



August 26, 2015

VIA ELECTRONIC MAIL

The Honorable Sylvia Burwell
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Request to Rescind Proposed/Draft LCD on Lower Limb Prostheses (DL33787)

Dear Secretary Burwell:

The Steering Committee of the Independence Through Enhancement of Medicare and Medicaid (ITEM) Coalition strongly opposes the policy changes in DL33787 and we request that you rescind this Proposed Local Coverage Determination (LCD) today.

ITEM Coalition is a national consumer and clinician-led coalition, with a membership of over 70 organizations, which advocates for access to and coverage of assistive devices and technologies for persons with injuries, illnesses, disabilities and chronic conditions of all ages. Our members represent individuals with a wide range of disabling conditions and comorbidities, as well as the providers who serve them, including conditions such as limb loss, multiple sclerosis, cerebral palsy, spinal cord injury, brain injury, stroke, and other conditions.

The Proposed LCD will do little more than restrict patient access to the current standard of care and force amputees into prostheses that are less functional and less able to meet their individual needs, including individuals who rely on a combination of multiple devices such as wheelchairs, assistive communication, ventilators as well as prostheses. Medicare may save some money in the short term, but spend far more on the consequences of not providing modern prostheses to amputees. This is not sound policy, as patient care will suffer, leading Medicare beneficiaries to become less active and less healthy over time due to an unnecessary loss of mobility.

It is important to note that due to the current standard of care, limb amputation is not the disability it once was, for Medicare beneficiaries and all Americans. Decades of government funded research and development through the Department of Veterans Affairs, the Department of Defense, the NIH, and the National Institute for Disability, Independent Living, and Rehabilitation Research (now located in HHS's Administration on Community Living), as well

as robust innovation in the prosthetic field has enabled individuals who have lost limbs to regain remarkable levels of function and independence.

The current standard of care in prosthetics routinely enables individuals with once disabling conditions to return to active, healthy lives, re-engage in employment where appropriate, pursue recreational and athletic interests, and even resuming active duty military assignments. The activity levels of today's amputees are truly amazing and this reduces health care costs over the long term by having a healthier, more active Medicare amputee population. The proposed LCD would slam the breaks on this American health care success story.

This comprehensive set of revisions to Medicare's entire lower limb prosthetic benefit in the Proposed LCD appears to be based on virtually no evidence. It is not clear why these proposed changes are even necessary given the fact that Medicare has spent less on prosthetic limb care every year since 2010. This Proposed LCD punishes patients by denying them access to the very advances that have produced such good outcomes for amputees in recent years.

Additionally, because many of the proposed policies involve major changes to the Uniform Code Set administered by CMS (which all insurers use to cover and pay prosthetic limb claims), these changes have the potential to impact *all* amputees who use prostheses throughout the nation. It is our concern that, if it is finalized, commercial payers and others like the VA will eventually adopt the changes in the Proposed LCD. This would set back prosthetic care in this country by several decades.

For these reasons, ITEM urges you to stop this Proposed LCD process today, rescind the proposal, reconsider these policies by engaging patients, prosthetists, and members of the team of rehabilitation professionals, and start from scratch to design a more reasonable LCD that reflects the needs for patients with limb loss and takes advantage of the outstanding gains we, as a country, have made in prosthetic limb rehabilitation.

If this LCD is not immediately rescinded, we request that CMS suspend the LCD until such time as CMS publishes the final rule for Prior Authorization of Certain DMEPOS, which we understand will impact lower limb prosthetic care and is in the final phases of regulatory clearance at the Office of Management and Budget. ITEM has great apprehension over the process of allowing Medicare contractors to finalize medical policy through an LCD that is materially affected by, and not integrated into, a pending federal regulation on the same policy. Commenters should at least have the opportunity to examine all relevant rules being promulgated by CMS before being forced to comment in a piecemeal manner.

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Thank you for your consideration of our concerns. If you have any questions, please contact Sara Rosta, ITEM Coalition Coordinator, at Sara.Rosta@ppsv.com or 202-349-4246.

Sincerely,

ITEM Steering Committee

Alexandra Bennewith, United Spinal Association

Lee Page, Paralyzed Veterans of America

Mark Richert, American Foundation for the Blind

Lisa Satterfield, American Speech-Language-Hearing Association

Laura Weidner, National Multiple Sclerosis Society

CC: Kevin Thurm, Senior Counselor, DHHS
Andy Slavitt, Acting Administrator, CMS