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Empower.

Reimbursement Guide.

January 2024.

Empower Product Information.

Amputation Types

- Unilateral transtibial, transfemoral, or knee disarticulation.
- Bilateral transtibial

Functional Level

- K3 (has ability or potential for ambulation with variable cadence)

[1]Empower Coding–U.S. only

L5973	Endoskeletal Ankle Foot System, Microprocessor Controlled Feature, Dorsiflexion and/or Plantar Flexion Control, Includes Power Source.
*L5969	Addition Endoskeletal Ankle Foot System, power assist, Includes any type motor (s)

*HCPCS code L5969 is not currently listed on the Medicare Fee Schedule. If you are working with a non-government payer that does not have L5969 on their fee schedule, please contact Ottobock Reimbursement for assistance at reimbursement911@ottobock.com

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 *Empower* ankle is a Class II medical device and is exempt from premarket notification [510(k)] requirements. Given the inherent risk of Class II medical devices, FDA determined that General Controls and Special Controls are sufficient to provide reasonable assurance of the device's safety and effectiveness; therefore, safety and effectiveness research is not required for this device. The *Empower* ankle has met the applicable General Control and Special Control requirements which include Establishment Registration (21CFR 807), Medical Device Listing (21 CFR part 807), Quality System Regulation/ cGMP (21CFR part820), Labeling (21CFR part 801), and Medical Device Reporting (21 CFR Part 803). The *Empower* ankle is listed under Assembly, Knee/Shank/Ankle/Foot, External; Product Code ISW; Listing Number E206060.

Warranty

Three-year manufacturer warranty (extendable to six years); Repair costs are covered except for those associated with damages resulting from improper use. Service inspection is required within 36 months (and within 72 months for six-year warranty)

[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 are based on reasonable judgment and are not recommended to replace the Supplier's judgment. These recommendations may be subject to revision based on additional information or alpha-numeric system changes.

Empower Evidence Summary.

	Mobility need or deficit of the patient	Evidence for benefits of the powered ankle-foot
Over-ground walking speed	Active patient walks almost as fast as able-bodied individuals but still has difficulty to keep up with them	The powered ankle-foot may help physically capable individuals with transtibial amputation to reach walking speeds of able-bodied individuals.
Stability while walking	Active patient feels a little unstable while walking.	The powered ankle-foot may help improve angular momentum and gait stability.
Uneven terrain ambulation	Active patient has to negotiate uneven terrain on a regular basis and wants to walk faster.	The powered ankle-foot may help increase walking speed on uneven/rocky terrain.
Slope ambulation	Active patient has to negotiate slopes on a regular basis and finds slope ambulation physically demanding.	The powered ankle-foot may increase prosthetic push-off to the level of able-bodied individuals and improve gait stability, net leg work symmetry and energy efficiency of slope ascent.
Musculo-skeletal pain	Active patient suffers from sound knee, amputated side knee and low-back pain while using a passive prosthetic foot.	Use of the powered ankle-foot may help alleviate sound knee pain, amputated side knee pain, and low-back pain to a clinically meaningful extent.
ADL function	Active patient is limited in ADL performance due to knee and/or low-back pain.	Use of the powered ankle-foot may alleviate musculoskeletal pain and facilitate significantly improved ADL function to a clinically meaningful extent, especially for walking distances >1 mile.
Energy expenditure	Active patient is limited in his functional capabilities by increased metabolic energy demand.	Use of the powered ankle-foot may help reduce metabolic energy consumption in some patients with transtibial amputation during level walking and slope ascent.
Stair ambulation	Active patient has difficulty ascending stairs.	The powered ankle-foot may increase push-off to the level of able-bodied individuals and reduce kinematic and kinetic asymmetries between the legs. However, patients will still have to rely heavily on a hip strategy to ascend stairs.

Over-ground walking speed

An amputation not only results in the loss of passive anatomical structures but also muscles that may be removed completely or lose their typical distal attachment points during surgery. That results in adaptations and compensatory mechanisms to cope with the lack of power and active movement to restore function and mobility to the best extent possible. In individuals with transtibial amputation (TTA), such compensations include the tendency to reduce walking speed [1,2]. Even physically capable TTA often have difficulty keeping up with able-bodied individuals. Three studies have shown that individuals with TTA may be able to increase their walking speed on level ground to velocities typical for able-bodied subjects when using the powered ankle-foot component BiOM, the predecessor of the current Empower® [3,4,5]. In the study of Ferris et al., patients with TTA walked 1.32 (±0.02) m/s with their passive energy-storage-and-return (ESAR) foot but were able to significantly ($p<0.05$) increase walking speed to 1.40 (±0.04) m/s with the powered foot [4]. The study of Gardinier et al. found that only subjects with TTA who walked faster than 1.25 m/s with their ESAR foot were consistently able to further increase their walking speed with the powered foot, whereas the vast majority of patients who walked slower than 1.25 m/s did not [5]. These two studies [4,5] are in line with the findings of a study in able-bodied subjects that found that in the natural human ankle during level walking, there is a net external energy generation only at walking speeds faster than 1.3 m/s. At slower walking speeds, there is usually a net external energy loss which means that in patients with lower-limb amputation, these walking speeds do not necessarily require powered push-off in a prosthetic foot [6]. That result is further supported by a systematic review of Müller et al. that found significant differences in push-off power between various types of passive and powered feet only at walking speeds faster than 1.22 m/s [7]. One study did not find a correlation between walking speed with a passive foot and the ability to further increase velocity with the powered foot [3]. However, this study was conducted on a treadmill where patients had to “pick” their self-selected walking speeds out of a range of velocities they were exposed to. Thus, it is uncertain whether patients “picked” their correct self-selected over-ground walking speeds [3]. In conclusion, walking with a self-selected over-ground velocity of 1.25 m/s or faster with a passive prosthetic foot may be a good criterion to identify individuals who have the potential to further increase their walking speed to the level of able-bodied subjects with the Empower.

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Stability during level walking

Individuals with lower limb amputation are medio-laterally more unstable during walking than able-bodied individuals. These differences in stability become more pronounced during walking in destabilizing environments such as a rocky surface [1] or with medio-lateral surface oscillations [2-4]. Studies have used the range of angular momentum to identify deficits in walking stability [5-7]. Angular momentum quantifies the rotation of body segments [8]. In the frontal plane, if an individual has a large range of angular momentum, they will likely have a large magnitude of angular momentum during a stumble which would require an extensive response including large joint torques to recover and avoid a fall to the side [9,10]. Whole body angular momentum, the sum of the angular momentum about the center of mass for each body segment, exhibits a high degree of contralateral segment cancelling [8]. Angular momentum has been related to fall risk as a large angular momentum during a stumble will likely lead to a fall [5]. Individuals with unilateral transtibial amputation (TTA) had a greater mean range of angular momentum across a range of speeds compared to able-bodied controls [5]. Angular momentum mean differences were also found during the higher fall risk task of downhill walking [6]. In a study comparing the angular momentum of individuals with TTA to that of able-bodied subjects, there were no significant differences between groups in whole body angular momentum range or variability during unperturbed walking. The range of frontal plane angular momentum was significantly greater for those with amputation than for controls for all segments ($p<0.05$). For the whole body and intact leg, angular momentum ranges were greater for patients with amputation. However, for the prosthetic leg, angular momentum ranges were less for patients than controls. Patients with amputation were significantly more affected by the perturbations. Though patients with amputation were able to maintain similar patterns of whole body angular momentum during unperturbed walking, they were more highly destabilized by the walking surface perturbations. Individuals with TTA appeared to predominantly use altered motion of the intact limb to maintain medio-lateral stability [11].

In the study of D´Andrea et al., patients with TTA walking over ground with passive-elastic prosthetic feet had 32% to 59% greater sagittal angular momentum ranges during the prosthetic leg stance phase compared to able-bodied individuals at 1.00 to 1.75 m/s ($p<0.05$). Patients using passive-elastic feet had 5% and 9% greater sagittal angular momentum ranges compared with using the powered foot BiOM, the predecessor of the current Empower®, at 1.25 and 1.50 m/s, respectively ($p<0.05$). Thus, individuals with TTA may be able to more effectively regulate their whole body angular momentum and, thus, gait stability, at higher walking speeds of 1.25 and 1.5 m/s when using a powered compared to passive-elastic prosthetic feet [12].

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Uneven terrain ambulation

Gates et al. investigated uneven terrain ambulation with the powered foot BiOM compared to regular ESAR feet on a walkway with loose rock in the motion capture lab in 11 individuals with transtibial amputation. Subjects had a 10% faster self-selected walking speed when wearing the powered (1.16 m/s) compared to the passive feet (1.05 m/s; $p = 0.031$). They walked with increased ankle plantarflexion on their prosthetic limb throughout the gait cycle when wearing the powered prosthesis. This was especially evident in the increased plantarflexion during push-off ($p<0.001$). There was a small (<3°), but statistically significant decrease in knee flexion during early stance when wearing the powered foot ($p = 0.045$). Otherwise, the kinematics of the knee and hip were nearly identical when wearing the different feet. Subjects had decreased medio–lateral motion of their center of mass when wearing the powered foot ($p = 0.020$), but there were no differences in medial–lateral margins of stability between the feet. In conclusion, individuals with transtibial amputation may be able to walk significantly faster on uneven terrain when using a powered as compared to a passive prosthetic foot [1].

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Slope ambulation

Conventional rigid prosthetic ankles lack dorsi- and plantarflexion which induces locomotion difficulties, especially when walking on slopes [1, 2]. The very limited ankle range of motion and power generation as well as reduced proprioception and tolerance of force compromise the stability of the residual limb during stance, demonstrated by shorter single support, increased early stance knee flexion, smaller joint moments and powers but increased negative (dampening) work at the residual knee measured in transtibial amputees compared to able-bodied subjects. These adaptations result in a slower walking speed on slopes with reduced knee and hip range of motion and hip moments, but greater amplitude and time of muscle activity in both limbs [1]. In a study of Russell Esposito et al. comparing 6 individuals with transtibial amputation (TTA) and 6 able-bodied controls during ambulation on a 5° slope, the powered foot BiOM increased ankle power compared to the passive feet to the extent that power was normalized to able-bodied controls during inclined walking [3]. The study of Rabago et al. compared walking on a 5° slope with ESAR and a powered foot. The powered foot BiOM produced significantly greater prosthetic ankle plantarflexion and push-off power generation than ESAR feet and more closely matched values of able-bodied persons. Both types of feet functioned similar when transitioning onto the prosthetic limb due to limited prosthetic dorsiflexion, which resulted in similar deviations and compensations. In contrast, when transitioning off the prosthetic limb, increased ankle plantarflexion and push-off power provided by the powered foot contributed to decreased intact limb knee extensor power production, lessening demand on the intact limb knee [4]. The study of Montgomery et al. investigated slope ambulation in 10 subjects with TTA walking at 1.25 m/s at inclines and declines of 0°, 3°, 6° and 9° using their own ESAR feet and the BiOM powered ankle–foot component. The use of the BiOM improved individual leg net work symmetry on 6° and 9° uphill slopes ($p<0.01$). Thus, people with TTA who use a powered ankle–foot component have the potential to increase gait symmetry during walking on uphill slopes [5].

Studies have used the range of the whole body angular momentum to identify deficits in walking stability [6-8]. Angular momentum quantifies the rotation of body segments [9]. In the frontal plane, if an individual has a large range of angular momentum, they will likely have a large magnitude of angular momentum during a stumble which would require an extensive response including large joint torques to recover and avoid a fall to the side [10,11]. Whole body angular momentum, the sum of the angular momentum about the center of mass for each body segment, exhibits a high degree of contralateral segment cancelling [9]. Angular momentum has been related to fall risk as a large angular momentum during a stumble will likely lead to a fall [6]. Individuals with unilateral transtibial amputation (TTA) had a greater mean range of angular momentum across a range of speeds compared to able-bodied controls [6]. Angular momentum mean differences were also found during the higher fall risk task of downhill walking [7]. In a study investigating slope walking with a powered or passive ESAR feet in individuals with TTA, the range of whole body angular momentum was greater compared to able-bodied individuals. On a 10° decline, individuals with TTA did not decrease their whole body angular momentum as much as able-bodied individuals and had reduced prosthetic limb braking ground reaction forces and knee power absorption. On a 10° incline, individuals with TTA had a greater relative increase of whole body angular momentum than able-bodied subjects, a more anterior placement of the prosthetic foot, and higher peak hip power generation. Use of the powered foot resulted in a smaller range of angular momentum during prosthetic stance relative to the passive foot condition, although it was still larger than in able-bodied individuals. The results suggest that prosthetic ankle power generation may help regulate dynamic balance during prosthetic stance but does not fully restore the whole body angular momentum of able-bodied individuals on slopes [12-14]. However, using the powered foot on uphill slopes reduced the contributions from the amputated leg hamstrings in all segments (effect size ≥ 0.46, p≤0.003), suggesting that added ankle power reduces the need for the hamstrings to compensate for lost ankle muscle function [15].

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Stair ambulation

Stair ambulation increases the kinetic demand compared with level walking [1-4] and emphasizes motor deficits. For amputees who usually suffer from restrictions of muscle strength and joint mobility, balance, or proprioception, stair ambulation becomes specifically challenging [5-8]. Thus, amputees negotiate stairs considerably slower and with greater stance asymmetry and increased muscular effort than able-bodied controls [5, 7].

During stair ascent, below-knee amputees use a particular compensation mechanism that could be a result of a strategy favoring knee stability on the prosthetic side [9]. They generate a strong hip moment to elevate the body during stance on their prosthetic side, compared to able-bodied subjects who mainly utilize a knee moment [6, 9]. The preparation of the next foot contact is also a challenge on both sides [6]. When preparing step contact for the sound limb, the missing active plantarflexion of the prosthetic foot leads to an insufficient vertical position of the body´s center of mass (CoM). When preparing step contact for the prosthetic limb, the missing dorsiflexion of the foot reduces toe clearance directly prior to the support phase. Both challenges are compensated for by the sound limb through an increased knee flexion during late swing and an increased plantar flexion during late stance [6].

The study of Aldridge et al. investigated stair ascent of 11 individuals with transtibial amputation with the powered foot BiOM compared to the use of passive ESAR and able-bodied subjects. Lower extremity peak kinematic and kinetic values were calculated at a self-selected and controlled cadence of 80 steps/min. Increased prosthetic limb peak ankle plantarflexion and push-up power were observed while using the BiOM as compared to ESAR. Peak ankle power was not significantly different between BiOM and able-bodied controls indicating normalization of ankle power generation. However, peak ankle plantarflexion was still significantly lower than in the controls. Limb asymmetries including greater prosthetic limb hip flexion and power during stance, and decreased prosthetic limb knee power during stance were were reduced in the BiOM compared to the ESAR condition, but these improvements did not attain statistical significance. The results suggest that the BiOM successfully increased ankle motion and restored ankle power during stair ascent. However, individuals with TTA must still rely on the use of a hip strategy while ascending stairs.

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Musculoskeletal pain

Biomechanical studies have found a correlation between push-off power of the trailing limb and collision work and, thus, knee loading of the leading limb during walking [1-5]. Consistent with that relationship, several biomechanical studies [6,7] and case series [8] with the powered foot BiOM, the predecessor of the current Empower® foot, have reported significant unloading of the sound knee of compared to the use of passive ESAR feet. At walking speeds of 1.5 and 1.75 m/s, the first peak of the sound-knee external adduction moment (EAM) was significantly reduced by 12 and 20%, respectively, and the sound-knee EAM rate by 15 and 22%, respectively [6]. Consequently, a cross-sectional study with concurrent and recalled numerical pain ratings in 57 individuals with transtibial amputation (TTA) who had been fitted a powered BiOM or Empower foot in the past found significantly lower original pain ratings with use of a powered foot not only for sound limb knee pain (p=0.001) but also for amputated limb knee pain (p=0.005) and low-back pain (p<0.001). After adjustment for recall bias, the ratings with a powered foot were still significantly lower for sound knee limb pain (p=0.001), amputated side knee pain (p=0.016) and low-back pain (p=0.001). The differences in medians reached or exceeded the minimally clinically important difference (MCID) of 1 point for both the original and recall-adjusted pain ratings [9].

At the individual level, significantly more subjects reported to have had no sound knee pain (p=0.004), no low-back pain (p=0.012), or no pain in all three body regions (p=0.031), respectively, when using a powered foot compared to a passive prosthetic foot. For the amputated side knee, the difference in subjects with no pain approached statistical significance (p=0.063). Likewise, significantly fewer individuals reported to have had problematic pain of ≥3 points on a numerical pain rating scale (NPRS) [10] in the sound knee (p=0.004), amputated side knee (p=0.007), lower back (p=0.013), or in all three body regions (p=0.012), respectively, with a powered foot. For those subjects with problematic pain ≥3 points NPRS when using a passive foot, the likelihood of experiencing a clinically meaningful improvement of ≥2 points NPRS with a powered foot, which equals a verbal "much better" rating [11,12], was 2 times (amputated side knee pain), 2.6 times (all 3 body regions), 3.3 times (low-back pain), or 3.7 times (sound knee pain) higher, respectively, than for the opposite transition from a powered to a passive foot [9]. The significant reduction in amputated limb knee pain is likely due to the plantarflexion range of motion of 22° of the powered feet that may result in significant amputated side knee unloading especially on uneven terrain and slopes [13-15]. The significant reduction in low-back pain with use of the powered feet is likely due to the better gait propulsion and force dissipation along the kinetic chain that minimize mechanical forces on proximal joints such as the knee, hip and lumbar vertebrae, and thereby reduce asymmetries in pelvic and trunk muscle activation [16].

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Physical Function and Activities of Daily Living (ADL)

A cross-sectional study with concurrent and recalled pain and functional ratings of 57 individuals with transtibial amputation (TTA) who had been fitted a powered BiOM or Empower foot in the past found significant improvements in the Activities of Daily Living scale of the Knee Injury and Osteoarthritis Outcomes Score (KOOS-ADL) with use of a powered compared to a passive prosthetic foot [1]. The KOOS-ADL assesses the difficulty of performing 17 activities of daily living [2-4]. Both the original and recall-adjusted KOOS-ADL scores were significantly higher (better) when using a powered foot (p<0.001 for both) compared to the passive foot ratings. The differences in medians reached the order of the published minimal detectable change (MDC) and minimally clinically important difference (MCID) of 10 points for the original score and well exceeded it for the recall-adjusted score. This study also assessed the Oswestry Disability Index (ODI) for back-pain related disability in 10 activities of daily living [4-9]. Again, the original and recall-adjusted ODI scores were significantly lower (better) for the powered than the passive feet (p<0.001 for both). The differences in medians reached the order of the published MDC and MCID of 12.8 points for the original score and well exceeded it for the recall-adjusted score. The greatest improvement with a powered foot in any single ADL in this study was in "walking more than 1 mile" in the ODI. Thus, the use of the powered ankle-foot mechanisms resulted in a significant and clinically meaningful ease in the execution of ADLs and a significant and clinically meaningful reduction in disability [1]. Only one of the numerous previous studies with the BiOM powered ankle-foot published patient-reported outcomes but did not show statistically significant differences compared to standard ESAR feet. However, the same study did report a relatively big improvement in the Ambulation subscale of the Prosthesis Evaluation Questionnaire (PEQ) with an estimated effect size of about 0.5 - but that did not attain statistical significance due to the small sample size of only 13 subjects [10].

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Metabolic energy consumption

An amputation not only results in the loss of passive anatomical structures but also muscles that may be removed completely or lose their typical distal attachment points during surgery. That results in adaptations and compensatory mechanisms to cope with the lack of power and active movement to restore function and mobility to the best extent possible. In individuals with transtibial amputation (TTA), such compensations include an about 25% higher metabolic energy consumption for walking than able-bodied persons [1-6]. Therefore, the addition of power to lower-limb prosthetics is considered a promising approach for reducing the metabolic demand of ambulation. Several studies [7-10] and case studies [11-13] have investigated the impact of the powered ankle-foot component BiOM, the predecessor of the current Empower® foot, on metabolic energy consumption of people with transtibial amputation (TTA) during level walking [7-13] and slope ascent [8, 10]. While the case studies found reductions in metabolic energy consumption for walking at self-selected walking speed on level ground between 7 and 20% [11-13], the results of the more formalized studies were somewhat inconsistent and conflicting. A study investigating treadmill walking of 7 individuals with TTA at 5 different walking speeds between 0.75 and 1.75 m/s found a significant increase of 11-25% ($p<0.05$) in cost of transport for use of passive ESAR feet compared to able-bodied controls at walking speeds of 1.00 to 1.75 m/s. However, with the powered ankle-foot component, cost of transport compared to ESAR feet was reduced and the differences to able-bodied subjects were no longer statistically significant [7]. Similarly, Esposito et al. found a significant 16% reduction on oxygen consumption for level walking at 1.24±0.05 m/s in their sample of 6 subjects with TTA with the BiOM powered foot compared to passive ESAR feet, resulting in the difference between powered foot use and able-bodied controls being no longer statistically significant [8]. In contrast, the studies of Gardinier et al. [9] and Montgomery et al. [10] did not find consistent reductions in metabolic energy consumption during level walking. However, Gardinier et al. reported that their subset of individuals with TTA and MFCL-4 mobility was significantly more likely ($p=0.014$) to exhibit metabolic energy cost savings than those subjects with lower functional ratings [9].

On a 5° incline, Esposito et al. found a 6.5% reduction in oxygen consumption with the powered foot compared to passive ESAR feet, but that difference did not attain statistical significance. However, the difference in metabolic energy consumption on the incline between powered foot use and able-bodied controls was no longer statistically significant either [8]. Montgomery et al. found a significant 5% reduction in net metabolic power when ascending 3° and 6° inclines with the powered BiOM foot compared to passive ESAR feet. On the 9° incline, the powered foot reduced net metabolic power by even 13%, but that difference did not attain statistical significance as 7 of the 10 subjects were unable to ascend this incline for a longer period of time [10]. Thus, some individuals with TTA may experience significant reductions in metabolic energy consumption when walking with a powered foot on level ground or inclines, but that effect appears to be highly individual.

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