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SUBMITTED ELECTRONICALLY via LLPLCDCOMMENTS@cgsadmin.com

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Re: ITEM Coalition Comments on Proposed LCD: Lower Limb Prostheses: DL33787

Dear Drs. Lalla, Hoover, Ballyamanda, and Jenny:

The undersigned members of the Independence Through Enhancement of Medicare and Medicaid ("ITEM") Coalition appreciate the opportunity to provide comments to the Centers for Medicare and Medicaid Services ("CMS") and the Durable Medical Equipment Medicare Administrative Contractors ("DME MACs") Medical Directors in response to the proposed Local Coverage Determination ("LCD") expanding Medicare coverage of micro-processor prosthetic knees to Medicare beneficiaries defined as limited community ambulators.[1]

The technology behind micro-processor knees is remarkable. A microprocessor controlled prosthetic knee ("MPK") uses integrated sensors and a microcomputer that collect and analyze data (e.g., movement, timing, position, velocity), and then adjusts, in real time, the flexion and extension resistance of the prosthetic joint during the swing- and/or stance-phase of the gait cycle. MPKs compared to non-MPKs ("NMPKs") improve stability when walking and standing, allowing amputees to traverse stairs, uneven surfaces, ramps and other barriers with greater confidence and ease. The MPK is able to detect when the amputee trips or stumbles, automatically reacting by increasing resistance in the knee and potentially preventing a fall or other injury.

[1] Proposed LCD: Lower Limb Prostheses: DL33787

The ITEM Coalition commends both CMS and the DME MACs for issuing this dramatically improved coverage policy for advanced lower limb prosthetic technology for Medicare beneficiaries. We strongly support this evidence-based and long-overdue coverage expansion. Our comments and requests for revisions to the LCD focus exclusively on language in the proposed LCD's documentation requirements that should be clarified in the final LCD to ensure that beneficiaries have appropriate access to advanced prosthetic technology with no delay, greater certainty of coverage, and minimal confusion as to what must be demonstrated to qualify for coverage.

The ITEM Coalition is a national consumer- and clinician-led coalition advocating for access to and coverage of assistive devices, technologies, and related services for persons with injuries, illnesses, disabilities, and chronic conditions of all ages. Our members represent individuals with a wide range of disabling conditions, as well as the providers who serve them, including individuals with limb loss and limb difference, spina bifida, multiple sclerosis, spinal cord injury, brain injury, stroke, paralysis, cerebral palsy, hearing, speech, and visual impairments, myositis, and other life-altering conditions.

On January 18, 2024, the DME MAC Medical Directors published a proposed LCD expanding Medicare coverage of fluid, pneumatic, and electronic/microprocessor prosthetic knees for Medicare Functional Classification Level ("MFCL") "K-2" beneficiaries and above. The current policy covers these prosthetic knees for K-3/K-4 amputees only, a more functional group of individuals. This proposed expansion to cover these prosthetic knees for K-2 amputees will greatly enhance the ability of Medicare beneficiaries with limb loss who are limited community ambulators to take advantage of the functional improvements and safety features that these advanced technology knees provide. With studies showing that between half and three quarters of Medicare beneficiaries with limb loss never file a post-amputation claim for prosthetic care, the impact of this policy improvement could be dramatic.

Needed Technical Clarifications in the Proposed LCD: As noted above, the ITEM Coalition is in strong support of this proposed coverage expansion; however, we wish to bring to your attention that there is language in the proposed LCD's documentation requirements that should be clarified in the final LCD to ensure there is no confusion on what must be demonstrated to qualify for coverage. Clarifying these sections of the proposed LCD will help limit delay in access to care and will help effectuate this new coverage policy for the benefit of Medicare beneficiaries with limb loss. A summary of our recommended clarifications is provided below.

- <u>Clinical Evaluation</u>: To qualify for coverage under the proposed policy, a "clinical evaluation" must be performed to determine the functional "K" level of the beneficiary. The final LCD should make it clear that the process is no different than current policy and that this clinical evaluation requirement anticipates that the treating prosthetist and/or treating practitioner will continue to be involved in the functional classification of the patient. The final LCD should also restate that federal law requires that the clinical notes of the prosthetist and/or treating practitioner must be considered for purposes of demonstrating medical necessity. The prosthetist and/or treating practitioner is often the closest provider to the patient in terms of selecting prosthetic options and should be

closely involved in the determination of the patient's functional potential. Of course, the patient him- or herself also plays a major role in this determination.

- Establishing a Rationale: The proposed LCD also requires that documentation establish a rationale to demonstrate how an MPK, fluid, or pneumatic knee will improve functional health outcomes and cites as examples "fall reduction, injury prevention, and lower energy expenditure." The final LCD should clarify how this is to be accomplished, who needs to perform these assessments, and other details that will operationalize this requirement, including what must be in the prosthetist's and/or treating practitioner's clinical notes to establish a sufficient rationale.

- Ruling Out NMPKs: The proposed LCD states that "All lower-level knee systems"—other than MPKs, fluid or pneumatic knees—must be "ruled out" based on the beneficiary's medical and functional needs before coverage of an MPK will be considered appropriate. This is a very high standard to document and raises questions as to how this will be accomplished and what, specifically, will meet this requirement. There are 220 different prosthetic knees on the market. If this statement in the LCD is taken literally, how can "all" knees other than advanced technology knees be ruled out before an MPK, fluid, or pneumatic knee will be approved for coverage? What documentation will be required to demonstrate compliance with this provision? Does this constitute a "fail-first" policy where the patient must be fitted with trial or demo NMPK knee systems and fail before qualifying for coverage for an MPK, fluid, or pneumatic knee? For the record, the ITEM Coalition would strongly oppose such a requirement because it could serve as a major barrier to timely access to care. The DME MACs should include greater clarity in the final LCD on this important requirement.

- MPKs Must Be Indicated for K-2 Amputees: The proposed LCD states with respect to MPKs only, that the electronic/microprocessor knee itself must be "indicated" for functional level 2 amputees. Broadly speaking, this is a fairly straight-forward requirement, but greater clarity in the final LCD would help practitioners determine who should make this judgment and how the determination is made? What would constitute an MPK, fluid or pneumatic knee that would *not* be indicated for a K-2 amputee? Must the Pricing, Data, and Analysis Contractor ("PDAC") make a prospective determination for each brand of MPK that it is, indeed, indicated for K-2 patients and, if so, what evidence will be necessary to secure this designation?

The documentation requirements in the proposed LCD are important to resolve in the final LCD. But overall, the ITEM Coalition believes that this proposed LCD represents a major advance forward in the treatment of individuals with lower limb loss who function currently as limited community ambulators and are not capable—with their existing prosthetic technology—of ambulating with variable cadence. The new coverage policy will clearly have an important positive impact on Medicare beneficiaries. For this reason, we extend our gratitude towards CMS and the DME MAC Medical Directors for issuing this proposed coverage expansion and look forward to expeditious publication of the final LCD.

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We appreciate your consideration of these comments. Should you have any further questions regarding this letter, please contact the ITEM Coalition Co-Coordinators at Peter.Thomas@PowersLaw.com or Michael.Barnett@PowersLaw.com or by calling 202-466-6550.

Sincerely,

The Undersigned Members of the ITEM Coalition

Access Ready Inc.
American Association on Health and Disability
American Medical Rehabilitation Providers Association
American Music Therapy Association
American Occupational Therapy Association
American Physical Therapy Association
Amputee Coalition*
Center for Medicare Advocacy
Institute for Matching Person & Technology
International Registry of Rehabilitation Technology Suppliers
Lakeshore Foundation
Long Island Center for Independent Living, Inc.
RESNA
Spina Bifida Association*
The Viscardi Center
United Spinal Association*

Indicates ITEM Coalition Steering Committee Member*

Cc: Chiquita Brooks-LaSure, CMS Administrator
Jason Bennett, Director, Technology Coding and Pricing Group
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