic knees are considered for coverage based upon functional classification.

A high activity knee control frame (L5930) is covered for beneficiaries whose functional level is 4.

A fluid or pneumatic knee unit (L5610, L5613, L5614, L5615, L5722, L5724, L5726, L5728, L5780, L5814, L5822, L5824, L5826, L5828, L5830, L5840, and L5841), or control addition, fluid (L5848), or electronic/microprocessor (L5856, L5857, L5858) is covered for beneficiaries whose functional level is 3 or above.

A fluid or pneumatic knee unit (L5610, L5613, L5614, L5615, L5722, L5724, L5726, L5728, L5780, L5814, L5822, L5824, L5826, L5828, L5830, L5840, and L5841), or control addition, fluid (L5848), or electronic/microprocessor (L5856, L5857, L5858) is also covered under limited circumstances for beneficiaries whose functional level is 2, when all of the following criteria (1-3) are met (see the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS section in the LCD related Policy Article):

1. The beneficiary has had a clinical evaluation to determine their functional level (see FUNCTIONAL LEVELS section above); and,
2. Supporting documentation in the medical record outlines, in the context of the beneficiary's overall medical health, the rationale for selection of a fluid, pneumatic, or electronic/microprocessor-controlled knee, including (at minimum) how the selected knee will:
  - a. Improve the beneficiary's functional health outcomes (e.g., fall reduction, injury prevention, lower energy expenditure); and,
  - b. Help the beneficiary accomplish their activities of daily living (ADLs); and,
3. Lower-level knee systems (e.g., knee systems which exclude use of fluid, pneumatic, or microprocessor) have been considered and ruled out based on the beneficiary's specific functional and medical needs.

In addition, for coverage of an electronic/microprocessor-controlled knee system (L5856, L5857, or L5858 plus associated components) for beneficiaries whose functional level is 2, all of the following criteria (1-4) must also be met (see the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS section in the LCD related Policy Article):

1. The electronic/microprocessor knee is indicated for functional level 2; and,

2. The electronic/microprocessor knee has integrated technology that allows the knee to detect when the user trips or stumbles and can automatically adjust to stabilize the knee unit (e.g., stumble recovery); and,
3. The beneficiary is able to make use of a product that requires daily charging; and,
4. The beneficiary is able to understand and respond to error alerts and alarms indicating problems with the function of the unit.

L5859 (ADDITION TO LOWER EXTREMITY PROSTHESIS, ENDOSKELETAL KNEE-SHIN SYSTEM, POWERED AND PROGRAMMABLE FLEXION/EXTENSION ASSIST CONTROL, INCLUDES ANY TYPE MOTOR(S)) is only covered when the beneficiary meets all of the criteria below:

1. Has a microprocessor (swing and stance phase type (L5856)) controlled (electronic) knee
2. K3 functional level only
3. Has a documented comorbidity of the spine and/or sound limb affecting hip extension and/or quadriceps function that impairs K3 level function with the use of a microprocessor-controlled knee alone
4. Is able to make use of a product that requires daily charging
5. Is able to understand and respond to error alerts and alarms indicating problems with the function of the unit

If these coverage criteria for the knee component are not met, L5859 will be denied as not reasonable and necessary.

Other knee systems (L5611, L5616, L5710, L5711, L5712, L5714, L5716, L5718, L5810, L5811, L5812, L5816, L5818) are covered for beneficiaries whose functional level is 1 or above.

Coverage is extended only if there is sufficient clinical documentation of functional need for the technologic or design feature of a given type of knee. This information must be retained in the treating practitioner's or prosthetist's files.

#### ANKLES:

An axial rotation unit (L5982, L5984, L5985, L5986) is covered for beneficiaries whose functional level is 2 or above.

#### HIPS:

A pneumatic or hydraulic polycentric hip joint (L5961) is covered for beneficiaries whose functional level is 3 or above.

#### SOCKETS:

More than 2 test (diagnostic) sockets (L5618, L5620, L5622, L5624, L5626, L5628) for an individual prosthesis are not reasonable and necessary unless there is documentation in the medical record which justifies the need. Exception: A test socket is not reasonable and necessary for an immediate prosthesis (L5400, L5410, L5420, L5430, L5450, L5460).

No more than two of the same socket inserts (L5654, L5655, L5656, L5658, L5661, L5665, L5673, L5679, L5681, L5683) are allowed per individual prosthesis at the same time.

Socket replacements are considered reasonable and necessary if there is adequate documentation of functional and/or physiological need. It is recognized that there are situations where the explanation includes but is not limited to: changes in the residual limb; functional need changes; or irreparable damage or wear/tear due to excessive beneficiary weight or prosthetic demands of very active amputees.

## GENERAL

A Standard Written Order (SWO) must be communicated to the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving a completed SWO, the claim shall be denied as not reasonable and necessary.

For Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) base items that require a Written Order Prior to Delivery (WOPD), the supplier must have received a signed SWO before the DMEPOS item is delivered to a beneficiary. If a supplier delivers a DMEPOS item without first receiving a WOPD, the claim shall be denied as not reasonable and necessary. Refer to the LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.

For DMEPOS base items that require a WOPD, and also require separately billed associated options, accessories, and/or supplies, the supplier must have received a WOPD which lists the base item and which may list all the associated options, accessories, and/or supplies that are separately billed prior to the delivery of the items. In this scenario, if the supplier separately bills for associated options, accessories, and/or supplies without first receiving a completed and signed WOPD of the base item prior to delivery, the claim(s) shall be denied as not reasonable and necessary.

An item/service is correctly coded when it meets all the coding guidelines listed in CMS HCPCS guidelines, LCDs, LCD-related Policy Articles, or DME MAC articles. Claims that do not meet coding guidelines shall be denied as not reasonable and necessary/incorrectly coded.

Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. Proof of delivery documentation must be made available to the Medicare contractor upon request. All services that do not have appropriate proof of delivery from the supplier shall be denied as not reasonable and necessary.

## Summary of Evidence

### Background

Lower extremity amputation is the loss or surgical removal of part of the lower limb as a result of disease, trauma, malignant tumors, or congenital anomaly. Approximately 180,000 lower extremity amputations are performed in the United States annually.<sup>1</sup> Diabetes and peripheral vascular disease are the leading causes of lower extremity amputation in the United States,<sup>2</sup> accounting for more than half of the nearly 100,000 major (i.e., proximal to the ankle) lower limb amputations per year.<sup>3</sup>

Loss of a lower limb negatively affects functional performance, at home and in the community, due to the importance of the lower extremity for balance, transferring, and ambulation. Lower limb amputation is associated with reduced mobility and an increased risk of falling.<sup>4,5</sup> A prosthetic knee is a component of the prosthesis required by an

individual with a transfemoral, knee disarticulation, or hip disarticulation amputation to help restore functional ability. With over 220 prosthetic knee products available, appropriate selection, based on an amputee's medical condition and rehabilitation goals, is of critical importance for a successful outcome.<sup>6,7</sup> An individual with a lower limb amputation can be classified based on their ability or potential to function with a prosthesis, which may assist in the selection of a suitable prosthetic knee joint.<sup>8</sup>

Prosthetic knees can be categorized based on their mechanism of control, either mechanical or microprocessor. A mechanical knee joint, or non-microprocessor-controlled knee (NMPK), can achieve control by manual locking, friction, or hydraulic or pneumatic valves that are adjusted during the prosthetic fitting. A microprocessor controlled prosthetic knee (MPK) uses integrated sensors and a microcomputer that collect and analyze data (e.g., movement, timing, position, velocity), and then adjusts, in real time, the flexion and extension resistance of the prosthetic joint during the swing- and/or stance-phase of the gait cycle.<sup>9</sup> Multiple MPK products are available with variable integration of microprocessor technology.<sup>10</sup> Microprocessor controlled knees can be activated only in swing phase, stance phase, or can provide both swing- and stance-phase control. The proposed benefits of MPKs compared with NMPKs include improved overall stability when standing and walking (e.g., navigation of ramps, stairs, and uneven terrain).<sup>9,11</sup> The addition of integrated technology to MPKs allows the knee to detect when the user trips or stumbles, then automatically increases resistance in the knee to provide support for recovery and potentially prevent a fall.

Microprocessor controlled prosthetic knees are currently covered by Medicare for beneficiaries classified as Medicare Functional Classification Level (MFCL) 3 or above, who have, at minimum, the ability or potential for ambulation with variable cadence. This summary of evidence will focus on the use of MPKs in limited community ambulators, classified as MFCL-2, who are described as having the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs, or uneven surfaces. Specifically, the analysis will concentrate on rate of falls, risk of falling, fear of falling, and gait performance with MPKs with integrated technology that allows the knee to detect when the user trips or stumbles and can automatically adjust to stabilize the knee unit compared to NMPKs in MFCL-2 Medicare beneficiaries with lower limb amputations requiring a prosthetic knee.

### **Measures of Fall Rate, Risk of Falling, Fear of Falling, and Rehabilitation Potential in Individuals with Lower Limb Loss**

In the community setting, more than 50% of individuals with lower limb amputation fall annually,<sup>12-14</sup> compared to the reported 26% fall rate in individuals without lower limb amputation over a 2-year period.<sup>15</sup> Nearly 50% of individuals with lower limb amputation report a fear of falling.<sup>14</sup> The consequences of falls in lower limb prosthetic users may include activity limitation, increased injuries, increased fear of falling, and reduced quality of life.<sup>16-18</sup> Factors that have been associated with fall rate and fall risk in individuals with lower limb amputations include the presence of other comorbidities (i.e., vascular disease), balance confidence,<sup>14</sup> balance ability,<sup>19</sup> time since amputation, and age.<sup>12</sup>

The challenges of determining fall rate and identifying individuals using a lower limb prosthetic who are at risk of falling have been described in the literature.<sup>20</sup> First, the definition of falls in lower limb prosthetic users is not uniform and lacks prosthetic-specific language (e.g., was the individual wearing their prosthetic at the time of the fall).<sup>5,21</sup> Second, the majority of fall research is retrospective in design and based on self-reported outcome measures (e.g., fall history) which may introduce recall and response bias into the studies.<sup>5,16</sup> And, finally, many performance-based tests of balance and mobility that have been used to screen for the risk of falling in patients with lower limb amputation are not specific to this population,<sup>20</sup> are not routinely administered in clinical practice,<sup>22,23</sup> and are rarely prospectively validated.<sup>18,24</sup>

In addition to patient-reported fall rates, other self-reported outcome measures that have been used in studies to

examine balance and mobility in individuals with lower limb amputations include, but are not limited to: (1) the Prosthesis Evaluation Questionnaire Addendum (PEQ-A) – a questionnaire to quantify balance confidence, stumbles and falls, and concentration;<sup>25</sup> (2) the Activities-specific Balance Confidence Scale (ABC) – a survey to assess how confident a patient is that they will not lose balance in 16 different tasks;<sup>20</sup> and, (3) the Prosthetic Limb Users Survey of Mobility (PLUS-M) – a survey which evaluates perceived ability to complete household and outdoor ambulation activities.<sup>20,26</sup>

Performance-based outcome measures that have been used in studies to examine the risk of falls in individuals with lower limb amputations include, but are not limited to: (1) the Timed-Up-and-Go (TUG) test – a timed assessment of functional mobility with transfers, walking and a turn; (2) the Berg Balance Scale (BBS) – an assessment of a subject's balance during performance of 14 tasks; (3) the L Test of Functional Mobility (L Test) – a modified TUG with longer walking distance and additional turn; and (4) the Four Square Step Test (FSST) – an assessment of an individual's coordination and stability while stepping over low objects forwards, backwards, and sideways.<sup>5,7,20</sup>

Outcome measures that have been used to assess the concern of falling in individuals with lower limb amputations include, but are not limited to: (1) the Modified Survey of Activities and Fear of Falling in the Elderly (mSAFE) – a questionnaire that evaluates the avoidance of activities of daily living due to the perceived fear of falling; (2) the Falls Efficacy Scale - International (FES-I) – a 16-item scale that measures an individual's level of concern of falling when performing physical and social activities; (3) the Consequences of Falling Scale (COF) – this 16-item scale quantifies perceived concerns regarding consequences that may occur after a fall; (4) the Perceived Control Over Falling Scale (PCOF) – a 4-item scale which assesses a subject's ability to control the environment and mobility; and, (5) the Perceived Ability to Manage Falls Scale (PAMF) – a 5-item scale which assesses the certainty that an individual would be able to manage a fall and find a way to get up.<sup>27,28</sup> Balance confidence tests such as the ABC scale and BBS have also been studied as surrogate measures of the fear of falling in individuals with lower limb amputations.<sup>28,29</sup>

Some inconsistencies in the ability of self-reported and performance-based tests to predict fall risk have been reported in the literature for individuals with lower limb amputations,<sup>5</sup> including, but not limited to: (1) variability in TUG cut-off scores (in seconds);<sup>17,24</sup> (2) variability in the ability of BSS to determine which individuals are at increased or decreased risk of falling;<sup>29,30</sup> and, (3) the paradoxical finding of a greater risk of falling despite higher ABC balance confidence scores in individuals with lower limb amputation compared to the general geriatric population,<sup>24</sup> suggesting that patient-perceived performance ability may overestimate actual performance ability.<sup>20</sup> In addition to the uncertainty in fall risk outcome measures, the reliability study that examined tests that assess the fear of falling in individuals with lower limb amputations was small and relied on convenience sampling, which may not be representative of the Medicare population.<sup>27</sup>

Challenges related to assigning functional levels to individuals with lower limb amputation have also been discussed in the literature, due to the lack of a standard objective measure of functional level and the lack of a standard predictive tool for rehabilitation potential.<sup>31-33</sup> Attempts have been made to develop and validate the Amputee Mobility Predictor (AMP) as an objective instrument to predict Medicare functional levels;<sup>34,35</sup> however, the predictive value of the instrument across the Medicare functional classification levels is variable.<sup>31</sup> Other predictive models of prosthetic mobility potential, based on retrospective data analysis, have been more recently proposed, but further application studies are needed.<sup>36,37</sup>

Review of the literature for this summary of evidence will include consideration of the ability of the outcome measures used in the studies to evaluate fall rate, risk of falling, and fear of falling with MPKs compared to NMPKs in Medicare-eligible prosthetic knee users characterized as MFCL-2 (limited community) ambulators. Specifically, potential recall and response bias for self-reported measures, and the reliability and validity of performance-based measures in individuals with lower limb amputations will be assessed.

## Food and Drug Administration (FDA) Status

Microprocessor-controlled knees may be classified as either Class I (general controls) devices under 21 CFR §890.3420 (external limb prosthetic component)<sup>38</sup> or as Class II (special controls) devices under 21 CFR §890.3500 (external assembled lower limb prosthesis).<sup>39</sup> Both classifications are exempt from 510(k) pre-market notification requirements.

## Literature Analysis

A retrospective study, by Davie-Smith, et al.,<sup>40</sup> examined patient-reported and functional outcome measures in a cohort of 31 (per protocol) low-activity participants (defined as either K2 or less active K3 ambulators; mean age: 60 years) with unilateral transfemoral amputation (TFA) when using an MPK compared to a NMPK. Outcome measures were the Health-Related Quality of Life (HR-QoL) survey and gait profile score (GPS) as primary outcomes, and the ABC, PLUS-M, Socket Comfort Score (SCS), self-reported falls, use of walking aids, AMP, L-test, and 2-minute walk test (2MWT) as secondary outcomes. The MPK assigned was determined by the participant's physician; assigned MPKs were the Kenevo (n = 13), C-Leg 3 (n = 2), C-leg 4 (n = 13), Orion (n = 1), Linx (n = 1), and Rheo (n = 2). After 6 months of MPK use, there were no significant improvements in HR-QoL (p = 0.014), GPS (p = 0.019), PLUS-M (p = 0.056), SCS (p = 0.071), median number of falls, or any 3DGA generated gait specific outcomes (only 15 participants completed the 3DGA). There were significant improvements in ABC score (p < 0.001), L-test time (p < 0.001), walking distance in the 2MWT (p < 0.001), AMP (p < 0.001), and mean number of falls (p < 0.001). Notably, the median number of falls per annum remained unchanged at zero (0) with MPKs compared to NMPKs, suggesting a non-normal distribution of falls in the study population. The change in AMP score resulted in 14 patients being reclassified to a higher MFCL. Limitations of this study include the retrospective design and small cohort size, the heterogeneity in type of MPK, suspension system, foot, and ankle, and the heterogeneity in the amount of physiotherapy or at-home exercises. Additionally, due to the lack of minimum clinically important difference data for most patient-reported and functional outcomes, the true clinical significance in the improvement is not known.

A multi-center, randomized crossover trial, by Lansade, et al.,<sup>41</sup> compared the efficacy of the Kenevo MPK to NMPKs in 35 participants (mean age: 64.5 years; 27 included in the per protocol analysis) with TFA or knee disarticulation, functioning at a moderate activity level [International Classification of Functioning (ICF) d4601 (moving around buildings other than the home) or d4602 (moving around outside the home and other buildings)]. The primary outcome measure was the TUG test; secondary outcome measures were the Locomotor Capability Index (LCI-5), use of walking aids, the Quebec User Evaluation of Satisfaction with Assistive Technology 2.0 (QUEST 2.0) questionnaire, the Medical Outcomes Study Short Form 36 v2 (SF-36v2) physical component and mental component sub-scores, and the number of falls in the last month of the trial. With MPKs, there were statistically significant improvements in balance as per median (Q1-Q3) TUG time (p = 0.001), mobility as per the global and basic LCI-5 score (p = 0.02), satisfaction as per the QUEST 2.0 (p = 0.001), and quality of life per the mental component of the SF-36v2 (p = 0.03). There were no significant differences in advanced LCI-5 score (p = 0.16), the physical component of the SF-36v2 (p = 0.08), use of walking aids (p = 0.97), or the incidence of falls (p = 0.61). No adverse events (AEs) were reported. The study limitations include small cohort size, short follow-up duration, and heterogeneity within the cohort regarding cause of amputations, the type of NMPK used as the comparator, and in the history of additional comorbidities (e.g., cardiovascular disease, neurological impairment).

Hahn, et al.<sup>42</sup> performed a retrospective, multi-center, cross-sectional cohort analysis of 1013 data sets to determine if a patient's age (average age: 55.6 years), mobility classification [based on the MOBIS mobility grading system; with MOBIS mobility grade (MG) 2 being similar to MFCL-2], or amputation etiology had an impact on their capability to utilize the functional benefits of an MPK (C-Leg or C-Leg Compact) based on a 1-day trial fitting. Functional outcomes included variance in gait cadence, gait pattern harmonization, relief of the sound limb, reduction of overall effort, divided attention, and safety. Self-reported fear of falling decreased in 82-87% of participants (ranging across age and MG groups), which corresponded to 83% of participants reporting a 'clear' or 'very clear'

increase in perceived safety. Prosthetists reported that 95% of participants had relief of the sound limb, 95% had harmonization of gait pattern, and 93% had the ability to vary gait speed; while 88% of participants reported a reduction in walking effort and 94% reported greater capacity to divide attention. At the end of the trial, 50% [95% Confidence Interval (95% CI): 45-54%] of MG2 participants were re-rated as MG3 after the trial and 22% (95% CI: 18-26%) of MG3 participants were re-rated as MG4. Finally, a correlation analysis was performed, and there was no correlation between age, MG, and vascular disease with an individual's ability to derive functional benefit from an MPK. The study limitations include that all data was collected from trial fittings in a commercial environment, using no common, validated assessment standard as part of the data collection; thus, this data may not translate to at home use of the prosthesis. Finally, self-report measures, such as fear of falling, may be subject to response bias.

A nonrandomized cross-over study, by Hafner, et al.,<sup>43</sup> compared the effects of use of an MPK vs. a NMPK on function and safety in 17 patients, with TFA, classified as MFCL-2 (n = 8) or MFCL-3 (n = 9) (average age MFCL-2: 57.1 years, MFCL-3: 41.9 years; p = 0.05). Functional performance was measured with walking speed and step length on a sloped (19 degree) sidewalk, the Hill Assessment Index (HAI), the Stair Assessment Index (SAI), walking speed during an obstacle course, and accuracy and speed of response to verbal tests administered while participants walked on a busy city block. The PEQ-A was used to assess safety, stability, satisfaction, and quality of life. In the functional outcomes, for both the MFCL-2 and MFCL-3 cohorts, there were statistically significant improvements in the SAI (MFCL-2: p = 0.008, MFCL-3: p = 0.004), hill walking speed (MFCL-2: p = 0.002, MFCL-3: p = 0.017), and obstacle course walking speed (MFCL-2: p = 0.02, MFCL-3: p = 0.007) when using MPKs compared to NMPKs. The MFCL-2 cohort also saw significant improvements in the attention speed test (p = 0.02) and HAI score (p = 0.008) with MPKs. Attention accuracy was not significantly different between the MPK and NMPK in either mobility cohort. On the PEQ-A, the MFCL-3 cohort had a significant improvement in satisfaction (p = 0.002), ambulation (p = 0.01), and utility subscores (p = 0.01); both cohorts reported significant improvement in multitasking while walking when using the MPK (MFCL-2: p = 0.04, MFCL-3: p = 0.03). The MFCL-2 cohort saw significant improvement in the number of self-reported uncontrolled falls (p = 0.01); however, there were no statistically significant improvements in the number of self-reported stumbles, number of semi-controlled falls, or in self-assessed fear outcomes. Finally, four (4) MFCL-2 participants were reclassified as MFCL-3, three (3) MFCL-3 participants were reclassified as MFCL-4, and two (2) MFCL-3 participants were reclassified as MFCL-2. Only change in AMP score was significantly correlated with change in functional level ( $r_s = 0.62$ , p = 0.008). This study was limited by the small sample size, lack of randomization and blinding, and use of self-reported fall and stumble rates, which may be subject to recall bias.

An observational study, performed by Kahle, et al.,<sup>44</sup> compared functional performance of 19 individuals (average age: 51 years; MFCL-2: n = 9, MFCL-3: n = 8, MFCL-4: n = 2), with TFA or knee disarticulation, using an MPK (C-Leg) compared to a NMPK, to determine which population of patients living with lower limb amputation would benefit from use of an MPK. Functional outcomes included self-selected and fastest-possible walking speed on uneven and even terrain, as well as the stair descent test. Self-reported outcomes included the Prosthesis Evaluation Questionnaire (PEQ), knee preference, and number of stumbles and falls. For function outcomes, with the MPK, there were significant reductions in time to complete the following walking tests: 75 m with self-selected walking speed (p = 0.03), 6m (p = 0.001) and 75m (p = 0.005) with fastest-possible walking speed, and 38m with fastest-possible walking speed on uneven terrain (p < 0.001). In self-reported outcomes, there were significant improvements with the MPK in PEQ score (p = 0.007), mean number of stumbles (p = 0.006), and mean number of falls (p = 0.03). Descriptive statistics reported that 63% (12/19) of participants improved their performance composite scores during stair descent with the MPK and that 74% (14/19) of participants would prefer to continue using the MPK. Limitations to this study included the small sample size, heterogeneity in baseline NMPKs used, the mixed cohort of Medicare Functional Classification Levels, potential for recall bias related to self-report of falls and stumbles, and potential for intervention bias as the pre- and post-testing was administered by a single, unblinded rater.

A prospective, non-randomized, crossover clinical trial, by Kaufman, et al.,<sup>25</sup> assessed if 23 (per protocol) individuals with unilateral TFA and low mobility, would benefit from using an MPK compared to a NMPK. Functional outcomes were assessed via an activity monitor, while self-reported outcomes of satisfaction and safety were assessed with the PEQ and PEQ-A, respectively. With the MPK, participants had a significant reduction in time spent sitting (p = 0.01)

and a significant increase in median activity counts ( $p = 0.02$ ). There was no significant change in gait complexity with the MPK ( $p = 0.35$ ). For safety and satisfaction, with the MPK, there was a statistically significant reduction in median number of falls per person per month compared to baseline ( $p = 0.01$ ) and a significant improvement in satisfaction on the PEQ ( $p < 0.01$ ). Upon return to the NMPK, the median number of falls increased to 3 falls per person per month, and patients reported a greater fear of falling. Limitations of this study included the small sample size, potential recall and response bias due to use of patient reported falls as a measure of safety, and potential bias due to missing data secondary to a substantial number of patients (27/50) who were lost to follow-up or refused continued participation.

A prospective, observational study, by Mileusnic, et al.,<sup>45</sup> examined clinical experiences with the Kenevo MPK in 29 individuals (average age: 63.2 years) with TFA or knee disarticulation and a mobility grade of MFCL-1, MFCL-2, or low MFCL-3. Safety, mobility, and preference were assessed using study-designed self-assessment questionnaires (self-reported measures of satisfaction, fear of falling, stumbles, and falls), the LCI-5, PLUS-M, and Houghton scale (self-assessed measure of prosthetic use). Participants completed baseline testing using their NMPK prior to fitting with the Kenevo and returned after 2 months of MPK use for repeat testing. Data was only included for analysis when data for both visits was available and complete, which ranged between 55-69% of participants, depending on the questionnaire. There were positive trends in fear of falling, rate of falling, and scores on the Houghton scale, PLUS-M, and LCI-5 after participants switched from their NMPK to the Kenevo MPK; however, none reached statistical significance (rate of falling:  $p = 0.161$ ,  $n = 12$ ; fear of falling:  $p = 0.075$ ,  $n = 12$ ; Houghton scale:  $p = 0.068$ ,  $n = 11$ ; PLUS-M:  $p = 0.124$ ,  $n = 11$ ; LCI-5:  $p = 0.097$ ,  $n = 11$ ). The rate of stumbles did significantly decrease ( $p = 0.044$ ) with the Kenevo MPK (50% of patients ( $n$  value not specified) reported never falling with the Kenevo compared to 8% with their NMPK). The number of subjects who reported never falling increased from 45% with their old prosthesis to 72% with the Kenevo ( $p = 0.161$ ,  $n = 12$ ). Self-reported fear of falling improved in 50% and worsened in 8% of participants with the Kenevo ( $n = 12$ ). Limitations of this study included the observational design, small sample size, completeness of data, mixed MFCL study population, and use of self-report of fall data, which may have been affected by recall and response bias.

Hahn, et al.<sup>31</sup> performed a systematic review and meta-analysis (SRMA) which focused on the effects of use of MPKs on safety, function, and patient-reported outcomes in individuals with lower limb amputations classified as limited community ambulators (MFCL-2). Papers were included in this analysis if they were randomized or non-randomized trials comparing MPK to NMPK use, included limited community ambulators as a primary group/separate statistics, and reported their results with validated measures of safety, function, mobility, or patient-self-reported. There were 15 publications that met inclusion criteria with 2,366 total participants (range of mean ages: 54.1 to 69 years), including 704 participants classified as MFCL-2. When looking at walking performance with an MPK, there was significant improvement in walking speed (5 studies), slope ambulation (3 studies), stair/uneven terrain mobility (2 studies), and activities of daily living (ADL) and multitasking ability (1 study each). After switching from a NMPK to an MPK, 5 studies reported that approximately 50% of subjects increased from MFCL-2 to MFCL-3. Seven (7) studies reported improvements in patient-reported mobility and one (1) study reported improvement in quality of life. For the meta-analysis, both the fixed effect models and the random effects models showed that the standardized mean differences (SMD) favored MPK over NMPK in fall reduction ( $p < 0.01$ ), fear of falling ( $p < 0.01$ ), TUG completion time ( $p = 0.04$ ), walking speed ( $p < 0.01$ ), patient-reported ambulation PEQ ( $p < 0.01$ ), and utility PEQ ( $p < 0.01$ ). None of the included studies reported an outcome measure where NMPK use had a significant benefit over MPK use. Limitations of this SRMA include the high dropout rates in some of the included studies and heterogeneity in clinical outcomes evaluated across the studies, which lead to small sample sizes for each of the outcomes. Additionally, generalizability to the Medicare-aged population may be limited, as only 5/15 studies had an average participant age that was inclusive of this population.

Jayaraman, et al.<sup>46</sup> performed a 13-month, longitudinal, randomized, crossover clinical trial to determine if MPKs compared to NMPKs improved safety and performance (e.g., walking speed and balance) in 10 participants (average age: 63 years) with unilateral TFA, secondary to vascular disease or diabetes, who are classified as limited community ambulators (MFCL-2). Performance-based outcome measures included the 10-meter walk test (10MWT),

6-minute walk test (6MWT), BBS, FSST, TUG, and AMP with prosthesis (AMPPro). Patient-reported safety outcome measures were the Modified Falls Efficacy Scale (MFES) and the PEQ-A. In an *a priori* defined *post-hoc* analysis, based on two-way repeated measures ANOVA methodology, there was significant improvement in the 10MWT when using the MPK compared to baseline in both speed ( $p = 0.008$ ) and time ( $p = 0.046$ ), but no significant difference in either speed or time when comparing the NMPK to baseline ( $p > 0.05$ ). There were also significant improvements in AMPPro scores in *post-hoc* testing when using both the MPK ( $p = 0.018$ ) and NMPK ( $p = 0.03$ ); however, the change did not bring participants into the K3 AMPPro score range for either intervention. Participants self-reported significant improvements in the PEQ-A when using the MPK compared to baseline ( $p = 0.008$ ), but not when using the NMPK compared to baseline. Finally, there was significant improvement in the MFES when comparing MPK to baseline ( $p = 0.003$ ), but not when comparing NMPK to baseline ( $p > 0.05$ ). No statistically significant changes were observed in the 6MWT, BBS, FSST, or TUG with a two-way repeated measures ANOVA. However, when MPK data from the present study was compared to previously published averages for K3 ambulators, 66% of participants improved their gait speed to above a standard K3 ambulator, and 50% of participants improved their BBS scores into a range indicative of a standard K3 ambulator. The limitations to this study include the small sample size (data indicate only 9/10 data sets were analyzed) and the change in prosthetic foot (which may have confounded some of the observed benefits).

Campbell, et al.<sup>47</sup> conducted a retrospective analysis, on 602 data sets, which compared functional mobility, quality of life, satisfaction with amputee status, and rate of injurious falls (resulting in a clinic/hospital visit) across four MPKs: C-Leg, Orion, Plié, and Rheo (178 participants each used C-Leg, Orion, and Plié; 68 used Rheo; average age: 56.95 to 61.23). All participants were MFCL-3 or MFCL-4. Outcomes included the PLUS-M to assess mobility and the PEQ to assess quality of life and satisfaction. Additionally, 419 participants were included in a fall analysis; 10% reported an injurious fall in the previous 6 months that resulted in a clinic or hospital visit, but there was no significant difference in fall rate between the 4 MPKs ( $p = 0.171$ ). When compared to NMPK historical benchmark data, C-leg ( $p < 0.001$ ) and Orion ( $p = 0.037$ ) users had significantly fewer injurious falls. When participants were grouped by age, there were statistically significant declines in mobility associated with age based on PLUS-M in C-Leg and Plié users; however, there was no statistically significant age-based PLUS-M differences in Rheo or Orion users. Finally, per PEQ survey responses, there was no statistical difference in satisfaction or quality of life across all MPKs. Limitations of this study included its retrospective observational design, use of only patient-reported outcome measures, unequal sample size of Rheo participants (potential selection bias), no standardization of duration of experience with MPK, exclusion of MFCL-1 and -2 participants (indirectness of study population), and inclusion of only falls that resulted in a clinic/hospital visit, which may under-represent the total number of falls.

A randomized crossover trial, by Theeven, et al.,<sup>48</sup> assessed the effect of switching to an MPK on functional performance of ADLs in 28 (per protocol) individuals (average age: 59.1 years) with unilateral TFA or knee disarticulation classified as MFCL-2. Due to the heterogeneity (i.e., variability in type and severity of comorbidities) of the MFCL-2 population, this study also aimed to determine if these within-group differences might hinder the detection of the effects of using an MPK and to determine if only a subpopulation (high, intermediate, and low activity levels) of individuals classified as MFCL-2 would derive benefit from its use. Functional performance was measured using the investigator-developed Assessment of Daily Activity Performance in Transfemoral Amputees (ADAPT) test in which performance time and perceived level of difficulty were recorded for 17 simulated daily activities. The 17 tasks were divided into 3 activity subsets (AS): AS<sub>1</sub> (standing activities that required balance), AS<sub>2</sub> (activities that required sitting down and standing up), and AS<sub>3</sub> (ambulation activities that rely upon prosthetic-related skills). At baseline, participants in the high and intermediate activity group performed AS<sub>1</sub> ( $p = 0.001$  and  $p = 0.007$ , respectively) and AS<sub>2</sub> ( $p = 0.003$  and  $p = 0.015$ , respectively) tasks significantly faster than the low activity group. There was no statistical difference between any activity groups in the AS<sub>3</sub> tasks, and a significant difference between the high and intermediate activity groups was only observed in the AS<sub>2</sub> tasks ( $p = 0.013$ ). When comparing all participants performance with the C-Leg (MPK<sub>A</sub>) and the C-Leg Compact (MPK<sub>B</sub>) vs. NMPK, there was a significant decrease in time needed to complete AS<sub>1</sub> tasks (MPK<sub>A</sub>:  $p = 0.0001$  and MPK<sub>B</sub>:  $p = 0.002$ ); and, the difficulty of tasks in the AS<sub>2</sub> and AS<sub>3</sub> categories was perceived as significantly less difficult with MPK<sub>A</sub> (AS<sub>2</sub>:  $p = 0.023$  and AS<sub>3</sub>:  $p = 0.008$ ) but not with MPK<sub>B</sub>. For the high and intermediate activity groups, there was a significant

decrease in time needed to complete AS<sub>1</sub> tasks with both MPK<sub>A</sub> ( $p = 0.010$  and  $p = 0.004$ , respectively) and MPK<sub>B</sub> ( $p = 0.019$  and  $p = 0.008$ , respectively). For only the intermediate activity group, AS<sub>2</sub> task time was significantly lower with MPK<sub>A</sub> ( $p = 0.016$ ). There was no statistically significant time difference in AS<sub>3</sub> tasks for any group. Participants in the low activity group saw no significant time difference in any tasks with any prosthetic knee. At the end of the study, 21 (high = 10, intermediate = 7, low = 4) participants indicated preference for MPK<sub>A</sub>, 7 (high = 2, intermediate = 3, low = 2) for MPK<sub>B</sub>, and 1 (intermediate) for the NMPK. Limitations of this study included a small sample size, use of an unvalidated measure of functional performance, and short duration of follow-up.

## Evidence Based Guidelines

### Amputation and prosthetics of the lower extremity: The Dutch evidence-based multidisciplinary guideline- 2020<sup>49</sup>

Summary of guidelines (in relevant part):

*The conclusions for the a priori-defined outcome were as follows:*

- *Compared with conventional prosthetic knees, autoadaptive knees may result in lower energy consumption during ambulation at a normal speed (**GRADE: low**) and improved mobility (**GRADE: low**).*
- *It is unclear whether autoadaptive knees are associated with differences in risks of falling, balance, level of physical function, user satisfaction, and gait parameters (**GRADE: very low**).*
- *It is unclear whether actuated knees or feet are associated with differences in energy consumption, risks of falling, balance, level of physical function, user satisfaction, and gait parameters compared with conventional knee and foot units (**GRADE: very low**).*

*Recommendation:*

- *Consider the use of autoadaptive knees for either persons with increased risks of falling and impaired ambulatory skills or persons using their prostheses intensively, for whom further improvement in physical function or energy consumption is expected.*

### VA/DoD Clinical Practice Guideline for Rehabilitation of Individuals with Lower Limb Amputations– 2019 50

Summary of guidelines (in relevant part):

*Recommendations:*

#### **Pre-Prosthetic Phase:**

*15. We suggest offering microprocessor knee units over non-microprocessor knee units for ambulation to reduce risk of falls and maximize patient satisfaction. There is insufficient evidence to recommend for or against any particular socket design, prosthetic foot categories, and suspensions and interfaces. [**Strength: Weak for**]*

# Developing Prescribing Guidelines for Microprocessor-Controlled Prosthetic Knees in South East England - 2014<sup>51</sup>

Summary of guidelines (in relevant part):

## Suitability

*The patient needs to meet all the following criteria in order to qualify for consideration for an MPK.*

### 1. Activity level

*Unilateral amputee K3 or K4 – patient is an active walker with a free knee – or K2 with demonstrable potential to improve to K3 which is later confirmed through a trial with an MPK. Bilateral amputee who is able to walk with a free knee.*

### 2. Mobility level

*SIGAM D or above.*

### 3. Amputation level

*Unilateral transfemoral;*

*Hip disarticulation;*

*Knee disarticulation;*

*Bilateral lower limb amputee (a major amputation on the contralateral side at or higher than mid-foot level).*

### 4. The patient must demonstrate

*Commitment to prosthetic rehabilitation;*

*Adequate strength and balance to activate the knee unit;*

*Cognitive reasoning ability to master control, operation and care of the device;*

*Sufficient cardiovascular abilities to meet the fitness demands of ambulating outdoors with a free knee (only in a unilateral amputees).*

## Indications

5. *Limited community ambulatory. Improved stability in stance demonstrates increased independence, less risk of falls and potential to advance to a less restrictive walking device. This is providing that the patient has sufficient cardiovascular reserve, strength and balance to use the prosthesis and demonstrable potential to return to an active lifestyle and improve their level of activity. Trial is required to prove a significant improvement reflected in reduced care needs or the ability to perform new functions or daily tasks not possible with a non-MPK.*

## **Professional Society Recommendations**

N/A

## **Expert Consensus Documents**

### **Centers for Medicare & Medicare Services Health Technology Assessment: Lower Limb Prosthetic Workgroup Consensus Document<sup>52</sup>**

*Microprocessor Knees (in relevant part):*

*The Workgroup was divided on the quality and strength of the literature pertaining to microprocessor knees (MPKs) for beneficiaries who ambulate at the K2 level. Some argued that the individual articles noted in the literature which discuss this topic, do adequately demonstrate that those who utilize their prosthesis at the K2 level might improve their functional abilities (e.g., walking speed on level and unlevel ground; ramp descent speed, falls, etc.) with MPK technology. Others argued that the studies comprising this literature were significantly flawed (e.g., small sample sizes, attrition, confounders such as training differences, sole use of laboratory studies, significant conflict of interests, etc.). Those arguing the limitations of these studies are aware that these findings may not agree with the conclusions of other federal agencies.*

*Therefore, the Workgroup acknowledges an amputee functioning at the K2 level may benefit from MPK technology. However, as a population, these individuals cannot be categorically defined for policy purposes. Consequently, the Workgroup recommends that if consideration is to be given to the provision of a microprocessor knee for an individual who currently utilizes his/her prosthesis at the K2 level, the rationale for that component must be justified in a pre-authorization request. To make that request stronger, a trial of usage should be considered by the prosthetist (prior to payment for the component) with pertinent results of that trial (i.e., pre/post data) as they relate to functional health outcomes including, but not limited to, falls/injuries and the accomplishment of activities of daily living / instrumental activities of daily living (ADLs/IADLs), being highlighted in the pre-authorization information. It will be the decision of the pre-authorization team to approve (or not) the request.*

## **Impact Analysis**

Kuhlmann et al., 2020<sup>53</sup> developed a decision-analytic model that focused on the amputee population, fall events, and prosthesis failure (i.e., the number of prosthesis revisions). Data for the models were collected from publicly accessible databases, published peer-reviewed literature, and data from prosthetic manufacturer Ottobock. The fall events model calculates the number of annual fall-related events among individuals with lower limb amputations requiring a prosthetic knee and with or without Diabetes Mellitus (DM); the model includes annual falls and falls requiring medical care, which are further classified into fatal and non-fatal medical falls. All fall and fall-related medical events are per 1000 person years. The predicted incidence rate of falls was lower in individuals without DM using the C-Leg compared to those using an NMPK (178 vs. 1102 falls, respectively); as well as in individuals with DM using the C-Leg compared to those using an NMPK (203 vs. 1201 falls, respectively). Fall-related fatalities and

hospitalizations also decreased in individuals without DM using the C-Leg compared to NMPK (3 vs. 17 fatal falls and 20 vs. 134 hospitalizations, respectively) and in individuals with DM using the C-Leg compared to NMPK (3 vs. 18 fatal falls and 23 vs. 146 hospitalizations, respectively). This study was limited by the lack of long-term data on the risk of falling, and small sample sizes. Additionally, there was indirectness to the main literature analysis, as the results were based on data from a cohort of individuals with mixed MFCLs, stratified based on diabetes status rather than functional level, and the fatal fall probability data came from a general elderly population without amputations.

An analysis by Chen et al., 2018<sup>54</sup> included a literature review evaluating the impact of MPK vs. NMPK use in individuals functioning at a level of K3 and K4, as well as a cohort-level Markov model for fall rate. Falls were divided into medical (i.e., requiring medical attention) or non-medical, and medical falls were subdivided into minor, major (i.e., requiring admission to a medical facility), or fatal. Data included was from peer-reviewed articles and non-peer reviewed literature, such as technical reports and an expert panel. Data on K2 individuals was only included in the sensitivity analysis. Based on the model, when MPK use is compared to NMPK use, the risk of major injurious falls is reduced by 79% (104 to 22 falls per 1000 person years) and the incidence of minor falls reduced from 78 to 16 falls per 1000 person years. Fall-related deaths per 1000 person years decreased from 14 with NMPK use to 3 with MPK use. Limitations from this study include use of fall data from individuals from the general elderly population without amputations (e.g., medical falls out of all falls), small sample sizes, and limited follow-up time. Additionally, the fall rate model is limited by indirectness, as it did not include data from K2 individuals, only K3 and K4 individuals.

### **Analysis of Evidence (Rationale for Determination)**

The aim of this summary of evidence was to determine if the use of MPKs with stumble recovery, or similar technology, compared to NMPKs improved the rate of falls, risk of falling, fear of falling, and gait performance in MFCL-2 Medicare beneficiaries with lower limb amputations requiring a prosthetic knee. Studies that were reviewed were analyzed for risk of bias (ROB). For RCTs, ROB was assessed using the Cochrane Collaboration’s tool for assessing risk of bias.<sup>55,56</sup> To evaluate the ROB in non-randomized studies, the ROB in Non-Randomized Studies of Interventions (ROBINS-I) tool was used.<sup>57</sup> The Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach was used as a method of grading the certainty of evidence, which can range from high to very low, and is defined as follows:<sup>58</sup>

<b>Certainty of Evidence</b>	<b>Definition</b>
High	Further research is very unlikely to change our confidence in the estimate of effect
Moderate	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
Low	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
Very Low	Any estimate of effect is very uncertain

### **Certainty of Evidence**

Fall Rate: Low to Very Low

- Number of Falls based on RCTs: Low
- Number of Falls based on observational studies: Very Low
- Fall Rate on a 5-point scale based on an observational study: Very Low
- Number of Uncontrolled Falls based on an observational study: Very Low

Risk of Falling: Low to Very Low

- Timed up and go (TUG) based on RCTs: Low
- BERG balance scale (BBS) based on an RCT: Low
- Four Square Strep Test (FSST) based on an RCT: Low
- Prosthesis Evaluation Questionnaire (PEQ-A) based on an RCT: Low
- Modified PEQ-A based on an observational study: Very Low
- Activities Specific Balance Confidence (ABC) based on an observational study: Very Low
- Prosthetic Limb User Survey of Mobility 12-item Short Form (PLUS-M) based on observational studies: Very Low
- Test of Functional Mobility (L-test) based on an observational study: Very Low

Fear of Falling: Low to Very Low

- Modified Fall Efficacy Scale (MFES) based on an RCT: Low
- Self-reported fear of falling based on observational studies: Very Low
- Customized PEQ-A Addendum based on observational studies: Very Low

Gait Performance: Low to Very Low

- 10-meter walk test (10MWT); 6-minute walk test (6MWT) follow-up: 13 months based on an RCT: Low
- 3D gait analysis generated gait profile score follow-up: 6 months based on an observational study: Very Low
- Gait Complexity Calculation based on an observational study: Very Low
- Gait Harmonizing Scale, Gait Cadence Variance Scale based on an observational study: Very Low
- Stair descent, Uneven Terrain Walking Speed based on observational studies: Very Low
- Function on an incline based on an observational study: Very Low

MPK Comparison in Fall Rate: Low to Very Low

- Assessment of Daily Activity Performance in Transfemoral Amputees (ADAPT) based on an RCT: Low
- Self-reported rate of injurious falls based on an observational study: Very Low

## Conclusion

Microprocessor-controlled prosthetic knees use integrated sensors and computers to collect and analyze data to adjust flexion and extension resistance of the prosthetic joint during the swing- and/or stance-phase of the gait cycle in real time. Purported benefits of MPKs compared to NMPKs include improved stability when the user is standing and walking, as well as fall prevention with the addition of technology which can automatically increase resistance in the knee unit to provide support when a stumble is detected.

The use of an MPK compared to a NMPK may reduce the rate of falling, risk of falling and fear of falling, as well as improve gait performance in individuals with lower limb amputations requiring a prosthetic knee who are classified as limited community ambulators (i.e., MFCL-2), based on low to very low certainty evidence. While multiple studies

examining these outcomes were limited by their nonrandomized design, small sample sizes, missing data, uncertainty related to the directness of the study cohorts, and/or reliance on outcome measures that are subject to recall or response bias, the conclusions of the studies were consistent, with no studies finding outcomes favoring NMPKs compared to MPKs. Additionally, computer simulated impact modeling suggest a large effect size related to both the incidence of falls and risk of falling in MPK users compared to NMPK users. Also notable, no studies were identified to support that the benefits of MPKs are limited to individuals classified as MFCL-3 and above; however, the currently available literature is insufficient to support extending coverage of MPKs to MFCL-1 beneficiaries. Of the original research analyzed for the Summary of Evidence, only one study included any MFCL-1 participants.

Microprocessor-controlled prosthetic knees may be a viable therapeutic option for some limited community ambulating Medicare beneficiaries with lower limb amputations. Therefore, the criteria in the Lower Limb Prostheses Local Coverage Determination will be expanded to allow coverage of fluid, pneumatic, or electronic/microprocessor control additions for prosthetic knees in MFCL-2 beneficiaries when supporting documentation in the medical record outlines the rationale for selection of the higher-level knee. This documentation must include how the selected knee will improve the beneficiary's functional health outcomes, will help the beneficiary accomplish their activities of daily living, and that lower-level knee options have been considered and ruled out based on the beneficiary's individual functional and medical needs.

In addition, for coverage of electronic/microprocessor-controlled knees for MFCL-2 beneficiaries, the MPK provided must be indicated for functional level 2 individuals and include integrated technology that allows the knee to detect when the user stumbles, automatically increases resistance in the knee to provide support for recovery, and potentially prevents a fall. Furthermore, the LCD stipulates that the beneficiary is able to make use of a product that requires daily charging and can understand and respond to alerts/alarms which may indicate knee dysfunction.

Criteria of higher-level foot systems will also be expanded to include MFCL-2 beneficiaries who meet the new coverage criteria for a fluid, pneumatic, or electronic/microprocessor control addition for a prosthetic knee, and who will require a compatible foot.

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## Coding Information

### CPT/HCPCS Codes

#### Group 1 Paragraph:

The appearance of a code in this section does not necessarily indicate coverage.

#### HCPCS MODIFIERS:

EY – No physician or other licensed health care provider order for this item or service

GA – Waiver of liability statement issued as required by payer policy, individual case

GY – Item or service statutorily excluded or does not meet the definition of any Medicare benefit

GZ – Item or service expected to be denied as not reasonable and necessary

K0 - Lower limb extremity prosthesis functional 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

K1 - Lower extremity prosthesis functional 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.

K2 - Lower extremity prosthesis functional 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.

K3 - Lower extremity prosthesis functional 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.

K4 - Lower extremity prosthesis functional 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.

KX – Requirements specified in the medical policy have been met

LT - Left side

RT - Right side

HCPCS CODES:

**Group 1 Codes:** (203 Codes)

CODE	DESCRIPTION
L5000	PARTIAL FOOT, SHOE INSERT WITH LONGITUDINAL ARCH, TOE FILLER
L5010	PARTIAL FOOT, MOLDED SOCKET, ANKLE HEIGHT, WITH TOE FILLER
L5020	PARTIAL FOOT, MOLDED SOCKET, TIBIAL TUBERCLE HEIGHT, WITH TOE FILLER
L5050	ANKLE, SYMES, MOLDED SOCKET, SACH FOOT
L5060	ANKLE, SYMES, METAL FRAME, MOLDED LEATHER SOCKET, ARTICULATED ANKLE/FOOT
L5100	BELOW KNEE, MOLDED SOCKET, SHIN, SACH FOOT
L5105	BELOW KNEE, PLASTIC SOCKET, JOINTS AND THIGH LACER, SACH FOOT
L5150	KNEE DISARTICULATION (OR THROUGH KNEE), MOLDED SOCKET, EXTERNAL KNEE JOINTS, SHIN, SACH FOOT
L5160	KNEE DISARTICULATION (OR THROUGH KNEE), MOLDED SOCKET, BENT KNEE CONFIGURATION, EXTERNAL KNEE JOINTS, SHIN, SACH FOOT

CODE	DESCRIPTION
L5200	ABOVE KNEE, MOLDED SOCKET, SINGLE AXIS CONSTANT FRICTION KNEE, SHIN, SACH FOOT
L5210	ABOVE KNEE, SHORT PROSTHESIS, NO KNEE JOINT ('STUBBIES'), WITH FOOT BLOCKS, NO ANKLE JOINTS, EACH
L5220	ABOVE KNEE, SHORT PROSTHESIS, NO KNEE JOINT ('STUBBIES'), WITH ARTICULATED ANKLE/FOOT, DYNAMICALLY ALIGNED, EACH
L5230	ABOVE KNEE, FOR PROXIMAL FEMORAL FOCAL DEFICIENCY, CONSTANT FRICTION KNEE, SHIN, SACH FOOT
L5250	HIP DISARTICULATION, CANADIAN TYPE; MOLDED SOCKET, HIP JOINT, SINGLE AXIS CONSTANT FRICTION KNEE, SHIN, SACH FOOT
L5270	HIP DISARTICULATION, TILT TABLE TYPE; MOLDED SOCKET, LOCKING HIP JOINT, SINGLE AXIS CONSTANT FRICTION KNEE, SHIN, SACH FOOT
L5280	HEMIPELVECTOMY, CANADIAN TYPE; MOLDED SOCKET, HIP JOINT, SINGLE AXIS CONSTANT FRICTION KNEE, SHIN, SACH FOOT
L5301	BELOW KNEE, MOLDED SOCKET, SHIN, SACH FOOT, ENDOSKELETAL SYSTEM
L5312	KNEE DISARTICULATION (OR THROUGH KNEE), MOLDED SOCKET, SINGLE AXIS KNEE, PYLON, SACH FOOT, ENDOSKELETAL SYSTEM
L5321	ABOVE KNEE, MOLDED SOCKET, OPEN END, SACH FOOT, ENDOSKELETAL SYSTEM, SINGLE AXIS KNEE
L5331	HIP DISARTICULATION, CANADIAN TYPE, MOLDED SOCKET, ENDOSKELETAL SYSTEM, HIP JOINT, SINGLE AXIS KNEE, SACH FOOT
L5341	HEMIPELVECTOMY, CANADIAN TYPE, MOLDED SOCKET, ENDOSKELETAL SYSTEM, HIP JOINT, SINGLE AXIS KNEE, SACH FOOT
L5400	IMMEDIATE POST SURGICAL OR EARLY FITTING, APPLICATION OF INITIAL RIGID DRESSING, INCLUDING FITTING, ALIGNMENT, SUSPENSION, AND ONE CAST CHANGE, BELOW KNEE
L5410	IMMEDIATE POST SURGICAL OR EARLY FITTING, APPLICATION OF INITIAL RIGID DRESSING, INCLUDING FITTING, ALIGNMENT AND SUSPENSION, BELOW KNEE, EACH ADDITIONAL CAST CHANGE AND REALIGNMENT
L5420	IMMEDIATE POST SURGICAL OR EARLY FITTING, APPLICATION OF INITIAL RIGID DRESSING, INCLUDING FITTING, ALIGNMENT AND SUSPENSION AND ONE CAST CHANGE 'AK' OR KNEE DISARTICULATION
L5430	IMMEDIATE POST SURGICAL OR EARLY FITTING, APPLICATION OF INITIAL RIGID DRESSING, INCL. FITTING, ALIGNMENT AND SUPENSION, 'AK' OR KNEE DISARTICULATION, EACH ADDITIONAL CAST CHANGE AND REALIGNMENT
L5450	IMMEDIATE POST SURGICAL OR EARLY FITTING, APPLICATION OF NON-WEIGHT BEARING RIGID DRESSING, BELOW KNEE
L5460	IMMEDIATE POST SURGICAL OR EARLY FITTING, APPLICATION OF NON-WEIGHT

CODE	DESCRIPTION
	BEARING RIGID DRESSING, ABOVE KNEE
L5500	INITIAL, BELOW KNEE 'PTB' TYPE SOCKET, NON-ALIGNABLE SYSTEM, PYLON, NO COVER, SACH FOOT, PLASTER SOCKET, DIRECT FORMED
L5505	INITIAL, ABOVE KNEE - KNEE DISARTICULATION, ISCHIAL LEVEL SOCKET, NON-ALIGNABLE SYSTEM, PYLON, NO COVER, SACH FOOT, PLASTER SOCKET, DIRECT FORMED
L5510	PREPARATORY, BELOW KNEE 'PTB' TYPE SOCKET, NON-ALIGNABLE SYSTEM, PYLON, NO COVER, SACH FOOT, PLASTER SOCKET, MOLDED TO MODEL
L5520	PREPARATORY, BELOW KNEE 'PTB' TYPE SOCKET, NON-ALIGNABLE SYSTEM, PYLON, NO COVER, SACH FOOT, THERMOPLASTIC OR EQUAL, DIRECT FORMED
L5530	PREPARATORY, BELOW KNEE 'PTB' TYPE SOCKET, NON-ALIGNABLE SYSTEM, PYLON, NO COVER, SACH FOOT, THERMOPLASTIC OR EQUAL, MOLDED TO MODEL
L5535	PREPARATORY, BELOW KNEE 'PTB' TYPE SOCKET, NON-ALIGNABLE SYSTEM, NO COVER, SACH FOOT, PREFABRICATED, ADJUSTABLE OPEN END SOCKET
L5540	PREPARATORY, BELOW KNEE 'PTB' TYPE SOCKET, NON-ALIGNABLE SYSTEM, PYLON, NO COVER, SACH FOOT, LAMINATED SOCKET, MOLDED TO MODEL
L5560	PREPARATORY, ABOVE KNEE- KNEE DISARTICULATION, ISCHIAL LEVEL SOCKET, NON-ALIGNABLE SYSTEM, PYLON, NO COVER, SACH FOOT, PLASTER SOCKET, MOLDED TO MODEL
L5570	PREPARATORY, ABOVE KNEE - KNEE DISARTICULATION, ISCHIAL LEVEL SOCKET, NON-ALIGNABLE SYSTEM, PYLON, NO COVER, SACH FOOT, THERMOPLASTIC OR EQUAL, DIRECT FORMED
L5580	PREPARATORY, ABOVE KNEE - KNEE DISARTICULATION ISCHIAL LEVEL SOCKET, NON-ALIGNABLE SYSTEM, PYLON, NO COVER, SACH FOOT, THERMOPLASTIC OR EQUAL, MOLDED TO MODEL
L5585	PREPARATORY, ABOVE KNEE - KNEE DISARTICULATION, ISCHIAL LEVEL SOCKET, NON-ALIGNABLE SYSTEM, PYLON, NO COVER, SACH FOOT, PREFABRICATED ADJUSTABLE OPEN END SOCKET
L5590	PREPARATORY, ABOVE KNEE - KNEE DISARTICULATION ISCHIAL LEVEL SOCKET, NON-ALIGNABLE SYSTEM, PYLON NO COVER, SACH FOOT, LAMINATED SOCKET, MOLDED TO MODEL
L5595	PREPARATORY, HIP DISARTICULATION-HEMIPELVECTOMY, PYLON, NO COVER, SACH FOOT, THERMOPLASTIC OR EQUAL, MOLDED TO PATIENT MODEL
L5600	PREPARATORY, HIP DISARTICULATION-HEMIPELVECTOMY, PYLON, NO COVER, SACH FOOT, LAMINATED SOCKET, MOLDED TO PATIENT MODEL
L5610	ADDITION TO LOWER EXTREMITY, ENDOSKELETAL SYSTEM, ABOVE KNEE, HYDRACADENCE SYSTEM
L5611	ADDITION TO LOWER EXTREMITY, ENDOSKELETAL SYSTEM, ABOVE KNEE - KNEE

CODE	DESCRIPTION
	DISARTICULATION, 4 BAR LINKAGE, WITH FRICTION SWING PHASE CONTROL
L5613	ADDITION TO LOWER EXTREMITY, ENDOSKELETAL SYSTEM, ABOVE KNEE-KNEE DISARTICULATION, 4 BAR LINKAGE, WITH HYDRAULIC SWING PHASE CONTROL
L5614	ADDITION TO LOWER EXTREMITY, EXOSKELETAL SYSTEM, ABOVE KNEE-KNEE DISARTICULATION, 4 BAR LINKAGE, WITH PNEUMATIC SWING PHASE CONTROL
L5615	ADDITION, ENDOSKELETAL KNEE-SHIN SYSTEM, 4 BAR LINKAGE OR MULTIAXIAL, FLUID SWING AND STANCE PHASE CONTROL
L5616	ADDITION TO LOWER EXTREMITY, ENDOSKELETAL SYSTEM, ABOVE KNEE, UNIVERSAL MULTIPLEX SYSTEM, FRICTION SWING PHASE CONTROL
L5617	ADDITION TO LOWER EXTREMITY, QUICK CHANGE SELF-ALIGNING UNIT, ABOVE KNEE OR BELOW KNEE, EACH
L5618	ADDITION TO LOWER EXTREMITY, TEST SOCKET, SYMES
L5620	ADDITION TO LOWER EXTREMITY, TEST SOCKET, BELOW KNEE
L5622	ADDITION TO LOWER EXTREMITY, TEST SOCKET, KNEE DISARTICULATION
L5624	ADDITION TO LOWER EXTREMITY, TEST SOCKET, ABOVE KNEE
L5626	ADDITION TO LOWER EXTREMITY, TEST SOCKET, HIP DISARTICULATION
L5628	ADDITION TO LOWER EXTREMITY, TEST SOCKET, HEMIPELVECTOMY
L5629	ADDITION TO LOWER EXTREMITY, BELOW KNEE, ACRYLIC SOCKET
L5630	ADDITION TO LOWER EXTREMITY, SYMES TYPE, EXPANDABLE WALL SOCKET
L5631	ADDITION TO LOWER EXTREMITY, ABOVE KNEE OR KNEE DISARTICULATION, ACRYLIC SOCKET
L5632	ADDITION TO LOWER EXTREMITY, SYMES TYPE, 'PTB' BRIM DESIGN SOCKET
L5634	ADDITION TO LOWER EXTREMITY, SYMES TYPE, POSTERIOR OPENING (CANADIAN) SOCKET
L5636	ADDITION TO LOWER EXTREMITY, SYMES TYPE, MEDIAL OPENING SOCKET
L5637	ADDITION TO LOWER EXTREMITY, BELOW KNEE, TOTAL CONTACT
L5638	ADDITION TO LOWER EXTREMITY, BELOW KNEE, LEATHER SOCKET
L5639	ADDITION TO LOWER EXTREMITY, BELOW KNEE, WOOD SOCKET
L5640	ADDITION TO LOWER EXTREMITY, KNEE DISARTICULATION, LEATHER SOCKET
L5642	ADDITION TO LOWER EXTREMITY, ABOVE KNEE, LEATHER SOCKET
L5643	ADDITION TO LOWER EXTREMITY, HIP DISARTICULATION, FLEXIBLE INNER SOCKET, EXTERNAL FRAME
L5644	ADDITION TO LOWER EXTREMITY, ABOVE KNEE, WOOD SOCKET
L5645	ADDITION TO LOWER EXTREMITY, BELOW KNEE, FLEXIBLE INNER SOCKET,

CODE	DESCRIPTION
	EXTERNAL FRAME
L5646	ADDITION TO LOWER EXTREMITY, BELOW KNEE, AIR, FLUID, GEL OR EQUAL, CUSHION SOCKET
L5647	ADDITION TO LOWER EXTREMITY, BELOW KNEE SUCTION SOCKET
L5648	ADDITION TO LOWER EXTREMITY, ABOVE KNEE, AIR, FLUID, GEL OR EQUAL, CUSHION SOCKET
L5649	ADDITION TO LOWER EXTREMITY, ISCHIAL CONTAINMENT/NARROW M-L SOCKET
L5650	ADDITIONS TO LOWER EXTREMITY, TOTAL CONTACT, ABOVE KNEE OR KNEE DISARTICULATION SOCKET
L5651	ADDITION TO LOWER EXTREMITY, ABOVE KNEE, FLEXIBLE INNER SOCKET, EXTERNAL FRAME
L5652	ADDITION TO LOWER EXTREMITY, SUCTION SUSPENSION, ABOVE KNEE OR KNEE DISARTICULATION SOCKET
L5653	ADDITION TO LOWER EXTREMITY, KNEE DISARTICULATION, EXPANDABLE WALL SOCKET
L5654	ADDITION TO LOWER EXTREMITY, SOCKET INSERT, SYMES, (KEMBLO, PELITE, ALIPLAST, PLASTAZOTE OR EQUAL)
L5655	ADDITION TO LOWER EXTREMITY, SOCKET INSERT, BELOW KNEE (KEMBLO, PELITE, ALIPLAST, PLASTAZOTE OR EQUAL)
L5656	ADDITION TO LOWER EXTREMITY, SOCKET INSERT, KNEE DISARTICULATION (KEMBLO, PELITE, ALIPLAST, PLASTAZOTE OR EQUAL)
L5658	ADDITION TO LOWER EXTREMITY, SOCKET INSERT, ABOVE KNEE (KEMBLO, PELITE, ALIPLAST, PLASTAZOTE OR EQUAL)
L5661	ADDITION TO LOWER EXTREMITY, SOCKET INSERT, MULTI-DUROMETER SYMES
L5665	ADDITION TO LOWER EXTREMITY, SOCKET INSERT, MULTI-DUROMETER, BELOW KNEE
L5666	ADDITION TO LOWER EXTREMITY, BELOW KNEE, CUFF SUSPENSION
L5668	ADDITION TO LOWER EXTREMITY, BELOW KNEE, MOLDED DISTAL CUSHION
L5670	ADDITION TO LOWER EXTREMITY, BELOW KNEE, MOLDED SUPRACONDYLAR SUSPENSION ('PTS' OR SIMILAR)
L5671	ADDITION TO LOWER EXTREMITY, BELOW KNEE / ABOVE KNEE SUSPENSION LOCKING MECHANISM (SHUTTLE, LANYARD OR EQUAL), EXCLUDES SOCKET INSERT
L5672	ADDITION TO LOWER EXTREMITY, BELOW KNEE, REMOVABLE MEDIAL BRIM SUSPENSION
L5673	ADDITION TO LOWER EXTREMITY, BELOW KNEE/ABOVE KNEE, CUSTOM

<b>CODE</b>	<b>DESCRIPTION</b>
	FABRICATED FROM EXISTING MOLD OR PREFABRICATED, SOCKET INSERT, SILICONE GEL, ELASTOMERIC OR EQUAL, FOR USE WITH LOCKING MECHANISM
L5676	ADDITIONS TO LOWER EXTREMITY, BELOW KNEE, KNEE JOINTS, SINGLE AXIS, PAIR
L5677	ADDITIONS TO LOWER EXTREMITY, BELOW KNEE, KNEE JOINTS, POLYCENTRIC, PAIR
L5678	ADDITIONS TO LOWER EXTREMITY, BELOW KNEE, JOINT COVERS, PAIR
L5679	ADDITION TO LOWER EXTREMITY, BELOW KNEE/ABOVE KNEE, CUSTOM FABRICATED FROM EXISTING MOLD OR PREFABRICATED, SOCKET INSERT, SILICONE GEL, ELASTOMERIC OR EQUAL, NOT FOR USE WITH LOCKING MECHANISM
L5680	ADDITION TO LOWER EXTREMITY, BELOW KNEE, THIGH LACER, NONMOLDED
L5681	ADDITION TO LOWER EXTREMITY, BELOW KNEE/ABOVE KNEE, CUSTOM FABRICATED SOCKET INSERT FOR CONGENITAL OR ATYPICAL TRAUMATIC AMPUTEE, SILICONE GEL, ELASTOMERIC OR EQUAL, FOR USE WITH OR WITHOUT LOCKING MECHANISM, INITIAL ONLY (FOR OTHER THAN INITIAL, USE CODE L5673 OR L5679)
L5682	ADDITION TO LOWER EXTREMITY, BELOW KNEE, THIGH LACER, GLUTEAL/ISCHIAL, MOLDED
L5683	ADDITION TO LOWER EXTREMITY, BELOW KNEE/ABOVE KNEE, CUSTOM FABRICATED SOCKET INSERT FOR OTHER THAN CONGENITAL OR ATYPICAL TRAUMATIC AMPUTEE, SILICONE GEL, ELASTOMERIC OR EQUAL, FOR USE WITH OR WITHOUT LOCKING MECHANISM, INITIAL ONLY (FOR OTHER THAN INITIAL, USE CODE L5673 OR L5679)
L5684	ADDITION TO LOWER EXTREMITY, BELOW KNEE, FORK STRAP
L5685	ADDITION TO LOWER EXTREMITY PROSTHESIS, BELOW KNEE, SUSPENSION/SEALING SLEEVE, WITH OR WITHOUT VALVE, ANY MATERIAL, EACH
L5686	ADDITION TO LOWER EXTREMITY, BELOW KNEE, BACK CHECK (EXTENSION CONTROL)
L5688	ADDITION TO LOWER EXTREMITY, BELOW KNEE, WAIST BELT, WEBBING
L5690	ADDITION TO LOWER EXTREMITY, BELOW KNEE, WAIST BELT, PADDED AND LINED
<b>CODE</b>	<b>DESCRIPTION</b>
L5692	ADDITION TO LOWER EXTREMITY, ABOVE KNEE, PELVIC CONTROL BELT, LIGHT
L5694	ADDITION TO LOWER EXTREMITY, ABOVE KNEE, PELVIC CONTROL BELT, PADDED AND LINED
L5695	ADDITION TO LOWER EXTREMITY, ABOVE KNEE, PELVIC CONTROL, SLEEVE SUSPENSION, NEOPRENE OR EQUAL, EACH

CODE	DESCRIPTION
L5696	ADDITION TO LOWER EXTREMITY, ABOVE KNEE OR KNEE DISARTICULATION, PELVIC JOINT
L5697	ADDITION TO LOWER EXTREMITY, ABOVE KNEE OR KNEE DISARTICULATION, PELVIC BAND
L5698	ADDITION TO LOWER EXTREMITY, ABOVE KNEE OR KNEE DISARTICULATION, SILESIAN BANDAGE
L5699	ALL LOWER EXTREMITY PROSTHESES, SHOULDER HARNESS
L5700	REPLACEMENT, SOCKET, BELOW KNEE, MOLDED TO PATIENT MODEL
L5701	REPLACEMENT, SOCKET, ABOVE KNEE/KNEE DISARTICULATION, INCLUDING ATTACHMENT PLATE, MOLDED TO PATIENT MODEL
L5702	REPLACEMENT, SOCKET, HIP DISARTICULATION, INCLUDING HIP JOINT, MOLDED TO PATIENT MODEL
L5703	ANKLE, SYMES, MOLDED TO PATIENT MODEL, SOCKET WITHOUT SOLID ANKLE CUSHION HEEL (SACH) FOOT, REPLACEMENT ONLY
L5704	CUSTOM SHAPED PROTECTIVE COVER, BELOW KNEE
L5705	CUSTOM SHAPED PROTECTIVE COVER, ABOVE KNEE
L5706	CUSTOM SHAPED PROTECTIVE COVER, KNEE DISARTICULATION
L5707	CUSTOM SHAPED PROTECTIVE COVER, HIP DISARTICULATION
L5710	ADDITION, EXOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, MANUAL LOCK
L5711	ADDITIONS EXOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, MANUAL LOCK, ULTRA-LIGHT MATERIAL
L5712	ADDITION, EXOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, FRICTION SWING AND STANCE PHASE CONTROL (SAFETY KNEE)
L5714	ADDITION, EXOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, VARIABLE FRICTION SWING PHASE CONTROL
L5716	ADDITION, EXOSKELETAL KNEE-SHIN SYSTEM, POLYCENTRIC, MECHANICAL STANCE PHASE LOCK
L5718	ADDITION, EXOSKELETAL KNEE-SHIN SYSTEM, POLYCENTRIC, FRICTION SWING AND STANCE PHASE CONTROL
L5722	ADDITION, EXOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, PNEUMATIC SWING, FRICTION STANCE PHASE CONTROL
L5724	ADDITION, EXOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, FLUID SWING PHASE CONTROL
L5726	ADDITION, EXOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, EXTERNAL JOINTS FLUID SWING PHASE CONTROL
L5728	ADDITION, EXOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, FLUID SWING AND

CODE	DESCRIPTION
	STANCE PHASE CONTROL
L5780	ADDITION, EXOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, PNEUMATIC/HYDRA PNEUMATIC SWING PHASE CONTROL
L5781	ADDITION TO LOWER LIMB PROSTHESIS, VACUUM PUMP, RESIDUAL LIMB VOLUME MANAGEMENT AND MOISTURE EVACUATION SYSTEM
L5782	ADDITION TO LOWER LIMB PROSTHESIS, VACUUM PUMP, RESIDUAL LIMB VOLUME MANAGEMENT AND MOISTURE EVACUATION SYSTEM, HEAVY DUTY
L5783	ADDITION TO LOWER EXTREMITY, USER ADJUSTABLE, MECHANICAL, RESIDUAL LIMB VOLUME MANAGEMENT SYSTEM
L5785	ADDITION, EXOSKELETAL SYSTEM, BELOW KNEE, ULTRA-LIGHT MATERIAL (TITANIUM, CARBON FIBER OR EQUAL)
L5790	ADDITION, EXOSKELETAL SYSTEM, ABOVE KNEE, ULTRA-LIGHT MATERIAL (TITANIUM, CARBON FIBER OR EQUAL)
L5795	ADDITION, EXOSKELETAL SYSTEM, HIP DISARTICULATION, ULTRA-LIGHT MATERIAL (TITANIUM, CARBON FIBER OR EQUAL)
L5810	ADDITION, ENDOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, MANUAL LOCK
L5811	ADDITION, ENDOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, MANUAL LOCK, ULTRA-LIGHT MATERIAL
L5812	ADDITION, ENDOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, FRICTION SWING AND STANCE PHASE CONTROL (SAFETY KNEE)
L5814	ADDITION, ENDOSKELETAL KNEE-SHIN SYSTEM, POLYCENTRIC, HYDRAULIC SWING PHASE CONTROL, MECHANICAL STANCE PHASE LOCK
L5816	ADDITION, ENDOSKELETAL KNEE-SHIN SYSTEM, POLYCENTRIC, MECHANICAL STANCE PHASE LOCK
L5818	ADDITION, ENDOSKELETAL KNEE-SHIN SYSTEM, POLYCENTRIC, FRICTION SWING, AND STANCE PHASE CONTROL
L5822	ADDITION, ENDOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, PNEUMATIC SWING, FRICTION STANCE PHASE CONTROL
L5824	ADDITION, ENDOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, FLUID SWING PHASE CONTROL
L5826	ADDITION, ENDOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, HYDRAULIC SWING PHASE CONTROL, WITH MINIATURE HIGH ACTIVITY FRAME
L5828	ADDITION, ENDOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, FLUID SWING AND STANCE PHASE CONTROL
L5830	ADDITION, ENDOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, PNEUMATIC/ SWING PHASE CONTROL
L5840	ADDITION, ENDOSKELETAL KNEE/SHIN SYSTEM, 4-BAR LINKAGE OR MULTIAXIAL,

CODE	DESCRIPTION
	PNEUMATIC SWING PHASE CONTROL
L5841	ADDITION, ENDOSKELETAL KNEE-SHIN SYSTEM, POLYCENTRIC, PNEUMATIC 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
L5850	ADDITION, ENDOSKELETAL SYSTEM, ABOVE KNEE OR HIP DISARTICULATION, KNEE EXTENSION ASSIST
L5855	ADDITION, ENDOSKELETAL SYSTEM, HIP DISARTICULATION, MECHANICAL HIP EXTENSION ASSIST
L5856	ADDITION TO LOWER EXTREMITY PROSTHESIS, ENDOSKELETAL KNEE-SHIN SYSTEM, MICROPROCESSOR CONTROL FEATURE, SWING AND STANCE PHASE, INCLUDES ELECTRONIC SENSOR(S), ANY TYPE
L5857	ADDITION TO LOWER EXTREMITY PROSTHESIS, ENDOSKELETAL KNEE-SHIN SYSTEM, MICROPROCESSOR CONTROL FEATURE, SWING PHASE ONLY, INCLUDES ELECTRONIC SENSOR(S), ANY TYPE
L5858	ADDITION TO LOWER EXTREMITY PROSTHESIS, ENDOSKELETAL KNEE SHIN SYSTEM, MICROPROCESSOR CONTROL FEATURE, STANCE PHASE ONLY, INCLUDES ELECTRONIC SENSOR(S), ANY TYPE
L5859	ADDITION TO LOWER EXTREMITY PROSTHESIS, ENDOSKELETAL KNEE-SHIN SYSTEM, POWERED AND PROGRAMMABLE FLEXION/EXTENSION ASSIST CONTROL, INCLUDES ANY TYPE MOTOR(S)
L5910	ADDITION, ENDOSKELETAL SYSTEM, BELOW KNEE, ALIGNABLE SYSTEM
L5920	ADDITION, ENDOSKELETAL SYSTEM, ABOVE KNEE OR HIP DISARTICULATION, ALIGNABLE SYSTEM
L5925	ADDITION, ENDOSKELETAL SYSTEM, ABOVE KNEE, KNEE DISARTICULATION OR HIP DISARTICULATION, MANUAL LOCK
L5926	ADDITION TO LOWER EXTREMITY PROSTHESIS, ENDOSKELETAL, KNEE DISARTICULATION, ABOVE KNEE, HIP DISARTICULATION, POSITIONAL ROTATION UNIT, ANY TYPE
L5930	ADDITION, ENDOSKELETAL SYSTEM, HIGH ACTIVITY KNEE CONTROL FRAME
L5940	ADDITION, ENDOSKELETAL SYSTEM, BELOW KNEE, ULTRA-LIGHT MATERIAL (TITANIUM, CARBON FIBER OR EQUAL)
L5950	ADDITION, ENDOSKELETAL SYSTEM, ABOVE KNEE, ULTRA-LIGHT MATERIAL (TITANIUM, CARBON FIBER OR EQUAL)
L5960	ADDITION, ENDOSKELETAL SYSTEM, HIP DISARTICULATION, ULTRA-LIGHT MATERIAL (TITANIUM, CARBON FIBER OR EQUAL)

CODE	DESCRIPTION
L5961	ADDITION, ENDOSKELETAL SYSTEM, POLYCENTRIC HIP JOINT, PNEUMATIC OR HYDRAULIC CONTROL, ROTATION CONTROL, WITH OR WITHOUT FLEXION AND/OR EXTENSION CONTROL
L5962	ADDITION, ENDOSKELETAL SYSTEM, BELOW KNEE, FLEXIBLE PROTECTIVE OUTER SURFACE COVERING SYSTEM
L5964	ADDITION, ENDOSKELETAL SYSTEM, ABOVE KNEE, FLEXIBLE PROTECTIVE OUTER SURFACE COVERING SYSTEM
L5966	ADDITION, ENDOSKELETAL SYSTEM, HIP DISARTICULATION, FLEXIBLE PROTECTIVE OUTER SURFACE COVERING SYSTEM
L5968	ADDITION TO LOWER LIMB PROSTHESIS, MULTIAXIAL ANKLE WITH SWING PHASE ACTIVE DORSIFLEXION FEATURE
L5969	ADDITION, ENDOSKELETAL ANKLE-FOOT OR ANKLE SYSTEM, POWER ASSIST, INCLUDES ANY TYPE MOTOR(S)
L5970	ALL LOWER EXTREMITY PROSTHESES, FOOT, EXTERNAL KEEL, SACH FOOT
L5971	ALL LOWER EXTREMITY PROSTHESIS, SOLID ANKLE CUSHION HEEL (SACH) FOOT, REPLACEMENT ONLY
L5972	ALL LOWER EXTREMITY PROSTHESES, FOOT, FLEXIBLE KEEL
L5973	ENDOSKELETAL ANKLE FOOT SYSTEM, MICROPROCESSOR CONTROLLED FEATURE, DORSIFLEXION AND/OR PLANTAR FLEXION CONTROL, INCLUDES POWER SOURCE
L5974	ALL LOWER EXTREMITY PROSTHESES, FOOT, SINGLE AXIS ANKLE/FOOT
L5975	ALL LOWER EXTREMITY PROSTHESIS, COMBINATION SINGLE AXIS ANKLE AND FLEXIBLE KEEL FOOT
L5976	ALL LOWER EXTREMITY PROSTHESES, ENERGY STORING FOOT (SEATTLE CARBON COPY II OR EQUAL)
L5978	ALL LOWER EXTREMITY PROSTHESES, FOOT, MULTIAXIAL ANKLE/FOOT
L5979	ALL LOWER EXTREMITY PROSTHESIS, MULTI-AXIAL ANKLE, DYNAMIC RESPONSE FOOT, ONE PIECE SYSTEM
L5980	ALL LOWER EXTREMITY PROSTHESES, FLEX FOOT SYSTEM
L5981	ALL LOWER EXTREMITY PROSTHESES, FLEX-WALK SYSTEM OR EQUAL
L5982	ALL EXOSKELETAL LOWER EXTREMITY PROSTHESES, AXIAL ROTATION UNIT
L5984	ALL ENDOSKELETAL LOWER EXTREMITY PROSTHESIS, AXIAL ROTATION UNIT, WITH OR WITHOUT ADJUSTABILITY
L5985	ALL ENDOSKELETAL LOWER EXTREMITY PROSTHESES, DYNAMIC PROSTHETIC PYLON
L5986	ALL LOWER EXTREMITY PROSTHESES, MULTI-AXIAL ROTATION UNIT ('MCP' OR EQUAL)

CODE	DESCRIPTION
L5987	ALL LOWER EXTREMITY PROSTHESIS, SHANK FOOT SYSTEM WITH VERTICAL LOADING PYLON
L5988	ADDITION TO LOWER LIMB PROSTHESIS, VERTICAL SHOCK REDUCING PYLON FEATURE
L5990	ADDITION TO LOWER EXTREMITY PROSTHESIS, USER ADJUSTABLE HEEL HEIGHT
L5991	ADDITION TO LOWER EXTREMITY PROSTHESES, OSSEOINTEGRATED EXTERNAL PROSTHETIC CONNECTOR
L5999	LOWER EXTREMITY PROSTHESIS, NOT OTHERWISE SPECIFIED
L7367	LITHIUM ION BATTERY, RECHARGEABLE, REPLACEMENT
L7368	LITHIUM ION BATTERY CHARGER, REPLACEMENT ONLY
L7510	REPAIR OF PROSTHETIC DEVICE, REPAIR OR REPLACE MINOR PARTS
L7520	REPAIR PROSTHETIC DEVICE, LABOR COMPONENT, PER 15 MINUTES
L7600	PROSTHETIC DONNING SLEEVE, ANY MATERIAL, EACH
L7700	GASKET OR SEAL, FOR USE WITH PROSTHETIC SOCKET INSERT, ANY TYPE, EACH
L8400	PROSTHETIC SHEATH, BELOW KNEE, EACH
L8410	PROSTHETIC SHEATH, ABOVE KNEE, EACH
L8417	PROSTHETIC SHEATH/SOCK, INCLUDING A GEL CUSHION LAYER, BELOW KNEE OR ABOVE KNEE, EACH
L8420	PROSTHETIC SOCK, MULTIPLE PLY, BELOW KNEE, EACH
L8430	PROSTHETIC SOCK, MULTIPLE PLY, ABOVE KNEE, EACH
L8440	PROSTHETIC SHRINKER, BELOW KNEE, EACH
L8460	PROSTHETIC SHRINKER, ABOVE KNEE, EACH
CODE	DESCRIPTION
L8470	PROSTHETIC SOCK, SINGLE PLY, FITTING, BELOW KNEE, EACH
L8480	PROSTHETIC SOCK, SINGLE PLY, FITTING, ABOVE KNEE, EACH

## General Information

### Associated Information

### Documentation Requirements

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider." It is expected that the beneficiary's medical records will reflect the need for the care provided. The beneficiary's medical records include the treating practitioner's office records, hospital records, nursing home records, home health agency

records, records from other healthcare professionals and test reports. This documentation must be available upon request.

## **GENERAL DOCUMENTATION REQUIREMENTS**

In order to justify payment for DMEPOS items, suppliers must meet the following requirements:

- SWO
- Medical Record Information (including continued need/use if applicable)
- Correct Coding
- Proof of Delivery

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information regarding these requirements.

Refer to the Supplier Manual for additional information on documentation requirements.

Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

## **POLICY SPECIFIC DOCUMENTATION REQUIREMENTS**

Items covered in this LCD have additional policy-specific requirements that must be met prior to Medicare reimbursement.

Refer to the LCD-related Policy article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information.

## **Appendices**

### **Utilization Guidelines**

Refer to Coverage Indications, Limitations and/or Medical Necessity.

### **Sources of Information**

Reserved for future use.

### **Bibliography**

1. Steiner CA, Karaca Z, Moore BJ, Imshaug MC, Pickens G. *Surgeries in Hospital-Based Ambulatory Surgery and Hospital Inpatient Settings, 2014*. Agency for Healthcare Research and Quality, Rockville, MD;2020.
2. Moxey PW, Gogalniceanu P, Hinchliffe RJ, et al. Lower extremity amputations—a review of global variability in incidence. *Diabetic Medicine*. 2011;28(10):1144-1153.
3. Barnes JA, Eid MA, Creager MA, Goodney PP. Epidemiology and Risk of Amputation in Patients With Diabetes Mellitus and Peripheral Artery Disease. *Arterioscler Thromb Vasc Biol*. 2020;40(8):1808-1817.
4. Thibaut A, Beaudart C, Maertens DENB, Geers S, Kaux JF, Pelzer D. 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*. 2022;58(3):452-461.
5. Clemens S, Doerger C, Lee S-PJGr. Current and emerging trends in the management of fall risk in people with lower limb amputation. 2020;9(3):134-141.

6. Alzeer AM, Bhaskar Raj N, Shahine EM, Nadiah WA. Impacts of Microprocessor-Controlled Versus Non-microprocessor-Controlled Prosthetic Knee Joints Among Transfemoral Amputees on Functional Outcomes: A Comparative Study. *Cureus*. 2022;14(4):e24331.
7. Sawers AB, Hafner BJ. Outcomes associated with the use of microprocessor-controlled prosthetic knees among individuals with unilateral transfemoral limb loss: a systematic review. *Journal of rehabilitation research and development*. 2013;50(3):273-314.
8. Theeven PJ, Hemmen B, Brink PR, Smeets RJ, Seelen HA. Measures and procedures utilized to determine the added value of microprocessor-controlled prosthetic knee joints: a systematic review. *BMC Musculoskeletal Disord*. 2013;14:333.
9. Berry DJPM, Clinics R. Microprocessor prosthetic knees. 2006;17(1):91-113.
10. Thiele J, Westebbe B, Bellmann M, Kraft M. Designs and performance of microprocessor-controlled knee joints. *Biomed Tech (Berl)*. 2014;59(1):65-77.
11. Henrikson NB, Hafner BJ, Dettori JR, et al. *Microprocessor-controlled Lower Limb Prostheses Health Technology Assessment*. 676 Woodland Square Loop SE P.O. Box 42712 Olympia, WA 98504-2712 Washington State Health Care Authority;2011.
12. Hunter SW, Batchelor F, Hill KD, Hill A-M, Mackintosh S, Payne MJP. Risk factors for falls in people with a lower limb amputation: a systematic review. 2017;9(2):170-180. e171.
13. Steinberg N, Gottlieb A, Siev-Ner I, Plotnik M. Fall incidence and associated risk factors among people with a lower limb amputation during various stages of recovery - a systematic review. *Disability and rehabilitation*. 2019;41(15):1778-1787.
14. Miller WC, Speechley M, Deathe B. The prevalence and risk factors of falling and fear of falling among lower extremity amputees. *Archives of physical medicine and rehabilitation*. 2001;82(8):1031-1037.
15. Talbot LA, Musiol RJ, Witham EK, Metter EJJbph. Falls in young, middle-aged and older community dwelling adults: perceived cause, environmental factors and injury. 2005;5:1-9.
16. Chihuri ST, Youdan GA, Jr., Wong CK. Quantifying the risk of falls and injuries for amputees beyond annual fall rates-A longitudinal cohort analysis based on person-step exposure over time. *Prev Med Rep*. 2021;24:101626.
17. Dite W, Connor HJ, Curtis HC. Clinical identification of multiple fall risk early after unilateral transtibial amputation. *Archives of physical medicine and rehabilitation*. 2007;88(1):109-114.
18. Tobaigy M, Hafner BJ, Sawers A. Recalled Number of Falls in the Past Year-Combined With Perceived Mobility-Predicts the Incidence of Future Falls in Unilateral Lower Limb Prosthesis Users. *Phys Ther*. 2022;102(2).
19. Wong CK, Chen CC, Blackwell WM, Rahal RT, Benoy SA. Balance ability measured with the Berg balance scale: a determinant of fall history in community-dwelling adults with leg amputation. *Journal of rehabilitation medicine*. 2015;47(1):80-86.
20. Sions JM, Beisheim EH, Seth M. Selecting, Administering, and Interpreting Outcome Measures among Adults with Lower-Limb Loss: An Update for Clinicians. *Curr Phys Med Rehabil Rep*. 2020;8(3):92-109.
21. Kim J, Major MJ, Hafner B, Sawers A. Frequency and Circumstances of Falls Reported by Ambulatory Unilateral Lower Limb Prosthesis Users: A Secondary Analysis. *PM R*. 2019;11(4):344-353.
22. Gaunard I, Spaulding SE, Amtmann D, et al. Use of and confidence in administering outcome measures among clinical prosthetists: results from a national survey and mixed-methods training program. 2015;39(4):314-321.
23. Hafner BJ, Spaulding SE, Salem R, et al. Prosthetists' perceptions and use of outcome measures in clinical practice: long-term effects of focused continuing education. 2017;41(3):266-273.
24. Sawers A, Hafner BJ. Using Clinical Balance Tests to Assess Fall Risk among Established Unilateral Lower Limb Prosthesis Users: Cutoff Scores and Associated Validity Indices. *PM R*. 2020;12(1):16-25.
25. 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. *Clinical biomechanics (Bristol, Avon)*. 2018;58:116-122.
26. Hafner BJ, Gaunard IA, Morgan SJ, Amtmann D, Salem R, Gailey RS. Construct Validity of the Prosthetic Limb Users Survey of Mobility (PLUS-M) in Adults With Lower Limb Amputation. *Archives of physical medicine and rehabilitation*. 2017;98(2):277-285.
27. Nugent K, Payne MW, Viana R, Hunter SWJP. The reliability of four standardized concern for falling scales

- among adults with a major lower extremity amputation. 2022.
28. Nugent K, Payne MW, Viana R, Unger J, Hunter SWJ, Ijorr. A concern for falling impacts quality of life for people with a lower limb amputation. 2022;45(3):253-259.
  29. Major MJ, Fatone S, Roth EJ. Validity and reliability of the Berg Balance Scale for community-dwelling persons with lower-limb amputation. *Archives of physical medicine and rehabilitation*. 2013;94(11):2194-2202.
  30. Wong CK, Rheinstein J, Stern MA. Benefits for Adults with Transfemoral Amputations and Peripheral Artery Disease Using Microprocessor Compared with Nonmicroprocessor Prosthetic Knees. *American journal of physical medicine & rehabilitation*. 2015;94(10):804-810.
  31. Hahn A, Bueschges S, Prager M, Kannenberg A. The effect of microprocessor controlled exo-prosthetic knees on limited community ambulators: systematic review and meta-analysis. *Disability and rehabilitation*. 2021:1-19.
  32. Kahle JT, Highsmith MJ, Schaepper H, et al. Predicting walking ability following lower limb amputation: an updated systematic literature review. 2016;18(2-3):125-137.
  33. Borrenpohl D, Kaluf B, Major MJ, Aopm, rehabilitation. Survey of US practitioners on the validity of the medicare functional classification level system and utility of clinical outcome measures for aiding K-level assignment. 2016;97(7):1053-1063.
  34. Dillon MP, Major MJ, Kaluf B, Balasanov Y, Fatone SJP, international o. Predict the Medicare Functional Classification Level (K-level) using the Amputee Mobility Predictor in people with unilateral transfemoral and transtibial amputation: A pilot study. 2018;42(2):191-197.
  35. Gailey RS, Roach KE, Applegate EB, et al. The amputee mobility predictor: an instrument to assess determinants of the lower-limb amputee's ability to ambulate. 2002;83(5):613-627.
  36. Norvell DC, Thompson ML, Baraff A, et al. AMPREDICT PROsthetics-Predicting Prosthesis Mobility to aid in prosthetic prescription and rehabilitation planning. 2022.
  37. Wurdeman SR, Stevens PM, Campbell JHJD, Technology RA. Mobility Analysis of Amputees (MAAT 4): Classification tree analysis for probability of lower limb prosthesis user functional potential. 2019.
  38. US Food and Drug Administration. (2001). Code of Federal Regulations: 21 CFR §890.3420. Physical medicine devices, physical medicine prosthetic devices, external limb prosthetic component, revised July 25, 2001.
  39. US Food and Drug Administration. (1998). Code of Federal Regulations: 21 CFR §890.3500. Physical medicine devices, physical medicine prosthetic devices, external assembled lower limb prosthesis, revised November 3, 1998.
  40. Davie-Smith F, Carse B. Comparison of patient-reported and functional outcomes following transition from mechanical to microprocessor knee in the low-activity user with a unilateral transfemoral amputation. *Prosthetics and orthotics international*. 2021;45(3):198-204.
  41. Lansade C, Vicaut E, Paysant J, et al. Mobility and satisfaction with a microprocessor-controlled knee in moderately active amputees: A multi-centric randomized crossover trial. *Annals of physical and rehabilitation medicine*. 2018;61(5):278-285.
  42. Hahn A, Lang MJ, JoP, Orthotics. 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. 2015;27(3):86-94.
  43. 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. *Journal of rehabilitation research and development*. 2009;46(3):417-433.
  44. Kahle JT, Highsmith MJ, Hubbard SL. Comparison of nonmicroprocessor knee mechanism versus C-Leg on Prosthesis Evaluation Questionnaire, stumbles, falls, walking tests, stair descent, and knee preference. *Journal of rehabilitation research and development*. 2008;45(1):1-14.
  45. Mileusnic MP, Hahn A, Reiter S, JoP, Orthotics. Effects of a novel microprocessor-controlled knee, kenevo, on the safety, mobility, and satisfaction of lower-activity patients with transfemoral amputation. 2017;29(4):198-205.
  46. Jayaraman C, Mummidisetty CK, Albert MV, et al. Using a microprocessor knee (C-Leg) with appropriate foot transitioned individuals with dysvascular transfemoral amputations to higher performance levels: a longitudinal randomized clinical trial. *Journal of neuroengineering and rehabilitation*. 2021;18(1):88.
  47. Campbell JH, Stevens PM, Wurdeman SR. OASIS 1: Retrospective analysis of four different microprocessor knee types. *Journal of rehabilitation and assistive technologies engineering*. 2020;7:2055668320968476.

48. 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. *Journal of rehabilitation medicine*. 2011;43(10):906-915.
49. Fard B, Persoon S, Jutte PC, et al. Amputation and prosthetics of the lower extremity: The 2020 Dutch evidence-based multidisciplinary guideline. *Prosthetics and orthotics international*. 2023;47(1):69-80.
50. Webster JB, Crunkhorn A, Sall J, Highsmith MJ, Pruziner A, Randolph BJ. Clinical Practice Guidelines for the Rehabilitation of Lower Limb Amputation: An Update from the Department of Veterans Affairs and Department of Defense. *American journal of physical medicine & rehabilitation*. 2019;98(9):820-829.
51. Sedki I, Fisher K. Developing prescribing guidelines for microprocessor-controlled prosthetic knees in the South East England. *Prosthetics and orthotics international*. 2015;39(3):250-254.
52. Centers for Medicare & Medicaid. Health Technology Assessment: Lower Limb Prosthetic Workgroup Consensus Document. [https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/LLP\\_Consensus\\_Document.pdf](https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/LLP_Consensus_Document.pdf). 2017. Accessed September 6, 2023.
53. Kuhlmann A, Kruger H, Seidinger S, Hahn A. Cost-effectiveness and budget impact of the microprocessor-controlled knee C-Leg in transfemoral amputees with and without diabetes mellitus. *Eur J Health Econ*. 2020;21(3):437-449.
54. Chen C, Hanson M, Chaturvedi R, Mattke S, Hillestad R, Liu HH. Economic benefits of microprocessor controlled prosthetic knees: a modeling study. *Journal of neuroengineering and rehabilitation*. 2018;15(Suppl 1):62.
55. Sterne JAC SJ, Page MJ, Elbers RG, Blencowe NS, Boutron I, Cates CJ, Cheng H-Y, Corbett MS, Eldridge SM, Hernán MA, Hopewell S, Hróbjartsson A, Junqueira DR, Jüni P, Kirkham JJ, Lasserson T, Li T, McAleenan A, Reeves BC, Shepperd S, Shrier I, Stewart LA, Tilling K, White IR, Whiting PF, Higgins JPT. RoB 2: a revised tool for assessing risk of bias in randomised trials. *BMJ*. 2019;366:l4898.
56. Higgins J LT, Sterne J. Revised Cochrane Risk of Bias Tool for Randomized Trials (RoB2) Additional Considerations for Crossover Trials. <https://www.riskofbias.info/welcome/rob-2-0-tool/rob-2-for-crossover-trials>. 2021. Accessed September 6, 2023.
57. Sterne JAC HM, Reeves BC, Savovic J, Berkman ND, Viswanathan M, Henry D, Altman DG, Ansari MT, Boutron I, Carpenter JR, Chan AW, Churchill R, Deeks JJ, Hróbjartsson A, Kirkham J, Jüni P, Loke YK, Pigott TD, Ramsay CR, Regidor D, Rothstein HR, Sandhu L, Santaguida PL, Schünemann HJ, Shea B, Shrier I, Tugwell P, Turner L, Valentine JC, Waddington H, Waters E, Wells GA, Whiting PF, Higgins JPT. ROBINS-I: a tool for assessing risk of bias in non-randomized studies of interventions. *BMJ* 2016; 355; i4919; doi: 10.1136/bmj.i4919.
58. GDT: G. GRADEpro Guideline Development Tool [Software]. McMaster University, 2015 (developed by Evidence Prime, Inc.). [grade.pro.org](http://grade.pro.org). (Accessed February 7, 2023).

## Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
09/01/2024	R11	Revision Effective Date: 09/01/2024 COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY: Revised: Coverage criteria for microprocessor-controlled ankle foot system, energy storing foot, dynamic response foot with multi-axial ankle, flex foot system, flex-walk system or equal, and shank foot system with vertical loading pylon, to include coverage for beneficiaries whose	<ul style="list-style-type: none"> <li>• Provider Education/Guidance</li> <li>• Reconsideration Request</li> </ul>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		<p>functional level is 2 when specified criteria are met  Revised: Coverage criteria for a fluid or pneumatic knee unit, control addition fluid, and electronic/microprocessor-controlled knee system, to include coverage for beneficiaries whose functional level is 2 when specified criteria are met  SUMMARY OF EVIDENCE:  Added: Information related to microprocessor-controlled prosthetic knees  ANALYSIS OF EVIDENCE:  Added: Information related to microprocessor-controlled prosthetic knees  BIBLIOGRAPHY:  Added: Information related to microprocessor-controlled prosthetic knees  CODING INFORMATION:  Added: GA, GY, GZ, and KX modifiers  RELATED LOCAL COVERAGE DOCUMENTS:  Added: Response to Comments article (A59857)</p>	
04/01/2024	R10	<p>Revision Effective Date: 04/01/2024  HCPCS CODES:  Added: HCPCS codes L5841 and L5783</p> <p><i>05/02/2024: Pursuant to the 21st Century Cures Act, these revisions do not require notice and comment because the revisions are non-discretionary updates per CMS HCPCS coding determinations.</i></p>	<ul style="list-style-type: none"> <li>• Provider Education/Guidance</li> <li>• Revisions Due To CPT/HCPCS Code Changes</li> </ul>
01/01/2024	R9	<p>Revision Effective Date: 01/01/2024  HCPCS CODES:  Added: HCPCS codes L5615 and L5926</p> <p><i>12/28/2023: Pursuant to the 21st Century Cures Act, these revisions do not require notice and comment because the revisions are non-discretionary updates per CMS HCPCS coding determinations.</i></p>	<ul style="list-style-type: none"> <li>• Revisions Due To CPT/HCPCS Code Changes</li> </ul>
10/01/2023	R8	<p>Revision Effective Date: 10/01/2023  HCPCS CODES:  Added: HCPCS code L5991</p> <p><i>12/14/2023: Pursuant to the 21st Century Cures Act, these revisions do not require notice and comment because the revisions are non-discretionary updates per</i></p>	<ul style="list-style-type: none"> <li>• Revisions Due To CPT/HCPCS Code Changes</li> </ul>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		<i>CMS HCPCS coding determinations.</i>	
01/01/2020	R7	<p>Revision Effective Date: 01/01/2020            COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY:            Revised: Format of HCPCS code references, from code 'spans' to individually-listed HCPCS            Revised: "physician" to "practitioner"            Revised: "physician's" to "treating practitioner's"            Revised: Order information as a result of Final Rule 1713            CODING INFORMATION:            Removed: Field titled "Bill Type"            Removed: Field titled "Revenue Codes"            Removed: Field titled "ICD-10 Codes that Support Medical Necessity"            Removed: Field titled "ICD-10 Codes that DO NOT Support Medical Necessity"            Removed: Field titled "Additional ICD-10 Information"            DOCUMENTATION REQUIREMENTS:            Revised: "physician's" to "treating practitioner's"            GENERAL DOCUMENTATION REQUIREMENTS:            Revised: Prescriptions (orders) to SWO</p> <p><i>03/12/2020: Pursuant to the 21st Century Cures Act, these revisions do not require notice and comment because they are due to non-discretionary coverage updates reflective of CMS FR-1713, HCPCS code changes, and non-substantive corrections (listing individual HCPCS codes instead of a HCPCS code-span).</i></p>	<ul style="list-style-type: none"> <li>• Provider Education/Guidance</li> <li>• Other</li> </ul>
11/01/2018	R6	<p>Revision Effective: 11/01/2018</p> <p>Coverage Indications, Limitations, and/or Medical Necessity:</p> <p>Removed: Weight range information related to L5859.</p> <p><i>11/01/2018: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</i></p>	<ul style="list-style-type: none"> <li>• Other (Product specification removed)</li> </ul>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
01/01/2018	R5	<p>Revision Effective: 01/01/2018</p> <p>HCPCS CODES:</p> <p>Added: L7700 to Group 1 Codes per annual HCPCS code release</p> <p><i>12/21/2017: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</i></p>	<ul style="list-style-type: none"> <li>• Revisions Due To CPT/HCPCS Code Changes</li> </ul>
01/01/2017	R4	<p>COVERAGE INDICATIONS, INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:</p> <p>Removed: Standard Documentation Language</p> <p>Added: New reference language and directions to Standard Documentation Requirements</p> <p>Added: General Requirements</p> <p>DOCUMENTATION REQUIREMENTS:</p> <p>Removed: Standard Documentation Language</p> <p>Added: General Documentation Requirements</p> <p>Added: New reference language and directions to Standard Documentation Requirements</p> <p>POLICY SPECIFIC DOCUMENTATION REQUIREMENTS:</p> <p>Removed: Standard Documentation Language</p> <p>Added: Direction to Standard Documentation Requirements</p> <p>Removed: PIM reference under Appendices</p> <p>RELATED LOCAL COVERAGE DOCUMENTS:</p> <p>Added: LCD-related Standard Documentation Requirements article</p>	<ul style="list-style-type: none"> <li>• Provider Education/Guidance</li> </ul>
07/01/2016	R3	<p>Effective July 1, 2016 oversight for DME MAC LCDs is the responsibility of CGS Administrators, LLC 18003 and 17013 and Noridian Healthcare Solutions, LLC 19003 and 16013. No other changes have been made to the LCDs.</p>	<ul style="list-style-type: none"> <li>• Change in Assigned States or Affiliated Contract Numbers</li> </ul>
10/01/2015	R2	<p><b>Revision Effective Date: 10/01/2015</b></p> <p><b>COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:</b></p> <p><b>Added: Standard language regarding Medicare coverage</b></p>	<ul style="list-style-type: none"> <li>• Provider Education/Guidance</li> <li>• Revisions Due To CPT/HCPCS Code Changes</li> </ul>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		<b>HCPCS CODING:</b> <b>Revised: HCPCS Narrative of L7367</b> <b>DOCUMENTATION REQUIREMENTS:</b> <b>Added: Continued need, continued use, and Prior Payer verbiage and updated standard language documentation</b> <b>Revised: Repair/Replacement verbiage</b>	

## Associated Documents

### Attachments

N/A

### Related Local Coverage Documents

### Articles

[A52496 - Lower Limb Protheses - Policy Article](#)

[A59857 - Response to Comments: Lower Limb Protheses - DL33787](#)

[A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs](#)

### Related National Coverage Documents

N/A

### Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS
07/12/2024	09/01/2024 - N/A	Currently in Effect (This Version)
04/26/2024	04/01/2024 - 08/31/2024	Superseded
12/21/2023	01/01/2024 - 03/31/2024	Superseded
12/07/2023	10/01/2023 - 12/31/2023	Superseded

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## Keywords

N/A