August 31, 2015

SUBMITTED VIA ELECTRONIC MAIL

Stacey Brennan, M.D.
DME MAC Medical Director
National Government Services
8115 Knue Road
Indianapolis, Indiana 46250
DMAC_DRAFT_LCD_Comments@anthem.com

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

Dear Dr. Brennan:

The Independence Through Enhancement of Medicare and Medicaid (ITEM) Coalition appreciates the opportunity to comment on the Proposed/Draft Local Coverage Determination (LCD) titled Lower Limb Prostheses (DL33787). 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, as well as the providers who serve them, including such conditions as limb loss, multiple sclerosis, cerebral palsy, spinal cord injury, brain injury, stroke, and other conditions. Many such individuals are Medicare beneficiaries either due to their status as seniors or people with disabilities less than age 65.

ITEM Coalition has serious concerns with the Proposed LCD and requests that you rescind it immediately. We request that you fully reconsider these policies impacting Medicare beneficiaries with limb amputations by engaging patients, prosthetists, and members of the team of rehabilitation professionals, examining the scientific literature, and starting from scratch to design a more reasonable and appropriate LCD for Lower Limb Prostheses.

Any LCD affecting assistive devices and technologies for people with disabilities should be based on sound medical and clinical evidence. If this LCD is issued in final form, it will create a dangerous precedent that risks access to similar benefits for individuals with other disability conditions. Over 100,000 people have signed a White House petition calling on the President to rescind this Proposed LCD. We agree with this groundswell of opposition to the proposed policy.

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. Medicare may save some money in the short term, but spend far more on the consequences of not providing modern technology to amputees. This is not sound policy. Patient care will suffer, leading Medicare beneficiaries to become more dependent on wheelchairs and other assistive walking devices, and relegating amputees to nursing homes rather than living independent and active lives.

It is important to note that due to the current standard of care, limb loss is not the disability it once was, for Medicare beneficiaries and all Americans. Decades of government research funding through the Department of Veterans Affairs, the Department of Defense, the NIH and other agencies, 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 returning to active, healthy lives, re-engaging in employment, pursuing 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. ITEM Coalition is alarmed that the Proposed LCD slams the brakes on this progress by dramatically restricting the current standard of prosthetic care, effectively lessening access to the most appropriate prosthetic technologies and, in turn, negatively impacting the ability of amputees to lead the fullest and most productive lives possible.

Furthermore, this comprehensive re-write of Medicare's entire lower limb prosthetic benefit in the Proposed LCD appears to be based on virtually no evidence. LCDs are not supposed to be based on cost-effectiveness or savings that can accrue to the Medicare program. They must be based on sound science. It is not clear why these proposed changes are even necessary given the fact that Medicare has spent less on prosthetic services and devices every year since 2010. It is not an exaggeration to say that this Proposed LCD penalizes 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 setback prosthetic care in this country by several decades.

Alarming Themes in the Proposed LCD

The Proposed LCD restricts patient access to the current standard of care through the:

- Elimination of coverage of multiple prosthetic knees, feet and ankles that have undergone years of development, coding assignment, and widespread use by Medicare beneficiaries, causing them to live with prosthetic technology that is outdated and not consistent with the current standard of care;

- Elimination of twenty years of precedent by barring consideration of a beneficiary's *potential* to function and instead relying on "their documented performance using their immediately previous prosthesis (either preparatory or definitive)" when making a determination of the amputee's functional level. This new standard will drive beneficiaries into less functional prostheses and older prosthetic limb technology;

- Creation of multiple, new barriers to prosthetic care that will delay and, in some cases, deny prosthetic care to beneficiaries with limb loss. These barriers include the requirement for the beneficiary to undergo a rehabilitation program using a 1970's-era prosthetic limb and perform a series of difficult functions in order to qualify for a permanent prosthetic limb;

- Fundamental reworking of the HCPCS coding system that has been developed and annually refined over the past forty years whereby "base" prosthetic codes are augmented with "add-on" codes to ensure that beneficiaries receive the most appropriate combination of prosthetic techniques, materials, and technologies to meet their specific functional needs and functional potential. (The DMAC Medical Directors have essentially usurped the authority of the HCPCS Coding Committee which has responsibility for maintaining and refining the Uniform Code Set used by all payers.);

- Elimination of coverage of some of the most effective suspension techniques to secure a snug fit between the residual limb and the prosthesis, techniques and technologies that are in widespread use today. Poor or inconsistent suspension during the course of a day's use of prosthetic limbs is a major contributor to skin breakdown and other complications;

- Elimination of access to certain prosthetic components if the amputee uses a cane or crutches to ambulate, or cannot achieve "the appearance of a natural gait" while using a prosthesis, perhaps one of the most offensive proposals to Medicare beneficiaries;

- Long list of requirements that a patient must satisfy before being eligible to receive prosthetic care, including upper body strength, adequate posture, cognitive capability, sufficient neuromuscular control, sufficient cardiovascular capacity, and numerous other prerequisites. This appears to be a thinly veiled attempt to use the existence of these conditions to disqualify amputees for coverage of more advanced levels of prosthetic care, or any prosthetic care at all. These requirements are overly broad, not medically supported, and will lead to denials of claims based solely on historical, clinical records, not the physician's judgment that a beneficiary is a candidate for prosthetic care;

- Elimination of the licensed/certified prosthetist—that has the most intricate knowledge of prosthetic care—in determining an amputee's functional capabilities/deficiencies which help determine the treatment plan designed to meet the specific functional needs of the amputee. The proposed LCD creates a new system where physicians, therapists, and others (not prosthetists) will be required to conduct subjective and objective functional assessments and develop significant documentation with little or no additional reimbursement;

- Reiteration of misguided Medicare policies that prohibit the prosthetist's clinical notes from being considered as part of the medical record and requires new and unnecessarily-detailed proof of delivery documentation;

- Policy proposals that seem motivated by cost savings alone, not clinical or medical evidence. Lack of an evidence base is contrary to the requirements of the Program Integrity Manual, Section 13.7.1, which states that LCDs shall be based on the strongest evidence available and may not take cost into account.

For these reasons, we ask you to rescind the Proposed LCD and reconsider the policies in it by engaging patients, prosthetists, and member of the team of rehabilitation professionals, and start from scratch to design a more reasonable LCD that reflects the need for patients with limb loss to take advantage of the outstanding gains we, as a country, have made in prosthetic limb rehabilitation.

* * * * * * * *

Thank you for your consideration of our concerns. If you have any questions, please contact Steve Postal, ITEM Coalition, at steven.postal@ppsv.com or 202-349-4243.

Sincerely,

ITEM Coalition 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

ITEM Coalition Members and Other Supporting Organizations

ACCSES
American Academy of Physical Medicine and Rehabilitation
American Association of People with Disabilities
American Association on Health and Disability
American Cochlear Implant Alliance

American Congress of Rehabilitation Medicine
American Foundation for the Blind
American Medical Rehabilitation Providers Association
American Music Therapy Association
American Occupational Therapy Association
American Speech-Language-Hearing Association
American Therapeutic Recreation Association
Amputee Coalition
The Arc of the United States
Association of Assistive Technology Act Programs (ATAP)
Association for Education and Rehabilitation of the Blind and Visually Impaired (AER)
Brain Injury Association of America
Caregiver Action Network
Center for Medicare Advocacy
Christopher & Dana Reeve Foundation
Clinician Task Force
Easter Seals
Disability Rights Education and Defense Fund
Falling Forward Foundation
Institute for Matching Person & Technology
Lakeshore Foundation
Medicare Rights Center
The Myositis Association
National Association for the Advancement of Orthotics & Prosthetics
National Association of State Head Injury Administrators
National Council on Independent Living
National Disability Rights Network
National Multiple Sclerosis Society
Paralyzed Veterans of America
Rehabilitation Engineering and Assistive Technology Society of North America (RESNA)
Spina Bifida Association
United Spinal Association

CC: Andy Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services

Kevin Thurm, Senior Counsel
Office of the Secretary, Health and Human Services

Sharon Lewis, Principal Deputy Administrator
Administration for Community Living