

## **“Potential” as a Fundamental Principle in Rehabilitation, but Systematically Dismissed in the Proposed LCD.**

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

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7/30/2015

### **Summary**

Investments made into rehabilitation assume that a patient has the potential to improve following an insult or injury. When that potential is absent, rehabilitation is replaced with palliative care. Amputation has been put forward as the rehabilitative alternative to the palliative management of the diseased lower extremity.

While the role of potential in amputee rehabilitation is appropriately acknowledged in the current language of the LCD, in the proposed revision, “potential” is replaced with “documented performance” when assigning K-level. The negative impacts of this proposed revision are exacerbated by the timing of K-level assessment and the limited resources available to the patient at that time.

Published observations in the literature suggest significant improvement in gait velocity and environmental obstacle negotiation well after the conclusion of a defined rehabilitation program. To assign K-level at this point in a patient’s recovery is premature and ignores the potential for additional improvements associated with time, training and healing.

At the proposed time of K-level assessment, most Medicare beneficiaries will be limited to a preparatory device that is both *limited* and *limiting* in its components and performance. Proposed policy language excludes any and all additional items not described in the base codes for preparatory devices. As a result, the preparatory prosthesis would be limited to a 1950’s era SACH foot, no knee mechanism, no interface between the immature limb and the rigid socket, no allowance of a diagnostic test socket, no optimization or alteration to alignment, and no suspension mechanism.

These limitations will fundamentally limit the patient’s ability to attain the documented performance standards required for higher levels of K-level assignment. For example, in the absence of a defined knee mechanism in the descriptors for preparatory prosthesis, it can be reasonably assumed that the single axis knee defined in the base code of a definitive transfemoral prosthesis would be assigned to all preparatory devices. However, a single axis knee has no inherent stability and only allows for ambulation at a constant, slow speed. Limited by this component, many patients will be unable to demonstrate the independent negotiation of environmental obstacles or variable cadence.

The proposed decision to systematically ignore patient potential given adequate time, training, recovery and prosthetic resources is inconsistent with the intent of physical rehabilitation and would negatively restrict their functional capabilities.

## Introduction

Rehabilitation is based on the fundamental premise that following an illness or injury, given adequate time and resources, *people have the potential to improve*. When that potential is absent, the focus of medical efforts and interventions change from rehabilitation to palliative care. This principle is exemplified in the title of a recent publication by Brown and Attinger at the Center for Wound Healing, Georgetown University Hospital, *“The Below Knee Amputation: To Amputate or Palliate.”*<sup>1</sup> In their introductory comments, the authors explain:

Despite advances in vascular surgery and wound healing, our ability to heal a diseased lower extremity remains limited. Our efforts to salvage such extremities are usually associated with a decrease in function. *Advances in prosthetic technology, on the other hand, have significantly increased the quality of life among patients with an amputated lower extremity.* In some patients, *their highest attainable function is often achieved with a properly performed below-knee amputation (BKA)*

Importantly, the authors present a well performed amputation with appropriate access to advanced prosthetic technology as the *rehabilitative* alternative to palliative care. Deciding between these options requires that the medical team consider the *potential* of each patient and whether the nature of their illness or injury warrants palliative care or the additional investments associated with amputation with subsequent rehabilitation. The goal of a lower limb amputation is to help patients return to their highest attainable function, a goal that is best realized when the healthcare system invests in each patient’s potential by providing them with access to appropriate advances in prosthetic technology.

## Existing Standard: Potential Functional Ability

This principle has historically been understood and integrated into the classification matrix used to determine a patient’s functional level, as reflected in the language of the current LCD.

“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>2</sup>

The individual K-level descriptors that follow all begin with a statement mirroring a reasonable understanding of the role of potential in determining likely functional abilities. For example, a K-level 1 is described as someone who has “...**the ability or potential** to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence.”<sup>2</sup>

## Proposed Revision: Documented Performance

In the proposed revision to the LCD, the principle of potential and Medicare’s willingness to invest in that potential is entirely excluded. In its place is an assessment based on “documented performance:”

“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).”<sup>3</sup>

The individual k-level descriptors that follow begin with altered verbiage ignoring any potential improvements in functional capabilities that might be realized with additional time, training, recovery and resources. For example, in the revised language, a K-level 1 is described as someone who has "... demonstrated the ability to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence." The required standards of *demonstrated ability* increase at each K-level. The effect of such policy language would be to limit available prosthetic components to those patients who cannot perform certain tasks during the early stages of rehabilitation, but might well be capable of doing so given adequate resources and training.

### **Performance Improves with Time and Training**

In the language of the proposed LCD revision, patients who experience their amputations as Medicare beneficiaries will be assigned a K-level, according to their documented performance at the conclusion of a mandatory but vaguely defined rehabilitation program. However, the proposal that a patient's performance at the end of a rehabilitation program is representative of their longer term abilities is unfounded and contradicted by published observations.

For example, Brooks et al reported on the 2 minute walk test performance of 290 lower limb amputees at baseline, at the conclusion of a rehabilitation program and again at a three month outpatient follow-up clinic. The mean performances observed at these periods were 30 meters, 41 meters and 70 meters respectively.<sup>4</sup> Thus, while gait speed increased by an average of 37% between baseline assessment and the conclusion of the rehabilitation program, it increased an additional 71% between the rehabilitation program and the outpatient follow up several months later.<sup>4</sup>

In another study, Barnett et al reported on the self-selected walking velocities of unilateral transtibial amputees as they negotiated a raised surface walkway designed to replicate the negotiation of stepping onto a curb, walking, turning 180 degrees, returning to and stepping off of a curb.<sup>5</sup> In examining mean walking speeds during curb descent, these increased by 22% between 1 and 3 months post completion of a national health care rehabilitation program. An additional 11% increase in walking velocity was reported between 3 and 6 months after the rehabilitation program.<sup>5</sup> In addition to velocity considerations, ascent and descent strategies changed appreciably during the 6 months after the rehabilitation program, suggesting increased confidence in the prostheses and highlighting continued potential for improvement.<sup>5</sup>

Given the collective roles of community ambulation, environmental obstacle negotiation and variable cadence in defining functional levels, any assignment of K-level at the conclusion of the rehabilitation programs referenced in these studies would have mischaracterized the true abilities that were ultimately attained by many of the involved amputees.<sup>4-5</sup> Similarly, the current proposal to define K-level based on demonstrated performance at the conclusion of a rehabilitation program is likely to underestimate the ultimate abilities of individual patients given adequate time, recovery and training.

### **Both Potential and Subsequent Ability are Further Limited by Restricted Resources**

One facet of an individual's potential is the improvement they will experience with time, recovery and training. A second facet is the improvements that occur when patients are given access to reasonable prosthetic technology. The unjust nature of the "documented performance" requirements are further exacerbated by a thoughtful consideration of the limited resources that would be made available to Medicare beneficiaries at this time in their post-surgical recovery, as illustrated in the language of the proposed LCD below:

**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).**<sup>3</sup>

**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. All additional items will be denied as not reasonable and necessary.**<sup>3</sup>

For the sake of brevity, we limit consideration to transfemoral amputees, however similar statements can be said of all amputation levels. The limitations of the device that would be made available to the patient to demonstrate their abilities are explained in further detail within the code narrative for a preparatory prosthesis:

L5590: Preparatory, Above Knee- Knee Disarticulation Ischial Level Socket, Non-alignable system, pylon no cover, SACH foot, laminated socket, molded to model.

Given the strict assertion that “all additional items (including additional components, add-ons, and upgrades) will be denied as not reasonable and necessary,” the limitations of this device include:

- A foot developed in the 1950s and described as “for patients whose physical condition precludes ambulating more than a few steps at a time.”<sup>6</sup>
- No knee mechanism
- No interface between the healing tissues of the residual limb and the hard socket.
- No use of a test socket to obtain a comfortable socket fit
- No mechanism to align the position of the components relative to the socket
- No suspension mechanism to hold the prosthesis on the limb and prevent movement of the limb within the socket and dislocation of the prosthesis from the person.

Patients cannot be expected to accurately demonstrate their abilities if they are not given access to reasonable technologies.

### **Restricting Prosthetic Components Limits Demonstrated Abilities**

There are a number of ways in which restricting prosthetic components limits a patient's demonstrated ability. This paper will confine itself to a very brief evaluation of the single axis knee. Importantly, the code narrative for a preparatory prosthesis does not include a knee mechanism. However, it can be reasonably assumed that the single axis knee, included in the descriptor for a definitive transfemoral prosthesis, would be included in the preparatory devices mandated by the proposed LCD.

The limitations of the single axis knee are clearly understood and described and must be considered against the requirements for demonstrated performance associated with individual K-levels such as transfers, ambulation, environmental obstacle negotiation and variable cadence. Quoting from the 3<sup>rd</sup> edition of the Atlas of Amputations and Limb Deficiencies:

“Unfortunately, the basic single-axis knee has two major biomechanical deficiencies. First, ***the knee has no inherent stability***, and therefore ***must be carefully controlled*** by the amputee

with every step to prevent collapse of the prosthesis. ***Because the typical new amputee today is an elderly individual with concomitant medical problems, such perfect control of every step is often an unrealistic expectation.***

Equally important, with a free swinging knee, the lower leg is essentially a pendulum with a rate of swing limited by its length. As a consequence, ***the amputee is forced to walk at a constant, slow speed.*** Attempts to accelerate result in excessive knee flexion in early swing, which slows cadence even further. Even with the addition of a friction adjustment or a spring extension aid, the ***cadence is still severely restricted.***"

The limitations of this single component within the proposed preparatory device must be considered against the requirements associated with the assignment of K-level. These include traversing low-level environmental barriers such as curbs, stairs, or uneven surfaces (K2), functioning physically and psychologically within the community independently (K2), personal independence during ambulation with variable cadence (K3), and demonstrating the ability to traverse most environmental barriers without physical or safety concerns (K3).<sup>3</sup>

Medicare beneficiaries cannot be reasonably expected to demonstrate the abilities described above when they are statutorily confined to a basic knee with no inherent stability, requiring the unrealistic expectation of conscientious control of each step to avoid collapse of the knee; a knee that forces the patient to walk at a constant, slow speed with severe cadence restrictions. Similar arguments could be put forth for the indefensible decision to deny or limit coverage on feet, socket interfaces and suspension mechanisms when reasonable established technologies exist that facilitate safety and empower the amputee's potential during ambulation and the negotiation of environmental obstacles. A patient's abilities can only be fully attained and realized when they are empowered with the appropriate resources.

## Summary

The premise of rehabilitation is to invest in the potential of a recovering individual to allow them to regain a measure of their lost abilities after illness or injury. When a healthcare system is designed to ignore potential rather than invest in it, the individual's rehabilitation is fundamentally compromised. While prior LCD language acknowledged this principle, the proposed LCD dismisses it entirely. This is done by requiring demonstrated performance after a limited rehabilitation period with a *fundamentally limited* and *fundamentally limiting* prosthesis. The end result of such changes would be a number of Medicare beneficiaries who are limited, not by their ability and potential, but by the policy itself, which refuses to adequately acknowledge or invest in the potential of its beneficiaries.

## **References**

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