The Proposed/Draft LCD creates "Improvement Standards," in Direct Violation of Jimmo v. Sebelius:

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

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Summary

Recent court actions have upheld the prohibition against "*Improvement Standards*" in Medicare policy. Medicare's response to the settlement agreement was an acknowledgement that, "*…there may also be specific instances where no improvement is expected but skilled care is, nevertheless, required in order to prevent or slow deterioration and maintain a beneficiary at the maximum practicable level of function* ..." and that, *"a beneficiary's lack of restoration potential cannot, in itself, serve as the basis for denying coverage, without regard to an individualized assessment of the beneficiary's medical condition and the reasonableness and necessity of the treatment*…"

However, the practice guidelines established by the proposed LCD would effectively create "improvement standards" in prosthetic care. Under the proposed guidelines, all patients, regardless of condition, limitations and needs would receive an identical preparatory prosthesis with no additions or enhancements. Reasonable prosthetic technologies historically viewed as both reasonable and medically necessary would only be made available to those patients who met the new "improvement standards" at the end of their rehabilitation program with their preparatory prosthesis.

The improvement standards would be out of reach for many patients, especially considering the limited prosthetic technology made available to them during the rehabilitation program. These standards include independent donning and doffing of the prosthesis, independent transfers with and without a prosthesis, daily wear tolerance, and sufficient balance and stability to ambulate with ease of movement and energy efficiency.

The majority of those patients who fail to meet these "improvement standards" would otherwise benefit from an individualized prosthetic prescription that considers their individual limitations. Prosthetic technologies long held as both reasonable and medically necessary for this cohort of patients might include axial feet, knees with inherent stability and interface liners. Such technologies are of particular value to the amputee with limited capabilities.

The prosed LCD refuses to acknowledge that there are "maximum practicable levels" of prosthetic function that fall short of the "improvement standards" and yet contribute to the health of well-being of the individual. To deny access to reasonable prosthetic components that would assist patients in reaching and maintaining the "maximum practicable levels" of function because of their inability to demonstrate a series of artificially defined standards creates a prosthetic "improvement standard" counter to Medicare's stated policy.

Introduction

On January 24, 2013, the U. S. District Court for the District of Vermont approved a settlement agreement in the case of *Jimmo v. Sebelius*, in which the plaintiffs alleged that Medicare contractors were inappropriately applying an "Improvement Standard" in making claims determinations for Medicare coverage. Medicare has maintained that there has never been an "Improvement Standard" in place when reasonable care is needed to prevent or slow deterioration and maintain a beneficiary at the maximum practicable level of function. However, the proposed language of the draft LCD would effectively create such a standard in prosthetic care, where many new amputees would be denied *reasonable and necessary* prosthetic care that would otherwise enable them to maintain a basic level of safe function and prevent further deterioration in their physical health.

Existing Standard: Recognition that there may be instances where no improvement is expected but individualized assessment and care are indicated

According to the Medicare Fact Sheet on the Jimmo v. Sebelius Settlement Agreement:

> "While an expectation of improvement would be a reasonable criterion to consider when evaluating, for example, a claim in which the goal of treatment is restoring a prior capability, Medicare policy has long recognized **that there may also be specific instances where no improvement is expected but skilled care is, nevertheless, required in order to prevent or slow deterioration and maintain a beneficiary at the maximum practicable level of function**."[1]
>
> "**The Medicare statute and regulations have never supported the imposition of an "Improvement Standard" rule-of-thumb in determining whether skilled care is required to prevent or slow deterioration in a patient's condition**. **A beneficiary's lack of restoration potential cannot, in itself, serve as the basis for denying coverage**, **without regard to an individualized assessment of the beneficiary's medical condition and the reasonableness and necessity of the treatment, care, or services in question."**[1]

The language clearly acknowledge is that there will be instances in healthcare where improvement is not reasonably expected but patients will still require care to prevent or slow deterioration and maintain "maximum practicable" level of function. Further, the lack of restoration potential cannot serve as a basis for denying coverage without an individualized assessment of the patient and the reasonableness of the services in question.

Existing Standard: Individualized expectations and prosthetic resources where decisions are based on the patient's current condition and other medical problems

In the existing language of the LCD, the standards for coverage are very general, reflecting the diversity of ability and potential within the amputee community:

> "A lower limb prosthesis is covered when the beneficiary:
>
> 1. Will **reach** or **maintain** a **defined functional state** within a reasonable period of time; and

2. Is motivated to ambulate."[2]

Further, the medical necessity for prosthetic components and additions are based on "the beneficiary's potential functional abilities." This phrase is further defined:

> "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."[2]

Under these guidelines, the physician and prosthetist could collectively consider the individual conditions of the patient and determine the most appropriate initial prosthetic components provided they were consistent with the patient's assigned K-level. For example, if a patient with a transfemoral amputation has a short residual limb which would thus have difficulty keeping a single axis knee joint fully extended and not buckling, the physician and prosthetist could select an alternative knee joint that would provide mechanical stability keeping the knee from buckling[1].

Proposed Revision: Establish "Improvement Standards" that must be met with an archaic, limited prosthesis before any individual challenges and limitations are considered or acted upon.

In the revised language of the proposed LCD, a series of "Improvement Standards" are introduced. To be eligible for a definitive prosthesis, a patient must demonstrate the following at the conclusion of a 90 day rehabilitation program:

- "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"[3]

- "**A definitive prosthesis** provided to a new amputee who has not successfully completed a prosthetic rehabilitation program **will be denied** as not reasonable and necessary."[3]

These policies would constitute an "Improvement Standard" in which individualized prosthetic care is withheld until patients are able to demonstrate the stated abilities. The standards are exclusionary to many prosthetic users who might lack full restoration potential but would still benefit from appropriate care. For example, some patients may require assistance with such tasks as donning/doffing the prosthesis or transfers, and yet still benefit from daily standing and ambulation with an appropriate prosthesis.

Reasonable Care Requires Individualized Assessment

In contrast to the position of the LCD that all patients can function adequately with a standard, basic prosthesis, consensus medical opinion holds that the *past history, current medical condition, and other medical problems* of a given patient should be taken into account when determining the most appropriate

prosthesis. The limitations assigned to the mandatory preparatory prosthesis fail to provide basic prosthetic technologies known to address challenges commonly faced by many amputees.

Individual Foot Considerations

In contrast to the severe limitation of SACH feet, single and multi-axial feet are known to provide rapid foot flat during weight acceptance, increasing the base of support throughout the gait cycle and enhancing knee stability.[4] This is of particular value to transtibial patients with weak knee extensors and transfemoral patients with weak hip extensors or a short residual femur. However, these individual patient considerations could not be taken into considerations and addressed during the earliest phases of prosthetic rehabilitation on the proposed LCD guidelines.

Individual Knee Considerations

Similarly, Michaels described a decision tree for the selection of the most appropriate knee mechanism.[5] The first question within that decision tree is: *Is the patient able to control prosthetic knee stability under all circumstances.* If the answer is yes, the single axis knee included in the base code for definitive transfemoral prostheses (and presumably included within the provision of a preparatory prosthesis) is recommended. If the patient is unable to do so, Michaels decision tree leads to the contemplation of three additional knee mechanism, including polycentric knee geometries, friction based stance control and manual lock features, all of which were designed decades ago to enhance the stability of the prosthesis, and none of which could be provided during the early phases of prosthetic rehabilitation under the proposed LCD guidelines.

Individual Interface Considerations

Many new amputees present with residual limbs that are at risk for tissue breakdown when they are called upon to support the weight of the body. It is well known that the use of gel liners can reduce pressures on the residual limb,[6] and results in improved limb comfort.[7] And yet, this established technology would be unavailable to the patient during their rehabilitation program with a preparatory prosthesis.

The examples above represent some of the established prosthetic technologies that could be used to help patients fulfill their individual capabilities while considering their individual challenges and limitations. However, none of them are made available to an individual patient until the reach the "Improvement Standards" prescribed in the proposed LCD.

"Maximum Practicable Levels" of Prosthetic Function exist beneath the Improvement Standards

The creation of the "improvement standards" within the proposed LCD neglects the reality that maximum practicable levels of prosthetic function exist beneath these standards, that patients with limited abilities benefit from the use of their prostheses at these levels and that access to reasonable prosthetic resources beyond the restricted nature of the mandated preparatory prosthesis will enable improved functionality. Sansam et al.[8] reported a patient's age, gender, level of amputation, contracture degree, ability to stand on one leg, and cognitive ability could explain as much as 59% of the patient's mobility level. It would be unreasonable to assign uniform improvement standards that fail to consider these and other individual characteristics.

A patient who is unable to independently don his prosthesis may is likely to benefit from a single axis foot that increases his stability during household transfers and ambulation. A patient who is unable to transfer

without the assistance of a walker is likely to benefit from a knee joint with some mechanism providing inherent stability. I patient who is unable to attain sufficient wear tolerance for a normal day's activities if given access to an interface liner that protects the fragile tissues of the residual limb. And yet none of these resources would be made available until after a patient cleared the "improvement standards" of the LCD.

Conclusion

The LCD proposes a number of "improvement standards" that must be met before a patient is eligible for coverage for well-established prosthetic technologies that good enhance their functionality. This position is counter to Medicare's stated position that "A beneficiary's lack of restoration potential cannot, in itself, serve as the basis for denying coverage, without regard to an individualized assessment of the beneficiary's medical condition and the reasonableness and necessity of the treatment, care, or services in question." Ultimately, patients should be allowed the opportunity to define success based on their personal limitations and be provided a reasonable prosthesis that permits reaching that defined level of success.

References

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