Redefining Amputee Care: The Impact of The Draft Proposal on Lower Limb Prosthetics
What is the Draft LCD Proposal?

- Drafted by Medicare Administrative Contractors (MACs) as a result of recommendations in a 2011 Office of Inspector General (OIG) report
- Proposes to make changes to how prosthetic devices are covered under Medicare
- Proposes to make changes to how patients qualify for prosthetic devices
- Proposes to make changes to what types of devices or components are provided to amputees
- Proposes to make changes to the rehabilitation process for new amputees

PROPOSED/DRAFT Local Coverage Determination (LCD):
Lower Limb Prostheses (DL33787)

Please Note: This is a Proposed/Draft policy.
Proposed/Draft LCDs are works in progress that are available on the Medicare Coverage Database site for public review. Proposed/Draft LCDs are not necessarily a reflection of the current policies or practices of the contractor.

Contractor Information

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<th>Contractor Name</th>
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<td>16003</td>
<td>DME MAC</td>
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Proposed/Draft LCD Information

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Why is everyone so concerned with this issue?

- Functional potential would no longer be considered
- The use of assistive devices would automatically limit your functional status
- Feet and ankle options would be limited
- Sockets and liner options would be limited
- You may be required to attain a “natural gait” with your prosthetic device or would not be eligible to receive one
- Certain health complications in your medical record could disqualify you for a prosthetic device or reduce your functional status
- The rehabilitation process for new amputees would be fundamentally altered and would force new amputees to rehab on out-of-date technology
## Changes Concerning Functional Levels

### Current Definitions

| K0 | 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. |
| K1 | Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at a fixed cadence. Typical of the limited and unlimited household ambulator. |
| K2 | Has the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs or uneven surfaces. Typical of the limited community ambulator. |
| K3 | 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 use beyond simple locomotion. |
| K4 | 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 an active child, active adult, or athlete. |

### Proposed Definitions

| K0 | Does not have the ability to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility. |
| K1 | Has demonstrated the ability to use a prosthesis for transfers or ambulation on level surfaces at a fixed cadence. Typical of the household ambulator. Who can walk for distances that are considered reasonable for walking inside the home but limited for walking in the community because of endurance, strength, or safety concerns. |
| | • Use of a walker or crutches while using a prosthesis results in a K1 classification. |
| K2 | Has demonstrated the ability for ambulation to traverse low-level environmental barriers such as curbs, stairs or uneven surfaces. Typical of the limited community ambulator who can ambulate without assistance and is able to function physically and psychologically within the community independently. |
| | • Use of a cane while using a prosthesis results in a K2 classification. |
| K3 | Has demonstrated sufficient and adequate lower extremity function for personal independence during ambulation with variable cadence. Typical of the unlimited community ambulator who has the ability to traverse most environmental barriers without physical or safety concerns and has vocational, therapeutic or exercise activity that demands prosthetic utilization beyond typical environmental barriers. |
| | • Does not require the use of any mobility assistive equipment such as a cane, crutches, walker, or wheelchair |
| K4 | Has demonstrated sufficient and adequate strength, endurance, range of motion, and coordination for personal independence during ambulation. Exhibiting recreational demands, high impact activities, or elevated energy levels, typical of the prosthetic utilization for the energetic child, active adult, or athlete. An “active community ambulator” who not only can walk distances with no difficulty but also run on even ground with little difficulty. |
| | • Does not require the use of any mobility assistive equipment such as a cane, crutches, walker, or wheelchair |

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What do changes in functional status definitions mean for me?

- Your “potential” functional ability may no longer matter.
- You would automatically be considered a K1 patient if you use a walker or crutches.
- You would automatically be considered a K2 patient if you use a cane.
- K3 and K4 patients would not be able to use any assistive devices including a wheelchair.
- Under the proposal, you may be required to attain “the appearance of a natural gait” in order to get a prosthetic device.
Feet and Ankles

- Proposal would consolidate several feet and ankle codes into a single code

- Proposal would limit K2 patients to fixed ankle–feet
Vacuum Sockets and Liners

- The proposal may make it more difficult to receive a custom fabricated socket insert.
- The proposal would eliminate suction suspension systems as an option for K1 level patients.
- The proposal would eliminate elevated vacuum sockets for all patients.
- The proposal would eliminate cushioned liners for patients who receive a molded distal cushion.
The proposal requires an in-person medical evaluation by a Licensed Certified Medical Practitioner.

The proposal may reduce or limit your functional status if your medical record includes references to:

- Cognitive issues
- Neuromuscular issues
- Cardiopulmonary issues
Redefining the Rehabilitation Process for New Amputees

- The proposal would redefine the rehabilitation process for amputees

- New definitions:
  - Immediate Prosthesis
    - Post operative prosthetic device
  - Preparatory Prosthesis
    - A “basic” device that does not take into account functional status – must complete a rehabilitation program on this device to get your definitive prosthesis
  - Definitive Prosthesis
    - Permanent prosthesis based on your functional status
Recommendations

- The Amputee Coalition recommends the following:
  - Rescind the draft proposal
  - Thoroughly revise the proposal to include changes to the concerns outlined, input from applicable parties, and better reflect the current path of amputee care
If attending to speak, keep to talking points:
- Concern that use of assistive devices would limit functional levels and your potential abilities would no longer be considered
- Choice of feet and ankles should be based on medical necessity
- Choice of sockets and liners should be based on medical necessity
- Patients could be provided a less functional device if your medical record references certain health complications
- Amputees should receive the most appropriate device at the most appropriate time

Be respectful, not accusatory

Keep comments informed to the proposal

Keep your personal story brief, focus on the content and impact of the proposal
August 31st Comment Deadline

- Submit formal comments to:
  - DMAC_Draft_LCD_Comments@anthem.com

- The Amputee Coalition has a sample letter you can submit with just a few clicks!

- Draft your own! Use the Amputee Coalition’s Medicare Issue Alert page for help!