

# Natural Gait: A Reasonable Goal but an Unreasonable Requirement

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

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## Summary

The proposed changes to the lower limb prosthetics LCD dictate that a prosthesis must enable multiple subjective, immeasurable requirements. Among these is the directive that the prosthesis must provide “the appearance of natural gait.” Such a directive dismisses the fact that the appearance of a natural gait is a subjective outcome and that amputees routinely present with gait deviations. In fact, some gait deviations may even be necessary and beneficial to prosthesis users. Such a directive also presumes the prosthetist to have complete control over amputee gait when in reality many gait deviations are beyond the prosthetist’s control. While the semblance of a natural walk is a reasonable goal for many patients, the unreasonable requirement of a subjectively assessed “natural gait” would almost certainly be used to deny coverage eligibility and reimbursement in prosthetic care.

Currently, the LCD allows for provision of reasonable prosthetic technology and components in order to improve functionality. The requirements are intentionally left ambiguous, deferring the determination of what will constitute *improved function* for a given individual to the medical professionals working with that patient. The proposed changes call for “the appearance of a natural gait”, yet do not provide a method to objectively quantify or determine this mandate.

The proposed LCD continues to find its requirements in conflict the literature. For example, In a study of community ambulating lower limb amputees, it was found that gait deviations do not correlate with patient satisfaction (Kark and Simmons, 2011).

Further, a “natural” gait may not always be in the best interest of the patient. For example, Hak et al. showed a shorter prosthetic step contributes to improved walking balance (Hak et al., 2014). Similarly, Bolger et al. observed that transtibial amputees successfully utilize an asymmetric force distribution between the prosthetic and sound limbs to effectively maintain balance (Bolger, 2014). Childers and Kogler found the *appearance* of a symmetric gait does not mean symmetric underlying forces (Childers and Kogler, 2014). These asymmetric forces may contribute to comorbid fractures, osteoarthritis, and muscle and ligament strains.

For other patients, co-morbid limitations would preclude their ability to attain a “natural gait”. This includes transfemoral patients with shorter residual limbs or weakened hip abductors that may walk with lateral trunk bending (Kapp, 2004). Similarly, patients that present with flexion contractures on their affected side will tend to walk with a shorter sound-side step due to limited range-of-motion in the affected limb (Kapp, 2004). Indeed the restrictions within the proposed LCD would create additional examples such as the patient with a transfemoral amputation that walks at different speeds but is limited to a non-fluid damping knee joint by the proposed LCD because they are in their mandated preparatory prosthesis or prefer to use a cane during outdoor ambulation. In this instance, *unnatural gait asymmetries* would occur as the patient waited for the delayed swing period of the friction knee.

Finally, the subjective nature of this directive may represent a continued effort to creatively to deny reimbursement for prostheses that have already been provided.

## Introduction

The proposed changes to the lower limb prosthetics LCD dictate that a prosthesis must enable multiple subjective, immeasurable requirements. Among these is the directive that the prosthesis must provide “the appearance of natural gait.” Such a directive dismisses the fact that the appearance of a natural gait is a subjective outcome and amputees routinely present with gait deviations. In fact, some gait deviations may even be necessary and beneficial to prosthesis users. According to Winter with regards to amputee walking,<sup>1</sup> “...any human system with major structural asymmetries in the neuromuscular and musculoskeletal systems cannot be optimal when the gait is symmetrical. Rather, a new nonsymmetrical optimal is probably being sought by the amputee within the constraints of his residual limb and the mechanics of his prosthesis.” Asymmetries between the prosthetic and sound limb will always exist following a lower limb amputation, compromising the capability of the patient and their prosthesis to demonstrate a “natural gait.” Finally, such a directive from the LCD also presumes the prosthetist to have complete control over amputee gait when in reality many gait deviations are beyond the prosthetist’s control. While the semblance of a natural walk is a reasonable goal for many patients, the unreasonable requirement of a subjectively assessed “natural gait” would almost certainly be used to deny coverage eligibility and reimbursement in prosthetic care.

## Existing Standard: Reasonable Care with Reasonable Requirements

Currently, the LCD allows for provision of reasonable prosthetic technology and components in order to meet reasonable requirements. The current LCD reads:

“For any item to be covered by Medicare, it must ... **be reasonable and necessary** for the diagnosis or treatment of illness or injury or **to improve the functioning of a malformed body member**”

This statement highlights the importance and need for any prosthesis provided to have a positive impact on the life of the beneficiary. However, the phrasing is intentionally left ambiguous, deferring the determination of what will constitute *improved function* for a given individual to the medical professionals working with that patient. This is done to avoid uniform, subjective mandates that may be unattainable in individual cases.

## Proposed Revision: Mandate of the Unreasonable (and Potentially Impossible)

Changes found within the proposed LCD are simply not reasonable, and potentially impossible. The proposed LCD states:

“The prosthesis provided **must provide**:

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

There is no inclusion of a prescribed method to objectively quantify or determine the appearance of a “natural gait.” There is no criterion expressed for qualifying a gait as “natural.”

Rather, there is the naive sentiment that a prosthetist and the prosthesis they provide have complete control over all gait deviations, many of which may actually even be beneficial for the amputee.

### **Another instance within the proposed LCD unsupported by the literature**

In a study of 20 community ambulating amputees, Kark and Simmons<sup>2</sup> reported that an amputee's satisfaction with their prosthesis correlates with their self-reported ambulation skill, the utility of their prosthesis, frustrations associated with using the prosthesis, and the perceived response and social burden with friends and family. By contrast, **gait deviations did not correlate to patient satisfaction**, leading to their conclusion:

**“Gait deviation was not a significant correlate of patient satisfaction.** Results suggest that improving self-perceived functional ability and attitudes toward the prosthesis, rather than minimizing gait deviation, will improve patient satisfaction.”

It is not understood why such weight is placed in a natural gait when it has very limited bearing on the beneficiaries' satisfaction. The role of patient satisfaction should not be dismissed, as noted further by Kark and Simmons<sup>2</sup>:

“Patient satisfaction and quality of care, although distinct, are highly correlated. This correlation is so well recognized that healthcare providers view satisfaction as a legitimate measure of quality of care, making it a necessary component of quality management systems.”

### **Is “Natural Gait” Always in the Patient’s Best Interest?**

By definition, “gait” refers to any means of locomotion that gets a person from one point to another<sup>3</sup>. Providing the patient with the ability to move from one point to another is highly reasonable and should be an expectation. This would include anything from walking to running to simple transfers that move a person from one point to another. Yet, it is not clear what will constitute “natural”. The term “natural” when referring to any human trait or quality is typically synonymous with “most common”. For lower limb amputees, walking or any other form of locomotion in a “natural” way may be neither possible, nor optimal.

Consider Hak et al.'s<sup>4</sup> findings regarding walking balance with patients that had a transtibial amputation. They observed that a shorter sound side step length kept an amputee's center of balance within the person's boundaries of support better, giving them better balance. They conclude<sup>4</sup>:

“The results of this study illustrate that the **asymmetry in the gait pattern** for people after transtibial amputation **is not necessarily a detrimental effect** of the impairment but could be beneficial in the regulation of gait stability.”

In this instance, gait deviations, or an *unnatural gait*, are suggested to be beneficial to the patient. Bolger et al.<sup>5</sup> had similar findings, showing transtibial amputees successfully utilize an asymmetric force

distribution between the prosthetic and sound limbs to effectively maintain balance. Again, highlighting the notion that a “natural” gait may not be possible or even beneficial for amputees.

The requirement of “natural gait,” naively assumes that a gait that appears symmetrical is in the best interests of the patient. This may not be the case. In a recent study, Childers & Kogler<sup>6</sup> effectively showed via a cycling task that even if the appearance of the movement is made to be symmetrical, this does not mean the underlying forces causing the movement are symmetric. The authors affirmed that the underlying forces will not and cannot be symmetrical in the presence of such major musculoskeletal asymmetries. Thus, the value of making movements appear symmetrical or “natural” can be reasonably questioned as the underlying forces may contribute to comorbid fractures, osteoarthritis, and muscle and ligament strains.

### **Is “Natural Gait” Attainable?**

Furthermore, Adamczyk and Kuo<sup>7</sup> were able to effectively demonstrate that it is not possible for a patient with a transtibial amputation to have a symmetrical walking pattern given the limitations of current prosthetic technology. These limitations have been partially reduced in more modern foot technologies including dynamically responsive feet that provide energy return in late stance. But, it is important to note that under the proposed LCD, such technologies would not be available for any patient’s preparatory prosthesis, and would be denied to any patient failing to attain the inflated standards proposed for K3 assignment. Ironically, the new LCD would deprive many amputees of the technology needed to more closely attain the “natural gait” that it appears to mandate.

For other patients, co-morbid limitations would preclude their ability to attain a “natural gait.” Transfemoral patients with shorter residual limbs or weakened hip abductors often walk with lateral trunk bending.<sup>8</sup> Similarly, patients often present with flexion contractures on their affected side which, while they can be accommodated within the prosthesis to allow the patient to walk, will cause the patient to walk with a reduced sound-side step length because of unavailable range-of-motion.<sup>8</sup> Another example that would actually be created by the LCD is the patient with a transfemoral amputation that walks at different speeds but is limited to a non-fluid damping knee joint as part of their preparatory prosthesis. When walking at faster speeds, these patients would unnaturally spend more time standing on the sound leg than their prosthetic leg as they wait for their mandated, archaic prosthetic knee to fully extend.<sup>9</sup>

### **Can an Optimal Prosthesis Ensure “Natural Gait?”**

Finally, putting a directive within the LCD that a prosthesis must provide the “appearance of a natural gait” infers that the prosthesis is entirely responsible for any gait deviations that disqualify the “appearance of a natural gait.” This is an unfounded assertion. Inadequate gait training during the mandated rehabilitation program could undermine a patient’s ability to attain a natural gait, as could the LCD requirement that active patients utilize a series of very different prosthetic components in their transition from an archaic preparatory prosthesis, into modern prosthetic technologies. Other deviations are simply the result of patient habit and preference,<sup>8</sup> yet such deviations could be used to deny reimbursement on an appropriately fitted and aligned prosthesis.

## **Reimbursement Implications**

The audit activity in recent years has underscored the creativity of continued efforts to deny reimbursement for prosthetic services that have already been provided. The inclusion of subjectively interpreted mandates imposed upon lower limb prostheses would almost certainly be used to ultimately deny reimbursement for cases where an individual with an appropriately made prosthesis failed to demonstrate a “natural gait” because of deficiencies in covered components, co-morbid limitations to their physical presentation, inadequate gait training or personal habits and preferences.

## **Conclusion**

The directive of “the appearance of a natural” is unreasonable. It dismisses the fact that many patients will present with gait deviations that do not limit their functionality. It also fails to recognize newly emerging scientific evidence that gait deviations may not only be unavoidable, but may potentially improve stability for the individual walking with a lower limb prosthesis. Finally, the mandate that a prosthesis provide the “appearance of a natural gait” infers that a prosthesis is the sole factor influencing a patient’s ability to walk without gait deviations. This is an inaccurate assumption which would tie a prosthetist’s reimbursement to factors beyond their control.

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