

# Using Cognitive Capability, Cardio-pulmonary Capacity and Neuromuscular Control as a Basis to Disqualify Amputees for Definitive Prosthetic Care in Proposed LCD: By What Standards and With What Rationale?

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

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## Summary

Under the current LCD, the treating physician evaluates an amputee with regard to such considerations as cognitive capability, cardio-pulmonary capacity and neuromuscular control to determine a reasonable “defined functional state” for the prospective prosthetic candidate. Under the draft LCD, the physician’s assessment is subverted by vaguely defined minimum standards in these three areas (ie, “*capable ...to effectively use.*”) This language invites equally subjective denials of eligibility based on audit and chart review rather than physician evaluation. For example, the use of hypertensive pharmaceuticals, prior stroke or history of vascular procedures could preclude coverage eligibility for prostheses, irrespective of their effects on the patient’s current function.

Compromises in cognitive capability, cardio-pulmonary capacity and neuromuscular control are commonly observed in the amputee population. While they can preclude successful use of a prosthesis in extreme cases, they do not do so consistently. For example, in their examination of over 200 amputee subjects, Roffman et al found that peripheral vascular disease, cardiac conditions, stroke and mental health concerns were more prevalent in the prosthetic users than in non-users (Roffman, 2014). Importantly, minimum standards of cognitive, cardio-pulmonary and neuromuscular function have not been objectively determined in the literature.

For example, there is no consistent measure or threshold for cognitive capability in the amputee population (Coffey, 2012) nor does cognitive compromise consistently preclude the use of a prosthesis (Phillips, 2012). In fact, patients with cognitive impairment experience functional improvements when given access to structured rehabilitation (Resnik and Daly, 1997).

Compromised neuromuscular control is extremely common among amputees. To illustrate, in their review of 4720 veterans with lower limb amputation, Prvu-Bettger et al observed that 43% had pre-existing neurological conditions (Prvu-Bettger, 2009). However, compromised neuromuscular control

does not preclude success with a prosthesis. In their study of transfemoral amputee with co-morbid hemiplegia, Brunelli et al observed that all patients were able to ambulate with a prosthesis when given access to an appropriate assistive device (Brunelli, 2006). Looking more broadly, in their systematic review of amputees with co-morbid hemiplegia, Herbert et al. observed that five of the seven studies from which a successful fit rate could be inferred had a success rate greater than 58% (Herbert et al, 2012).

Compromised cardiovascular compromise is ubiquitous among lower limb amputees with 82% of amputations in the US due to dysvascular etiology. However, this does not preclude success with a prosthesis, nor has the literature confirmed minimal cardiovascular standards for successful use of a prosthesis. To the contrary, in their study of 95 lower limb amputees with peripheral vascular disease, 84% ambulated within one level of their pre-amputation status at a 2 year follow up (Pinzur 1992). Similarly, reporting upon 543 unilateral amputees, 78 of which had co-morbid ischemic heart disease and 17 of which had co-morbid hypertension, Siriwardena and Bertrand reported that the majority of their cohort were ambulatory with their prosthesis 12 months after their amputations (Siriwardena and Bertrand, 1990).

Finally, the draft LCD attempts to tie K-level to the presence and extent of co-morbid compromises to cognitive capability, cardio-pulmonary capacity and neuromuscular control. Significantly, there is no scientific evidence relating the presence or extent of these comorbid conditions to the functional standards included in the individual K-level descriptors.

While comorbid compromise to cognitive capability, cardio-pulmonary capacity and neuromuscular control can limit or preclude prosthetic performance in extreme cases, there are no established minimal standards in the literature. As such, the impact of such comorbidities on a patient's functional abilities should be determined by the treating physician, not vaguely defined, unsupported policy language. Ultimately, the addition of these poorly defined subjective criteria would only serve to prevent otherwise capable amputees from receiving appropriate prosthetic care.

## Introduction

The proposed LCD revisions mandate minimum standards of cognitive capability, neuromuscular control and cardio-pulmonary capacity for patients to qualify for coverage of a definitive prosthesis. While extreme deficits in any of these three areas could potentially compromise or preclude successful prosthetic ambulation, the proposed revisions are unreasonably subjective and not supported by scientific evidence. Of equal concern, the poorly defined minimum standards of “*sufficient*” and “*capable...to effectively use*”<sup>1</sup> could be used to deny useful prosthetic coverage to individuals who would otherwise derive significant benefits from an appropriate prosthesis. Co-morbid conditions associated with some level of compromise in cognition, neuromuscular control or cardiopulmonary capacity are common in lower limb amputees and **do not inevitably preclude effective utilization of a lower limb prosthesis**. In fact, many patients with various levels of cognitive, neuromuscular and/or cardio-pulmonary compromise become successful, daily users of their prostheses.

## Existing Standard: Coverage for Lower Limb Amputations

In the current LCD, coverage for prosthetic technology is based on the reasonable expectation that the patient will benefit from an appropriate prosthetic fitting:

“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.”<sup>2</sup>

The open language of the policy allows the physician to evaluate such considerations as cognitive capability, cardio-pulmonary capacity and neuromuscular control in their determination of the “functional state” that might be reasonably expected of the individual.

## Proposed Revisions: Restrictions to prosthetics are based on vague disqualifications.

In the proposed revisions, coverage eligibility is dependent upon extremely vague descriptions of co-morbid medical conditions. Under the new proposal, the patient’s abilities and limitations would be determined through an evaluation by “a licensed/certified medical professional who has experience and training in the functional assessment of beneficiaries with amputations”<sup>1</sup>:

“The examination must be a comprehensive functional assessment that describes the beneficiary’s overall health status at the time of the examination. The treating physician or LCMP performing the examination must clearly and specifically document:

- The beneficiary is **cognitively capable of using the prosthesis** to ambulate effectively at the determined functional level (K0–K4).
- The beneficiary **has sufficient neuromuscular control** to effectively and appropriately make use of the prosthesis at the determined functional level (K0–K4).
- The **beneficiary has sufficient cardio-pulmonary capacity** to effectively use the prosthesis at the determined functional level (K0–K4).”<sup>1</sup>

The vague language of “capability” and “effective use” are poorly defined, inviting subjective interpretations by future auditors seeking to deny eligibility for prosthetic services on the grounds of any compromise to cognitive capability, neuromuscular control and cardio-pulmonary capacity. This is particularly concerning because of the frequency with which amputees who successfully utilize a

prosthesis present with these very conditions and yet derive significant benefits from their prosthetic devices.

### **Conflicts between the Proposed LCD and the State-of-the-Science**

The proposed LCD adds criteria for provision of an initial definitive prosthesis that are vague, poorly defined, and inconsistent with accepted standards of practice, thus allowing for subjectively based denials of coverage. Within the amputee community, while modest deficits to cognitive, cardio-pulmonary, and neuromuscular systems are common, they are rarely contraindications to the successful use of a prosthesis.

Roffman et al (2014) examined over 200 amputee patients to investigate which factors might impact successful prosthetic fitting.<sup>3</sup> The patients' co-morbidity data was recorded with commonly encountered conditions including peripheral vascular disease (PVD), cardiac conditions, stroke, and mental health conditions.<sup>3</sup> The high incidence of all these conditions is not surprising as the majority of lower limb amputations are performed due to complication with vascular disease<sup>4</sup> which can be a contributing factor for all these co-morbid conditions.<sup>5</sup> Importantly, **the prevalence of all these cognitive, neuromuscular and cardio-pulmonary conditions was higher in the prosthetic users than the non-users.**<sup>2</sup>

In an extensive literature review on this topic, Erjavek et al, were unable to find any supportive evidence that cognitive, neuromuscular or cardio-vascular conditions consistently limit or preclude successful use of prostheses.<sup>6</sup> While a number of factors potentially affect short and long-term prosthetic use, successful rehabilitation and societal reintegration have been rigorously investigated, **the literature is not aligned on definitions of “sufficient” cognition, neuromuscular control or cardiovascular status.** The use of these vague terms in the draft LCD, therefore, is unsupported by the extensive research done in this area.

### **The Concept of “Cognitively Capable”**

In a systematic review of 30 publications addressing the measurement of cognitive function in lower limb amputees, Coffey et al. failed to find agreement on an objective measure for “cognition”.<sup>7</sup> Phillips et al. conducted an in-depth study that administered an extensive battery of neuropsychological tests to patients with amputation after PVD. Importantly, they did not conclude that cognitive issues would preclude successful fitting of a prosthesis. Rather, the authors recognized that even those patients with significant impairment could still benefit from structured prosthetic rehab programs.<sup>5</sup> A related study by Resnik and Daly supported this conclusion, finding that individuals with cognitive impairment improved functionally over the course of a structured rehabilitation program and maintained their discharge level of functioning at one year follow-up.<sup>8</sup>

The vague description of being “cognitively capable” of prosthetic use is unsupported by related attempts within the academic literature. There is no evidence that cognitive compromise consistently precludes prosthetic utilization. In fact, the opposite trends have been observed, with cognitively challenged patients showing improved functionality when granted access to structured rehabilitation resources. Thus the inclusion of the arbitrarily defined and subjectively interpreted phrase “cognitively capable” is unsupported by the literature and could be unreasonably used to deny eligibility for prosthetic coverage for patients who are ultimately capable of successful prosthetic rehabilitation.

## What is “Sufficient Neuromuscular control?”

The issues surrounding what would constitute a “neuromuscular condition” are very broad. The rates of amputation due to vascular compromise such as arteriosclerosis, PVD and diabetes are very high, all of which have been associated with compromises to neuromuscular control. In addition, it is also not uncommon to see the dual impairment of comorbid CVA (hemiparesis) and amputation in the same patient. In fact estimates of the prevalence of a stroke in patients with lower extremity amputation range as high as 42%.<sup>9</sup> Accordingly, such neuromuscular conditions are not uncommon in patients who undergo lower-extremity (LE) amputation. **In their retrospective study of 4720 veterans with lower limb amputation, Prvu-Bettger et al found that 43% had pre-existing neurological conditions at the time of their amputation,** the most common of which were peripheral nerve injuries and hemiplegia.<sup>10</sup> While few studies have thoroughly examined the impact of these conditions on the prognosis for prosthetic rehabilitation,<sup>9-10</sup> the management of co-existing neurological conditions is a common aspect of prosthetic rehabilitation.

For example, Brunelli et al. studied 45 patients with a transfemoral amputation and hemiparesis admitted to rehabilitation after the second event.<sup>9</sup> **While the severity of hemiplegia was variable across their subjects, all were fitted with a prosthesis. At the end of the rehabilitation period all of the patients were able to ambulate independently.** Ultimately, 16 subjects used a walker, 16 used 2 crutches, 11 used a cane and 2 subjects ambulated without any assistive device at all.<sup>9</sup> **These results strongly support that with sufficient rehabilitation, an appropriate prosthesis and the use of suitable assistive devices, co-morbid neurologic conditions need not be unilaterally judged to be poor predictors of outcome.**

In summarizing the available data on the likelihood of patients with comorbid hemiplegia being successfully fit with a prosthesis, in their systematic review on the topic Herbert et al. observed that of the seven studies from which a successful prosthetic fit rate could be inferred, five had a success rate greater than 58 percent.<sup>11</sup> When more than half of those patients afflicted by the severe comorbid neuromuscular condition of hemiplegia successfully return to useful ambulation with a prosthesis, the presence of neuromuscular compromise cannot be reasonably used to deny eligibility for prosthetic coverage.

## What is “Sufficient Cardio-vascular Capacity?”

Dysvascular etiology accounts for the vast majority (82%) of amputations in the US, and the incidence is expected to rise as rates of co-morbid diseases such as peripheral vascular disease and diabetes continue to increase.<sup>4</sup> With this being the case it is obviously important to consider cardio-vascular health when evaluating a patient’s potential for successful prosthetic rehabilitation. However, **the proposed revision to coverage policy pertaining to cardio-vascular capacity is unclear,** stating only that “The beneficiary (must have) sufficient cardio-pulmonary capacity to effectively use the prosthesis at the determined functional level (K0–K4).” The language fails to detail a level of “cardio-vascular capacity” that would be considered sufficient to qualify for prosthetic coverage. Within these vagaries, the ultimate determination of eligibility would be at the discretion of claim auditors, who could use this LCD language to deny coverage based on a history of hypertensive medication, saphenous graft surgery or other vascular procedures.

Patients who have had an amputation due to PVD, diabetes, arteriosclerosis and other cardio-vascular conditions are, by definition, compromised in their cardio-vascular capacity. This, in and of itself, does not automatically assure poor success with a prosthesis. Many patients undergo amputation of the

lower limb due to dysvascular conditions, yet the majority of these patients are successfully fit with a prosthesis. Pinzur et al. studied 95 patients with amputation due to peripheral vascular insufficiency and graded their functional ambulation before surgery and at a 2 year follow-up.<sup>12</sup> Their results showed that at 2 years post-amputations, 84% of the patients ambulated within one level of their pre-amputation status, demonstrating that **patients with peripheral vascular insufficiency can both obtain and maintain walking independence.**<sup>12</sup>

In a related study, Siriwardena and Bertrand reported on the walking abilities of 543 unilateral amputees with arteriosclerosis at 3, 6, 9, and 12 months post amputation.<sup>13</sup> In addition to arteriosclerosis, an additional 78 patients were diagnosed with ischemic heart disease, with 17 other patients diagnosed with hypertension. Yet despite these cardiopulmonary deficits, the majority of these patients were ambulatory with their prostheses 12 months after their amputations.<sup>13</sup> Clearly comorbid cardiovascular compromise does not preclude an individual's ability to ambulate with a prosthesis.

### **Using Comorbidity to Assign K-level**

Within the proposed LCD, the qualifying statements associated with each of the potential co-morbidities described above are tied to the patient's ability to make use of their prosthesis at "the determined functional level (K0 – K4)." If adopted, K-level assignment would become dependent upon the presence and extent of cognitive, neuromuscular, and cardiopulmonary challenges despite a lack scientific evidence as to how each of these challenges relate to the functional abilities associated with specific K-levels. These qualifying statements could then be used to deny eligibility for safe and useful prosthetic components that allow patients to reach elevated activity levels if they have documented deficits in their medical history.

### **Conclusion**

In its attempts to establish minimum criteria that must be met in order to be eligible for ongoing prosthetic care, the LCD has introduced vague, subjective standards that could be used to deny coverage to the majority of lower limb amputees. Cognitive, neuromuscular and cardiovascular compromises are common among lower limb amputees, but rarely preclude the successful use of a prosthesis. In fact, in many instances, post amputation prosthetic rehabilitation may serve to improve these comorbid conditions. In the absence of any evidence based standards for such criteria, their introduction could only be used to prevent otherwise capable amputees from receiving prosthetic care.

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