



QUALITY FOR LIFE

Overview

This material is intended to assist practitioners in obtaining the best possible reimbursement outcome for the C-Leg[®] microprocessor knee. This material is not designed to be submitted as the documentation or justification for C-Leg reimbursement. The documentation and justification for reimbursement must be unique to the patient and components being fit and can only be effectively drafted by the treating Prosthetist. Form letters and copied papers of product description **do not** provide adequate justification for medical necessity or a return to Activities of Daily Living (ADL), and are therefore commonly rejected by paying sources.

This packet of information will help you draft the best possible C-Leg justification for your initial request for reimbursement and assist you in structuring arguments if your reimbursement request is denied. Please contact your local Otto Bock Sales Representative at 800.328.4058 or our Coding and Reimbursement Specialist at 866.282.3530 if you have any questions or concerns.

Patient Recommendation

The C-Leg microprocessor knee was designed for and is recommended for patients who have the potential to achieve the K3 activity level or above. Of course, there are exceptions, and in our recommendation we want to allow for unique and individual circumstances. For example, patients with hip disarticulations and bilateral amputations have had excellent results with the C-Leg and Compact.

There may also be a number of patients in the K2 activity level who would benefit from the stability of the C-Leg, but this decision should only be made with sound and thorough justification. It is not recommended for K1 individuals or for competitive sports events such as the Paralympics, as these patients will be better served by specially designed prostheses optimized for their needs.



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Medical Necessity Checklist

Before you submit a claim for insurance reimbursement, it is important to understand the elements that an insurer requires in order to approve an insurance claim.

Follow these steps to improve the reimbursement process:

- Review laws that apply to insurance coverage. Does your patient's policy **include** prosthetic coverage? If the insurer denies the claim, they must prove that the prosthetic is excluded from coverage.
- Review the definition of medical necessity. Different insurance companies use different definitions. Ask the insurer for a copy of their definition of medical necessity. Insurance companies create a Summary Plan Description, which is a document that describes individual insurance plans. If you get a copy, you can review how the plan defines medical necessity.
- Craft your letter of medical necessity specifically for your audience. The letter should give a good description of your patient and specifically state why a C-Leg® is needed. Remember that the people who review the letter are not experts in prosthetics or gait analysis, so use words they will understand.

Elements of an Effective Letter

- Introduce who you are and why you are writing.
- Explain your patient's condition, describe how this impacts their daily activities and indicate how your patient's life will be affected if they do not get a C-Leg.
- Give a clear explanation of the C-Leg. Specifically state how the C-Leg's function is necessary to daily activities. Do not assume that the person reading the letter understands what basic mobility problems are faced by a person with a transfemoral amputation. Use clear language to explain these challenges.
- Explain why the C-Leg will help limit other insurance expenses, such as hospitalizations due to falls.
- Clearly state the insurance company's definition of medical necessity, then provide a simple explanation of how your patient's C-Leg meets this criteria.
- When your letter refers to your patient, use his or her name to paint a clearer picture of this person. Include their age, family status and even their job in a short description. The goal is to give the insurance company a picture of who this person is rather than simply thinking of him or her as a policy number.
- Send a copy of the prescription along with the letter of medical necessity. Make sure your letter refers to the prescription so the reader knows what it is.
- Include pictures of the C-Leg. You can find pictures of the C-Leg by going online to www.ottobockus.com. Click on the Newsroom link near the top of the left hand navigation bar and then again on the Image Download Page link near the middle of the page to access various C-Leg pictures available to you.

Submitting for C-Leg Reimbursement

The documentation included for the initial reimbursement submission must clearly identify the status of the patient and justify the prosthetic device being fit. For best reimbursement results, the following should be completed and submitted to the payer:

A. Letter of Medical Necessity

Medical Necessity is based on the patient's functional abilities. Functional abilities are based on the reasonable expectations of the Prosthetist and treating physician. This includes but is not limited to:

- Past history of the patient
- Current and/or change of condition of the patient including status of residual limb and other medical conditions.
- The patient's desire to ambulate. Describe the functional level the patient is expected to reach and illustrate the patient's desire and what they will do to reach that goal.

A basic model for writing a Letter of Medical Necessity uses the following logic:

- Describe the patient. *(History, desire to ambulate, physical condition, amputation, previous and current conditions, etc.)*
- Describe the product. *Explain the benefits of the C-Leg. Include examples of what the C-Leg will enable the patient to do that other knee joints will not.*
- Describe why the patient needs the product. Include why a lower functioning K3 level component is not appropriate for your patient's physical condition. *Combine the patient and product description to illustrate how that specific patient will benefit from the use of a C-Leg. It is very important to relate the product features to the specific patient and their Activities of Daily Living (ADL). Include an explanation of how (if applicable) the C-Leg will enable the patient to return to work sooner than if fit with another prosthetic knee. Avoid using terms that apply to patient convenience or comfort issues.*

B. 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 specific ADL.
- Can be documented using the evaluation form available on our website.
http://www.ottobockus.com/products/lower_limb_prosthetics/c-leg_evaluation_protocol.pdf

C. Physical Description

Describe the patient and his or her amputation, history and any related physical conditions. May be documented using the evaluation form available on our website. (See above website link.)

D. Functional Description

Describe the patient's activity or functional level and their needs related to daily activities. May be documented using the evaluation form available on our website. (See above website link.)

E. Identify Codes

Clearly indicate all the codes being used and how each one relates specifically to the patient's daily activities.

F. Other Key Terms

- Reasonable and necessary. *Medicare defines this as the patient reaching or maintaining a defined functional state within a reasonable period of time and is motivated to ambulate.*
- Least costly, most functional. *The least costly alternative compared to another service/product that provides the same benefits. Include what the C-Leg can provide that other prosthetic knees cannot. Remember to relate back to your patient's physical condition and the need from a medical necessity perspective.*



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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"> • Attachment I: FDA 510(K) Premarket Notification - Otto Bock C-Leg 1999 • Attachment II: FDA Product Classification – Exempt from Premarket Notification
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.	<ul style="list-style-type: none"> • Significant increase in microprocessor knee loading gait parameters ($p < .01$)¹ • Significant improvement in balance ($p < .01$)¹ • Significant improvement in sensory organization/equilibrium score ($p < .05$)¹ • Significant improvement in total daily energy expenditure (TDEE) in free-living environment ($p < .05$)¹ • Significant increase in physical activity-related energy expenditure (PAEE) ($p = .04$)¹ • Improvement with microprocessor controlled knee as compared to non-microprocessor controlled knee (established alternative)¹ • Significant decrease in frequency of stumbles and falls ($p < .05$)² • Significant decrease in frustration with falling ($p < .05$)² • Significant decrease in falling while multitasking while ambulating ($p < .05$)² • Significant improvement with Stair Descent Index (SDI) ($p < .001$)² • Significant improvement with Amputee Body Image Scale (ABIS) ($p < .001$)³ 	<ul style="list-style-type: none"> • Reference #1: Kaufman, et al (2007) • Reference #2: Hafner, et al (2007) • Reference #3: Bunce, et al (2007)
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"> 1. Significant decrease in stumbles and falls as demonstrated by: <ul style="list-style-type: none"> • Significant improvement in balance ($p < .01$)¹ • Significant improvement in sensory organization/equilibrium score ($p < .05$)¹ • Significant decrease in frequency of stumbles and falls ($p < .05$)² • Significant decrease in frustration with falling ($p < .05$)² • Significant decrease with multitasking while ambulating ($p < .05$)² 2. Significant increase in activity level as demonstrated by significant improvement in total daily energy expenditure (TDEE) in free-living environment ($p < .05$) 3. Significant satisfaction as demonstrated by: <ul style="list-style-type: none"> • Significant improvement with Amputee Body Image Scale (ABIS) ($p < .001$)³ • Prosthesis Evaluation Questionnaire (PEQ) – significant improvement with microprocessor controlled knee as compared to non-microprocessor controlled knee (established alternative)^{1,2} 	
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"> • Significant increase in microprocessor knee loading gait parameters ($p < .01$)¹ • Significant improvement in balance ($p < .01$)¹ • Significant improvement in sensory organization/equilibrium score ($p < .05$)¹ • Significant improvement in total daily energy expenditures (TDEE) in free-living environment ($p < .05$)¹ • Significant increase in physical activity-related energy expenditure (PAEE) ($p = .04$)¹ • Prosthesis Evaluation Questionnaire (PEQ) – significant improvement with microprocessor controlled knee as compared to non-microprocessor controlled knee (established alternative)¹ • Significant decrease in stumbles and falls ($p < .05$)² • Significant decrease in frustration with falling ($p < .05$)² • Significant decrease with multitasking while ambulating ($p < .05$)² • Significant improvement with Stair Descent Index (SDI) ($p < .001$)² • Prosthesis Evaluation Questionnaire (PEQ) – significant improvement with microprocessor controlled knee as compared to non-microprocessor controlled knee (established alternative)² • Significant improvement with Amputee Body Image Scale (ABIS) ($p < .001$)³ 	<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"> • Significant improvement in total daily energy expenditure (TDEE) in free-living environment ($p < .05$)¹ • Significant increase in physical activity-related energy expenditure (PAEE) ($p = .04$)¹ • Significant increase in patient perception of microprocessor controlled knee as compared to non-microprocessor controlled knee (established alternative) ($p = .02$)¹ • Significant decrease in frequency of stumbles and falls in environmental setting ($p < .05$)² • Significant decrease in frustration with falling in environmental setting ($p < .05$)² • Significant improvement with Amputee Body Image Scale (ABIS) over six-month period ($p < .001$)³ 	<p>Reference #1: Kaufman, et al (2007)</p> <p>Reference #2: Hafner, et al (2007)</p> <p>Reference #3: Bunce, et al (2007)</p>