By electronic mail to: DMAC_Draft_LCD_Comments@anthem.com

August 31, 2015

Stacey V. Brennan, M.D., FAAFP
Medical Director, DME MAC, Jurisdiction B
National Government Services
8115 Knue Rd
Indianapolis, IN 46250-1936

Re: **PROPOSED/DRAFT Local Coverage Determination (LCD): Lower Limb Prostheses (DL33787)**

Dear Dr. Brennan:

The American Association for Homecare (AAHomecare) submits the following comments on the proposed/draft LCD for lower limb prostheses that was published on July 16, 2015.

AAHomecare represents durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers, manufacturers, and others in the homecare community. Members operate more than 3,000 homecare locations in all 50 states. In light of our members' expertise and experience, AAHomecare is uniquely qualified to comment on the proposed/draft policy.

AAHomecare requests that the draft be withdrawn to allow opportunities for stakeholders and DME MAC Medical Directors to discuss the impact of the revisions. We believe the draft is inherently flawed and is inappropriately being used to change the L code system. The draft also disavows the K-levels for which Medicare amputees are eligible to receive different types of prostheses, and also the way that lower limb prosthetic services are delivered to Medicare beneficiaries. We believe the draft used in its current form will result in beneficiary access issues for amputees.

Access Issues for Amputees

AAHomecare is concerned that the draft LCD creates unnecessary barriers to care that not only impede amputee's ability to restore their independence, but also fall below today's standard of care for amputees. The draft LCD specifies that before a beneficiary may receive a definitive prosthesis, they must first be fit with an immediate prosthesis and then by a preparatory prosthesis. This is a dramatic departure from current coverage criteria which permit a beneficiary to receive prosthetic care immediately after the

amputation. The DME MAC proposal would interpose a 12 month delay between the time a beneficiary receives an immediate prosthesis and the time he or she receives a definitive prosthesis. But in order to qualify for a prosthesis under the draft LCD an amputee must also meet a number of new cognitive, physical and functional coverage criteria that mostly favor young and otherwise healthy amputees. Requiring every amputee to be fit with either an immediate post-surgical or preparatory prosthesis, in order to receive a definitive prosthesis is outdated and below today's standards of care for amputees. And imposing cognitive and functional coverage criteria on amputees in order for them to qualify for a prosthesis unfairly limits access to prosthetic care for individuals who have health conditions or require additional care for reasons that are unrelated to their need for the prosthesis.

Some amputees might benefit from this plan of prosthetic care, but the standards in the draft LCD needlessly delay necessary care and impede the ability for amputees to achieve independence. Likewise, the requirement that an amputee must wait 90 days after receiving a preparatory prosthesis to receive a definitive prosthesis imposes a needless delay in care and interferes with a beneficiary's ability to achieve his or her rehabilitation goals for independence. Individuals will have better outcomes if coverage of a definitive prosthesis begins as soon as they have the capability to ambulate effectively using a definitive prosthesis. We see no benefit in forcing capable amputees to wait for 90 days to receive a definitive prosthesis. In situations where an amputee's progress exceeds the clinical benefit of a preparatory prosthesis, this requirement creates an unnecessary barrier to appropriate prosthetic care.

The draft LCD also states that any adjustments, repairs or component replacements for the initial 90 days are included as part of the delivery of the prosthesis. This statement does not allow separate reimbursement caused by loss, theft, irreparable damage or a change in the patient's condition or functional abilities for adjustments, repairs, and component replacements. AAHomecare believes that adjustments, repairs, and component replacement necessitated by loss, theft, irreparable damage, or a change in the patient's condition should continue to be eligible for separate reimbursement even when it is required within the first 90 days after delivery of the prosthesis.

We have similar concerns about barriers to access with the proposal to require amputees to meet cognitive, physical and functional criteria in order to qualify for a definitive prosthesis. This is another significant departure from the current LCD. The draft LCD would assess amputees on whether they meet specific functional criteria rather than assessing them based on their functional *potential* with an appropriate prosthesis. This creates an enormous hurdle for amputees who are denied the possibility of achieving fully functional independence that would otherwise be possible with the correct prosthesis.

These new requirements also make it very difficult for amputees who have unrelated health conditions to qualify for a prosthesis. Coverage barriers for patients with unrelated health conditions that have no bearing on their ability to effectively use a prosthesis should be eliminated from the LCD if a final LCD is published. Limiting access to proper prosthetic care for patients with unrelated health conditions would be "penny wise and pound foolish," forcing individuals who could otherwise be independent into more intensive forms of care at higher costs for payers. It is also not in the best interest of providing overall quality healthcare for Medicare amputees.

AAHomecare understands the importance and value of rehabilitation as an integral part of the beneficiary's ability to properly use their prosthesis. However, as it states in the draft, we do not agree that the patient must successfully complete a comprehensive rehabilitation program prior to receiving a definitive prosthesis. We do not believe this requirement is necessary for all patients and does not fit with our belief for individualized medical care. There will be an access issue, especially for people living in rural areas, who do not have easy access to amputee specific rehabilitation program. The requirement in the draft LCD may prevent these patients from being eligible to receive any prosthetic intervention, which will result in access issue and being forced to use a wheelchair instead. Patients should not be denied the right

to walk after an amputation simply because they do not live in an area of the country where rehabilitation programs are easily accessible.

Lastly, the draft limits Medicare coverage to one socket code and descriptor per individual prosthesis. This prohibits the use of specific socket design features that may be necessary to meet the patient's clinical needs. The failure to have coverage for these design features that are medically necessary for patients will force amputees to receive basic prosthetics that are not design to effectively address their needs. Having prosthetic sockets that provide intimate fit the patient are essential to providing quality, individualized care, and may prevent any further injuries.

Stakeholder Discussion Recommendation

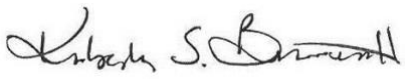
We strongly encourage a stakeholder discussion regarding the appropriate standard of care for amputees. Including the full scope of individuals with knowledge of the care and fitting of amputees and including amputees in the discussion will result in a more reasonable policy that will protect the integrity of the Medicare program, while ensuring continued quality access to prosthetic services that most appropriately meet the specific clinical needs of the individual amputee. Providing a limited public comment period largely over a Congressional recess period, including a relatively brief meeting to allow for members of the public to express their concern about the draft policy does not, in any way, allow for sufficient opportunity for affected stakeholders to participate in the LCD and Policy Article development process.

Conclusion

AAHomecare believes that the proposed/draft LCD for lower limb prostheses is flawed in both its intent and content. Finalizing the proposal in its current form, or based on the framework of this proposal will result in beneficiary access issues for amputees in need of high quality, medically necessary prosthetic services. AAHomecare requests that the draft LCD and Policy Article be withdrawn to allow appropriate time for robust discussions between the DME MAC Medical Directors and stakeholders.

Thank you for the opportunity to submit these comments. We look forward to working with you on developing a more reasonable policy that considers the needs of the patient while also maintaining the integrity of the Medicare program.

Sincerely,



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