

August 28, 2015

**SUBMITTED VIA ELECTRONIC MAIL**

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**Re: Proposed/Draft LCD on Lower Limb Prostheses (DL33787)**

Dear Dr. Brennan:

On behalf of the American Physical Therapy Association (APTA) and its 90,000 member physical therapists, physical therapist assistants, and students of physical therapy, APTA respectfully submits the following comments regarding the National Government Services (NGS) draft local coverage determination (LCD) for Lower Limb Prostheses (DL33787). We commend NGS for recognizing the vital importance of providing coverage to Medicare beneficiaries for lower limb prosthetics. However, we are concerned about several provisions in the LCD that could impede a beneficiary's ability to receive medically necessary care as an amputee.

Physical therapists are licensed health care professionals, and their work with patients with prosthetics to restore functional capacity and mobility is a recognized part of the physical therapy practice. Physical therapists play a primary role in the assessment and treatment of patients with amputations to provide care for evaluation of prosthetics, pre-prosthetic training, and prosthetic training. Physical therapists treat patients in a number of settings including hospitals, skilled nursing facilities, outpatient practices, and home health agencies.

The draft LCD will have an impact on the provision and quality of services delivered by physical therapists and physical therapist assistants and, therefore, we are interested and involved stakeholders in the development and implementation of this policy. APTA's

primary concern with this draft policy is the detrimental impact these proposed LCD changes will have on the care of patients with amputations and the patients' ability to function, including their activity and participation in daily living.

While the draft policy does not contain any language excluding physical therapists from treating patients with prosthetics, it does impact the ability of a therapist to provide the appropriate medically necessary care if they are providing therapy to a patient who has received an ill-fitting, or non-customized prosthetic or component based on Medicare coverage policies. This would inhibit the patient's functional capacity and ability to improve function as well as potentially cause medical issues that further complicate the condition.

APTA understands the difficult balance of providing quality care that is medically necessary while attempting to curtail costs. However, this LCD has the potential to result in lower quality of care while ultimately increasing costs. In the long run, costs could be higher to Medicare due to complications associated with prosthetics that were inappropriate for the patient due to restrictive requirements, were provided untimely, or were not provided at all.

APTA submits the following concerns and highlights some potential adverse patient impacts:

### **1. Definition:**

**Preparatory Prosthesis:** *“A preparatory prosthesis is an unfinished, functional replacement for an amputated limb, fitted and aligned to accelerate the rehabilitation process, control edema, and prepare the residual limb for the external forces associated with the wearing of a prosthesis on a day-to-day basis. It is provided after the initial surgery after the wound has healed but before the residual limb has matured. Preparatory prostheses are for use during the time after amputation when the residual limb is healing and maturing prior to the provision of the definitive prosthesis.” (p. 3, paragraph 2)*

The draft LCD fails to acknowledge accepted standards of care by limiting the definition of a preparatory prosthesis to an artificial limb provided only “after the initial surgery.” In practice, physical therapists may create and fit preparatory prostheses when the residual limb still needs to mature and/or the patient requires additional intermediary use of a prosthesis in preparation for a definitive prosthesis, or when the patient is unable to use the limb for an extended period of time due to other conditions or medical complications. Restricting the use of a preparatory prosthesis at other times as the qualified health care professional deems medically necessary could result in increased costs, decreased patient function, skin breakdown, and subsequent infection.

### **2. Initial Immediate Prosthesis**

**LCD Section II. “Initial immediate prostheses (L5400-L5460) are covered for a beneficiary with a new or revised amputation when all of the requirements below are**

*met: (1) The beneficiary has had an appropriate above or below knee amputation; (2) The immediate prosthesis is provided after surgery, while the surgical incision is still healing; and (3) The beneficiary is motivated to ambulate using the prosthesis.” (p. 3, paragraph 9)*

**“Unable or Unwilling:** *“If the beneficiary is unable or unwilling to use the prosthesis, the claim will be denied as not reasonable and necessary.” (p. 4, paragraph 2, p.5, paragraph 2 and p.6, paragraph 2 – below bullet point section)*

The words “unable or” should be eliminated. In clinical practice, some patients become unable to use a prosthesis after receiving it even when the qualified practitioner correctly confirms the beneficiary’s willingness to ambulate, as well as for reasons that the qualified practitioner could not predict. An amputee is dealing with the psychological impacts of an amputation, and that can impact the timeline of accepting the prosthesis. The patient should not be penalized for this through the imposition of subjective language that is easily subject to misinterpretation, and this should certainly not be a basis for impeding a patient’s ability to receive a prosthesis.

**LCD Section III.** *“A preparatory prosthesis (L5500-L5600) is covered for a beneficiary with a new or revised amputation when all of the requirements below are met: (1) The beneficiary has had an appropriate above or below knee amputation; (2) The preparatory prosthesis is provided to a beneficiary starting a rehabilitation program; (3) The preparatory prosthesis is provided after the surgical incision has healed; and (4) The beneficiary is motivated to ambulate using the prosthesis.” (p. 4, paragraph 11)*

APTA agrees with other stakeholders that the draft LCD should clarify the setting(s) in which a “rehabilitation program” occurs. Depending on the circumstances and timing of the injury and recovery, the rehabilitation needs of a new amputee may vary widely. Considering these factors (among others), both outpatient and inpatient rehabilitation programs should be considered sufficient.

We also recommend the deletion of the requirement that the surgical incision must have “healed” before the patient receives a preparatory prosthesis. Many patients’ incisions do not heal quickly due to circulatory problems, diabetes, and other medical conditions. To delay the order for the initial prosthesis until the incision is healed is problematic for the patient because this will delay their rehabilitation. It is important to begin prosthetic training as soon as possible after surgery (even during healing) so that a patient’s progress is not delayed.

Additionally, requirements that patients must have a healed incision site and must be starting a rehabilitation program will create additional documentation hurdles for prosthetic providers, which also may further delay a patient’s access to medically necessary care.

#### **LCD Section IV. Definitive Prosthesis**

*“An initial definitive prosthesis is covered ...*

- ***[if t]he beneficiary [ ] has successfully completed a rehabilitation program.” (p. 5, final paragraph, 2<sup>nd</sup> bullet point)***

The draft LCD’s prohibition on coverage for a definitive prosthesis unless the patient has successfully completed a rehabilitation program threatens to limit amputees’ access to medically necessary prostheses. Access to a definitive prosthesis should not be tied to an individual amputee’s ability to complete an undefined rehabilitation program but, rather, should rest on a qualified health care professional’s written order confirming the patient’s readiness for a definitive prosthesis.

APTA is concerned about the numerous patients in rural areas who may not be able to access these programs due to issues such as transportation. Requiring amputees to complete a rehabilitation program when they are otherwise ready to utilize a definitive prosthesis may result in unnecessary delays to their clinical treatment, resulting in harm to the patient and additional medical complications.

- ***[if t]he definitive prosthesis is provided after the surgical incision is stable (healed).” (p. 5, final paragraph, 3<sup>rd</sup> bullet point)***

Generally, APTA agrees that a qualified practitioner delivers the definitive prosthesis as stated above, however, there are clinical situations that necessitate early fitting of the definitive prosthesis while the surgical incision is still healing. Requiring wound healing and completion of a rehabilitation program will delay the patient’s progress. It is important for prosthetic training to begin as soon as possible after surgery and to continue until the residual limb becomes used to weight bearing and has matured. To delay the ordering of the definitive prosthesis until after rehabilitation has been completed does not make sense. Using wound “healing” as a requirement could result in the need for more rehabilitation than would have been necessary if provided sooner, because additional rehabilitation will be needed after the prosthetic is received.

Additionally, while the residual limb is healing, the best way to ensure proper shaping and healing of the residual limb is to provide proper wrapping and weight bearing using a prosthetic device. If the patient is required to wait until the wound has healed, additional rehabilitation will be needed after receipt of the prosthesis for proper gait training with the prosthesis from the “toughening” of the residual limb within the socket, thereby increasing the costs.

- ***“...[if t]he definitive prosthesis is provided after the residual limb has matured.” (p. 5, final paragraph, 4<sup>th</sup> bullet point)***

The term “matured” should be defined to avoid confusion, as a patient’s residual limb continues to change during the first year (or more) of prosthetic use. The draft LCD should clarify this clinical fact.

- ***“...[if t]he beneficiary is cognitively capable of using the prosthesis to ambulate effectively at the determined functional level (K0 – K4).” (p. 5, final paragraph, 6<sup>th</sup>***

*bullet point)*

- ***“...[if t]he beneficiary has sufficient neuromuscular control to effectively and appropriately make use of the prosthesis at the determined functional level (K0 – K4).” (p. 5, final paragraph, 7<sup>th</sup> bullet point)***
- ***“...[if t]he beneficiary has sufficient cardio-pulmonary capacity to effectively use the prosthesis at the determined functional level (K0 – K4).” (p. 6, 1<sup>st</sup> bullet point)***

The above sections of the draft LCD related to cognitive, neuromuscular, and cardiovascular requirements to receive a definitive prosthesis are problematic. Many prosthetic users successfully achieve advanced functional status despite other conditions affecting their overall health. APTA is concerned that a claims reviewer’s determination who has limited direct knowledge of the amputee’s overall health condition, personal factors—such as family support and capability to successfully use a prosthetic—will be adversely substituted for a physician’s expert determination who actively manages that patient’s health care. This process will harm amputees by impeding their ability to receive medically necessary care. The individual amputee’s clinical needs are minimized in the interest of reducing administrative costs and burdens. While cognitive, neuromuscular, or cardiovascular conditions may affect a patient’s ability to use a prosthesis and are factors to consider when determining patient readiness for a definitive prosthesis, they should not be used to deny coverage for a patient who would benefit functionally from a definitive prosthesis.

### ***3. 90 day Provisions***

***“Medicare payment for prosthetics includes all fitting and adjustments necessary in the 90 days after provision (date of service (DOS)) of the prosthesis, therefore all additions, adjustments, modifications, replacement etc. to any components provided as part of the prosthesis [etc.] and billed separately during the 90 days after provision of the prosthesis will be denied as unbundling.”***

The requirement that all components provided during the 90 days after provision of the prosthesis will be denied, along with “[a] replacement preparatory prosthesis provided sooner than 90 days after a previous preparatory prosthesis will be denied ...” as unbundling is problematic. Related to this is the additional draft LCD statement, “a definitive prosthesis may not be provided sooner than 90 days after the preparatory prosthesis.” Absent are any pathways for an individual who requires replacement within that period to obtain the needed component or prosthetic. Often, the patient’s residual limb undergoes changes during the initial phase of training with the prosthesis. For example, if the residual limb shrinks enough, the patient would require a socket replacement. However, under this LCD, this replacement will be deemed medically unnecessary. By denying socket replacements—even when a patient’s residual limb has undergone significant shape and volume changes—will slow their rehabilitation by

delaying their access to well-fitting sockets, and could cause skin breakdown and risk for infection, further complicating and increasing the costs of their medical condition.

***4. Suspension Systems: “Claims for more than one method or type of suspension per prosthesis will be denied as not reasonable and necessary.” (page 8, last paragraph)***

The Suspension Systems section of the LCD eliminates coverage of some of the most effective suspension and fitting techniques to secure a snug fit between the residual limb and the prosthesis, as well as techniques and technologies that are in widespread use today. Poor or inconsistent suspension and fit of prosthetic limbs is a major contributor to skin breakdown and reduced function. Many of these patients lost their limbs due to circulatory problems. Introducing old technology that may create ill-fitting sockets and pistoning can cause skin breakdown that will be difficult to heal due to poor circulation.

The draft LCD’s prohibition on multiple suspension systems is inconsistent with the current standard of care. Qualified practitioners commonly use auxiliary suspension when amputees’ activities require additional securing of the prosthesis to their residual limb. For example, a qualified practitioner may fit an above-knee amputee with both a suction socket *and* a neoprene suspension sleeve for added security during activities where that individual may perspire, which can affect suction suspension. The draft LCD should not circumvent the clinical decisions of the qualified practitioner treating the beneficiary by prohibiting this type of individualized solution. Therefore, this section should be deleted.

***5. Eliminates or restricts coverage of multiple prosthetic knees, feet, and ankles***

We are concerned about the draft LCD restrictions on obtaining prosthetic knees, feet, and ankles as the needs of the patient change. Based on the evaluation of the patient, including motion and strength of the residual limb, upper extremity strength, overall endurance, balance, etc, the physical therapist can determine which type of knee or foot components would facilitate the patient’s independence and return to usual activity and participation. By restricting the components necessary for safe gait, balance, and function, this could increase the patient’s risk for falls, risk for skin breakdown due to poor gait mechanics, and the risk of non-use by the patient. As the patient increases their ability to use the prosthesis, a component may change based on the patient’s activity level. As patients become more mobile and return to their previous activity level, the components may need to change to accommodate the increased activity level.

***6. Functional Status***

APTA is concerned about the use of the phrase “the prosthesis must provide the appearance of a natural gait” under the Functional Status section. “Natural gait” is a subjective term, and potentially discriminatory, particularly when dealing with individuals with disabilities. Therefore, this phrase should be eliminated. Often patients attain excellent mobility with prosthesis yet do not have what would be deemed “a natural gait.”

We reiterate that equally as problematic is the language used throughout the draft LCD that beneficiaries must have “sufficient” cognitive capability, neuromuscular control, and cardiopulmonary capacity to “effectively” use prosthesis.

Additionally, the elimination of patient potential from revised functional level categories may significantly limit access to higher functional levels for patients who are progressing in the rehabilitation process.

### ***7. Restricted Access to Higher Quality Prosthetic Components***

Regardless of functional capabilities, the LCD could restrict access to higher quality prosthetic components if the patient has any form of mobility aid (walker, cane, etc.) already paid for under Medicare. A patient should not be penalized for using a walker, cane, or crutches for bathroom access during the night or for using the equipment to alleviate temporary skin irritation or soreness, by having access to prosthetic components restricted that would provide the patient greater mobility and a better quality of life.

APTA thanks NGS for the opportunity to comment on the Lower Limb Protheses draft LCD, and we look forward to working with NGS to craft patient-centered reimbursement policies that reflect quality health care for all Medicare beneficiaries. If you have any questions regarding our comments, please contact Gayle Lee, Senior Director, at (703) 706-8549 or [gaylee@apta.org](mailto:gaylee@apta.org).

Sincerely,

A handwritten signature in black ink that reads "Sharon L. Dunn". The signature is written in a cursive, flowing style.

Sharon L. Dunn, PT, PhD, OCS  
President