August 5, 2015

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

CC:
Andy Slavitt
Administrator
Centers for Medicare & Medicaid Services
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Submitted electronically to DMAC_Draft_LCD_Comments@anthem.com

Re: Proposed/Draft Local Coverage Determination (LCD): Lower Limb Prostheses (DL33787)

Dear Dr. Brennan,

The Amputee Coalition appreciates the opportunity to respond to the proposed revisions to the Medicare Local Coverage Determination (LCD) as it relates to Lower Limb Prostheses, published on July 16, 2015.

The Amputee Coalition is the nation's leading organization on limb loss, dedicated to enhancing the quality of life for amputees and their families, improving patient care and preventing limb loss. We represent the over 2 million Americans living with limb loss. Our mission is to reach out to and empower people affected by limb loss to achieve their full potential through education, support and advocacy, and to promote limb loss prevention. We are submitting this letter to ensure that people living with limb loss or limb difference have access to the most appropriate prosthetic device for their needs, at the most appropriate time, to remain independent and live well.

The Amputee Coalition appreciates the commitment of CMS in working to improve patient protections and reduce fraud and abuse while also ensuring that the agency continues to consider the needs of people with disabilities and, more specifically, those living with limb loss.

With that said, the Amputee Coalition is very concerned about the potential impact this draft proposal will have on patient access to medically necessary prosthetic devices. We are also troubled that the draft proposal represents a misunderstanding of the rehabilitation and delivery process for people with limb loss and of the needs of the patient at various points of recovery.

Below, we've outlined our concerns for certain provisions in the drafted policy with suggestions that would better address the medical needs that people with limb loss require. Once again, we do this to ensure patients have access to the most appropriate prosthetic devices, as deemed medically necessary, at the most appropriate time.

1) **Redefining K-levels would severely impact access to appropriate medical care**

The Amputee Coalition is greatly concerned that the proposed revision to Medicare's functional status definitions (K-levels) eliminates any consideration of a patient's potential to improve their mobility and health through the use of medically appropriate prosthetic device(s). By eliminating consideration of the functional potential of the patient, patients would be assigned a functional level that would only be based on their ability to ambulate at the time of their in-person medical evaluation. We believe that the designation of a patient's functional level should be based on their ability to ambulate, their overall health status, their functional potential, their activities of daily living before amputation, and their expected activities of daily living after they've received the appropriate prosthetic device. The problem with eliminating the patient's potential in the functional status definitions is that the initial in-person medical evaluation typically takes place shortly after amputation. During this time, a patient's full potential may not be evident for any number of clinical reasons. This would result in an assessment that drives an inappropriate care plan that does not meet the patient's needs. Additionally, asking patients to get multiple in-person medical evaluations to determine functional status further along in the rehab process as their limb matures would place an undue burden on patients and medical professionals.

The Amputee Coalition is also extremely disappointed to see that the proposal would automatically limit patients' functional status based on the use of additional assistive devices they may need to ambulate. By limiting patients who use a walker or crutches to a K1 functional level, limiting any patient using a cane to a K2 functional level, and making it so that patients at the K3 and K4 functional levels are not able to use any assistive device (including a wheelchair), this proposal does not reflect the actual lived experience of people with limb loss. While lower-limb prosthetic devices provide amputees with significant and unmatched functional ability, there are times when a patient still needs to use an assistive device regardless of their K-level classification. Nighttime bathroom access, periods of soreness or skin irritation, and changes in humidity or swelling could make using an assistive device for a short period of time a necessity for any amputee, regardless of their K-level. Additionally, should a component ever break, or the prosthetic device fit improperly due to changes in the residual limb, the patient would then be without an alternative assistive device under this proposal.

The Amputee Coalition also recognizes that while the prosthetic device must provide stability, ease of movement, and energy efficiency as outlined in the draft proposal, "the appearance of a natural gait" may be difficult to attain for some patients. It may take months or even years for an individual to attain what may be considered a "natural gait," and some individuals may never be able to attain what a casual observer would consider a "natural gait." When an individual loses a limb, their ability to ambulate is of the utmost importance, and a natural gait may or may not come with time. The Amputee Coalition is concerned that requiring the "appearance of a natural gait" is a very subjective qualifier and

may result in amputees failing to receive appropriate prosthetic care because of a subjective assessment from someone that their gait is not natural.

Recommendation
Solely defining K-levels to what the patient's demonstrated ability is at the time of assessment would severely limit the ability of patients to receive a prosthetic device that would allow them to reach their full functional ability. The Amputee Coalition recommends that the functional status definitions (K-levels) remain consistent with current definitions and that restrictions in functional status related to the use of additional assistive devices be removed from any future consideration. People with limb loss will invariably need access to additional assistive devices, and this need should not limit their functional status determination. The Amputee Coalition further recommends that should Medicare (CMS) or the Durable Medical Equipment (DME) Medicare Administrative Contractors (MACs) be interested in redefining K-levels, that Medicare convene an appropriate group of patients, professionals and associations to produce more objective ways of determining functional status that are scientifically proven for use in the amputee population.

Additionally, the Amputee Coalition believes that the in-person medical evaluation by Licensed/Certified Medical Professionals (LCMPs) and those that are a part of the patient's medical team must be able to account for the potential functional level of a patient. An in-person medical evaluation and a functional status determination for a patient must be made by the team of professionals who are working with that patient. Allowing for continued evaluation of functional potential will help to ensure that patients receive the most appropriate prosthetic device for their needs so they can remain active and independent members of the community. The Amputee Coalition further recommends that the language "the appearance of a natural gait" be removed from the requirement of what a prosthesis must provide.

2) **Foot and ankle system coding changes would significantly impact access to appropriate prosthetic devices for patients**

Combining several feet and ankles into a single generic code would significantly harm patient access to the feet and ankles that best meet their individual needs. Each code the proposal seeks to consolidate represents styles of feet and ankles that provide a distinct purpose for patients, allowing the prosthetic device to be tailored to a patient's specific functional needs. Combining these codes would result in patients being fit with generic feet and ankles that may not be best suited to the patient's functional needs. We are concerned that the medical team, in working with the patient, would be forced to use a generic code instead of determining the most appropriate feet and ankles for the patient's needs.

Additionally, the Amputee Coalition has significant concern that limiting K2 patients to fixed ankle-feet could cause significant challenges for those patients when a more appropriate foot and ankle could be available. Advances in technology have allowed multiaxial, dynamic response feet and hydraulic ankles that can provide patients with additional stability and assistance in meeting functional needs. Once again, the medical team, in working with the patient, should be able to determine the most appropriate

feet and ankles for the patient's needs. Hydraulic ankles and multiaxial, dynamic response feet provide additional options for qualified patients; the Amputee Coalition is troubled to think that these options would be limited to only K3 and K4 level patients when K2 level patients could see significant improvement in functional ability and stability with access to these prosthetic devices.

Recommendation
The Amputee Coalition recommends that existing codes for feet and ankles remain unchanged and not be consolidated as outlined in the proposal. Reclassifying multiple prosthetic feet and ankles into a single code would significantly limit patients' access to the most appropriate foot and ankle for their medical needs.

We further recommend that multiaxial, dynamic response feet and hydraulic ankles continue to be provided to K2 through K4 level patients when they are deemed to be the most medically appropriate components to ensure patients can reach their full potential.

3) **Limitations in socket technologies and liner inserts would impact patients' ability to get the most appropriate components for their needs**

The socket is arguably the most important component of any prosthetic device. In order for a prosthetic device to be effective for a patient, it must first and foremost fit properly and provide adequate comfort to be worn. Just as no two patients are the same, no two residual limbs are alike, which means every amputee's residual limb has its own unique shape and requirements when it comes to an appropriate socket system. Therefore, the Amputee Coalition is concerned that patients and their medical team would not have all socket system options available in order to ensure a proper fit for the patient.

The Amputee Coalition is also concerned that the proposed policy would eliminate suction suspension systems as an option for K1 level patients, and that elevated vacuum systems would be completely eliminated as an option for all patients. These technologies provide reliable and valid options for patients who would be best suited to these types of socket systems.

Additionally, the Amputee Coalition is troubled to see that custom fabricated socket inserts are only covered in the event that a non-custom fabricated socket insert is unable to provide an "adequate" interface between the residual limb and socket. The Amputee Coalition believes that it is vital for patients and their medical team to make the most appropriate determination of what type of socket insert would provide the most appropriate or "adequate" interface. There is also significant concern that the draft proposal does not clearly articulate what is deemed "adequate," or who determines the adequacy of socket liners for a patient.

Finally, while molded distal cushions can provide comfort for patients, the Amputee Coalition is concerned that the draft proposal eliminates cushioned liners for patients who receive a molded distal cushion. A molded distal cushion is not meant to replace a cushioned liner, or vice versa, but for patients who may need a cushioned liner with a molded distal cushion, we are concerned that this proposal would eliminate that option for patients and their medical team.

Recommendation

It is recommended that the proposal restore coverage for suction suspension systems as a viable option for K1 level patients, and that coverage for elevated vacuum sockets continue to be provided when patients and their medical team determine that is the most appropriate course of action. Without these changes to the draft proposal, patients may not be able to receive the most appropriate socket for their medical needs. Because the socket is such a vital part of the prosthetic device and to a patient's rehabilitation, socket options must be available to patients and their medical team in order to make an appropriate determination of the patient's medical needs, and what will work best for that individual.

The Amputee Coalition further recommends that the proposal clearly outline who is to make the determination of socket insert "adequacy" when evaluating whether a patient should be fitted with a custom fabricated socket insert or a non-custom socket insert. Additionally, cushioned liners should be made available as an option for all patients, should it be the most appropriate liner for their needs. These determinations must be able to be made by the patient and their medical team, and the decision about what is best for the patient must not be affected by this drafted policy proposal. The medical team should continue to have options available for the most appropriate socket fit to ensure the patient can reach their full potential.

4) Clarification is needed for in-patient medical evaluations and determinations

The Amputee Coalition believes that while an in-person medical evaluation is important and must include the appropriate documentation, it is also important to make sure their care is not impacted solely because of arbitrary markers in that documentation. We are considerably worried that, under this proposal, patients could be classified at a lower level or denied a prosthetic device simply because they may not be able to attain the appearance of a natural gait, or if the patient's medical record references cognitive, cardiopulmonary or neuromuscular deficiencies or limitations. These factors must certainly be taken into consideration when determining a patient's overall functional level, but we are alarmed that, under this draft proposal, the inclusion of any of these limitations alone could be a basis for denying a prosthetic device or limiting a patient's K-level classification, which would severely impact patient care and the ability of a person to fully rehabilitate.

The Amputee Coalition believes that while an in-person medical evaluation should be completed by an LCMP, the prosthetist should be included as a part of the patient's medical team in determining functional ability and the types of components that would be most appropriate for the patient. The Amputee Coalition believes that prosthetists have unique, specialized training and experience that can be valuable to the medical team and patient. Their experience and knowledge of different prosthetic components can help the medical team determine the appropriate prosthetic component for each individual patient.

Recommendation

The Amputee Coalition believes that the proposal must be modified to clarify that references to any singular medical issues in the medical record will not be the sole cause of denial for a prosthetic device

or automatically result in a limitation of functional status classification. The proposal should be modified to ensure that the determination of a prosthetic device and functional status classification for patients will be taken as a whole, based on the patient's functional needs, potential and medical capacity as determined by LCMPs, their team and the patient.

5) **The draft proposal redefines the rehabilitation process for amputees, ignoring current recommended practices in prosthetic device delivery and rehabilitation**

Overall, the Amputee Coalition is greatly concerned with the way the draft proposal defines different prostheses and the path of rehabilitative care for patients. We have significant concerns, especially as it relates to the new definitions for an "immediate prosthesis" and "preparatory prosthesis." In the draft proposal, it states that an immediate prosthesis and preparatory prosthesis do not require functional (K-level) determinations, and it specifically indicates that "Preparatory prostheses use basic prosthetic components, which provide adjustability and alignment changes as limb maturity occurs."

These new definitions are of great concern and seem to show a lack of understanding of current accepted medical practices in care of a person with limb loss.

The current accepted medical practice post-amputation is for a patient to first receive a functional status classification (K-level) through an in-person medical evaluation. Once this has occurred and been documented in the patient's medical record, then the components for a permanent prosthetic device are ordered and fit. The permanent prosthetic device (or as the draft policy defines, a "definitive prosthesis") is provided as early in the rehabilitation process as possible so the patient is able to rehab on the prosthetic device they will be using full-time. As the individual's limb develops from post-operative to a mature limb, multiple sockets must be made in order to allow the patient to continue to use and rehab with their prosthetic device.

The new definitions of an immediate and preparatory prosthesis suggest that new amputees would be forced to rehab with antiquated technology that they will not even be using once they get their definitive prosthesis. Just as it is inappropriate to have someone learn to drive a car by teaching them to ride a bike, you cannot train someone to walk again on "basic components" and then hand them something more advanced and expect them to know how to use it properly and get the most out of it. Both a bike and a car may get you from point A to point B, but in very different ways. Similarly, a basic preparatory prosthesis and a more advanced definitive prosthesis can help someone walk again, but the way you use those prosthetic devices is very different. Moreover, the outdated single-axis knees and SACH feet that would be required componentry for preparatory prostheses come with a much higher fall risk and less shock absorption than modern knees and feet, exposing new amputees to preventable falls and residual limb wounds. The Amputee Coalition is greatly concerned that the draft proposal would require patients to start rehab with a preparatory prosthesis and then, only once their rehab has been completed, provide them with their definitive prosthesis. This permanent prosthetic device could have significantly different features that would fundamentally change how the person should have gone through rehab.

Along those lines, the Amputee Coalition is also concerned that the draft proposal requires patients to be enrolled in a rehab program to obtain a preparatory prosthesis and to have completed a rehab program before the delivery of a definitive prosthesis. This requirement, universally applied, would create a serious burden on people from medically underserved regions of the country where such therapy may not be locally available, and could place a serious financial burden on patients with out-of-pocket expenses. Once again, this proposal does not represent generally accepted practices and would force patients to rehab on a prosthetic device that has technology that would not meet their functional needs and that is not going to be their permanent prosthetic device.

The Amputee Coalition recognizes that there may be some situations where having an immediate or preparatory prosthesis may be the appropriate path for a patient if that's determined by their medical team. However, the Amputee Coalition believes that the appropriate rehabilitation path and prosthetic delivery for most amputees is to have an in-person medical evaluation and, with their medical team (including their prosthetist), determine the prosthetic device and rehab program that will best meet their medical needs. Once a functional status classification has been made, the definitive prosthesis is ordered for the patient so they can train on the prosthetic device they will be using permanently.

Throughout the process, from initial amputation up to and beyond when the residual limb has matured, multiple sockets may be necessary to ensure an appropriate fit. Indeed, some patients with certain cardiovascular and lymphatic conditions can never be said to have a truly mature, permanently stable residual limb, and will struggle with volume changes throughout their entire lives. Other major components of the prosthetic device itself should not change unless the patient and their medical team determine a better course of action for specific components within that timeframe. Otherwise, the only major component that is likely to change during this period is the socket.

Recommendation

The Amputee Coalition recommends eliminating the new definitions of, and requirement for, immediate and preparatory prostheses, and that new guidelines be issued with input from experts around the appropriate time for a definitive prosthesis to be ordered and fit to a patient, and the appropriate time that rehabilitation should take place with the patient's definitive prosthetic device.

The Amputee Coalition further recommends that, before moving forward with a final draft that would change the LCDs for Lower Limb Prostheses, CMS and the DME MACs convene an appropriate group of patients, professionals and associations to determine the appropriate path for amputee patient care and prosthetic device delivery. This group could help determine the most appropriate path and the accepted best practices to ensure patients are receiving the most appropriate prosthetic device at the most appropriate time.

The Amputee Coalition would be happy to participate in such a discussion and believes that among others, the panel should include experts in physiatry, physical therapy, occupational therapy, physicians, surgeons, prosthetists, case managers, social workers, mental health workers and patients.

Conclusion

As the voice for the limb loss community, the Amputee Coalition believes that patients should receive the most adequate coverage for their needs at the time they need it. As CMS and the DME MACs consider comments on this proposal, the Amputee Coalition strongly urges the agency and contractors to leave the current LCD unaltered, or to thoroughly revise the proposal being considered. Any final proposal for changes to the LCD should more accurately reflect the current path of care an amputee receives, and include the above recommendations to ensure patients have appropriate and timely access to medically necessary care.

We would like to thank you for this opportunity to share our comments on the proposed revisions to the Medicare Local Coverage Determination (LCD) as it relates to Lower Limb Prostheses.

Please do not hesitate to contact Susan Stout or Dan Ignaszewski at the Amputee Coalition if you would like to discuss these issues in greater detail. Susan Stout is available by phone at 952/435-9726 or via email at sstout@amputee-coalition.org, and Dan Ignaszewski is reachable at 202/742-1885 or via email at dan@amputee-coalition.org. Thank you again for your consideration.

Sincerely,

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