March 31, 2022

Stacey V. Brennan, M.D., FAAFP
Medical Director
DME MAC Jurisdiction B National Government Services
8115 Knue Rd.
Indianapolis, IN 46250-1936
Sent via email:

Dear Dr. Brennan,

As a result of evolving standards of care and the level of evidence accumulated over the past 20 years supporting improved health outcomes associated with the use of microprocessor-controlled prosthetic knees (MPK) with integrated stumble recovery in individuals with transfemoral amputation (TFA) or knee disarticulation (KD), Otto Bock Healthcare LP respectfully requests a formal reconsideration of the current Local Coverage Determination (LCD) for Lower Limb Prostheses (L33787). This formal request for reconsideration is submitted on behalf of an underserved subpopulation of Medicare beneficiaries with mobility at the level of limited community ambulators (Medicare Functional Classification Level 2) who could benefit from having access to the treatment option of MPK.

Specifically, we request reconsideration of LCD L33787 with the addition of the following language:

Electronic/microprocessor knees billed with L5828+L5848+L5856 (plus additional codes awarded by PDAC) that have integrated stumble recovery are only covered for beneficiaries whose functional level is K2 when all of the criteria below are met:

1. Beneficiary has a documented history of falls, or documented increased risk of falling, or documented increased fear of falling.
2. Improved stability in stance, provided by an electronic/microprocessor knee with integrated stumble recovery, may provide increased independence with less risk of falls (with or without a mobility aid).
3. Beneficiary is able to make use of a product that requires charging on a regular basis.
4. Beneficiary is able to understand and respond to error alerts and alarms indicating problems with the function of the unit.

However, MPK billed with L5828+L5848+L5856 (plus additional codes awarded by PDAC) should be covered for beneficiaries whose functional level is K2 only when all of the criteria below are met:

1. Microprocessor knee being provided is indicated for K2.
2. Microprocessor knee being provided has integrated stumble recovery. With stumble recovery the knee joint “recognizes” the pattern of movement that accompanies a fall and responds with

immediate high damping. This allows the user's full weight to be placed on the prosthetic leg, preventing the fall in many cases or minimizing the impacts of falling.

3. Microprocessor knee being provided has been demonstrated to benefit individuals with MFCL-2 mobility in reducing falls, reducing the risk of falling, and reducing fear of falling.

In the past 15 years, a significant body of evidence has emerged about MPK with integrated stumble recovery and their clinical benefits in limited community ambulators. We believe this evidence clearly supports the reconsideration of MPK for individuals with TFA or KD and MFCL-2 mobility as reasonable and necessary for this defined patient subpopulation of Medicare beneficiaries. We outline our rationale for reconsideration and initiate a formal request with this letter and the supplemental evidence contained herein.

Contents

1. Statutorily Defined Benefit Category

Lower limb prostheses are covered under the Medicare Artificial Legs, Arms and Eyes benefit (Social Security Act §1861(s)(9)). Microprocessor Knees fall under this benefit category. The Part B Durable Medical Equipment Medicare Administrative Contractors (DME MAC) currently write coverage determinations under the Lower Limb Prostheses LCD (L33787) and they process claims for LL prostheses, which includes Microprocessor Knees.

2. Proposed Language to Be Added to LCD (L33787)

Electronic/microprocessor knees with integrated stumble recovery billed with L5828+L5848+L5856 (+additional codes awarded by PDAC) are only covered for beneficiaries whose functional level is K2 when the beneficiary meets all of the criteria below:

1. Beneficiary has a documented history of falls, or documented increased risk of falling, or documented increased fear of falling.
2. Improved stability in stance, provided by an electronic/microprocessor knee with integrated stumble recovery may provide increased independence with less risk of falls (with or without a mobility aid).
3. Beneficiary is able to make use of a product that requires charging on a regular basis.
4. Beneficiary is able to understand and respond to error alerts and alarms indicating problems with the function of the unit.

3. History of the Implementation of Medicare Functional Classification Levels

In 1995, the DME MAC added the Medicare Functional Classification Levels (MFCL) to the LCD for Lower Limb Prostheses to identify a lower limb amputee's functional potential and/or ability to ambulate to guide selection of prosthetic technology to meet their functional needs. At that time, only mechanically operating, non-microprocessor-controlled prosthetic knee (NMPK) joints were available, which had and still have very limited functionality for activities that require standing, walking, or traversing in multiple directions. NMPK have very limited stance control adjustability, lack stumble recovery, and provide only limited adaptation to variable terrain.

The stability features of most types of NMPK (locked, friction-brake, polycentric, multiaxial knees) mainly aim at locking the knee during stance and, thus, preventing it from collapsing during weight bearing while walking on level ground [1-4]. Although an important component, this is not the only concern of overall prosthesis safety. A locked knee prevents knee collapse during stance under all circumstances, but at the cost of walking with a stiff prosthetic leg, which requires extensive

compensatory mechanisms to ensure sufficient toe clearance. Other types of NMPK, such as friction brake, 4-bar linkage, multiaxial, and fluid (hydraulic) stance control knees offer increasing function and voluntary control, but at the cost of reducing the level of stability during weight bearing. As a result, a higher level of motor control and coordination skills are required of the patient to operate these prosthetic knees safely [1-4]. The result of this inverse relationship is an important rule of thumb: the more stable a NMPK, the less voluntary control and function it supports, and vice versa.

At the time of the implementation of the MFCL, prosthetic knees with non-MP hydraulic swing and stance control were correctly considered too difficult to safely operate for amputees with MFCL-2 mobility. Limited community ambulators generally do not have sufficient motor control and coordination skills to balance instability and actively stabilize a prosthetic knee in critical situations with their residual limb. This left the more stable, but less functional friction brake ("safety"), 4-bar linkage and multiaxial knees as prosthetic stance control options for patients with TFA or KD and MFCL-2 mobility. As these patients were believed to be able to walk with fixed cadence only, friction swing control was considered sufficient for these beneficiaries. Eventually, early research with evolving MPK mainly focused on demonstrating added functional value in community ambulators, resulting in Medicare coverage that limited fluid (hydraulic and pneumatic) knees and MPK to those amputees with the potential to function at MFCL-3 and 4, which remains the criteria for coverage in 2022 (LCD L33787). However, since the implementation of Medicare Functional Classification Levels, MPK technology has evolved to be more suitable to limited community ambulators, and an increasing number of clinical studies have been published providing compelling scientific evidence for the benefits of MPK in this population.

4. Justification: Peer-Reviewed Scientific Evidence to Support Coverage of MPK for Limited Community Ambulators

a. Falls and fall-related injuries are a medical problem in the population of individuals with transfemoral amputation and MFCL-2 mobility

The pivotal study of Miller et al. [5] on the prevalence of falling in a large sample of 435 individuals with lower-limb amputation found that 52% of all subjects reported at least one fall in the previous 12 months. Of the 116 individuals with unilateral TFA/KD, 77 subjects (66%) had reported at least one fall in the prior year. In the logistic regression model for risk factors of falling, having a TFA/KD resulted in an odds ratio of 2.78 (95% confidence interval [CI] 1.71-4.51) [5]. Unfortunately, this study did not report an analysis of fall prevalence and risk factors of falling by MFCL.

A newer study [6] that performed a retrospective medical chart review of 268 individuals with lower-limb amputations (105 with TFA) for falls in the past 12 months included a multivariable regression analysis which found an increased fall risk for people with vascular comorbidities (odds ratio [OR]= 3.46, 95% confidence interval [CI] = 1.40–8.54) and an attenuated fall risk for people with TFA (OR=0.08, 95% CI: 0.01–0.82) and vascular amputations (OR=0.38, 95% CI: 0.15–0.95). Significant relationships existed between age and amputation level (OR=1.06, 95% CI: 1.02–1.11). For example, although people with

vascular amputations were less likely to fall than those with nonvascular amputations, people with concurrent vascular comorbidities were more likely to fall than those without. People with TFA were less likely to fall; however, fall risk increased with each year of age compared with people with transtibial amputations [6]. **These factors that increase the risk of falling are exactly those with high prevalence in the age range of the Medicare population. Interestingly, the MFCL did not have a significant impact on the risk of falling in that study, so individuals with MFCL-2 mobility were about as likely to fall as subjects with MFCL-3 mobility.**

A study analyzing risk factors for fall-related injury among 257 people with lower-limb loss [7] found that 45 subjects (17.5%) reported at least a single fall-related injury. Of the 125 individuals with TFA, 14 (11%) reported fall-related injuries. Most subjects reported two or more falls within the previous 12 months (n=161, 63.1%), were male (n= 77, 68.9%), and were White (n=212, 83.8%). Most falls were associated with gait (44.5%), activities of daily living (ADL, 15.7%), or ramps and/or stairs (12%). The likelihood of fall-related injury was elevated among females versus males (OR=2.90, 95% CI: 1.35-6.24), people of non-White versus White race (OR=4.79, 95% CI: 1.06-21.76), people with vascular amputations due to peripheral artery disease or diabetes versus non-vascular amputations (OR=2.22, 95% CI: 1.04- 4.73) and people with transtibial versus transfemoral amputations (OR=2.32, 95% CI: 1.01-4.89) [7].

These big studies have demonstrated that falling and fall-related injuries are a major medical problem in the population of individuals with lower-limb amputations. Though people with transtibial amputations appear to be at a higher risk of falling and sustaining injuries, individuals with transfemoral amputations have a substantial risk of falling and fall-related injuries as well, especially when they grow older and suffer from vascular comorbidities. These are the typical characteristics of the population of Medicare beneficiaries with TFA or KD.

b. Scientific evidence for the benefits of MPK in the population of individuals with transfemoral amputation and MFCL-2 mobility

A recently published update of a systematic review and meta-analysis of the clinical studies conducted with MPK in limited community ambulators [8] found a substantial expansion of the body of evidence since the first systematic review of that kind had been published in 2014 [1]. The number of pertinent publications included increased from 6 to 15, increasing the number of subjects studied from 57 to 704 and allowing for a meta-analysis of 13 outcome measures that had not been possible in the previous systematic review. The methodological quality and validity of the studies included was rated “high” in 11 publications, “moderate” in 3 publications, and “low” in one publication. In total, the 15 publications had assessed 185 outcome measures. In the domain of safety, 21 of the 36 (58%) outcomes assessed demonstrated statistically significant benefits of MPK over NMPK in individuals with TFA and MFCL-2 mobility, as did 71 of the 107 (66%) performance-based and 24 of the 42 (57%) patient-reported outcome measures. Not a single outcome measure in either domain showed a significant benefit of NMPK in this patient subpopulation [8].

With use of an MPK, significant reductions in falls were found by 5 studies, significant improvements in indicators for the risk of falling in 6 studies, significant improvements in the fear of falling by 5 studies, and significant improvements in patients' perception of safety in 3 studies. The meta-analysis revealed a number of statistically significant effects and benefits of MPK in limited community ambulators with TFA. Seven publications with 117 subjects allowed for the meta-analysis of the number of falls and found a significant reduction with use of MPK compared to NMPK with a standardized mean difference SMD (= effect size) of -0.59 (95% CI: -0.85 to -0.32) and a significant effect in both the fixed and random effects models ($p<0.01$ for both). The lowest reduction in falls found in any of the included studies was 60% [9], whereas the highest reduction in falls found in a study was 80% [10]. These results clearly support the conclusion that MPK significantly reduce falls to a clinically meaningful extent in limited community ambulators [8]. However, it is also important to note that there are differences between the various MPK available in the U.S. market and verified by PDAC today that have been demonstrated by studies in individuals with MFCL-3 mobility. In a large cross-sectional study with chart review of 602 subjects, only the Ottobock C-Leg and the Blatchford Orion resulted in significantly reduced fall-related injuries compared to NMPK, whereas the Freedom Plié and the Össur Rheo Knee did not [11].

The meta-analysis also showed that MPK significantly reduce the risk of falling among individuals with TFA and MFCL-2 mobility. Four studies with a total of 45 subjects allowed for a meta-analysis of the completion times of the Timed-up-and-go test (TUG), whereas 3 studies with a total of 30 participants were included in the meta-analysis of the Activity-specific balance confidence (ABC) scale. Both the TUG and the ABC are validated indicators for the risk of falling in diverse patient populations, including individuals with lower-limb amputations [TUG: Ref. 12-14; ABC: Ref. 15]). The meta-analysis of TUG completion times found a significant reduction and, thus, reduction in the risk of falling with MPK with a standardized mean difference (SMD) of -0.45 (95% CI: -0.97 to -0.02) and a significant effect in both the fixed and random effects models ($p=0.04$ for both). The meta-analysis of the ABC scores found a significant improvement and, thus, reduction in the risk of falling with MPK with a SMD of 7.90 (95% CI: 0.34-15.46) and a significant effect in the fixed effect model ($p=0.04$) [8].

For fear of falling, the meta-analysis included 6 studies with 405 subjects and found a significant reduction with MPK use with a SMD of 1.75 (95% CI: 1.60-1.90) and a significant effect in the fixed effects model ($p<0.01$) and a SMD of 1.20 (95% CI: 0.55-1.85) and a significant effect in the random effects model ($p<0.01$) [8]. Reducing the fear of falling is of great importance to individuals with TFA and MFCL-2 mobility as it often limits the participation in activities and, thus, may result in a vicious cycle of reduced physical activity, leading to physical deconditioning with the result of further increased risk of falling [16, 17].

Significant improvements in performance-based outcomes with an MPK were reported for walking speed on level ground in 5 studies, for slope ambulation in 3 studies, for stair ambulation and uneven terrain mobility in 2 studies each, for ADL performance in one study, and for activity and multitasking ability in one study each. In addition, 5 studies reported significant improvements in functional level from MFCL-2 to MFCL-3. A meta-analysis of 6 studies with 519 participants showed that individuals with MFCL-2 mobility had a significant 51% chance (95% CI: 47-55%) to improve their mobility level to MFCL-3 with use of a MPK. The meta-analysis of 6 studies with 71 individuals found a significant increase in

self-selected walking speed with a MPK with a SMD of 0.47 (95% CI: 0.14-0.81) and significant effects in both the fixed and random effects models (p<0.01) [8].

Significant improvements in patient-reported prosthetic function and mobility when using an MPK were found in 7 studies and for quality of life in one study. Meta-analyses of 4 studies with 78 subjects for the Ambulation domain and of 3 studies with 69 individuals for the Utility domain of the Prosthesis Evaluation Questionnaire (PEQ) demonstrated significant improvements in both domains with MPK use with SMDs of 9.24 (95% CI: 3.77-14.70) in the fixed effect model [p<0.01]) and 9.32 (95% CI: 3.51-15.63 in the random effects model [p<0.01]) for Ambulation and a SMD of 7.76 (95% CI: 2.05-13.47) with significant effects in both the fixed and random effects model with p<0.01 for both for Utility [8].

The authors of the systematic review concluded that the significant effects and benefits of MPK in individuals with TFA and MFCL-2 mobility have a similar magnitude as those seen earlier in clinical studies with subjects with MFCL-3 mobility and may no longer justify to generally withhold MPK technology from limited community ambulators [8].

5. Recommendations of Clinical Guidelines for use of Microprocessor Knees

a. VA/DoD Clinical Practice Guideline for Rehabilitation of Individuals with Lower Limb Amputations

The VA/DoD Clinical Practice Guideline for Rehabilitation of Individuals with Lower Limb Amputations, published in 2017 [18], does not restrict access of individuals with TFA/KD to MPK technology based on their functional level or other physical criteria. Following is the recommendation:

#	Recommendation	Strength*	Category†
	C. 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.	Weak for	Reviewed, New-added

"Discussion

According to two fair quality SRs [systematic reviews], microprocessor knees may reduce risk of falls and maximize patient satisfaction in limited and unlimited community ambulators. *[93,94]* Both reviews reported a decrease in stumble and fall frequency with accommodation and use of a microprocessor knee system relative to a non-microprocessor knee system. *[93,94]* The studies further support the prescription of microprocessor knees over non-microprocessor knees to improve an individual's ability to walk faster on level ground, uneven surfaces, and downhill, thus providing the user with an improved

sense of security and improved overall satisfaction. *[93,94]* The Work Group considered that the benefits to the patients, particularly decreasing risk of falling, far outweigh potential harms. The patient focus group participants also expressed a desire to have access to prosthetic devices that fit well and maximize their safety and function, so patient values and preferences were another important consideration when assessing the strength of the recommendation.

Falling is a major issue in patients with transfemoral amputations. Increased number of falls, fear of falling, as well as deterioration in balance, coordination, and endurance, resulting in activity avoidance, decreased independence and mobility have all been reported in this population. *[93]* Therefore, the prescription of microprocessor knees is supported for ambulatory individuals with complex medical conditions affecting balance, as well as for the geriatric population. These populations benefit from microprocessor knees, which have been demonstrated to decrease stumbles and prevent falls by an SR included in our evidence review *[93]* and two SRs that were excluded because they were superseded by a more recent and comprehensive SR. *[95,96]*

There is insufficient evidence to support using one type of microprocessor knee over another, but the provider should consider the many characteristics of each type of knee when making a selection. Most importantly, the potential impact on the patient's functional level should be considered as there are a variety of microprocessor knee options available. Some knees may be best suited for the limited community ambulator *[93]* while others are more appropriate for the highly active patient. *[72,97,98]* Another consideration when choosing the right microprocessor knee for an individual is the mechanism of charging the knee; some have removable batteries, others have a port for a plug, while others have inductive charging systems. Still another consideration would be the default mode of the device when the power source is depleted. Some knees default to a locked knee while others default to free swing.

Finally, for the active user, additional options include activity modes and waterproof/water resistance features, if appropriate. More research is needed to understand which patient subgroups benefit most from access to microprocessor knee units.

There are inconclusive studies regarding differences in socket design, prosthetic foot categories, as well as advantages and disadvantages of various types of suspensions and interfaces. Each component of a prosthetic prescription should be carefully selected based on the capabilities and anticipated compliance of the user as well as the integrity and shape of the residual limb. Patient desired outcomes, patient goals, and the compatibility of the entire prosthetic system should also be a consideration when prescribing prosthetic components."

Citations from the List of References of the VA/DoD Practice Guideline

72. Highsmith MJ, Kahle JT, Miro RM, et al. Prosthetic interventions for people with transtibial amputation: Systematic review and meta-analysis of high-quality prospective literature and systematic reviews. *J Rehabil Res Dev.* 2016;53(2):157-184.
93. Kannenberg A, Zacharias B, Probsting E. Benefits of microprocessor-controlled prosthetic knees to limited community ambulators: Systematic review. *J Rehabil Res Dev.* 2014;51(10):1469-1496.
94. Samuelsson KA, Toytari O, Salminen AL, Brandt A. Effects of lower limb prosthesis on activity, participation, and quality of life: A systematic review. *Prosthet Orthot Int.* Jun 2012;36(2):145-158.

95. Highsmith MJ, Kahle JT, Bongiorni DR, Sutton BS, Groer S, Kaufman KR. Safety, energy efficiency, and cost efficacy of the C-Leg for transfemoral amputees: A review of the literature. *Prosthet Orthot Int.* Dec 2010;34(4):362-377.

96. Sawers AB, Hafner BJ. Outcomes associated with the use of microprocessor-controlled prosthetic knees among individuals with unilateral transfemoral limb loss: A systematic review. *J Rehabil Res Dev.* 2013;50(3):273-314.

97. Hafner BJ, Willingham LL, Buell NC, Allyn KJ, Smith DG. Evaluation of function, performance, and preference as transfemoral amputees transition from mechanical to microprocessor control of the prosthetic knee. *Arch Phys Med Rehabil.* Feb 2007;88(2):207-217.

98. 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. J Rehabil Res Dev. 2008;45(1):1-14.

b. Lower Limb Prosthetic Workgroup Consensus Document

The Centers for Medicare and Medicaid Services (CMS) assembled a multi-disciplinary Lower Limb Prosthetic Workgroup in 2016 after the public had responded to a Proposed/Draft Local Coverage Determination (LCD): Lower Limb Prostheses (DL33787), released 7/16/2015. The Lower Limb Prosthetic workgroup wrote a consensus statement to "inform Medicare policy regarding best practices for beneficiary access to lower limb prosthetics," and identified evidence gaps [19].

Regarding the use of MPKs in individuals who utilize their prosthesis on the MFCL-2 mobility level, the Lower Limb Prosthetic Workgroup wrote:

"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." In the meantime, the VA/DoD Clinical Practice Guideline for Rehabilitation of Individuals with Lower Limb Amputations [19] and a number of additional publications on MPK use in patients with MFCL-2 mobility [20-24] including the recent systematic review and meta-analysis [8] presented above have become available. These studies have added further undeniable evidence in favor of the use of MPKs in individuals using their prosthesis as limited community ambulators.

Consequently, the Workgroup recommended that if consideration was 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 would have to 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." [19]

However, in its Final Considerations, the Lower Limb Prosthetic Workgroup recommended that "CMS strongly consider opening a National Coverage Determination to consider the use of microprocessor knees in those individuals utilizing their prostheses at the K2 level." [19]

CMS responded that it would "consider opening a National Coverage Determination to evaluate the use of microprocessor knees in those individuals utilizing their prostheses as a limited community ambulator, meaning they utilize the prosthesis in the home and to traverse low level community barriers such as curbs, stairs and uneven surfaces. (These activities are consistent with the K2 level of function defined in the current LCD). CMS welcomes external requests on this topic submitted according to the process described at: https://www.cms.gov/Medicare/Coverage/DeterminationProcess/Downloads/FR08072013.pdf.

6. Microprocessor Prosthetic Knee Technology currently available and PDAC-verified

Based on their technical principles and published evidence for benefits in individuals with TFA and KD, not all MPK currently available in the U.S. market and verified by PDAC for billing of L5856 may be suitable for use in subjects with MFCL-2 mobility [11, 20, 21]. The following table gives an overview on the 6 MPK that have currently been verified by PDAC. Disclaimer: For non-Ottobock MPK, all information listed here is based on publicly accessible resources, such as the peer-reviewed publications, manufacturers´ websites, marketing materials/brochures, and instructions for use (IFU), if accessible.

	Ottobock Kenevo	**Ottobock C-Leg**	**Össur Rheo Knee / Rheo XC**	**Blatchford Orion**	**Freedom Plié by Proteor**	**Freedom Quattro by Proteor**	**Allux Knee by Proteor**	**Daw SLK Multi-Matrix Knee**
PDAC-verified L-codes	L5828, L5845, L5848, L5856	L5828, L5845, L5848, L5856	L5828, L5845, L5848, L5850, L5856, L5925	L5828, L5845, L5848, L5856	L5828, L5845, L5848, L5850, L5856	L5828, L5845, L5848, L5850, L5856, L5925	K1014, L5845, L5848, L5856	L5613, L5845, L5848, L5856
Basic technical principle(s)	Single-axis, linear hydraulic swing and stance control	Single-axis, linear hydraulic swing and stance control	Single-axis, rheo-magnetologic swing and stance control	Single-axis, linear hydraulic swing and stance control	Single-axis, pneumatic swing control, linear hydraulic stance control	Single-axis, linear hydraulic swing and stance control	4-bar linear hydraulic swing control, single-axis linear hydraulic stance control	5-bar (multiaxial) linear hydraulic swing and stance control

	Ottobock Kenevo	Ottobock C-Leg	Össur Rheo Knee / Rheo XC	Blatchford Orion	Freedom Plié by Proteor	Freedom Quattro by Proteor	Allux Knee by Proteor	Daw SLK Multi-Matrix Knee
Manufacturer-designated K-levels/indications	K1, K2	K2, K3, K4	K2, K3, K4* (*Rheo XC only)	K2, K3, K4	K3, K4	K3, K4	K3, K4	K3, K4
Stumble Recovery function	Yes	Yes	Yes	Yes	Yes	Yes	Unknown	Unknown
Functions specifically designed for K2 patients	Yes • Stumble Recovery Plus • Swing release for irregular gait patterns • Sitting down support • Passive standing-up support	No	No	No	No	No	No	No
Peer-reviewed publications on benefits in K3 patients	No	Yes >40 publications	Yes 10 publications	Yes 3 publications	No	No	No	No

	Ottobock Kenevo	Ottobock C-Leg	Össur Rheo Knee / Rheo XC	Blatchford Orion	Freedom Plié by Proteor	Freedom Quattro by Proteor	Allux Knee by Proteor	Daw SLK Multi-Matrix Knee
Proven significant reduction in falls in K3 patients	No	Yes	No	Yes	No	No	No	No
Proven significant reduction in fall-related injuries in K3 patients	No	Yes	No	Yes	No	No	No	No
Peer-reviewed publications on benefits in K2 patients	Yes 4 publications	Yes 11 publications	Yes 1 publication, but no specific results for Rheo (aggregated results for 4 MPK only)	Yes 1 publication, but no specific results for Orion (aggregated results for 4 MPK only)	Yes 1 publication, but no specific results for Plié (aggregated results for 4 MPK only)	No	No	No
Proven significant reduction in falls in K2 patients	Yes	Yes	Yes but no specific results for Rheo (aggregated results for 4 MPK only)	Yes but no specific results for Orion (aggregated results for 4 MPK only)	Yes but no specific results for Plié (aggregated results for 4 MPK only)	No	No	No

	Ottobock Kenevo	Ottobock C-Leg	Össur Rheo Knee / Rheo XC	Blatchford Orion	Freedom Plié by Proteor	Freedom Quattro by Proteor	Allux Knee by Proteor	Daw SLK Multi-Matrix Knee
Proven significant reduction in the risk of falling in K2 patients	Yes	Yes	No	No	No	No	No	No
Proven significant reduction in the fear of falling in K2 patients	Yes	Yes	No	No	No	No	No	No

7. Target Medicare Population

Based on published evidence for the frequency of falls [5-7], fall-related injuries [6], risk of falling [12-15], and fear of falling [5, 16, 17], which are often combined, we estimate that up to 50% of the Medicare beneficiaries with TFA/KD and MFCL-2 mobility may demonstrate the medical necessity for MPK fitting.

8. Determining if MFCL-2 Beneficiary is a Candidate for MPK

Risk of falling may be assessed with the performance-based TUG and/or the patient-reported ABC scale. A large study established an increased risk of falling for TUG completion times ≥19 seconds in transtibial amputees [11]. A number of other studies could not confirm this threshold, but their samples had a high share of individuals with MFCL-3 mobility for whom the TUG is not physically challenging enough and thus, insensitive. However, for Medicare beneficiaries with TFA/KD and MFCL-2 mobility, the TUG appears to be an appropriate test and may indicate an increased risk of falling when the subject needs ≥19 seconds to complete [12].

The ABC scale [12-15] inquires the patient´s self-assessed balance confidence during 16 activities of daily living using either 0-100 numerical analogue scale in increments of 10 units [12-15] or a 5-point Likert scale [29]. On the 100-point scale, scores <67 (<3.35 on the 5-point scale) indicate an increased risk of falling [12-15, 27-29].

Fear of falling may be assessed with the FES-I that inquires how concerned the patient is that he/she might fall during 16 activities of daily living on a 4-point Likert scale. In older adults, low concern with falls is indicated by scores 16-19, moderate concern with falls by scores 20-27, and high concern with falls by scores 28-64 [30]. High concern with falls may result in activity avoidance and, thus, deconditioning [16, 17].

9. Which Microprocessor Knees Should Be Covered for Individuals with MFCL-2 Mobility?

Due to technical and functional differences between the various MPK available in the U.S. market, MPK billed with L5828+L5848+L5856 (plus additional codes awarded by PDAC) should be covered for beneficiaries whose functional level is K2 only when all of the criteria below are met:

1. Microprocessor knee being provided is indicated for K2.
2. Microprocessor knee being provided has integrated stumble recovery. With stumble recovery the knee joint “recognizes” the pattern of movement that accompanies a fall and responds with immediate high damping. This allows the user's full weight to be placed on the prosthetic leg, preventing the fall in many cases or minimizing the impacts of falling.

3. Microprocessor knee being provided has been demonstrated to benefit individuals with MFCL-2 mobility in reducing falls, risk of falling, and fear of falling.

PDAC may be assigned the evaluation of these qualifying criteria for MPK for individuals with MFCL-2 mobility.

10. Is this item or services intended for use by health care providers or beneficiaries?

For this formal request, the intended use of an MPK is for Medicare beneficiaries with TFA or KD who are limited community ambulators (MFCL-2).

11. Private Payer Coverage of Microprocessor Knees for Limited Community Ambulators

The following are guidelines from the Veterans Health Administration Prosthetic Clinical Management Program Clinical Practice Recommendations for Microprocessor Knees (Berry 2000). This Patient Selection Criteria is contained in 19 commercial payer policies:

PATIENT SELECTION AND IDENTIFICATION

Indications for use of the microprocessor knee should include:

- Adequate cardiovascular and pulmonary reserve to ambulate at variable cadence.
- Adequate strength and balance in stride to activate the knee unit.
- Should not exceed the weight or height restrictions of the device.
- Adequate cognitive ability to master technology and gait requirements of device.
- Hemipelvectomy through knee-disarticulation level of amputation, including bilateral; lower extremity amputees are candidates if they meet functional criteria as listed.
- Patient is an active walker and requires a device that reduces energy consumption to permit longer distances with less fatigue.
- Daily activities or job tasks that do not permit full focus of concentration on knee control and stability—such as uneven terrain, ramps, curbs, stairs, repetitive lifting, and/or carrying.
- **Medicare Level K 2—limited community ambulator, but only if improved stability in stance permits increased independence, less risk of falls, and potential to advance to a less restrictive walking device, and patient has cardiovascular reserve, strength, and balance to use the prosthesis. *The microprocessor enables fine-tuning and adjustment of the hydraulic mechanism to accommodate the unique motor skills and demands of the functional level K2 ambulator.***
- Medicare Level K 3—unlimited community ambulator.
- Medicare Level K 4—active adult, athlete who has the need to function as a K 3 level in daily activities.

- Potential to lessen back pain by providing more secure stance control, using less muscle control to keep knee stable.
- Potential to unload and decrease stress on remaining limb.
- Potential to return to an active lifestyle.

The following payers have the above VA Selection Criteria in their policy and may cover a microprocessor knee (L5856) for functional level K2 if improved stability in stance permits increased independence, less risk of falls, and potential to advance to a less restrictive walking device, and patient has cardiovascular reserve, strength, and balance to use the prosthesis. *The microprocessor enables fine-tuning and adjustment of the hydraulic mechanism to accommodate the unique motor skills and demands of the functional level K2 ambulator.*

Insurance Company	**Policy Title**	**Policy Number**	**Applies to non-Medicare plans**
Arkansas BCBS	Microprocessor-Controlled Prostheses for the Lower Limb	C2006011 22 36 C2006011	Arkansas BlueCross BlueShield Arkansas Blue Advantage Arkansas Blue Advantage – Walmart Arkansas Health Advantage
BCBSA	Microprocessor-Controlled Prostheses for the Lower Limb	1.04.05	BCBS Licensees can subscribe to use BCBSA policies.
BCBS Federal Employee Program	Microprocessor-Controlled Prostheses for the Lower Limb	FEP 1.04.05	Federal Employee Program nationwide
California BS	Microprocessor-Controlled Prostheses for the Lower Limb	1.04.05	Blue Shield of California
Health Care Service Corporation (HCSC)	Microprocessor-Controlled Prostheses for the Lower Limb	DME104.012	BlueCross BlueShield of Illinois BlueCross BlueShield of Montana BlueCross BlueShield of New Mexico BlueCross BlueShield of Oklahoma BlueCross BlueShield of Texas
Idaho BCBS	Microprocessor-Controlled Prostheses for the Lower Limb	MP 1.04.05	Blue Cross of Idaho
Kansas BCBS	Microprocessor-Controlled Prostheses for the Lower Limb		BlueCross BlueShield of Kansas
Louisiana BCBS	Microprocessor-Controlled Prostheses for the Lower Limb	00426	Blue Cross and Blue Shield of Louisiana HMO Louisiana, Inc.
Massachusetts BCBS	Microprocessor-Controlled Prostheses for the Lower Limb	133 BCBSA Reference Number: 1.04.05	Blue Cross and Blue Shield of Massachusetts Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc
Michigan BCBS	Microprocessor-Controlled Prostheses for the Lower Limb		Blue Cross Blue Shield BlueCare Network of Michigan

Insurance Company	Policy Title	Policy Number	Applies to non-Medicare plans
Mississippi BCBS	Microprocessor-Controlled Prostheses for the Lower Limb	A.1.04.05	BlueCross BlueShield of Mississippi
Missouri, Kansas City BCBS	Microprocessor-Controlled Prostheses for the Lower Limb	1.04.05	Blue Cross and Blue Shield of Kansas City (Blue KC)
North Carolina BCBS	Microprocessor-Controlled Prostheses for the Lower Limb		BlueCross BlueShield of North Carolina (Corporate Medical Policy)
Nebraska Blue	Microprocessor-Controlled Prostheses for the Lower Limb	VII.65	Blue Cross and Blue Shield of Nebraska
NJ Horizon BCBS	Microprocessor-Controlled Prostheses for the Lower Limb	031	Horizon BlueCross Blue Sheild of New Jersey
Premera Blue Cross	Microprocessor-Controlled Prostheses for the Lower Limb	1.04.503	Premera Blue Cross WA & Alaska (Includes Lifewise HealthPlan of WA & OR)
Regence BCBS	Powered and Microprocessor-Controlled Knee and Ankle-Foot Prostheses and Microprocessor-Controlled Knee-Ankle-Foot Orthoses	81	Cambia HealthPlan (includes Regence BlueShield Idaho, Regence BlueCross Oregon, Regence BlueCross Blue Shield Utah, Regence Blue Shield Washington; Asuris Northwest Health; BridgeSpan Health; and LifeMap)
South Carolina BCBS	Microprocessor-Controlled Prostheses for the Lower Limb	CAM 10405	BlueCross BlueSheild of South Carolina, BlueChoice HealthPlan of South Carolina
Vermont BCBS	DME Orthotics and Prosthetics	1.03.VT206 (uses BCBSA 1.04.05 for MPC)	BlueCross BlueSheild of Vermont
Wyoming BCBS	Microprocessor-Controlled Prostheses for the Lower Limb	1.04.05.01	BlueCross BlueShield of Wyoming, Blue Select of Wyoming

Additional Payers that may cover a microprocessor knee (L5856) for functional level K2

Insurance Company	Policy Title	Policy Number	
Harvard Pilgrim HealthPlan	Lower Limb Prosthesis		Allows MPK for beneficiaries with Level 2-4 rehabilitation potential and K1 on a case by case basis
Rhode Island BCBS	Orthotics and Prosthetics		Prosthetics are mandated
Select Health	COMPUTERIZED MICROPROCESSOR-CONTROLLED KNEE PROSTHESES	233	K-Level not specified. Patient must meet criteria.
Tennessee BCBS	Microprocessor-Controlled Prostheses for the Lower Limb		K-Level not specified. Patient must meet criteria.
WA State HealthTechnology Clinical Committee (HTTC) includes WA L&I, Uniform Medical, WA Medicaid, & Seattle VA	Coverage of Conditions and Treatments (Coverage Decisions)		The MCP knee permits a worker to return to work or be considered employable because use of the knee is expected to advance the worker to a K3 functional level, OR there is a documented safety concern that will be addressed by using a MCP knee, such as high risk for falls (e.g., has had documented falls using an advanced swing and stance phase control hydraulic knee unit, or has documented medical comorbidities that impact balance).

12. Summary

Falls and fall-related injuries, risk of falling, and fear of falling are major medical problems in the population of individuals with TFA/KD, especially in Medicare-aged older subjects who utilize their prosthesis as limited community ambulators (MFCL-2) [5-7].

MPK are currently covered for Medicare beneficiaries with the potential or ability to function as a community ambulator (MFCL-3/-4) under the current Lower-Limb Prosthesis LCD 33787.

A recently published systematic review and meta-analysis of 15 studies with a total of 704 participants [8] has confirmed the benefits of MPK with integrated stumble recovery billed with L5828+L5848+L5856 (plus additional L-codes as awarded by PDAC) in Medicare-aged subjects with MFCL-2 mobility, including those whose amputations were of vascular etiology, in:

- significant reduction in falls [1, 8-10, 24, 25, 32]
- significant improvement in indicators for the risk of falling [1, 8, 9, 23, 31, 32]
- significant improvement in the fear of falling [8, 9, 10, 22, 26, 33]

However, in lieu of the features of the MPK used in the clinical trials with individuals with MFCL-2 mobility, we request coverage be limited to MPK with integrated stumble recovery that are indicated for use in individuals with MFCL-2 mobility and have been demonstrated to benefit such individuals in reduced falls, risk of falling, and fear of falling in clinical trials published in peer-reviewed medical journals.

With Medicare´s public vision of fostering new technologies, we would like to support that vision to deliver this prosthetic technology to a group of Medicare beneficiaries currently excluded by the respective LCD. Ottobock continues to invest, research and study new alternatives to older technology that provide better results and value to all those with limb loss in Medicare and the overall population.

Thank you for your consideration.

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