

JUN 30 2016



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation  
Washington, DC 20201

JUN 30 2016

The Honorable Jason Chaffetz  
Chairman  
Committee on Oversight and Government Reform  
U.S. House of Representatives  
Washington, DC 20515

Dear Chairman Chaffetz:

Thank you for your letter sharing your concerns about the local coverage determination (LCD) for lower limb prostheses proposed by the Durable Medical Equipment Medicare Administrative Contractors (DME MACs). The Centers for Medicare & Medicaid Services (CMS) is committed to providing high quality care to all Medicare beneficiaries, including any beneficiary in need of a prosthesis. CMS and its contractors are aware of concerns about access to prostheses for Medicare beneficiaries under the proposed LCD. Therefore, the DME MACs decided not to finalize the draft Lower Limb Prostheses LCD (DL33787).

Instead, CMS has convened a multidisciplinary Lower Limb Prostheses Interagency Workgroup (Workgroup). The purpose of the Workgroup is to develop a consensus statement to inform Medicare policy based on a review of the available clinical evidence that defines best practices in the care of beneficiaries who require lower limb prostheses. We are including some background information on LCDs and the Workgroup in this letter, to supplement documents we are providing in response to your specific requests.

#### **Authority for LCDs**

In recognition that different regions of the country may have varying medical needs, the Medicare statute authorizes the Medicare contractors to make local coverage determinations (either through formal local policies or on a case-by-case basis), provided such decisions do not conflict with any national policy (generally in the form of a national coverage determination (NCD)). An LCD is a decision by a Medicare Administrative Contractor (MAC) – or for durable medical equipment, the four DME MACs working collaboratively – on whether to cover a particular item or service on a MAC-wide basis in accordance with Section 1862(a)(1)(A) of the Social Security Act (i.e., a determination as to whether the item or service is “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member”). While local coverage decisions (formerly through Local Medical Review Policies) have existed since the Medicare program began, the term “local coverage determination” was first defined in statute in the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA). BIPA established, in section 1869(f) of the Social Security Act, a process for beneficiaries to appeal decisions under NCDs and LCDs. The Medicare statute also references LCDs in section 1862(l)(5), which directs the Secretary to evaluate LCDs to determine whether an NCD is appropriate and whether greater consistency can be achieved among LCDs. However, LCDs are still recognized as an opportunity for coverage

that reflects local practices and more expeditious coverage of new technology than would be available through the NCD process.

### **Lower Limb Prostheses LCDs**

In August 2011, the Office of Inspector General (OIG) issued a report entitled “Questionable Billing by Suppliers of Lower Limb Prostheses” based on a study conducted as part of the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative.<sup>1</sup> The report recommended that CMS revise several aspects of the LCD on this topic. Specifically, the OIG suggested that CMS clarify the definitions of beneficiaries’ potential functional levels, require that licensed/certified medical professionals evaluate beneficiaries to determine their potential functional levels, and consider revising the LCD to deny as medically unnecessary certain combinations of prostheses, such as more than one definitive base prosthesis or prostheses for different sites of amputation billed for the same limb on the same date. CMS concurred and stated that it would review the definitions for the functional levels and take other actions as appropriate.

The DME MACs issued a subsequent draft LCD on July 16, 2015 defining the conditions for which lower limb prostheses would be considered “reasonable and necessary.” The draft LCD was open for public comment for a 45 day period (as is required by CMS for all draft LCDs). In developing LCDs, the contractors must also hold an open public meeting to allow for input from stakeholders and the clinical community. A public meeting was held on August 26, 2015 and the comment period for the Lower Limb Prostheses draft LCD ended on August 31, 2015. Over 200 individuals attended the public meeting to voice their concerns.

Additionally, CMS leadership met with interested professionals from several clinical societies and consumer advocacy groups and received feedback directly from the community, which we passed along to the DME MACs for their further consideration.

Given the critically important nature of these services to Medicare beneficiaries and the absence of a national policy on the topic, CMS urged the contractors to thoroughly consider all aspects of their proposed approach and reiterated the importance of taking stakeholder concerns into account. Subsequently, CMS announced on November 2, 2015 that the draft LCD would not be finalized at the time and established the Lower Limb Prostheses Interagency Workgroup. In the meantime, absent a new LCD, the previous LCD on lower limb prostheses will remain in effect.

### **Lower Limb Prostheses Interagency Workgroup**

After a review of the public comments received through multiple channels, CMS convened a multidisciplinary Lower Limb Prostheses Interagency Workgroup (Workgroup). The Workgroup will function much like the CMS Interagency Mobility Assistance Equipment Work Group (IWWG) of 2004, which created a consensus document that served as the basis of an NCD on that topic.

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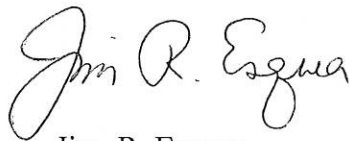
<sup>1</sup> “Questionable Billing by Suppliers of Lower Limb Prostheses,” OIG, August 2011, <http://oig.hhs.gov/oei/reports/oei-02-10-00170.pdf>

The goal of the Workgroup is to develop a consensus statement to inform Medicare policy after reviewing the available clinical evidence that defines best practices in the care of beneficiaries who require lower limb prostheses. The Workgroup may also identify areas where evidence gaps exist related to the prescription of lower extremity prostheses, and make recommendations concerning the study designs and outcome measures that best inform patient-oriented function, quality of life, and service satisfaction in this realm.

The Workgroup is comprised of clinicians, researchers, and policy specialists from the following federal agencies: Walter Reed National Military Medical Center, the Department of Veteran Affairs, the Department of Defense, the Administration on Community Living and the National Institute of Aging, as well as CMS. The Workgroup first met in February 2016 and is expected to meet through early next year. As the Workgroup moves forward, CMS will ensure there is opportunity for public engagement including public comment on a draft consensus statement, which we expect to be available in mid-2017.

Enclosed are documents responsive to your request. Please note that some of the enclosed documents may contain sensitive information that, if further disclosed, could compromise significant interests regarding the Medicare program, particularly regarding lower-limb prostheses. We trust that you share our goal of protecting Medicare beneficiaries, and therefore we request the Committee refrain from publishing or otherwise making public the enclosed materials and to share these materials only with those who must review them as part of their official duties. Again, thank you for your interest in this important issue.

Sincerely,

A handwritten signature in cursive script that reads "Jim R. Esquea".

Jim. R. Esquea  
Assistant Secretary for Legislation

cc: The Honorable Elijah E. Cummings  
Ranking Member

Enclosure