

Tragic Timeline: Required Delays to Individualized Prosthetic Care

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

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Summary

Currently, individualized prosthetic rehabilitation begins shortly after the amputation, with the treating physician and prosthetist evaluating and considering the history, current condition and co-morbid medical problems of the patient while the residual limb is recovering from the surgery. Under the draft LCD, the early prosthetic care of an individual recovering from amputation would be rationed by the common diagnosis of “amputee,” with no initial consideration of individual limitations, abilities, challenges and environments.

Policy-excused neglect would begin during the use of an immediate prosthesis, when coverage would no longer be available for those patients requiring a replacement of their immediate post-operative socket due to substantial volume loss. It would continue during the mandatory 90 day preparatory prosthetic phase when individual considerations would be soundly ignored in the provision of a uniform, limiting, basic prosthesis.

The LCD would mandate that this training device be used for at least three months regardless of the patient’s successes or failures with the prosthesis. At the conclusion of that period, patients would be required to demonstrate minimum competencies to *earn* eligibility for an individualized prosthetic prescription. Those unable to do so would remain in their training device in perpetuity, with no access to definitive prosthetic care.

Those capable of meeting these standards would then begin a series of medical appointments and delays as they move from one professional to the next to satisfy the policy demands of the draft LCD. Throughout this time consuming process, they would remain in their limited training prosthesis, despite having demonstrated their candidacy for a definitive one.

The cumulative effect of the draft LCD policies would be a substantial delay in the time between an amputation and the thoughtful consideration of which prosthetic components are most appropriate for a given individual’s physical presentation, environment, and activities. In the best cases, individualized care would be delayed some 6-12 months. In alternate scenarios, patients who could be successfully fit with a prosthesis under the current LCD would become victims of attrition to a process designed to ration prosthetic utilization to the most able individuals with little regard to those facing additional challenges such as weakness, shorter residual limb lengths and other limiting comorbidities.

Introduction

Existing Standard: Timely Provision of an Individualized Prosthesis

In the current LCD, the individual consideration and provision of the most appropriate prosthesis for a given patient is not subject to policy-mandated delays. Rather, it begins with the collective assessment of the treating physician and prosthetist based on the following:

“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.**”

Under this model, the unique characteristics of every patient are considered and addressed from the outset of treatment.

Proposed Revisions: A Series of Cumbersome, Restrictive Timelines that Rations Access to Prosthetic Technology and Delays Care

The draft LCD proposes the introduction of arbitrary time frames and waiting periods before determining whether a patient is eligible for individualized prosthetic rehabilitation. Those that are would be encumbered with added visits to doctors or other Licensed/Certified Medical Professionals for in person examinations and the generation of prescriptions. The flow of care from immediate to preparatory to definitive prostheses is largely based on arbitrary, restrictive time frames that fail to consider the individual needs of the patient.

Immediate Prosthesis

In the draft LCD, the immediate prosthesis is “*provided after surgery, while the surgical incision is still healing*” to a “*beneficiary is motivated to ambulate using the prosthesis*”.¹ The draft LCD establishes the time frame of the immediate prosthesis phase to be until the wound heals and the patient is ready for a preparatory prosthesis.

The draft LCD proposes arbitrary restrictions on revisions or replacements of this immediate prosthesis:

“Medicare payment for prosthetics includes all fitting and adjustments necessary in the 90 days after provision ... of the prosthesis, therefore **all additions, adjustments, modifications, replacement** etc. to any components provided as part of the prosthesis and billed separately **during the 90 days after provision of the prosthesis will be denied as unbundling....Socket or other component replacements provided during the 90 days after provision of the immediate prosthesis will be denied as unbundling**”¹

The immediate prosthesis phase, or the time required to heal a wound and attain readiness for a preparatory prosthesis, can vary dramatically, from as short as 3 week to as long as 4 months.²⁻³ In their recent publication, Ali et al articulate the need for frequent cast changes with the immediate prosthesis, beginning as early as 1

week and continuing until the fitting of the preparatory prosthesis to account for remolding of the residual limb and to assess wound healing.² Such additional cast changes, currently covered by the existing LCD when required, would be precluded from coverage by the draft LCD irrespective of the amount of volume reduction experienced by the limb and the medical necessity for reapplication. In the absence of enabling cast changes as required, the useful period of the immediate prosthesis would be arbitrarily limited by policy, rather than determined by medical evaluation.

Preparatory Prosthesis Phase: From Wound Healing to 90 days (and well beyond)

The LCD revisions dictate that the preparatory prosthesis be “*provided after the surgical incision has healed.*” During this period the beneficiary must start or be scheduled to start a rehabilitation program.¹ The preparatory phase is characterized by significant shrinking of the residual limb as patients increase their weight bearing and begin ambulation.³ Modifications are expected as the patient’s residual limb remodels, and their functional capacity increases.³ However, as with the Immediate Prosthesis Phase, the LCD makes no allowances for those individuals who may require substantial changes to their prosthesis during this phase.

Upon receipt of the preparatory prosthesis the LCD asserts that any “additions, adjustments, modifications, replacement etc to any components provided as part of the prosthesis,” billed within 90 days of the patient’s receipt of the prosthesis will be denied. In addition, the LCD later states, “A replacement preparatory prosthesis provided sooner than 90 days after a previous preparatory prosthesis will be denied...” Finally, the LCD later clarifies that “a definitive prosthesis may not be provided sooner than 90 days after the preparatory prosthesis.” **Accordingly, there is ultimately no mechanism to address individual situations in which drastic changes in limb volume are experienced.** Such patients would need to wait 90 days from the receipt of their prosthesis before they would be eligible for a replacement preparatory or definitive prosthesis.

By LCD definition, the preparatory prosthesis is restricted to the most basic prosthetic components, including a 1950’s era SACH foot,⁴ the single axis knee (*described as the most unstable knee configuration available in existing prosthetic technology*)⁵ and an absence of any protective interface between the healing residual limb and the liner (See *Requiring "Demonstrated Performance" with Antiquated Prostheses to Qualify for a Modern Era Prosthesis* at www.saveprosthetics.org). The ability of many patients to tolerate, let alone rehabilitate with such a prosthesis would be very questionable. The LCD addresses such situations stating simply, “*If the patient is unable or unwilling to use the prosthesis, the claim will be denied as not reasonable and medically necessary.*” Restated, failures to progress during this 90 day preparatory phase would be view as the fault of an unable, unwilling patient, rather than an uncompromising, ration-based coverage policy.

Exceptional patients who are able to progress within the limitations of the coverage policy during this phase would not be eligible for an individualized definitive prosthesis until the conclusion of the policy-based 90 day time frame, irrespective of their limb maturity or functionality

By severely restricting both the level of prosthetic technology and the prosthetist’s ability to revise the preparatory prosthesis to match patient changes, set-backs or improvements, individual progress would be largely determined by the LCD policy rather than the patient.

Definitive Prosthesis Phase: a Cumbersome Process For Those That are Able to Earn It.

After the preparatory phase is completed, operationally defined as when a patient presents with a mature residual limb at least 90 days after the receipt of their preparatory prosthesis, the patient enters into a process that will hopefully end in the fitting of an appropriate definitive prosthesis. As the “*definitive prosthesis may not be provided sooner than 90 days after the preparatory prosthesis,*” individualized prosthetic care cannot begin until at least 3 months *after* the surgical incision has healed.

However, the draft LCD states that “*An initial definitive prosthesis is (only) covered for a beneficiary who meets all of the criteria below.*”¹ It then proceeds to describe a series of burdensome and time consuming requirements, the effects of which would range from *inconvenient* to *prohibitive* according to the abilities and limitations of each individual amputee. The cumulative time requirements become increasingly important as preparatory prostheses, which are only meant to be used as a short term gait training tool⁶ would need to meet the continued needs of individual patients as they continue in their attempts to earn access to a definitive prosthesis intended for longer term use.

Hurdle #1: Meeting the rehabilitation goals:

To qualify for a definitive prosthesis, the patient would need to “successfully complete”¹ their rehab during the preparatory prosthesis phase. “Successful completion” dictates that the following goals have been met:

“...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

Significantly, the use of a preparatory prosthesis during a rehabilitation program is designed to get the patient **prepared** for the use of a definitive prosthesis, not perfect their gait and function. Under the draft LCD, patients would not have access to their final prosthetic technology during these assessments. Rather, would be trying to achieve very difficult goals while using a very basic prosthesis.

While individual patients may be reasonably able to perform some of the goals, others become increasingly unrealistic for many amputees. For example, the research has consistently and clearly shown that lower extremity amputee patients at all levels expend more energy during walking than able-bodied persons.⁷ To assume that anyone with a prosthesis will achieve an “ease of movement and energy efficiency” with a rationed prosthesis that limits functionality, and do so within 3 months of the healing of their surgical incision is both overly ambitious and unsupported by the literature. Yet patients who are unable to do so will have no recourse but try to meet the demands of daily activity with a training prosthesis intended for short term use.

Hurdle #2: Adding delay – getting to the prescription

Before qualifying for a definitive prosthesis a patient must then see their physician for an in-person, comprehensive specialty examination to assess their readiness for a definitive prosthesis. The examination would be required to include the patient’s over-all health status, cognitive capacity, neuromuscular control, cardio-pulmonary function and global activity.

In metropolitan areas, **the average await time to see a physician is 18.5 days.**⁷ That number is likely higher for people seeking longer appointments with specialists (like physiatrists) or for people accessing a specialist from a rural area. If a 30 day wait time is assumed, the patient is now 4 months removed from the healing of their surgical incision. While a comprehensive evaluation is reasonable and appropriate, the mandate that it occur at the conclusion of the rehabilitation period would serve to further delay the time to individualized prosthetic care and lengthen the time that patients are required to endure the limitations of their training prostheses.

However, the referring physician would also have the option of referring this specialty evaluation to another medical professional with expertise in prosthetic care, such as a Physical Therapist (PT). If this occurs, the process of receiving a definitive prosthesis would be pushed even farther out, as many PT clinics have a wait time of 2 weeks or more. If this conservative estimate is used, the patient would now be 4 ½ months removed from the healing of their surgical incision.

The physician would then need to see the patient again if the specialty evaluation was referred out to another medical professional. Conservatively assuming the evaluation report was delivered to the physician within a week and taking into account an average of 3 weeks to get another visit, the wait for individualized prosthetic care has now increased to 5 ½ months.

At this second “post evaluation” visit the physician can write the prescription to for the prosthesis. The LCD allows the physician 45 days to deliver that prescription and a written report of the examination to the prosthetist. The patient’s wait time for individualized, definitive prosthetic care is now up to 7 months from the healing of their surgical incision. Moreover, following the mandatory 3 month trial of the required preparatory prosthesis phase, the patient will have now spent an additional 4 months in a very limiting training prosthesis.

When the prescription is made available, the prosthetist must perform a mandated “in-person evaluation “*...to evaluate prosthetic needs consistent with the overall functional capabilities identified by the medical examination*”¹ and within the limits of the prescription. After this evaluation, the prosthetist will design the best possible system for the patient, order the components and fit and fabricate the device. Typically the finished definitive prosthesis can be delivered in 3-4 weeks.

Ultimately, within the parameters of the draft LCD, eight months could reasonably lapse between the healing of the patient’s surgical incision and receipt of individualized prosthetic care. While the LCD suggests that the preparatory prosthesis phase is a 3 month requirement, the associated delays of multiple appointments with numerous specialists, coupled with inherent delays in the transfer of medical information such as chart notes and evaluations would add several additional months of delay to the receipt of the definitive prosthesis.

Conclusion

The cumulative effect of the draft LCD policies is a substantial delay in the time between amputation and a thoughtful consideration of which prosthetic components are most appropriate of a given individual’s physical presentation, environment, and activities. Under the current LCD, individualized care begins immediately after the amputation. Under the draft LCD, initial care is rationed by the common diagnosis of “amputee.” In the best cases, individualized care is delayed some 6-12 months. In alternate scenarios, patients who could be successfully fit with a prosthesis under the current LCD would become victims of attrition to a process that appears to have been designed to ration prosthetic utilization to the most able individuals with little regard to those facing additional challenges such as weakness, shorter residual limb lengths and other limiting comorbidities.

References

1. Medicare Draft LCD: Lower Limb Prosthesis (DL33787).
2. Ali MM, Loretz L, Shea A, Poorvu E, Robinson WP, Schanzer A, Messina LM, Baril DT. A contemporary comparative analysis of immediate postoperative prosthesis placement following below-knee amputation. *Ann Vasc Surg.* 2013 Nov;27(8):1146-53.
3. Preoperative Management of the Lower Extremity Amputee. Stages of Care. http://www.oandp.org/olc/lessons/html/SSC_02/07stages.asp?frmCourseSectionId=514F4373-8EDF-434A-BA08-C221FA8ABD71. Accessed 8/11/15.
4. Staros A. The SACH (solid-ankle cushion-heel) foot. *Ortho Pros Appl J.* 1957 June-Aug:23-31.
5. Uustal H, Baerga E. Prosthetics and orthotics. In: Cuccurullo SJ, editor. *Physical Medicine and Rehabilitation Task Force.* 1st ed. New York, New York: Demos Medical Publishing; 2004. p. 416-57
6. Esquenazi A and DiGiacomo R. Rehabilitation After Amputation. *J Am Podiatr Med Assoc.* 2001; 91(1): 13-22.
7. The Washington Post. January 29, 2014. <http://www.washingtonpost.com/news/wonkblog/wp/2014/01/29/in-cities-the-average-doctor-wait-time-is-18-5-days/>. Accessed 8/11/15.