Aetna considers lower limb prostheses medically necessary for performing normal daily activities when the following criteria are met:

1. Member is motivated to ambulate; and
2. Member meets the specific criteria for lower limb prostheses set forth below; and
3. Member will reach or maintain a defined functional state within a reasonable period of time.

Aetna considers lower limb prostheses experimental and investigational because of insufficient evidence in the peer-reviewed literature when these criteria are not met.

Aetna does not cover a replacement prosthesis unless the member's medical needs are not being met by the current prosthetic or it is broken and cannot be repaired.

Aetna considers "water leg" (an attachment for persons with lower limb prostheses to shower) a convenience item, and not medically necessary.
Foot Prosthesis:

- A solid ankle-cushion heel (SACH) foot is considered medically necessary for persons whose functional level is 1* or above.
- An external keel SACH foot or single axis ankle/foot is considered medically necessary for persons whose functional level is 1* or above.
- A flexible-keel foot or multi-axial ankle/foot is considered medically necessary for persons whose functional level is 2* or above.
- A flex foot system, energy storing foot, multi-axial ankle/foot, dynamic response foot with multi-axial ankle, shank foot system with vertical-loaded pylon or flex-walk system or equal is considered medically necessary for persons whose functional level is 3* or above.
- An user-adjustable heel height feature is considered not medically necessary.

Note: Foot covers are included in the reimbursement for a prosthetic foot component and are not separately payable.

Knee Prosthesis:

- A fluid or pneumatic knee is considered medically necessary for persons whose functional level is 3* or above.
- A single axis constant friction knee and other basic knee systems are considered medically necessary for persons whose functional level is 1* or above.
- A high-activity knee control frame is considered medically necessary for members whose function level is 4*.

Ankle Prosthesis:

- An axial rotation unit is considered medically necessary for persons whose functional level is 2* or above.

Hip Prosthesis:

- A pneumatic or hydraulic polycentric hip joint is considered medically necessary for members whose functional level is 3 or above.
Sockets:

- Test (diagnostic) sockets for immediate post-surgical or early-fitted prostheses are considered not medically necessary.
- Two test (diagnostic) sockets for an individual prosthesis are considered medically necessary. Additional documentation of medical necessity is required for more than 2 test sockets.
- No more than 2 of the same socket inserts per individual prosthesis at the same time are considered medically necessary.
- Socket replacements are considered medically necessary if there is adequate documentation of functional and/or physiological need, including but is not limited to: changes in the residual limb; functional need changes; or irreparable damage or wear/tear due to excessive weight or prosthetic demands of very active amputees.

Prostheses have no proven value for persons whose potential functional level is 0.*

Accessories:

Stump stockings and harnesses (including replacements) are considered medically necessary when they are essential to the effective use of the artificial limb.

Prosthetic sheaths/socks, including a gel cushion layer (prosthetic gel stockings; 6 in 6 months) are considered medically necessary.

A prosthetic donning sleeve is considered not medically necessary.

Microprocessor-Controlled Lower Limb Prostheses:

Aetna considers microprocessor-controlled leg prostheses (“Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type”) (e.g., Otto Bock C-Leg; Otto-Bock Genium Bionic Prosthetic System (Otto Bock HealthCare, Minneapolis, MN), Intelligent Prosthesis
(Endoliete North America, Centerville, OH), and Ossur Rheo Knee/Ossur RKXC Knee (Ossur-Flexfoot, Aliso Viejo, CA)) medically necessary in otherwise healthy, active community ambulating adults (18 years of age or older) (functional level 3* or above) with a knee disarticulation amputation or a trans-femoral amputation from a non-vascular cause (usually trauma or tumor) for whom this prosthesis can be fitted and programmed by a qualified prosthetist trained to do so.

A powered flexion-extension assist ("Addition to lower extremity prosthesis, endoskeletal knee-shin system, powered and programmable flexion/extension assist control, includes any type of motor(s)" ) is only considered medically necessary when the member meets all of the criteria below:

1. Has a microprocessor (swing and stance phase type) controlled (electronic) knee; and
2. K3 functional level only; and
3. Weight greater than 110 lbs and less than 275 lbs; and
4. Has a documented comorbidity of the spine and/or sound limb affecting hip extension and/or quadriceps function that impairs K-3 level function with the use of a microprocessor-controlled knee alone; and
5. Is able to make use of a product that requires daily charging; and
6. Is able to understand and respond to error alerts and alarms indicating problems with the function of the unit.

Aetna considers microprocessor-controlled leg prostheses (e.g., Otto Bock C-Leg, Otto-Bock Genium Bionic Prosthetic System, Intelligent Prosthesis, and Ossur Rheo Knee) experimental and investigational for gait management in spinal cord injury because of insufficient evidence in the peer-reviewed literature.

Aetna considers the C-Leg Protector experimental and investigational because its clinical value has not been established.

**Prosthetic Shoe:**

Aetna considers a prosthetic shoe medically necessary for a
partial foot amputation when the prosthetic shoe is an integral part of a covered basic lower limb prosthetic device.

Aetna considers microprocessor-controlled ankle-foot prosthesis (e.g., PowerFoot BiOM, iWalk, Bedford, MA; Proprio Foot, Ossur, Aliso Viejo, CA) experimental and investigational because there is inadequate evidence of their effectiveness.

Aetna considers the Ossur Symbiotic Leg experimental and investigational because its clinical value has not been established.

**Powered Lower Limb Prosthesis:**

Aetna considers powered lower limb prosthesis (e.g., Power Knee, Ossur, Foothill Ranch, CA) experimental and investigational because there is inadequate evidence of their effectiveness.

**Robotic Lower Body Exoskeleton Suits:**

Aetna considers robotic lower body exoskeleton suits (e.g., the ReWalk, Argo Medical Technologies Ltd, Marlborough, MA) experimental and investigational because there is inadequate evidence of their effectiveness.

*Note: Clinical assessments of a member’s rehabilitation potential should be based on the functional classification levels listed in the appendix.*

**Non-Medically Necessary Prostheses:**

Aetna considers the following not medically necessary:

- Duplication or upgrade of a functional prosthesis; or
- Lower limb prosthesis for a functional level of 0; or
- Prosthetics used for activities other than normal daily living, including, but may not be limited to, those utilized for sporting activities such as skiing; or
- Repair or replacement of a prosthesis for appearance, comfort, convenience or individual abuse, misuse or neglect; or
• Repair or replacement of parts of a duplicate prosthesis; or
• Test sockets for an immediate prosthesis; or
• Water prosthesis (designed to be used for showering, swimming, etc.).

See also CPB 0399 - Myoelectric Upper Limb Prosthesis (../300_399/0399.html), and CPB 0630 - Prosthetic Limb Vacuum Systems (../600_699/0630.html).

**Background**

A prosthesis or prosthetic is an artificial device that replaces a missing body part. Examples of prostheses include eyes, maxillofacial (jaw and face), arms, breasts, ears, legs, hands and feet.

A lower limb prosthesis is designed to replace portions of the lower extremity to improve function. A prosthetic knee performs several functions: it provides support during the stance phase of ambulation, produces smooth control during the swing phase and maintains unrestricted motion for sitting and kneeling. The prosthetic knee may have a single axis with a simple hinge and a single pivot point or it may have a polycentric axis with multiple centers of rotation, which is more similar to the anatomic human knee. Pylons are the connection between the residual limb and the prosthetic joint.

The prosthetic foot also has several basic functions: provides a stable weight-bearing surface, absorbs shock, replaces lost muscle function and biomechanics of the foot, replicates the anatomic joints of the ankle and foot and restores appearance.

Multiaxial prosthetic feet permit movements in any direction: plantar flexion, dorsiflexion, inversion, eversion and a slight amount of rotation around a vertical axis. Multiaxial feet are appropriate for those who ambulate on uneven terrain, such as community ambulators and active adults or athletes.

The solid ankle cushion heel (SACH) consists of a rigid keel covered by semi-noncompressible foam and a synthetic rubber heel wedge. The cushion heel compresses when weight is
applied, allowing the forefoot to approach the floor. The amount of simulated plantar flexion depends on the relative softness of the heel material and weight of the amputee. Because the keel is rigid, the SACH foot does not provide dorsiflexion; this makes its usefulness on uneven surfaces limited.

Conventional lower limb prostheses employ exclusively mechanical control: these may include a pneumatic or hydraulic damping cylinder, which is adjusted by a prosthetist, to provide optimum gait parameters at the patient’s conventional walking speed. If a patient walks at a different speed, the patient must compensate for the pendulum action of the prosthesis to alter stride length or step rate by tilting the pelvis, or by other maneuvers, to delay extension to ensure that the foot is in the right place for the next step. These maneuvers lead to an abnormal gait and require extra effort and concentration. Aetna’s policy on standard lower limb prostheses is based on Medicare DME MAC criteria.

The microprocessor-controlled lower limb prosthesis (also known as computerized lower limb prostheses) is relatively new to the United States, although a different brand of microprocessor-controlled lower limb prosthesis has been in use in Europe for many more of years. These prostheses employ a microprocessor-controlled knee extension damper, which is designed to detect step time and alter knee extension level to suit walking speed. More advanced microprocessor controlled lower limb prostheses, such as the C-leg, also have multiple sensors that gather and calculate data on, for example, amount of vertical load, sagittal plane ankle movement, and specifics of knee joint movement. These prostheses are claimed to be a significant improvement over the conventional mechanically controlled prostheses.

Claimed advantages of the microprocessor-controlled lower limb prostheses include: decreased effort involved in walking; improved gait symmetry; increased confidence by the patient in the prosthesis; more natural movement, including on stairs, inclines, and uneven terrain; the perception that participation in activities such as sports is possible; and the avoidance of falls.
The Otto Bock C-leg was cleared by the Food and Drug Administration (FDA) based on a 510(k) application; FDA clearance was based on the Otto Bock C-leg's substantial equivalence to a predicate device that was on the market prior to the date of enactment of the 1976 Medical Device Amendments to the Food, Drug and Cosmetic Act.

A number of systematic evidence reviews have identified limitations in current literature on microprocessor controlled knees. The majority of this literature evaluates intermediate outcomes, although some studies have focused on actual functional outcomes. However, the bulk of all of these studies show improvement in outcomes when the microprocessor-controlled knee is used as compared to a more traditional non-microprocessor-controlled knee.

The first systematic evidence review of microprocessor controlled knees was prepared by the Department of Veterans Affairs Technology Assessment Program (VA TAP) (MDRC, 2000). The VA TAP assessment reviewed the evidence supporting the use of computerized lower limb prostheses such as the Otto Bock C-leg and the Intelligent Prosthesis, a microprocessor-controlled lower limb prosthesis that is slightly different than the Otto Bock C-Leg (MDRC, 2000). The VA TAP found, upon review of published studies, that users' perceptions of the microprocessor-controlled prosthesis are favorable. They also found that, although the energy requirements for ambulation (compared to requirements for conventional prostheses) are decreased at walking speeds slower or faster than the amputee's customary speed, energy requirements are not significantly different at customary speeds. The VA TAP found that the reported results on ability to negotiate uneven terrain, stairs, or inclines are "mixed."

At that time, the VA TAP found the evidence of effectiveness of the microprocessor-controlled lower limb prostheses (Intelligent Prosthesis, Otto Bock C-leg) to be limited (MDRC, 2000). Regarding the evidence of effectiveness, the report drew the following conclusions: “The published research is a small body of work. Less then 3 % of the published and indexed articles represent structured research, with the larger fraction of
published articles being purely descriptive or frankly promotional. Most of the available structured research is based on a slightly different microprocessor-controlled prosthesis (the [Endolite] Intelligent Prosthesis (IP), Blatchford, United Kingdom). The IP is associated with many of the same potential benefits as the C-LEG.”

The VA TAP reported (MDRC, 2000): “Published studies have enrolled highly selected samples of amputees who do not have additional medical problems, whose amputations were secondary to trauma or congenital defects, and who are fit and active. These and similar characteristics have been shown to be independently predictive of successful rehabilitation or return to normal living after amputation, and may confound the results of the non-randomized, uncontrolled microprocessor-controlled prosthesis studies that have been published to date.

- Results in the highly selected patients who have participated in the available published studies may not be directly transferable to VA amputees, who are likely to have multiple additional medical problems and amputations secondary to vascular disease.
- The selective inclusion for research patients noted above undoubtedly introduce bias into study results, precluding definitive attribution of improvements in gait, energy expenditure, etc., to the computerized prosthesis.”

An assessment conducted by the Washington State Department of Labor and Industries (2002) concluded "[d]ue to the small number of studies and study participants, evidence of the broad effectiveness of microprocessor-controlled prosthetic knees remains inconclusive."

An evidence review prepared by the Evidence Based Group of the Workers Compensation Board of British Columbia (Martin, 2003) concluded that, "[t]o date, the published research on computerized knee prosthesis is very limited. Less than 3 % of published and indexed research represents structured research. Most published articles are purely descriptive or promotional in nature." The evidence review noted: “Published studies enrolled
highly selected sample of amputees who did not have additional medical problems and who were fit and active. These characteristics have been shown to be independently predictive of successful rehabilitation or return to ‘normal’ living after amputation. Thus, these variables are most likely to confound the results of the non-randomized, uncontrolled studies on microprocessor controlled knee prosthesis that have been published to date.” The evidence review concluded that, “at present, the small number of studies on computerized knee prostheses does not conclusively show the effectiveness of the prostheses" in reducing energy expenditure particularly in normal speed walking, improving ability to walk on uneven terrain, improving ability to climb and descend stairs, and increasing walking distance.

Additional studies have been published since these technology assessments were published. Although each of these studies have flaws, the bulk of the studies show improvement in outcomes when the microprocessor-controlled knee is used as compared to a standard hydraulic knee. Similar to previously published studies, Stinus (2000) authored an uncontrolled descriptive study involving a selected group of 15 patients, reporting on their subjective assessments of the microprocessor-controlled lower limb prosthesis compared with previously fitted mechanically controlled prosthetic knee joints. This study did not include objective assessments of improvements in function and reductions in disability compared with conventional prostheses. Schmalz, et al (2002) reported on the results of a randomized controlled clinical study comparing conventional hydraulic knees with electronically controlled knee joints during walking on a treadmill. The investigators reported reductions in oxygen consumption in persons with electronically controlled knees compared to patients with conventional hydraulic knees when walking at speeds other than the amputee’s customary walking speeds. This study, however, did not assess differences in function between these groups. Similarly, a study by Chin et al (2003) of 8 traumatic amputees fitted with an Intelligent Prosthesis compared to 14 normal non-amputee controls reported a 24 % greater energy expenditure compared to controls walking at equal speeds. However, this study did not assess
reductions in disability and improvements in function with the Intelligent Prosthesis.

In a subsequent study, Chin et al (2005) reported on changes in oxygen consumption of 3 amputees after prescription of a microprocessor-controlled prosthesis. The change in energy expenditures reported was highly variable among subjects, with 1 subject reporting a minor (4.9 %, 11.6 % and 105 %) reductions in oxygen consumption, another reporting changes in energy expenditures of 10.3 %, 14.9 % and 23.3 % depending upon speed, and the third subject reporting larger changes in energy expenditures (39.6 %, 24.6 % and 23.3 %). The study provided no details about how these cases are selected. Thus, one is not able to determine whether one can generalize from this selected set of individual cases to other amputees. The study suffers from the same flaws as the previous study by the same investigator group; it does not represent a stronger study, in terms of design, than previous published studies. The study by Chin et al (2005) is a pre-/post-study, without concurrent controls; other factors may have accounted for changes in energy expenditures after prescription of the microprocessor controlled prosthesis, including the training program and practice subjects received to improve their ability to walk with a microprocessor-controlled prosthesis before their energy expenditures were re-assessed. The study by Chin et al also suffered from the limitations of his previous study in that it assessed differences in oxygen consumption, an intermediate endpoint, and did not assess clinically relevant endpoints of reductions in disability and improvement in function.

A study by Johansson et al (2005) compared the magnetorheological-based Ossur Rheo prosthesis to the hydraulic-based Otto-Bock C-Leg microprocessor-controlled prosthesis to a standard hydraulic-based (Mauch) prosthesis. The study found no statistically significant difference between the C-Leg microprocessor controlled prosthesis and a standard hydraulic (Mauch) prosthesis in metabolic expenditure (as measured by oxygen consumption) with walking, the primary study endpoint. The investigators (from a group headed by an inventor and patent-holder of the Ossur Rheo microprocessor-
controlled leg prosthesis) reported a 5% lower average metabolic consumption with walking using the Ossur Rheo prosthesis, and a 2% lower average metabolic consumption with walking using the C-leg microprocessor-controlled prosthesis compared to a standard hydraulic (Mauch) prosthesis; the latter difference did not achieve statistical significance. There is also a question about the clinical significance of such small differences in metabolic consumption, especially among the younger active amputees for whom microprocessor-controlled prostheses are most commonly prescribed.

The study by Johansson et al (2005) also evaluated differences in kinetics, kinematics, and electromyographic data between the C-Leg, the Ossur Rheo prosthesis, and standard hydraulic prostheses in walking sessions performed in the laboratory. However, the study fails to show how any identified differences in these intermediate outcomes, while statistically significant, translated into tangible, clinically significant reductions in disability and improvements in function. The small size of the study (n = 8) may limit one's ability to generalize its findings to other amputees. Observed differences between microprocessor-controlled prostheses and the standard hydraulic-based Mauch prosthesis may be due, in part, to the fact that half of the study subjects had been using a microprocessor-controlled prosthesis as their usual prosthesis prior to study initiation, and only 1 study subject used the Mauch hydraulic prosthesis as her usual prosthesis prior to study initiation. In addition, laboratory-based evaluation of prostheses and their components may not necessarily reflect the characteristics of the prostheses when used outside of the clinical setting (in real life situations), and in subjects with more experience with use of these particular prosthetics.

A study by Datta et al (2005) comparing the Intelligent Prosthesis microprocessor-controlled prosthesis to conventional pneumatic leg prostheses in 10 amputees found no significant difference in metabolic expenditures (oxygen consumption) at average walking speeds. The study also found no significant differences in temporal and spatial parameters of gait between the 2 types of knee joint, nor any significant differences in gait by observational
video analysis. The study found statistically significantly lower energy expenditures using the Intelligent prosthesis (0.30 ml/kg.m) compared to the standard pneumatic prosthesis (0.33 ml/kg.m) only when subjects walked at about half normal speed. However, the clinical significance of this degree of difference in metabolic expenditure, which is only manifest at slow walking speeds, is in question, especially for younger, healthy subjects.

A study by Swanson et al (2005) evaluated body image and function in 8 amputees using the Otto-Bock C-Leg. However, the study did not include a comparison group of individuals using a standard hydraulic-based prosthesis. Thus, no conclusions can be drawn regarding differences in body image and function levels of individuals using the C-Leg and individuals using a standard hydraulic-based prosthesis.

In a randomized, controlled cross-over study comparing the C-leg to a standard mechanical knee (Mauch SNS knee), Orendurff et al (2006) found that, at measured walking speeds, the C-Leg did not significantly improve gait efficiency in trans-femoral (TF) amputees. Eight TF amputees were randomized to the Mauch SNS knee and the C-Leg microprocessor-controlled knee. The subjects were given a 3-month acclimation period in each knee. Then, their net oxygen cost (mL/kg/m) was measured while they walked overground at 4 speeds in random order: 0.8 m/s, 1.0 m/s, 1.3 m/s, and self-selected walking speed (SSWS). The C-Leg caused small reductions in net oxygen cost that were not statistically significant compared with the Mauch SNS at any of the walking speeds (p > 0.190). Subjects chose higher SSWSs with the C-Leg compared with the Mauch SNS (mean +/- standard deviation = 1.31 +/- 0.12 m/s versus 1.21 +/- 0.10 m/s, respectively, p = 0.046) but did not incur higher oxygen costs (p = 0.270), which suggests greater efficiency only at their SSWS.

A randomized cross-over study by Segal et al (2006) comparing the C-Leg to a standard mechanical knee (Mauch SNS knee) found no significant differences in gait biomechanics. After subjects had a 3-month acclimation period with each prosthetic knee, typical gait biomechanical data were collected in a gait laboratory. The investigators reported that, at a controlled walking speed (CWS),
peak swing phase knee-flexion angle decreased for the C-Leg group compared with the Mauch SNS group (55.2° +/- 6.5° versus 64.41° +/- 5.8°, respectively; p = 0.005); the C-Leg group was similar to control subjects' peak swing knee-flexion angle (56.0° +/- 3.4°). Stance knee-flexion moment increased for the C-Leg group compared with the Mauch SNS group (0.142 +/- 0.05 versus 0.067 +/- 0.07 N²m, respectively; p = 0.01), but remained significantly reduced compared with control subjects (0.477 +/- 0.1 N²m). Prosthetic limb step length at CWS was less for the C-Leg group compared with the Mauch SNS group (0.66 +/- 0.04 versus 0.70 +/- 0.06 m, respectively; p = 0.005), which resulted in increased symmetry between limbs for the C-Leg group. Subjects also walked faster with the C-Leg versus the Mauch SNS (1.30 +/- 0.1 versus 1.21 +/- 0.1 m/s, respectively; p = 0.004). The C-Leg prosthetic limb vertical ground reaction force decreased compared with the Mauch SNS (96.3 +/- 4.7 versus 100.3 +/- 7.5% body weight, respectively; p = 0.0092). The investigators concluded: "Our study demonstrated minimal differences between the gait biomechanics of subjects walking with the C-Leg compared with the Mauch SNS, a non-computerized prosthetic knee, during constant speed ambulation at approximately TF amputee SSWS."

Klute et al (2006) found that a microprocessor controlled knee had no effect on amputees functional level compared to mechanical knees. To investigate the effect of prosthetic interventions on the functional mobility of lower-extremity amputees, the investigators conducted a cross-over study involving 5 TF amputees comparing a microprocessor controlled knee (C-Leg) to a non-microprocessor controlled knee (Mauch SNS). The investigators reported that knee type had no effect on the daily activity level or duration for TF amputees.

A study by Seymour et al (2007) (n = 13) comparing the C-leg to various non-microprocessor controlled knees reported decreased oxygen consumption with the C-leg. However, this study is of weaker design than the studies by Orendurff et al (2006) and Segal et al (2006) described above, in that it was a simple pre-post study, which is of weaker design than a randomized controlled clinical trial. Another recently reported study
comparing functional performance of microprocessor controlled and mechanical knees is also of weaker design (Hafner et al, 2007) \(n = 21\).

There is limited evidence for the use of microprocessor-controlled knees in patients with unilateral hip disarticulation. Chin et al (2005) compared the energy expenditure during walking in 3 patients, aged between 51 and 55 years, with unilateral disarticulation of the hip when using the mechanical-controlled stance-phase control knee (Otto Bock 3R15) and the microprocessor-controlled pneumatic swing-phase control knee (Intelligent Prosthesis, IP). All had an endoskeletal hip disarticulation prosthesis with an Otto Bock 7E7 hip and a single-axis foot. The energy expenditure was measured when walking at speeds of 30, 50, and 70 m/min. Two patients showed a decreased uptake of oxygen (energy expenditure per unit time, ml/kg/min) of between 10.3 % and 39.6 % when using the IP compared with the Otto Bock 3R15 at the same speeds. One did not show any significant difference in the uptake of oxygen at 30 m/min, but at 50 and 70 m/min, a decrease in uptake of between 10.5 % and 11.6 % was found when using the IP. The use of the IP decreased the energy expenditure of walking in these patients.

The California Technology Assessment Forum (CTAF, 2007) recommended the use of a C-Leg microprocessor-controlled prosthetic knee in otherwise healthy, active K3-K4 community ambulating adults with a trans-femoral amputation from a non-vascular cause (usually trauma or tumor) for whom this prosthesis can be fit and programmed by a qualified prosthetist trained to do so. (Note: Medicare level K3 refers to unlimited community ambulator, while level K4 refers to active adult, athlete, who has the need to function at a K3 level in daily activities).

A technology assessment of microprocessor-controlled prosthetic knees prepared by the CTAF (2007) noted that the majority of available literature evaluated intermediate outcomes; however, 3 studies were identified that focused on actual functional outcomes. The CTAF assessment found that the bulk of all of these studies show improvement in outcomes when the
microprocessor-controlled knee is used as compared to a more traditional non-microprocessor-controlled (NMC) knee. The CTAF assessment reported: "While it is unclear how some of the intermediate outcomes impact on clinical or functional outcomes, the functional outcomes of improved gait biomechanics, improved balance, few falls, improved performance on an obstacle course and going down stairs and hills, as well as fewer self-reported falls have obvious benefit for the prosthetic users. While none of the studies is without flaws; however, the bulk of the evidence is in favor of the studied microprocessor-controlled prosthetic knees for the populations enrolled." The CTAF assessment concluded that it appears that healthy, active adults with a trans-femoral amputation for a non-vascular cause (usually trauma or tumor) derive functional benefit from wearing a microprocessor-controlled knee.

According to the CTAF assessment, there are questions remaining about microprocessor-controlled prosthetic knees (CTAF, 2007). The CTAF assessment notes that many of the studies attempted to enroll more individuals, but some of their enrollees either could not be fit with the prosthesis or could not adapt to it. It is unclear whether there are particular predictors of who these people might be -- is it something to do with the interface between stump and socket, or are there other important predictors? The CTAF assessment also observed that all of the studies were of individuals who were long-term users of an NMC previously; is there a population who should be offered a microprocessor-controlled prosthetic knee as their initial prosthesis? The CTAF assessment commented that most of the studies enrolled active adults, and only a few enrolled moderately active or older dysvascular adults -- is there a group of moderately active adults whose activity level would improve even more with this technology? "Perhaps these researchers would have observed even greater differences if they had studied somewhat less active individuals with the potential for enhanced mobility with a more responsive prosthesis."

The Proprio Foot (Ossur, Alsio Viejo, CA) is a microprocessor-controlled prosthetic ankle-foot system for lower-extremity amputees. It is designed to adjust to uneven ground, ramps,
stairs, and other environmental obstacles. It consists of 4 parts: (i) an energy storing prosthetic foot, (ii) a battery-powered prosthetic ankle that dorsiflexes and plantarflexes during swing phase, (iii) a microprocessor that controls dorsiflexion and plantarflexion in real time and in response to changes in the underlying terrain by sampling ankle position more than 1,000 times per second, and (iv) a lithium-ion battery and charger. Its Terrain Logic software permits the adjustment to surface gradients of up to 20 degrees.

Published evidence on microprocessor-controlled ankle-foot orthoses is limited to small studies examining the short-term effects on kinematic parameters, which are considered short-term surrogate outcomes (Fradet et al, 2010; Alimusaj et al, 2009; and Wolf et al, 2009). However, there is a lack of data on other relevant aspects of ambulation (e.g., daily step frequency, estimated step distance, stopping and standing safely, adaptation to different walking speeds, and fall frequency). In addition, there is a lack of reliable published evidence of the impact of microprocessor-controlled ankle-foot prostheses compared to standard ankle-foot prostheses on other relevant outcomes, including energy expenditure, cognitive requirements of ambulation, and patient-centered outcomes (quality of life, impact on activities of daily living, work, and work performance).

A systematic evidence review prepared for the Washington State Health Technology Advisory Committee (Henrickso, et a., 2011) found no studies of the Proprio Foot or other microprocessor controlled foot devices that met inclusion criteria for the systematic evidence review. The review stated that "[t]here is insufficient evidence to evaluate the comparative effectiveness, safety, or cost effectiveness of microprocessor-controlled foot devices."

Bellmann et al (2012) examined the immediate biomechanical effects after transition to a new microprocessor-controlled prosthetic knee joint. Subjects were men (n = 11; mean age ± SD, 36.7 ± 10.2 years; Medicare functional classification level, 3 to 4) with unilateral TF amputation. Two microprocessor-controlled prosthetic knee joints: C-Leg and a new prosthetic knee joint,
Genium were used in this study. Main outcome measures included static prosthetic alignment, time-distance parameters, kinematic and kinetic parameters, and center of pressure. After a half-day training and an additional half-day accommodation, improved biomechanical outcomes were demonstrated by the Genium: lower ground reaction forces at weight acceptance during level walking at various velocities, increased swing phase flexion angles during walking on a ramp, and level walking with small steps. Maximum knee flexion angle during swing phase at various velocities was nearly equal for Genium. Step-over-step stair ascent with the Genium knee was more physiologic as demonstrated by a more equal load distribution between the prosthetic and contralateral sides and a more natural gait pattern. When descending stairs and ramps, knee flexion moments with the Genium tended to increase. During quiet stance on a decline, subjects using Genium accepted higher loading of the prosthetic side knee joint, thus reducing same side hip joint loading as well as postural sway. The authors concluded that in comparison to the C-Leg, the Genium demonstrated immediate biomechanical advantages during various daily ambulatory activities, which may lead to an increase in range and diversity of activity of people with above-knee amputations. Results showed that use of the Genium facilitated more natural gait biomechanics and load distribution throughout the affected and sound musculoskeletal structure. This was observed during quiet stance on a decline, walking on level ground, and walking up and down ramps and stairs.

Bellmann et al (2012) reported a biomechanical study to assess objective gait measurements and calculate joint kinematics and kinetics as subjects ascended stairs. The investigators stated that results demonstrated that climbing stairs step over step is more biomechanically efficient for an amputee using the Genium prosthetic knee than the previously possible conventional method where the extended prosthesis is trailed as the amputee executes one or two steps at a time. The investigators explained that there is a natural amount of stress on the residual musculoskeletal system, and it has been shown that the healthy contralateral side supports the movements of the amputated side. The mechanical power that the healthy contralateral knee
joint needs to generate during the extension phase is also reduced. Similarly, there is near normal loading of the hip joint on the amputated side.

Highsmith et al (2016) conducted a study to determine if laboratory determined benefits of Genium are detectable using common clinical assessments and if there are economic benefits associated with its use. This study utilized a randomized AB crossover study with 60 day follow-up including cost-effectiveness analysis. Twenty transfemoral amputee (TFA) patients tested with both knees in mobility and preference measures. Incremental cost-effectiveness ratios (ICER) were calculated based on performance measures. Stair Assessment Index scores improved with Genium. Mean stair completion times and descent stepping rate were not different between knees. Stair ascent stepping rate for C-Leg was greater compared with Genium (p = 0.04). Genium use decreased Four square step test completion time and increased functional level and step activity (p ≤ 0.05). Further, Genium use improved (p ≤ 0.05) function and safety in 3 out of 5 Activities of Daily Living (ADL) survey domains. Finally, more subjects preferred Genium following testing. Functional measures were used to calculate ICERS. ICER values for Genium fall within established likely-to-accept value ranges. The authors concluded that, compared with C-Leg, Genium use improved stair walking performance, multidirectional stepping, functional level, and perceived function. In this group of community ambulators with TFA, Genium was preferred, and, while more costly, it may be worth funding due to significant improvements in functional performance with ADLs.

Kannenberg et al (2013) conducted a study with 10 unilateral transfemoral amputees (Medicare Functional Classification level 3 and 4) to investigate whether the Genium Knee is able to further improve the perceived safety and difficulty of 45 activities of daily living as compared with the C-Leg. Results show that after 3 months of Genium use, it could be shown that perceived safety improved in 27 activities (60 %) and perceived difficulty improved in 24 activities (53 %). Improvements were seen in the categories of Family and Social Life as well as Mobility and Transportation. The authors concluded that these findings create the basis for
further improvement of independence and participation of amputees in family, business, and social life by using the Genium Bionic Prosthetic Knee.

The Prosthesis Evaluation Questionnaire (PEQ) evaluates prosthetic-related function and quality of life. The PEQ has been used in microprocessor knee literature to compare perceptive response between C-Leg and non-microprocessor-controlled knee mechanisms. Highsmith et al (2014) studied perceived differences in prosthetic function and quality of life following accommodation with a Genium compared with a C-Leg. Twenty people with TFA participated in this randomized crossover study. C-Leg users randomized to test first with their own C-Leg or a Genium then crossed over into the other condition for repeated testing. Non-knee prosthetic attributes were held constant. Participants completed the PEQ for each knee condition to compare perceived differences in prosthetic function and quality of life. Genium use resulted in significant improvements (p ≤ 0.05) in the following scales -- Perceived Response, Social Burden, Utility, and Well-Being -- as well as in individual items related to improved standing comfort, satisfaction with walking ability, and improved gait in tight spaces, hills, and slippery surfaces (p < 0.025). As a result of using the Genium, patients perceive improvements in prosthetic-related quality of life and function. Further, patients perceive improvements in very specific mobility functions related to ambulation on complex settings.

Highsmith et al (2016) conducted a study using a randomized experimental crossover of TFA patients using Genium and C-Leg microprocessor knee (MPKs) (n = 20). Biomechanical gait analysis by 3D motion tracking with floor mounted force plates of TFA patients ambulating at different speeds on 5° ramps was completed. Knee moment DoA was significantly different between MPK conditions in the slow and fast uphill as well as the slow and self-selected downhill conditions. In a sample of high-functioning TFA patients, Genium knee system accommodation and use improved knee moment symmetry in slow speed walking up and down a five degree ramp compared with C-Leg. Additionally, the Genium improved knee moment symmetry when walking downhill at comfortable speed. These results likely
have application in other patients who could benefit from more consistent knee function, such as older patients and others who have slower walking speeds.

Lura et al (2015) used a randomized experimental crossover of persons with transfemoral amputation using the Genium and C-Leg microprocessor knees (n = 25), with an observational sample of non-amputee controls (n = 5). Gait analysis by 3D motion tracking of subjects ambulating at different speeds on level ground and on 5° and 10° ramps was completed. The investigators found that use of the Genium resulted in a significant increase in peak knee flexion for swing (5°, p < 0.01, d = 0.34) and stance (2°, p < 0.01, d = 0.19) phases relative to C-Leg use. There was a high degree of variability between subjects, and significant differences still remain between the Genium group and the control group's knee flexion angles for most speeds and slopes. The investigators concluded that the Genium knee generally increases flexion in swing and stance, potentially decreasing the level of impairment for persons with transfemoral amputation. The investigators stated that this study demonstrates functional differences between the C-Leg and Genium knees to help prosthetists determine if the Genium will provide functional benefits to individual patients.

Highsmith et al (2014) conducted a project to determine if walking speed increases and if ambulatory-related exertion decreases in transfemoral amputees (TFAs) using the novel Genium microprocessor knee. A second purpose was to determine if directional and postural control improves with the Genium knee. Twenty-five (n = 25) subjects consented to participate in the study; 20 subjects had unilateral TFA, and 5 non-amputees served as controls. A randomized A–B cross-over design was used. Gait speed increases in TFAs were not observed in preliminary analyses. However, gait biomechanical improvements such as swing phase knee flexion angle consistency were reported. Such improvements may be perceptible to the user in short and mid-distance walking tests. Significant differences were observed between TFAs and controls for walking test times, but no differences were found between knee systems. A trend of decreased perceived exertion was
observed with Genium compared with C-Leg, but differences did not reach significance. Controls consistently rated greater exertion during walking, possibly as a result of walking faster. TFAs show considerable impairment compared to controls in directional control, and the Genium tends to improve rearward-directed control. The C-Leg significantly improves control over the prosthetic forefoot. Postural control was not different between the two knee systems. During short to medium distances, the Genium sustains walking speed improvements realized by the C-Leg but at potentially decreased levels of perceived exertion. However, C-Leg use results in improved anterolateral directional control compared with Genium, likely due to its toe load requirement. Conversely, Genium use tended to improve control in rearward directions.

Powered prosthetic devices, which utilize signals from muscle activity in the remaining limb to bend and straighten the device, are being researched. These devices use sensors and electronics to process data and control movement and power of the knee. Examples of these devices are the Power Knee (Ossur, Foothill Ranch, CA). According to the manufacturer, the Power Knee is the first motorized prosthetic knee available for TF amputees weighing up to 275 pounds. It is designed for use by functional level K3 individuals with a documented co-morbidity in their sound limb or spine and by bilateral amputees. The knee houses an electro-mechanical actuator that actively initiates and controls all aspects of the user’s gait. It also provides powered knee flexion and extension under full user load. The motor initiates appropriate movement and function based on data collected through accelerometers, gyroscopes, a torque sensor, and a load sensor. When users walk with the Power Knee, the device samples knee position and loads at the rate of 1,000 times/second to provide appropriate power for the user in all 3 phases of the extension portion of the gait cycle. At heel strike, the motor permits and encourages active stance flexion, functioning to replace foot/ankle, knee, and hip muscles. This allows a flexion moment that more accurately replicates able-bodied gait while simultaneously providing full support and stability for users. The motor-controlled knee flexion at heel strike also reduces the impact on users, permitting a smoother
transition from the sound side to the prosthetic side, facilitating a more symmetrical gait. When users walk down declines and stairs, the Power Knee allows leg-over-leg descent. When users stand still, it permits them to stand with the prosthetic knee flexed, as the electro-mechanical motor actively support the user's weight. The Power Knee’s motor actively extends the knee from a flexed (seated) position into an extended (standing) one. The motor provides an affirmative, dynamic response that resists gravity, lifting the user up. Upon initial use, a practitioner must program and align the knee. Once programming and alignment are complete, the user needs only to press the power button to use the device. The user must also charge the lithium-polymer batteries that power the device. A 3.5-hour charge is recommended to ensure maximum battery life. On a full charge, battery life is up to 12 hours depending on the user’s activities. Each Power Knee comes with 2 batteries.

The BiOM is a below knee robotic prosthesis that designed for use by individuals with lower extremity amputation. This prosthesis, which includes the foot, ankle, and lower calf, uses robotics to replicate the calf muscles and Achilles tendon. With each step, the BiOM provides a powered push-off which propels the wearer forward. Powered plantar flexion enables the prosthesis to normalize the gait and metabolic demands to those of non-amputees. With its bionic functionality, this prosthesis can resolve clinical issues faced by amputees, including tiredness, slowness, and a feeling of being unstable on their feet. The robotic muscle power provided by the BiOM during toe-off requires less energy from the user. It also provides more power when the user walks faster and less when the user walks slower, which produces a natural gait at variable speeds. Users are able to negotiate stairs and inclines with increased confidence and stability due to improved articulation and the design’s ability to mechanically yield and conform.

Mancinelli et al (2011) stated that passive-elastic foot prostheses cannot produce network. Consequently, passive-elastic foot prostheses are limited in their ability to enable a biologically-realistic gait pattern in transtibial amputees. This shortcoming results in difficulties in balance and walking and leads to high
levels of oxygen consumption during locomotion. A powered prosthesis has the potential for overcoming these problems and allowing transtibial amputees to achieve a biologically-realistic gait pattern. In this study, these researchers compared the effects of the Ceterus by Ossur, a traditional passive-elastic prosthesis, with those of the PowerFoot Biom (iWalk, Cambridge, MA), a recently-developed powered prosthesis. Gait biomechanics and metabolic cost were compared in a group of 5 transtibial amputees during level-ground walking. The results provided preliminary evidence that the use of a powered prosthesis leads to a decrease in the level of oxygen consumption during ambulation due to improvements in ankle kinematics and kinetics primarily during late stance. An average decrease in oxygen consumption of 8.4% was observed during the study when subjects used the PowerFoot compared to the Ceterus. An average increase of 54% was observed in the peak ankle power generation during late stance. The authors concluded that these findings suggested that powered prostheses have the potential for significantly improving ambulation in transtibial amputees.

Aldridge and colleagues (2012) noted that during stair ascent (STA) persons with transtibial amputation (TTA) typically adopt a hip strategy to compensate for the limited ankle motion and joint power that is characteristic of conventional energy storing and returning (ESR) prosthetic feet. The purpose of this investigation was to determine if providing ankle power via a powered prosthetic device (BiOM) normalized STA kinematics and kinetics. A total of 11 individuals with TTA participated in 2 STA gait analysis sessions: (i) using an ESR foot, and (ii) using the BiOM. Eleven height- and weight-matched able-bodied controls (CONT) were also assessed. Lower extremity peak kinematic and kinetic values were calculated at a self-selected and controlled cadence (80 steps/min). Increased prosthetic limb peak ankle plantar-flexion and push-up power were observed while using the BiOM as compared to ESR. Peak ankle power was not significantly different between BiOM and CONT indicating normalization of ankle power generation. However, peak ankle plantar-flexion was significantly lower than CONT. Limb asymmetries including greater prosthetic limb hip flexion and power during stance, and decreased prosthetic limb knee power during stance were
observed in the BiOM and ESR conditions. The authors concluded that these findings suggested that the BiOM successfully increased ankle motion and restored ankle power during STA. These differences did not, however, reduce the use of a hip strategy while ascending stairs. They stated that additional device specific training may be necessary to utilize the full benefits of the device.

However, due to the small sample sizes in these studies, it is unclear if these preliminary findings would be observed in the general TTA population. Further investigation is needed to establish a meaningful clinical outcome benefit of the iWalk BiOM prosthetic foot over the conventional ankle-foot prosthesis. Furthermore, the Washington State Health Care Authority (2011) does not cover microprocessor-controlled lower limb prostheses for the feet and ankle (e.g., the iWalk PowerFoot BiOM).

Wearable robotic exoskeletons have been developed to reportedly help individuals ambulate despite partial or complete paraplegia. The devices include fitted braces for the legs and upper body with motorized hip and knee joints, a backpack containing a computer and rechargeable batteries, an array of upper body motion sensors and a computer based wireless control system worn on the individual’s wrist. Crutches are also used to provide the user with additional stability when walking, standing or rising from a chair. Typically, these devices are indicated for use by people with paraplegia due to spinal cord injuries at levels T7 to L5 when accompanied by a specially trained caregiver and for individuals with spinal cord injuries at levels T4 to T6 where the device is limited to use in rehabilitation institutions. Examples of devices include, but may not be limited to, the following: ESKO GT system (for use only in rehabilitation institutions); Indego powered exoskeleton; and ReWalk personal system. Generally, the use of these devices requires that individuals are able to stand using an assistive device (e.g., standing frame) and their hands and shoulders are able to support crutches or a walker.

Federici et al (2015) reviewed the clinical effectiveness of various types of active, powered, wearable lower limb exoskeletons for
the rehabilitation of gait disorders in paraplegic patients resulting from central nervous system lesions caused by, for example, SCIs or CVAs. The most commonly studied exoskeletons were the HAL, ReWalk, and the Vanderbilt lower limb exoskeleton. Studies of exoskeleton use in neurorehabilitation contexts have mostly evaluated the safety of the devices, the physical and cognitive effort required to use them, how easy it is to learn to use them and how effectively they enhance patients’ gait. The studies confirmed that the HAL, Tibion Bionic Technologies, and Ekso devices were safe to use in controlled environments, and with the assistance of expert professionals (i.e., physiotherapists). The authors found no studies evaluating the effectiveness of exoskeletons outside laboratory or clinical settings, and hence no evidence of their effectiveness in everyday living environments, for example for walking on rough surfaces such as a sidewalk or a staircase with uneven steps. The authors noted that there is a dearth of experimental evidence demonstrating that exoskeletons are more effective than other rehabilitative techniques and technologies. They also noted that none of the publications reviewed analyzed users’ experiences with an exoskeleton in activities of daily living.

Louie et al (2015) systematically reviewed the literature to determine the gait speed attained by individuals with SCI when using a powered exoskeleton to walk, factors influencing this speed, and characteristics of studies involving a powered exoskeleton (e.g., inclusion criteria, screening, and training processes). A systematic search in computerized databases was conducted to identify articles that reported on walking outcomes when using a powered exoskeleton. Individual gait speed data from each study was extracted. Pearson correlations were performed between gait speed and (i) age, (ii) years post-injury, (iii) injury level, and (iv) number of training sessions. Fifteen articles met inclusion criteria, 14 of which investigated the powered exoskeleton as an assistive device for non-ambulatory individuals and one which used it as a training intervention for ambulatory individuals with SCI. The mean gait speed attained by non-ambulatory participants \( (n = 84) \) while wearing a powered exoskeleton was \( 0.26 \, \text{m/s} \), with the majority having a thoracic-level motor-complete injury. Twelve articles reported individual
data for the non-ambulatory participants, from which a positive correlation was found between gait speed and (i) age ($r = 0.27$, 95% CI: 0.02 to 0.48, $p = 0.03$, 63 participants), (ii) injury level ($r = 0.27$, 95% CI: 0.02 to 0.48, $p = 0.03$, 63 participants), and (iii) training sessions ($r = 0.41$, 95% CI: 0.16 to 0.61, $p = 0.002$, 55 participants). The authors stated that this systematic review has some limitations. The level of evidence in the current literature is limited to studies with a small number of participants. In addition, a true control group (without a device to walk) is not relevant as most participants would not have been able to walk without the exoskeleton; however, future studies could compare different orthotic, FES, or exoskeleton systems. There was heterogeneity in the study characteristics (device, control of stepping, training duration, outcome measurement), which made it challenging to compare results and reduces the ability to generalize results. However, the authors attempted to overcome this by aggregating participant data to allow statistical analysis to explore correlations between participant characteristics and outcomes. The authors stated that, in the future, it would be useful for studies to report on the exact intensity of training, using such measures as number of steps or walking time.

Lajeunesse et al (2016) stated that rehabilitation professionals have little information concerning lower limb exoskeletons for people with paraplegia. This study has 4 objectives: (i) outline the characteristics of the exoskeletons' design and their usefulness evidence as assistive mobility devices in the community for the ReWalk, Mina, Indego, Ekso (previously known as the eLEGS) and Rex; (ii) document functional mobility outcomes of using these exoskeletons; (iii) document secondary skills and benefits achieved with these exoskeletons, safety, user satisfaction and applicability in the community; and (iv) establish level of scientific evidence of the selected studies. These researchers performed a systematic review of the literature (January 2004 to April 2014) using the databases PubMed, CINAHL and Embase and groups of keywords associated with "exoskeleton", "lower limb" and "paraplegia". A total of 7 articles were selected. Exoskeleton use is effective for walking in a laboratory but there are no training protocols to modify identified outcomes over the term usage (ReWalk: 3 months, Mina: 2 months and Indego: 1 session).
Levels of evidence of selected papers are low. The authors concluded that the applicability and effectiveness of lower limb exoskeletons as assistive devices in the community have not been demonstrated. They stated that more research is needed on walking performance with these exoskeletons compared to other mobility devices and other training contexts in the community. Characteristics of the exoskeletons' design and their usefulness evidence as assistive mobility devices in the community were addressed for the ReWalk, Mina, Indego, Ekso and Rex; ReWalk, Indego and Mina lower limb exoskeletons were effective for walking in a laboratory for individuals with complete lower-level SCI. The ReWalk has the best results for walking, with a maximum speed of 0.51 m/s after 45 sessions lasting 60 to 120 mins; it is comparable to the average speed per day or per week in a manual wheelchair. The level of scientific evidence is low. These investigators stated that further studies are needed to provide more information about performance over the longer term when walking with an exoskeleton, compared to wheelchair mobility, the user's usual locomotion, the use of different exoskeletons or the training context in which the exoskeleton is used.

An industry funded consulting firm published a systematic evidence review (Miller et al, 2016) that included a total of 14 studies (8 ReWalk, 3 Ekso, 2 Indego, and 1 unspecified exoskeleton) representing 111 patients were included in the analysis. Training programs were typically conducted three times per week, 60 to 120 minutes per session, for 1 to 24 weeks; 10 studies utilized flat indoor surfaces for training and 4 studies incorporated complex training, including walking outdoors, navigating obstacles, climbing and descending stairs, and performing activities of daily living. Following the exoskeleton training program, 76% of patients were able to ambulate with no physical assistance. The weighted mean distance for the 6-minute walk test was 98 m. The physiologic demand of powered exoskeleton-assisted walking was 3.3 metabolic equivalents and rating of perceived exertion was 10 on the Borg 6 to 20 scale, comparable to self-reported exertion of an able-bodied person walking at 3 miles per hour. Improvements in spasticity and bowel movement regularity were reported in 38%
and 61% of patients, respectively. No serious adverse events occurred. The incidence of fall at any time during training was 4.4%, all occurring while tethered using a first-generation exoskeleton and none resulting in injury. The incidence of bone fracture during training was 3.4%. The authors asserted that these risks have since been mitigated with newer generation exoskeletons and refinements to patient eligibility criteria. The authors noted that as with any meta-analysis, interpretation of outcomes may be confounded by issues related to individual study designs and by issues inherent in the analysis of summary data. There was considerable variation in the consistency of outcome reporting among studies. Development of minimum reporting standards for powered exoskeleton clinical trials is recommended to facilitate comparisons among studies. Additionally, the number of studies limited the ability to explore sources of heterogeneity such as age, level of injury, and duration of injury.

This analysis was funded by ReWalk and the authors are from “Miller Scientific Consulting”. The meta-analysis combined results using a variety of exoskeleton devices, subject characteristics, and settings and reported “considerable variation in outcome reporting among studies” and substantial heterogeneity among most study outcomes. A major drawback of this meta-analysis was a lack of critical assessment of the quality of the studies included in the meta-analysis.

The ReWalk exoskeleton (Argo Medical Technologies Ltd, Marlborough, MA) is designed for persons with a spinal cord injury (SCI) who retain upper-limb strength and mobility to manage stabilizing crutches. It is worn outside clothing and weighs 44 pounds. It consists of an upper-body harness, lower-limb braces, motorized joints, ground-force sensors, a tilt sensor, a locomotion-mode selector, and a backpack carrying a computerized controller and rechargeable battery. The device is strapped to the user at the waist, alongside each lower limb, and at the feet. Ordinary crutches help maintain stability. The ReWalk exoskeleton comes in 2 sizes: (i) one that fits persons 5 feet 3 inches to 5 feet 9 inches in height, and (ii) one that accommodates persons up to 6 feet 3 inches. The ReWalk can be
worn by individuals weighing up to 220 pounds. Two types of the ReWalk exoskeletons are available: (i) the institutional version, the ReWalk-I, which is designed for rehabilitation centers and physician private practices, and (ii) a personal version, the ReWalk-P, which is designed for an individual’s sole use.

In a pilot study, Zeilig et al (2012) evaluated the safety and tolerance of use of the ReWalk exoskeleton ambulation system in people with SCI. Measures of functional ambulation were also assessed and correlated to neurological spinal cord level, age, and duration since injury. A total of 6 volunteer participants were recruited from the follow-up outpatient clinic. Safety was assessed with regard to falls, status of the skin, status of the spine and joints, blood pressure, pulse, and electrocardiography (ECG). Pain and fatigue were graded by the participants using a visual analog scale pre- and post-training. Participants completed a 10-statement questionnaire regarding safety, comfort, and secondary medical effects. After being able to walk 100 m, timed up and go, distance walked in 6 minutes and 10-m timed walk were measured. There were no adverse safety events. Use of the system was generally well-tolerated, with no increase in pain and a moderate level of fatigue after use. Individuals with lower level of SCI performed walking more efficiently. The authors concluded that volunteer participants were able to ambulate with the ReWalk for a distance of 100 m, with no adverse effects during the course of an average of 13 to 14 training sessions. The participants were generally positive regarding the use of the system. Moreover, the authors stated that the potential benefits of the ReWalk are many, including improved functional mobility, cardio-vascular and respiratory status, bone metabolism, and bowel and bladder function, as well as reduction of spasticity and neuropathic pain, but efficacy still needs to be demonstrated in a larger study. Also, these researchers noted that this study did not include any female subjects, individuals with tetraplegia, children, or older adults; future large-scale inclusive studies are needed.

In an open, non-comparative, non-randomized study, Esquenazi et al (2012) evaluated the safety and performance of ReWalk in enabling people with paraplegia due to SCI to carry out routine ambulatory functions. All 12 subjects have completed the active
intervention; 3 remained in long-term follow-up. After training, all subjects were able to independently transfer and walk, without human assistance while using the ReWalk, for at least 50 to 100 m continuously, for a period of at least 5 to 10 mins continuously and with velocities ranging from 0.03 to 0.45 m/sec (mean of 0.25 m/sec). Excluding 2 subjects with considerably reduced walking abilities, average distances and velocities improved significantly. Some subjects reported improvements in pain, bowel and bladder function, and spasticity during the trial. All subjects had strong positive comments regarding the emotional/psychosocial benefits of the use of ReWalk. The authors concluded that the ReWalk holds considerable potential as a safe ambulatory powered orthosis for motor-complete thoracic-level SCI patients. Most subjects achieved a level of walking proficiency close to that needed for limited community ambulation. A high degree of performance variability was observed across individuals. Some of this variability was explained by level of injury, but other factors have not been completely identified. Further development and application of this rehabilitation tool to other diagnoses are expected in the future.

Fineberg et al (2013) conducted a study using vertical ground reaction force (vGRF) to show the magnitude and pattern of mechanical loading in persons with spinal cord injury (SCI) during powered exoskeleton-assisted walking with ReWalk. The authors conducted a cross-sectional study to analyze vGRF during powered exoskeleton-assisted walking compared with vGRF of able-bodied gait. Six persons with thoracic motor-complete SCI (T1-T11 AIS A/B) and three age-, height-, weight- and gender-matched able-bodied volunteers participated. SCI participants were trained to ambulate over ground using a ReWalk. vGRF was recorded using the F-Scan system (TekScan, Boston, MA, USA). Peak stance average (PSA) was computed from vGRF and normalized across all participants by percent body weight. Peak vGRF was determined for heel strike, mid-stance, and toe-off. Relative linear impulse and harmonic analysis provided quantitative support for analysis of powered exoskeletal gait. The investigators reported that participants with motor-complete SCI, ambulating independently with a ReWalk, demonstrated
mechanical loading magnitudes and patterns similar to able-bodied gait. Harmonic analysis of PSA profile by Fourier transform contrasted frequency of stance phase gait components between able-bodied and powered exoskeleton-assisted walking.

Asselin et al (2015) reported on heart rate and oxygen demand of powered exoskeleton-assisted walking in persons with paraplegia. As part of an ongoing clinical study (NCT01454570), eight non-ambulatory persons with paraplegia were trained to ambulate with a ReWalk powered exoskeleton. Measurements of oxygen uptake (VO2) and heart rate (HR) were recorded for 6 mins each during each maneuver while sitting, standing, and walking. The average value of VO2 during walking (11.2 +/- 1.7 ml/kg/min) was significantly higher than those for sitting and standing (3.5 +/- 0.4 and 4.3 +/- 0.9 ml/kg/min, respectively; p < 0.001). The HR response during walking was significantly greater than that of either sitting or standing (118 +/- 21 versus 70 +/- 10 and 81 +/- 12 beats per minute, respectively: p < 0.001).

Yang et al (2015) sought to evaluate exoskeletal-assisted walking (EAW) velocity, number of sessions, and level of assistance (LOA) and the relationships among them. The secondary aims were to report on safety and the qualitative analysis of gait and posture during EAW in a hospital setting. Twelve individuals with SCI ≥ 1.5 years who were wheelchair users participated. They wore a powered exoskeleton (ReWalk; ReWalk Robotics, Inc., Marlborough, MA) with Lofstrand crutches to complete 10-meter (10 MWT) and 6-minute (6MWT) walk tests. LOA was defined as modified independence (MI), supervision (S), minimal assistance (Min), and moderate assistance (Mod). Best effort EAW velocity, LOA, and observational gait analysis were recorded. Seven of 12 participants ambulated ≥ 0.40 m/s. Five participants walked with MI, 3 with S, 3 with Min, and 1 with Mod. Significant inverse relationships were noted between LOA and EAW velocity for both 6 MWT (Z value = 2.63, Rho = 0.79, p = .0086) and 10 MWT (Z value = 2.62, Rho = 0.79, p = .0088). There were 13 episodes of mild skin abrasions. MI and S groups ambulated with 2-point alternating crutch pattern, whereas the Min and Mod groups favored 3-point crutch gait. The authors concluded that the ReWalk is a safe device for in-hospital ambulation.
Talaty et al (2013) reported preliminary analysis of how walking kinematics differed across 12 subjects using the ReWalk. All subjects met basic criteria to be able to use the ReWalk – including items such as sufficient bone mineral density, leg passive range of motion, strength, body size and weight limits. All subjects received approximately the same number of training sessions. However there was a wide distribution in walking ability. Walking velocities ranged from under 0.1 m/s to approximately 0.5 m/s. The authors stated that this variability was not completely explained by injury level. The remaining sources of that variability are not clear at present.

Raab et al (2016) reported on a single case study investigating to what extent the quality of life (QoL) of patients with spinal cord injury can be influenced by the training with an exoskeleton. The study was carried out at a hospital for neurological rehabilitation in Germany. One patient (male, 22 years), initially unable to walk independently after traumatic spinal cord injury with neurological level Th11 (ASIA Impairment Scale C) was recruited for this study 1 year after injury. The progress of the first 6 months of ReWalk training was documented and as primary outcome measure the QoL was measured with SF-36 questionnaire. Secondary outcome measures were ASIA scale, Berg-Balance-Scale and Dynamic Gait Index. The authors reported that, at the end of the study period the patient was able to walk independently supervised by one person. QoL, mobility, risk of falling, motor skills and control of bladder and bowel functions were improved. A positive effect of robot-assisted gait training on various areas of the QoL was shown. The authors stated that subsequent studies should aim to verify this effect through a higher number of patients and to different injury levels.

Benson et al (2016) conducted a longitudinal, prospective, self-controlled study to assess the feasibility of conducting a well-powered trial evaluating the neurological and functional effects of using an exoskeleton in individuals with chronic motor complete or incomplete spinal cord injury at a UK specialist spinal cord injuries center. Enrolled subjects were assigned to 20 ReWalk exoskeleton training sessions over a 10-week training period. Feasibility measures, clinical and mobility outcome measures and
measures appraising subjects' disability and attitude towards assistive technology were assessed before, during and after the study. Descriptive statistics were applied. Out of 60 candidates, 10 (17%) were enrolled and 5 (8%) completed the training program. Primary reasons for not enrolling were ineligibility (n = 24, 40%) and limited interest to engage in a 10-week training program (n = 16, 27%); 5 out of 10 enrolled subjects experienced grade I/II skin aberrations. While walking speeds were higher and walking distances were longer in all exoskeleton users when compared with non-use, the exoskeleton did generally not meet subjects' high expectations in terms of perceived benefits. The authors concluded that the conduct of a controlled trial evaluating the benefits of using exoskeletons that require a lengthy user-commitment to training of individuals with chronic motor complete or incomplete spinal cord injury comes with considerable feasibility challenges. Vigilance is required for preventing and detecting medical complications in spinal cord injury exoskeleton users.

Lonini et al (2016) noted that clinical scores for evaluating walking skills with lower limb exoskeletons are often based on a single variable, such as distance walked or speed, even in cases where a host of features are measured. In a pilot study, these researchers ascertained how to combine multiple features such that the resulting score has high discriminatory power, in particular with few patients. A new score is introduced that allows quantifying the walking ability of patients with SCI when using a powered exoskeleton. A total of 4 SCI patients were trained to walk over ground with the ReWalk exoskeleton. Body accelerations during use of the device were recorded by a wearable accelerometer and 4 features to evaluate walking skills were computed. The new score is the Gaussian naive Bayes surprise, which evaluates patients relative to the features' distribution measured in 7 expert users of the ReWalk. These investigators compared their score based on all the features with a standard outcome measure, which is based on number of steps only. All 4 patients improved over the course of training, as their scores trended towards the expert users' scores. The combined score (Gaussian naive surprise) was considerably more discriminative than the one using only walked distance (steps). At the end of training, 3
out of 4 patients were significantly different from the experts, according to the combined score (p < 0.001, Wilcoxon Signed-Rank Test). In contrast, all but 1 patient were scored as experts when number of steps was the only feature. The authors concluded that integrating multiple features could provide a more robust metric to measure patients' skills while they learn to walk with a robotic exoskeleton; testing this approach with other features and more subjects remains as future work.

The Ekso robotic exoskeleton is a motorized orthosis device for use in rehabilitation activities for people who have weak or paralyzed legs and sufficient arm strength to use crutches (NICE, 2017). It is intended to help people to relearn to stand and walk. The innovative aspect of the Ekso GT robotic exoskeleton is the SmartAssist software that is incorporated in the device (NICE, 2017). This allows physiotherapists to set the power for each leg independently to best suit the user. Multiple patients can use each Ekso robotic exoskeleton, with it being adapted to their specific needs. The intended place in therapy would be instead of, or in addition to, existing rehabilitation activities including physiotherapy, exercise, strength training, walking therapies with or without support, and functional electrical stimulation.

A MedTech Innovation Briefing (NICE, 2017) stated that the key points from the evidence summarized in this briefing are from 1 systematic review and 5 case series, involving a total of 41 patients in a rehabilitation setting. After using Ekso, these patients were able to walk without assistance from physiotherapists and their walking speed and distance increased. No serious adverse events were reported. The briefing stated that key uncertainties around the evidence are that the included studies were small and non-comparative. The briefing stated that the resource impact is currently unclear because of a lack of evidence.

Kolakowsky-Hayner et al conducted a prospective pilot study in a spinal cord injury rehabilitation center outpatient gym to evaluate feasibility and safety of Ekso to aid ambulation in individuals with SCI. Eight individuals, at least 18 years of age, with complete T1 SCI or below, within 2 years of injury, completed initial inpatient
rehabilitation. All participants signed informed consent, had been cleared from requiring spinal orthoses, met inclusion criteria, and were pre-screened based on device requirements and medical stability. The subjects received 6 weekly sessions with graduated time and less assistance in the Ekso device.

Outcome measures included skin evaluation, blood pressure, pain level, spasticity, time and level of assistance needed to transfer into and don device; time ambulating; time up in device; assistive devices used during ambulation; step length; distance walked; level of assistance during use; losses of balance; number of falls and level of assistance needed to doff and transfer out of device. The investigators reported no major skin effects, minimal pain reports, no known fractures, swelling, or other adverse events. Level of assistance ranged from dependent to moderate independent, average set up time was 18.13 minutes, and loss of balance and falls were infrequent. The investigators concluded that bionic exoskeletons such as Ekso are safe for those with complete thoracic SCI in a controlled environment, in the presence of experts, and may eventually enhance mobility in those without volitional lower extremity function. There appears to be a training effect in the device but further trials are needed.

The investigators stated that future studies of bionic exoskeletons as gait training devices are warranted, and that future studies of bionic exoskeletons as a clinical tool to alleviate secondary complications should be considered.

Kozlowski et al (2015) sought to quantify the time and effort required by persons with SCI to learn to use the Ekso exoskeleton for assisted walking. A convenience sample was enrolled to learn to use the first-generation Ekso powered exoskeleton to walk. Participants were given up to 24 weekly sessions of instruction. Data were collected on assistance level, walking distance and speed, heart rate, perceived exertion, and adverse events. Time and effort was quantified by the number of sessions required for participants to stand up, walk for 30 minutes, and sit down, initially with minimal and subsequently with contact guard assistance. Of 22 enrolled participants, 9 screen-failed, and 7 had complete data. All of these 7 were men; 2 had tetraplegia and 5 had motor-complete injuries. Of these, 5 participants could stand, walk, and sit with contact guard or close supervision
assistance, and 2 required minimal to moderate assistance. Walk times ranged from 28 to 94 minutes with average speeds ranging from 0.11 to 0.21 m/s. For all participants, heart rate changes and reported perceived exertion were consistent with light to moderate exercise.

In a case series from an academic research center, Kressler et al (2014) explored responses to overground bionic ambulation (OBA) training with the Ekso exoskeleton three days per week for 6 weeks from an interdisciplinary perspective including key components of neuromuscular activation, exercise conditioning, mobility capacity, and neuropathic pain. Persons (n = 3; 2 men, 1 woman) aged 26 to 38 years with complete spinal cord injury (SCI) (American Spinal Injury Association Impairment Scale grade A) between the levels of T1 and T10 for 1 year or longer. To obtain a comprehensive understanding of responses to OBA, an array of measures were obtained while walking in the device, including walking speeds and distances, energy expenditure, exercise conditioning effects, and neuromuscular and cortical activity patterns. Changes in spasticity and pain severity related to OBA use were also assessed. With training, participants were able to achieve walking speeds and distances in the OBA device similar to those observed in persons with motor-incomplete SCI (10-m walk speed, 0.11 to 0.33 m/s; 2-min walk distance, 11 to 33 m). The energy expenditure required for OBA was similar to walking in persons without disability (i.e., 25 % to 41 % of peak oxygen consumption). Subjects with lower soleus reflex excitability walked longer during training, but there was no change in the level or amount of muscle activity with training. There was no change in cortical activity patterns. Exercise conditioning effects were small or nonexistent. However, all participants reported an average reduction in pain severity over the study period ranging between 1.3 and 1.7 on a 0-to-6 numeric rating scale. The authors concluded that OBA training improved mobility in the OBA device without significant changes in exercise conditioning or in neuromuscular or cortical activity. However, pain severity was reduced and no severe adverse events were encountered during training. OBA therefore opens the possibility to reduce the common consequences of chronic, complete SCI such as reduced functional mobility and neuropathic pain.
In contrast to other exoskeletons, HAL (hybrid assistive limb) exoskeleton (Cyberdyne Inc., Japan) offers the possibility of monitoring muscle contractions via surface EMG-electrodes at the extensor-flexor muscle region of the lower extremities (Sczensy-Kaiser et al., 2015). This allows for voluntary machine-supported motion using minimal signals recorded from hip and knee flexors and extensors.

Nilsson et al (2014) investigated the safety and feasibility of the exoskeleton Hybrid Assistive Limb (HAL) for intensive gait training as part of a regular inpatient rehabilitation program for hemiparetic patients with severely impaired gait early after stroke. Eligible were patients until 7 weeks after hemiparetic stroke. Training with HAL was performed 5 days per week by the autonomous and/or the voluntary control mode offered by the system. The study protocol covered safety and feasibility issues and aspects on motor function, gait performance according to the 10 Meter Walking Test (10MWT) and Functional Ambulation Categories (FAC), and activity performance. Eight patients completed the study. Median time from stroke to inclusion was 35 days (range of 6 to 46). Training started by use of the autonomous HAL mode in all and later switched to the voluntary mode in all but one and required one or two physiotherapists. Number of training sessions ranged from 6 to 31 (median 17) and walking time per session was around 25 minutes. The training was well tolerated and no serious adverse events occurred. All patients improved their walking ability during the training period, as reflected by the 10MWT (from 111.5 to 40 seconds in median) and the FAC (from 0 to 1.5 score in median).

Sczesny-Kaiser et al (2015) sought to assess whether robotic-assisted bodyweight supported treadmill training (BWSTT) with hybrid assistive limb (HAL) exoskeleton affects cortical excitability in the primary somatosensory cortex (S1) in SCI patients, as measured by paired-pulse somatosensory evoked potentials (ppSEP) stimulated above the level of injury. Eleven SCI patients took part in HAL assisted BWSTT for 3 months. Pulse paired stimulation techniques of somatosensory evoked potentials (PpSEP) were conducted before and after this training period, where the amplitude ratios (SEP amplitude following double
pulses - SEP amplitude following single pulses) were assessed and compared to eleven healthy control subjects. To assess improvement in walking function, the investigators used the 10-m walk test, timed-up-and-go test, the 6-min walk test, and the lower extremity motor score. PpSEPs were significantly increased in SCI patients as compared to controls at baseline. Following training, ppSEPs were increased from baseline and no longer significantly differed from controls. Walking parameters also showed significant improvements, yet there was no significant correlation between ppSEP measures and walking parameters. The investigators concluded that the findings suggest that robotic-assisted BWSTT with HAL in SCI patients is capable of inducing cortical plasticity following highly repetitive, active locomotive use of paretic legs. While there was no significant correlation of excitability with walking parameters, brain areas other than S1 might reflect improvement of walking functions. The investigators posited that EEG and neuroimaging studies may provide further information about supraspinal plastic processes and foci in SCI rehabilitation.

In a pilot study, Aach et al (2014) examined if locomotor training with the exoskeleton hybrid assistive limb (HAL) exoskeleton is safe and can increase functional mobility in chronic paraplegic patients after SCI. This trial was a single-case experimental A-B (pre-post) design study by repeated assessments of the same patients. The subjects performed 90 days (5 times per week) of HAL exoskeleton body weight supported treadmill training with variable gait speed and body weight support. A total of 8 patients with chronic SCI classified by the American Spinal Injury Association (ASIA) Impairment Scale (AIS) consisting of ASIA A (zones of partial preservation [ZPP] L3 to S1), n = 4; ASIA B (with motor ZPP L3 to S1), n = 1; and ASIA C/D, n = 3, who received full rehabilitation in the acute and sub-acute phases of SCI. Functional measures included treadmill-associated walking distance, speed, and time, with additional analysis of functional improvements using the 10-m walk test (10MWT), timed-up and go test (TUG test), 6-minute walk test (6MWT), and the walking index for SCI II (WISCI II) score. Secondary physiologic measures including the AIS with the lower extremity motor score (LEMS), the spinal spasticity (Ashworth scale), and the lower extremity
circumferences. Subjects performed standardized functional
testing before and after the 90 days of intervention. Highly
significant improvements of HAL-associated walking time,
distance, and speed were noticed. Furthermore, significant
improvements have been especially shown in the functional
abilities without the exoskeleton for over-ground walking
obtained in the 6MWT, TUG test, and the 10MWT, including an
increase in the WISCI II score of 3 patients. Muscle strength
(LEMS) increased in all patients accompanied by a gain of the
lower limb circumferences. A conversion in the AIS was
ascertained in 1 patient (ASIA B to ASIA C); 1 patient reported a
decrease of spinal spasticity. The authors concluded that hybrid
assistive limb exoskeleton training resulted in improved over-
ground walking and led to the assumption of a beneficial effect
on ambulatory mobility. However, they stated that evaluation in
larger clinical trials is needed.

Chihara et al (2016) investigated factors predicting the effects of
HAL in 15 patients at our institution with central nervous system
injury, primarily due to stroke, who underwent training using HAL
during the acute phase. Patients were classified as either “with
HAL suitability” or “without HAL suitability” based on scores from
10-m walking speed, gait, satisfaction, and pain. In both groups,
Brunnstrom stage before HAL intervention, Fugl-Meyer
assessment (FMA), stroke impairment assessment set (SIAS), and
functional independence measure (FIM) were evaluated.
Although motor function items did not differ significantly, FIM
cognitive function items (p = 0.036), visuospatial perception items
on SIAS (p = 0.0277), and pain items on SIAS (p = 0.0122) differed
significantly between groups. The authors stated that these
results indicated that training using HAL does not involve pain in
patients with central nervous system injury during the acute
phase, and exhibits positive effects in patients without pain and
with high communication ability and visuospatial perception
function.

Wall et al (2015) reviewed the literature on clinical applications of
the Hybrid Assistive Limb (HAL) system for gait training. A
systematic literature search was conducted using Web of Science,
PubMed, CINAHL and clinicaltrials.gov and additional search was
made using reference lists in identified reports. Abstracts were screened, relevant articles were reviewed and subject to quality assessment. Out of 37 studies, 7 studies fulfilled inclusion criteria. Six studies were single group studies and 1 was an explorative randomized controlled trial. In total, these studies involved 140 participants of whom 118 completed the interventions and 107 used HAL for gait training. Five studies concerned gait training after stroke, 1 after spinal cord injury (SCI) and 1 study after stroke, SCI or other diseases affecting walking ability. Minor and transient side effects occurred but no serious adverse events were reported in the studies. Beneficial effects on gait function variables and independence in walking were observed. The accumulated findings demonstrate that the HAL system is feasible when used for gait training of patients with lower extremity paresis in a professional setting. Beneficial effects on gait function and independence in walking were observed but data do not allow conclusions. The investigators stated that further controlled studies are recommended.

The Indego exoskeleton (Parker Hannifin Corporation, Macedonia, OH) incorporates 4 motors for powered movement of bilateral hip and knee joints in the sagittal plane, in addition to built-in ankle-foot-orthoses (AFOs) at both ankle joints to provide ankle stability and transfer the weight of the exoskeleton to the ground.

Hartigan et al (2015) conducted a study to evaluate mobility outcomes for individuals with SCI after 5 gait-training sessions with the Indego powered exoskeleton, with a primary goal of characterizing the ease of learning and usability of the system. Sixteen subjects with SCI were enrolled in a pilot clinical trial at Shepherd Center, Atlanta, Georgia, with injury levels ranging from C5 complete to L1 incomplete. An investigational Indego exoskeleton research kit was evaluated for ease of use and efficacy in providing legged mobility. Outcome measures of the study included the 10-meter walk test (10MWT) and the 6-minute walk test (6MWT) as well as measures of independence including donning and doffing times and the ability to walk on various surfaces. At the end of 5 sessions (1.5 hours per session), average walking speed was 0.22 m/s for persons with C5-6 motor complete tetraplegia, 0.26 m/s for T1-8 motor complete
paraplegia, and 0.45 m/s for T9-L1 paraplegia. Distances covered in 6 minutes averaged 64 meters for those with C5-6, 74 meters for T1-8, and 121 meters for T9-L1. Additionally, all participants were able to walk on both indoor and outdoor surfaces.

Evans et al (2015) conducted a pilot study to evaluate the acute cardiorespiratory and metabolic responses associated with Indego exoskeleton-assisted walking overground and to determine the degree to which these responses change at differing walking speeds. Five subjects (4 male, 1 female) with chronic SCI (AIS A) volunteered for the study. Expired gases were collected during maximal graded exercise testing and two, 6-minute bouts of exoskeleton-assisted walking overground. Outcome measures included peak oxygen consumption (VO2peak), average oxygen consumption (VO2avg), peak heart rate (HRpeak), walking economy, metabolic equivalent of tasks for SCI (METsSCI), walk speed, and walk distance. Significant differences were observed between walk-1 and walk-2 for walk speed, total walk distance, VO2avg, and METsSCI. Exoskeleton-assisted walking resulted in % VO2peak range of 51.5 % to 63.2 %. The metabolic cost of exoskeleton-assisted walking ranged from 3.5 to 4.3 METsSCI.

Takahashi and colleagues (2015) stated that in persons post-stroke, diminished ankle joint function can contribute to inadequate gait propulsion. To target paretic ankle impairments, these researchers developed a neuromechanics-based powered ankle exoskeleton. Specifically, this exoskeleton supplies plantar-flexion assistance that is proportional to the user's paretic soleus electromyography (EMG) amplitude only during a phase of gait when the stance limb is subjected to an anteriorly directed ground reaction force (GRF). In a feasibility study, these investigators examined the short-term effects of the powered ankle exoskeleton on the mechanics and energetics of gait. Investigators fabricated a lightweight ankle exoskeleton for each individual's paretic limb. A total of 5 subjects with stroke walked with a powered ankle exoskeleton on the paretic limb for 3 sessions (5 mins each session). They analyzed the peak paretic ankle plantar-flexion moment, paretic ankle positive work, symmetry of GRF propulsion impulse, and net metabolic power.
The exoskeleton increased the paretic plantar-flexion moment by 16% during the powered walking trials relative to unassisted walking condition (p < 0.05). Despite this enhanced paretic ankle moment, there was no significant increase in paretic ankle positive work, or changes in any other mechanical variables with the powered assistance. The exoskeleton assistance appeared to reduce the net metabolic power gradually with each 5-min repetition, though no statistical significance was found. In 3 of the subjects, the paretic soleus activation during the propulsion phase of stance was reduced during the powered assistance compared to unassisted walking (35% reduction in the integrated EMG amplitude during the 3rd powered session). The authors concluded that the findings of this feasibility study demonstrated that the exoskeleton can enhance paretic ankle moment.

Moreover, they stated that future studies with greater sample size and prolonged sessions are needed to evaluate the effects of the powered ankle exoskeleton on overall gait outcomes in persons post-stroke.

Wilcox et al (2016) examined peak interaction forces and electromyography (EMG) analysis to examine whether such interaction forces are due to the muscular activity of the participant or the movement of the REX Personal (Rex Bionics, New Zealand) exoskeleton itself. Interestingly, the authors found that peak forces preceded peak EMG activity. This study did not find a significant correlation between EMG activity and force data, which would indicate that the interaction forces can largely be attributed to the movement of the exoskeleton itself.

However, we also report significantly higher correlation coefficients in muscle/force pairs located at the anterior aspect of the right leg. In their previous research, the authors have shown peak interaction forces at the same locations, which suggests that muscular activity of the participant makes a more significant contribution to the interaction forces at these locations.

Arazpour et al (2013) analyzed the energy expenditure during walking with mechanical orthoses (hip knee ankle foot orthosis (HKAFO) and the isocentric reciprocating gait orthosis (IRGO)) compared with a new powered gait orthosis (PGO) in patients with SCI. Five patients with SCI who were experienced users of
HKAFOs participated in this study. Subjects were also fitted with an IRGO and PGO and underwent a specific gait training program. Patients walked along a flat walkway using the three types of orthosis at their self-selected walking speed. A stop watch and a polar heart rate monitor were used to measure the speed of walking and heart rate. The authors reported that walking speed, the distance walked and the physiological cost index (PCI) all improved with both the new PGO and the IRGO as compared with the HKAFO.

Gholizadeh et al (2014a) noted that a number of prosthetic suspension systems are available for trans-tibial amputees. Consideration of an appropriate suspension system can ensure that amputee's functional needs are satisfied. The higher the insight to suspension systems, the easier would be the selection for prosthetists. These investigators attempted to find scientific evidence pertaining to various trans-tibial suspension systems to provide selection criteria for clinicians. Databases of PubMed, Web of Science, and ScienceDirect were explored to find related articles. Search terms were as follows: "Transtibial prosthesis (32), prosthetic suspension (48), lower limb prosthesis (54), below-knee prosthesis (58), prosthetic liner (20), transtibial (193), and prosthetic socket (111)". Two reviewers separately examined the papers. Study design (case series of 5 or more subjects, retrospective or prospective), research instrument, sampling method, outcome measures and protocols were reviewed. Based on the selection criteria, 22 articles (15 prospective studies, and 7 surveys) remained. Sweat control was found to be a major concern with the available suspension liners. Donning and doffing procedures for soft liners were also problematic for some users, particularly those with upper limb weakness. Moreover, the total surface bearing (TSB) socket with pin/lock system is favored by the majority of amputees. The authors concluded that no clinical evidence was available to suggest what kind of suspension system could have an influential effect as a "standard" system for all trans-tibial amputees. However, among various suspension systems for trans-tibial amputees, the Iceross system was favored by the majority of users in terms of function and comfort.
Gholizadeh et al (2014b) examined the scientific evidence pertaining to various trans-femoral suspension systems to provide selection criteria for clinicians. Databases of PubMed, Web of Science, and ScienceDirect were explored. The following key words, as well as their combinations and synonyms, were used for the search: transfemoral prosthesis, prosthetic suspension, lower limb prosthesis, above-knee prosthesis, prosthetic liner, transfemoral, and prosthetic socket. The study design, research instrument, sampling method, outcome measures, and protocols of articles were reviewed. On the basis of the selection criteria, a total of 16 articles (11 prospective studies and 5 surveys) were reviewed. The main causes of reluctance to prosthesis, aside from energy expenditure, were socket-related problems such as discomfort, perspiration, and skin problems. Osseo-integration was a suspension option, yet it is rarely applied because of several drawbacks, such as extended rehabilitation process, risk for fracture, and infection along with excessive cost. The authors concluded that no clinical evidence was found as a "standard" system of suspension and socket design for all trans-femoral amputees. However, among various suspension systems for trans-femoral amputees, the soft insert or double socket was favored by most users in terms of function and comfort.

According to the Ottobock website, the C-Leg Protector 4X160 represents the modern solution for C-Leg and C-Leg compact wearers. The C-Leg Protector covers and protects the joints of the C-Leg Product Line, including the tube adapter, and provides a cosmetic contour in the calf area. The manufacturer states that the result is an attractive appearance without any functional restrictions. The website states that the C-Leg Protector can be used on right or left sides and is quick and easy to adjust. According to the manufacturer, during everyday use, the patient can put it on, take it off, and clean it easily if needed.

The Ossur Symbiotic Leg (Ossur Americas, Foothill ranch, CA), a microprocessor knee/foot unit, combines the capabilities of the bionic products, RHEO KNEE and PROPRIO FOOT, into a single integrated unit offering functionality for TF (above knee) amputees. The prosthesis was designed to enable users to experience confident mobility on all terrains without gait...
deviations or compensations. This new product, which is the first of its kind in the market, has been in user testing for over a year and will be available on a limited basis in late 2011.

Alimusaj et al (2009) stated that conventional prosthetic feet cannot adapt to specific conditions such as walking on stairs or ramps. Amputees are therefore forced to compensate their prosthetic deficits by modifying the kinematics and kinetics of their lower limbs. The Proprio-Foot (Ossur) intends to reduce these compensation mechanisms by automatically increasing dorsiflexion during stair ambulation thanks to an adaptive microprocessor-controlled ankle. These investigators analyzed the biomechanical effects of the dorsiflexion adaptation in transtibial (TT) amputees during stair ambulation. A total of 16 TT amputees and 16 healthy controls underwent conventional 3D gait analysis. Kinematics and kinetics of the lower limbs were compared during stair ascent and descent performed by patients with the prosthetic foot set to a neutral ankle angle and with an adapted dorsiflexion ankle angle of 4 degrees. Norm distance as well as minimum and maximal values of sagittal kinematics and kinetics were calculated for comparisons between patients and control subjects. For both stair ascent and descent, an improvement of the knee kinematics and kinetics could particularly be noticed on the involved side with an increase of the knee flexion and an increase of the knee moment during stance. The authors concluded that despite its additional weight compared to a conventional prosthetic ankle, the Proprio-Foot should be beneficial to active TT amputees whose knee musculature strength does not constitute a handicap.

Wolf et al (2009) stated that the technological advances that have been made in developing highly functional prostheses are promising for very active patients but it is unknown whether they cause an increase in biomechanical load along with possibly negative consequences for pressure conditions in the socket. Therefore, this study monitored the socket pressure at specific locations of the stump when using a microprocessor-controlled adaptive prosthetic ankle under different walking conditions. A total of 12 unilateral TT amputees (TTAs) between 43 and 59 years of age were provided with the Proprio-Foot (Ossur) and
underwent an instrumented 3D gait analysis in level, stair, and incline walking, including synchronous data capturing of socket pressure. Peak pressures and pressure time integrals (PTI) at 3 different locations were compared for 5 walking conditions with and without using the device's ankle adaptation mode. Highest peak pressures of 2.4 k Pa/kg were found for incline ascent at the calf muscle as compared to 2.1 k Pa/kg in level walking with large inter-individual variance. In stair ascent a strong correlation was found between maximum knee moment and socket pressure. The most significant pressure changes relative to level walking were seen in ramp descent anteriorly towards the stump end, with PTI values being almost twice as high as those in level walking. Adapting the angle of the prosthesis on stairs and ramps modified the pressure data such that they were closer to those in level walking. The authors concluded that pressure at the stump depended on the knee moments involved in each walking condition. Adapting the prosthetic ankle angle is a valuable means of modifying joint kinetics and thereby the pressure distribution at the stump. However, large inter-individual differences in local pressures underline the importance of individual socket fitting.

Fradet et al (2010) noted that the fixed neutral position of conventional prosthetic feet causes difficulties for TTAs when walking on ramps. New microprocessor-controlled prosthetic ankles such as the Proprio-Foot (Ossur) aim to reduce these difficulties by modifying the prosthetic ankle angle according to the gait condition. These researchers evaluated the biomechanical effects of adaptation of the prosthetic ankle on ramp ambulation in TTAs. A total of 16 TTAs and 16 controls underwent a conventional 3D gait analysis while walking up and down a ramp. Trans-tibial amputees walked with the prosthetic foot set to a neutral mode angle and set to the adapted mode. Norm distance, sagittal kinematics and kinetics were calculated for comparisons between TTAs and controls. During ramp ascent, the dorsiflexion brought about by the adapted prosthetic ankle reduced the increased knee extension noted on the TTAs' involved side and the increased plantar-flexion on their sound side. During ramp descent, the plantar-flexion of the adapted mode increased the adaptation mechanisms observed in TTAs.
The authors concluded that these findings suggested that the adapted mode leads to more physiologic kinematics and kinetics in the lower limbs in TTAs during ramp ascent but not during ramp descent. However, in the adapted mode, patients reported feeling safer during ramp descent, thus indicating that there might be other safety related measures such as toe-clearance or co-efficient of friction influencing this perception. (This study appeared to have the same subjects (n = 16) and controls (n = 16) as the 2009 study by Alimusaj et al; and Fradet was the 2nd author in that study).

Ludviksdottir (2012) evaluated the effect on mobility and safety for lower limb amputees (LLA; n = 8) when changing from a carbon fiber prosthetic foot to a bionic foot. Results suggested that user mobility improves when using the bionic foot and subjects experienced fewer falls and stumbles. The authors concluded that despite the limitation of the study, which is small sample size (n = 8) and mixing above knee and below knee amputees, the results indicated that improvements in perceived mobility and reduced risk of falling while using the bionic foot may relate to the intelligent functions offered by the bionic foot; in particular, the toe-lift in swing and terrain adaptation, functions which are not offered by mechanical prosthetic feet. They stated that to confirm these preliminary findings, a larger study is needed.

Rosenblatt et al (2014) stated that people with amputation are at increased risk of falling compared with age-matched, non-disabled individuals. This may partly reflect amputation-related changes to minimum toe clearance (MTC) that could increase the incidence of trips and fall risk. This study determined the contribution of a dorsiflexing prosthesis to MTC. These researchers hypothesized that regardless of speed or incline the active dorsiflexion qualities of the ProprioFoot would significantly increase MTC and decrease the likelihood of tripping. A total of 8 TTAs walked on a treadmill with their current foot at 2 grades and 3 velocities, then repeated the protocol after 4 weeks of accommodation with the ProprioFoot. A mixed-model, repeated-measures analysis of variance was used to compare MTC. Curves representing the likelihood of tripping were derived from the
MTC distributions and a multiple regression was used to determine the relative contributions of hip, knee, and ankle angles to MTC. Regardless of condition, MTC was approximately 70% larger with the ProprioFoot (p < 0.001) and the likelihood of tripping was reduced. Regression analysis revealed that MTC with the ProprioFoot was sensitive to all 3 angles, with sensitivity of hip and ankle being greater. The authors concluded that the ProprioFoot may increase user safety by decreasing the likelihood of tripping and thus the pursuant likelihood of a fall.

Rosenblatt et al (2016) noted that individuals with TTA are at increased risk of falling. The absence of an ankle joint and the associated musculature in these individuals can reduce clearance between the prosthetic foot and ground during the swing phase of gait, which may increase the risk of stumbling and in turn falling. In a prospective, cohort study, these researchers attempted to associate minimum toe clearance (MTC; defined as a local minimum of the vertical displacement of the toe from toe-off to heel-strike relative to its position during mid-stance) during gait in the laboratory with community-based, trip-related stumbles by individuals with TTA using conventional feet. Participants completed electronic surveys to prospectively report stumbles and falls for 1 year thereafter. A volunteer sample of 8 unilateral, trans-tibial amputees who were K3- or K4-level ambulators and current patients at a local prosthetic clinic participated in this study. All participants completed the entire 1-year follow-up study. Prosthetic-side MTC while walking on a level treadmill at self-selected velocity (SSV) and self-reported trip-related stumbles in the community were recorded. Prosthetic-side MTC was more than 50% lower for participants who reported 1 or more trip-related stumbles on that side compared with participants who reported zero trip-related stumbles on the prosthetic side (MTC = 12.3 ± 0.8 mm versus 25.6 ± 5.4 mm, respectively; p = 0.036). The authors concluded that this was the 1st study relating laboratory-based measures to prospective stumbles by prosthesis users. The results suggested that prosthesis users with low MTC may be at increased risk of experiencing a trip-related stumble in the community. They stated that these preliminary findings justified the need for a larger study to relate MTC and the causes of community-based
stumbles and falls by individuals with TTA.

This study had several drawbacks: (i) given the small sample size (n = 8), the study may be under-powered to detect a relationship between prosthetic-side MTC and any-cause stumbles, although, as discussed, these results were expected and logical. To minimize the influence of small sample size, these researchers included data from 2 participants (P7 and P14) who did not walk on a treadmill at 0 % grade and at SSV. However, inclusion was justified, and given the large effect size, even excluding these subjects would not result in p > 0.05, (ii) based on the definition, self-report of stumbles may be more subjective than that of falls, which may explain the high inter-subject variability in this measure (e.g., the high number of stumbles reported by participant P7 may reflect individual hyper-vigilance with regard to balance loss. This subject may have reported events that other participants ignored or deemed unimportant to report. Increasing sample size would reduce this variability, and (iii) the results of this study were limited to subjects who were 30 years of age and older and may not generalize to younger prosthesis users.

**Powered Lower Limb Prosthesis:**

Carey et al (2015) stated that the choice of a myoelectric or body-powered upper-limb prosthesis can be determined using factors including control, function, feedback, cosmesis, and rejection. Although body-powered and myoelectric control strategies offer unique functions, many prosthesis users must choose one. These investigators performed a systematic review to determine differences between myoelectric and body-powered prostheses to inform evidence-based clinical practice regarding prescription of these devices and training of users. A search of 9 databases identified 462 unique publications. A total of 31 of them were included and 11 empirical evidence statements were developed. Conflicting evidence has been found in terms of the relative functional performance of body-powered and myoelectric prostheses. Body-powered prostheses have been shown to have advantages in durability, training time, frequency of adjustment, maintenance, and feedback; however, they could still benefit
from improvements of control. Myoelectric prostheses have been shown to improve cosmesis and phantom-limb pain and are more accepted for light-intensity work. The authors concluded that current evidence is insufficient to conclude that either system provides a significant general advantage. Prosthetic selection should be based on a patient’s individual needs and include personal preferences, prosthetic experience, and functional needs. This work demonstrated that there is a lack of empirical evidence regarding functional differences in upper-limb prostheses.

Appendix

Clinical assessments of a member’s rehabilitation potential should be based on the following classification levels:

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 0:</td>
<td>Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility.</td>
</tr>
<tr>
<td>Level 1:</td>
<td>Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.</td>
</tr>
<tr>
<td>Level 2:</td>
<td>Has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs or uneven surfaces. Typical of the limited community ambulator.</td>
</tr>
<tr>
<td>Level 3:</td>
<td>Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.</td>
</tr>
<tr>
<td>Level 4:</td>
<td>Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.</td>
</tr>
</tbody>
</table>

For medically necessary frequency of replacement of prosthetics,

Note: Consistent with DME MAC policy, when an initial below knee prosthesis (L5500) or a preparatory below knee prosthesis (L5510-L5530, L5540) is provided, prosthetic substitutions and/or additions of procedures and components are considered medically necessary in accordance with the functional level assessment except for codes L5629, L5638, L5639, L5646, L5647, L5704, L5785, L5962, and L5980 which will be considered not medically necessary.

- Addition to lower extremity, below knee, acrylic socket (L5629)
- Addition to lower extremity, below knee, leather socket (L5638)
- Addition to lower extremity, below knee, wood socket (L5639)
- Addition to lower extremity, below knee, air-fluid, gel or equal, cushion socket (L5646)
- Addition to lower extremity, below knee suction socket (L5647)
- Custom shaped protective cover, below knee (L5704)
- Addition, exoskeletal system, below knee, ultra-light material (titanium, carbon fiber or equal) (L5785)
- Addition, endoskeletal system, below knee, flexible protective outer surface covering system (L5962)
- All lower extremity prostheses, flex foot system (L5980)

Consistent with DME MAC policy, when a below knee preparatory prefabricated prosthesis (L5535) is provided, prosthetic substitutions and/or additions of procedures are considered medically necessary in accordance with the functional level assessment except for codes L5620, L5629, L5645, L5646, L5670, L5676, L5704, and L5962 which will be considered not medically necessary.

- Addition to lower extremity, test socket, below knee (L5620)
• Addition to lower extremity, below knee, acrylic socket (L5629)
• Addition to lower extremity, below knee, flexible inner socket, external frame (L5645)
• Addition to lower extremity, below knee, air, fluid, gel or equal, cushion socket (L5646)
• Addition to lower extremity, below knee, molded supracondylar suspension ('PTS' or similar) (L5670)
• Addition to lower extremity, below knee, knee joints, single axis, pair (L5676)
• Custom shaped protective cover, below knee (L5704)
• Addition, endoskeletal system, below knee, flexible protective outer surface covering system (L5962)

Consistent with DME MAC policy, when an above knee initial prosthesis (L5505) or an above knee preparatory (L5560-L5580, L5590-L5600) prosthesis is provided, prosthetic substitution and/or additions of procedures and components are considered medically necessary in accordance with the functional level assessment except for codes L5610, L5631, L5640, L5642, L5644, L5648, L5705, L5706, L5964, L5980, and L5710-L5780, L5790-L5795 which will be considered not medically necessary.

• Addition to lower extremity, endoskeletal system, above knee, hydracadence system (L5610)
• Addition to lower extremity, above knee or knee disarticulation, acrylic socket (L5631)
• Addition to lower extremity, knee disarticulation, leather socket (L5640)
• Addition to lower extremity, above knee, leather socket (L5642)
• Addition to lower extremity, above knee, wood socket (L5644)
• Addition to lower extremity, above knee, air, fluid, gel or equal, cushion socket (L5648)
• Custom shaped protective cover, above knee (L5705)
• Custom shaped protective cover, knee disarticulation (L5706)
• Addition, endoskeletal system, above knee, flexible protective outer surface covering system (L5964)
• All lower extremity prostheses, flex foot system (L5980)
• Addition, exoskeletal knee-shin system, single axis, manual lock (L5710)
• Additions, exoskeletal knee-shin system, single axis, manual lock, ultra-light material (L5711)
• Addition, exoskeletal knee-shin system, single axis, friction swing and stance phase control (safety knee) (L5712)
• Addition, exoskeletal knee-shin system, single axis, variable friction swing phase control (L5714)
• Addition, exoskeletal knee-shin system, polycentric, mechanical stance phase lock (L5716)
• Addition, exoskeletal knee-shin system, polycentric, friction swing and stance phase control (L5718)
• Addition, exoskeletal knee-shin system, single axis, pneumatic swing, friction stance phase control (L5722)
• Addition, exoskeletal knee-shin system, single axis, fluid swing phase control (L5724)
• Addition, exoskeletal knee-shin system, single axis, external joints fluid swing phase control (L5726)
• Addition, exoskeletal knee-shin system, single axis, fluid swing and stance phase control (L5728)
• Addition, exoskeletal knee-shin system, single axis, pneumatic/hydra pneumatic swing phase control (L5780)
• Addition, exoskeletal system, above knee, ultra-light material (titanium, carbon fiber or equal) (L5790)
• Addition, exoskeletal system, hip disarticulation, ultra-light material (titanium, carbon fiber or equal) (L5795)

Consistent with DME MAC policy, when an above knee preparatory prefabricated prosthesis (L5585) is provided, prosthetic substitution and/or additions of procedures and components are considered medically necessary in accordance with the functional level assessment except for codes L5624, L5631, L5648, L5651, L5652, L5705, L5706, L5964, and L5966 which will be considered not medically necessary.

• Addition to lower extremity, test socket, above knee (L5624)
• Addition to lower extremity, above knee or knee disarticulation, acrylic socket (L5631)
• Addition to lower extremity, above knee, air, fluid, gel or equal, cushion socket (L5648)
• Addition to lower extremity, above knee, flexible inner socket, external frame (L5651)
• Addition to lower extremity, suction suspension, above knee or knee disarticulation socket (L5652)
• Custom shaped protective cover, above knee (L5705)
• Custom shaped protective cover, knee disarticulation (L5706)
• Addition, endoskeletal system, above knee, flexible protective outer surface covering system (L5964)
• Addition, endoskeletal system, hip disarticulation, flexible protective outer surface covering system (L5966)

Codes for ultra-light materials may only be used when materials such as carbon fiber, fiberglass, Kevlar, or other advanced composite lamination materials are used in the fabrication of a socket for an endoskeletal prosthesis. They are not used for ultralight materials used in other components of a prosthesis – e.g., knee/shin system, pylon, ankle, foot, etc.

<table>
<thead>
<tr>
<th>CPT Codes / HCPCS Codes / ICD-10 Codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by &quot;+&quot;:</td>
</tr>
<tr>
<td><strong>HCPCS codes covered if selection criteria are met:</strong></td>
</tr>
<tr>
<td>L5000 - L5782, L5785 - L5972, L5974 - L5988, L5999</td>
</tr>
<tr>
<td>L5930</td>
</tr>
<tr>
<td>L5940</td>
</tr>
<tr>
<td>L5950</td>
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<tr>
<td>Code</td>
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<tr>
<td>L5960</td>
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<tr>
<td>L7367-L7368</td>
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<tr>
<td>L7510-L7520</td>
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<tr>
<td>L8400-L8410</td>
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<tr>
<td>L8417</td>
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<td>L8420-L8430</td>
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<tr>
<td>L8440-L8460</td>
</tr>
<tr>
<td>L8470-L8485</td>
</tr>
</tbody>
</table>

**HCPCS codes not covered for indications listed in the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L5969</td>
<td>Addition, endoskeletal ankle-foot or ankle system, power assist, includes any type motor(s)</td>
</tr>
<tr>
<td>L5973</td>
<td>Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, includes power source</td>
</tr>
<tr>
<td>L5990</td>
<td>Addition to lower extremity prosthesis, user adjustable heel height</td>
</tr>
<tr>
<td>L7600</td>
<td>Prosthetic donning sleeve, any material, each</td>
</tr>
</tbody>
</table>

**ICD-10 codes covered if selection criteria are met:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q72.811-Q72.899</td>
<td>Other reduction defects of lower limb</td>
</tr>
<tr>
<td>S88.011+-S88.929+</td>
<td>Traumatic amputation of lower leg</td>
</tr>
<tr>
<td>S98.011+-S98.929+</td>
<td>Traumatic amputation of foot</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Z89.411 - Z89.619</td>
<td>Acquired absence of leg, toe(s), foot, and ankle</td>
</tr>
<tr>
<td>Z89.511 - Z89.529</td>
<td>Acquired absence of leg below knee</td>
</tr>
<tr>
<td>Z89.611 - Z89.629</td>
<td>Acquired absence of leg above knee</td>
</tr>
</tbody>
</table>

**Microprocessor-controlled leg prostheses:**

**HCPCS codes covered if selection criteria are met:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L5856</td>
<td>Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase; includes electronic sensor(s) any type [not covered for gait management in spinal cord injury]</td>
</tr>
<tr>
<td>L5857</td>
<td>Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing phase only; includes electronic sensor(s), any type [not covered for gait management in spinal cord injury]</td>
</tr>
<tr>
<td>L5858</td>
<td>Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, stance phase only, includes electronic sensor(s) any type [not covered for gait management in spinal cord injury]</td>
</tr>
<tr>
<td>L7367 - L7368</td>
<td>Lithium ion battery, rechargeable, replacement and ion battery charger</td>
</tr>
</tbody>
</table>

**HCPCS codes not covered for indications listed in the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L5973</td>
<td>Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, includes power source</td>
</tr>
</tbody>
</table>

**ICD-10 codes covered if selection criteria are met:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>S98.011+ - S98.929+</td>
<td>Traumatic amputation of foot at ankle level</td>
</tr>
<tr>
<td>S88.011+ - S88.929+</td>
<td>Traumatic amputation of lower leg</td>
</tr>
<tr>
<td>Z89.411 - Z89.619</td>
<td>Acquired absence of leg, ankle and foot</td>
</tr>
</tbody>
</table>
ICD-10 codes not covered for indications listed in the CPB:

<table>
<thead>
<tr>
<th>S12.000+ - S12.9xx+</th>
<th>Fracture of vertebral column</th>
</tr>
</thead>
<tbody>
<tr>
<td>S22.000+ - S22.089+</td>
<td></td>
</tr>
<tr>
<td>S32.000+ - S32.2xx+</td>
<td></td>
</tr>
<tr>
<td>S14.0xx+ - S14.9xx+</td>
<td>Injury of nerves and spinal cord</td>
</tr>
<tr>
<td>S24.0xx+ - S24.9xx+</td>
<td></td>
</tr>
<tr>
<td>S34.01x+ - S34.9xx+</td>
<td></td>
</tr>
</tbody>
</table>

The above policy is based on the following references:


5. Buckley JG, Spence WD, Solomonidis SE. Energy cost of walking: Comparison of 'intelligent prosthesis' with


12. Martin CW; WCB Evidence Based Group. Otto Bock C-leg®: A review of its effectiveness for special care services. Assessment prepared for Workers Compensation Board of British Columbia, Compensation and Rehabilitation Services Division. Vancouver, BC: Workers Compensation Board of British Columbia; November 27, 2003. Available at:


47. No authors listed. ReWalk™: A lightweight exoskeleton that enables those with spinal cord injury who use a wheelchair to walk upright. Date of Review: April 2011 (updated October 2012). The OptumInsight™ Health Technology Pipeline. April 26, 2013.


52. Wolf SI, Alimusaj M, Fradet L, et al. Pressure characteristics at the stump/socket interface in transtibial amputees using


69. Highsmith, M. Jason; Kahle, Jason T.; Lura, Derek J.; Lewandowski, Amanda L.; Quillen, William S.; Kim, Seok


74. Memorandum from Janet Murphy, Acting Deputy Secretary for Health for Operations and Management (10N), Department of Veterans Affairs, to medical center directors regarding clinical protocol for veteran use of the ReWalk Powered Exoskeleton, Washington, DC, December 10, 2015.


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Amendment to
Aetna Clinical Policy Bulletin Number: 0578 Lower Limb Prostheses

There are no amendments for Medicaid.