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Medical Director
DME MAC Region B

Via email: DMAC_Draft_LCD_Comments@anthem.com

RE: Comments to Local Coverage Determination DL-33787

Dr. Brennan:

Thank you for the opportunity to comment on the DME MACs' joint proposal for substantial modifications to the Local Coverage Determination and Policy Article applicable to Medicare reimbursement for lower extremity prosthetics. As one of CMS's deemed DMEPOS accrediting organizations—and an orthotics and prosthetics (O&P) certifying organization, as well—the Board of Certification/Accreditation (BOC) is uniquely qualified to address aspects of this proposal that, if implemented, would have a horrific effect on the prosthetic professionals BOC certifies and the patients those practitioners serve.

For more than 30 years, BOC has been dedicated to quality patient care by providing nationally recognized credentials to professionals and providers of comprehensive orthotic and prosthetic care. BOC credentials acknowledge the competence, professionalism, and safe practice environments of BOC-certified professionals and BOC-accredited facilities. As a member of the O&P Alliance, BOC actively advocates for state and federal policies that improve the practice of O&P and the quality of services provided to patients who require these health care services. In addition to supporting policies that enhance the care provided by O&P practitioners, BOC—on our own and through the Alliance—takes action when we identify policies that could have an adverse effect on the quality of care that our constituents offer their patients.

Prosthetists' Education, Training, Scope of Practice

Pursuant to a physician's order, a prosthetist evaluates a patient's condition, takes measurements and impressions of the involved body segments, and creates and properly fits prosthetic devices. Prosthetists are integral to the physical and emotional well-being of patients, providing instruction and training on how to properly use and maintain the prosthetic device(s).

BOC-certified prosthetists (BOCPs) are healthcare professionals who are qualified to provide and/or supervise the assessment, treatment plan development and implementation, follow-up, and practice management of people using prescribed prostheses.

BOCPs are recognized professionally as having completed rigorous education and training programs. The eligibility prerequisites of the BOCP certification program are:

- Completion of a Master's degree in O&P from a program that is accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP; www.caahep.org) and

- Completion of a prosthetist residency (typically 12 months) approved by the National Commission on Orthotic and Prosthetic Education (NCOPE; www.ncope.org).

Once a candidate meets eligibility prerequisites, BOC evaluates and verifies the candidate's competence in prosthetics with three comprehensive examinations: a Multiple Choice, a Clinical Simulation, and a Video Practical examination. BOC's prosthetist certification program is fully accredited by the National Commission for Certifying Agencies (NCCA), as are all of BOC's other O&P certification programs.

Introduction to BOC's Concerns

BOC has numerous concerns with the draft LCD, and participated in the development of the O&P Alliance's response and its thorough section-by-section commentary. In this letter, we will give a higher-level response to some of those concerns.

The draft LCD's lack of clinical evidence supporting the definitions and proposed changes are glaring, and—especially considering the patient population involved—this greatly concerns us. The potential negative impacts on these beneficiaries are further exacerbated by the continued refusal to recognize the certified/licensed prosthetist's role and expertise in the provision of prosthetic care and as a member of the rehabilitative team.

Some requirements of the draft LCD would inevitably cause delays in the provision of prosthetic care. Owing to the time-sensitive nature of the provision of these prostheses, such delays could be devastating to this vulnerable patient population.

Finally, some of the new requirements are simply not fair. Additional documentation and other requirements, which are almost always outside of providers' or the patients' control, are setting up providers and patients for denials.

Lack of Clinical Evidence to Support Definitions and Proposed Changes

The lack of clinical evidence to substantiate the proposed changes to the LCD is vexing. While the DME MACs hold suppliers to the letter of the law when processing claims for reimbursement, it would appear the DME MACs have disregarded the evidence supporting the policy as written in the Program Integrity Manual (PIM), Chapter 13, § 13.7.1. This policy states, the "contractor LCDs shall be based on the strongest evidence available." When the proposed changes were initially published on July 16, 2015, there were no indications of footnoted evidence to defend the changes to the current LCD. It was not until the American Orthotic & Prosthetic Association (AOPA) requested the clinical evidence that a bibliography was offered for review on July 30, 2015. The articles or publications listed do not meet the supporting evidence requirements as listed in the PIM, such as "Medical opinion derived from consultations with medical associations or other health care experts." Here is where BOC can be of service: our certified prosthetists are subject matter experts (SMEs) and would be willing to assist in improving the current LCD. We ask that when updating benefit coverage, the DME MACs include input from SMEs who are currently practicing in the field.

Negative Impact on Beneficiaries Living with Limb Loss

There are approximately 2 million people in the United States living with limb loss today, and approximately 185,000 new amputees each year. Through the draft LCD, restrictions on medically necessary prosthetic care would have an extraordinarily negative impact on the lives of returning wounded warriors, children born with limb loss, and countless others who have experienced the pain of limb loss through accidents, cancer, and tragedies like the Boston Marathon bombing.

As a nationally recognized and accredited O&P credentialing body for more than 30 years, BOC is well-aware of the necessity to ensure safe practice environments and clinically sound practices. BOC has worked with CMS to prevent fraud by accrediting DMEPOS suppliers and certifying orthotists and prosthetists, ensuring patients are given the proper care in the proper clinical environments. BOC joins the other major stakeholder groups—patients, physicians, and prosthetists—in opposition to the draft LCD and we believe the promise of cost-saving measures will, in fact, have the opposite effect.

First, the draft LCD will dramatically reduce patient access to quality care by limiting the types of prostheses that will be covered to those that are administratively necessary versus those that are medically necessary. The draft LCD will reward younger and healthier amputees who are administratively deemed worthy of greater functional levels, while hurting those who still have medical needs despite their age or comorbidities. It will limit some amputees' ability to remain contributing members of society. To these patients, their prostheses are not a luxury, but the means by which they can continue to work, exercise, remain healthy, and care for their families. The draft LCD would take all that away from them.

Second, the draft LCD will increase the long-term cost of care for patients. The Dobson-DaVanzo study demonstrates that by decreasing comorbidities, prosthetic services **decrease** the long-term cost of care—despite the up-front cost of the prostheses. For example, when patients are limited in their functional abilities and become more sedentary, they are at higher risk for developing more costly medical needs than if they were able to remain active. Dobson-Davanzo clearly showed that with effective prosthetic care, the lifetime cost of care was reduced and patients lived healthier and longer lives.

It's really this simple: the negative impacts on patients of the draft LCD will be that it will cost them their active lives, and it will cost more money in the long-term for Medicare to provide additional care. The positive impacts of rescinding the draft LCD will be the restoration of patients' active lives, and Medicare will spend less money on their care. BOC requests that Medicare return to a patient-focused continuum of care, which will increase patient access to quality and medically necessary care, increase patients' functional abilities, increase their independence, and help them be active, contributing members of society. If Medicare continues along the path of implementing the draft LCD, there will be an overwhelming and costly impact on the lives of the 2 million-plus Americans living with limb loss.

Delays in Beneficiary Care or Denial of Service

There are quite a few components of the draft LCD that hold a high probability of introducing additional delays to the appropriate service. The 90-day restriction that is introduced for fitting/adjustments as well as the 90-day restriction on sockets/components (page 4, paragraphs 9 and 10, respectively) have the potential to delay medically necessary modifications, including

replacement of worn components, replacement sockets due to changes in the residual limb, and replacement after removal owing to the development of a medical issue. In these cases, time is of the essence in providing appropriate new prosthetic devices to prevent the development of further comorbidities.

The requirement that beneficiaries complete a rehabilitation program (page 5, final paragraph) prior to being eligible for an initial definitive prosthesis also has many potential drawbacks. There are instances (rural beneficiaries, those without access to requisite transportation) where beneficiaries may not have access to a rehabilitation program and requiring them to complete one prior to being considered eligible could completely derail their prosthetic treatment.

The introduction of the requirement for the beneficiary to be seen and assessed by a licensed/certified medical professional (LCMP) has the potential for severe delays. The LCMP adds another delay by requiring that the beneficiary take the time to execute an additional appointment when they are already managing appointments regarding the condition that led to the amputation, as well as follow-ups. Delaying their ability to obtain a medically necessary prosthesis will have a detrimental impact on beneficiaries' rehabilitation.

Finally, we are dismayed that prosthetists are not included in the draft LCD's definition of the LCMP and we wish to underscore the O&P Alliance's recommendation of the inclusion of licensed and/or certified prosthetists as LCMPs. Prosthetists are the primary healthcare practitioners specifically educated, trained, and experienced in providing such assessments. The prosthetists' scope of practice specifically permits the comprehensive functional assessment of amputees. It is also worth noting that assessments of function for purposes of providing a prosthetic limb may be outside the scope of practice for some of the identified professionals, particularly physician assistants and nurse practitioners.

Recognition of the Prosthetist as a Healthcare Professional

Not only will the draft LCD put patients at risk and limit their access to care, but it also fails to recognize prosthetists as healthcare professionals. Prosthetists are certified medical practitioners who are qualified to provide the assessment, treatment plan, and implementation of prescribed prosthetic devices to patients. As stated above, they have completed rigorous education and training programs and have passed a series of exams to demonstrate their competency to treat patients. Once certified, prosthetists are held to a standard of ongoing continuing education and a code of ethics.

Prosthetists are the most-appropriate health care providers to evaluate the medical necessity of the proper prosthetic for patient care. Prosthetists are key members of the rehabilitative team and they will be treating their patients long after the surgeons and/or prescribing physicians complete their work.

The prosthetist is the medical professional most qualified to determine to what functional level a patient can be returned, as well as to provide the proper fit and ongoing maintenance care for the device and the patient. Prosthetists are trained in much more than the patient's anatomy. They are trained to assess the current functional level, as well as the potential functional level, and are experts on prosthetic device components. It is necessary for the prescribing physician and the prosthetist to work together to help their patients, and without each other, they would not be able to deliver the same quality care the patient needs. BOC again asks Medicare to

include the clinical notes of the prosthetist as relevant in determining medical necessity, as it is clear the prosthetist is a central part of the clinical team.

It also should be noted that the Benefits Improvement and Protection Act of 2000 (BIPA 2000) already set a precedent for recognizing prosthetists as part of the clinical team. Specifically, Section 427 established the policies for suppliers that bill CMS for the provision of custom-fabricated orthotics and prosthetics and defined who is a qualified supplier and who is a qualified practitioner. BOC is named as one of the organizations given the authority to certify qualified practitioners and accredit qualified suppliers.

Section 1834 of the Social Security Act applies these definitions from BIPA 2000. Below is the relevant excerpt from the Social Security Act.

> (iii) Qualified practitioner defined.—In this subparagraph, the term "qualified practitioner" means a physician or other individual who—
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> > (I) is a qualified physical therapist or a qualified occupational therapist;
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> > (II) in the case of a State that provides for the licensing of orthotics and prosthetics, is licensed in orthotics or prosthetics by the State in which the item is supplied; or
> >
> > (III) in the case of a State that does not provide for the licensing of orthotics and prosthetics, is specifically trained and educated to provide or manage the provision of prosthetics and custom–designed or –fabricated orthotics, and is certified by the American Board for Certification in Orthotics and Prosthetics, Inc. or by the Board for Orthotist/Prosthetist Certification [now known as the Board of Certification/Accreditation], or is credentialed and approved by a program that the Secretary determines, in consultation with appropriate experts in orthotics and prosthetics, has training and education standards that are necessary to provide such prosthetics and orthotics.

Since prosthetists are included along with physicians, physical therapists, and occupational therapists in the definition of "qualified practitioner," statutorily they are considered part of the rehabilitative team that works together to ensure positive outcomes. By excluding prosthetists' important notes in the patients' medical record, the draft LCD fails to recognize the prosthetist as a member of the clinical team. Not only should the draft LCD be rescinded, but this exclusion should be corrected in the future.

Draft LCD Is Unclear, Unfair, and Inconsistent

The draft LCD's lower limb prosthesis eligibility requirements are undefined and ambiguous. Terms such as "sufficient," "good," and "adequate" are not clearly defined. By what measure of compliance will a beneficiary meet the requirement for "*sufficient* trunk control" or "*good* upper body strength" or "*adequate* knee stability"? Without well-defined requirements, claims will be unfairly audited and fees will be unjustly recouped.

As a deemed DMEPOS accrediting organization, BOC is charged with assessing facilities' compliance with the Medicare DMEPOS Quality Standards. In the Intake and Assessment section of the standards, the supplier's responsibilities include assessing the beneficiary's need for and use of the orthoses/prostheses and determining the appropriate orthoses/prostheses

and specifications based on beneficiary need for use of the orthoses/prostheses to ensure optimum therapeutic benefits and appropriate strength, durability, and function as required for the beneficiary. Therefore, the draft LCD directly conflicts with the Quality Standards. And the fact that these Quality Standards were written while the existing LCD was in effect illustrates prior trust in the prosthetist's judgment.

Closing Comments

Please rescind the draft LCD. A good starting point would be to accept the O&P Alliance's invitation and consult with the Alliance members, including BOC, and other stakeholders who are affected by this policy to make any needed changes to the current LCD in a fair and effective way. The insights resulting from these conversations could lead to reasonable policy changes that are truly beneficial to all parties involved.

BOC and our fellow O&P Alliance members are ready to work with CMS to protect patient access to medically necessary care, and encourage the recognition of the prosthetist as an integral part of the rehabilitation team.

Thank you again for this opportunity to comment and thank you in advance for protecting amputees' rights to the prostheses they need and deserve.

Very respectfully,

James L. Hewlett, BOCO
Chairman, BOC Board of Directors