

Unable or Unwilling: Policy Discrimination against Bilateral Amputees and Other More Challenged Patients

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

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Summary

Within the draft LCD, three types of prosthesis are defined, Immediate, Preparatory and Definitive. In the coverage criterion for each type, the LCD asserts, “**If the beneficiary is unable or unwilling to use the prosthesis, the claim will be denied as not reasonable and necessary.**” However, an analysis of the LCD suggests several policy changes that seem designed to subvert the *ability* and *willingness* of individual patients to succeed with limited prosthetic resources. This is especially true of individuals presenting with greater levels of difficulty. If the standards of “*reasonable*” and “*necessary*” are to be applied to prosthetic coverage determinations, they should also be applied to the proposed policies themselves. However, especially with regard to amputees facing greater challenges and limitations, the proposed LCD is neither reasonable nor necessary and would leave many previously capable patients as either unable or unwilling to succeed with a prosthesis.

The policies outlined within the draft LCD initially deny access to both enabling prosthetic technologies and adequate time and training to fully utilize the prosthesis before amputees’ functional abilities are fairly assessed. Rather, under the proposed LCD patients would be given access to only the most basic prosthetic technologies and 90 days to train with them before their prosthetic abilities and function are placed on trial. To be able and willing to wear such a prosthesis in this early, vulnerable stage of rehabilitation would be challenging for many healthy unilateral amputees, and impossible for those with additional challenges such as bilateral amputation and high level amputations through the pelvis.

Rather than aiding and enabling those individuals with increased disability and physical challenges, the proposed LCD will have increased barriers to success. As a result, individuals with bilateral amputation, more proximal amputations at the pelvis level, and those with other comorbidities will fail to reach their true potential.

Introduction

Within the draft LCD, three types of prosthesis are defined, Immediate, Preparatory and Definitive. In the coverage criterion for each type, the LCD asserts, “**If the beneficiary is unable or unwilling to use the prosthesis, the claim will be denied as not reasonable and necessary.**” However, an analysis of the LCD suggests several policy changes that seem designed to subvert the *ability* and *willingness* of individual patients to succeed with limited prosthetic resources. This is especially true of individuals presenting with greater levels of difficulty, including patients with bilateral amputation, those with amputations at the level of the pelvis and those with co-morbid injuries and illness. If the standards of “*reasonable*” and “*necessary*” are to be applied to prosthetic coverage determinations, they should also be applied to the proposed policies themselves. However, especially with regard to amputees facing greater challenges and limitations, the proposed LCD is neither reasonable nor necessary and would leave many previously capable patients as either unable or unwilling to succeed with a prosthesis.

Existing Standard: Individual Evaluation, Consideration and Definition of Functional Potential

Under the current LCD, prosthetic rehabilitation begins with an individual evaluation that is used to determine individual potential functional abilities. This evaluation includes past history, current presentation and other medical problems:

“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.”

Based on that evaluation, the rehabilitation team determines a functional state that can be reasonably expected of the individual. Individualized prosthetic coverage is made available to a patient who will reach that individually defined functional state:

“A lower limb prosthesis is covered when the beneficiary:

- Will reach or maintain a **defined functional state** within a reasonable period of time; and
- Is motivated to ambulate.”

Proposed Revisions: Uniform Minimal Standards of the Patient and Prosthesis Regardless of Individual Presentation and Limitations

Under the proposed LCD, this standard would be drastically altered by the provision of a uniform, basic prosthesis at the time the amputation wound has healed. This preparatory prosthesis would not consider individual variations in patient presentation, nor would it allow for the incorporation of any prosthetic technologies beyond the most limited components. At the conclusion of a 90 day

rehabilitation program with the Spartan device, both the patient and the prosthesis would be held to minimal performance standards, irrespective of patient presentation.

Requirements of the patient, irrespective of their presentation:

“A beneficiary **must meet the following minimal requirements** to be functionally successful with a lower extremity prosthesis:

- Sufficient trunk control
- Good upper body strength
- Adequate knee stability with good quadriceps strength and control
- Good static and dynamic balance or a Tinetti total score of > 24
- Adequate posture”

Requirements of the prosthesis, irrespective of the patient’s presentation:

“**The prosthesis provided must provide:**

- Stability,
- Ease of movement,
- Energy efficiency, and
- The appearance of a natural gait”

Requirements of the patient with their prosthesis, irrespective of their presentation:

“In the 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”

Under the proposed LCD, failure to meet any of these requirements indicates that a patient will not be successful with a definitive prosthesis, and would therefore be ineligible for long term prosthetic care. As articulated elsewhere in the LCD, **the patient is now considered “unable and unwilling to use the prosthesis,” and prosthetic coverage is no longer “reasonable and necessary.”**

The Self-fulfilling Prophecy Fulfilled

The policies outlined within the draft LCD would ultimately create a self-fulfilling prophecy in which patients are initially denied access to both enabling prosthetic technologies and adequate time and training to fully utilize the prosthesis before their functional abilities are fairly assessed. Rather, they would be given access to only the most basic prosthetic technologies and 90 days to train with them before their prosthetic abilities and function are placed on trial. To be able and willing to wear such a prosthesis in this early, vulnerable stage of rehabilitation would be challenging for many healthy unilateral amputees, and impossible for those with additional challenges. Individuals with bilateral limb loss would be especially challenged to meet this criterion.

Prevalence of Bilateral Amputees

The minimal requirements that would be established would be difficult for a large number of Medicare beneficiaries that are sadly forsaken and forgotten within the proposed LCD. Taylor et al. looked at functional outcomes after major lower limb amputation in a cohort of 553 patients, reporting 23.6% resulted in bilateral amputation (Taylor et al., 2005). In their convenience sample of 201 dysvascular amputees Kulkarni et al. reported that 24% presented with bilateral transtibial amputations (Kulkarni, 2006). However, these numbers may actually be an underestimation on the number of bilateral amputees given that up to 55% of persons with diabetes who have a lower extremity amputation will require amputation of the contralateral leg within 2-3 years (Pandian, Hamid, & Hammond, 1998). By conservative estimates, roughly one quarter of the amputees who are covered by Medicare have bilateral limb loss.

The Impact of Minimal Functional Requirements on Bilateral Amputees

Many bilateral amputees would be challenged to meet the minimal performance standards established by the LCD. For example, in the absence of a sound side limb, most bilateral amputees would be unlikely to perform the Tinetti balance assessment without a walker or cane 3 months after their amputation, and would therefore fail to demonstrate “adequate static and dynamic balance” as it is not possible to score above the threshold of 24 set in the proposed LCD if assistive devices are used (Tinetti, 1986). Similarly, ease of movement with a pair of 1950’s era prostheses would be challenging as would any pretense of energy efficiency. DuBow et al. report energy expenditure for bilateral transtibial amputees to be 123% of that measured in similar non-amputees (DuBow et al., 1983). Energy efficiency is inherently even poorer when the amputation is due to vascular disease rather than trauma (Waters and Mulroy, 2004). Likewise, the ability of such individuals to don and doff their prostheses independently, particularly early in the rehabilitation process might be suspect. Finally, their ability to demonstrate sufficient daily wear tolerance would be challenging in the absence of cushioning gel liners to protect tissues of the residual limb. Specifically, while unilateral amputees shift loads to the sound limb to off-load their residual limb in times of limb soreness due to increased demands (Michael and Jorge, 2013), bilateral amputees are unable to do so. Uellendahl (2004), with regard to bilateral amputees, provides the following practice guideline, “transtibial amputees benefit from soft interface materials such as silicone, urethane, or thermoplastic gel liners that, along with appropriate socket design, spread forces evenly over the greatest possible area.”

Current Prosthetic Utilization by Bilateral Amputees

Importantly, under the current LCD bilateral amputees can and do attain levels of prosthetic proficiency, even among the most challenged and at-risk populations. In their report on the long term mobility and mortality of patients with peripheral arterial disease following bilateral amputation, 45% of those patients amputated bilaterally below the knee retained the ability to walk, as did 30% of those with a single preserved anatomic knee joint (Inderbitzi, Buettiker, & Enzler, 2003). Taylor et al. (Taylor et al., 2005) similarly reported 43% of the bilateral dysvascular amputees were ambulatory 1 year after their amputation.

The mandates from the proposed LCD conflict with published practice guidelines. Uellendahl (2004), in the most recent edition of the *Atlas of Amputations and Limb Deficiencies: Surgical, Prosthetic, and Rehabilitation Principles*, states with regards to prosthetic fittings with bilateral amputees, "foot and ankle components that provide good shock absorption" should be used. He continues more specifically stating best practice includes "modern foot and ankle components that offer compliance and some measure of dynamic response". Uellendahl (2004) finally states, "a more flexible foot is generally preferred over one that is rigid." **Despite the LCD's high regard for the *Atlas of Amputations and Limb Deficiencies: Surgical, Prosthetic, and Rehabilitation Principles*, as evidenced by 26% of the references utilized to formulate the proposed LCD coming from the *Atlas***, these practice guidelines provided by Uellendahl are not upheld. Rather, similar to all patients, bilateral amputees would be forced to use a rigid SACH foot with poor shock absorption in their preparatory prosthesis. Then, if they can clear the unreasonable hurdles to get a definitive prosthesis, they will similarly find that the consolidation of foot codes has eliminated their potential for feet with vertical shock absorption (L5987) which are a lighter alternative to a prosthetic foot with an additional shock absorbing pylon component added.

Further mandates include a vague and unclear directive regarding the suspension used with the preparatory prosthesis. The LCD mandates no add-ons to the preparatory prosthesis base code, but there is no suspension within the base code narrative. Uellendahl (2004) further states regarding suspension, "Suspension of a prosthesis is always critical and assumes even more importance for the bilateral amputee. Any amount of pistonning in the socket will increase the effective length of the prosthesis during swing phases and the bilateral amputee cannot actively vault to compensate." Uellendahl (2004) clearly specifies, "Suction suspension is recommended whenever possible, for all cases and levels of [bilateral] amputation." Suction suspension, however, is not possible in the above-knee application for a maturing residual limb that will quickly reduce in volume unless a silicone or gel liner is used. Within the proposed LCD, the use of a silicone or gel liner will be considered custom and will not be covered for patients in any prosthesis unless a foam liner is unable to be effective.

What Happens When LCD Standards are Not Met?

While the LCD allows patients with bilateral amputation to receive a very basic preparatory prosthesis, there is high likelihood these patients will not meet the standards to qualify them for provision of a definitive prosthesis. The policies of the LCD assume that amputees that are unable to meet these minimal functional requirements will simply abandon prosthetic use. Tragically, because of the Spartan nature of the mandated preparatory prosthesis, this would likely be the case for many bilateral amputees. However, others would continue to function with their prostheses, albeit at a level dismissed by the LCD. As the draft LCD has no mechanism for patients who fail to meet the minimal functional requirements to receive ongoing, long term prosthetic care, these patients would have no alternative but to attempt to derive long term utilization from preparatory prostheses designed for short term use.

While their general health is often compromised, bilateral dysvascular amputees are reported to have as high as 67% 5-year survival rate and 42% 10-year survival rate (Kulkarni, Pande, & Morris, 2006). Inderbitzi et al. report an average life expectancy after the second amputation of 3.2 years while 31% lived longer than 5 years (Inderbitzi, Buettiker, & Enzler, 2003). These tenures are far beyond the

reasonable lifespan of a preparatory prosthesis, especially an antiquated, simple device intended for a 90 day period prior to functional evaluation. It is not clear how these individuals that are not eligible for ongoing prosthetic care with a definitive prosthesis will be managed. Furthermore, the economics of the situation are questionable when Inderbitzi et al. (Inderbitzi, Buettiker, & Enzler, 2003) reported 82% of the individuals they reviewed that were ambulatory with prostheses returned to their individual homes as compared to 63% of those who were mobile with a wheelchair.

From Unilateral to Bilateral

Finally, the high standards and mandate on preparatory prostheses will severely hinder the 55% of patients that have the other leg amputated within 2-3 years as they will now be faced with the possibility of walking with a more modern technology definitive prosthesis received with their initial amputation, and a completely different prosthetic setup for their preparatory prosthesis. This is analogous to walking all day with a high heel and a tennis shoe, and goes against the practice guidelines from Michael & Jorge (Michael and Jorge, 2013) that state, “The prosthetist should consider both prostheses together rather than simply generate a “right-side” and a “left-side” prescription recommendation.”

Impact on Other Forgotten Patients

Bilateral amputees are not the only individuals with increased disability that will be discriminated against. Patients with hip disarticulation and transpelvectomy constitute a small percentage of lower limb amputees, with incidence reported as high as 3.0% (Michael and Jorge, 2013). Yet, they do exist and a small percentage do ambulate. These individuals will similarly fail to meet the high standards established, forcing them into wheelchairs. There are also aging polytrauma patients with upper extremity amputation to accompany their lower extremity amputation. This population will also face increased scrutiny and likelihood that their devices will not be available in their Medicare years due to high standards. The patients and their providers are not allowed to determine for each individual what constitutes prosthetic success.

Conclusion

The proposed LCD will deny claims as “not reasonable and necessary” for cases when the beneficiary is “*is unable or unwilling to use the prosthesis*”. However, an analysis of the LCD includes several policy changes that disregard the *ability* and *willingness* of individual patients to succeed with limited prosthetic resources. Rather than aiding and enabling those individuals with increased disability and physical challenges, the proposed LCD will have increased barriers to success. As a result, individuals with bilateral amputation, more proximal amputations at the pelvis level, and those with other comorbidities will fail to reach their true potential.

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