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C-Leg Reimbursement Guide.

January 2024.

C-Leg 4 Product Information.

[1]*C-Leg 4* Coding (U.S. only)

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

The following codes are PDAC Verified for *C-Leg 4*

L5828[2]	Hydraulic Swing and Stance Phase Knee
L5845	Stance flexion feature
L5848[2]	Hydraulic stance extension feature
L5856[2]	Microprocessor control feature, swing and stance phase, includes sensors

Health Canada Compliance

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

FDA Status

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

Warranty

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

Who Can Provide a *C-Leg*?

The *C-Leg 4* 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.

[2]For Medicare, Patient must be functional level 3 to use this code. Please verify coverage with your payer.

C-Leg 4 Features and Benefits.

Introduced in 1997, the C-Leg was the first prosthetic knee joint to control and adapt to an individual's complete gait pattern during stance and swing phase using a microprocessor. Today's C-Leg 4 actively controls all aspects of the swing and stance phase with the microprocessor-controlled hydraulics and adapts to variation in walking speeds. The result is a system that recognizes which phase of gait and situation the patient is in—and adapts in real time. The new functionality of C-Leg 4 includes patented technology which provides intuitive standing function and backward walking recognition and adjustments.

Stumble Recovery Plus

Swing phase flexion and extension resistance: The Stumble Recovery Plus feature on the C-Leg 4 takes stability to a new level by actively controlling and adjusting swing flexion and extension resistance in real time. If there is any disruption of swing flexion or swing extension the stance resistance is automatically increased. This ensures that the proper amount of resistance is in place to enable recovery in the event of a stumble.

Varied Cadence

Microprocessor controlled hydraulic swing: The C-Leg 4's main microprocessor gathers information from the various data sources and processes this information to adjust the knee joint´s functionality in real time. This allows the patient to walk more naturally and vary cadence with the knee, adapting more accurately and more quickly than without a microprocessor. Hydraulic swing resistance also provides smooth deceleration when changing walking speed, thus reducing the need for compensation.

Small or Quick Steps

A new ruleset of the C-Leg 4 allows for easier stance release when taking small or quick steps. This is beneficial, for example, when cooking in a kitchen or in a crowded elevator.

Knee Extension Assist:

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

Stairs, Slopes, Ramps, Challenging Terrain

Stance flexion: The C-Leg 4 provides hydraulic resistance against knee flexion (bending) mimicking the eccentric action of the quadriceps muscle. This allows the patient to securely walk up and down slopes and ramps, negotiate uneven/challenging terrain, and to descend stairs step-over-step. This resistance can be increased throughout the range and provides customized added support when ascending stairs and ramps.

Support for Sitting

Stance flexion: This feature also provides supported sitting down and allows the clinician to adjust the stance flexion beyond the programmed level of stance if additional stability for sitting is needed.

Back-up, Step Away

Inertial Motion Unit (IMU): The patented IMU on the *C-Leg 4* provides stability when taking steps backwards/backing-up. Contrast this to traditional microprocessor knees which do not accommodate backward walking, causing the knee to collapse when stepping backward.

Activity Reports

The practitioner is able to print out reports including average number of steps per day, average walking speed, ranges of different walking speeds/cadences, number of steps on slopes, ramps and stairs and time totals for walking, sitting, and standing.

Smooth and Natural Gait

Hydraulic stance extension damping:

The C-Leg 4 provides microprocessor-controlled progressive resistance in real time during stance extension resulting in a more natural gait. Without this increased resistance the patient would feel a pronounced "snap back" or "jerk" at the knee and would also present with an unnatural looking gait pattern.

Intuitive or Deliberate Standing

The C-Leg 4 allows for selection of intuitive or deliberate stance which offers customized support during static activities of daily living. With intuitive stance the patient is able to intuitively stand on a flexed and stable knee on level, uneven, or inclined surfaces (ramps or hills). Deliberate stance allows for standing on a flexed knee, but it takes longer to activate and deactivate. Deliberate stance is often preferred by bilateral amputees.

Manual Lock

The manual locking feature allows the user to lock the knee in full extension for safer standing if needed or more comfortable standing due to equal weight distribution on the prosthetic and sound sides. The manual lock is activated and deactivated by the patient by either by motion pattern or via a cellular telephone App.

Protective Covers

C-Leg 4's Protective Covers are used to provide greater defense for protecting the knee unit. These covers are custom designed for this knee unit only and are able to withstand sudden jolts that may penetrate the knee unit.

Patients with Dysvascular Amputation

One of the clinical trials that studied the benefits of a microprocessor controlled prosthetic knee (*C-Leg*) in above-knee amputees (1) enrolled a significant share of patients with a dysvascular amputation who comprised 78% of patients in a subgroup further analyzed in a systematic review of microprocessor knee studies (2). This subgroup of mostly dysvascular above-knee amputees experienced a significant 80% reduction in falls from 2.1 ± 1.5 to 0.4 ± 0.7 (p=.05) within a 60-day period when using the *C-Leg* as compared to their previous non-microprocessor-controlled knees. Furthermore, patients were able to significantly increase their fast-walking speed on level ground by 14.4% (p=.01) and on uneven terrain by 19.9% (p=.008), representing a significant improvement in the overall walking capabilities of the patients by using the *C-Leg*. Quality of stair descent as assessed by the Montreal Rehabilitation Performance Profile also improved significantly by 62.8% (p=.04) (2).

These results of clinical studies demonstrate that dysvascular above-knee amputees may benefit to the same extent from using a *C-Leg* as patients with a traumatic or malignancy-related amputation.

1. 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.
2. 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.

Evidence Summary.
C-Leg Microprocessor Knee

	Mobility need or deficit of the patient	Evidence for benefits of the *C-Leg*
Safety	Patient often stumbles and/or falls.	*C-Leg* has been demonstrated to reduce the number and frequency of stumbles and falls.
Safety	Patient avoids activities of daily living due to safety concerns and lack of balance and/or balance confidence	*C-Leg* has been shown to improve balance and balance confidence. This may result in the patient doing more activities with the prosthesis.
Slope negotiation	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.	*C-Leg* has been shown to improve the quality of slope and hill descent to the more natural gait pattern of sound subjects and to significantly improve the downhill walking speed.
Stair negotiation	Patient has to ambulate on stairs on a regular basis and struggles with stair descent, needs to descent stairs faster.	*C-Leg* has been demonstrated to improve quality of stair descent from step-to pattern (body and prosthetic leg are lowered to the next step with the sound limb, sound limb is then placed on this step) to step-over-step pattern (normal). This pattern is an indicator of improved balance confidence and allows for descending stairs much faster.
Negotiation of uneven terrain /obstacles in the walkway	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).	*C-Leg* has been shown to have superior safety and allows for significantly walking faster on uneven terrain and obstacle courses with and without concurrent activities.
Cognitive demand/multi -tasking during walking	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).	*C-Leg* has been demonstrated to increase multitasking capacities and cognitive burden while walking with the prosthesis. A recent study found no difference in the effect of a concurrent cognitive task on walking when users of MPKs were compared to sound, non-amputated subjects.
Gait symmetry as risk factor for pain and long-term comorbidities	Patient has an asymmetric gait pattern that may cause or contribute to low back pain and/or joint pain in the sound limb and puts the patient at risk for developing long-term comorbidities such as osteoarthritis and spinal degeneration.	*C-Leg* has been demonstrated to produce a knee flexion moment at loading response contributing to shock absorption. The result is significantly greater kinetic gait symmetry that may contribute to alleviating low back and intact limb joint pain and long-term comorbidities and degeneration.
Overall mobility	Patient is a limited community ambulator (MFCL-2, K2).	In K2 amputees, *C-Leg* has 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%; improve stair negotiation and some patients were able to complete activities considered typical for K3 mobility, both in the community and in the house.

Safety
Reduced stumbles and falls

Several clinical and biomechanical studies have investigated the safety of prosthesis use as well as balance and balance confidence while walking with a prosthesis. Two systematic reviews (1, 2) analysed a total of eight 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). All of these studies had been conducted with the *C-Leg* or *C-Leg* Compact. Hafner et al. (3), Kahle et al. (4), and Hafner and Smith (5) 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. (4) found a significant reduction of the number of stumbles and falls ($p<.05$). In a later publication (5), this group re-analysed their data separately for subjects with Medicare Functional Classification Levels 2 (MFCL-2, K2, limited community ambulator) and MFCL-3 (K3, community ambulator) mobility. Patients with MFCL-2 mobility had a significant reduction in the frequency of stumbles ($p<.05$) and uncontrolled falls ($p=.01$), as well as a significant 80% reduction ($p=.01$) in the number of uncontrolled falls (5). Kahle et al. reported a statistically significant 57% reduction in stumbles ($p=0.006$) and a significant 64% reduction in falls ($p=.03$). A systematic review that analysed only the subgroup of this study with MFCL-2 (K2) mobility found a significant 80% reduction in falls ($p<.05$) in this patient group (1). Burnfield et al. studied the effect of using a *C-Leg* Compact on validated indicators of the risk of falling (6). Compared to non-MPKs, the use of the *C-Leg* 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 ($p=.018$), and thus below the established threshold of 19 sec that indicates an increased risk of multiple falls in below-knee amputees (7).

Blumentritt et al. (8) simulated typical situations of everyday life that expose prosthesis users to an increased risk of falling in an instrumented motion analysis laboratory to evaluate the safety of the *C-Leg* and various types of non-MPKs. Among the situations simulated were stepping onto obstacles, sudden stopping and stepping to the side with the prosthetic or sound leg first, respectively, as well as tripping that would result in a fall if the prosthetic knee did not provide enough stability or a stumble recovery function. In all conditions tested, the *C-Leg* never collapsed whereas the non-MPKs, depending on the type of knee mechanism, either collapsed in some or even all safety-critical situations (8).

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 (9-15). Kaufman et al. (16) directly evaluated balance with the prosthesis using the Sensory Organization Test (SOT) assessed with dynamic posturography. Compared to their previous non-MPKs, patients demonstrated a significantly improved balance performance ($p=0.01$) when using the *C-Leg* (16). Using a 50-question survey in 368 patients, Berry et al. (17) evaluated balance more subjectively in several items. About 70% of patients rated the *C-Leg* “better” or “safer” in those questions related to balance confidence and perceived safety of prosthesis use. These items of interest were positioned in two separate sections of the survey, each of which demonstrated a statistically significant improvement ($p=0.0001$) with the *C-Leg* (17). Hafner et al. (5) confirmed the significantly increased confidence ($p=.08$) and multi-tasking ability ($p=.04$) while walking with the *C-Leg* using several items of the Prosthesis Evaluation Questionnaire (PEQ). Burnfield et al. assessed balance confidence with the validated Activity-specific balance confidence (ABC) scale that improved significantly from 60.1 to 75.7 ($p=.001$) when using the *C-Leg* Compact as compared to non-MPKs (6). Scores below 67 indicate an increased risk of falling (8-10) and are associated with fear of falling and avoidance of activities (9, 18, 19).

Summarizing all studies that had investigated the safety of MPKs compared to non-MPKs, two systematic reviews of the literature have concluded that the *C-Leg* and *C-Leg* Compact (used in all studies), significantly reduced falls and significantly improved balance and balance confidence (1, 2).

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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). Sound people use reciprocal (step-over-step) slope and hill descent, in which the supporting leg lowers the whole body down using knee flexion 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 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. Both gait patterns expose the patient as a disabled person to the public. The *C-Leg* has 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) (5), significantly improve objective balance performance as measured with the Sensory Organization Test (p=.01) (9) and balance confidence as assessed with the Activity-specific balance confidence (ABC) scale (p=.001) (5), and to be safe during stepping onto obstacles, sudden stopping on and side-stepping with the prosthetic leg as well as to provide effective stumble recovery during tripping (10). Consequently, the *C-Leg* has been demonstrated to significantly improve the quality of slope and hill descent (p=.002) (2), allowing for a significantly more natural gait pattern (1-5) as well as a significantly 23-40% faster downhill walking speed (p=.008 to < .001) (1-5). Patients with MFCL-2 mobility may be able to significantly increase their downhill walking speed by 27-36% (p=.002/<.001) when using the *C-Leg* (1, 3, 5). Patients with MFCL-3 mobility may significantly increase their downhill walking speed by 23-40% (p=.002) on a *C-Leg* as compared to non-microprocessor controlled prosthetic knees (2, 3).

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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 (8-10), uneven terrain and obstacles in the walkway expose above-knee amputees to an increased risk of stumbling and falling (9-10). Therefore, many patients usually avoid walking on uneven terrain or walkways with obstacles or negotiate them very cautiously and slowly. The *C-Leg* has been shown to significantly reduce falls by up to 80% (p<.05 to .01) (1-3), significantly improve validated indicators of the risk of falling such as the timed up and go test (p=.018) (6), significantly improve objective balance performance as measured with the Sensory Organization Test (p=.01) (7) and balance confidence as assessed with the Activity-specific balance confidence (ABC) scale (p=.001) (6), and to be safe during stepping onto obstacles, sudden stopping on and side-stepping with the prosthetic leg as well as to provide effective stumble recovery during tripping (9). Consequently, timed walk tests on uneven terrain and obstacle courses have shown that patients using the *C-Leg* are able to negotiate these terrains at significantly faster walking speeds (3, 5). Uneven terrain may be negotiated 21% faster (p=.001) (3) and obstacle courses 7-10% faster (p=.02 to .004) without a concurrent task (2, 4, 5) and even 27% faster (p=.007) while carrying a 10 lbs. basket (5). Thus, above-knee amputees are able to negotiate uneven terrain and clear obstacles in the walkway significantly better and faster with the *C-Leg* 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. Sound 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, 5). That´s why above-knee amputees usually use a step-to pattern to descend stairs: The supporting sound leg lowers the body down to the next step where the patient lands on 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. The *C-Leg* has been shown to significantly reduce falls by up to 80% (p<.05 to .01) (1-3), significantly improve validated indicators of the risk of falling such as the timed up and go test (p=.018) (7), significantly improve objective balance performance as measured with the Sensory Organization Test (p=.01) (8) and balance confidence as assessed with the Activity-specific balance confidence (ABC) scale (p=.001) (7). Consequently, the *C-Leg* has been demonstrated in several studies to significantly improve the gait pattern (p<.001) and allow for nearly normal step-over-step stair descent in which the supporting prosthetic leg can be used to lower the body down to the next step (1-5). It has also been shown that both patients with MFCL-2 (p=.008) and MFCL-3 (p=.004) mobility can adopt a reciprocal stair descent with the *C-Leg* and usually do so (1-5) as 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 mechanisms have been designed for ambulation on level ground and require a permanent alertness of the patient to actively stabilize the knee (9-11), above-knee amputees usually spend a lot of concentration and mental energy on screening their walkway for any kind of perturbation (2, 4, 10, 11). Therefore, their capacity to execute a concurrent task while walking with the prosthesis is considerably limited. The *C-Leg* has been shown to significantly reduce falls by up to 80% (p<.05 to .01) (2, 3), significantly improve validated indicators of the risk of falling such as the timed up and go test (p=.018) (7), significantly improve objective balance performance as measured with the Sensory Organization Test (p=.01) (8) and balance confidence as assessed with the Activity-specific balance confidence (ABC) scale (p=.001) (7), and to be safe during stepping onto obstacles, sudden stopping on and side-stepping with the prosthetic leg as well as to provide effective stumble recovery during tripping (10). Consequently, tests assessing the cognitive demand and the capacity to execute a concurrent task while walking with the prosthesis have shown significant improvements when using the *C-Leg* as compared to non-microprocessor-controlled knees (2, 4, 5). One study found a significant 33% reduction (p<.001) in cognitive burden while walking as measured on the Prosthetic Cognitive Burden Scale (PCBS) and 40% less attention paid to walking during concurrent cognitive tasks (p<.001) when using the *C-Leg* (6). The studies of Möller et al. (12) and Ramstrand et al. (13) found a significant reduction in cortical brain activity during walking (12) and dual tasking (13) as well as improved executive function during dual tasking (13) when using microprocessor as compared to non-microprocessor-controlled knees. Another study demonstrated a significant 28% reduction (p<.05) in the difficulty multitasking while walking when the patients used the *C-Leg* (4). The later sub-analysis showed that the *C-Leg* was able to significantly improve multi-tasking while walking by 21% (p=.004) in patients with MFCL-2 mobility and mental energy expenditure by 36% (p<.05), confidence while walking by 23% (p=.004), and multi-tasking while walking by 26% (p=.03) in patients with MFCL-3 mobility (2). The study of Seymour et al. demonstrated that, no matter if the patients did or did not have to carry a 10 lbs. basket, they were able to negotiate a defined obstacle course at the exact same walking speed or time, respectively, when using the *C-Leg* (5). In contrast, when using their non-microprocessor-controlled knees, they walked 23% slower while carrying the 10 lbs. basket compared to the hands-free condition (5). Furthermore, a recent study found no difference between the effects of a concurrent cognitive task on walking in patients using a microprocessor-controlled prosthetic knee and sound, non-amputated subjects (1). Thus, above-knee amputees are able to significantly improve their multi-tasking capacities while walking on the prosthesis with a *C-Leg* compared to any non-microprocessor-controlled knee.

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Improving gait symmetry to reduce the risk of pain and long-term comorbidities

Walking is more difficult for transfemoral amputees to perform because they need to depend on an artificial limb for body weight support and gait mobility. Walking biomechanics is altered with the use of a prosthesis. Research on non-amputee subjects reported global symmetry when the general behavior of the limbs was considered (3). In contrast, the gait of persons with a unilateral transfemoral amputation is asymmetrical (4). Asymmetry, or lack of symmetry, appears to be a relevant aspect for differentiating a normal and pathological gait. Altered load distribution may lead to back and/or intact limb pain (5, 6, 8), osteoarthritis in the intact limb (5, 7, 8), osteopenia/osteoporosis in the residual limb (7, 8), and other musculoskeletal problems (6, 8). These degenerative changes can prevent the performance of everyday tasks and lead to a reduction in the quality of life.

A study of Kaufman et al. demonstrated that amputees have significantly improved kinetic gait symmetry (in forces and moments loading the joints of both limbs) when using a *C-Leg* (p=.01 to .002) compared to non-microprocessor knees (1). Similarly, to the study of Segal et al. (2), they also found the *C-Leg* to produce a knee flexion moment at loading response that contributes to shock absorption, whereas non-microprocessor knees usually produce a knee extension moment that transfers loads directly to the residual hip and spine (1, 2). The results of the study suggest that the *C-Leg* improves amputee gait through more natural movements that could explain the improved balance and stability found in a number of other studies (9-13). Greater kinetic gait symmetry improves the load distribution between the prosthetic and sound limbs and may thus contribute to alleviating low back and intact limb joint pain as well as reduce long-term comorbidities and degeneration (1).

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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). The *C-Leg* has been shown to significantly reduce falls (p<.05 to .01) (1-3), significantly improve validated indicators of the risk of falling such as the timed up and go test (p=.018) (4), significantly improve objective balance performance as measured with the Sensory Organization Test (p=.01) (11) and balance confidence as assessed with the

Activity-specific balance confidence (ABC) scale (p=.001) (4), and to be safe during stepping onto obstacles, sudden stopping on and side-stepping with the prosthetic leg as well as to provide effective stumble recovery during tripping (9). 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. With the *C-Leg*, patients with MFCL-2 mobility significantly reduced uncontrolled falls by up to 80% (p<.05 to =.01) as well as validated indicators of the risk of falling (1-3). 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). It is therefore no longer justified to generally withhold microprocessor-controlled prosthetic knees from patients with MFCL-2 mobility.

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