AMERICAN ACADEMY OF ORTHOTISTS AND PROSTHETISTS

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SUBMITTED VIA ELECTRONIC MAIL

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

Dear Dr. Brennan:

The American Academy of Orthotists and Prosthetists (the Academy) has very significant concerns regarding the Proposed Draft Local Coverage Determination (LCD) titled: Lower Limb Prostheses (DL33787). The Academy represents certified and licensed practitioners of orthotics and prosthetics across the United States and is the education and research arm of the profession. As such, we are dedicated to the advancement of research, education, literature, advocacy, and collaboration with other organizations and agencies. We are committed to the provision of the highest quality evidence-based care, delivered to patients who utilize orthotic and prosthetic devices–including veterans, US Military Service Personnel, children, the elderly, and millions of Americans with disabilities.

In reviewing the newly proposed LCD, we were extremely disappointed by the highly restrictive nature of the policy and found many aspects of it to be confusing, conflicting, or vague. As advocates for the amputee patients that we serve, we feel it necessary to voice our objection to many of the proposed changes contained within the LCD.

In a general sense, the proposal appears to portray an almost fundamental lack of understanding of the physical, emotional, and psychosocial challenges that amputees are faced with and must overcome. This is reflected by the array of arbitrary and medically unsubstantiated barriers, qualifiers and access limits to existing and currently utilized standards of care. For example, proposing a 'one-style-fits-all' early fitting protocol would literally reverse patient care levels back several decades. This is unimaginable.

It also appears that very little consideration was given to the significant negative impacts these restrictive policy proposals would have on amputees and their ability to live independent, functional and productive lives. To take this population of people backward in time to such antiquated basic technology levels would be akin to demanding that 1970's internal knee replacement components be utilized in the future versus using current technology.

Many of our concerns relate to the requirements proposed in the Rehabilitation Program, Functional Status (K-Level) and Prosthetic Requirements for Functional Level sections. One of the most onerous aspects of the proposed LCD has to do with the removal of the consideration of a patient's potential for attaining a particular functional level. This is contrary to what rehabilitation intends to accomplish and would restrict an amputee's access to technology that would enhance their ability to achieve higher levels of functional ability. This is completely contrary to every principle of medical care wherein the overriding goal is always to maximize a patient's potential to achieve the most complete recovery possible. This is further exacerbated by the proposed automatic categorization of patients who utilize any type of assistive device during ambulation. Rather than seeing these devices as enhancements to ambulation, the proposed protocol embraces them as a rationale for limiting amputees to a less functional prosthesis. This is counterintuitive and an unfair penalty to amputees who use devices to allow them to ambulate more effectively and efficiently.

Equally troublesome is the new list of requirements that patients must satisfy to even qualify for either a preparatory or a new definitive prosthesis. As you are aware, in the case of qualifying for a definitive prosthesis, one must demonstrate such things as "sufficient" trunk control, "adequate" posture and the "appearance of a natural gait." These are subjective and unnecessary hurdles which have nothing at all to do with a patient's ability to effectively utilize and benefit from a lower limb prosthesis. Further, under the proposed policy, these and other capabilities must be demonstrated on a one-time basis, using either a technology-devoid preparatory prosthesis or an ill-fitting or worn-out definitive prosthesis that requires replacement. In addition, should a beneficiary be having a bad day with regard to a sore residual limb or other transient factors during the time of their evaluation, they will be assigned to an inappropriately lower K level and will therefore be constrained from receiving a more functional prosthesis. Such prohibitive practices will surely result in less ambulation and activity, decreased quality of life, increased comorbidities and increased healthcare costs. Therefore, this particular attempt to save precious healthcare resources will likely result in greatly increased utilization, cost and tax payer burden.

The overall tenor of the LCD implies that if there were no financial element involved in the provision of prosthetic services, the multiple hurdles put forward to constrain amputee access to care would never have been considered. However, there is a financial component to providing such services, as there should be. The response to that reality should not, however, be one which diminishes the lives of persons with the life-altering challenge of missing limbs. It must be recognized that there is no time off or vacation from having a lower limb amputation. It is a full-time disability that affects a person's every step with regard to balance, comfort, function, energy expenditure and their overall quality of life. With that as a reality, there is no moral or ethical rationale for limiting, or denying the technological advances that have been developed to serve the needs of our country's amputee citizens.

Further, these people have *paid* for their care–a clinically-appropriate prosthesis is not a gift that is simply being given to them by the government. These beneficiaries have earned the right to be given optimal care as stated in the June 2014 DMEPOS Qualification Standards Booklet ICN905709.pdf, which states in Appendix C, page 20, that the supplier shall: "Determine the appropriate orthoses/prostheses and specifications based on beneficiary need for use of the orthoses/prostheses to ensure *optimum therapeutic benefits* (emphasis added) and appropriate strength, durability, and function as required for the beneficiary." Therefore, Medicare is

obligated to provide care that allows amputees to achieve their maximum rehabilitation potential. The newly proposed LCD language directly contradicts that obligation.

In a continuum of flawed policy, the LCD perpetuates the unjust and logically indefensible position that if any aspect of a prosthetic service is denied, then the prosthesis in its entirety is denied. This policy makes no sense because the medical necessity for the prosthesis has been previously established by the ordering physician and an entire healthcare team supporting the patient. The policy completely ignores the time, expertise and expenditure of resources for components and fabrication that are invested by the prosthetist to produce the prosthesis. The policy further refuses to acknowledge that the intended outcome has been achieved by the prosthetist, as the patient is now in possession of a fully functional, finished prosthesis which enables them to return to a functional and productive capacity. The obvious and equitable solution to this unreasonable policy would be to limit the discussion and financial liability only to those questioned or disputed aspects of the prosthetic service.

With regard to the role and standing of prosthetic practitioners, the LCD continues the theme of trying to diminish the professional credibility of practitioners which began with the "Dear Physician" letter in 2011. These ongoing attempts to marginalize and minimize the validity and value of the prosthetic practitioner are unjustified and inappropriate. The prosthetic and orthotic profession is often misinterpreted as one where practitioners are simply providing devices, and nothing could be further from the truth. Today's practitioners are highly-trained professionals who spend years in didactic studies, clinical rotations and residency programs. They then sit for certification and/or licensure examinations to attain their credential(s) and must pursue continuing professional education in order to maintain their credential. Many practitioners direct residents, teach students and participate in the conduct of research. There are no better-prepared or more thoroughly educated professionals in the realm of prosthetics (or orthotics). Prosthetists are responsible for developing a prosthetic treatment plan and executing that plan through provision of an appropriately fitted and aligned prosthesis which represents only a singular aspect of the overall modality of care. To continue to support the arbitrary removal of the prosthetists' notes from the medical record, while further disregarding their unquestioned expertise in amputee care and functional evaluation, is simply a denial of established facts.

This proposed LCD is representative of what happens when proposed policy changes are developed in a vacuum without consultation with, or the benefit of input from, the profession being addressed or the patients being affected. As it is currently written, this proposal shows no regard whatsoever for the patients we serve. If this LCD, or anything resembling it, were to be implemented, the collateral damage and unintended consequences would be incalculable. The negative implications of this document have already struck a nerve across the citizenry of this country–a nerve that is sensitive to unfair and unjust treatment of individuals with disabilities for the sake of cost-cutting measures, a fact validated by >100,000 signatures on the "We the People" petition to the President calling for rescission of this proposed LCD.

Punitive measures such as those represented in this proposal, which are directed against both a group of people with disabilities and the providers who serve them, are totally inappropriate. If there are issues of concern requiring attention, the solution lies in a thoughtful and reasoned approach based on evidence–an approach which includes selected representatives from each of the stakeholder groups involved who can clarify and examine those concerns and arrive at a mutually agreed-upon resolution that will serve all entities equitably and fairly. The Academy stands ready to play a role in such a joint effort and encourages CMS to adopt such an approach.

For the immediate future, we request that this draft LCD be rescinded in its entirety due to the deleterious effects it will have upon Medicare beneficiaries with limb amputations in particular and ultimately the entire amputee population of the United States.

Sincerely,

The Board of the American Academy of Orthotists and Prosthetists