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Kenevo.
Reimbursement Guide

January 2024

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 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 Healthcare Common Procedure Coding System (HCPCS) for prosthetics is an add-on code system. Rather than issuing new HCPCS Level II national codes to describe the various microprocessor knees that came to market, the Alpha-Numeric HCPCS Panel instead issued add-on codes (L5856, L5857, L5858 and L5859) to upgrade the mechanical (non-microprocessor) knee codes.

The following codes are PDAC verified for *Kenevo*, effective 12/24/2020:

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

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 damages resulting from improper use.

Health Canada Compliance.

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

FDA Status.

Under FDA's regulations, the *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.

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.

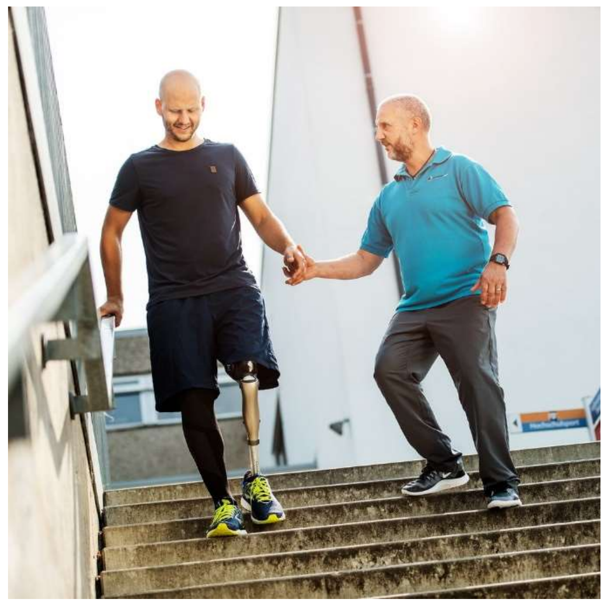
Microprocessor Swing and Stance Phase Control (L5856).

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 half way (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.

Kenevo Evidence Summary.

		Mobility need or deficit of the patient	Proven benefits of MPK/*Kenevo* in K2 patients
Safety	1.	Patient often stumbles and/or falls	MPK have been demonstrated to significantly reduce falls by up to 80%, significantly improve indicators for the risk of falling, and to reduce the frequency of stumbles.
Safety	2.	Patient avoids activities of daily living due to safety concerns and lack of balance and/or balance confidence	MPK/*Kenevo* have been shown to improve the risk of falling, balance, and balance confidence. This may result in the patient doing more activities with the prosthesis.
Slope negotiation	3.	Patient has to ambulate on slopes/hills on a regular basis and struggles with slope descent and/or has to descend slopes and hills faster.	MPK have been shown to improve slope and hill negotiation with a more natural gait pattern and to significantly improve downhill walking speed.
Stair negotiation	4.	Patient has to ambulate on stairs on a regular basis and struggles with stair descent, needs to descent stairs faster.	MPK have been demonstrated to significantly improve the quality of stair descent. This is an indicator of improved balance confidence and allows for descending stairs much faster.
Negotiation of uneven terrain /obstacles in the walkway	5.	Patient has to ambulate on uneven terrain and/or clear obstacles in the walkway on a regular basis and struggles to do so and/or has to ambulate faster (e.g., for chasing kids).	MPK have been shown to have superior safety and allows for significantly walking faster on uneven terrain and obstacle courses.
Cognitive demand/multi-tasking during walking	6.	Patient has to do concurrent activities while walking with the prosthesis on a regular basis and struggles with these activities (e.g., needs to stop walking or walk slower)	MPK have been demonstrated to increase multitasking capacities and cognitive burden while walking with the prosthesis.
Overall mobility	7.	Patient is a limited community ambulator (MFCL-2, K2)	MPK have been shown to reduce uncontrolled falls by up to 80%; improve validated indicators of the risk of falling; increase walking speed on level ground by 14-25%, on uneven terrain by up to 20%, and slope descent by 30%; and improve stair negotiation. About 50% of K2 patients in the studies were able to improve their mobility to K3. *Kenevo* has been found to reduce additional wheelchair use from 87% to 37%.

Safety: Reduced stumbles and falls.

Several clinical and biomechanical studies have investigated the safety of prosthesis use as well as balance and balance confidence of individuals with patients with Medicare Functional Classification Level 2 (MFCL-2, K2, limited community ambulator) while walking with a prosthesis. A systematic review (1) analysed a total of six studies of sufficient methodological quality that compared the safety of microprocessor controlled prosthetic knees (MPK) with that of non-MP controlled prosthetic knees (non-MPK) in subjects with MFCL-2 mobility. Hafner et al. (2) and Kahle et al. (3) observed persons with a transfemoral amputation transitioning from a non-MPK to a *C-Leg* prosthesis to collect data on stumbles and falls. Hafner et al. (2) found a significant 80% reduction in the number of uncontrolled falls (p<.01) and a significant reduction in the frequency of stumbles (p<.05). Kahle et al. (3) reported a statistically significant 57% reduction in stumbles (p=0.006) and a significant 64% reduction in falls (p=.03) in their mixed sample of subjects with MFCL-2 and -3 mobility. A systematic review that analysed only the subgroup of this study with MFCL-2 mobility found a significant 80% reduction in falls (p<.05) in this patient subgroup (1). The significant reduction in falls was recently confirmed by a study of Kaufman et al. (4) that enrolled 50 patients with MFCL-2 mobility who were randomized to transition from their customary non-MPK to one out of four different MPK (p=.01). Burnfield et al. (5) and Lansade et al. (6) studied the effect of using MP stance control knees, the Ottobock *Compact* (5) or *Kenevo* (6), respectively, on validated indicators of the risk of falling in individuals with MFCL-2 mobility. Compared to non-MPKs, the use of the *Compact* significantly improved the average time to complete the Timed-up-and-go-test (TUG) by 28% from 24.5 sec to 17.7 sec (p=.018) (5). In the study with 27 subjects using the *Kenevo*, the median time required to complete the TUG was significantly reduced from 21.4 sec to 17.9 sec (p=.001) (6). Thus, in both studies, the TUG time decreased well below the established threshold of 19 sec that indicates an increased risk of multiple falls in below-knee amputees when using a MP stance control knee (7).

Safety: Improved balance and balance confidence.

Balance and balance confidence with the prosthesis are related to and/or associated with falling, fear of falling, and activity avoidance in persons with an above-knee amputation (8-14). Burnfield et al. assessed balance confidence in subjects with MFCL-2 mobility with the validated Activity-specific balance confidence (ABC) scale that improved significantly from 60.1 to 75.7 (p=.001) when using the MP stance control knee *Compact* as compared to non-MPKs (5). Scores below 67 indicate an increased risk of falling (8-10) and are associated with fear of falling and avoidance of activities (8, 15, 16). Kaufman et al., in their study that had enrolled 50 subjects with MFCL-2 mobility, saw a significant increase in median activity per day (p=.02) and spent significantly less time sitting (p=.01) when using a MPK, indicating an improved confidence in the prosthesis (4). This is supported by the findings of Theeven et al. (17) who found significantly improved performance in activities of daily living (ADL) and community ambulation in their study with 30 individuals with MFCL-2 mobility when using a MPK compared to their customary non-MPK. The biggest improvements were seen in activities that were performed with the arms and hands but required good lower body stability to execute (17). Likewise, Lansade et al. demonstrated a significant improvement in ADL performance assessed with the Locomotor Capabilities Index (LCI-5) in their study with 27 patients with MFCL-2 mobility using *Kenevo* as compared to non-MPKs (6). Similarly, Hafner et al. found a significantly increased multi-tasking ability (p=.04) of individuals with MFCL-2 mobility while walking with the *C-Leg*, indicating an improved confidence in the prosthesis (2). An observational study with 29 subjects assessing *Kenevo* as compared to NMPK typically prescribed and fit in patients with MFCL-2 mobility found that the percentage of participants who experienced no falls at all within 8 weeks increased from 45% to 72% (n.s.), the percentage of subjects who experienced no stumbles at all increased from 8% to 50% (p=.044), and 50% of individuals reported a reduction in the fear of falling when using the *Kenevo* (18).

Summarizing all studies with individuals with MFCL-2 mobility that had investigated the safety of MPKs compared to non-MPKs, a systematic review of the literature (1) and two more recent bigger clinical studies (4, 6) have concluded that MPK significantly reduced falls and significantly improved indicators for the risk of falling as well as balance and balance confidence.

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Improved slope descent.

Ambulation on sloped terrain such as ramps and hills is associated with increased potential for slipping, loss of balance, and falling. Among the many causes for this is the fact that ramp and slope walking requires changes in the range of motion and strength compared to traditional stepping patterns used to traverse flat ground (2, 6). Able-bodied people use reciprocal (step-over-step) slope and hill descent, in which the supporting leg lowers the whole body down using knee flexion controlled by an eccentric contraction of the quadriceps muscle while the swinging leg swings and lands past the supporting leg. Usually, the step length is even between both legs. In above-knee amputees, most non-microprocessor controlled prosthetic knee mechanisms do not allow for any or enough knee flexion during weight-bearing to lower the body with the supporting prosthetic leg or are too difficult to control for most patients to do so safely (2, 7). That's why above-knee amputees usually use a step-to or even a side-step pattern to descend slopes and hills. In the step-to pattern, the supporting sound leg lowers the body using knee flexion controlled by an eccentric contraction of the quadriceps while the prosthetic leg swings and lands past the sound leg. Then the sound leg is positioned next to the prosthetic leg to become the supporting leg again for lowering the body down for the next step with the prosthetic limb (5, 6).

The side-step pattern is similar to the step-to pattern, but in addition the patient turns the whole body to one side to descend the slope not with a straight but oblique step-to pattern to further reduce the downhill-slope force to be controlled (3, 4, 6). Both patterns allow for only slow slope and hill descent, with the side-step pattern being even slower than the straight step-to pattern and expose the patient as a disabled person to the public. In subjects with MFCL-2 mobility, MPK have been shown to significantly reduce falls by up to 80% ($p<.05$ to .01) (1, 3, 8, 9), significantly improve validated indicators of the risk of falling such as the timed up and go test ($p=.018$ / $p=.001$) (5, 11), and balance confidence as assessed with the Activity-specific balance confidence (ABC) scale ($p=.001$) (5). Consequently, patients with MFCL-2 mobility have been demonstrated to significantly improve their downhill gait pattern and significantly increase their downhill walking speed by 27-36% ($p=.002/<.001$) when using a MPK as compared to a non-MPK (1, 3, 5).

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Improved negotiation of uneven terrain and obstacles in the walkway.

Negotiation of uneven terrain and clearance of obstacles in the walkway are common activities in daily living. As most non-microprocessor controlled knee mechanisms have been designed for ambulation on level ground (7-9), uneven terrain and obstacles in the walkway expose above-knee amputees to an increased risk of stumbling and falling (8-9). Therefore, many patients usually avoid walking on uneven terrain or walkways with obstacles, or negotiate them very cautiously and slowly. In subjects with MFCL-2 mobility, MPK have been shown to significantly reduce falls by up to 80% ($p<.05$ to .01) (1-4), significantly improve validated indicators of the risk of falling such as the timed up and go test ($p=.018$ / $p=.001$) (5, 6), and balance confidence as assessed with the Activity-specific balance confidence (ABC) scale ($p=.001$) (5). Consequently, timed walk tests on uneven terrain and obstacle courses have shown that patients with MFCL-2 mobility using MPK are able to negotiate these terrains at significantly faster walking speeds (2, 3). Uneven terrain may be negotiated 20% faster ($p=.001$) (3) and obstacle courses 11% faster ($p=.02$) without and 12 faster ($p=.02$) with a concurrent mental task (2). Thus, above-knee amputees with MFCL-2 mobility are able to negotiate uneven terrain and clear obstacles in the walkway significantly better and faster with a MPK than with any non-microprocessor controlled knee.

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Improved stair descent.

Stairs are often encountered barriers in daily living and require greater lower-extremity range of motion and strength to negotiate, compared to level ground walking. Able-bodied people use reciprocal (step-over-step) stair descent, in which the supporting leg lowers the whole body down to the next step where the swinging leg becomes the supporting leg after landing. In above-knee amputees, most non-microprocessor controlled prosthetic knee mechanisms do not allow for any or enough knee flexion during weight bearing to lower the body with the supporting prosthetic leg or are too difficult to control for most patients to do so safely (4-6). That´s why above-knee amputees usually use a step-to pattern to descend stairs: The supporting sound leg lowers the body down using an eccentric contraction of the quadriceps to control knee flexion allowing the patient to land on the next step with the prosthetic leg. Then the sound leg is positioned on the same step next to the prosthetic leg to become the supporting leg again for lowering the body down to the next step (2, 4, 5, 6). This step-to pattern allows for only slow stair descent and exposes the patient as a disabled person. In subjects with MFCL-2 mobility, MPK have been shown to significantly reduce falls by up to 80% (p<.05 to .01) (1-3, 8), significantly improve validated indicators of the risk of falling such as the timed up and go test (p=.018 / p=.001) (7, 9), and balance confidence as assessed with the Activity-specific balance confidence (ABC) scale (p=.001) (7). Consequently, patients with MFCL-2 mobility have been demonstrated in several studies to significantly improve their gait quality when descending stairs (p=.04 / p=.008) and adopt a significantly more natural stair descent pattern in which the supporting prosthetic leg may even be used to lower the body down to the next step (1-3). This gait pattern is considerably faster than a step-to pattern and does not expose them as disabled persons to the public.

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Reduced cognitive demand / Improved multitasking capacity while walking.

The need to execute a concurrent task while walking is a common activity in daily living. As most non-microprocessor controlled knee (NMPK) mechanisms have been designed for ambulation on level ground and require a permanent alertness of the patient to actively stabilize the knee (5-7), above-knee amputees usually spend a lot of concentration and mental energy on screening their walkway for any kind of perturbation (2, 5, 6, 7). Therefore, their capacity to execute a concurrent task while walking with the prosthesis is considerably limited. In subjects with MFCL-2 mobility, MPK have been shown to significantly reduce falls by up to 80% ($p<.05$ to .01) (2, 3, 8, 9), significantly improve validated indicators of the risk of falling such as the timed up and go test ($p=.018$ / $p=.001$) (4, 10), and balance confidence as assessed with the Activity-specific balance confidence (ABC) scale ($p=.001$) (4). Consequently, tests assessing the self-reported ability for multitasking while walking with the prosthesis demonstrated a significant improvement by 21% ($p=.04$) when patients with MFCL-2 mobility were using the *C-Leg* as compared to NMPK (2). An observational study with 29 subjects assessing *Kenevo* as compared to NMPK typically prescribed and fit in patients with MFCL-2 mobility found that 79% of participants reported much less or less concentration required to walk with *Kenevo* (1). Thus, MPK may reduce cognitive demand and improve capacity for multitasking while walking with the prosthesis in patients with MFCL-2 mobility.

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Improved overall mobility, especially in K2 patients.

The more proximal the amputation, the greater is the physical and functional impairment to the individual, including a decreased likelihood of regaining household or community ambulation and an increased risk of falling (13-15). In subjects with an above-knee amputation, the prosthetic knee is a very important component, tasked with restoring knee biomechanics while at the same time providing maximum stability and safety. Most non-microprocessor controlled knee mechanisms have been designed for ambulation on level ground and require a permanent alertness of the patient to actively stabilize the knee in case of any pertubations (8-10). In subjects with MFCL-2 mobility, MPK have been shown to significantly reduce falls by up to 80% ($p<.05$ to .01) (1-3, 16), significantly improve validated indicators of the risk of falling such as the timed up and go test ($p=.018$ / $p=.001$) (4, 17), and balance confidence as assessed with the Activity-specific balance confidence (ABC) scale ($p=.001$) (4). Consequently, many patients are able to improve their overall mobility when using the *C-Leg*. Two studies demonstrated that 44% (3) or 50% (2), respectively, of patients with MFCL-2 mobility increased their overall mobility level to MFCL-3. Performance-based outcome measures suggest that these patients may be able to walk about 14-25% faster ($p=.01$ to .000) on level ground (1, 3, 5), around 20% quicker ($p=.008$) on uneven surfaces (1, 3), and descend a slope 30% faster ($p=.002$ to .001) when using the *C-Leg* (1, 2, 4). Furthermore, negotiation of stairs is significantly improved ($p=.04$ to .008) (1-3) and patients are enabled to perform many activities of community ambulation and in the house that are considered typical of MFCL-3 mobility (1, 6, 7). In addition, an observational study with 29 subjects assessing *Kenevo* as compared to NMPK typically prescribed and fit in patients with MFCL-2 mobility found that when using the NMPK, 87% of patients reported to use a wheelchair with their prosthesis. When using *Kenevo*, only 37% of subjects (p=.0046) still required an additional wheelchair (18). It is therefore no longer justified to generally withhold microprocessor-controlled prosthetic knees from patients with MFCL-2 mobility.

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