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Lower Limb Prosthesis Documentation Guide.

Medicare and Medicare Advantage.

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Lower Limb Prosthesis Documentation Guide. Medicare and Medicare Advantage.

On September 1, 2024, Medicare issued a revised Local Coverage Determination (LCD) and Policy Article for Lower Limb Prosthetics that expands coverage of advanced prosthetic knees and feet to functional level K2 patients who meet specific criteria for coverage. Additionally, they added a list of functional characteristics to assist with determining your patient's K-level, based on "CMS Health Technology Assessment: Lower Limb Prosthetic Workgroup Consensus Document, 2017." This brochure has been updated with these new criteria and some helpful examples.

Table of Contents.

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Lower Limb Prosthesis Documentation Checklist [1,2,3]

(effective 9/01/2024)

- ❑ **History of Amputation:** Cause, date & side of amputation(s);
- ❑ **Physical Examination:** Weight, Height, Cardiopulmonary, Musculoskeletal, Neurological
- ❑ **Current Ambulatory Problems:** Functional limitations caused by current prosthesis, current condition, or comorbidities.
- ❑ **Ambulatory Aids/Personal Assistance Used**
- ❑ **Current Activities of Daily Living** and how impacted by the functional limitations
- ❑ **Clinical Evaluation to Determine Functional Level (K-Level)**
  - Past & current functional activities
  - Realistic activities patient would like to resume
  - Desire & Motivation
  - Current/potential K-level, time frame to achieve it, rationale & treatment plan
- ❑ **Status of current prosthetic components** (**foot, ankle, knee, socket) and Reason for Replacement**.
- ❑ **Document your recommendation for the new prosthesis or prosthetic components.**
- ❑ **If ordering a fluid (hydraulic), pneumatic, or microprocessor knee (MPK) for K2 level patient, document:**
  1. History of falls/stumbles or injuries. Highlight activities patient avoids due to fear of falling and/or activities that are too difficult with current prosthesis.
  2. How the MPK will improve patient's functional health outcomes (fall reduction, injury prevention, or lower energy expenditure).
  3. Activities of daily living (ADLs) that will be improved
  4. Which lower-level knee systems were considered and why the technology is insufficient for the beneficiary's functional and medical needs.
- ❑ **If ordering a MPK for a functional level 2 patient also document the following**:
  1. The MPK is indicated for K2 and has a stumble recovery feature.
  2. The patient can make use of a product requiring daily charging and can understand and respond to error alerts and alarms indicating problems with the function of the unit.
- ❑ **If ordering a Microprocessor Controlled ankle-foot, Energy Storing foot, Dynamic Response foot w/ multi-axial ankle, Flex Foot, Flex Walk, or Shank foot w/ vertical loading pylon for K2 MPK patient, document the following:**
  1. The patient meets fluid (hydraulic), pneumatic or microprocessor knee criteria above (1-4)
  2. A higher-level foot is needed for safe and proper use of the prescribed knee system (above).

References:
[1]CMS.gov. L33787 Lower Limb Prosthesis Local Coverage Determination (LCD). Revision effective date 9/01/2024
[2]CMS.gov. A52496 Lower Limb Prosthesis-Policy Article. Revision effective date 9/01/2024
[3]CGS. Documentation Checklist. Lower Limb Prosthesis. Revision effective date 09/01/2024

LLP Documentation Details.

PHYSICAL EVALUATION

A recent physical evaluation by the treating practitioner is required. The focus should be the amputation, prosthesis, and ambulatory difficulties.

a. **History of the Amputation**

- Diagnosis/etiology of amputation(s)
- Date, affected side(s), level of amputation(s)

b. **Physical Examination Relevant to Patient's Ambulation Difficulties**

- Height, weight, recent loss/gain
- Describe conditions 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 joints).
- Cardiopulmonary, musculoskeletal (arm and leg strength, ROM), neurological (gait, balance, coordination).

c. **Current Ambulatory Difficulties**

Describe the nature and extent of functional limitations on a typical day whether from current prosthesis, current medical condition or comorbidities. Include:

- History of present conditions(s) relevant to functional deficits.
- History of falls and injuries with current/previous prosthesis (including type of injury, type of medical attention sought, etc.). If there is no history of falls/injuries, assess risk of falling with the prosthesis (e.g., TUG, ABC scale).
- Impact of the prosthesis on falls (e.g., prosthetic knee buckles often, insufficient toe clearance results in frequent tripping, etc.).
- Comorbidities and symptoms limiting ambulation/dexterity and resulting in ambulatory problems or impacting the use of the new prosthesis.
- Ambulatory Assistance currently used (e.g., cane, walker, wheelchair, caregiver, etc.)

d. **Current Activities of Daily Living** (e.g., transferring, ascending stairs, grocery shopping, housekeeping, property maintenance, exercise, working, etc.) and how patient's ability to do the activities is impacted by the functional limitations previously described.

e. **Activity avoidance due to fear of falling** (e.g., walking on uneven terrain, slopes, stairs, walking the dog, activities in tight spaces [e.g., kitchen, bathroom, activities involving turns and stepping back, etc.)

CLINICAL EVALUATION TO DETERMINE THE FUNCTIONAL K-LEVEL (see page 7)

The clinical evaluation to determine the patient's current/potential K-level may be completed by a prosthetist; however, the treating practitioner's medical records must support the K Level assigned.

Document the following:

a. Activities that patient was able to do prior to the amputation (described in K-Levels terms).

b. Current ability to ambulate.

c. Realistic activities that patient desires to resume (and has the potential for) using the new prosthesis. Include activities that patient has been avoiding due to fear of falling.

If patient was a limited/community ambulator earlier in life, but not prior to the amputation due to a medical condition (e.g., neuropathy, ulcers, and neuropathic pain), include why you believe the patient will be a limited/ 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.).

d. Document both patient's desire and motivation to ambulate.

e. State the patient's current Functional K-Level or "potential" Functional K-Level. This should be based on past-history, current condition, desire and motivation (documented above). If the patient has potential to reach a higher functional level designation in a reasonable time, state your opinion of how long it will take _____ and include rationale and a treatment plan (e.g. mobility aid, PT, gait training, etc.).

Note: Once determined, the "potential" higher functional level is assigned to the patient and used going forward when ordering componentry, when documenting in the medical record, and when billing. For example, a new amputee might be at a lower level when evaluated but have the potential to reach K2. This patient is then considered to be a K2 ambulator.

DOCUMENT STATUS OF CURRENT PROSTHESIS (if applicable):

a. **Condition of each component** (e.g. socket, knee, pylon, ankle, foot).
b. **Replacement of a Prosthesis/Component**

Note: The reason for replacement must be documented by the treating practitioner, either on the order or in the medical record, so this could be documented on the final order after patient sees the prosthetist.

If replacing a component with an identical or nearly identical item, 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.
- Irreparable change in condition of the device.
- Prosthesis is lost or irreparably damaged in some type of incident.
- Cost of 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/component is no longer appropriate. (e.g., weight gain/loss, falls, increased risk of falling, decreased stability, etc.).
    - **If item is damaged or lost**, describe the incident.
    - **If the current prosthesis/component** is the most appropriate type of replacement (explain).

DOCUMENT RECOMMENDATION FOR THE NEW/REPLACEMENT PROSTHESIS OR PROSTHETIC COMPONENT(S).

Note: A prosthetist may document the rationale for choosing the prosthesis or prosthetic component within their chart notes, providing the documentation is supported by and is not in conflict with medical records from the treating practitioner.

This should include your rationale for the selection, based on patient's K-level, past history of ambulation, current condition, desire and motivation (documented above).

EXAMPLES OF RECOMMENDATIONS FOR NEW/REPLACEMENT PROSTHESIS.

New Amputee:

[pt name] has the potential to regain at least K2-level mobility within 4-6 months with a prosthesis that includes a microprocessor knee (MPK) with stumble recovery. An MPK would speed up rehabilitation as it would dramatically reduce falls compared to a non-MP mechanical knee, which would also address the fear of falling the patient already has. In addition, an MPK doesn't require to learn non-physiologic walking with untimely hip extension during stance to stabilize a mechanical knee and prevent it from collapsing.

I am prescribing 20 sessions of physical therapy to prepare him for prosthesis use through muscle strengthening and training of balance and coordination as well as providing gait training and rehabilitation with the prosthesis with an MPK.

Cognitively, [pt name] uses a smart phone and should easily learn to make use of an MPK with daily charging and understanding and responding to error alerts and alarms indicating problems with the function of the unit.

Upgrading to MPK from Mechanical Knee:

I recommend that [pt name] get a new K2-level microprocessor knee with stumble recovery. A safer mechanical knee would provide less function than her current knee and further restrict her mobility. Only a microprocessor knee can provide the necessary safety and function to help her resume gardening and maintaining her home.

Microprocessor knees are the only type of prosthetic knee components on the market today available for K2 level patients in need of a stumble recovery feature. A K2-level microprocessor knee will help prevent falls and stumbles and allow her to take steps backwards without the knee collapsing.

I am prescribing 4 weeks of physical therapy to help her safely learn to use the microprocessor knee functions and will reevaluate at that time. She should be able to safely get back to all her previous activities within 4-8 weeks. I am also recommending that her prosthetist evaluate if she needs a new foot to accommodate the microprocessor knee. Additionally, her socket is worn and has some cracks around the edges, and she will need a new socket.

These recommendations should improve her quality of life and functional health outcomes by allowing her to safely get back to her previous activities. Cognitively, she uses a smart phone and should easily learn to make use of her new microprocessor knee, which requires daily charging, and she is capable of understanding and responding to error alerts and alarms indicating problems with the function of the unit.

MEDICARE EXPANSION OF COVERAGE OF ADVANCED KNEES AND FEET FOR K-2 AMBULATORS.

Effective 09/01/2024.

Note: A prosthetist may document the following criteria within their chart notes, providing the documentation is supported by and is not in conflict with medical records from the treating practitioner.

Fluid, Pneumatic or Microprocessor Knees, previously only covered for K-3 ambulators, may now be covered for patients categorized as functional level K-2 when all of the following criteria are met and documented.

1. Document activities of daily living (ADLs) that will be improved with the new device (e.g., transferring, ascending stairs, grocery shopping, housekeeping, working).
    - Highlight activities patient avoids due to fear of falling and/or activities that are too difficult with current prosthesis. Suggestion: Use the Patient-specific Functional Score (PSFS) to rate personal difficulty.
2. Document how the proposed device will improve patient's functional health outcomes (e.g., fall reduction, injury prevention, lower energy expenditure).
    - For fall reduction/injury prevention include history of falls/stumbles and injuries, and TUG or ABC test scores for risk of falling. Provide as much detailed information on past injuries as possible.
3. Document which lower-level knee systems were considered and why the technology is insufficient for the beneficiary's functional and medical needs.
4. If prescribing a microprocessor knee for a K-2 patient, also document the following:
    - The MPK must be indicated for K2 and have a stumble recovery feature.
    - The patient can make use of a product requiring daily charging and can understand and respond to error alerts and alarms indicating problems with the function of the unit.

Similarly, advanced feet (Microprocessor Controlled ankle-foot, Energy Storing foot, Dynamic Response foot w/ multi-axial ankle, Flex Foot, Flex Walk, or Shank foot w/ vertical loading pylon) previously only covered for K-3 ambulators, may now be covered for K-2 patients using an advanced knee when all the following criteria are documented:

1. Patient meets criteria 1-4 (above).
2. A higher-level foot is needed for safe and proper use of the prescribed advanced knee system (above).

TESTING TO CORROBORATE K-LEVEL EVALUATION.

Recommended tests you might use:

- Timed Up and Go (TUG) assesses mobility, balance and fall risk in older adults.
- Prosthetic Evaluation Questionnaire (PEQ) has validated functional outcome measures specific to prosthesis-related changes in quality of life
- Patient Specific Functional Scale (PSFS) assesses functional ability to complete specific activities.

References:

[1]CMS.gov. L33787 Lower Limb Prosthesis Local Coverage Determination (LCD). Revision effective date 9/01/2024

[2]CMS.gov. A52496 Lower Limb Prosthesis-Policy Article. Revision effective date 9/01/2024

[3]CGS. Documentation Checklist. Lower Limb Prosthesis. Revision effective date 09/01/2024

Medicare Functional Levels (K-Levels).[1,2]

Effective 09/01/2024.

Note: Patient does not need to have all traits, just those that apply to their documented activities. Choose the K-Level that best fits your patient/patient's functional potential.

Level 1:
Patient 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. Traits patient may have (with or without assistive device and/or personal assistant or supervisor):

- Cognitive ability to safely use a prosthesis
- Capable of safe ambulation in the home or on flat surface like a home
- Requires the use of a wheelchair for most activities outside of their residence.
- Is not capable of most of the functional activities designated in Level 2.

Level 2:
Patient has the ability or potential for ambulation with the ability to transverse low level environmental barriers such as curbs, stairs or uneven surfaces. This level is typical of the limited community ambulator. Traits patient may have patient can, with or without an assistive device/handrail(s)/personal assistant or supervisor:

- Performs the Level 1 tasks designated above
- Ambulates on a flat, smooth surface (e.g., concrete, asphalt) such as might be found outside the home. (e.g., porch, deck, patio garage, driveway)
- Negotiates a curb
- Accesses public or private transportation
- Negotiates 1-2 stairs
- Negotiate a ramp built to ADA specifications.
- May require a wheelchair for longer distances beyond yard/driveway, apartment building, etc.
- Is only able to increase walking speed for short distances or with great effort.
- Is not capable of accomplishing most of the tasks at Level 3 (or does so infrequently with great effort).

Level 3:
Patient has the ability or potential for ambulation with variable cadence, typical of the community ambulator with ability to transverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion. Traits patient may have:

- With or without an assistive device/handrail(s), the individual is independently capable (i.e. requires no personal assistance or supervision) of performing the Level 2 tasks above, and can:
- Walks on terrain that varies in texture and level (e.g., grass, gravel, uneven concrete)
- Negotiates 3-7 consecutive stairs
- Walks up/down ramps built to ADA specification
- Opens and closes doors
- Ambulates through a crowded area (e.g., grocery store, big box store, restaurant)
- Crosses a controlled intersection within their community within the time limit provided (varies by location)
- Accesses public or private transportation
- Performs dual ambulation tasks (e.g. carry an item or meaningfully converse while ambulating)
- The individual does not perform the activities of Level 4.

Level 4:
Patient has the ability or potential for prosthetic ambulation that exceeds the basic ambulation skills, exhibiting high impact, stress or energy levels typical of the prosthetic demands of the child, active adult, or athlete. With or without an assistive device/handrail(s) is independently capable (i.e. requires no personal assistance or supervision) of performing high impact domestic, vocational or recreational activities such as:

- Running
- Repetitive stair climbing
- Climbing of steep hills
- Being a caregiver for another individual
- Home maintenance (e.g. repairs, cleaning)

References: [1]CMS.gov. L33787 Lower Limb Prosthesis Local Coverage Determination (LCD). Revision effective date 9/01/2024[2]CMS.gov. A52496 Lower Limb Prosthesis-Policy Article. Revision effective date 9/01/2024

Changes to the Medical Record: Amendments, Corrections and Delayed/Late Entries.

The CMS Program Integrity Manual instructs the Medicare Auditors to consider all properly written amendments, corrections, and late/delayed entries in patient medical records. This means that the treating practitioner can add clarification to the medical record after-the-fact if something was missed when the patient was there; however, there are specific record keeping principles that need to be followed.

Recordkeeping Principles

"Regardless of whether a documentation submission originates from a paper record or an electronic health record, documents submitted to Medicare containing amendments, corrections or addenda must:

- Clearly and permanently identify any amendment, correction, or delayed entry as such, and
- Clearly indicate the date and author of any amendment, correction, or delayed entry, and
- Clearly identify all original content, without deletion"

Paper Medical Record

- Use a single line strike through so the original content is still readable, and
- The author of the alteration must sign and date the revision.

Electronic Health Records (EHR):

Records sourced from electronic systems containing amendments, corrections or delayed entries must:

- Distinctly identify any amendment, correction or delayed entry, and
- Provide a reliable means to clearly identify the original content, the modified content, and the date and authorship of each modification of the record.

(CGS JC)

Specific Rules for Amendments, Corrections and Late Entries

Late Entries

"A late entry supplies additional information that was omitted from the original entry. The late entry bears the current date, is added as soon as possible, is written only if the person documenting has total recall of the omitted information and signs the late entry." (Noridian JE)

Addendums

"An addendum is used to provide information that was not available at the time of the original entry. The addendum should also be timely and bear the current date and reason for the addition or clarification of information being added to the medical record and be signed by the person making the addendum." (Noridian JE) *[An example would be a test not yet available at the time of the exam.]*

Corrections (see instructions above under Record Keeping Principles)

References

CMS Program Integrity Manual. 3.3.2.5 Amendments, Corrections and Delayed Entries in Medical Documentation. (Rev. 12633; Issued: 05-09-24: Effective: 06-10-24; Implementation: 06-10-24)

CGS JC. Entries in Medical Records: Amendments, Corrections, and Delayed Entries. (January 19, 2016 – revised 01-13-20)

Noridian JD. Addendum Reference. Last Updated Jul 19, 2024

Noridian JE Part B Medical Review. Documentation Guidelines for Amended Medical Records. (Last Updated 10-31-2022)