Clinical Policy Title: Microprocessor-controlled leg prostheses

Clinical Policy Number: 14.02.04

Effective Date: January 1, 2015
Initial Review Date: September 17, 2014
Most Recent Review Date: September 21, 2016
Next Review Date: September 2017

Related policies:
None.

ABOUT THIS POLICY: Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Keystone First when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First’s clinical policies are not guarantees of payment.

Coverage policy

Keystone First considers the use of a microprocessor-controlled leg prosthesis to be clinically proven and, therefore, medically necessary when all of the following criteria are met:

- Within a reasonable period of time, member will reach or maintain a defined functional level of three or more on the CMS rehabilitation potential classification, as shown in Table 1 (page 3).
- There is documentation of motivation to ambulate.
- There is documentation of the determination of medical necessity for any components/additions to the prosthesis based on amputee’s potential functional abilities, which are based on reasonable expectations of the prosthetist and treating physician including, but not limited to, past history (with prosthetic use), current condition (status of residual limb and nature of other medical problems) and future use of the prosthesis.

Documentation requirements for microprocessor-controlled leg prosthesis (All requirements must be met):

- Current functional capabilities and expected potential.
- Explanation for difference, if any.
• Need for covering long distances at the variable rates typical of normal ambulation, but not restricted to within home (including residential stair climbing), or local community ambulation.
• Physical ability (cardiovascular and pulmonary reserves) to tolerate prosthesis weight and ambulation at faster than normal speeds.
• Cognitive ability to master use and care requirements.

Limitations:

• All other uses of microprocessor-based prostheses, including for foot or ankle, are not medically necessary.
• Members who are not able to use a microprocessor-controlled leg prosthesis due to poor balance or ataxia, or who fail to meet height or weight recommendations of manufacturer, may not be able to use a microprocessor C-Leg® prosthesis appropriately.
• Additions to prosthesis (e.g., endo-skeletal knee-shin system, powered and programmable flexion/extension assist control with any type of motor), may be covered only for amputees who meet all of the following criteria:
  • Has microprocessor (swing and stance phase type) knee.
  • Functional level three only.
  • Weight between 110 lbs and 275 lbs.
  • Documented comorbidity of spine and/or sound limb affecting hip extension and/or quadriceps function that impairs level three function, with use of microprocessor knee alone.
  • Is able to make use of a product requiring daily charging.
  • Is able to understand and respond to error alerts and alarms indicating problems with the unit.

Alternative covered services:

• Conventional mechanical leg prostheses.

Background

Amputation is the surgical removal of a limb, most commonly the leg. Leg amputation is classified by the location above (transfemoral) or below (transtibial) the knee. Amputation is often preceded by a long period of chronic disease such as diabetes, painful disabling peripheral arterial disease, or by major trauma. Other causes include cancer and birth defects.

Loss of a leg is a life changing event associated with emotional upheaval and profound psychosocial challenges along with anxiety, restricted mobility and social isolation. Depression and post-traumatic symptoms remain frequent complaints for up to three years after amputation (Norlyk 2013). Also frequent and troubling to the amputee are phantom limb phenomena (i.e., pain or other sensations apparently attributable to the missing limb). The high personal and health care costs make amputation prevention the goal of many chronic disease management programs.

Conventional mechanical leg prostheses with hydraulic or polycentric knees require whole body compensation for abnormal gait, and may be associated with stress-related injuries to the unaffected
leg, such as knee osteoarthritis. Conventional prostheses also require unusual energy expenditure versus normal ambulation and are particularly inefficient on uneven terrain or stairs.

Microprocessor-controlled knee or leg prostheses (MCP) use feedback from sensors to adjust movement on a real-time, as needed basis. Theoretical advantages include improved safety, speed and function on uneven terrain. The C-Leg® (Ottobock USA, Austin, TX) was FDA-approved for marketing in 1999 and is the best-represented MCP in published research. Next generation devices, such as the Genium® Bionic prosthetic system (Ottobock USA, Austin, TX), use additional environmental input (gyroscope and accelerometer) along with more sophisticated processing intended to support more natural movement.

Other considerations for the MCP include:

- Prosthetist and treating physician determine knee type, using guidelines in Table 1 below.
- Basic prostheses include a single axis, constant friction knee; others are considered based on functional classification below and with documentation.
- Bilateral amputees may not fit into the usual classification system.

| Table 1. Clinical assessments of rehabilitation potential based on CMS classification levels |
|---------------------------------|---------------------------------------------------------------|
| **Level/type of knee** | **Description** |
| 0 | Lacks ability or potential to ambulate or transfer safely with or without assistance: a prosthetic would not enhance quality of life (QoL) or mobility. |
| 1 | Ability or potential to use prosthesis:  
- Transfers or ambulation on level surfaces at fixed cadence.  
- Typical of limited and unlimited household ambulatory. |
| 2 | Ability or potential for ambulation:  
- Traverse low environmental barriers (e.g., curbs, stairs and uneven surfaces).  
- Typical of limited community ambulatory. |
| 3 or above — fluid, pneumatic, or microprocessor | Ability or potential for ambulation at variable cadence:  
- Typical of community ambulatory who is able to traverse environmental barriers.  
- Vocational, therapeutic or exercise activity demanding prosthetic use beyond simple locomotion. |
| 4 — high activity knee control frame | Ability or potential for prosthetic use exceeding basic ambulation skills:  
- Exhibiting high impact, stress or activity levels.  
- Typical of prosthetic demands of child, active adult or athlete. |

**Searches**

Keystone First searched PubMed and the databases of:

- UK National Health Services Center for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).
We conducted searches in August 10, 2016. Search terms were "artificial limbs" (MeSH) and "Leg" (MeSH) and free text terms “C-Leg,” “microprocessor-controlled leg prostheses” and “amputation.”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

- Flynn (2000) reviewed the MCP literature published up to that date and found only a very small percentage of studies. Many of these studies used the Intelligent Prosthesis (Chas A Blatchford and Sons, Ltd., Hampshire, UK), reported structured research with highly selected subjects and used criteria that seriously limited the generalizability of results.
- While the evidence picture has improved somewhat since then, the most robust studies are small crossover trials classified by Kelly (2012) as methodologically weak. Biased subject selection remains an ongoing problem.
- By 2014, C-Leg became the primary subject of systematic reviews and credible research. No other microprocessor-controlled prostheses were identified in searches for reviews.

**Policy updates:**

None.

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hayes (2014)</strong></td>
<td><strong>Key points:</strong></td>
</tr>
</tbody>
</table>
| C-Leg for patients with above-knee amputation | • Manufacturer instructions: C-Leg intended for transfemoral or knee-disarticulation amputees who are able to discern acoustic signals and/or mechanical vibrations, and whose residual limb is fully healed.  
• Systematic review of one case-matched CCT; nine repeated measures controlled studies; one cross-sectional study.  
• All studies enrolled 10 – 50 subjects using a variety of knees; biased subject selection; inconsistent follow-up (FU) periods and outcome measures.  
• Result promising, but overall low quality evidence. |

<table>
<thead>
<tr>
<th><strong>Kelly (2012) for Quality Improvement Scotland</strong></th>
<th><strong>Key points:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Evidence of effectiveness: 17 studies, one systematic review; one randomized crossover trial; and one non-randomized.</td>
</tr>
<tr>
<td>Citation</td>
<td>Content, Methods, Recommendations</td>
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</tbody>
</table>
| Clinical- and cost-effectiveness of C-Leg vs. alternatives              | • Most subjects were ages 30 – 55 with trauma-related amputations.  
• Safety: most studies reported significant reductions in self-reported stumble or fall events.  
• Energy efficiency: usually increased with C-Leg but not always significantly.  
• Overall: for healthy and active younger people with transfemoral amputation, C-Leg may improve health outcomes (body image, safety, energy efficiency, gait, function) compared with mechanically controlled knees.                                                                                                                                                                                                                                                                                           |
| Theeven (2013)                                                         | **Key points:**  
• Studies comparing microprocessor-controlled knees to mechanically controlled.  
• Thirty-seven articles (study designs not reported) used 72 different outcome measures.  
• Goal: to catalog and classify according to International Classification of Functioning, Disability, and Health (ICF) and to identify gaps in knowledge.  
• Evidence for daily functioning with MCP is very limited and focuses on younger, fit and active subjects.                                                                                                                                                                                                                                                                                                                                                     |
| Work Loss Data Institute (2013)                                        | **Key points:**  
• Microprocessor-controlled knees are recommended, but recommendations are not linked to specific studies.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Samuelson (2012)                                                       | **Key points:**  
• Review of eight controlled before and after studies (209 subjects).  
• Mean age 48.5 years (18 – 83).  
• Study quality variable and results inconsistent.  
• More and better research needed.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Ho (2009) for the Canadian Agency for Drugs & Technologies in Health    | **Key points:**  
• Four randomized control trials (RCTs) compared MCP to mechanical prosthesis in healthy, active non-vascular cause amputees.  
• Trials in older amputees are rare.  
• C-Leg appears to give positive outcomes at acceptable costs.                                                                                                                                                                                                                                                                                                                                                                                                           |
| Gerzeli (2009)                                                         | **Key points:**  
• Fifty patients in Italian medical center with each prosthesis.  
• Quality-adjusted life years (QALYs) from interviews with standardized instrument; healthcare and social costs from five year life cycle of prostheses.  
• Incremental cost/QALY: C-Leg, €35,971; no significant differences between groups.                                                                                                                                                                                                                                                                                                                                                                               |
| Brodtkorb (2008)                                                       | **Key points:**  
• C-Leg vs. non-MCP for 20 active transfemoral amputees at three Danish and five Swedish clinics.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
### Citation

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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</table>
| microprocessor controlled knees | • Since no RCTs available, effectiveness data based on patient reports.  
• Costs: C-Leg, €25,146; 5.98 QALYs/patient; other: €17488; 3.60 QALYs/patient.  
• Cost-utility: C-Leg, 3,218/QALY gained.  
• C-Leg yields positive outcomes at an acceptable cost, based on limited evidence. |
| Adams (2005) for Veterans Health Administration Clinical predictors of outcomes | **Key points:**  
• Seven preliminary studies evaluate short- and intermediate-term predictors associated with prosthetic use and mobility in older patients with non-traumatic causes of amputation.  
• Advancing age was a negative predictor for most outcomes evaluated. |
| Van der Linde (2004) Effects of prosthetic components on functioning | **Key points:**  
• Insufficient evidence.  
• Prescribers still must rely on expert opinion or consensus. |
| Flynn (2000) Veterans Health Administration C-Leg | **Key points:**  
• Relevant English language peer-reviewed studies published through 2000. Less than 3% of studies are hypothesis testing structured research (mostly using the Blatchford Intelligent Prosthesis); remainder observational, descriptive, promotional or pre-clinical.  
• Overall quality: very low with high risk of selection bias.  
• To the extent that reporting allows, most studies enrolled highly selected samples not generalizable to other populations: amputees without additional medical problems, with amputations due to congenital malformations or trauma, and who were fit and active pre-amputation.  
• Energy requirements vs. conventional prostheses decreased at faster or slower than customary speed, but no significant differences at customary speed.  
• Inconsistent results for uneven terrain. |

### Glossary

**Ataxia** — A neurologic sign consisting of involuntary head or neck movements. Ataxia is nonspecific but implies dysfunction of the parts of the central nervous system, such as the cerebellum, which coordinate movement.

**Critical limb ischemia** — A severe form of peripheral arterial disease in the leg or legs, characterized by severe pain at rest and non-healing sores or ulcers, caused by atheromatous plaques in the arteries that restrict blood flow. It is a common underlying cause for amputation, although often treatable with minimally invasive endovascular techniques to reopen blockages.

**Femur** — The long bone in the thigh.

**Tibia** — The heavier of two long bones in the lower leg.

### References
Professional society guidelines/other:


Peer-reviewed references:


Clinical trials:

Searched clinicaltrials.gov on August 10, 2016 using terms leg AND prosthesis | Open Studies. 42 studies found.

CMS National Coverage Determinations (NCDs):

No NCDs identified as of the writing of this policy.

Local Coverage Determinations (LCDs):


Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
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<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q72.00</td>
<td>Congenital complete absence of unspecified lower limb</td>
</tr>
<tr>
<td>Q72.01</td>
<td>Congenital complete absence of right lower limb</td>
</tr>
<tr>
<td>Q72.02</td>
<td>Congenital complete absence of left lower limb</td>
</tr>
<tr>
<td>Q72.03</td>
<td>Congenital complete absence of lower limb, bilateral</td>
</tr>
<tr>
<td>S78.111A</td>
<td>Complete traumatic amputation at level between right hip and knee, initial encounter</td>
</tr>
<tr>
<td>S78.112A</td>
<td>Complete traumatic amputation at level between left hip and knee, initial encounter</td>
</tr>
<tr>
<td>S78.119A</td>
<td>Complete traumatic amputation at level between unspecified hip and knee, initial encounter</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
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<td>S78.121A</td>
<td>Partial traumatic amputation at level between right hip and knee, initial encounter</td>
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<tr>
<td>S78.122A</td>
<td>Partial traumatic amputation at level between left hip and knee, initial encounter</td>
</tr>
<tr>
<td>S78.129A</td>
<td>Partial traumatic amputation at level between unspecified hip and knee, initial encounter</td>
</tr>
<tr>
<td>S78.911A</td>
<td>Complete traumatic amputation of right hip and thigh, level unspecified, initial encounter</td>
</tr>
<tr>
<td>S78.912A</td>
<td>Complete traumatic amputation of left hip and thigh, level unspecified, initial encounter</td>
</tr>
<tr>
<td>S78.919A</td>
<td>Complete traumatic amputation of unspecified hip and thigh, level unspecified, initial encounter</td>
</tr>
<tr>
<td>S78.921A</td>
<td>Partial traumatic amputation of right hip and thigh, level unspecified, initial encounter</td>
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<td>S78.922A</td>
<td>Partial traumatic amputation of left hip and thigh, level unspecified, initial encounter</td>
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<td>Partial traumatic amputation of unspecified hip and thigh, level unspecified, initial encounter</td>
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<td>S88.011A</td>
<td>Complete traumatic amputation at knee level, right lower leg, initial encounter</td>
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<td>S88.012A</td>
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<td>S88.019A</td>
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<td>S88.021A</td>
<td>Partial traumatic amputation at knee level, right lower leg, initial encounter</td>
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<tr>
<td>S88.022A</td>
<td>Partial traumatic amputation at knee level, left lower leg, initial encounter</td>
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<tr>
<td>S88.111A</td>
<td>Complete traumatic amputation at level between knee and ankle, right lower leg, initial encounter</td>
</tr>
<tr>
<td>S88.112A</td>
<td>Complete traumatic amputation at level between knee and ankle, left lower leg, initial encounter</td>
</tr>
<tr>
<td>S88.119A</td>
<td>Complete traumatic amputation at level between knee and ankle, unspecified lower leg, initial encounter</td>
</tr>
<tr>
<td>S88.121A</td>
<td>Partial traumatic amputation at level between knee and ankle, right lower leg, initial encounter</td>
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<tr>
<td>S88.122A</td>
<td>Partial traumatic amputation at level between knee and ankle, left lower leg, initial encounter</td>
</tr>
<tr>
<td>S88.129A</td>
<td>Partial traumatic amputation at level between knee and ankle, unspecified lower leg, initial encounter</td>
</tr>
<tr>
<td>S88.911A</td>
<td>Complete traumatic amputation of right lower leg, level unspecified, initial encounter</td>
</tr>
<tr>
<td>S88.912A</td>
<td>Complete traumatic amputation of left lower leg, level unspecified, initial encounter</td>
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<td>Partial traumatic amputation of right lower leg, level unspecified, initial encounter</td>
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<td>Partial traumatic amputation of left lower leg, level unspecified, initial encounter</td>
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<td>Z89.612</td>
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<tr>
<td>Z89.619</td>
<td>Acquired absence of unspecified leg above knee</td>
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</table>

<table>
<thead>
<tr>
<th>HCPCS Level II</th>
<th>Description</th>
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<tbody>
<tr>
<td>L5828</td>
<td>Addition, endoskeletal knee-shin system, single axis, fluid swing and stance phase control.</td>
</tr>
<tr>
<td>L5845</td>
<td>Addition, endoskeletal knee-shin system, stance flexion feature, adjustable.</td>
</tr>
<tr>
<td>L5848</td>
<td>Addition, endoskeletal knee-shin system, fluid stance extension, dampening feature, with or without adjustability.</td>
</tr>
<tr>
<td>L5856</td>
<td>Addition to lower extremity prosthesis, endo-skeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type.</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.</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.</td>
</tr>
<tr>
<td>L5859</td>
<td>Addition to lower extremity prosthesis, endoskeletal knee-shin system, powered and programmable flexion/extension assist control, includes any type motor(s).</td>
</tr>
</tbody>
</table>