

# Requiring “Demonstrated Performance” with Antiquated Prostheses to Qualify for a Modern Era Prosthesis

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

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## Summary

Lower limb prostheses have had significant technological advances that have empowered those that require these devices for daily living. The proposed changes to the LCD for lower limb prostheses however does not acknowledge these improvements and instead forces patients to begin the long and difficult rehabilitation period after a lower limb amputation utilizing technology 50+ years old.

Under the proposed LCD changes, Patients would need to demonstrate their K-level functionality with a preparatory prosthesis restricted to an antiquated device using a SACH foot, no liner, no knee mechanism, and without any suspension. For perspective, the SACH foot was introduced in 1956 (Staros, 1957), in the same era as the first implantable cardiac pacemaker developed by Wilson Greatbatch (Aqualina, 2006). It would be unthinkable for Medicare to mandate coverage on modern pacemakers only after patients have *proven* themselves deserving following a cardiac rehabilitation period with Greatbatch’s pacemaker. Yet this would become the case for the prosthetics patient as the current proposed changes to the LCD would modify the practice of prosthetic rehabilitation to a “rewards-based” system impeding patient access to modern technology.

The current state-of-the-science regarding the use of the SACH foot rather than newer technologies such as multi-axial feet clearly shows worse balance, worse residual limb health, worse utility of the prosthesis, less overall general well-being, reduced walking speed, and worse stair negotiation for low activity ambulators ( $\leq$  K2) (Paradisi et al., 2015). For higher activity ambulators the use of SACH feet when compared against modern Energy Storage and Return (ESAR ) feet results in reduced walking speeds (Hafner et al, 2002), and worse energy efficiency/ more energy required to ambulate (Casillas et al., 1995).

The preparatory prosthesis does not have provisions for a knee mechanism. However, it would likely include a friction control, single axis knee (as is specified in the definitive prosthesis base code narrative). The single axis is the most mechanically unstable available prosthetic knee (Uustal and Baerga, 2004), requiring a conscious effort to control the knee from buckling with every step which is

difficult for the typical elderly amputee as well as individuals with short amputations (Smith, Michael, & Bowker, 2004). Additionally, the knee does not allow for ambulation at different speeds (Mauch, 1968).

Finally, there is no allowance for interface liners to protect the immature residual limb from the hard socket. This is contradicted by evidence that shows gel liners reduce pressures that cause limb ulcers (Boutwell et al., 2012), improve socket comfort (Baars and Geertzen, 2005), and decrease dependency on upper extremity assistive devices to ambulate (Datta et al., 1996).

In conclusion, the proposed changes to the LCD are such that prosthetic practice would become a rewards-based system, whereby patients must prove themselves with antiquated devices before having access to modern technology that better addresses both their individual limitations and capabilities.

## Introduction

Lower limb prostheses have had significant technological advances that have empowered users to more fully engage in the challenges and opportunities of daily living. However, the proposed LCD changes would deny access to these improvements during the earliest stages of recovery, forcing patients to begin their long and difficult post-amputation rehabilitation utilizing technology that is over 50 years old. **This document is meant to address the following fundamental flaw within the proposed LCD: Mandatory preparatory prostheses will have defined, unreasonable restrictions that limit prosthetic technology at a very vulnerable period in amputee rehabilitation. These restrictions would preclude access to available safety mechanisms, limit both comfort and performance and ultimately undermine prosthetic acceptance and ambulation.**

Under the proposed LCD changes, K-level assignment will be based on “demonstrated ability” rather than functional “potential.” For new amputees, this will need to be done with their preparatory prosthesis which has been restricted to a device using a SACH foot, no liner, no knee mechanism, and without any suspension. For perspective, the SACH foot was introduced in 1956.<sup>1</sup> In its time, the SACH foot was as revolutionary as other technological inventions of the era including the first implantable cardiac pacemaker developed by Wilson Greatbatch (1958).<sup>2</sup> It is unthinkable for Medicare to mandate coverage on modern pacemakers only after patients have *proven* themselves deserving following a cardiac rehabilitation period with Greatbatch’s original pacemaker. **Current proposed changes to the LCD modify the practice of prosthetic rehabilitation to a “rewards-based” system impeding patient access to modern technology.**

### Existing Standard: Immediate patient access to appropriate technologies

Currently, the LCD allows for provision of prosthetic technology and components based on medical necessity consistent with the patient’s functionality. It reads:

“A determination of the **medical necessity for certain components**/additions to the prosthesis is **based on the beneficiary’s potential functional abilities**. 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.”<sup>3</sup>

The following guidelines pertinent to preparatory prostheses are provided<sup>6</sup>:

“When an initial below [above] knee prosthesis ... or a preparatory below [above] knee prosthesis ... is provided, **prosthetic substitutions and/or additions of procedures and components are covered in accordance with the functional level assessment**”<sup>3</sup>

This language allows the prosthetist and physician to jointly evaluate the patient's history, condition and medical problems *and select prosthetic components based on both functional abilities and limitations.*

### **Proposed Revision: Patients rewarded with modern technology only after proving themselves**

The draft LCD proposes coverage changes that mandate the initial use of archaic technology and procedures. Under the proposed system, patients would only have access to modern technology after the demonstrated performance of prescribed standards with the severely limited device:

**“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.”

This is followed with mandates on determination of a patient's functional level:

**“The beneficiary's functional level is based on their overall health status, the objective results of the medical assessment and their documented performance using their immediately previous prosthesis (either preparatory or definitive).”**

Accordingly, patients will be required to prove their prosthetic abilities with devices that fail to address either their individual capabilities or limitations.

### **Conflicts Between the Proposed LCD and the State-of-the-Science**

The proposed LCD is fundamentally unsound as it denies access to fairly basic, modern era components that would enhance safety, comfort and performance during this early stage of rehabilitation. These limitations would be seen with archaic feet and knees and the withholding of available interface materials between the residual limb and the socket.

#### **Feet**

The SACH foot was introduced in 1956<sup>1</sup> and is among the most studied prosthetic devices. While serving as an advancement over other prosthetic feet of its time, it is now antiquated technology that has proven to be insufficient in numerous aspects of amputee mobility when compared to more modern technologies such as multi-axial and energy-storage-and-return feet (ESAR).

For example, a recent study by Paradisi et al. reported upon *significant improvements in balance* that occurred when K1 and K2 level walkers were switched from SACH feet to multi-axial feet.<sup>4</sup> Additional observations included *increased mobility, improved residual limb health, improved utility of the prosthesis, improved overall general well-being, increased comfortable walking speed, and improved times to ascend and descend stairs.*<sup>4</sup> These observations strongly suggest that lower functioning patients would have greater success during their rehabilitation program if given access to improved technologies such as multi-axial feet. Additionally, with regard to K-level assignment, the observed

benefits of the multiaxial foot over the SACH foot have obvious implications on a patient's ability to demonstrate the negotiation of environmental obstacles and variable gait speed.

Instead of enabling the patient with such benefits, the proposed LCD changes would force patients to endure a rehabilitation period and subsequently demonstrate their prosthetic abilities with a foot that has been shown to have *poor compliance over uneven ground resulting in greater instability*<sup>5</sup>, and *reduced ability to negotiate inclines and especially declines*.<sup>6</sup> Additionally, the SACH foot has been associated with *reduced walking speeds*,<sup>7</sup> *shorter stride lengths*,<sup>7-8</sup> and *increased self-reported difficulty with walking*.<sup>9</sup>

Even greater separation is observed when the SACH foot is compared against ESAR feet designed for K3-4 level walkers. Within Hafner et al.'s 2002 review of the topic there is discussion of 9 different studies that all showed *the SACH resulted in reduced walking speeds compared to the ESAR type feet available*.<sup>10</sup> In addition, walking with the SACH foot, as compared to ESAR feet, leads to *reduced energy efficiency* and a gait that *requires more energy to walk*.<sup>11-13</sup> There are negative implications of these limitations on a patient's ability to demonstrate variable cadence ambulation.

### **Knees**

There is currently no provision for a knee mechanism within the code narrative provided for preparatory prostheses and thus it is unclear if the expectation for patients with transfemoral amputations is to rehabilitate without a knee joint. As the proposed LCD carries a general theme of limiting patients to basic, antiquated technology, it can be assumed that the single axis knee, included in the base code for a definitive transfemoral prosthesis, will be similarly defined with the preparatory prosthesis descriptors.

Importantly, the joint configuration of a single axis is mechanically unstable, and when such a prosthetic knee joint is limited to friction controlled damping *it is the most unstable knee configuration available in existing prosthetic technology*.<sup>14</sup> The knee will *not* afford patients with the "ability to traverse most environmental barriers without physical or *safety concerns*" given the inherent mechanical instabilities. This inherent instability requires every step to be consciously and actively controlled to keep the knee from buckling<sup>15</sup>, a difficult feat for the typical new amputee that is an elderly individual with concomitant medical problems. In order to modestly increase mechanical stability, the knee can be set within the prosthesis in a more posterior location.<sup>14</sup> However, this will make it increasingly difficult to initiate swing phase, increasing the difficulty of walking and associated energy expenditure.<sup>14</sup>

In addition, the single axis knee utilizes a constant friction mechanism in its attempts to keep the knee from over-accelerating as the person initiates swing phase. The inherent instabilities associated with a person walking at varying speeds with a friction knee have been documented as far back as 50 years ago.<sup>16</sup> More recently, Hicks et al demonstrated that adjusting friction in a single axis, constant friction knee has no effect on changing the swing velocity of the knee, noting that a friction knee can only allow for a fixed cadence due to pendulum dynamics.<sup>17</sup> If a patient attempts to increase their walking speed with a friction regulated knee, the knee 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.

Restated, the single axis knee that would likely be defined within the base codes of preparatory prostheses *does not permit increased walking speeds*. These limitations were addressed decades ago when pneumatic and hydraulic yielding knees were invented to enable and adapt to increased ranges of walking speeds. Subsequent studies have confirmed that compared to ambulation with a hydraulic or pneumatic knee, walking with a single axis, friction knee results in a *decreased range of walking speeds*, more asymmetric swing and stance phases, and a walking pattern more atypical from healthy, non-amputees.<sup>18</sup> Yet the proposed LCD would require patients be confined to this component while they attempt to demonstrate variable cadence in order to be classified as a K3 or K4 level walker.

### **Limb Interfaces**

Finally, the proposed LCD prevents the use of gel liners with the preparatory prosthesis. The use of gel liners can reduce pressures on the residual limb,<sup>19</sup> decreases dependency on upper extremity assistive devices<sup>20</sup> and results in improved comfort.<sup>21</sup> The significance of these related benefits is enhanced by the realization that comfort is reported by amputees as a top factor affecting prosthetic use.<sup>22</sup> In the absence of adequate comfort, many potential prosthetic candidates may abandon their devices.

### **Conclusion:**

The proposed changes to the draft LCD are such that prosthetic practice will be a rewards-based system, whereby patients must prove themselves with antiquated devices before having access to modern technology. The unreasonable limitations of these mandated devices would substantially restrict the abilities of individual patients to attain the required documented performance standards proposed for higher K-level assignments. More importantly, by refusing to consider the individual needs and capabilities of individual patients, the policy would ultimately compromise patient safety, participation and prosthetic acceptance.

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