

# Inflating the “Indicators of Success” in the Proposed LCD: Using Maximal Prerequisites to Set Minimum Functional Requirements.

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

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## Summary

Under the current LCD, prosthetic coverage is extended to anyone who is motivated to ambulate and has a physician who determines that will likely “reach or maintain a defined functional state.” By contrast, the draft LCD adds several minimal requirements for functional success that must be met before a patient would be eligible for coverage. Among these is a requirement that the individual demonstrate good static and dynamic balance as indicated by a score on the Tinetti Performance Oriented Mobility Assessment (Tinetti POMA) of greater than 24.

The arbitrary choice of the Tinetti POMA as *the* appropriate measure to determine successful use with a lower limb prosthesis is both unreasonable and unsupported in the literature. The Tinetti was developed as a screening tool for balance problems and fall risk in older adults (Tinetti, 1986). It has only been proven reliable and valid for populations of older adults, people with stroke and people with Parkinson’s (Rehabmeasures.org). Importantly, it has never been tested with amputees (Rehabmeasures.org). Thus, there is no literature to suggest that this test would correctly identify balance deficits in amputee patients.

In addition, a cut-off score of greater than 24 as a “minimum standard” for new amputees is unreasonably high and places undue burden on patients with amputations. To the extent that cut-off scores have been established for the Tinetti, to establish such things as low versus high fall risk, they have only been for healthy older adults and people with stroke or Parkinson’s disease (Rehabmeasures.org). Within these groups, the highest published cut-off score is 21 (Rehabmeasures.org). In fact, the average Tinetti scores for healthy older adults are 26.2 for males and 25.1 for females (Ko, 2009). Thus, the proposed “minimum requirement” demands that new amputees, using an archaic 1950’s era preparatory prosthesis three months after their amputation attain Tinetti scores roughly equal to healthy older adults to qualify for a definitive prosthesis.

Another concern associated with the Tinetti is its inherent bias against the use of an assistive device. In fact, the best score a person using a cane or walker can obtain on the Tinetti is 24/28. Thus, under the proposed policy anyone who uses an AD would be viewed as lacking the minimum functional requirements to be functionally successful with a prosthesis and ineligible for K-level assignment and the receipt of a definitive prosthesis. According to available data, this suggests that the proposed LCD could exclude as many as ¾ of the transfemoral and ½ of the transtibial patients from K-level assignment and receipt of a definitive prosthesis (Gauthier-Gagnon, 1999).

Of greatest concern, under these proposed guidelines, the Tinetti would be used to identify those patients at the greatest risk of fall and injury only to exclude them from the very technologies that would facilitate their safety and community mobility. Instead, they would be limited to the most basic technologies of SACH feet and single axis knees, both of which are known to contribute to instability and increased difficulty with gait (Uustal & Baerga, 2004 and Bonnet, 2015).

## Introduction

Appropriately measuring the impact of rehabilitation and prosthetic interventions post lower extremity amputation is an essential part of healthcare both at the individual and societal level.<sup>1</sup> However, *accurately predicting* walking capability following prosthetic rehabilitation has proven elusive.<sup>2</sup> Incorrectly estimating walking potential can have significant consequences for individual patients.

There is no current consensus in the literature as to what constitutes an “appropriate measure,” nor has a specific instrument been identified as “the gold standard” for measurement of functional ability in the amputee population.<sup>3-5</sup> Currently, MFCL levels or K-levels are used to classify patients with amputations into “functional levels”; these levels serve as the basis for prosthetic prescription.<sup>6</sup> However, to date no functional test or measurement tool has been found to reliably classify patients with amputations into their appropriate K-Level. Even the AMPRO and AMPnoPRO, developed by Gailey et al to establish a way to quantitatively assign K-levels, were not able to reliably identify appropriate cut-off scores for each K-level due to a wide variation in range of scores.<sup>4</sup> In absence of a more precise instrument, classification via the MFCL system remains largely subjective.<sup>4</sup>

However, the proposed suggestion of a Tinetti Performance Oriented Mobility Assessment (POMA) score of greater than 24 as a minimal requirement for success with a prosthesis betrays a fundamental misunderstanding of the instrument itself, its psychometric properties and the amputee community. The use of this standard would unfairly deny eligibility to reasonable prosthetic candidates and ultimately subverts the intent of the Tinetti POMA; namely, to identify patients at elevated fall risks and provide appropriate interventions to reduce that risk.

### Existing standard: Accommodative Standards Reflection Diverse Potential

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

“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>

### Proposed Revision: Minimum Requirements for Functional Success

The proposed changes to the LCD attempt to add greater objectivity by basing the determination of medical necessity on a “comprehensive evaluation of functional health status.”<sup>7</sup> The LCD draft additionally proposes a set of “minimum requirements to be functionally successful with a lower limb prosthesis”<sup>7</sup>:

“A beneficiary **must meet the following minimal requirements** to be functionally successful with a lower extremity prosthesis:

- Sufficient trunk control
- Good upper body strength

- Adequate knee stability with good quadriceps strength and control
- **Good static and dynamic balance or a Tinetti total score of > 24**
- Adequate posture<sup>7</sup>

According to the LCD, every patient would be required to meet these minimal standards at the conclusion of their rehabilitation program *as a prerequisite to K-level assignment and subsequent receipt of a definitive prosthesis*. While several of the standards are set within a reasonable expectation of clinical outcomes, the requirement of “good static and dynamic balance or a **Tinetti total score of > 24**” **is not a reasonable clinical expectation for most amputees** and would preclude many patients from eligibility for a definitive prosthesis. Setting a score of greater than 24 on the Tinetti POMA as prerequisite to success with a prosthesis displays a general ignorance of the test itself, its published psychometric properties and the populations in which it has been scientifically investigated. Further, available data suggests that this requirement would likely preclude at least half of all amputees from eligibility for a modern era, definitive prosthesis.

### **Tinetti POMA: History and Intended Populations**

The Tinetti POMA was originally designed nearly 30 years ago as a way **to screen older adults for balance and gait impairments**.<sup>8</sup> The measure has been tested and shown to be reliable in populations of older adults, CVA and Parkinson’s disease. Concurrent validity has been demonstrated for otherwise healthy older adults with adequate correlations between scores on the Tinetti POMA and the Timed up and Go, the Functional Reach Test, and comfortable gait speed.<sup>9</sup> However, *the utility of the measure among disabled populations is suspect*, with the correlations between the Tinetti POMA and other outcome measures described only as “*moderate*” for patients with Stroke,<sup>10</sup> and “*adequate*” for patients with Parkinson’s disease.<sup>11</sup> Neither the Content Validity for the complete measure nor the Construct Validity for the individual test items have ever been established for this measure.

More importantly, **the Tinetti has never been tested in an amputee population**. Therefore no data exists on its reliability or validity when used for patients with lower limb amputations. There is no literature describing the characteristics of the Tinetti when administered in the amputee population and no evidence that the test is sensitive to the unique nature of this population. Restated, **this choice of instrument as a measure of functional capabilities in an individual post amputation is not supported by any scientific literature**.

### **Tinetti POMA: Cut off Scores**

Equally unsupported is the choice of a cut-off score of greater than 24 to represent the difference between “good static and dynamic balance” and presumably inadequate balance ability. The recent literature contains several studies that have established cut-off scores for the Tinetti POMA that appear to reliably distinguish between individuals with adequate balance and those with poor balance and a higher fall risk.<sup>11-15</sup> These cut-off scores have been established for older adults,<sup>13,15</sup> for people with stroke<sup>14</sup> and for people with Parkinson’s disease.<sup>11-12</sup> However, these cut-off scores range from 17.5<sup>12</sup> to 21.<sup>15</sup> With a maximum possible score of 28, not only is the cut-off score of 24 unsupported anywhere in the recent literature, it is also simply too high. Normative data for the Tinetti has found average scores

for health elderly adults to be 26.2 (males) and 25.1 (females).<sup>16</sup> **Under the proposed “minimum requirements,” new amputees, 90 days removed from their amputation, utilizing an archaic 1950’s era preparatory prosthesis would have to attain Tinetti scores roughly equal to healthy elderly adults.** Setting an arbitrarily selected cut-off score of this magnitude at this early stage of rehabilitation would inappropriately label many patients who are functioning quite reasonably after their amputation as not meeting the “*minimal requirements to be functionally successful with a lower extremity prosthesis.*”

### **Tinetti POMA: Influence of Assistive Devices**

However, the most troubling issue surrounding this choice of measure and cut-off score is the bias it creates for patients who use an assistive device (AD) to complete the test. If a patient scores perfectly on the Tinetti but uses an assistive device to perform it, their maximum possible score is 24. Restated, **under the proposed policy anyone who uses an assistive device to take the test would be viewed as lacking the minimum functional requirements to be functionally successful with a prosthesis and would be ineligible for K-level assignment and the receipt of a definitive prosthesis.**

Reporting upon a large cohort of experienced lower limb prosthetic users, most of whom actively and regularly engaged in outdoor activities with their prostheses, Gauthier-Gagnon reported that roughly half of the transfemoral amputees and a third of the transtibial amputees preferred to use a single cane during indoor activities.<sup>17</sup> If these numbers are expanded to include the use of walkers, crutches and two canes, and the subject performed the Tinetti with their preferred terminal devices, only 28% of the transfemoral amputees and 49% of the transtibial amputees in their cohort would have been eligible for K-level assignment and subsequent receipt of a modern era definitive prosthesis.<sup>17</sup> A policy that would exclude half of all transtibial amputees and three quarters of all transfemoral amputees from eligibility for further prosthetic management is fundamentally naïve, uninformed and irresponsible.

### **Tinetti POMA: Assessing Fall Risk**

Within the literature, the Tinetti is often used to identify patients who face an elevated fall risk. To the extent that it is able to do so, the current LCD would use that information to deny at-risk patients from eligibility for modern prosthetic technologies that could decrease their fall risk. The single axis knee included in the base code for a definitive transfemoral prosthesis and likely included in the preparatory transfemoral prosthesis, has been described as *the most unstable knee configuration available in existing prosthetic technology.*<sup>18</sup> Similarly, the SACH foot included in the preparatory prosthesis has been associated with *greater instability*<sup>19</sup> and *increased self-reported difficulty with walking.*<sup>20</sup> Yet under the proposed policy, those patients identified as being at the greatest fall risk with their current basic prosthesis would be ineligible for further prosthetic management and forced to continue their attempts at prosthetic rehabilitation in their compromised state. To identify patients at elevated falls risks and then deny them access to modern components that would empower them with greater stability and security is simply unconscionable.

## **Conclusion**

Establishing appropriate predictive measures to better anticipate the functional capabilities and needs of patients post amputation is a commendable goal. However, the measures used must be validated and appropriate for the target population. Additionally, any cut-off scores set as minimum standards must likewise be informed by data sets obtained from the target population. The suggested use of the Tinetti with its inflated cut-off score as a “minimal requirement,” suggest a fundamental ignorance of the measure itself, its psychometric properties and the amputee community. The greatest value of the Tinetti appears to be the identification of those individuals at the greatest fall risk with their current prosthesis. Yet under the proposed guidelines, this information would be used to exclude those individuals that have the greatest risk from the technologies that could augment their safety and engagement in society.

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