



QUALITY FOR LIFE

### **If C-Leg® Coverage is Denied**

It is not uncommon for coverage to be denied for the C-Leg upon the initial submission. However, the more complete your documentation is on the initial submission, the less likely coverage will be denied (see Initial Submission for Reimbursement).

#### **A. If coverage is denied, you need to find out:**

- What is being denied? Is the whole product being denied or just one or two codes?
- Why, specifically, is it being denied? What is the one reason they are denying coverage?
- Get their definition to the reason for denial. For example, if coverage is denied because they do not pay for “deluxe items,” you need to get their definition of what a “deluxe item” is.

Once you find out what is being denied and why, you can determine the one issue or point you need to refute in an appeal. The appeal should explicitly target the one reason for the reimbursement denial.

#### **B. Possible Reasons For Denied Coverage**

- Experimental or investigational
- Deluxe item
- Biomechanical device
- Medical necessity
- Basic or standard services
- Prior use of a hydraulic knee required

#### **C. Arguments To Help Refute Denied Coverage Experimental or Investigational**

Prosthetists, the FDA, CMS/Medicare, AAOP, the VA, and insurance companies nationwide do not define the microprocessor knee as an “experimental” or “investigational” prosthesis. These professionals and organizations have recognized and accepted microprocessor-controlled knees as a standard level of prosthetic treatment. Further indication of acceptance of microprocessor-controlled knees is Medicare’s subsequent assignment of L-Codes L5858 and L5856 in 2006, L5848 in 2003, and L5846 in 1996. These codes are mostly, if not exclusively, associated with microprocessor-controlled knees. Other indications of acceptance include FDA

clearance and VA fitting guidelines and criteria. The C-Leg has been in use since 1997 in Europe and Canada and since 1999 in the United States. Currently thousands of above-knee amputees in over 20 different countries around the world use the C-Leg.

### **Deluxe Item**

Again, if this is the reason for denial you first need to get their definition of what a “deluxe item” is. If they will only pay for a “standard” prosthesis, you need to get the insurer’s definition of what “standard” is. Deluxe is typically defined as anything other than “standard.” “Standard” is typically defined as “the basic device(s) that have only the components essential to the functioning of the device and which return the individual to a functioning level.” As a profession, the standard goal regarding a patient and their functional level is to achieve the level of function of the missing limb. Therefore, the microprocessor does not meet the criteria defined as “deluxe” as it is not capable of accomplishing all ADL requirements or functions of the missing limb and is not provided for the convenience of the patient or provider. The microprocessor knee therefore fits the definition of a “standard” device.

### **Biomechanical Device**

All prosthetic devices are “biomechanical devices.” If the payer has paid for any prosthetic device, they have paid for a “biomechanical device.” To help support this argument, obtain a definition of a “biomechanical device” from an expert that the payer will then need to refute. For example, according to S.P. Sutera, PhD, Professor of Biomedical Engineering, Washington University in St. Louis, all prosthetic devices, regardless of their technology or level of sophistication, are defined as a “biomechanical device.” *“In terms of function, it (microprocessor-controlled knee) is no more or less ‘biomechanical’ than any of its predecessors and therefore its exclusion cannot be scientifically or medically founded on the basis of ‘biomechanical.’”*

### **Medical Necessity**

A denial based on Medical Necessity can be reflected by clearly addressing the following points:

- Letter of Medical Necessity. See “Letter of Medical Necessity” outline from *Initial Submission for Reimbursement Guideline*
- Prosthetic documentation
- Verify the status of the existing knee, foot, socket, components, etc.
- Identify rationale to replace existing components
- Indicate why existing components do not allow the patient to achieve ADL
- Physical description of the patient and his or her amputation, history and any related physical conditions
- Functional description of the patient’s activity or functional level and their needs related to ADL
- L-Codes being used. Clearly indicate all the codes being used and how each one relates specifically to the patient’s ADL
- The prosthetic device being prescribed is reasonable and necessary
- See the chart on the back page of this document for information about how to use specific studies.

## **Basic or Standard Services**

Generally, “basic” or “standard” refers to treatment that is established and accepted by the medical community as routine or normal or is a device that has functioning components essential to the device that will return an individual to a functional level. The microprocessor knee mechanism is established and accepted by the medical community at large as a standard prosthesis and is a routinely prescribed prosthetic option for individuals meeting criteria for the knee. The microprocessor knee is also recognized by Medicare and the Veterans Administration. Therefore, the microprocessor knee meets the criteria to be considered as “standard” or “basic” prosthetic care.

The microprocessor knee is specifically designed to enable the wearer to accomplish ADL and allows the user to:

- Walk down stairs step over step
- Walk at variable cadence
- Walk down ramps
- Walk on uneven ground (gravel, grass, cobblestones)
- Achieve stability and security while in a flexed position
- Achieve a smooth and natural transition during gait from heel strike to mid-stance by allowing the knee to be in a flexed position at heel strike
- Engage a stumble recovery feature in the event of tripping or slipping on uneven or slick surfaces

The microprocessor-controlled knee cannot accommodate the following ADL:

- Sensory capabilities for heat, cold or touch
- Voluntary movement of knee, ankle and foot
- Walk up stairs step over step
- Ability to get wet, shower or swim
- Change heel heights of shoes

Because microprocessor knees can accommodate some, but not all functions and capabilities of the amputated limb, it does not completely return the individual to the same functional level prior to amputation. Because not all ADL can be accommodated, the microprocessor knee is a basic, standard or conventional prosthesis.

## **Prior Use of a Hydraulic Knee Required**

This reason for denial indicates a patient must have proven to be successful in a hydraulic knee for a specific period of time before a C-Leg will be approved. This denial can be detrimental to the patient. By learning how to use another hydraulic knee prior to the C-Leg, the patient will only develop habits and would need to be retrained on the C-Leg. By fitting a patient with a non-microprocessor controlled knee the patient will not benefit from the increased stability that is offered through the C-Leg. Patients have experienced great success using the C-Leg at the initial fitting because they benefit from the increased stability.

This chart outlines research results and how to use the information in your appeal.

Potential Coverage Criteria	Appeal Argument	References
1. The technology must have final approval from the appropriate governmental regulatory bodies.	Otto Bock C-Leg was approved by the FDA in July 1999 as a Class II Exempt Medical Device	<ul style="list-style-type: none"> <li>• Attachment I: FDA 510(K) Premarket Notification - Otto Bock C-Leg 1999</li> <li>• Attachment II: FDA Product Classification – Exempt from Premarket Notification</li> </ul>
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.	<ul style="list-style-type: none"> <li>• Significant increase in microprocessor knee loading gait parameters (<math>p &lt; .01</math>)<sup>1</sup></li> <li>• Significant improvement in balance (<math>p &lt; .01</math>)<sup>1</sup></li> <li>• Significant improvement in sensory organization/equilibrium score (<math>p &lt; .05</math>)<sup>1</sup></li> <li>• Significant improvement in total daily energy expenditure (TDEE) in free-living environment (<math>p &lt; .05</math>)<sup>1</sup></li> <li>• Significant increase in physical activity-related energy expenditure (PAEE) (<math>p = .04</math>)<sup>1</sup></li> <li>• Improvement with microprocessor controlled knee as compared to non-microprocessor controlled knee (established alternative)<sup>1</sup></li> <li>• Significant decrease in frequency of stumbles and falls (<math>p &lt; .05</math>)<sup>2</sup></li> <li>• Significant decrease in frustration with falling (<math>p &lt; .05</math>)<sup>2</sup></li> <li>• Significant decrease in falling while multitasking while ambulating (<math>p &lt; .05</math>)<sup>2</sup></li> <li>• Significant improvement with Stair Descent Index (SDI) (<math>p &lt; .001</math>)<sup>2</sup></li> <li>• Significant improvement with Amputee Body Image Scale (ABIS) (<math>p &lt; .001</math>)<sup>3</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Reference #1: Kaufman, et al (2007)</li> <li>• Reference #2: Hafner, et al (2007)</li> <li>• Reference #3: Bunce, et al (2007)</li> </ul>
3. The technology must improve the net health outcome.	<p>Improvement in Net Health Outcomes with microprocessor controlled knees as compared to non-microprocessor controlled knees (established alternative) include:</p> <ol style="list-style-type: none"> <li>1. Significant decrease in stumbles and falls as demonstrated by: <ul style="list-style-type: none"> <li>• Significant improvement in balance (<math>p &lt; .01</math>)<sup>1</sup></li> <li>• Significant improvement in sensory organization/equilibrium score (<math>p &lt; .05</math>)<sup>1</sup></li> <li>• Significant decrease in frequency of stumbles and falls (<math>p &lt; .05</math>)<sup>2</sup></li> <li>• Significant decrease in frustration with falling (<math>p &lt; .05</math>)<sup>2</sup></li> <li>• Significant decrease with multitasking while ambulating (<math>p &lt; .05</math>)<sup>2</sup></li> </ul> </li> <li>2. Significant increase in activity level as demonstrated by significant improvement in total daily energy expenditure (TDEE) in free-living environment (<math>p &lt; .05</math>)</li> <li>3. Significant satisfaction as demonstrated by: <ul style="list-style-type: none"> <li>• Significant improvement with Amputee Body Image Scale (ABIS) (<math>p &lt; .001</math>)<sup>3</sup></li> <li>• Prosthesis Evaluation Questionnaire (PEQ) – significant improvement with microprocessor controlled knee as compared to non-microprocessor controlled knee (established alternative)<sup>1,2</sup></li> </ul> </li> </ol>	
4. The technology must be as beneficial as any established alternatives.	<p>Microprocessor prosthetic knee compared to non-microprocessor controlled knee (established alternative):</p> <ul style="list-style-type: none"> <li>• Significant increase in microprocessor knee loading gait parameters (<math>p &lt; .01</math>)<sup>1</sup></li> <li>• Significant improvement in balance (<math>p &lt; .01</math>)<sup>1</sup></li> <li>• Significant improvement in sensory organization/equilibrium score (<math>p &lt; .05</math>)<sup>1</sup></li> <li>• Significant improvement in total daily energy expenditures (TDEE) in free-living environment (<math>p &lt; .05</math>)<sup>1</sup></li> <li>• Significant increase in physical activity-related energy expenditure (PAEE) (<math>p = .04</math>)<sup>1</sup></li> <li>• Prosthesis Evaluation Questionnaire (PEQ) – significant improvement with microprocessor controlled knee as compared to non-microprocessor controlled knee (established alternative)<sup>1</sup></li> <li>• Significant decrease in stumbles and falls (<math>p &lt; .05</math>)<sup>2</sup></li> <li>• Significant decrease in frustration with falling (<math>p &lt; .05</math>)<sup>2</sup></li> <li>• Significant decrease with multitasking while ambulating (<math>p &lt; .05</math>)<sup>2</sup></li> <li>• Significant improvement with Stair Descent Index (SDI) (<math>p &lt; .001</math>)<sup>2</sup></li> <li>• Prosthesis Evaluation Questionnaire (PEQ) – significant improvement with microprocessor controlled knee as compared to non-microprocessor controlled knee (established alternative)<sup>2</sup></li> <li>• Significant improvement with Amputee Body Image Scale (ABIS) (<math>p &lt; .001</math>)<sup>3</sup></li> </ul>	<p>Reference #1: Kaufman, et al (2007)</p> <p>Reference #2: Hafner, et al (2007)</p> <p>Reference #3: Bunce, et al (2007)</p>
5. Improvement must be attainable outside investigation settings.	<ul style="list-style-type: none"> <li>• Significant improvement in total daily energy expenditure (TDEE) in free-living environment (<math>p &lt; .05</math>)<sup>1</sup></li> <li>• Significant increase in physical activity-related energy expenditure (PAEE) (<math>p = .04</math>)<sup>1</sup></li> <li>• Significant increase in patient perception of microprocessor controlled knee as compared to non-microprocessor controlled knee (established alternative) (<math>p = .02</math>)<sup>1</sup></li> <li>• Significant decrease in frequency of stumbles and falls in environmental setting (<math>p &lt; .05</math>)<sup>2</sup></li> <li>• Significant decrease in frustration with falling in environmental setting (<math>p &lt; .05</math>)<sup>2</sup></li> <li>• Significant improvement with Amputee Body Image Scale (ABIS) over six-month period (<math>p &lt; .001</math>)<sup>3</sup></li> </ul>	<p>Reference #1: Kaufman, et al (2007)</p> <p>Reference #2: Hafner, et al (2007)</p> <p>Reference #3: Bunce, et al (2007)</p>