# Raising the Bar While Shortening the Pole: The Conflict of Requiring "Stability, Ease of Movement, Energy Efficiency and a Natural Gait" With a Limited Device

**Developed in Response to Draft LCD, Lower Limb Prostheses (DL33787), released by CMS July 2015**

Shane R. Wurdeman, PhD, MSPO, CP, FAAOP
Clinical Research Review Committee – Hanger Clinic
Houston TX

Phil Stevens, MEd, CPO, FAAOP
Clinical Research Review Committee, Chair – Hanger Clinic
Salt Lake City, UT

**8/3/2015**

**Summary**

The proposed LCD raises the required standards for the beneficiary while restricting the prosthesis they can use to attain these standards to basic, antiquated technology. The duality of these changes, creating new performance standards while restricting prosthetic resources to the minimum available technology would create a paradigm in which many amputees would be unable to attain their full functional capacity.

Under the current LCD guidelines, the physician and prosthetist collectively consider the individual conditions of the patient and determine the most appropriate initial prosthetic components provided they are consistent with the patient's assigned K-level. Under the revised LCD, uniform are provided prostheses to all patients irrespective of their individual presentation.

Under the proposed LCD, candidacy for a modern era prosthesis requires that the patient attain each of several benchmark standards, including independent donning and doffing of the prosthesis, independent transfers, daily wear tolerance and ease of movement and energy efficiency. Each of these new requirements would be challenged to various degrees by the archaic nature of the mandated preparatory prosthesis.

Limitations to basic prosthetic knee and foot technologies could challenge or prohibit independent transfers among newer transfemoral amputees. Daily wear tolerance would be challenged by the prohibition against any protective interface between the healing residual limb and the rigid prosthetic socket. Finally, component restrictions would prevent many lower limb amputees from ever attaining "ease of movement and energy efficiency."

Consensus medical opinion has defined several prosthetic components that enable safer transfers, such as axial feet allowing more surface to be in contact with the ground, knee technologies with inherent stability, and suspension liners allowing partial donning before entire body weight placed on prosthesis. Liner interfaces help to reduce limb pressures,(Boutwell et al., 2012) decrease dependency on upper extremity assistive devices,(Datta et al., 1996) and result in improved comfort (Baars and Geertzen,

2005), all of which would contribute to the objective of daily wear tolerance. While foot solutions exist the would facilitate “ease of movement and energy efficient gait,” patients are relegated to the use of SACH feet; known to compromise balance even for low activity individuals(Paradisi et al., 2015) and increasing energy expenditure for more active users (Casillas et al., 1995). Thus patients are denied access to the very components that might facilitate their attainment of elevated performance standards.

Ultimately, the proposed LCD creates a number of performance requirements for new amputees and their preparatory prostheses. However, within the same document there are regulations that prevent the provision of individualized prostheses equipped to accomplish these goals. Ultimately, performance standards should be based on the limitations and abilities of the individual patient who is then provided with a prosthesis designed to facilitate rather than undercut their ability to reach that level of success.

## Introduction

The proposed LCD raises the required standards for the beneficiary while restricting the prosthesis they can use to accomplish such standards. The attainability of these standards for many patients would be questionable if they were given access to reasonable prosthetic technology. However, the LCD further mandates that these standards be attained at the conclusion of a rehabilitation program in which the prosthesis made available to new amputees is both limited and limiting, with only the most basic prosthetic components. The duality of these changes, creating new performance standards while restricting the prosthesis to antiquated prosthetic technology would create a paradigm in which many amputees would be unable to attain their full functional capacity.

## Existing Standard: Personalized prosthetics where decisions, practices, and expected outcomes recognize the patient's current condition and other medical problems

In the existing language of the LCD, the standards for coverage are very general, reflecting the diversity of capability and potential within the amputee community:

> "A lower limb prosthesis is covered when the beneficiary:
> 1. Will reach or maintain a defined functional state within a reasonable period of time; and
> 2. Is motivated to ambulate."

Further, the medical necessity for prosthetic components and additions are based on "the beneficiary's potential functional abilities." This phrase is further defined below:

> "Potential functional ability is based on the reasonable expectations of the prosthetist, and treating physician, considering factors including, but not limited to:
> - The **beneficiary's past history** (including prior prosthetic use if applicable); and
> - The **beneficiary's current condition** including the status of the residual limb and **the nature of other medical problems**; and
> - The beneficiary's desire to ambulate."

Under these guidelines, the physician and prosthetist have been able to collectively consider the individual conditions of the patient and determine the most appropriate initial prosthetic components provided they were consistent with the patient's assigned K-level. For example, if a patient with a transfemoral amputation had a short residual limb that would likely preclude is ability to safely utilize a single axis knee, the physician and prosthetist could select an alternative knee joint that would provide mechanical stability to reduce the likelihood of the knee buckling.[1]

## Proposed Revision: "Cookbook prosthetics" where all individuals are expected to accomplish the same performance standards using the same simple, archaic prosthetic componentry

In the revised language of the proposed LCD, a series of standards are introduced to "ensure successful use of a prosthesis." For the patient, at the conclusion of a 90 day rehabilitation program, they 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"

Failure to do so results in none-coverage for any advanced in prosthetic care:

> "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."

Thus, candidacy for a modern era prosthesis would require that the patient attain each of the capabilities outlined above. Yet each of these new requirements would be challenged to various degrees by the archaic nature of the mandated preparatory prosthesis. Limitations to basic prosthetic knee and foot technologies, currently viewed as both reasonable and medically necessary could challenge or prohibit independent transfers among newer transfemoral amputees. Daily wear tolerance would be challenged by the prohibition against any protective interface between the healing residual limb and the rigid prosthetic socket. Finally, component restrictions would prevent many lower limb amputees from ever attaining "ease of movement and energy efficiency."

## Mandatory use of a disabling prosthesis

For many patients, the augmented performance standards would only realistic when they are provided with the proper prosthetic tools. However, this is precluded by language elsewhere in the proposed LCD. The severe limitations of the preparatory prostheses made available to patients in their attempts to reach the prescribed performance standards are described below:

> "preparatory prostheses use **basic prosthetic components**, which provide adjustability and alignment changes as limb maturity occurs. Preparatory prostheses (L5500-L5600) are all-inclusive as described by the code narrative and in the CODING GUIDELINES section in the related Policy Article. **There is no coverage for any additional components, add-ons, upgrades, additions, adjustments, modifications, replacement etc. substitution of components, etc. provided for concurrent use with a preparatory prosthesis**."

Under these mandates, preparatory prostheses will constitute a hard socket with a solid-ankle-cushioned heel (SACH) foot and no knee mechanism if a patient has a transfemoral or proximal amputation. The preparatory prosthesis base code narratives do not include any suspension, and the inability to add L5910 and L5920 will remove the ability of the preparatory prosthesis to "provide adjustability and alignment changes" as defined within the proposed LCD. As the proposed LCD stands currently, patients would be unable to utilize interface liners of any sort including gel, silicone, urethane, or foam. They will also be required to utilize the SACH foot which was first introduced in 1956.[2]

## Elevated Standards of Performance

### Don and Doff the prosthesis without assistance

The ability to independently don and doff the prosthesis is constrained by the limited nature of the prosthesis. In the absence of any prescribed method of suspension, the reasonableness of this requirement is uncertain as suspension type does affect the patient's mobility.[3] Suspension refers to the method used to create a linkage between the prosthesis and the residual limb. If there is no suspension,

then the prosthesis will not stay on the residual limb unless the person uses their hands to hold the prosthesis onto the residual limb. Bending over to hold the prosthesis onto the residual limb creates a highly unstable position, as well as a difficult movement strategy that is highly inefficient and lacks any sort of natural gait appearance. If the patient does not hold the prosthesis onto their residual limb with their hands, then there is a highly unstable scenario with the patient's first step as the prosthesis will no longer be under the patient to accept weight transfer.

The long held industry standards for suspension generally involve an interface liner, the use of which is precluded by the restrictive definition of the preparatory prosthesis. Thus, until a suspension mechanism is defined for the various levels of amputation, the ability of patients of various abilities to independently don their prosthesis is uncertain.

**Independent transfers**

Limitations to basic prosthetic knee and foot technologies could challenge or prohibit independent transfers among newer amputees. Consensus medical opinion has defined several prosthetic components that enable safer transfers. Locking liners allow patients to partially don their prosthesis in sitting and then fully seat their limb in weight bearing. Axial feet allow the entire surface of the foot to come in contact with the floor during transfers and through-out each step. This consideration is especially relevant to transfemoral amputees as such mechanisms reduce the instabilities that would otherwise be experienced around the knee. A number of knee technologies with inherent safety mechanisms have been designed and accepted in recent decades, including weight activated stance control knees that increase their resistance to flexion when loaded, and polycentric knees that position the functional axis of rotation proximal and posterior to the physical joint, making it easier for the user to control the relative extension of the knee. All of these readily available technologies could assist patients in reaching the new standards of the LCD. However, the preclusion of suspension liners, axial feet and knees with inherent stability will severely limit the abilities of many newer amputees to demonstrate this ability.

**Daily Wear Tolerance**

As stated earlier, the language of the LCD precludes the use of interface liners. The use of gel liners can reduce pressures on the residual limb,[4] decreases dependency on upper extremity assistive devices[5] and results in improved comfort.[6] The significance of these related benefits is enhanced by the realization that comfort is reported by amputees as a top factor affecting prosthetic use.[7] In the absence of adequate comfort, many potential prosthetic candidates may abandon their devices. In short, the utilization of interface liners, well-established as a reasonable standard of care in modern prosthetics, is restricted by the proposed LCD, undermining the abilities of many amputees to attain the new standard of demonstrating daily wear tolerance.

**Ease of Movement and Energy Efficiency**

Furthermore, all individuals are expected to reach the same benchmark standards of "sufficient balance and stability to ambulate with ease of movement and energy efficiency." This stipulation is as ridiculous and short sighted as mandating all patients in a weight loss program must lose 100 pounds regardless of the patient's weight or any individual consideration of what level of weight loss would improve quality of life and functionality.

In terms of gait and mobility, stability is difficult with antiquated technology for both active individuals and lower activity individuals. Paradisi et al.[8] showed for lower activity individuals (19 K2, 1 K1), the use of a multi-axial foot as opposed to the SACH foot resulted in *significantly improved balance*. Paradisi et al. also reported *increased mobility*, *improved residual limb health*, improved utility of the prosthesis, and overall *improved general well-being* as well as *increased comfortable walking speeds* and improved times to ascend and descend stairs using the multi-axial foot. Yet these benefits would be unavailable to patients during the rehabilitation phase as they attempt to meet the standards of "ease of movement and energy efficiency."

Instead, the LCD language mandates that new patients must use a SACH foot, making it nearly impossible for a prosthesis to provide "stability, ease of movement, and a natural gait." The rigidity of the SACH foot causes problems with increased time for foot flat in early stance after the heel contacts the ground.[9] The non-compliance of the SACH foot then creates problems with conforming to uneven ground.[10] Such limitations undermine the notion of demonstrating "ease of movement." The rigidity of the SACH creates increased difficulty with inclines and especially declines[11]. It is important to remember that walking outside in the community will always present inclines, declines, and uneven terrain as the world is not flat.

For more active patients, achieving an energy efficient gait with "ease of movement" could be facilitated by the use of well-established energy-storage-and-return feet (ESAR). Snyder et al.[12] reported *increased walking speed* when patients used an energy-storage-and return (ESAR) type foot compared to a SACH foot. This was likely due to the reported increased stride length with the ESAR foot[12]. Powers et al.[13] also reported *increased stride length* with an ESAR foot compared to SACH feet. Macfarlane et al.[14] found that patients walking with an ESAR type foot reported *less difficulty with movement*. Hafner et al.'s review[15] discusses 9 different studies that all showed *increased self-selected walking speed* with ESAR type feet compared to SACH, reinforcing the reality that the SACH foot simply does not provide "ease of movement". Regarding energy efficiency and energy cost, multiple studies have found patients walk with *improved energy efficiency with ESAR feet* compared to SACH feet[16-18]. Hsu et al.[17] and Casillas et al.[16] reported *improved energetic cost with ESAR feet*. Yet this technology, widely understood, accepted and utilized in modern prosthetics, would be unavailable to patients as they are required to demonstrate "ease of movement and energy efficiency."

Patients with amputations proximal to the knee joint will face further difficulties achieving rehabilitation goals. There is no knee mechanism specified in the preparatory prosthesis base code, however the definitive prosthesis base code narrative includes a constant friction, single axis knee. For a patient that will walk at different speeds, not having a knee joint with a fluid medium (e.g. hydraulic or pneumatic) will compromise stability as the knee joint itself is unable to increase its swing velocity to allow ambulation at faster speeds. Mauch[19] detailed the inherent instabilities from a friction knee for a person walking at varying speeds nearly 50 years ago. If a patient changes walking speed, a knee that utilizes friction for yielding purposes will be flexed at instances when the patient is transferring weight onto the limb, which will cause the knee joint to buckle and a fall to ensue. This is hardly conducive to "ease of movement and energy efficiency," and yet it would potentially be the only knee joint available to new amputees at the very time when ease and efficiency are required.

## Conclusion

The proposed LCD mandates that individuals demonstrate independent donning and transfers along daily wear tolerance to qualify for a definitive prosthesis. Similarly, the preparatory prosthesis must

provide stability, ease of movement, energy efficiency, and the appearance of a natural gait. Within the same document however, there are regulations that prevent the provision of a prosthesis reasonably equipped to accomplish these goals. Ultimately, performance standards should consider the individual patient along with their limitations and abilities. Further, any such standards must allow for the provision of prosthetic technology that enables the attainment of such standards.

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