August 31, 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
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Patrick Conway
Deputy Administrator for Innovation & Quality,
CMS Chief Medical Officer
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted electronically to DMAC_Draft_LCD_Comments@anthem.com

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

Dear Dr. Brennan,

While the Amputee Coalition has already provided formal comments on the proposed revisions to the Medicare Local Coverage Determination (LCD) as it relates to Lower Limb Prostheses, published on July 16, 2015, we are also submitting this addendum to our comments to include more specific concerns identified in the proposal and to outline more specifically how we believe our concerns can be addressed in the document.

LCD Definitions

1) Replacement Prosthesis: *"A replacement prosthesis is defined as the replacement of a complete, existing definitive prosthesis or major component part of an existing definitive prosthesis, such as socket, knee, foot/ankle, etc. (not all-inclusive), previously reimbursed by Medicare. Claims for a replacement must meet the payment rules for replacement of items in effect on the date of service for the replacement claim." (p. 2, paragraph 6)*

The Amputee Coalition is concerned that the proposal defines a "replacement prosthesis" in a way that will make it more difficult for amputees to receive timely and appropriate care. We are concerned that the proposal suggests that the replacement of a single "major component" is the same as replacing an entire prosthesis. This is absolutely not the case. If someone's socket does not fit properly because their mature residual limb has changed shape, they need a new socket quickly to be able to remain

mobile and independent. Likewise, if another major component like a knee or ankles and feet fail, they must be replaced in a timely manner in order to remain safe and effective for the patient. The Amputee Coalition recommends that the proposal be modified to recognize that individual components of a prosthetic device be recognized as individual components and not as a "complete" prosthesis.

Suggested change:

"A replacement prosthesis is defined as the replacement of a complete, existing definitive prosthesis. Major component parts of an existing definitive prosthesis, such as socket, knee, foot/ankle, etc. (not all-inclusive), previously reimbursed by Medicare do not necessarily constitute a complete prosthesis and may be replaced when appropriate documentation outlining the reason for replacement of an individual major component are supported. Claims for a replacement prosthesis or replacement components of a prosthesis must meet the payment rules for replacement of items in effect on the date of service for the replacement claim."

2) Replacement: *"A repair to a prosthesis or a major component means to fix or mend the non-functioning item to restore it to normal working condition. A repair includes the replacement of minor parts but does not include the complete replacement of the prosthesis or major component. A repair includes reasonable labor charges for the diagnosis of the problem and time necessary to make the repair." (p. 2, paragraph 7)*

As referenced above, the Amputee Coalition believes that major components that need replacement should be considered as a replacement when appropriate documentation justifies this. We do not believe that singular major components of a prosthesis should be considered equivalent to a complete prosthesis. By allowing major components to be replaced when they've failed or in the case of the socket no longer provide an appropriate fit, patients will be able to receive timely care to ensure their device is safe and functional for their needs.

Suggested change:

"A repair to a prosthesis or a major component means to fix or mend the non-functioning item to restore it to normal working condition. A repair includes the replacement of minor parts as well as major components when appropriate documentation outlining the reason for replacement of an individual component are supported, but does not include the complete replacement of the prosthesis. A repair includes reasonable labor charges for the diagnosis of the problem and time necessary to make the repair."

3) Preparatory Prosthesis: *"A preparatory prosthesis is an unfinished, functional replacement for an amputated limb, fitted and aligned to accelerate the rehabilitation process, control edema, and prepare the residual limb for the external forces associated with the wearing of a prosthesis on a day-to-day basis. It is provided after the initial surgery after the wound has healed but before the residual limb has matured. Preparatory prostheses are for use during the time after*

amputation when the residual limb is healing and maturing prior to the provision of the definitive prosthesis." (p. 3, paragraph 2)

We are concerned that the definition of a preparatory prosthesis is inappropriately limited and does not accurately represent accepted standards of care. There may be times that a preparatory prosthesis is required when patients are unable to use their definitive prosthesis for an extended period of time due to health conditions or medical complications, or if a major component of their definitive prosthesis has failed, and a short term replacement from the coding options outlined for preparatory prostheses would be sufficient for patients to remain ambulatory at least until appropriate documentation and authorization can be obtained for the replacement of the definitive device's major component.

Suggested change:

"*A preparatory prosthesis is a functional replacement for an amputated limb, fitted and aligned to accelerate the rehabilitation process, control edema, and prepare the residual limb for the external forces associated with the wearing of a prosthesis on a day-to-day basis. It is provided after the initial surgery after the wound has healed but before the residual limb has matured or in cases where the medical team determines components from a preparatory prosthesis are justified and supported by documentation. Preparatory prostheses are for use during the time after amputation when the residual limb is healing and maturing prior to the provision of the definitive prosthesis, or when the patient's medical team determines it is the right course of action for the patient."*

4) New Amputation and Revised Amputation: *"A new amputation is defined as the first amputation of a lower extremity, a revision to the original amputation site, or as a subsequent amputation proximal to the initial amputation site" (p. 3, paragraph 4)* and *"A revised amputation is defined as additional surgery to an existing amputation site" (p. 3, paragraph 5)*

First the Amputee Coalition believes these definitions are repetitive as the "new amputation" definition already contains "a revision to the original amputation site." Additionally, we want to ensure that under these definitions, amputees are not denied or restricted access to any services or devices, and are not subject to additional hurdles in order to receive appropriate care. After a revision to an amputee's residual limb, they may or may not need a new immediate prosthesis, they may or may not need to go through a rehabilitation program. The patient and their medical team must be able to determine the most appropriate path of care, including the most appropriate device and path for rehabilitation, after a new amputation or after a revision.

Suggested change:

Delete the definition for a "revised amputation" as it appears to be repetitive with the language outlined under the "new amputation" definition.

5) Mature Limb: *"A mature residual limb is defined as one that has healed, reached its optimal volume, and been shaped appropriately to accommodate the chosen socket configuration." (p. 3, paragraph 6)*

The Amputee Coalition believes that this definition as written may result in amputees receiving denials or delays based on arbitrary language such as "optimal volume, and being "shaped appropriately" as these situations cannot be easily applied across the patient population. The definition as written also does not account for changes that occur to the residual limb throughout the patient's life even once a limb has reached maturity.

Additionally, because of these volume and shape changes even after provision of the definitive prosthesis, we must also note that the Social Security Act contains language that allows for the replacement of the entire prosthesis, prosthetic socket, or components based **solely** on medical necessity as determined by the ordering physician, (see 42 U.S.C.§§ 1395m(h)(1)(G), 1395x(s)(9).) Therefore, arbitrary useful lifetime restrictions are not appropriate and should be removed from the draft LCD.

Suggested change:

"A mature residual limb is defined as one that has sufficiently healed, stabilized in volume, and is deemed appropriately prepared for a definitive prosthesis by the patient's medical team. It is recognized that a mature residual limb will continue to change volume and shape with increased use and function with a definitive prosthesis"

Preparatory Prosthesis

6) *"A preparatory prosthesis (L5500-L5600) is covered for a beneficiary with a new or revised amputation when all of the requirements below are met: (1) The beneficiary has had an appropriate above or below knee amputation; (2) The preparatory prosthesis is provided to a beneficiary starting a rehabilitation program; (3) The preparatory prosthesis is provided after the surgical incision has healed; and (4) The beneficiary is motivated to ambulate using the prosthesis." (p. 4, paragraph 11)*

The Amputee Coalition is concerned that the draft proposal does not, and cannot realistically define the word "appropriate." The word "appropriate" should be deleted. Additionally, the proposal limits coverage to only amputees who have had a "above or below knee amputation." This does not fully reflect the different levels of lower limb amputations that can occur.

The Amputee Coalition is also concerned that the patient must be "starting a rehabilitation program" in order to qualify for a preparatory prosthesis. As addressed below under the "Definitive Prosthesis" section, many amputees may never need a preparatory prosthesis, and therefore may prepare to start a rehabilitation program on their definitive prosthesis. The provision that a patient would have to be

starting a rehabilitation program should be removed. Before changes are made to rehabilitation requirements in any future proposals, the Amputee Coalition recommends the DME MACs, and Medicare meet with appropriate stakeholders to determine changes to device delivery and what a rehab program entails. This provision involves far more than DME and prosthetics to establish appropriate rehab guidelines and coverage for new amputees. Any changes to or requirements for a rehabilitation program for amputees should be made with appropriate input from patients and professionals and take into account the impact of such a change on all patients, including those who may have difficulty accessing such a program in their communities. The Amputee Coalition welcomes this conversation and would be happy to convene such a group.

The Amputee Coalition further recommends that replacements of medically necessary components to maintain a patient's functional level be allowed throughout the provision of the preparatory prosthesis and we suggest the following language:

"A preparatory prosthesis is covered for a beneficiary with a new or revised amputation when all of the requirements below are met: (1) The beneficiary has had a lower limb amputation; (2) The preparatory prosthesis is provided after the beneficiary's medical team has determined the surgical incision has healed; and (3) The beneficiary is motivated to ambulate using the prosthesis."

We also recommend removing all instances in any definitions for an immediate, preparatory, or definitive prosthesis that read "if any part of the device is denied as not reasonable or necessary then entire device will be denied." We recommend that if a single component of a device is denied as not reasonable and necessary, that component is the only part that should be denied and not the entire prosthesis. Denying the entire device will result in additional paperwork and justification for components that otherwise would have been covered. If a specific component is the only thing that is denied, denying the full device could result in delays in care due to increased documentation requirements and visits with healthcare professionals that could be minimized if single components are denied instead of the full device. If the question of if the beneficiary is in need of that type of component and the only thing that is in question is the level of that component, the entire device should not be denied.

Additionally, we recommend revising the language on page 5 paragraph 4 to read as follows: "*Preparatory prostheses are fitted and often used during a rehabilitation program or during a rehabilitation phase if the patient is not participating in a formal rehabilitation program."*

Finally, we recommend striking the language that would not allow a preparatory prosthesis to be fit to a mature limb. As mentioned above, there may be instances where an individual with a mature limb would benefit from such a device. This decision must be allowed to be made by the patient's medical team to determine what the best approach is for each individual the patient.

Definitive Prosthesis

7) *"An initial definitive prosthesis is covered for a beneficiary who have met the criteria below: (1) The beneficiary has had an appropriate above or below knee amputation; (2) The definitive prosthesis is provided to a beneficiary who has successfully completed a rehabilitation program; (3) The definitive prosthesis is provided after the surgical incision is stable (healed); (4) The definitive prosthesis is provided after the residual limb has matured; (5) The beneficiary is motivated to ambulate using the prosthesis; (6) The beneficiary is cognitively capable of using the prosthesis to ambulate effectively at the determined functional level (K0-K4); (7) The beneficiary has sufficient neuromuscular control to effectively and appropriately make use of the prosthesis at the determined functional level (K0-K4); (8) The beneficiary is has sufficient cardio-pulmonary capacity to effectively use the prosthesis at the determined functional level (K0-K4); (9)The beneficiary has had an in-person medical evaluation with the ordering physician to establish their overall functional capabilities (NOTE: The ordering physician may delegate this assessment to a licensed/certified medical professional (LCMP) defined as a physical therapist (PT) or occupational therapist (OT), or physician with training and expertise in the functional evaluation of beneficiaries with amputations. Refer to the DOCUMENTATION REQUIREMENTS section for additional information.) This specialty evaluation must: (10) Evaluate and document the beneficiary's over-all health status taking into consideration factors related to the amputation and prosthesis use as well as the effect of co-morbidities on potential function. The evaluation must include a complete physical examination including an objective neuromuscular evaluation, cardio-pulmonary capacity evaluation and cognitive evaluation; (11) Determine a global activity level as described by the functional level modifiers. (K levels); (12) That the treating physician and/or the LCMP that perform the in-person assessment must have no financial relationship with the supplier; (13) The beneficiary has had an in-person evaluation by the prosthetist to evaluate prosthetic needs consistent with the overall functional capabilities identified by the medical examination; (14) The beneficiary is able to ambulate using the device at or above the identified functional level." (p. 5, paragraph 10)*

The Amputee Coalition is concerned that the provisions and requirements outlined in the draft proposal regarding a definitive prosthesis do not accurately reflect the clinically accepted path of amputee care. First, the Amputee Coalition reiterates from our initial submitted comments that accepted practice in amputee care finds that many amputees are able to receive their definitive prosthesis earlier in the rehabilitation process and need not have completed a rehabilitation program in order to receive their definitive prosthesis. We are also concerned that the proposal requires delivery of a definitive prosthesis only after the residual limb has "matured." As discussed above, a patient's residual limb may change shape and volume periodically throughout their lifespan. Additionally, many amputees are able to receive their definitive prosthesis shortly after their surgical incision is stable (healed). The patient's medical team must be able to make a determination of the best time for a definitive device to be provided. While the amputee's residual limb may continue to reshape throughout their rehabilitation necessitating a remolded socket, the other major components of a definitive device do not typically change.

With regards to the determination of a beneficiary's cognitive, neuromuscular, and cardiopulmonary capacities to effectively use a prosthesis, the Amputee Coalition believes this determination must be made by the patient's medical team and the LCD should incorporate that clarification. In addition to this, it must be clarified that the simple presence of a single or even multiple co-morbidities alone cannot be the sole reason for limiting a beneficiary's functional status. It is the job of the beneficiary's medical team to determine whether or not their over-all health status is sufficient for the functional level defined.

Finally, for the requirement that the beneficiary must be able to ambulate using the device at or above the identified functional level, we recommend including language that takes into account the patient's expected potential to ambulate using the device during the course of rehabilitation.

The Amputee Coalition further recommends the DME MACs and Medicare work with stakeholders including patients and professionals to discuss changes to the LCD that will ensure the prosthetist is included as a part of the medical team in making a functional status determination to ensure the patient receives the most appropriate device for their needs.

Suggested changes:

"An initial definitive prosthesis is covered for a beneficiary who have met the criteria below: (1) The beneficiary has had a lower limb amputation; (2) The definitive prosthesis is provided after the surgical incision is stable (healed); (3) The beneficiary is motivated to ambulate using the prosthesis; (4) The beneficiary is cognitively capable of using the prosthesis to ambulate effectively at the determined functional level (K0-K4) as determined by the beneficiary's medical team when taking into account the patient's daily activities and over-all health status; (5) The beneficiary has sufficient neuromuscular control to effectively and appropriately make use of the prosthesis at the determined functional level (K0-K4) as determined by the beneficiary's medical team when taking into account the patient's daily activities and over-all health status; (6) The beneficiary is has sufficient cardio-pulmonary capacity to effectively use the prosthesis at the determined functional level (K0-K4) as determined by the beneficiary's medical team when taking into account the patient's daily activities and over-all health status; (7)The beneficiary has had an in-person medical evaluation with the ordering physician to establish their overall functional capabilities (NOTE: The ordering physician may delegate this assessment to a licensed/certified medical professional (LCMP) working with a prosthetist and may includes a physical therapist (PT) or occupational therapist (OT), or physician with training and expertise in the functional evaluation of beneficiaries with amputations or physician's assistant or advanced practice nurse with appropriate training and legal scope of practice to include this medical assessment. Refer to the DOCUMENTATION REQUIREMENTS section for additional information.) This specialty evaluation must: (8) Evaluate and document the beneficiary's over-all health status taking into consideration factors related to the amputation and prosthesis use as well as the effect of co-morbidities on potential function. The evaluation must include a complete physical examination including an objective neuromuscular evaluation, cardio-pulmonary capacity evaluation and cognitive evaluation; (9) The simple presence of a co-morbidity such as those mentioned above cannot limit a beneficiary's functional status determination if the beneficiary's medical team determines their over-all health status is sufficient for the functional level defined; (10) Determine a global activity level as described by the

functional level modifiers. (K levels); (11) That the treating physician and/or the LCMP that perform the in-person assessment must have no financial relationship with the supplier. (12) The beneficiary has had an in-person evaluation by the prosthetist to evaluate prosthetic needs consistent with the overall functional capabilities identified by the medical examination/medical team; (13) The beneficiary is able to ambulate using the device at or above the identified functional level, or is expected to be able to by the beneficiary's medical team during the course of rehabilitation."

8) Reference to Preparatory Prosthesis and Rehabilitation: *Preparatory prostheses are fitted and used during a rehabilitation program while the residual limb is reshaping and maturing. Definitive prostheses and components fitted to a non-mature residual limb will be denied as not reasonable and necessary." (p. 6, paragraph 6)*

9) The Amputee Coalition recommends striking this paragraph for reasons mentioned above as there may be instances in which a preparatory prosthesis may not be needed by a new amputee and would fundamentally alter accepted practices in amputee care. If the patient's medical team is able to put a patient directly into a definitive prosthesis, this improves patient access to timely care and reduces costs to Medicare by not requiring multiple levels of devices for a single patient when changing out individual components such as a socket would result in fewer devices and lower cost.90 Day requirement after Preparatory Prosthesis is Delivered: *"Medicare payment for prosthetics includes all fitting and adjustments necessary in the 90 days after provision of a prosthesis, therefore a definitive prosthesis may not be provided sooner than 90 days after the preparatory prosthesis." (p. 6, paragraph 7)*

We recommend striking this paragraph as it would require patients to be in a preparatory prosthesis for far too long when many may be able to move more quickly from a preparatory prosthesis to a definitive prosthesis. Once again, eliminating this paragraph would ensure patients receive appropriate access to timely care.

10) Socket replacements in first 90 days: *"Socket or other component replacements provided during the 90 days after provision of the prosthesis will be denied as unbundling." (p. 6, paragraph 8)*

Keeping in mind current practice for amputee care and that a definitive device may be able to be provided sooner in the rehabilitation process than outlined in the draft proposal, the Amputee Coalition recommends striking this paragraph. Sockets often need to be replaced as the residual limb matures, and patients must be able to receive an appropriate socket at the right time throughout their rehabilitation. This does not mean that the overall components of the definitive device should not be delivered, but simply that patients should be able to receive their definitive device components when the medical team deems it appropriate even though the socket may change periodically. With the changes outlined above, patients should be able to receive a definitive device before their residual limb has fully "matured," and therefore additional sockets may be necessary as the amputee is going through the rehabilitation process.

Sockets

11) Molded Distal Cushion and Gel Liners: *"A molded distal cushion (L5668) is not covered when used in conjunction with a liner or insert that incorporates materials that provide cushioning (L5646, L5648, L5673, L5679, L5681, L5683, L8417). Claims for L5668 used in this scenario will be denied as not reasonable and necessary, same/similar item." (p. 7, paragraph 8)*

This provision fails to recognize that molded distal cushions and cushioned liners are not the same or similar and may be vital for some patients. The Amputee Coalition recommends striking this paragraph.

12) Custom fabricated socket inserts: *"A custom fabricated socket insert (L5673, L5679, L5681, L5683) is covered when non-custom socket inserts (L5645, L5654,-l5665) are unable to provide an adequate interface between the residual limb and socket caused by irregular contours in the shape of the residual limb that can't be compensated for by changing to a different type of non-custom insert." (p. 8, paragraph 3)*

The Amputee Coalition believes that the determination of adequacy and need of a custom liner must be made by the patient's medical team, including the prosthetist.

Suggested changes:

"A custom fabricated socket insert (L5673, L5679, L5681, L5683) is covered when non-custom socket inserts (L5645, L5654,-l5665) are unable to provide an adequate interface as determined by the beneficiary's medical team (including the prosthetist) between the residual limb and socket caused by irregular contours in the shape of the residual limb that can't be compensated for by changing to a different type of non-custom insert."

13) Active suction suspension: *"Active suction is created by using a suction pump as part of the socket design (L5781, L5782). Active suction systems claim to improve residual limb volume management and moisture evacuation. In addition, active systems claim to increase suspension, proprioception and improve gait. There is insufficient published clinical evidence to support these claims. Claims for L5781 and L5782 will be denied as not reasonable and necessary." (p. 9, paragraph 9)*

The Amputee Coalition disagrees with the assertion that "insufficient published clinical evidence" exists to support the use of elevated vacuum systems. To support our position, the Amputee Coalition has attached research detailing the efficacy of vacuum systems across a range of measures at the end of this letter. In keeping with this research, the Amputee Coalition recommends striking this paragraph.

14) Suction Suspension Restriction: *"A [suction/vacuum] suspension socket system is covered for functional level K2-K4." (p. 9, paragraph 10)*

This restriction prohibiting K1 functional level amputees from receiving a suspension socket system lacks any justification. In times when a patient's medical team determines this system is appropriate for a K1 patient, this type of socket system should be provided. For this reason, the Amputee Coalition recommends striking this paragraph.

15) KXXX1 Foot Code: *"A KXXX1 (ALL LOWER LIMB EXTREMITY PROSTHESES, FOOT, DYNAMIC RESPONSE) is only covered for functional levels K3-K4." (p. 10, paragraph 4)*

Consolidating existing codes into a single code described by KXXX1 will significantly impact patient access to the most appropriate prosthetic feet for their needs. The existing codes each represent feet that contain unique features and designs to meet specific clinical needs for a wide range of amputees. The existing codes for unique types of feet should not be consolidated and this provision should be removed from the proposal.

16) Multiaxial ankles: *"An L5968 (ADDITION TO LOWER LIMB PROSTHESIS, MULTIAXIAL ANKLE WITH SWING PHASE ACTIVE DORSIFLEXION FEATURE) is only covered for functional levels K3-K4." (p. 10, paragraph 10)*

The Amputee Coalition believes that many K2 level patients are able to benefit from the added benefits L5968 devices provide. Additionally there is no justification provided for this change. With this in mind we recommend modifying this provision to include K2 patients in addition to K3 and K4 level patients.

17) Power Assist Foot Restriction: *"The microprocessor foot or ankle system addition with power assist which includes any type of motor (L5969) will be denied as not reasonable and necessary because they do not meet the medical evidence requirements outlined in the Centers for Medicare & Medicaid Services (CMS) Program Integrity Manual (Internet-only Manual 100-08), Chapter 13, § 13.7.1." (p. 10, paragraph 11)*

The Amputee Coalition encourages further review and consideration by CMS and the MACs to make these devices eligible for coverage so that if a patient and their medical team determine it is the most appropriate device for their needs, that the patient is able to access it.

Rehabilitation Program

18) Rehabilitation requirements: *"A prosthetic rehabilitation program is required for a new amputee to ensure successful use of a prosthesis. In a prosthetic rehabilitation program, the beneficiary must:*
    - *Don and doff the prosthesis without assistance*
    - *Transfer without assistance using and without using the prosthesis*
    - *Have sufficient wear tolerance to use the prosthesis for a normal day's activities*

- *Attain sufficient balance and stability to ambulate with ease of movement and energy efficiency with the preparatory prosthesis after final residual limb volume stabilization and prior to provision of the definitive prosthesis*
  Preparatory prosthesis provided to a beneficiary who is not schedule for, participating in or has not recently (defined as within the previous 90 days) completed a prosthetic rehabilitation program for the affected residual limb will be denied as not reasonable and necessary.
  A definitive prosthesis provided to a new amputee who has not successfully completed a prosthetic rehabilitation program will be denied as not reasonable and necessary" (p. 13, last paragraph, p. 14, first and second paragraph)

For reasons outlined previously in our comments, the Amputee Coalition recommends eliminating the requirements of being scheduled for, participating in, or successfully completed a rehabilitation program should be eliminated from the requirements. Additionally, the requirement that a prosthetic rehabilitation program be required for a new amputee may prove a significant hurdle for amputees in rural areas or where access to such a program may not be available. While the Amputee Coalition believes that all amputees should be afforded the right to be able to participate in an appropriate rehabilitation program, we do not believe that it should be a requirement in order to receive an appropriate device. For these reasons we recommend the following language be used and the final two paragraphs referenced above be stricken:

"A prosthetic rehabilitation program is recommended for a new amputee to ensure successful use of a prosthesis. In a prosthetic rehabilitation program, the beneficiary must:

a. *Don and doff the prosthesis without assistance*
b. *Transfer without assistance using and without using the prosthesis*
c. *Have sufficient wear tolerance to use the prosthesis for a normal day's activities*
d. *Attain sufficient balance and stability to ambulate with ease of movement and energy efficiency"*

Functional Status (K-Level)

19) Tinetti Score requirement: *"Good static and dynamic balance or a Tinetti total score of > 24" (p. 13, paragraph 2)*

The Amputee Coalition does not believe the Tinetti score requirement of >24 is an appropriate measure for amputees and we recommend this reference be stricken from the proposal. Any objective measures of balance should be made appropriately and with sound research supporting any defined requirements. With the lack of any sufficient research indicating the Tinetti score is a good reference for determining amputee balance, this reference should be eliminated from the proposal. Any future considerations of such a measure must be made with patients, researchers, and professionals to determine appropriate and realistic measures for amputees.

20) "Natural Gait" provision: *"The prosthesis provided must provide: …The appearance of a natural gait"*

The Amputee Coalition finds this requirement for assessing an amputee's functional status to be inappropriate. Many high-functioning amputees walk with noticeable gait deviations not only as a result of their amputation, but possibly due to other complications that are not related to the amputation. This requirement must be removed as it would effectively limit prosthetic coverage based upon a standard that is vague, impossible to describe and entirely subjective. This would severely impact patient care and at best severely limit amputees to a lower functional status if they cannot attain the "appearance of a natural gait", and at worst deny those devices entirely. This requirement must be stricken from the proposal.

21) In person medical assessment: *"An in-person, comprehensive medical assessment to determine the functional capabilities of the beneficiary must be performed by a licensed/certified medical professional with expertise in the treatment of amputees prior to the provision of any prosthesis. (p. 13, paragraph 7)*

The Amputee Coalition is concerned that while this requirement may be well intentioned, we recognize that there are many communities throughout the country where an LCMP "with expertise in the treatment of amputees" simply is not available to provide the comprehensive medical assessment. While we believe that all amputees should seek the most qualified professionals to provide these evaluations, this requirement may prove to be a hindrance and insurmountable hurdle for amputees in many rural and underserved communities. For this reason, we recommend revising the paragraph to read:

"An in-person, comprehensive medical assessment to determine the functional capabilities of the beneficiary must be performed by a licensed/certified medical professional in consultation with the medical team including a licensed/certified prosthetist."

22) Limiting Functional Status Based on Use of Assistive Devices:

"K0 Does not have the ability to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility.

K1: Has demonstrated the ability to use a prosthesis for transfers or ambulation on level surfaces at a fixed cadence. Typical of the household ambulator. Who can walk for distances that are considered reasonable for walking inside the home but limited for walking in the community because of endurance, strength, or safety concerns.
Use of a walker or crutches while using a prosthesis results in a K1 classification.

K2: Has demonstrated the ability for ambulation to traverse low-level environmental barriers such as curbs, stairs or uneven surfaces. Typical of the limited community ambulator who can ambulate without

assistance and is able to function physically and psychologically within the community independently. Use of a cane while using a prosthesis results in a K2 classification.

K3: Has demonstrated sufficient and adequate lower extremity function for personal independence during ambulation with variable cadence. Typical of the unlimited community ambulator who has the ability to traverse most environmental barriers without physical or safety concerns and has vocational, therapeutic or exercise activity that demands prosthetic utilization beyond typical environmental barriers.
Does not require the use of any mobility assistive equipment such as a cane, crutches, walker, or wheelchair

K4: Has demonstrated sufficient and adequate strength, endurance, range of motion, and coordination for personal independence during ambulation. Exhibiting recreational demands, high impact activities, or elevated energy levels, typical of the prosthetic utilization for the energetic child, active adult, or athlete. An "active community ambulator" who not only can walk distances with no difficulty but also run on even ground with little difficulty.
Does not require the use of any mobility assistive equipment such as a cane, crutches, walker, or wheelchair"

The Amputee Coalition feels that broad sweeping determinations that would automatically classify patients based on their use of assistive devices is erroneous and ill-advised. The Amputee Coalition believes all amputees should have the right to reach their full potential and believes it would be in Medicare's best interest to ensure patients are able to be as mobile and independent as possible. As an example, if a patient is able to be a K3 "unlimited community ambulator" with the use of a cane, why would one want to limit that patient's mobility and independence by forcing them into a K2 level device that would potentially result in decreased mobility and independence. Additionally, many amputees may need the use of assistive devices in order to remain mobile and independent and mobile.

Additionally, the patient's functional **potential** is eliminated in these new K Level definitions. We are seriously concerned about eliminating the ability of the medical team to consider the amputee's "potential," many amputees will be placed in devices that do not truly meet their functional needs. Rehabilitation is centered on allowing patients to reach their full potential to achieve outcomes that they may be unable to achieve before rehabilitation. Under this proposal, if a patient has the potential to become an unlimited community ambulator (K3), but who may only be a limited community ambulator (K2) today, they would be limited to K2 components for their prosthetic device and may not be able to achieve an "unlimited community ambulator" status because their device does not meet their needs. It can take months or even years for amputees to be able to achieve their optimal walking ability to be able to reach their full potential. Patient potential is essential in giving patients the ability to meet those goals before, during, and after rehabilitation.

The Amputee Coalition also has sufficient concern that should an amputee be designated a functional status, if they are able to show they can exceed that status at any point, that Medicare would cover a replacement prosthetic with the higher functional status determination. In other words, if a patient is designated at a K2 level early in their rehabilitation, but just a few months, or even a year later, is able to show their medical team that they should be a K3 designation, the patient must be able to receive an appropriate device. Under this proposal, by not including the patient's potential, patient's would face a longer path to reach their full potential, and Medicare could actually pay more for prosthetic devices as patients functional level improves and they are able to transition into a higher functional status and more advanced prosthetic device. As a result, Medicare could wind up paying for a K2 level device early in the rehab process, and then in just a matter of months, or within a year or two, have to pay for a K3 level device if the patient is able to show the appropriate improvement costing Medicare more in the long run.

Per the Amputee Coalition's previous comments regarding this section of the proposal, the Amputee Coalition recommends deleting any limitations in functional status related to the use of assistive devices in the K level definitions, and reinserting the ability for a patient's **potential** functional abilities to be considered when determining their functional status.

Independent Medical Evaluation

23) Examination requirements: *"The examination must be a comprehensive functional assessment that describes the beneficiary's overall health status at the time of the examination. The treating physician or LCMP performing the examination must clearly and specifically document:*
    - *The beneficiary has had an appropriate above or below knee amputation*
    - *The beneficiary has successfully participated in a rehabilitation program*
    - *The surgical incision is stable (healed)*
    - *The residual limb has matured*
    - *The beneficiary is motivated to ambulate using the prosthesis*
    - *The beneficiary is cognitively capable of using the prosthesis to ambulate effectively at the determined functional level (K0-K4)*
    - *The beneficiary has sufficient neuromuscular control to effectively and appropriately make use of the prosthesis at the determined functional level (K0-K4)*
    - *The beneficiary has sufficient cardio-pulmonary capacity to effectively use the prosthesis at the determined functional level (K0-K4)" (p. 21, last paragraph)*

The concerns with the requirements under this provision have been addressed in a number of provisions referenced above. We recommend revising the language in this provision to read as follows:

"The examination must be a comprehensive functional assessment that describes the beneficiary's overall health status at the time of the examination. The treating physician or LCMP performing the examination must clearly and specifically document:

- *The beneficiary has had a lower limb amputation*
- *The surgical incision is stable (healed)*
- *The beneficiary is motivated to ambulate using the prosthesis*
- *The beneficiary is cognitively capable of using the prosthesis to ambulate effectively at the determined functional level (K0-K4) as determined by their medical team*
- *The beneficiary has sufficient neuromuscular control to effectively and appropriately make use of the prosthesis at the determined functional level (K0-K4) as determined by their medical team*
- *The beneficiary has sufficient cardio-pulmonary capacity to effectively use the prosthesis at the determined functional level (K0-K4) as determined by their medical team"*

Conclusion:

The Amputee Coalition believes this addendum to our previous comments provides additional support and documentation outlining our concerns and provides specific appropriate recommendations to address those concerns. It is our position that the best course of action given the number of issues contained in the proposal would be to rescind the proposal and that CMS and the DME MACs meet with appropriate stakeholders including patients and professionals serving the limb loss community to establish a better, more comprehensive, and outcomes based approach to changes in patient care, device delivery, and billing for prosthetic devices. The Amputee Coalition is interested in being a part of the solution and would be honored to convene an appropriate group of experts and stakeholders that could provide guidance for future coverage determinations and changes to amputee patient care that ensures patients receive appropriate access to prosthetic care while ensuring efficiency for the Medicare program.

Thank you for your consideration of these additional comments. If you have additional questions or concerns, please do not hesitate to contact Susan Stout or Dan Ignaszewski at the Amputee Coalition to discuss these issues in greater detail. Susan Stout is available via email at sstout@amputee-coalition.org, and Dan Ignaszewski is reachable at dan@amputee-coalition.org, and both are available via phone at 703/330-1699. Thank you again for your consideration.

Sincerely,

Susan Stout

Susan D. Stout
President & CEO
Amputee Coalition

Terrance Sheehan, MD
Medical Director
Amputee Coalition

Daniel L. Ignaszewski
Director of Government Relations & Marketing
Amputee Coalition

Please find the research supporting elevated vacuum referenced in the Amputee Coalition's comments below. Jason Kahle has given the Amputee Coalition license to reference this document.

2015 LCD PROPOSED CHANGES REGARDING VACUUM ASSISTED SUSPENSIO-

Mechanical Suspension- Page 9

"Active suction is created by using a suction pump as part of the socket design (L5781, L5782). Active suction systems claim to improve residual limb volume management and moisture evacuation. In addition, active systems claim to increase suspension, proprioception and improve gait. There is insufficient published clinical evidence to support these claims. Claims for L5781 and L5782 will be denied as not reasonable and necessary."

Published Evidence – Jason T. Kahle, MSMS, CPO, FAAOP

Kahle JT, Orriola JJ, Johnston W, Highsmith MJ. The effects of vacuum-assisted suspension on residual limb physiology, wound healing, and function: a systematic review. Technol Innov 2014, 15: 333-341.

Summary: This is a systematic review (SR) of only Level III (strong methodological quality) or higher evidence. Evidence statements from reports included in this SR are:

- Beil, et al. 2002, VAS created an environment of less positive pressure in stance, or greater negative pressure in swing, creating less of a variance between pressure during the 2 phases of gait. This resulted in a more stable residual limb volume.
- Klute, et al. 2011, The use of VAS significantly reduced pistoning.
- Traballessi, 2012, VAS allows socket fitting and prosthetic use in the presence of a recent amputation and wound healing. There was no delay in healing during VAS prosthetic use.
- Kahle and Highsmith, 2013, VAS allows a reduction in socket surface area (sub-ischial design) without compromising skeletal biomechanics while reducing socket pressure. All subjects preferred the VAS TFA design.
- Board, et al. 2001, VAS reduced pistoning and stabilized RL volume.
- Goswami, et al. 2003, VAS minimizes RL volume fluctuation. A RL will accommodate to socket size while using VAS, better accommodating fluctuations.
- Farraro, 2011, Subjects using VAS had a lower predicted incidence of falls.

2 Known Level III articles have been published since this SR:

Kahle JT, Highsmith MJ, Gait and Posture, 2014

Summary: It is important to understand when testing an intervention (in this case the VAS socket) against a known standard of care (IRC socket with ~30% more surface

area) equivalence is a “win” for the intervention. Simply stated, in a socket design that is less obtrusive and subjectively superior, there was no significant compromise in measures of gait and balance. The variable that allowed this alternative interface design (TFA) was **vacuum assisted suspension.**

Regarding gait, step length was statistically significantly more symmetrical towards the IRC ($p = 0.04$), when calculating degree of asymmetry. The ambulatory base of support was narrower ($p = 0.03$) when using the brimless socket. All other gait and balance measures failed to reach statistical significance on comparing the IRC to the brimless.

All subjective measures reached statistical significance in favor of improvement with the brimless design, compared to the IRC. Further, as a result of utilizing the brimless interface, eight of the nine PEQ categories achieved the minimal detectable change (MDC). MDC values of all groups except one were different significantly.

Samitier CB, et al, Prosthetics Orthotics International, 2014

Summary: Subjects using **vacuum assisted suspension** sockets (TTA) significantly improved.

Using the vacuum-assisted socket system, the patients significantly improved in balance, gait, and transfers: scores of the Berg Balance Scale increased from 45.75 (standard deviation = 6.91) to 49.06 (standard deviation = 5.62) ($p < 0.01$), Four Square Step Test decreased from 18.18 (standard deviation = 3.84) s to 14.97 (3.9) s ($p < 0.01$), Timed Up and Go Test decreased from 14.3 (standard deviation = 3.29) s to 11.56 (2.46) s ($p < 0.01$). The distance walked in the 6-Min Walk Test increased from 288.53 (standard deviation = 59.57) m to 321.38 (standard deviation = 72.81) m ($p < 0.01$).

Evidence Harmony – Andreas Kannenberg, MD

As confirmed by a recent systematic review of the research (1), vacuum-assisted socket systems are known to provide excellent suspension and prosthesis control by eliminating relative movements and reducing pressure and shear forces between the residual limb and the socket (1-5), and to prevent volume fluctuations of the residual limb that may result in loose socket fit (5) that needs to be compensated for by putting on several pairs of socks in the course of the day.

Dysvascular transtibial amputees, especially those with MFCL-3 mobility grade, benefit from the improved suspension of vacuum-assisted socket systems by reducing their risk of falling, improving their balance and overall walking capabilities. A recently published clinical study (6) has demonstrated that, after 4 weeks of use of a vacuum-assisted socket (Harmony® VASS, Ottobock), dysvascular below-knee

amputees with MFCL-3 mobility presented statistically significant improvements in the four square step test (FSST, p=.01) and timed up and go test (TUG, p=.01) as validated indicators of the risk of falling, the Berg Balance scale (BBS, p=.03) as a validated outcome measure of balance, and the 6-minute walk test (6MWT, p=01) and the Locomotor Capabilities Index (LCI-5, p=.04) as validated outcome measures of the overall walking capabilities. The improvements in these outcome measures showed similar trends in the MFCL-2 subgroup of this study, but, due to the relatively small patient subgroup, attained statistical significance only for the fall risk indicator FSST (p=.046) and overall prosthesis use as measured with the Houghton scale (p=.046). The authors conclude that the improvements in safety and function can be explained by the dramatically better suspension in the vacuum socket that seems to be achieved by residual limb volume control (5), resulting in improved proprioception and motor control of the prosthesis (6). Thus, vacuum socket technology can help amputees maintain or even further improve an active lifestyle.

Furthermore, there is evidence that vacuum socket technology can improve residual limb health. Wounds and distal limb pain are usually caused by relative movements and the resulting shear forces between the residual limb and regular (including suction) below-knee sockets. This problem can be further deteriorated by residual limb volume fluctuations: The volume of the residual limb usually shrinks over the day due to the high pressure acting on it in each and every step, resulting in an increasingly loose fit of the socket that, in turn, aggravates the relative movements and resulting shear forces. The standard treatment of residual limb wounds includes that the patient discontinues the use of the prosthesis to unload the wound from pressure and shear forces to allow for healing. As a result, the patient then has to use a wheelchair or two crutches to walk until substantial wound healing is achieved, which can take weeks or sometimes even months. One randomized prospective clinical trial (7) and two case studies (8, 9) have meanwhile shown that a vacuum-assisted sockets allow for using the prosthesis in spite of residual limb wounds without interfering with wound healing or causing pain or discomfort. In the randomized prospective clinical trial (7), residual limb wounds healed equally fast while continuously using the prosthesis with a vacuum-assisted socket as in the control group that had discontinued prosthesis use. As a result, the intervention group using the vacuum-assisted socket was able to stay active and walking and demonstrate better mobility and increased prosthesis use over several months after the start of the study/wound treatment. The authors of the clinical trial (7) and the case studies (8, 9) assume that the residual limb volume control (5) and the consequent reduction/elimination of relative movements and the resulting shear forces between the residual limb and the socket (1-5) is the reason why vacuum-assisted socket systems neither interfere with wound healing nor cause considerable pain or discomfort while wearing these sockets in the presence of residual limb wounds. Although not yet studied, but supported by field experience and anecdotal reports from prosthetists, it can therefore also be assumed that the

reduction/elimination of these relative movements and shear forces may also contribute to the prevention of residual limb wounds and pain. For the reasons and scientific evidence stated above, we are convinced that the technology of vacuum-assisted sockets is medically necessary to support mobility and an active lifestyle and preserve residual limb health in below-knee amputees with MFCL mobility grades K2-K4.

References

1. Kahle JT, Orriola JJ, Johnston W, Highsmith MJ. The effects of vacuum-assisted suspension on residual limb physiology, wound healing, and function: a systematic review. Technol Innov 2014, 15: 333-341.
2. Beil TL, Street GM: Comparison of interface pressure with pin and suction suspension systems. J Rehabil Res Dev 2004, 41 (6A): 821-828.
3. Goswami J, Lynn R, Street GM, Harlander M: Walking in a vacuum-assisted socket shifts stump fluid balance. Prosthet Orthot Int 2003, 23: 107-113.
4. Beil TL, Street GM, Covey SJ: Interface pressures during ambulation using suction and vacuum-assisted prosthetic sockets. J Rehabil Res Dev 2002, 39 (6): 693-700.
5. Board WJ, Street GM, Caspers C: A comparison of trans-tibial amputee suction and vacuum socket conditions. Prosthet Orthot Int 2001, 25: 202-209.
6. Samitier CB, Guirao L, Costea M, Camos JM, Pleguezuelos E: The benefits of using a vacuum-assisted socket system to improve balance and gait in elderly transtibial amputees. Prosthet Orthot Int 2014; published online 26 September 2014, DOI: 10.1177/0309364614546927.
7. Traballesi M, Delussu AS, Fusco A, Iosa M, Averna T, Pellegrini T, Brunelli S: Residual limb wounds or ulcers heal in transtibial amputees using an active suction socket system. A randomized controlled study. Eur J Phys Rehabil 2012; 48(4): 618-623.
8. Hoskins RD, Sutton EE, Kinor D, Schaeffer JM, Fatone S: Using vacuum-assisted suspension to manage residual limb wounds in persons with transtibial amputation: A case series. Prosthet Orthot Int 2013;38(1):68-74.
9. Traballesi M, Averna T, Delussu AS, Brunelli S: Trans-tibial prothesization in large area of residual limb wound: Is it possible? A case report. Disabil Rehabil 2009, 4 (5): 373-375.

Evidence –Presented and In Review for Publication Matt Wernke, PhD

Article published in Academy Today. Abstract for the 2015 AAOP conference and Thranhardt winner.

http://www.oandp.org/AcademyTODAY/2015Apr/3.asp

Summary: This evidence is currently in review with JRRD for the RCT comparing elevated vacuum to non-elevated vacuum suspension. The manuscript provides much more detail on the methods and results than the abstract from AAOP last year. A few key outcomes and summary points from the paper are:

1) Skin Health Measurement: Transepidermal water loss is a measure of epidermal barrier function and is linked to early indication of ulcer development. Increased measurement of transepidermal water loss (measured by a probe placed on the skin surface) indicates a disruption in epidermal barrier function and lower values indicate a preservation of epidermal barrier function. The results found a significant decrease in TEWL values after 16 weeks of elevated vacuum suspension use compared to the non-vacuum condition. Water loss increased during the 16 weeks of non-EVS use and decreased during the 16 weeks of EVS use.

2) In-socket probe based measurement: Transcutaneous oxygen measurement was deployed within a socket and capture tissue oxygenation levels during rest and activity. Tissue oxygenation while out of a socket was compared to oxygenation levels during activity. The results found that after 16 weeks of use, there was no longer a significant decrease in tissue oxygenation during activity that had been observed during the other time point measurements and non-vacuum suspension.

3) Out of socket circulation imaging: Out of socket circulation imaging was collected before and after activity since the measurements had to be performed out of the socket. The percent change between pre- and post-activity measurements were used for comparison. The results found a significant reduction in reactive hyperemia (transient increase in blood flow following a period of occlusion) with 16 weeks of EVS use. Reactive hyperemia is considered a negative response in these terms since it occurs after occlusion. That fact that elevated vacuum suspension significantly reduced reactive hyperemia suggests improved blood flow during activity and use of the prosthesis. This is supported by the in socket probe based measurements which found improved tissue oxygenation (likely from improved blood flow) during activity thereby reducing/eliminating the occlusive period.

Taken together, the results suggest that EVS-dependent differences in the prosthetic socket residual limb interface account for residual limb health improvement in part by beneficial changes in residual limb perfusion and stress applied to the soft tissues of the residual limb.

Current Department of Defense Funded projects:

Principle Investigators: Highsmith MJ, Kahle JT

MR140125 - "The Effect of Prosthetic Socket Interface Design on Socket Comfort, Residual Limb Health, and Function for the Transfemoral Amputee"

Award Amount: $936,000.00

Summary: This study of 15 subjects uses VAS in TFA interface design to primarily determine if sub-ischial socket design will reduce local and total skin temperature and perspiration.

Principle Investigator: Fatone S.

OR090122- Development of Subischial Prosthetic Sockets with Vacuum-Assisted Suspension for Highly Active Persons with Transfemoral Amputations

Award Amount: $2,099,865.00

Summary: The prosthetic socket technology in this proposal will enable clinicians to provide better prosthetic care and rehabilitation of highly active military service persons with transfemoral amputation. Increased comfort, hip range of motion, and connectivity between the residual limb and prosthesis will result in better functional performance for individuals with combat-related transfemoral amputations.