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SUBMITTED ELECTRONICALLY via LLPLCDCOMMENTS@cgsadmin.com

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Re: Amputee Coalition Comments on Proposed LCD: Lower Limb Prostheses

Dear Drs. Lalla, Hoover, Carroll, and Odell:

The Amputee Coalition appreciates the opportunity to provide comments to the Centers for Medicare and Medicaid Services and the Durable Medical Equipment Medicare Administrative Contractor Medical Directors in response to the proposed Local Coverage Determination for Lower Limb Prostheses, which expands Medicare coverage of microprocessor-controlled prosthetic knees to some Medicare beneficiaries who are limited community ambulators with an assigned activity level of K2.

The Amputee Coalition is a 501c3 organization that provides support, education, and advocacy for the over 5.6 million individuals who have experienced amputations or were born with limb difference living in the US. Every day our organization receives and shares stories of individuals who are thriving after limb loss. A common story we hear is, if not for my prosthesis, I would

not be able to play with my grandchildren, mow my lawn, attend community events, or walk in my neighborhood. We also hear the stories of the challenges experienced by members of this community. Unfortunately, falls are among the most common experiences shared by individuals living with limb loss and limb difference.

The Amputee Coalition supports the proposed revisions to the Local Coverage Determination for Lower Limb Prostheses and applauds the expansion of beneficiary access to hydraulic and pneumatic knees, microprocessor-controlled knees, and related prosthetic feet as the standard of care for a segment of the population who can benefit most from these technologies, those who have been assigned an activity level of K2. The benefits of added stability and stumble recovery that these technologies offer, specifically for aging individuals living with limb loss or limb difference are well documented. This technology is not only supported by the science, but by countless success stories shared by the individuals who have had access to this technology.

The subsequent comments outline the Amputee Coalition's request for revisions to language in the final LCD that will provide additional clarification related to the following questions: 1. How will a prosthesis that is classified for a beneficiary with a K3 activity level or above be "indicated" as medically necessary for a beneficiary who has been assigned an activity level of K2, and what will be considered as contraindication(s)? 2. What steps will be required to rule out non-microprocessor-controlled knees when it is determined that a beneficiary will benefit from stabilization and stumble recovery, and a physician has prescribed a microprocessor-controlled knee? 3. What documentation, specifically, will be necessary for a beneficiary to have in their medical record to receive the appropriate prosthesis for their stability and mobility needs?

The Amputee Coalition anticipates a celebration among Medicare beneficiaries living with limb loss or limb difference who will now have an opportunity to benefit from technology that can help them become more stable ambulators in their homes and communities. The Amputee Coalition respectfully requests the Centers for Medicare and Medicaid Services and the Durable Medical Equipment Medicare Administrative Contractor Medical Directors to provide clear guidance for clinicians regarding the qualification of the term "indicated," keeping in mind that all beneficiaries are unique in their lifestyle and daily activity needs. The features of different brands/types of microprocessor-controlled prostheses may vary in meaningful ways in addition to the presence of stabilization and stumble recovery technology. The Amputee Coalition requests that any measures taken to clarify the process by which a prosthesis is indicated for K2 patients also allow beneficiaries the opportunity, with guidance from their clinicians, to select the most appropriate prostheses to meet their total lifestyle needs to accomplish their activities of daily living.

The proposed LCD states that "All lower-level knee systems"—other than microprocessor-controlled, fluid, or pneumatic knees—must be "ruled out" based on the beneficiary's medical and functional needs before coverage of a microprocess-controlled prosthesis will be considered appropriate. The Amputee Coalition is concerned about the implications that this language has from an experiential perspective for the beneficiary. Will beneficiaries be expected to fail on a less-than-appropriate device before the appropriate one can been prescribed and provided? Greater clarification regarding how a prosthesis is ruled out should be provided to prevent negative beneficiary experiences as well as the potential for regression in beneficiaries' rehabilitation.

As stated earlier in this comment letter, the Amputee Coalition receives stories from Medicare beneficiaries on a regular basis; the experiences described highlight amazing examples of human perseverance, they also detail the challenges experienced by beneficiaries while navigating a complex healthcare system, specifically the disconnect that can occur when multiple providers from nonaffiliated facilities are responsible for documenting medical necessity. The final LCD should include language that is as clear as possible and reflects the realities of this complex continuum of care to take all necessary measures to prevent beneficiaries from the burden of uncertainty regarding whether they qualify to receive a device that includes technology that will improve or help maintain stability during ambulation.

The Amputee Coalition also supports the ITEM Coalition's recommendation that the final LCD restate that federal law requires that the clinical notes of the prosthetist must be considered for purposes of demonstrating medical necessity. The prosthetist is often the closest provider to the beneficiary in terms of selecting prosthetic options and should be closely involved in the determination of the beneficiary's functional potential.

Overall, the Amputee Coalition believes that this proposed LCD advances the standard of care for Medicare beneficiaries and represents a step forward in the treatment of individuals with lower limb loss or limb difference who currently function as limited community ambulators. The Amputee Coalition, again, extends its gratitude to CMS and the DME MAC Medical Directors for issuing this proposed coverage expansion and look forward to expeditious publication of the final LCD.

Respectfully,

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