

Restrictive Devices: Penalizing Patients for Their Use of Assistive Devices after Lower Extremity Amputation

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

Helen L. Rogers, PT, PhD
Clinical Research Review Committee – Hanger Clinic
Houston TX

Phil Stevens, MEd, CPO, FAAOP
Clinical Research Review Committee, Chair – Hanger Clinic
Salt Lake City, UT

8/5/2015

Summary

The proposed draft of the LCD for Lower Limb Prosthetics suggests revising the K-level classifications to include the use of assistive devices as a factor in determining K-levels. The draft proposes that the use of a walker, crutches or cane is a marker of disability that precludes function at higher levels.

The proposed revisions essentially state that the use of a walker or crutches restricts a patient to household ambulation, i.e., a K1 level. The revisions also assume that an individual who uses a cane is unable to function beyond limited community ambulation, i.e., a K2 level. To achieve a level of K3, a patient must not use any assistive devices. The literature, however, supports that independent, full community ambulators often use assistive devices (AD) to enhance their gait. (Bateni et al. 2005, Lin et al. 2014)

These revisions also define the use of an assistive device (AD) as a limiting factor, representing a decline in an individual's functional capabilities. The literature disagrees, describing the use of ADs as a standard of care for prosthetic rehabilitation in which AD's are commonly utilized to enable progressive recovery (Kirby et al. 2002).

There is a good deal of support in the literature for use of both walkers and crutches among independent community ambulators. A study of community dwelling older adults showed that walker use significantly increased gait speed and stride length, decreased the base of support needed for balance and decreased double limb support time. Use of crutches significantly improved cadence and gait variability, increased stride length and stride time, and decreased the amount of time spent in double limb support (Hardi et al 2014). Another study with prosthesis wearers demonstrated that walker use increased gait speed and facilitated safe, smooth gait patterns (Tsai et al. 2013)

The literature is even more supportive of the use of canes. Fully half of transtibial and transfemoral amputees that are highly active in outdoor activities use a cane to enable these activities. (Gauthier-Ganon, 1999). In the study of community dwelling older adults mentioned above, cane use increased stride length and stride time and improved cadence and gait variability (Hardi et al 2014). Ashton-Miller

et al. examined the use of a cane on loss of balance in independent community ambulators with peripheral nerve injuries, and observed that use of a cane significantly reduced loss of balance during periods of perturbation and visual challenge (Ashton-Miller et al. 1996). Finally, Gianfrancesco et al. studied the effect of cane use on gait quality in patients with MS. The subjects were independent ambulators in their community and did not use a cane. Yet cane use still resulted in significantly higher walking velocities, improved gait symmetry and better gait coordination. (Gianfrancesco et al. 2011)

The revisions proposed LCD draft are unsubstantiated in the literature and have serious implications. Viewing AD use as a limiting, rather than enabling factor for functional mobility ignores the reality that AD use improves the very gait parameters that would result in improved function and higher K levels. When K-level assignment is artificially lowered because of AD use, the prosthetic technology available to these patients would likewise be artificially restricted. Thus, penalizing patients for AD use precludes them from access to components best suited for the environments they will encounter with the use of the ADs. For example, patients who walk at faster speeds with the assistance of a cane would be limited to a K2 classification; policy restrictions would prevent them from obtaining a fluid controlled knee joint capable of *accommodating* those faster speeds.

The attempt by the proposed LCD to redefine “assistive devices” as “restrictive devices is inconsistent with rehabilitation literature and standards of practice. Assistive devices must be seen as enabling resources that enhance capabilities rather than markers of disability.

Introduction

The proposed draft of the LCD for Lower Limb Prosthetics suggests a revision of the K-level classifications to include the use of assistive devices as a restrictive parameter in determining the functional capability of the lower limb amputee. The draft asserts that the use of a walker or crutches limits a patient's classification to that of K-1, indicating that the use of a walker or crutches somehow prevents an individual from walking in the community. Similarly, the use of a cane would result in a restriction to a K-2 level, asserting that any individual who uses a cane is unable to achieve variable cadence or a functional ability beyond that of limited community ambulation. *These revisions view the use of an assistive device (AD) as an inherently limiting factor that represents decreased functional capabilities.* These assumptions are diametrically opposed to the views of physiatrists, physical therapists, prosthetists, and others in the rehabilitation community who see the use of an AD as a common component of the recovery process and one that plays an important role in restoring functional ability in ADL, work and recreation settings.¹⁻³ In 2002, Kirby et al. evaluated the use of ADs throughout the course of post amputation rehabilitation.⁴ This study found that, rather than a marker for certain predetermined levels of disability, AD use is a clearly established standard of care in prosthetic rehabilitation, in which patients progress through a hierarchy of ADs from walkers to crutches to canes in a relatively standard order.⁴ The attempt of the LCD draft to penalize the use of ADs during of prosthetic rehabilitation is inconsistent with established rehabilitation practices and literature where ADs are seen as enabling tools rather than markers of disability.

Existing Standard: Classification of Functional Capabilities for Levels K-1, K-2 and K-3

The issues addressed in this paper surround K-level classifications 1-3 (K-0 is not applicable and K-4 represents a high level of ambulation not generally associated with use of an AD). The existing K-level classifications do not have any mention or restriction of AD use. Rather, the classifications are based on the patient's functional ability or potential with regard to the management of environmental barriers and variable gait speeds:

K-1: Has the ability or potential to use a prosthesis for transfers or **ambulation on level surfaces** at **fixed cadence**. Typical of the limited and unlimited **household ambulator**.⁵

K-2: Has the ability or potential for ambulation with **the ability to traverse low level environmental barriers** such as curbs, stairs or uneven surfaces. Typical of the **limited community ambulator**.⁵

K-3: Has the ability or potential for **ambulation with variable cadence**. Typical of **the community ambulator** who has the ability to **traverse most environmental barriers** and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.⁵

In its current form, K-level assignment is executed without regard to which tools might be utilized to facilitate the defined levels of functional ambulation.

Proposed revisions: Patient-centered restrictions to K-level classification

Within the proposed changes, the use of an AD would determine K-level assignment with no further consideration of patient presentation. Ironically, the requirements for the various K-level assignments have also been raised, requiring many of the very considerations that an AD could reasonably address.

“K1: Has demonstrated the ability to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the household ambulator. Who can walk for distances that are considered reasonable for walking inside the home but **limited for walking in the community because of endurance, strength, or safety concerns.**

- **Use of a walker or crutches while using a prosthesis results in a K1 classification.”⁶**

In this instance, the use of a walker assigns an individual to a K1 classification. That individual is then represented as someone who is limited in their community walking because of endurance, strength or safety concerns. This assignment boldly ignores the reality that for many patients, the use of a walker may address the “endurance, strength or safety concerns” that have been added to policy language to preclude a higher K-level assignment.

K2: Has demonstrated the ability for ambulation to **traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces.** Typical of the limited community ambulator who can **ambulate without assistance** and is able to function physically and psychologically within the community independently.

- **Use of a cane while using a prosthesis results in a K2 classification.**⁶

Again, this language simply ignores the reality that in many instances the appropriate use of a walker (which would preclude a K2 level assignment) would actually enable a household ambulator (K1) to function at the level of a limited community ambulatory (K2), “*safely traversing low-level environmental barrier*”s.⁶ It also asserts that the use of a cane limits an individual to a K2 classification and defines them as a limited community ambulator.

K3: Has demonstrated sufficient and adequate lower extremity function for **personal independence during ambulation with variable cadence.** Typical of the unlimited community ambulator who has **the ability to traverse most environmental barriers without physical or safety concerns** and has vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond typical environmental barriers.

- **Does not require the use of any mobility assistive equipment such as a cane, crutches, walker, or wheelchair.**⁶

Here the proposed language ignores the reality that in many instances, the appropriate use of a cane (which would, by the revised definition, preclude a K3 level assignment) would

actually enable a limited community ambulator (K2) to function at a K3 level, demonstrating personal independence during variable speed ambulation and traversing most environmental barriers without physical or safety concerns. Rather, it makes the unfounded assertion that the use of any assistive equipment is a marker of disability that somehow precludes an individual's ability to function at the level of an unassisted community ambulator.

Community Ambulation in the Peer Reviewed Literature

According to the language of the proposed LCD, anyone using a walker or crutches is automatically viewed as unable to ambulate at a community level and anyone using a cane is unable to ambulate as an unlimited community ambulator. These assertions are simply inconsistent with the standards of academic literature as many of the studies that describe the use of ADs are performed with cohorts of *community dwelling adults*. In 2005 Bateni et al. performed a systematic review of articles investigating the effects of walker or cane use on gait performance in healthy adults and patients with various orthopedic (including amputation), neurologic and visual impairments.⁷ *Of the 36 articles studied, 22 included subjects with impairments who were independent community ambulators with their respective assistive devices.*⁷ Similarly, Lin et al reported upon a sample of Medicare covered, *community dwelling adults* who had at least one self-care or mobility limitation. Within their cohort of over 4000 individuals, assistive devices were reported as the primary means of addressing existing activity limitations.⁸ In the academic literature, community ambulation is consistently based on functional capabilities and participation with no arbitrary penalization for AD use.

Do AD's Augment or Diminish "Capability?"

In the proposed LCD, K-level assignment represents an "assessment of the beneficiary's functional capabilities." Suggesting that AD use diminishes "capability" is wholly inaccurate and contrary to well-known and established principles of rehabilitation.

Use of a Walker or Crutches

Hardi et al. studied 65 community dwelling older adults who used a cane, crutches or walker for assistance with gait.⁹ The results showed that for those who use walkers, utilization of the device significantly *increased gait speed, lengthened the subject's stride, lessened the base of support needed to maintain balance and decreased the amount of time spent in double limb support.*⁹ Similarly, the subjects who used crutches showed significant *improvements in cadence, longer strides, decreased time in double limb support and improved gait variability.*⁹ These measures demonstrate the many improvements in gait quality and dynamic balance that are experienced when subjects use walkers and crutches to enhance their gait.⁹

In a separate investigation, Tsai et al tested the effect of different walker types on the gait velocity, smoothness, safety and patient preference among prosthetic wearers.¹⁰ The authors observed that walker use increased gait speed and facilitated safe, smooth gait patterns.¹⁰

The benefits observed with the use of walkers and crutches, such as improved gait quality and balance are clearly consistent with the newly proposed criteria for K2 ambulation, “*typical of the limited community ambulator who can ambulate without assistance and is able to function physically and psychologically within the community independently*”.⁶ Yet according the draft LCD, the very resources that enable this level of increased function would be arbitrarily defined as markers of restrictive disability.

Use of a Cane

The benefits of cane use as an enabler of outdoor walking and the negotiation of environmental obstacles is well established in the literature. Gautheir-Ganon reported upon a cohort of 117 transfemoral amputees, 62% of whom reported active use of their prosthesis in 75% - 100% of their outdoor activities. However, only 15% did so without AD. By contrast, nearly half of them used a single cane to enable these elevated outdoor activity levels.¹¹ Similar trends were observed among 201 transtibial amputees. Sixty-six percent reported highly active use of their prostheses outdoors. While roughly one third of the cohort did so without an AD, over 50% preferred the use of a single cane when outdoors.¹¹ Far from a marker of disability, these data suggest that cane use empowers elevated community ambulation levels.

Ashton-Miller et al. examined the effect of cane use on balance among independent community ambulators with peripheral nerve injuries.¹² The authors observed that the addition of a cane significantly reduced the subjects’ loss of balance during periods of mechanical perturbation and periods of visual challenge (ie, eyes open and closed).¹² Despite their abilities to function independently in their community, these patients improved their functional mobility and enhanced their balance, stability and safety with the use of a cane.¹²

Similarly, Gianfrancesco et al. investigated the effect of cane use on gait quality in independent community ambulators with multiple sclerosis.¹³ Cane use resulted in significantly higher walking velocities, improved gait symmetry and better gait coordination.¹³

Ironically, the observed improvements in balance, gait speed, coordination and outdoor utilization of a prosthetic are the very benefits that would enable amputee patients to be classified at the K3 level, “*unlimited community ambulators who have the ability to traverse most environmental barriers without physical or safety concerns*”.⁶ Yet despite these benefits, the proposed LCD would view *cane use* as an inherent maker of disability, precluding the K3 level assignment that it simultaneously enables.

The literature consistently asserts the beneficial effects of a cane as an assistive device enabling the very characteristics that are used to define K3 level function. The research shows that in many instances a cane is the most useful AD for improving gait to a higher functional level.^{7,14} The cane has been shown to be better than other assistive devices for increasing walking speed,¹³⁻¹⁴ and for improving function in challenging walking environments.¹² It has also been shown to improve balance during standing and walking.^{7,12,15-16}

In addition, many users of canes do not exhibit significant difficulty with walking. Rather, the cane is used as a safety measure to avoid falling and to improve balance confidence.¹⁷⁻¹⁸ By denying a K3 level classification to higher level ambulators simply because they use a cane, this LCD goes against a significant amount of published evidence that proves the effectiveness of proper AD use. This position would undermine the potential of many amputees who would be capable of higher level of ambulation if allowed the beneficial effects of a cane.

Prosthetic Implications of Penalizing AD Use

Available prosthetic componentry is determined by K-level assignment. When K-level assignment is artificially lowered because of AD use, the prosthetic technology available to these patients is likewise artificially restricted. The regulations that define which components can be used with a given K-level are based on the mechanical characteristics of the devices that will allow for improved safety and function in the patient's anticipated environment. Penalizing patients for AD use would preclude them from access to those components best suited for their ambulatory practices and environments. For example, those patients who are able to walk at faster walking speeds with the assistance of a cane would be unjustifiably limited in their ability to do so by policy restrictions that prevent them from obtaining a fluid controlled knee joint capable of accommodating faster walking speeds.

The policy language would be especially disruptive among those with amputations at the transfemoral or hip disarticulation level who may be the more frequent users of canes; canes can provide some somatosensory information from the hand to mediate the greater proprioceptive challenge posed by a higher level amputation.⁷ Given access to appropriate prosthetic resources, many of these patients can attain variable cadence in community settings. However, if their use of a cane to enhance their capabilities restricts them to inadequate prosthetic resources, their capabilities may well go unrealized.

Conclusion

It is important for LCD language and policy to reflect an accurate understanding of the factors that positively and negatively affect functional capability. Appropriate use of ADs enhances capability. By contrast, capability is compromised by inappropriate restrictions of prosthetic technologies that would enable safer function in anticipated walking environments. The arbitrary, unfounded nature of the proposed LCD claims are inconsistent with proven rehabilitation techniques and literary evidence. The evidence today overwhelmingly supports the position that the use of an AD facilitates improvements in all aspects of functional mobility and may enable higher levels of function consistent with higher levels of K-level assignment. The proposed K-level classifications cannot arbitrarily redefine an "assistive device" as a "restrictive device."

References

1. Agree EM, Freedman VA. A quality-of-life scale for assistive technology: results of a pilot study of aging and technology. *Phys Ther.* 2011;91:1780–1788.
2. Roffman CE, Buchanan J, Allison GT. Predictors of non-use of prostheses by people with lower limb amputation after discharge from rehabilitation: development and validation of clinical prediction rules. *J of Physiother.* 2014;60: 224–231.
3. Tyson SF, Rogerson L. Assistive walking devices in nonambulant patients undergoing rehabilitation after stroke: the effects on functional mobility, walking impairments, and patients' opinion. *Arch Phys Med Rehabil.* 2009;90:475-9.
4. Kirby RL, Tsai HY, Graham MM. Ambulation aid use during the rehabilitation of people with lower limb amputations. *Assist Technol.* 2002 Winter;14(2):112-7.
5. Medicare LCD: Lower Limb Prostheses (L11464).
6. Medicare Draft LCD: Lower Limb Prosthesis (DL33787).
7. Bateni H, Maki BE. Assistive devices for balance and mobility: benefits, demands, and adverse consequences. *Arch Phys Med Rehabil.* 2005;86:134-45.
8. Lin, I.-F., & Wu, H.-S. (2014). Activity limitations, use of assistive devices or personal help, and well-being: variation by education. *Journals of Gerontology, Series B: Psychological Sciences and Social Sciences*, 69(7), S16–S25.
9. Härdi I, Bridenbaugh SA, Gschwind YJ, Kressig RW. The effect of three different types of walking aids on spatio-temporal gait parameters in community-dwelling older adults. *Aging Clin Exp Res.* 2014;26:221-8.
10. Tsai HA, Kirby RL, MacLeod DA, Graham MM. Aided gait of people with lower-limb amputations: comparison of 4-footed and 2-wheeled walkers. *Arch Phys Med Rehabil* 2003;84:584-91.
11. Gauthier-Ganon C, Grise MC, Potvin D. Enabling factors related to prosthetic use by people with transtibial and transfemoral amputation. *Arch Phys Med Rehabil* 1999;80:706-13.
12. Ashton-Miller JA, Yeh MW, Richardson JK, Galloway T. A cane reduces loss of balance in patients with peripheral neuropathy: results from a challenging unipedal balance test. *Arch Phys Med Rehabil.* 1996;77:446-52.
13. Gianfrancesco MA, Triche EW, Fawcett JA, Labas MP, Patterson TS, Lo AC. Speed- and cane-related alterations in gait parameters in individuals with multiple sclerosis. *Gait and Posture.* 2011;33:140-142.
14. Allet L, Leemann B, Guyen E, Murphy L, Monnin D, Herrmann FR, Schnider A. Effect of different walking aids on walking capacity of patients with poststroke hemiparesis. *Arch Phys Med Rehabil.* 2009; 90:1408-13.
15. Laufer, Y. The use of walking aids in the rehabilitation of stroke patients. *Rev Clin Gerontol.* 2004;14:137–144.
16. Milczarek, JJ, KirbyRL, Harrison ER, MacLeod DA. Standard and four-footed canes: their effect on the standing balance of patients with hemiparesis. *Arch Phys Med Rehabil.* 1993;74:281–285.
17. Cornman, JC, Freedman VA, Agree EM. (2005). Measurement of assistive device use: Implications for estimates of device use and disability in late life. *Gerontologist.* 2005;45:347-358.
18. Scherer MJ. Outcomes of assistive technology use on quality of life. *Disabil Rehabil.* 1996;18:439–448.