ottobock.

Kenevo.

Reimbursement Guide.

Product Information.

Kenevo is appropriate for:

- (K2) Limited Community Ambulators and (Low K3) Full Community Ambulators who walk with speeds of up to 1.9 mph
- Amputees with a history of falls and fall-related injuries or increased risk of falling established with validated outcome measures, such as TUG, FSST, or ABC scale.
- Amputees that require a high level of safety while walking and standing
- Amputees that require a high degree of support while sitting down and standing up

[1]HCPCS Coding (U.S. only).

The following codes are PDAC verified for *Kenevo*:

L5828	Hydraulic Swing and Stance Phase Knee (base mechanical knee code)
L5845	Stance flexion feature
L5848	Stance extension damping feature
L5850	Knee extension assist
L5856	Microprocessor control feature, swing and stance phase, includes sensors
L5925	Above knee manual lock

Warranty.

Kenevo comes with a three-year manufacturer warranty (extendable to six years) which includes a complimentary condition-based service inspection within the 3-year term. During the warranty period, repair costs are covered except for those associated with damage resulting from improper use.

FDA Status.

Under FDA's regulations, the *Kenevo* Microprocessor-Controlled Prosthetic Knee is a Class I device, exempt from the premarket notification [510(k)] requirements. The *Kenevo* prosthetic knee has met all applicable control requirements which include Establishment Registration (21CFR 807), Medical Device Listing (21 CFR part 807), Quality System Regulation (21CFR part820), Labeling (21CFR part 801), and Medical Device Reporting (21 CFR Part 803). The *Kenevo* prosthetic knee is listed under JOINT, KNEE, EXTERNAL LIMB COMPONENT; Listing Number is E253231, and Manufacturer Registration Number is 3005190268.

Health Canada Compliance.

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

Who Can Provide a *Kenevo*?

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

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

Kenevo Justification.

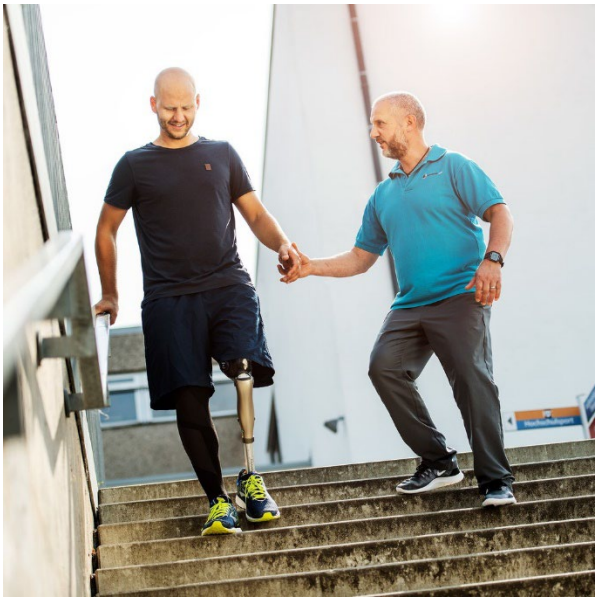
Microprocessor Swing and Stance Phase Control (L5856).

Microprocessor Stance Phase Control:

Kenevo is a default stance knee, which means that it always has high stance flexion resistance to support the body weight until stance is disengaged. Its microprocessor stance control monitors each step to reliably detect the safest moment to release swing. This ensures safe body weight support even for the highly variable gait patterns of patients with low mobility and walking aid use.

Microprocessor Controlled Swing Phase "Stumble Recovery Plus"

The microprocessor swing control of the *Kenevo* provides an enhanced stumble recovery feature. Stumble Recovery Plus allows for increased stance flexion resistance and therefore, more support from the *Kenevo* hydraulic unit if a stumble is detected while the knee is actively flexing or extending during swing phase. Like the C-Leg microprocessor knee, the hydraulic of the *Kenevo* employs two motorized valves that operate independent of one another allowing for smooth dampened swing phase flexion and extension. The flexion valve is prepared with increased resistance to limit falls and provide support for the user's body weight if a stumble or any interruptions of swing occurs. In addition, swing release is based on the loading profile of each step and activated later than in microprocessor knees designed for higher-functioning individuals. This is because limited community ambulators usually walk slower, with more irregular gait (bigger variations from step-to-step), shuffling steps, or with additional walking aids such as crutches or a walker that result in reduced loading of the prosthesis. This function delivers much needed stability during late stance and ensures that swing is released consistently while providing sufficient toe clearance on every step.



Hydraulic Swing and Stance (L5828).

Hydraulic Stance Control

Hydraulic stance control provides resistance against knee flexion to support the body weight of the patient and prevent knee collapse. Knee flexion during weight- bearing is damped and controlled, mimicking the eccentric contraction of the quadriceps muscle during gait, to provide for shock absorption during level walking to minimize hip and low-back stress. It also enables step-over-step slope and stair descent and uneven terrain ambulation, allowing patients to "ride" the knee when descending stairs and slopes.

Hydraulic Swing Control

The hydraulic swing phase control of *Kenevo* accommodates walking speeds of up to 3 km/h (1.9 mph). It also provides for terminal swing extension damping that prevents a hard terminal impact that would be hard to control for the patient by decelerating the prosthetic shank prior to heel strike. This mimics the eccentric contraction of the anatomical hamstrings and gluteus maximus muscle. Full extension is then reached smoothly in preparation for heel strike.

Hydraulic Stance Flexion (L5845).

Knee flexion during stance, i.e., during weight bearing, is important for level-walking as well as for the negotiation of uneven terrain, slopes, and stairs. Non-amputated subjects control knee stance flexion with their muscles, specifically with the quadriceps muscle, and walk with a knee stance flexion of 15-25° on level ground. Individuals with an above-knee amputation can be fit with a prosthetic knee joint that allows for stance flexion during loading to improve shock absorption and relief of the hip and lumbar spine.

Hydraulic Stance Extension Damping (L5848).

After the knee is flexed during stance phase (stance flexion), it needs to extend again to advance the body forward through mid-stance. This feature provides a smooth extension of knee. Without this function, the patient would feel a pronounced “snap back” or “jerk” at the knee and would also present with an unnatural looking gait pattern. Energy is conserved by having this feature, as the patient will not have to attempt to control this motion with residual limb muscles.

Supported Safe Stand-to-Sit.

The *Kenevo* automatically detects when your K2 patient begins to sit down, adjusting the hydraulic resistance so the knee joint provides progressive support during sitting. This allows the amputee to shift the body weight to both legs and complete the sit-down motion in a smooth and controlled manner and at a controlled rate.

Once the amputee is seated, if the knee is still extended, *Kenevo* will relax into a seated position and will switch to energy-saving mode. Benefits include:

- Supports safety and balance during sitting down.
- Automatic unlock allows for hands-free operation without the need to unload the prosthesis, which is especially important for those who use walking aids such as canes or walkers.
- Relieves the contralateral side and increases the area of support by shifting load to both legs.

Supported Safe Sit-to-Stand.

The *Kenevo* also automatically detects when the patient begins to stand up.

If the patient pauses during the standing-up motion, the knee will not collapse as long as the patient has made it at least halfway (prosthesis has reached at least 45° flexion), which allows the patient to rest on the prosthesis and reposition their weight to the sound limb if standing up in a single motion is too tiring.

The knee switches automatically to Supported Stand-to-sit function if the patient tends to fall backward.

Inertial Motion Unit (IMU) Control.

Backward Steps

This patented microprocessor control technology provides safety and stability when your K2 patient is forced to step backwards (such as when opening a door). Many microprocessor knees do not accommodate backward stepping, which may cause the knee to collapse if a backward step is taken.

Intuitive Standing

Maintaining safety and balance while standing is critical for K2 patients. *Kenevo* allows the patient to intuitively stand on a flexed and stable knee when on level, uneven, or inclined surfaces (e.g. ramps and hills).

Contrast this to traditional K2 prosthetic knees, which require the user to extend the hip to stabilize the knee or cognitively ensure that their center of mass stays ahead of their knee axis to prevent unexpected buckling of the prosthetic knee.

Unlike mechanical knees, *Kenevo* offers clinicians a range of programmable stance stability options that can be customized to support each patient's individual capabilities.

Knee Extension Assist.

The knee extension assist is used in promoting knee extension at the beginning of swing phase extension. This function allows the user to walk more efficiently at variable cadence since the spring extension assist mechanically limits the knee flexion at the end range and begins to bring the knee into extension for a more symmetrical gait at faster walking speeds. It also ensures the knee comes to full extension for the beginning of stance phase for a more secure loading condition during level walking but in particular when descending stairs where full extension facilitates the positioning of the foot on the edge of a stair.

Manual Lock

The manual lock allows the patient to manually lock the knee at full extension. The user can manually lock and unlock the knee joint by tapping the patella area of the knee three times with their hand while in a standing position which activates the manual locking switch. This function can be used in situations where an enhanced feeling of safety from the manual lock is required while walking or standing.

Evidence Essentials
Kenevo/Microprocessor Knees for K2

	Mobility need or deficit of the patient	Evidence for benefits of Kenevo/MPK vs. NMPK in K2 patients
Safety	Patient stumbles and/or falls repeatedly Patient avoids activities due to fear of falling Patient sustained fall-related injuries	- **Significant reduction in falls of up to 80%** (Hahn et al., 2021; Davie-Smith et al., 2021; Kaufman et al., 2018; Mileusnic et al., 2017; Wong et al., 2015; Hahn et al., 2015; Kannenberg et al., 2014; Hafner et al., 2009; Kahle et al., 2008) - **Significant reduction in fear of falling** (Hahn et al., 2021; Jayaraman et al., 2021; Mileusnic et al., 2017; Wong et al., 2015; Hahn et al., 2015) - **Significant reduction in the frequency of stumbles** (Mileusnic et al., 2017; Kannenberg et al., 2014; Hafner et al., 2009) - **Significant improvements in balance and indicators for the risk of falling, such as Timed-up-and-go-test, ABC scale, PEQ Addendum; Modified Falls Efficacy Scale, etc.** (Hahn et al., 2021; Davie-Smith et al., 2021; Jayaraman et al., 2021; Lansade et al., 2018; Hahn et al., 2016; Wong et al., 2015; Kannenberg et al., 2014; Burnfield et al., 2012; Hafner et al., 2007 and 2009)
Mobility	Patient has difficulty negotiating slopes/hills	- **Significant improvement in quality of slope descent towards more natural gait pattern** (Kannenberg et al., 2014; Burnfield et al., 2012; Hafner et al., 2009) - **Significant increase in downhill walking speed of up to 36%** (Kannenberg et al., 2014; Burnfield et al., 2012; Hafner et al., 2009) - **Significant improvement in patient-reported slope ambulation** (Hahn et al., 2016)
Mobility	Patient has difficulty negotiating uneven terrain and obstacles	- **Significant increase in walking speed on uneven terrain and obstacle courses of up to 20%** (Kannenberg et al., 2014; Hafner et al., 2009; Kahle et al., 2008) - **Significant improvement in patient-reported uneven terrain and obstacle negotiation** (Hahn et al., 2016)
Mobility	Patient has difficulty descending stairs with reciprocal (step-over-step) gait	- **Significant improvement in quality of stair descent towards more natural gait pattern** (Kannenberg et al., 2014; Hafner et al., 2009; Kahle et al., 2008;) - **Significant improvement in patient-reported stair ambulation** (Hahn et al., 2016)
Mobility	Patient has difficulty with dual tasking while walking with the prosthesis	- **Significantly improved capacity and performance in executing a concurrent task while walking with the prosthesis** (Mileusnic et al., 2017; Hahn et al., 2016; Hahn et al., 2015; Kannenberg et al., 2014; Hafner et al., 2009)

Mobility	Patient has difficulty with performing activities of daily living	- **Significantly improved performance in the execution of various activities of daily living** (Kannenberg et al., 2014; Theeven et al., 2011 and 2012) - **Significant improvement in PRQ Ambulation and PEQ Utility** (Hahn et al., 2021) - **Almost significant (p=0.056) but clinically meaningful improvement in patient-reported mobility (PLUS-M)** (Davie-Smith et al., 2021)
Mobility	Patient is limited in his/her mobility Patient uses a wheelchair and a prosthesis	- **Significant increase in over-ground walking speed of up to 25%** (Hahn et al., 2021; Davie-Smith et al., 2021; Jayaraman et al., 2021; Eberly et al., 2014; Kannenberg et al., 2014; Kahle et al., 2008) - **Significant improvement in distance walked in the 2-minute walk test** (Davie-Smith et al., 2021) - **Significant reduction in additional use of a wheelchair from 87% to 37% of subjects** (Mileusnic et al., 2017) - **Patients spent significantly more time active and significantly less time sitting** (Kaufman et al., 2018) - **About 50% of K2 patients are able to improve their overall mobility level to K3** (Hahn et al., 2021; Hahn et al., 2016; Hahn et al., 2015; Kannenberg et al., 2014; Hafner et al. 2009; Kahle et al., 2008)
Quality of life	Patient has reduced quality of life	- **Significant improvement in health-related quality of life** (Davie-Smith et al., 2021)

References

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

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. Prosth Orthot Int 2021;45(3):198-204.

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

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. Disabil Rehabil 2021 Oct 25:1-19.

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

Hafner BJ, Smith DG. Differences in function and safety between Medicare Functional Classification Level-2 and -3 transfemoral amputees and influence of prosthetic knee joint control. J Rehabil Res Dev 2009;46(3):417-434.

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. J Neuroeng Rehabil. 2021;18(1):88.

Kahle JT, Highsmith MJ, Hubbard SL. Comparison of Non-microprocessor Knee Mechanism versus C-Leg on Prosthesis Evaluation Questionnaire, Stumbles, Falls, Walking Tests, Stair Descent, and Knee Preference; J Rehabil Res Dev 2008;45(1):1-14.
Kannenberg A, Zacharias B, Pröbsting E: Benefits of microprocessor prosthetic knees to limited community ambulators: A systematic review. J Rehabil Res Dev 2014;51(10):1469-1495.

Kaufman KR, Bernhardt KA, Symms K. Functional assessment and satisfaction of transfemoral amputees with mobility (FASTK2): A clinical trial of microprocessor-controlled vs. non-microprocessor-controlled knees. Clin Biomech (Bristol, Avon) 2018 Oct;58:116-122.

Mileusnic M, Hahn A, Reiter S. Effects of a novel microprocessor-controlled knee, Kenevo, on the safety, mobility, and satisfaction of lower-activity patients with transfemoral amputation. J Prosthet Orthot 2017;29(4):198-205.

Lansade C, Vicaut E, Paysant J, Ménager D, Cristina MC, Braatz F, Domayer S, Pérennou D, Chiesa G. Mobility and safety with a microprocessor-controlled knee in moderately active amputees: A multi-centric randomized crossover trial. Ann Phys Rehabil Med 2018;61(5):278-285.

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

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

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

Ottobock North America, Reimbursement
P 800 328 4058 F 800 230 3962
US: https://shop.ottobock.us
CA: https://shop.ottobock.ca
reimbursement911@ottobock.com