

Documentation Requirements for LL Prosthetics

January 1, 2018

Ottobock has relied upon the CMS guidance and recommendations set forth in this document’s reference section below.

Medicare’s Criteria in a Nutshell

Medical necessity for prosthetic components or additions to the prosthesis is based on:

1. The patient’s past history [activities],
2. The patient’s current condition [residual limb and any medical conditions that might affect patient’s ability to use the new prosthesis], and
3. Desire to ambulate. [desire to use the new prosthesis and get back to those previous activities]

A lower limb prosthesis is covered when:

4. Prescribed by a physician
5. The member will reach or maintain a defined functional state (K-Level) within a reasonable period of time, and
6. The member is motivated to ambulate

Medicare requires that all 6 criteria be documented in the physician’s medical record. Following is a guide:

Notes:

- Medicare wants to see chart notes reflecting the need for the care (e.g., treatment plan, history and physical, operative report) from the patient’s medical records charted when the patient is being seen (physician’s office, hospital, nursing home, etc.).
- To be on the safe side, it is recommended that this information be collected up-front to be sure the physician’s documentation supports the claim.
- Each document must be signed and dated, and include the signee’s printed name and credentials. We highly recommend that an Attestation or Signature Log be included when responding to audit requests.
- Electronic signature and date is only allowed on electronic documents.

- All documents that support medical necessity must be signed and dated prior to the delivery date.
- Each page/chart note must clearly identify the patient.
- The amputation side should be clearly and consistently identified.

Physician Documentation:

The following information must be included in the ordering physician’s medical records:

Recent history and physical examination (focus should be on the amputation, prosthesis, and ambulatory difficulties).

- a. **History of the Injury, Illness, or Condition**
 - Diagnosis/etiology of amputation(s)
 - Date and affected side (s)
 - Clinical course
 - Therapeutic interventions and results
 - Prognosis
- b. **Physical Examination**
 - Height, weight, recent loss/gain
 - Cognitive ability to use & care for new prosthesis
 - Description of the residual limb (e.g. local and/or phantom pain; wound healing issues; skin irritation, breakdown, infection; limb volume changes or swelling; weight fluctuations; muscle atrophy or contractures; osteoarthritis, or other arthritic conditions of the residual limb joint(s)).
 - Cardiopulmonary, musculoskeletal, neurological, arm and leg strength, ROM, gait, balance, coordination

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c. **Functional Limitations**

Describe the nature and extent of limitations on a typical day that might affect the patient's ability to use/ambulate with the new prosthesis. Note: Any condition identified must be ruled out. Examples:

- **Cardiopulmonary** conditions that might limit the patient's capacity [e.g. congestive heart failure (CHF), coronary heart disease (CHD), endocarditis, myocarditis, arrhythmias, peripheral arterial (occlusive) disease (PAD/PAOD), chronic venous insufficiency (CVI) with recurring ulcers, lymphedema].
- **Musculoskeletal** conditions (e.g. osteoarthritis sound side leg joints, spinal stenosis, severe low back pain).
- **Neurological** conditions that cause impairments in gait, balance or coordination (e.g. MS, stroke, SCI, Parkinson's, peripheral nerve lesions, lumbar disc herniation with motor paresis, dementia/Alzheimer's disease, depression, psychiatric disorders/diseases).
- **Other comorbidities** (e.g. chronic kidney failure, chronic liver failure, cancer with chemotherapy/radiation, general deconditioning).

d. **Impact of the Limitations:** Description of current activities of daily living and how they are impacted by the deficit(s) identified. Is the patient more limited by his/her medical conditions or by the function of the prosthesis?

e. **Ambulatory Assistance** currently used (e.g. cane, walker, wheelchair, care giver).

Note: Medicare does not consider a person who permanently uses an ambulatory aid to be functioning at K3 level.

If this is a temporary situation, state in your opinion how long it will take for your patient to be back to functioning at K3 level (free of the assistive device).

Functional Levels (K-Levels)

Level 0: 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 [*i.e. patient likely will not be able to ambulate at all*].

Level 1: Has the ability or potential to use prosthesis for transfers or ambulation on level surfaces at fixed cadence [*i.e. patient likely will be able to use the prosthesis within his/her dwelling only*].

Level 2: Has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs or uneven surfaces [*i.e. patient will likely be able to use prosthesis within his/her dwelling and a limited radius in the community*].

Level 3: 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. [*i.e. patient will likely have a prosthetic ability comparable with that of a non-amputated person with no mobility restrictions*].

Level 4: 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.

f. **Define the Patient's Functional State:**

Describe patient's functional capabilities in terms of the K-Levels (above) as they relate to the patient's activities. These should be **real activities**, such as "walking the dog" and related K-level functions that patient encounters (e.g. long-distance ambulation, obstacles, types of terrain, slopes, stairs, ramps, crowds, public transportation)

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Following is what must be in the record:

- **Patient’s activities prior to amputation**
- **Patient’s current activities**
- **Activities that patient desires to get back to** (and has the potential for) using the new prosthesis.

Note: If patient was a community ambulator (K3/K4) earlier in life, but not prior to the amputation due to a medical condition (e.g. neuropathy, ulcers, and neuropathic pain) or if patient was never a community ambulator (K3/K4) and now has demonstrated capacity to be one, include why you believe the patient will be a community ambulator with the new prosthesis (e.g. sound limb is asymptomatic, achievements during rehabilitation/physical therapy, diseased limb was the primary cause of the mobility restrictions, etc.).

g. Document the Current Prosthesis:

- **Condition of each component** (e.g. socket, knee, pylon, ankle, foot) should be documented.
- **Reasons for replacement**
One of the following reasons should be documented for each component being replaced.
 - Patient’s functional needs have changed
 - Due to physical changes the component no longer fits
 - Device is irreparably worn
 - Device is lost or damaged beyond repair
 - Cost to repair will be greater than 60% of the cost to purchase a new device.
- **If the patient’s condition has changed**, describe why the current prosthesis is no longer appropriate. (e.g. weight gain/loss, decreased stability, etc.)
- **If the device was damaged or lost**, describe the incident.

h. Previous Prostheses:

- Document patient’s past experience with prosthetic components (what has been tried, and the result).
- **Desire and Motivation:** Document patient’s desire to use the new prosthesis and motivation to ambulate.

i. Recommendation for the type of new Prosthesis/ Component(s) and the medical reason for your decision.

- The recommendation must be based on patient’s prior activities, current condition, and desire to ambulate. Include a statement as to what your decision is based on.
- The Brand name of the prosthetic components is not required.

j. Prognosis: Document patient’s prognosis using the new device, including your opinion as to approximately how long it will take patient to reach the higher K-Level (if applicable).

Dispensing Order

- The prosthesis/component may be delivered upon receipt of a dispensing order; however, a signed Detailed Written Order (DWO) must be obtained prior to billing. The DWO can be your dispensing order if signed prior to delivery.
- The dispensing order must comply with state prescribing and/or other applicable laws. It is the practitioner’s responsibility to ensure this compliance.
- The dispensing order can either be verbal and documented in the patient’s chart OR written by the ordering physician.
- For Medicare, there only needs to be one date on the dispensing order. This will be the “order” date.

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The following elements must be included in the dispensing prescription:

- **Patient's name**
- **Date of order**
 - For written order: use the date of the prescription
 - For verbal order: use the date the call was received
- **Description of item**
- **Signature**
 - For written order: Physician's signature and date, printed name and credential
 - For verbal order: Printed name of person taking order, signature, date, time.

Detailed Written Order (DWO)

- The provider may write the detailed order; however, the physician must review and sign it.
- Two dates are required on a provider generated DWO (order date and physician's signature date)
- The DWO must be signed & dated by the ordering physician prior to submitting the claim, but could also be the Dispensing Order if signed prior to delivery.
- Signature/date stamps are not allowed.

The following elements must be included in a "provider generated" DWO:

- **Order date**
 - Use the date of the dispensing order if you have one.
 - If you do not already have a dispensing order, use the date that the DWO is generated by the provider. (today's date)
 - The physician's signature date does not have to match the order date.
- **Patient's name** on each page

- **Describe what is being ordered** (list all items, options or additional features that will be separately billed or require an upgraded code)
 - **Effective 11/20/2017:** You may use **one** of the following methods:
 - **Narrative description** (AK polycentric knee w/friction)
 - **HCPCS code** (L5613),
 - **HCPCS code narrative** (Addition to lower extremity, endoskeletal system, above knee, knee disarticulation, 4-bar linkage, with friction swing phase control)
 - **Brand name/model number** (4R36 Titan polycentric knee joint)
- *We recommend including brand name and model number for items with multiple codes.

Note: Always include **RT/LT**

- **Physician demographics** (printed name, credential, address, phone, NPI)
- **Physician's handwritten signature and date**

Note: If this is the only order and the prosthesis will be delivered same day, the physician should include the time of signature to prove that the order was signed prior to delivery.

Prosthetist's Documentation

- Medical records must support that the device is still medically necessary.
- Medicare expects that a lost/damaged item would be reported to some authority (e.g. police, homeowners insurance, etc.) and requires that a copy of that report be available. If patient did not report the accident/loss, you will need a signed statement from the patient describing the incident.

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a. **Functional Evaluation** (K-level should match physician's evaluation)

(see section f. **Physician Documentation**)

- **Activities prior to amputation**
 - Activities that patient did in the past and would like to get back to using a new device (e.g. home, work, therapeutic, exercise).
- **Current activities.**
 - Focus on activities that the new prosthesis will allow that the current prosthesis does not.
 - Describe difficulties, such as falls, stumbles, not making it across street before light changes, inability to change speed when needed, etc.
 - How will patient be able to do it better with the new prosthesis?
- **Potential future activities.** If these vary from prior activities, an explanation will be required)

b. **History of Prosthetic Use**

- Your records should have a history of each prosthesis patient has used/trialed in the past.
 - Brand of component
 - How long did patient use it?
 - What was the result?

c. **Current Prosthesis**

- **History of each component being replaced** (age, condition, how did it work out?)
- **Description of the labor involved** (e.g. casting, modification, time, tools used, materials used, where was material applied, etc.)
- **Reason for replacement** (e.g. item lost or damaged beyond repair; change in patient's condition and device no longer fits or does not meet functional needs; item is worn and cannot be repaired or the cost to repair is greater than 60% of the Medicare allowable for a new device).

d. **Recommendation for the type and brand of the new prosthesis:**

- Must be based on physician's recommendation
- Include rationale for your decision
- Include medical necessity and justification for each code that will be billed.

e. **Patient's motivation and desire** to use the new prosthesis (and to ambulate for lower extremity)

f. **Chart note for each visit with patient** with printed name, credential, signature and date on each note.

g. **Patient's name on each page.**

Proof of Delivery (POD)

- **NEW** A signature date is no longer required; however, if there is one on the form, it must be the date of service on your claim.
- If the DWO is signed on same day as the delivery and it is the only order, both documents will need to indicate the time of the signature.

Elements to be included on the POD when device is delivered direct to the patient:

- Delivery Date
- Patient's name
- Address where item is delivered (your office, patient's home, SNF, etc.)
- The quantity delivered for each item
- Amputation side for each item, LT/RT
- **Describe what will be delivered**
Effective 12/21/2017: You may use **one** of the following methods:
 - **Narrative description** (AK polycentric knee w/friction)
 - **HCPCS code** (L5613),
 - **HCPCS code narrative** (Addition to lower extremity, endoskeletal system, above knee, knee disarticulation, 4-bar linkage, with friction swing phase control)

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- **Brand name/model number** (4R36 Titan polycentric knee joint)
*We recommend including brand name and model number for items with multiple codes.
- **Signature and printed name** of the patient or designee
Note: If designee signs, include the designee’s relationship to the patient and the reason why patient could not sign. This person cannot have any financial connection to the provider.
- **Effective 11/20/17 POD when patient is recently eligible for FFS Medicare and already own a LL prosthesis**
 - Statement that supplier has examined the item, signed by the beneficiary. Statement must meet POD requirements. AND
 - Supplier attestation that the item meets Medicare requirements.

Beneficiary Authorization

- A new authorization is required anytime a new prosthesis/component(s) is provided. In other words, a new authorization is required anytime a new HCPCS code is billed.
- This authorization should give you:
 - Permission to submit claims on behalf of beneficiary.
 - Permission to pay you directly (assigns the benefits to the provider).
 - Release to authorize the provider to obtain confidential medical information about the beneficiary in order to process the claim.

Example of an Authorization:

Name of Beneficiary: _____
 HICN: _____
 I authorize (supplier)_____ to submit claims to Medicare on my behalf. I request that payment of authorized Medicare benefits be made either to me or on my behalf to (supplier)_____ for any services furnished me by that supplier.
 I authorize any holder of medical information about me to release to (supplier) _____ and/or the Centers for Medicare & Medicaid Services and its agents any information needed to determine these benefits or the benefits payable for related services.
 Signature _____
 Date _____

Advanced Beneficiary Notice (ABN) if required

- ➔ NOTE: Medicare does not allow “blanket” ABN’s to be issued. In other words one cannot give an ABN to every patient, in anticipation that Medicare might deny. ABNs are to be used on a case-by-case basis when there is a clear indication that the device will be denied as not medically necessary/not reasonable and necessary.

References:

- Joint DME MAC. Local Coverage Article: Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426)
- CGS & Noridian Supplier Manuals