THE ORTHOTIC AND PROSTHETIC ALLIANCE

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SUBMITTED VIA ELECTRONIC MAIL

Stacey Brennan, M.D.
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Re: Proposed/Draft LCD on Lower Limb Prostheses (DL33787)

Dear Dr. Brennan:

On behalf of the Orthotic & Prosthetic Alliance (the O&P Alliance), a coalition of the five major national orthotic and prosthetic organizations representing over 13,000 O&P professionals and 3,575 accredited O&P facilities, please accept this written submission commenting on the Proposed/Draft Local Coverage Determination (LCD) on Lower Limb Prostheses.

To contact the O&P Alliance directly, please call Peter Thomas, O&P Alliance Counsel, at your convenience at 202-872-6730 or email Peter.Thomas@ppsv.com. Thank you for your consideration of our views.

Sincerely,

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SECTION I: INTRODUCTION AND OVERVIEW

The Orthotic and Prosthetic Alliance (The Alliance) appreciates the opportunity to comment on the Proposed/Draft Local Coverage Determination (LCD) titled *Lower Limb Prostheses (DL33787)*. The Alliance is a coalition of the five major national orthotic and prosthetic (O&P) organizations representing the O&P profession, over 13,000 O&P professionals and 3,575 accredited O&P facilities, and the patients we serve. The Alliance is committed to ensuring that people with injuries, illnesses, and disabilities have access to and coverage of the full spectrum of professional orthotic and prosthetic patient care. The draft LCD puts both of those principles in jeopardy.

For that reason, we request that you rescind this draft LCD. Any proposed changes with such far-reaching implications must involve thoughtful and extensive dialogue with relevant stakeholders: patients, physicians, prosthetists, and other relevant members of the rehabilitation team. Rather than updating the current LCD with policy changes based on the most recent clinical evidence, the draft LCD is little more than a veiled pretext for cost savings. (This is despite the fact that the Medicare program reduced spending on lower limb prostheses by 13.8% between 2010 and 2013, the most recent year that data is available.)[1]

The draft LCD is a comprehensive re-write of Medicare's entire lower limb prosthetic benefit. Remarkably, the Durable Medical Equipment Medicare Administrative Contractors (DME MACs) cite virtually no evidence to support the document. The only "evidence" they do cite—in a bibliography produced weeks after publication of the draft LCD—fails to support the proposed changes. The draft LCD will dramatically reduce amputees' access to medically necessary prostheses while largely ignoring the current standard of prosthetic care in the United States.

Following decades of federal and private investment in research and development to meet the needs of returning wounded warriors and return all amputees to optimal function, American prosthetic care today is a major health care success story. But the draft LCD would throw the brakes on that progress and shift gears into a violent reverse by erecting new barriers to modern prosthetics, while simultaneously relegating amputees to older, cheaper, less safe and less functional prostheses.

[1] Based on Medicare's Part B National Summary Data Files, 2005-2013.

Many of the proposed policies involve major changes to the Uniform Code Set administered by the Centers for Medicare and Medicaid Services (CMS). All insurers in the United States use that same code set to cover and reimburse prosthetic limb claims. So the draft LCD has implications well beyond the Medicare program, and because private payers generally follow Medicare's coverage decisions, these changes will inevitably impact *all* amputees in the U.S.

In light of these facts, it is not surprising that the draft LCD has stimulated an immediate and significant backlash. It contains so many restrictions, simplistic assumptions, misunderstandings, inconsistencies, fundamental alterations to existing policy, and unsupported policy statements that it cannot be fixed through a series of edits and tweaks. Virtually every major stakeholder group — from patients who rely on prostheses to be functional and independent; to physicians who prescribe prostheses; to prosthetists who design, fabricate, and fit prostheses; to all members of the rehabilitation team who assist in amputee rehabilitation — oppose the draft LCD. In just over two weeks, more than 100,000 people signed a "We the People" petition requesting rescission of the draft LCD, triggering an obligation on the White House to respond. This unprecedented opposition to the DME MACs' proposal only reinforces the correct course of action: rescind the draft LCD.

Due to the comprehensive nature of the proposed changes in the draft LCD, The Alliance's response is divided into four sections.

- Section I: Addresses overall reactions to the proposed set of policies and raises concerns with the process CMS and its contractors used to issue the draft LCD.
- Section II: Responds in detail to the Coverage section of the draft LCD.
- Section III: Responds in detail to the Documentation section of the draft LCD.
- Section IV: Contains an appendix of supporting materials

Throughout this response, The Alliance will use the term "qualified practitioner" to refer to those health care professionals it believes are properly qualified to provide prosthetic items and services and should be permitted to oversee and direct the care necessary in providing lower limb prostheses to patients with amputations. "Qualified practitioner" is the term used under statute, pursuant to the Benefits Improvement and Protection Act of 2000, Section 427 (BIPA 427), to describe individuals who are considered "qualified" to provide O&P services.[2] The statute identifies the following individuals as "qualified": physicians, qualified physical and occupational therapists, and both individuals licensed by their State to provide O&P services and individuals credentialed by an approved credentialing body[3] who are specifically trained and educated to provide customized O&P services. While CMS has never issued a regulation implementing BIPA 427's requirements, the provision remains a properly promulgated part of the Social Security Act. Therefore, CMS should defer to the statutory designation of which health care professionals are appropriate for overseeing and providing O&P care, including the provision of lower limb prostheses.

[2] *See* 42 U.S.C. § 1395m(h)(1)(F)(iii).

[3] The American Board for Certification in Orthotics, Prosthetics, and Pedorthics or the Board for Certification/Accreditation, International. The law also permits credentialing by other "equivalent" accreditation organizations as deemed by the Secretary of HHS.

A. Policy Implications of the Draft LCD

1. A Solution in Search of a Problem

To justify changes that limit amputees' access to prosthetic care in the way the draft LCD does, the DME MACs should be able to identify a problem so serious that it cannot be solved in any other way. But the DME MACs offer no explicit objective or motivation for these changes. In informal conversations between members of The Alliance and DME MAC and PDAC officials, one argument offered to justify this comprehensive policy shift is the specter of fraud, abuse, and overbilling. But Medicare data do not support this claim.

Medicare's own numbers suggest that from 2005 to 2010, Medicare increased spending on lower limb prostheses. But 2010 was the high watermark. For *all* prosthetic limbs, not just lower extremity prostheses, CMS spent $608 million in 2005 and increased this spending each year until 2010, when CMS spent $770 million.[4] This increase in spending coincides with a national focus on serving the needs of wounded warriors, enhanced government and private sector spending on prosthetic research and development, and incredible advances in prosthetic technology and function for amputees, both military and civilian.

However, Medicare spending for lower limb prostheses has declined every year since 2010, representing just 0.17 percent of *overall* Medicare spending for all patients and all services that year. Total Medicare spending for all prostheses decreased each year to $664 million in 2013, a reduction of 13 percent, that represented just 0.13 percent of total Medicare spending for that same year.[5] When Medicare data becomes available for 2014, we expect Medicare will have expended approximately what the program spent in 2005: roughly $608 million. The DME MACs and the Pricing Data Analysis and Coding (PDAC) contractor collect and maintain Medicare data on a real-time basis. They have access to the same data well before The Alliance is able to access it. These contractors should know about the overall decrease in spending on lower limb prostheses over the past five years.

Finally, Medicare data also demonstrate that while spending since 2010 decreased significantly for more advanced prosthetic components, it increased for less functional and less advanced technology. The auditing risk that accompanied the provision of more functional K3 prosthetic components during these years drove amputees into antiquated and less expensive K1 and K2 prosthetic components, with technology largely stemming from the 1970s. For instance, while allowed Medicare charges for billed K3 prosthetic knees and feet decreased by 30.8% between 2010 and 2013, allowed charges for K1 and K2 prosthetic knees and feet *increased* by 28% during this same time period. The impact of the aggressive auditing activity during this time period is apparent in the data. If the draft LCD is finalized, spending on modern prosthetic technology will continue to decrease dramatically, which has the impact of denying Medicare

[4] Based on Medicare's Part B National Summary Data Files, 2005-2013.
[5] Kaiser Family Foundation, "The Facts on Medicare Spending and Financing," (June 24, 2015); www.kff.org/Medicare/fact-sheet/medicare-spending-and-financing-fact-sheet.

beneficiaries the very technologies they have come to rely on to be healthy, functional, and as independent as possible.

Therefore, any assertion by the DME MACs or PDAC that the fundamental changes to the Medicare prosthetic benefit included in the draft LCD are prompted by concerns of over-spending and excess use of unnecessarily advanced technology by Medicare beneficiaries is unfounded and not supported by their own data.

2. Survival of the Fittest

The draft LCD creates a series of filters, barriers, time constraints, documentation requirements, and clinical care directives that reward younger and healthier new amputees and penalize those who have secondary conditions, who need greater assistance to regain function, who may be deconditioned following injury or illness, or who may be less resilient in the course of their rehabilitation. Only those who endure the added hurdles and persevere through months of delay will be deemed worthy of a definitive prosthesis. Under the draft LCD, a conservative estimate of the delay to obtain a definitive prosthesis after healing from the amputation itself is six to 12 months.[6]

Under the current LCD, individualized prosthetic care begins immediately after the amputation. A six to twelve-month delay under the draft LCD would be devastating for amputees. Patients who are successfully fit with a prosthesis under the current LCD will become victims of attrition resulting from a process that appears to have been designed to ration prosthetic utilization to the most able individuals with little regard to those facing additional health care challenges.

Those who do not achieve the prerequisites for a definitive prosthesis will presumably retain their basic preparatory prosthesis until such time as they either overcome the inherent limitations in these devices to secure a definitive prosthesis, or give up, resigning themselves to a less active and less functional life, consigned to assistive walking devices and wheeled mobility. Some Medicare patients will wind up in nursing homes and some will die prematurely. This is not hyperbole; it is Darwinian prosthetics—"survival of the fittest."

One particularly alarming example is instructive. A new prerequisite is the requirement that a patient demonstrate "good static and dynamic balance or a Tinetti total score of > 24." The Tinetti test is designed to prevent falls in older adults by screening for balance and gait impairments. It has never been tested in an amputee population. 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. This is a prime example of the lack of evidence behind the draft LCD and the punitive nature of new standards being proposed.

[6] See Section IV: Tragic Timeline: Required Delays to Individualized Prosthetic Care, prepared in response to Draft LCD DL33787, Rogers, Dobson and Stevens (August 13, 2015).

3. Stacking the Deck Against the Amputee Patient

The draft LCD removes the concept of a patient's functional "potential"—a bedrock concept in medical rehabilitation—from the functional assessment. This stacks the deck against amputees, limiting their ability to fully recover following amputation and live as independently as possible. Rather than assessing the patient's functional *potential* with an appropriate prosthesis, the draft LCD replaces this time-honored concept with a requirement that amputees demonstrate performance of a variety of functional requirements on their most recent prosthesis *before* being eligible for a definitive prosthesis. Worse yet, new amputees are severely limited in the type of preparatory prosthesis they are permitted to receive in the early stages of their rehabilitation.

Under the draft LCD, the typical preparatory prosthesis will be limited to a 1950s era SACH foot with a non-alignable pylon, and in the case of an above knee amputee, no mechanical knee joint. There is no coverage for any additional components with preparatory prostheses, including add-ons, upgrades, additions, adjustments, modifications, replacements, or substitution of components. With a preparatory prosthesis, all modifications to the socket within 90 days of delivery are not separately billable. Therefore, even extensive changes in residual limb volume will not be addressed clinically, unless the prosthetist donates the additional prosthetic care to meet the changing needs of the patient.

The fact that the draft LCD even contemplates this antiquated and unsafe level of care as being appropriate is alarming. This approach contradicts the way prostheses have been provided for decades; specifically that the base code describes the type of prosthesis being provided and the addition codes describe the additional features and components included in the design. With this approach, new above-knee amputees would be unable to sit down while wearing their preparatory prosthesis for 90 days after they received it (or until they received a definitive prosthesis) since there is no mechanical knee joint to bend in order to sit down.

The draft LCD also establishes absurd functional benchmarks with no evidence-based foundation and no link to functional levels. The LCD states that anyone who uses a cane to assist in walking must be considered a K2 (rather than a K3) amputee. This eliminates a wide range of prosthetic options that comprise the current standard of care for amputees in this country. Those who make use of a crutch or walker cannot be considered a K2 amputee, but instead, a K1. This rule converts limited community ambulators into individuals who get a prosthesis suitable for little more than transferring safely from one seated positon to another.

Medicare policy should promote and encourage the use of all prosthetic components and assistive devices necessary to enable the beneficiary to regain ambulation, health, function, and independence as possible. The draft LCD does the opposite. It erects unnecessary and unfounded access barriers to prosthetic care that have the cumulative effect of stacking the deck against amputees and in the long term will result in increased costs to Medicare for this population.

4. Penny Wise and Pound Foolish Proposals

The draft LCD offers numerous examples of trying to save Medicare dollars in the short term by deeming various components, fitting techniques and prosthetic services not medically necessary or not separately billable. Yet, not only is virtually no evidence offered to justify these proposals, but the vast majority of the changes will translate into additional costs for the program in the long term.

The draft LCD establishes a series of requirements at the end of rehabilitation; if the patient cannot achieve them, a definitive prosthesis may be denied. These requirements include "donning and doffing the prosthesis without assistance, transferring without assistance using and without using the prosthesis, having sufficient wear tolerance to use the prosthesis for a normal day's activities, attaining sufficient balance and stability to ambulate with ease of movement and energy efficiency with the antiquated preparatory prosthesis after final residual limb volume stabilization and prior to provision of the definitive prosthesis." In addition, the draft LCD imposes multiple prerequisites and barriers to qualifying for a definitive prosthesis such as sufficient trunk control, good upper body strength, and adequate knee stability and posture, to name a few.

Taken together, these are formidable goals for any amputee, especially those with comorbid conditions or beneficiaries of advanced age. There is little question that some amputees under Medicare will not achieve them and this means a definitive prosthesis will not be considered medically necessary. As inhumane and clinically inappropriate a policy this is, it may save money for Medicare in the short term. However, Dobson-DaVanzo has demonstrated that O&P services are cost-effective for the Medicare program and increase the quality of life and independence of the patient. In particular, Medicare data analysis of prosthetic users demonstrates that the provision of more advanced technology can lead to reduced costs over the provision of less advanced technology, presumably due to greater activity levels, fewer falls, a less sedentary lifestyle and, generally, reduced need for health care services.[7]

Another example of the same issue in the draft LCD is the new limitation on add-on codes, which would preclude the use of diagnostic "test" sockets for preparatory prostheses. Test sockets are clear thermoplastic sockets that are fit to the amputee without any socket interface so the prosthetist can assess the fit of the socket by examining pressure points on the skin of the residual limb during weight bearing. Test sockets at this delicate stage in a patient's rehabilitation are critically important for ensuring proper fit and function of the preparatory limb.

Removing coverage for test sockets is one of the more cost-inefficient proposals in the draft LCD, especially when one considers that Medicare's own data demonstrates that Medicare spent virtually the same amount on test sockets in 2005 as it did in 2013 ($19,136,194 in 2005 and $19,627,394 in 2013). These diagnostic sockets help ensure properly fitting and functioning prostheses, and yet, the draft LCD eliminates coverage of them for preparatory prostheses. This and many other policies included in the draft LCD can only be described as "penny wise and pound foolish."

[7] Retrospective Cohort Study of the Economic Value of Orthotic and Prosthetic Services Among Medicare Beneficiaries, Final Report, Dobson DaVanzo and Associates (2013)

5. Simplistic View of the Amputee Experience with Prostheses

There are numerous examples throughout the draft LCD that raise serious questions as to clinical basis of the policies proposed. Numerous proposed changes in the LCD reveal an overly simplistic view of prosthetic design and function. For instance, the draft LCD states that "Claims for more than one method or type of suspension per prosthesis will be denied as not reasonable and necessary (duplicate item)" and "A molded distal cushion (L5668) is not covered when used in conjunction with a liner or insert that incorporates materials that provide cushioning."

Both of these proposed policies illustrate the view apparently held by the DME MACs that the fit of an artificial limb to a person's residual limb constitutes little more than gluing two pieces of wood together. The fact is that the human-device interface involved in prosthetics is not a static bond. It changes dramatically throughout the day and over time. It goes without saying that each residual limb is unique. There are variations in length, strength, circulation, skin integrity, bony structures, neuromas, scar tissue, and tolerance to pressure and torque. Some residual limbs perspire excessively, creating volume changes and loss of fit throughout the course of a day's use of the prosthesis. Skin is, by definition, malleable and animate, compared to the prosthesis, which is relatively stable and inanimate.

Rather than restricting coverage of features that provide an enduring fit and function of the prosthesis during ambulation and throughout the course of the day, the draft LCD should encourage coverage of complimentary features the amputee patient believes s/he needs to feel comfortable, safe, stable, and confident while ambulating on the prosthesis. The more active and functional the amputee is on the prostheses, the less chance of unnecessary disability and dependency, and all of its associated costs. This constitutes patient-centered care and will lead to better outcomes.

6. CMS Contractors Are Practicing Medicine

The draft LCD is so proscriptive in the processes it requires in order to qualify for various types of prosthetic care that it largely usurps the role and professional judgment of the treating physician, working with the prosthetist and the rehabilitation team, to determine the timing and substance of the rehabilitation and prosthetic plans of care. Major changes in the Healthcare Common Procedural Coding System (HCPCS) coding of multiple prosthetic components will result in new reimbursement levels that will inevitably compromise access to some advanced components. Reimbursement often helps drive clinical practice in that non-covered or non-viable prosthetic technologies are simply not prescribed by physicians or provided by prosthetists. Most alarming is that the proscriptive elements of the draft LCD appear to be crafted out of whole cloth with little or no evidentiary basis or connection to current clinical care and best practices.

Finally, the draft LCD doubles down on the marginalization of the licensed and/or certified prosthetist, the health care professional with the most intimate understanding of prosthetic patient care and the myriad prosthetic options available to meet unique patient needs.

Not only does the draft LCD reiterate the policy of not counting "supplier generated records" as part of the patient's medical record—a position The Alliance strongly opposes—but it further removes the prosthetist from having any meaningful role in the assessment of the patient's functional level, and to some degree, the patient's prosthetic treatment plan. We urge CMS and its contractors to recognize the clinical notes of the prosthetist as relevant in determining medical necessity; prosthetists are part of the clinical team that helps determine the functional level of amputees.

B. The DME MACs Did Not Comply With the Medicare Statute, CMS Regulations, or the Program Integrity Manual

The DME MACs violated the Medicare statute and binding CMS regulations and manuals when developing the draft LCD. LCDs are by definition limited to coverage issues and may not determine coding or payment. As a result, the draft LCD does not even qualify as an LCD. Moreover, the DME MACs did not base the draft LCD on published authoritative evidence and on standards of practice generally accepted by the medical community as required by the Program Integrity Manual (PIM). Because the LCD invalidly exceeds the scope of an LCD and does not comply with the PIM, it must be rescinded.

The Medicare statute is clear that an LCD is strictly limited to whether an item or service is "reasonable and necessary" and hence covered by Medicare:

> [T]he term "local coverage determination" means a determination by a fiscal intermediary or a carrier under part A of this subchapter or part B of this subchapter, as applicable, respecting whether or not a particular item or service is covered on an intermediary- or carrier-wide basis under such parts, in accordance with section 1395y(a)(1)(A) of this title.[8]

Section 1395y(a)(1)(A) excludes from coverage items and services which "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." CMS has confirmed that the Medicare statute "limits an LCD as a determination only under section 1862(a)(1)(A) of the Act's 'reasonable and necessary provision.'"[9] CMS has issued a regulation that mirrors the statutory definition and adds that "[a]n LCD does not include a determination of which procedure code, if any, is assigned to a service or determination with respect to the amount of payment to be made for the service."[10]

The draft LCD invalidly exceeds the scope of an LCD by creating new codes under the HCPCS—otherwise known as the Uniform Code Set—and withdrawing other codes from coverage. A total of seven codes for prosthetic feet have been discontinued and four of these codes have been collapsed into a new code that the DME MACs have created. The draft LCD

[8] 42 U.S.C. § 1395ff(f)(2)(B).
[9] Medicare Program: Review of National Coverage Determinations and Local Coverage Determinations, 68 Fed. Reg. 63,692, 63,693 (Nov. 7, 2003) (discussing Section 1869(f)(2)(B) of the Social Security Act, 42 U.S.C. § 1395ff(f)(2)(B)).
[10] 42 C.F.R. § 400.202.

eliminates the principal on which the prosthetic coding system is based; the assignment of a "base" code to describe the type of prosthesis (e.g., below-knee prosthesis) coupled with "add-on" codes to accurately describe the combination of components and fitting techniques and mechanisms that meet the Medicare beneficiary's individualized treatment plan. The draft LCD also collapses what were previously three codes describing different types of "multiaxial" components into a single, newly-proposed code.

The draft LCD also usurps the authority of HCPCS Coding Work Group at CMS. CMS regulations establish the HCPCS level II codes as the standardized coding system for describing and identifying health care devices, supplies, and related services in health care transactions that are not identified by the HCPCS level I, CPT codes.[11] HCPCS is a system for identifying items and services. It is not a methodology or system for making coverage or payment determinations, which makes any changes proposed by the DME MACs on such bases improper. While HCPCS codes are used for billing purposes, decisions regarding the addition, deletion, or revision of HCPCS codes are to be made independent of the process for making determinations regarding coverage and payment.

The HCPCS Coding Work Group meets regularly throughout the year to consider coding modifications, additions, and deletions of the HCPCS code set. The Work Group is tasked with maintaining this code set, which, under the Health Insurance Portability and Accountability Act of 1996, and a subsequent re-delegation of authority in 2003,[12] applies to all health care payers throughout the country, including the VA. For this reason, representatives of private plans, Medicaid plans, and VA officials participate in the Workgroup, which is primarily comprised of Medicare officials and staff.

By issuing major coding changes in the context of this draft LCD, the DME MACs have inappropriately usurped the authority of the HCPCS Coding Work Group and have short-circuited the code modification process. All manufacturers, practitioners, and patients who rely on the prosthetic components described by these affected codes participated in a lengthy, costly process in the past to secure proper coding. Hours of thoughtful deliberation by the HCPCS Coding Work Group produced a well-defined code set that has been annually refined. The draft LCD wipes all of this precedent away in one stroke. Worse yet, it denies those who disagree with the proposed coding changes the chance to receive a preliminary coding decision, a public hearing on each code modification, and a final decision by the HCPCS Coding Work Group—the current process used for any new coding application under the HCPCS system.

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[11] The HCPCS level II coding system was selected as the standardized coding system for the U.S. health care system because of its wide acceptance among both public and private insurers. Public and private insurers are required to use the code system, making any changes made by the DME MACs especially critical given their resulting impact on other non-Medicare payers.

[12] Pub. L. No. 104-191. The Health Insurance Portability and Accountability Act of 1996 contains this delegation of authority regarding the HCPCS code set, and on its website the HCPCS Coding Work Group cites to the October 2003 delegation of this authority to CMS. *See* Centers for Medicare & Medicaid Services, Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures (rev. Sept. 2012), *available at* https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/HCPCSLevelIICodingProcedures7-2011.pdf.

For these reasons, the coding changes included in the draft LCD should be removed from the document.

C. Required Evidence to Support the LCD

The DME MACs failed to adhere to procedures set forth in the PIM when developing the draft LCD. Chapter 13, § 13.7.1 of the PIM requires contractor LCDs to "be based on the strongest evidence available." The extent and quality of supporting evidence is key to defending challenges to LCDs. The initial action in gathering evidence to support LCDs shall always be a search of published scientific literature for any available evidence pertaining to the item or service in question." The PIM requires LCDs to be based on:

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and

- General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:
    - Scientific data or research studies published in peer-reviewed medical journals;
    - Consensus of expert medical opinion (i.e., recognized authorities in the field); or
    - Medical opinion derived from consultations with medical associations or other health care experts.

LCDs are expected to consider the full range of available evidence and evaluate the quality of the evidence before making any conclusions. Furthermore, for those LCDs (like the draft LCD) that specify that certain items or services are never reasonable or necessary, sufficient evidence must be referenced to refute any support for coverage that may exist.

The draft LCD falls far short of the standards set forth in the PIM for clinical evidence. When the draft was originally made available for comment, it neither cited to nor included *any* references to clinical evidence in support of the proposed changes. Only upon prompting by AOPA, a member of The Alliance, was a bibliography supplied. Once provided, the bibliography showed that it was prepared after the fact. It was dated July 30, 2015, which was after the draft LCD was published on July 16th, indicating that the listed sources were not, in fact, the initial evidentiary support that prompted the proposed changes.

The bibliography gives no insight into which references were relied upon to support the myriad changes made to the current coverage policy for lower limb prostheses, and many of the references are outdated or irrelevant. More than a quarter of the references are non-clinical, and not a single reference involves a peer-reviewed study. Three of the sources are more than 20 years old, and one is almost 50 years old. Another reference, focusing on "emerging trends," is over a decade old. Two of the references relate to topics not even addressed in the LCD (i.e., fitting bilateral amputees, hip disarticulation and hemi-pelvectomy amputees). Seven of the references relate to the same collected volume: Atlas of Amputations and Limb Deficiencies. Overall, the level of evidence cited by the DME MACs falls dramatically short when assessed against the PIM's requirements for evidence in developing LCDs.

Through conversations with DME MAC and PDAC officials, it appears that some of the changes proposed in the draft LCD rely on CMS' "inherent reasonableness" authority. Inherent reasonableness is a statutory and regulatory provision that permits CMS to pursue reimbursement level adjustments to certain services through regulation.[13] However, the draft LCD and the procedures employed by the DME MACs in promulgating the proposed changes fail to adhere to the procedural requirements under the inherent reasonableness standard, including identifying a qualifying reimbursement discrepancy, providing required justification for the changes, and publication of these policy changes in the Federal Register. The failure to satisfy the statutory and regulatory requirements of the inherent reasonableness standard make such changes void. In particular, if the proper procedures were followed, the impact on small businesses (i.e., prosthetists) would have been required to be considered and would have revealed the extremely detrimental effect of the changes to the profession and on access to quality patient care.

For these reasons, as well as the specific reasons tied to the various provisions of the draft LCD discussed in detail below, the proposed changes must be rescinded. However, The Alliance is ready, willing, and able, along with other relevant stakeholders, to meet with the contractors and CMS officials to discuss—in depth—concerns with the lower limb prosthetic benefit. We wish to be part of the solution.

If the draft LCD is not rescinded, then it should be suspended indefinitely. The 45-day period provided for comments and feedback on the proposed changes is hardly sufficient given the extensive nature of the changes and the interplay between different sections of the LCD. Few provisions of the current LCD on lower limb prostheses remain unchanged in the draft including changes to coverage, coding, and payment that relate to every aspect of lower limb prostheses. The opportunity for comment at the August 26, 2015 meeting is insufficient. In addition, public comments on changes of this magnitude should be heard by officials responsible for administering the prosthetic benefit at CMS, not just the DME MACs.

If nothing else, the LCD should be suspended at least until the final rules are released for prior authorization of lower limb prostheses. The Alliance understands that CMS' final rule for Prior Authorization of Certain DMEPOS is pending clearance at the Office of Management and Budget. While we have no idea whether we will support or oppose the final rule, it makes no sense for Medicare contractors to finalize medical policy through an LCD that is materially affected by, and not integrated into, a pending federal regulation on the same policy. Commenters should have the opportunity to examine all relevant rules being promulgated by CMS before being forced to comment in a piecemeal manner.

[13] *See* 42 U.S.C. § 1395u(b)(8)-(9); *see also* 42 C.F.R. § 405.502(g).

SECTION II: COVERAGE

LCD: "DEFINITIONS" SECTION

1. **Initial Prosthesis:** ***"An initial prosthesis is defined as the first (initial) prosthesis reimbursed by Medicare. This includes … 'replacement' of an existing prosthesis obtained prior to or outside of the Medicare program." (p. 2, paragraph 5)***

The draft LCD creates confusion where none previously existed. Specifically, HCPCS Codes L5500 and L5505 both use the term "initial" to describe direct-formed, plaster sockets with associated limb components. But the draft LCD expands the concept of an initial prosthesis to include "replacement of an existing prosthesis," which is at odds with both the common understanding of the term and the language already existing in the HCPCS code set.

2. **Replacement Prosthesis:** ***"A replacement prosthesis is defined as the replacement of a complete, existing definitive prosthesis or major component part of an existing definitive prosthesis, such as socket, knee, foot/ankle, etc. (not all-inclusive), previously reimbursed by Medicare. Claims for a replacement must meet the payment rules for replacement of items in effect on the date of service for the replacement claim." (p. 2, paragraph 6)***

The draft LCD defines "replacement prosthesis" in a way that will hurt amputees by decreasing their access to timely care. Specifically, it takes the counterintuitive position that replacement of a "major component" is the same thing as replacing the entire prosthesis, thereby requiring a full independent medical examination[1] and all the associated supporting documentation without regard for the practical realities of why a major component gets replaced in the first place. Major components like prosthetic sockets, knees, and ankles/feet are essential in order for amputees to walk safely. These devices require quick replacement or else the patient will face either increased safety risks (from using something that is not operating in an optimal fashion) or a total loss of ambulatory mobility (from not having a prosthesis with medically necessary components).

In addition, when attempting to define "major components," the draft LCD lists several items, but then includes the parenthetical, "not all-inclusive." By failing to identify all major components, qualified practitioners are left wondering what documentation they and other health care providers must obtain and provide on a claim-by-claim basis. At a minimum, the draft LCD and Policy Article should define "major component" comprehensively to remove any question as to what qualifies as one.

[1] See Item 18 in Section III for The Alliance's comments regarding the proposed "independent medical examination."

3. **Repair:** ***"A repair includes the replacement of minor parts but does not include the complete replacement of the prosthesis or major component. A repair includes reasonable labor charges for the diagnosis of the problem and time necessary to make the repair." (p. 2, paragraph 7)***

The draft LCD fails to define the term, "minor parts." It should clarify what is included in minor parts and we recommend revising the language as follows: "A repair includes the use of materials and consumable tools as well as reasonable labor charges for the diagnosis of the problem and time necessary to make the repair."

4. **Immediate Prosthesis:** ***"An immediate prosthesis, also referred to as a post-operative prosthesis, is applied in the operating room immediately following amputation. It helps control initial swelling, reduce pain, protect the amputation site by enveloping the residual limb in a rigid dressing, and allows for immediate, although light, ambulatory rehabilitation. Immediate prostheses are for use during the time after amputation when the residual limb is healing prior to the provision of a preparatory prosthesis." (p. 3, paragraph 1)***

The draft LCD is at odds with accepted standards of care to the extent that it implies that an immediate prosthesis can *only* be applied in the operating room. By limiting the definition in this way, the draft LCD will act as a barrier to the medically necessary fitting of an immediate prosthesis in places other than the operating room. We recommend changing the language to make clear that the immediate prosthesis "is applied during the initial healing phase following an amputation or revision to an amputation."

5. **Preparatory Prosthesis:** ***"A preparatory prosthesis is an unfinished, functional replacement for an amputated limb, fitted and aligned to accelerate the rehabilitation process, control edema, and prepare the residual limb for the external forces associated with the wearing of a prosthesis on a day-to-day basis. It is provided after the initial surgery after the wound has healed but before the residual limb has matured. Preparatory prostheses are for use during the time after amputation when the residual limb is healing and maturing prior to the provision of the definitive prosthesis." (p. 3, paragraph 2)***

The draft LCD fails to acknowledge accepted standards of care by limiting the definition of a preparatory prosthesis to an artificial limb provided only "after the initial surgery." In fact, qualified practitioners fit and deliver preparatory prostheses when the residual limb still needs to mature and/or the patient requires additional intermediary use of a prosthesis in preparation for a definitive prosthesis. Qualified practitioners regularly fit and deliver preparatory prostheses when patients are unable to use their limb for an extended period of time due to (1) other conditions or medical complications and (2) the failure of a major component and the resulting delay in obtaining necessary documentation or authorization from payers.

In addition, the draft LCD's description of a preparatory prosthesis as "unfinished" implies that the prosthesis is incomplete and not fully functional for use. We recommend eliminating the term "unfinished."

6. **Definitive Prosthesis: "*A definitive prosthesis is a replacement for the missing limb or part of a limb, meeting standards for comfort, fit, alignment, function, appearance, and durability. It is provided after the surgical wound has healed and the residual limb has matured." (p. 3, paragraph 3)***

The "standards for comfort, fit, alignment, function, appearance, and durability" in the draft LCD's definition of a definitive prosthesis require clarification. Put simply, standards without any definitions are not standards. It is unfair to amputees who require a definitive prosthesis to have their eligibility for such a device contingent upon standards that lack any objective criteria.

In addition, the draft LCD must provide guidance regarding what qualifies a residual limb as "mature."[2] While it defines a mature limb as one that has healed, reached its optimal volume, and been shaped appropriately to accommodate the chosen socket configuration, the draft LCD fails to address the clinical reality that residual limbs continue to change in volume and shape for a significant period of time *after* both healing has occurred and the patient has receive a definitive prosthesis.

7. **Revised Amputation: *"A revised amputation is defined as additional surgery to an existing amputation site." (p. 3, paragraph 5)***

The draft LCD includes revised amputations in the definition of a "new amputation," so it is unclear why this additional definition is necessary. This should not be used to restrict access to the same services provided to all other patients with amputations, including new sockets and any other necessary components.

8. **Mature Limb: "*A mature residual limb is defined as one that has healed, reached its optimal volume, and been shaped appropriately to accommodate the chosen socket configuration." (p. 3, paragraph 6)***

The draft LCD's terminology – "reached *optimal volume*" and "*shaped appropriately* to accommodate the chosen socket configuration" – is vague and undefined. In the absence of clarification, these nebulous terms could be broadly interpreted in ways that deny amputees access to appropriate definitive prostheses.

The Alliance recommends describing a mature limb as one that has "stabilized in volume and is deemed appropriately prepared for a definitive prosthesis." We further recommend the following: "It is recognized that the residual limb will continue to change volume and shape with increased use and function with a definitive prosthesis." Because of these volume and shape changes even after provision of the definitive prosthesis, we must also note that the Social Security Act contains language that allows for the replacement of the entire prosthesis, prosthetic socket, or components based **solely** on medical necessity. Therefore, arbitrary useful lifetime restrictions[3] are not appropriate and should be removed from then draft LCD.

[2] *See* The Alliance's comment regarding Item 8, below.
[3] *See* 42 U.S.C. §§ 1395m(h)(1)(G), 1395x(s)(9).

9. **LCMP:** ***"A 'Licensed or Certified Medical Professional (LCMP)' is defined as a Physician (MD/DO), Physician Assistant (PA), Nurse Practitioner (NP), or Physical Therapist (PT) with training, experience, and whose scope of practice permits the comprehensive functional assessment of beneficiaries with amputations." (p. 3, paragraph 7)***

The draft LCD fails to acknowledge the practical reality that assessments of function for purposes of providing a prosthetic limb may be outside the scope of practice for some of the identified professionals, particularly PAs and NPs.

The Alliance recommends the inclusion of licensed and/or certified prosthetists on this list. These qualified practitioners are the primary allied health professionals specifically educated and trained to provide such assessments and they have experience in conducting them.[4] The defined scope of practice of licensed and/or certified prosthetists permits the comprehensive functional assessment of amputees and these qualified practitioners have performed them for decades.

We are cognizant of the DME MACs' view that certified and/or licensed prosthetists may have a potential conflict of interest. As is already well documented, we strongly disagree with that view. The licensed and/or certified prosthetist's potential conflict of interest is no different than that which exists for any other health care provider who treats beneficiaries and is reimbursed for that treatment. The failure to recognize the licensed and/or certified prosthetist as a LCMP solely on the basis of a *perceived* conflict of interest is discriminatory and should be corrected.

LCD: "IMMEDIATE PROSTHESES" SECTION

10. ***"Initial immediate prostheses (L5400-L5460) are covered for a beneficiary with a new or revised amputation when all of the requirements below are met: (1) The beneficiary has had an appropriate above or below knee amputation; (2) The immediate prosthesis is provided after surgery, while the surgical incision is still healing; and (3) The beneficiary is motivated to ambulate using the prosthesis." (p. 3, paragraph 9)***

The code range (L5400-L5460) identified in the draft LCD as describing an immediate prosthesis inappropriately excludes two L codes. The draft LCD currently lists L5500 and L5505 as preparatory prosthesis codes despite the fact that the descriptor for each starts with the word, "initial." Both of these codes describe complete prostheses that are fit immediately following or shortly after surgery.

The draft LCD's classification of these codes under the "preparatory prostheses" heading will lead to some amputees receiving these less durable, initial prostheses when they should have gotten the more robust preparatory prostheses that is clinically appropriate before getting fit with a definitive prosthesis. This could result in harm to the patient through the use of these prostheses for longer than is clinically beneficial.

[4] Gaunaurd I, et al. *Use of and Confidence Administering Outcome Measures Among Clinical Prosthetists: Results from a National Survey and Mixed-Methods Training Program.* Prosth. Orthot. Intl. (2014).

In addition, the draft LCD fails to define what constitutes an "appropriate" amputation. The word "appropriate" should be omitted.

Finally, the draft LCD limits coverage of immediate prostheses to only above-knee or below-knee amputees. The draft LCD must make immediate prostheses available to hemi-pelvectomy, hip disarticulation, and knee disarticulation amputees.

A. Qualifying Amputation: "*If there is no qualifying amputation, claims will be denied as statutorily non-covered, no benefit." (p. 4, paragraph 1)*

The draft LCD fails to explain what constitutes a "qualifying" amputation. The word "qualifying" should be omitted.[5]

B. Unable or Unwilling: "*If the beneficiary is unable or unwilling to use the prosthesis, the claim will be denied as not reasonable and necessary." (p. 4, paragraph 2)*

The words "unable or" should be deleted.[6] The draft LCD fails to acknowledge the practical clinical reality that some patients become unable to use a prosthesis *after* receiving it (a) despite the fact that the qualified practitioner correctly confirmed the amputee's willingness and motivation to ambulate, and (b) for reasons that the qualified practitioner could not expect or foresee.

C. Related Additions: "*If any part of a prosthesis is denied as not reasonable and necessary, all related additions will also be denied as not reasonable and necessary." (p. 4, paragraph 3)*

This language is confusing because it is inconsistent with the very next paragraph, which prohibits the billing of *any* additions for immediate prostheses. Including language in sections to which it does not apply or where it directly contradicts other language in the section is inappropriate and leads to unnecessary confusion and ambiguity. This sentence should therefore be deleted from this section of the draft LCD.[7]

D. No Add-Ons: "*Immediate prostheses (L5400-L5460) are complete and all-inclusive as described by the code narratives and in the CODING GUIDELINES section in the related Policy Article. There is no coverage for any additional components, add-ons, upgrades, substitution of components, etc. (not all-inclusive) provided for use with an immediate or post-operative prosthesis. All additional items will be denied as not reasonable and necessary." (p. 4, paragraph 4)*

[5] The Alliance's comment here also applies to the identical language on page 5, paragraph 1 and page 6, paragraph 1 (following the bullet point list) of the draft LCD.
[6] The Alliance's comment here also applies to the identical language on page 5, paragraph 2 and page 6, paragraph 2 (following the bullet point list) of the draft LCD.
[7] The Alliance's comment suggesting deletion of this sentence also applies to the identical language on page 5, paragraph 3 of the draft LCD.

As referenced in the previous comment, this language is confusing because it is inconsistent with the preceding paragraph, which implies the possibility of billing for "related additions." Including language in sections to which it does not apply or where it directly contradicts other language in the section is inappropriate and leads to unnecessary confusion and ambiguity. All sections of an LCD need to be consistent and any information that does not relate to a specific segment should be omitted.

Also, the draft LCD's prohibition on additional components, add-ons, upgrades, and substitution of components will hurt amputees by denying them access to medically necessary items that have long been the standard of care. For example, when delivering an item described by L5400, qualified practitioners commonly provide a suspension belt (L5684, L5688, or L5690), which is a removable and separate component. The belt serves a valuable clinical need by helping support the weight of a rigid dressing when the amputee stands and ambulates.

This belt can get soiled or misplaced, requiring its subsequent replacement. But the draft LCD's blanket prohibition on replacement items demonstrates a lack of knowledge about how prosthetic care is delivered. The qualified practitioner should retain the ability to replace medically necessary elements of the immediate prosthesis to maintain and improve the patient's function.

E. New Amputees: "*Immediate prostheses (L5400-L5460) provided other than to a new amputee will be denied as not reasonable and necessary." (p. 4, paragraph 6)*

It is unclear whether an amputee who undergoes subsequent revision surgery would qualify for an immediate prosthesis. The draft LCD's failure to define the term "new amputee" could therefore lead to denial of this clinically-accepted standard of care even when medically appropriate. We recommend revising the language to include the phrase, "or to an amputee who has had a revised amputation."

F. Healing: "*Immediate prostheses (L5400-L5460) provided after the surgical incision has healed will be denied as not reasonable and necessary." (p. 4, paragraph 7)*

While The Alliance has no objection conceptually to this statement, the draft LCD contains no guidance for how this criteria would be measured.

G. No Add-Ons: "*Medicare payment for prosthetics includes all fitting and adjustments necessary in the 90 days after provision (date of service (DOS)) of the prosthesis, therefore all additions, adjustments, modifications, replacement etc. to any components provided as part of the prosthesis and billed separately during the 90 days after provision of the prosthesis will be denied as unbundling." (p. 4, paragraph 8)*

While the Alliance has no general objection to this section, the draft LCD fails to address the scenario where a qualified practitioner must replace a component due to wear or loss. For example, suspension belts are typically provided with immediate prostheses and can become damaged (e.g., soiled) or lost. The qualified practitioner should not be required to replace without reimbursement such components of the prosthetic limb that are damaged or lost during the post-operative period. We recommend creating an exception (similar to Section V. in the

"Sockets" portion of the draft LCD) providing for coverage for the replacement of an item if certain conditions are met. For example: "A suspension belt (L5684, L5688, L5690, L5692, L5694) is covered if it becomes soiled, damaged or lost."

H. 90-Day Restriction for Fitting/Adjustments: "*Medicare payment rules for prosthetic items include all necessary fitting, adjustments, etc. necessary during the 90 days following the date of service. A replacement immediate prosthesis (L5400-L5460) provided sooner than 90 days after a previous immediate prosthesis will be denied as same/similar item." (p. 4, paragraph 9)*

The draft LCD is inconsistent with current standards of care by prohibiting replacement of a cast due to wound issues or edema. If the qualified practitioner has to remove the initial immediate prosthetic cast because of a medical issue, this provision would prevent the amputee from getting a medically necessary prosthesis until the 90-day period had run. This will (a) delay the patient's rehabilitation, and (b) increase the likelihood that additional comorbidities will arise that would not exist if a second prosthesis was covered under specific conditions.

I. 90-Day Restriction for Sockets/Components: "*Socket or other component replacements provided during the 90 days after provision of the immediate prosthesis will be denied as unbundling." (p. 4, paragraph 10)*

See The Alliance's responses to Items 10.G. and H., above.

LCD: "PREPARATORY PROSTHESES" SECTION

11. *"A preparatory prosthesis (L5500-L5600) is covered for a beneficiary with a new or revised amputation when all of the requirements below are met: (1) The beneficiary has had an appropriate above or below knee amputation; (2) The preparatory prosthesis is provided to a beneficiary starting a rehabilitation program; (3) The preparatory prosthesis is provided after the surgical incision has healed; and (4) The beneficiary is motivated to ambulate using the prosthesis." (p. 4, paragraph 11)*

See The Alliance's response to Item 10, above, regarding the draft LCD's use of the word "appropriate."

The draft LCD should clarify the setting(s) in which a "rehabilitation program" occurs. Depending on the circumstances and timing of the injury and recovery, the rehabilitation needs of a new amputee may vary widely. Considering these factors (among others), both outpatient and inpatient rehabilitation programs should be considered sufficient, at minimum. This is an important and entirely new element of the draft LCD that should be the subject of collaboration between the DME MACs and stakeholders, far beyond the parameters of a single four-hour public meeting.

In addition, any definition of a rehabilitation program should explicitly require the involvement of a qualified practitioner to ensure adequate steps are taken to prepare the patient for use of a prosthesis.

The draft LCD also limits coverage of preparatory prostheses to above-knee or below-knee amputees. It must be amended to include coverage for hemi-pelvectomy, hip disarticulation, and knee disarticulation amputees.

The Alliance is concerned about the requirement that a preparatory prosthesis is covered only *after* the surgical incision has healed. The draft LCD should permit preparatory prostheses once the surgical incision has healed enough to allow for effective prosthetic intervention as determined by the ordering physician.

A. **Mature Residual Limb: "*Preparatory prostheses are fitted and used during a rehabilitation program (see below) while the residual limb is reshaping and maturing. Preparatory prostheses fitted to a mature residual limb will be denied as not reasonable and necessary." (p. 5, paragraph 4).***

The draft LCD use of the term "mature residual limb" fails to account for continuous limb volume and shape changes that may occur for an extended period of time post-amputation. This creates the possibility that amputees will be denied medically appropriate preparatory prostheses on the grounds that the limb is already "mature."

Also, see The Alliance's comments in Item 11, above, concerning the definition of a rehabilitation program.

B. **No Add-Ons: "*Preparatory prostheses use basic prosthetic components, which provide adjustability and alignment changes as limb maturity occurs. Preparatory prostheses (L5500-L5600) are all-inclusive as described by the code narrative and in the CODING GUIDELINES section in the related Policy Article. There is no coverage for any additional components, add-ons, upgrades, additions, adjustments, modifications, replacement etc. substitution of components, etc. provided for concurrent use with a preparatory prosthesis. All additional items will be denied as not reasonable and necessary." (p. 5, paragraph 5)***

The draft LCD's proposal to limit all Medicare beneficiaries to a SACH foot and prohibit above-knee or higher-level amputees from using a prosthetic knee mechanism with their preparatory prosthesis, regardless of functional level, is antiquated and fails to reflect current standards of practice in the prosthetic profession. When a new amputee has the potential to satisfy a K2 or higher functional level, it is standard practice to introduce a foot and knee system that will more closely align with their ultimate functional level. The draft LCD should permit the use of alternate foot and knee systems (e.g., L5972, L5974, L5975, L5976, L5978, L5812, L5814, L5822, L5824) when the beneficiary has higher functional potential.

The Alliance recommends striking everything after the first sentence because inclusion of language under specific sections to which it does not apply or where it directly contradicts other

language in the section is inappropriate and leads to unnecessary confusion and a lack of clarity. Certain add-ons provided with prosthetic limbs require periodic replacement (e.g., socks). The draft LCD would hurt amputees by denying them access for these medically necessary replacements. This language is also later contradicted by language on page 7, paragraph 3, which sets out conditions for coverage of replacement sockets for preparatory limbs.

C. **90-Day Restriction for Fitting/Adjustments: "*Medicare payment for prosthetics includes all fitting and adjustments necessary in the 90 days after provision of the prosthesis, therefore all additions, adjustments, modifications, replacement etc. to any components provided as part of the prosthesis and billed separately during the 90 days after provision of the prosthesis will be denied as unbundling. Medicare payment rules for prosthetic items include all necessary fitting, adjustments, etc. necessary during the 90 days following the date of service. A replacement preparatory prosthesis (L5500-L5600) provided sooner than 90 days after a previous preparatory prosthesis will be denied as same/similar item." (p. 5, paragraphs 6 and 7).***

The draft LCD is inconsistent with current standards of care. Certain add-on items provided with prosthetic limbs, including preparatory prostheses, require periodic replacement (e.g., socks). The draft language would hurt amputees by denying them access to medically necessary replacement items. The Alliance recommends revising this section to allow for replacement of medically necessary components to maintain patients' functional level.

D. **90-Day Restriction for Sockets/Components: "*Socket or other component replacements provided during the 90 days after provision of the prosthesis will be denied as unbundling." (p. 5, paragraph 8)***

The draft LCD makes inappropriate clinical care decisions and uses an arbitrary timeline regarding when a patient requires a socket replacement, thus prohibiting access to medically-necessary socket replacements. By denying socket replacements even when a patient's residual limb has undergone significant shape and volume changes, this provision will hurt amputees and slow their rehabilitation by delaying their access to well-fitting sockets. The Alliance recommends striking this section.

E. **New Amputee Restriction: "*Preparatory prosthesis (L5500-L5600) provided other than to a new amputee will be denied as not reasonable and necessary." (p. 5, paragraph 9)***

While The Alliance has no objection conceptually to this statement, the draft LCD fails to define what constitutes a "new amputee." If a patient has been an amputee but has a new amputation or a revision of an existing amputation, s/he should have access to a preparatory prosthesis. The Alliance recommends revising this section to allow for a preparatory prosthesis for an amputee who has had either a new amputation or a revision to an existing amputation.

LCD: "DEFINITIVE PROSTHESES" SECTION

12. "*An initial definitive prosthesis is covered …"*

- ***"[if t]he beneficiary has had an appropriate above or below knee amputation." (p. 5, final paragraph, 1st bullet point)***

The draft LCD fails to define the word "appropriate." The word "appropriate" should be omitted. Further, the draft LCD must provide coverage for medically-necessary definitive prostheses required by hemi-pelvectomy, hip disarticulation, and knee disarticulation amputees.

- ***"[if t]he beneficiary [ ] has successfully completed a rehabilitation program." (p. 5, final paragraph, 2nd bullet point)***

The draft LCD's prohibition on coverage for a definitive prosthesis unless the patient has successfully completed a rehabilitation program threatens to limit amputees' access to medically-necessary prostheses. Access to a definitive prosthesis should not be tied to an individual amputee's ability to complete an undefined rehabilitation program, but rather, should rest on a physician's written order confirming the patient's readiness for a definitive prosthesis.

While The Alliance recognizes the value of organized rehabilitation, it remains concerned that patients with transportation issues or who live in rural areas may not be able to access these programs in a timely fashion or, in some instances, at all. Requiring amputees to complete a rehabilitation program when they are otherwise ready to utilize a definitive prosthesis may result in unnecessary delays to their clinical treatment, harming the patient. Also, see The Alliance's comments under #11, above.

- ***"[if t]he definitive prosthesis is provided after the surgical incision is stable (healed)." (p. 5, final paragraph, 3rd bullet point)***

While The Alliance acknowledges that a qualified practitioner typically delivers the definitive prosthesis as described in this sentence, there may be clinical situations that necessitate early fitting of the definitive prosthesis while the surgical incision is still healing.

- ***"[if t]he definitive prosthesis is provided after the residual limb has matured." (p. 5, final paragraph, 4th bullet point)***

While The Alliance has no general objection, the draft LCD fails to define the term, "matured." This could lead to confusion in cases where the patient's residual limb continues to change during the first year (or more) of prosthetic use. This is typical and the draft LCD should acknowledge that clinical fact.

- ***"[if t]he beneficiary is cognitively capable of using the prosthesis to ambulate effectively at the determined functional level (K0 – K4)." (p. 5, final paragraph, 6th bullet point)***

The draft LCD's insistence on establishing cognitive, neuromuscular, and cardiovascular requirements[8] to receive a definitive prosthesis fails to acknowledge the reality that many prosthetic users can and do successfully achieve advanced functional status despite other conditions affecting their overall health. Substituting a remote claims reviewer (who has no direct knowledge of the amputee's overall health condition and capability to successfully use a prosthesis) for a physician who actively manages that patient's health care will hurt amputees. It will sacrifice the individual amputee's clinical needs merely to gain some illusive administrative "efficiency."

While cognitive, neuromuscular, or cardiovascular conditions may affect a patient's ability to use a prosthesis and are factors worth considering when determining patient readiness for a definitive prosthesis, they should not, by themselves, be used to deny coverage for a patient who would benefit functionally from a definitive prosthesis.

- ***"[if t]he beneficiary has sufficient neuromuscular control to effectively and appropriately make use of the prosthesis at the determined functional level (K0 – K4)." (p. 5, final paragraph, 7th bullet point)***

See The Alliance's response to the immediately preceding bullet point, above.

- **"[if t]he beneficiary has sufficient cardio-pulmonary capacity to effectively use the prosthesis at the determined functional level (K0 – K4)."** ***(p. 6, 1st bullet point)***

See The Alliance's response to the immediately preceding bullet point, above.

- ***[if t]he beneficiary has had an in-person medical evaluation with the ordering physician to establish their overall functional capabilities. … This specialty evaluation must:***
    - ***Evaluate and document the beneficiary's overall health status taking into consideration factors related to the amputation and prosthesis use as well the effect of comorbidities on potential function. The evaluation must include a complete physical examination including an objective neuromuscular evaluation, cardio-pulmonary capacity evaluation and cognitive evaluation;***
    - ***Determine a global activity level as described by the functional level modifiers. (K-levels); and***
    - ***[sic] That the treating physician and/or the LCMP that performed the in-person assessment must have no financial relationship with the supplier." (p. 6, 2nd bullet point)***

While The Alliance understands the intent of this language, it does not represent the applicable standard of prosthetic care provided by qualified practitioners. Rather, the ordering physician prescribes a prosthesis and refers the patient to a qualified practitioner. The qualified practitioner then performs the evaluation and functional assessment of the amputee's need for a prosthesis.

[8] The two bullet points following this one contain specific references to neuromuscular and cardiovascular status. In the interest of efficiency, we have addressed both of those requirements in this bullet point.

The draft LCD implicitly and inappropriately concludes that the physician who orders the prosthesis has failed to take into consideration the patient's overall health status as well as any comorbidities that might prevent the amputee from being a prosthetic candidate. This concept is misguided and will only lead to unnecessary additional costs.

To prevent the qualified practitioner from completing the specialty evaluation makes no clinical sense based on the functions and skills to be assessed. These individuals are specially educated and trained to perform such assessments. In fact, the DMEPOS Quality Standards[9] mandate that the prosthetic supplier perform this type of evaluation, in the Intake and Assessment section of Appendix C. Not including them in the list of professionals able to carry out those evaluations precludes amputees from getting expert assessments by the people best qualified to make them.

The Alliance also recommends replacing all references to "the supplier" in the draft LCD with "the qualified practitioner." This term, defined as part of [insert citation], describes all individuals qualified to provide prosthetic care to amputees.

- ***"[if t]he beneficiary has had an in-person evaluation by the prosthetist to evaluate prosthetic needs consistent with the overall functional capabilities identified by the medical examination." (p. 6, 3rd bullet point)***

Consistent with current practices, The Alliance maintains that the functional assessment should be permitted to be performed by a prosthetist, with the ordering physician reviewing and approving the resulting plan of care. This is similar to the process used for approving therapy plans of care for physical therapists. If the ordering physician approves the prosthetist's assessment and plan of care, the prosthetist's documentation and the ordering physician's written approval should be sufficient to establish the patient's needs for the prosthesis provided.

For further commentary, see The Alliance's response to the preceding bullet point.

- ***"[if t]he beneficiary is able to ambulate using the device at or above the identified functional level." (p. 6, 4th bullet point)***

The draft LCD fails to acknowledge the clinical reality that an individual patient's ambulatory status varies over time. Medical issues may directly affect the amputee's ability to ambulate during or subsequent to the provision of the prosthesis. The draft LCD must acknowledge these potential circumstances.

A. Denial of Part Requires Denial of Whole: ***"If any part of a prosthesis is denied as not reasonable and necessary, all related additions will also be denied as not reasonable and necessary." (p. 6, paragraph 3)***

[9] https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/DMEPOS_Qual_Stand_Booklet_ICN905709.pdf

The draft LCD takes the illogical position that failure to comply with coverage guidelines for a single component or any subpart thereof (if described by an add-on code) renders the entire prosthesis or component medically unnecessary. If implemented, this would create untenable financial risk for qualified practitioners. A single inadvertent error would prevent reimbursement for a prosthesis in which the qualified practitioner potentially has had to invest thousands of dollars.

A more rational, less punitive solution would be to allow denial of only the single code describing the individual component or subpart thereof in this situation – not the entire prosthesis. This section should be deleted from the draft LCD.

B. No Add-Ons: "*Definitive prosthesis (L5000 through L5341) are [sic] all-inclusive for all components necessary for a complete prosthesis. Separate components (sockets, knees, ankles, feet, pylons, etc. (not all-inclusive)) billed with these codes will be denied as unbundling." (p. 6, paragraph 4)*

This language ignores the fact that the entire system of reimbursement for prostheses is based on base codes and add-ons. But the rest of the draft LCD acknowledges the applicability of the base code/add-on system, thereby contradicting this provision. It should be deleted in its entirety.

C. Non-Mature Residual Limb: *"Preparatory prostheses are fitted and used during a rehabilitation program while the residual limb is reshaping and maturing. Definitive prostheses and components fitted to a non-mature residual limb will be denied as not reasonable and necessary." (p. 6, paragraph 5).*

This section shows a complete lack of clinical understanding about amputations and the provision of prostheses. Residual limbs often continue to change shape and volume for the first year or more post-amputation. The draft LCD creates an illogical scenario where prosthetists will have claims for socket replacements denied because the original socket was fitted to a "non-mature residual limb." This could in turn lead to a retroactive denial of the entire prosthesis under the language in Item 12.A., above. This language serves no purpose and should be struck from the LCD.

D. 90-Day Restriction for Fitting/Adjustments: "*Medicare payment for prosthetics includes all fitting and adjustments necessary in the 90 days after provision of the prosthesis, therefore all additions, adjustments, modifications, replacement etc. to any components provided as part of the prosthesis and billed separately during the 90 days after provision of the prosthesis will be denied as unbundling." (p. 6, paragraph 6)*

This provision of the draft LCD will hurt amputees by prohibiting access to medically-necessary replacement components based on an arbitrary timeline without regard to the unique clinical circumstances. Under this proposal, amputees would be forced to try to wear prostheses that fit them poorly due to changes in their residual limbs that require socket, liner or sock replacements. Because Medicare arbitrarily prohibits qualified practitioners from providing these medically necessary interventions, these patients will either (a) continue to try to use ill-fitting prostheses, leading to possible skin breakdown, ulcerations, or other avoidable comorbidities, or (b) stop

wearing their prostheses altogether to avoid the problems referenced in (a), thereby reducing their mobility and delaying their rehabilitation.

The Alliance recommends revising this section to allow for unique clinical situations where replacement components, adjustments, and modifications are necessary to maintain the patient's function, even when that occurs within 90 days after provision of the definitive prosthesis.

E. 90-Day Restriction for Definitive After Preparatory: "*Medicare payment for prosthetics includes all fitting and adjustments necessary in the 90 days after provision of a prosthesis, therefore a definitive prosthesis may not be provided sooner than 90 days after the preparatory prosthesis." (p. 6, paragraph 7)*

The draft LCD's restriction on providing a definitive prosthesis for 90 days following provision of a preparatory prosthesis will hurt amputees who have the ability to use a definitive prosthesis in fewer than 90 days. Coverage for a definitive prosthesis should be available as soon as the patient can walk effectively with a definitive prosthesis. Amputees should not have to wait 90 days in situations where their progress has exceeded the clinical benefit a preparatory prosthesis provides.

F. 90-Day Restriction for Sockets/Other Components: "*Socket or other component replacements provided during the 90 days after provision of the prosthesis will be denied as unbundling." (p. 6, paragraph 8)*

See The Alliance's response to Item 12.E. above.

DRAFT LCD: "COMPONENTS" SECTION

13. Sockets: *One socket (L5630, L5632-L5636, L5638-L5653) per individual definitive prosthesis is covered. (p. 7, paragraph 2)*

The Alliance is concerned that limiting coverage to one socket code and descriptor per individual prosthesis precludes the possibility of socket design features (e.g. total contact, ischial containment, flexible sockets, etc.) that are the current standard of practice. Restricting the ability to integrate socket design features that provide the amputee a therapeutic benefit will hurt amputees by resulting in prosthetic sockets that do not meet their specific clinical needs. In addition, the draft LCD's proposal does not represent current accepted standards of practice. Finally, these codes are not duplicative as they describe completely different elements of the prosthesis. This section should be omitted.

14. L5700-L5703 for Preparatory Prosthesis: *"Socket replacements (L5700-L5703) for a preparatory prosthesis are covered when either 1 or 2 are met: (1) There are changes in the residual limb that cannot be accommodated thought the use of socket inserts and/or liners and/or stump stockings, and/or modifications to the existing socket; or (2) When the existing socket is irreparable due to damage or wear." (p. 7, paragraph 3)*

This provision of the draft LCD contradicts earlier language[10] stating that replacements and additions to a preparatory prosthesis within the first 90 days are not covered. Inclusion of language that directly contradicts other language in the LCD is inappropriate and results in unnecessary confusion and a lack of clarity.

The Alliance agrees that coverage of replacement sockets under the circumstances described is appropriate. Therefore, the earlier inconsistent language referenced in the footnote in the previous paragraph should be deleted.

Lastly, the fact that the draft LCD excludes socket design feature codes for preparatory prostheses like total contact, ischial containment, and flexible sockets renders it incompatible with current accepted standards of practice. These codes remain crucial to ensuring the proper fit of the prosthetic socket, regardless of whether the qualified practitioner incorporates them into a socket replacement for a preparatory prosthesis or a socket replacement for a definitive prosthesis. The draft LCD's failure to acknowledge that reality will hurt amputees who medically require a socket with one or more of these features while using a preparatory prosthesis.

15. Other Socket Replacement Codes: "*Sockets [sic] replacements (L5630, L5632-L5636, L5638-L5653) are not separately payable when billed with an immediate or preparatory prosthesis (L5400-L5600). Claims for sockets billed with an immediate or preparatory prosthesis will be denied as unbundling." (p. 7, paragraph 5)*

The fact that the draft LCD excludes socket design feature codes like total contact, ischial containment, and flexible sockets renders it incompatible with current accepted standards of practice. These codes remain crucial to ensuring the proper fit of the prosthetic socket, regardless of whether the qualified practitioner incorporates them into a socket replacement for a preparatory prosthesis or a socket replacement for a definitive prosthesis. The draft LCD's failure to acknowledge that reality will hurt amputees who medically require a socket with one or more of these features while using a preparatory prosthesis.

16. Test Sockets: "*More than two (2) test (diagnostic) sockets (L5618-L5628) for an individual definitive prosthesis are not reasonable and necessary." (p. 7, paragraph 6)*

This arbitrary limitation on the number of diagnostic sockets required to obtain a well-fitting socket will hurt those amputees with unique clinical issues who require more than two diagnostic sockets. The language should be revised to state that medical necessity determines the number of diagnostic sockets allowed.

The Alliance is also concerned that the LCD does not provide coverage for test sockets used in ensuring the proper fit of a socket for a *preparatory* prosthesis. The use of test sockets is covered for definitive prostheses and should also be permitted when fabricating a socket for a preparatory prosthesis, as it is a valuable tool in ensuring the intimate fit of the socket required for proper prosthetic function.

[10] See page 5, paragraph 5 of the draft LCD.

17. Acrylic Resin Laminations: "*Acrylic resin laminations (L5629, L5631) provide for an intimate fit and a firm, smooth, bearing surface. Acrylic laminations are only covered for sockets that are not molded to a patient or patient model e.g. wood (L5639, L5644). Acrylic laminations are not separately payable when billed with any other socket type (L5630, L5632-L5636, L5638, L5640-L5643, L5645-L5653) as this function is included in the base code. Claims for acrylic resin laminations billed with a socket other than L5639 or L5644 will be denied as unbundling." (p. 7, paragraph 7)*

The draft LCD's language regarding acrylic resin laminations reveals a total misunderstanding of the role these laminations play in the prosthetic fabrication process. Acrylic resin laminations have nothing to do with an "intimate fit, firm, smooth surface. [sic]" Qualified practitioners choose acrylic resins to match best with the lay-up materials being used in the lamination process to meet goals of strength, end product weight, and durability in sockets of *all* types. To state that these codes can apply only to an exoskeletal wood socket's outside lamination is dead wrong.

The draft LCD's proposed limitation of acrylic resin laminations to wood sockets would prevent them from being used as additions to the other socket base codes. This would put amputees who require additional strength and durability from their sockets at increased risk. Acrylic resin laminations should therefore remain eligible for coverage as a separate and unique feature of the prosthetic socket as they have historically.

If the DME MACs and CMS insist that acrylic resin lamination is already inherent in all lower limb prosthesis base codes (other than those for wood sockets), they must then adjust the published Medicare fee schedule for the base codes to cover the costs associated with this more expensive material and the related processes associated with integrating it into the prosthetic socket.

18. Molded Distal Cushion: "*A molded distal cushion (L5668) is not covered when used in conjunction with a liner or insert that incorporates materials that provide cushioning (L5646, L5648, L5673, L5679, L5681, L5683, L8417). Claims for L5668 used in this scenario will be denied as not reasonable and necessary, same/similar item." (p. 7, paragraph 8)*

This section should be deleted from the draft LCD because it fails to acknowledge the important role played by molded distal cushions in designing a prosthetic socket *regardless of whether* a liner or insert is also included in the design. A liner or insert does not provide the degree of cushioning of a molded distal cushion. The proposed limitation discriminates against patients with, for example, boney, hypersensitive and scarred residual limbs. A qualified practitioner, in conjunction with the ordering physician, both of whom are in the best position to understand that patient's specific clinical situation, should be responsible for assessing the amputee's need for a molded distal cushion.

19. Total Contact: *"A total contact addition to lower extremity (L5637 (below knee), L5650 (above knee)) is a socket feature where the intimate fit of the socket around the residual limb creates a negative pressure, therefore, total contact design keeps the prosthesis in position without a pelvic joint and belt. Total contact design is inherent in the production*

of a molded suction socket and is included in the payment for any molded socket. Claims for L5637 and L5650 will be denied as unbundling when billed with a molded socket design." (p. 7, paragraph 9)

The draft LCD's description of total contact is incorrect and inconsistent with current clinical practice. Total contact is a socket design feature used to evenly distribute weight-bearing forces throughout the entire socket, therefore reducing pressure and excessive weight bearing on the distal end of the residual limb. A simple review of the relevant clinical literature confirms this. Total contact has nothing to do with a pelvic joint and belt suspension, nor does it have any role in suspending the prosthesis.

Claiming that total contact "is inherent" in molded socket codes is also incorrect. The base code for both below knee and above knee prostheses was not intended to include this specific feature. For example, the base code L5321 (above-knee endoskeletal prosthesis) specifically states, "molded socket, open end" indicating that total contact is not inherent in the fabrication of a molded socket.

For all of the foregoing reasons, this section should be deleted.

20. Socket Inserts (L5654-L5665): "*A non-custom fabricated socket insert (L5645, L5654-L5665) is a soft form insert that is contoured to fit around the residual limb and fits inside the socket to provide an interface for padding, comfort and to reduce movement of the residual limb within the socket. No more than two (2) non-custom fabricated socket inserts of the same type (same HCPCS code) are allowed per individual prosthesis. It is not necessary to combine different types (different codes) of socket inserts. Combinations of differing types of socket inserts (different HCPCS codes used together on the same limb) will be denied as not reasonable and necessary, same/similar items." (p. 8, paragraph 1)*

The draft LCD and Policy Article's classification of HCPCS codes L5654-L5665 as "non-custom" reflects a fundamental lack of understanding of those codes. Every item described by L5654 – L5665 requires a qualified practitioner to direct the *custom fabrication* of the insert over a mold of the patient's residual limb. Therefore, the term "non-custom" needs to be revised to "custom."[11]

In addition, determining the need for combinations of inserts should be based on the individual needs of a specific patient, not arbitrarily limited by policy. Prohibiting the use of a combination of inserts discriminates against patients with unique residual limbs needing this type of intervention. The section should delete the limitation on combining socket insert codes.

Furthermore, the language about soft foam[12] inserts "reduc[ing] movement of the residual limb within the socket" should be deleted. These types of socket inserts do not necessarily reduce

[11] The same correction must be made in the following paragraph (p. 8, paragraph 2) of the draft LCD, which again incorrectly refers to these items as "non-custom" liners.

[12] The Alliance believes that this provision of the draft LCD is meant to refer to soft *foam* inserts rather than "soft form" inserts.

movement. Instead, reducing such movement is the purpose of the total contact designed socket, discussed under Item 19, above.

Lastly, the draft LCD erroneously lists Code L5645 as a socket insert. It is not. L5645 describes a structural design feature of a socket and should be deleted from this section.

21. Custom-Fabricated Inserts: ***A custom fabricated socket insert (L5673, L5679, L5681, L5683) is covered when non-custom socket inserts (L5645, L5654-L5665,) are unable to provide an adequate interface between the residual limb and socket caused by irregular contours in the shape of the residual limb that can't be compensated for by changing to a different type of non-custom insert. (p. 8, paragraph 3)***

The draft LCD inappropriately implies that Codes L5673 and L5679 are custom-fabricated only. In fact, the items described by these codes can be *either* custom-fabricated over an existing model *or* prefabricated, as the code language explicitly states. For accuracy, this section should be revised accordingly.

The draft LCD and Policy Article's classification of HCPCS codes L5654-L5665 as "non-custom" reflects a fundamental lack of understanding of those codes. Every item described by L5654 – L5665 requires a qualified practitioner to *custom fabricate* the insert over a mold of the patient's residual limb. Therefore, the term "non-custom" needs to be revised to "custom."

The draft LCD erroneously lists Code L5645 as a socket insert. It is not. L5645 describes a structural design feature of a socket and should be deleted from this section.

22. Custom Fabricated/Custom Fit: "*A custom fabricated socket insert (L5673, L5679, L5681, L5683) is made from a model created from a mold of the beneficiary's residual limb. … Codes L5673 and L5679 describe inserts created from an existing beneficiary model. Codes L5673 and L5679 includes products that are (1) custom fabricated to an existing beneficiary model, or (2) prefabricated but custom fitted to an existing beneficiary model." (p. 8, paragraph 4)***

L5673 and L5679 describe both custom-fabricated *and* roll-on style prosthetic liners that are prefabricated and available in predetermined sizes and thicknesses. These prefabricated liners do not typically require custom fitting over a model of the patient's residual limb in order to fit and function properly.

In addition, the statement in the draft LCD that coverage for L5673 and L5679 exists only when a non-custom socket insert fails to meet the patient's clinical needs is incorrect because the draft LCD incorrectly describes custom-fabricated liners as non-custom.[13] Equally important, the draft LCD's attempted restrictions for when L5673 and L5679 socket inserts can be used is inconsistent with the current standard of care. These roll-on style liners are the accepted standard of care for many amputees and restricting access to them through the draft LCD will force amputees into outdated, less effective alternatives that would harm them.

[13] See Item 20 of The Alliance's comments, above.

23. Socket Insert Initial Issue Limits: ***"If a beneficiary qualifies for a custom fabricated socket insert [ ] at initial issue only one (1) unit of either L5681 or L5683 is covered. One (1) unit of either L5673 or L5679 is also covered. Claims for more than one (1) unit of L5681 or L5683 (per prosthesis) will be denied as not reasonable and necessary, duplicate item." (p. 8, paragraph 6)***

This section should be revised to state that the second unit of L5681 or L5683 will be denied as a duplicate item. The first unit should not be denied if it is an allowed code.

24. Replacement Inserts (L5681, L5683): "*Replacement of either L5681 or L5683 is covered only if there has been both; (1) sufficient change in the residual limb such that replacement inserts produced from the existing beneficiary model no longer are functional as an adequate interface between the residual limb and the socket, and (2) non-custom socket inserts are demonstrated to provide an inadequate interface between the residual limb and socket." (p. 8, paragraph 7)*

While The Alliance understands the intent of this provision, the draft LCD's failure to define the conditions for coverage of a replacement insert could lead to denials. As long as the qualified practitioner has the discretion to determine that the patient has met the two criteria, the language is sufficient.

25. Replacement Inserts (L5673, L5679): ***Replacement of L5673 or L5679 is covered only if (1) the existing insert is no longer functional as an adequate interface between the residual limb and the socket, and (2) non-custom socket inserts are demonstrated to provide an inadequate interface between the residual limb and socket. (p. 8, paragraph 8)***

See The Alliance's response to Item 24, above.

26. Suspension Systems, General: "*Claims for more than one method or type of suspension per prosthesis will be denied as not reasonable and necessary (duplicate item)." (p. 8, paragraph 10)*

This section contradicts page 10, paragraph 1 of the draft LCD, which describes the use of a suspension/sealing sleeve (L5685) in conjunction with suction suspension.

Also, the draft LCD's prohibition on multiple suspension systems is inconsistent with the current standard of care. Qualified practitioners commonly use auxiliary suspension when amputees' activities require additional securing of the prosthesis to their residual limb.

For example, a qualified practitioner may fit an above-knee amputee with both a suction socket *and* a neoprene suspension sleeve for added security during activities where that individual may perspire, which can affect suction suspension. The draft LCD should not circumvent the clinical decisions of the qualified practitioner treating the beneficiary by prohibiting this type of individualized solution. This section should therefore be deleted.

27. Suspension in Complete Systems: "*Some prostheses are complete or all-inclusive systems. Separate billing for a suspension system with these items will be denied as unbundling." (p. 9, paragraph 1)*

This section of the draft LCD is non-specific and confusing. The draft LCD does not define "some prostheses." The Alliance is not familiar with any definitive prostheses matching this description. If the draft LCD is referring to an immediate prosthesis, that limitation should be so stated. Otherwise we believe this statement is inaccurate and should be deleted.

28. Mechanical Suspension and Liners: "*Claims for a suspension system (L5666, L5670-L5672) are not separately paid when the suspension system is incorporated as part of a socket/liners combination where the liner contains an already integrated suspension mechanism (L5673, L5679, L5681, L5683, L5685)." (p. 9, paragraph 3)*

The draft LCD incorrectly includes L5671 in this section. L5671 describes the locking mechanism fabricated into the bottom of the socket. It receives and locks the pin that is threaded into the bottom of L5673, L5681 and L5683 liners into place. Those liners would not work in the absence of the L5671 locking mechanism. L5671 must be removed from the first set of codes listed in this provision of the draft LCD.

Also, L5679 describes a liner that does *not* have a pin threaded into it. Therefore, it does not have an integrated suspension mechanism. As a result, no qualified practitioner would use these liners with a locking mechanism described by L5671. In other words, L5679 liners require some other suspension mechanism; there would have to be some other suspension mechanism along with this type of liner. L5679 should be omitted from this section. This request is consistent with the next paragraph concerning L5671.

29. Shuttle, Lanyard or Equal Restrictions: "*An L5671 (ADDITION TO LOWER EXTREMITY, BELOW KNEE / ABOVE KNEE SUSPENSION LOCKING MECHANISM (SHUTTLE, LANYARD OR EQUAL), EXCLUDES SOCKET INSERT) is a 2-part mechanical locking system where one part (locking mechanism) is built into the socket. The second part (locking pin) is added as a part of the socket insert (L5673, L5679, L5681, or L5683). L5671 is only covered when used in combination with a socket insert (L5673, L5681, or L5683) with an integrated pin." (p. 9, paragraph 4)*

The draft LCD incorrectly includes L5679 as part of a two-part locking mechanism system, even though the descriptor for that code explicitly states that it is "not for use with locking mechanism." L5679 should therefore be omitted from this provision.

In addition, the draft LCD inappropriately restricts the use of L5671 to mechanical lock systems that rely on a shuttle lock/pin system. As the description for L5671 states, lanyard-based or other systems are also used to achieve a mechanical lock for suspension purposes and should be explicitly included in the draft LCD as covered services.

30. Suction Valve and Pin-Lock: "*Some L5671 products incorporate a suction valve (L5647, L5652). These valves are used with suction suspension and are not reasonable and necessary for use with a pin-lock mechanical suspension system." (p. 9, paragraph 5)*

The draft LCD's prohibition on multiple suspension systems is inconsistent with the current standard of care. Qualified practitioners commonly use auxiliary suspension when amputees' activities require additional securing of the prosthesis to their residual limb.

For example, a qualified practitioner may fit an above-knee amputee with both a suction socket *and* a neoprene suspension sleeve for added security during activities where that individual may perspire, which can affect suction suspension. The draft LCD should not circumvent the clinical decisions of the qualified practitioner treating the beneficiary by prohibiting this type of individualized solution. This section should therefore be deleted.

31. Multiple Mechanical Suspension Systems: "*Use of multiple mechanical suspension systems will be denied as not reasonable and necessary (duplicate)." (p. 9, paragraph 6)*

See The Alliance's response to Item 30, above.

32. Suction Suspension. *"Active suction is created by using a suction pump as part of the socket design (L5781, L5782). Active suction systems claim to improve residual limb volume management and moisture evacuation. In addition, active systems claim to increase suspension, proprioception and improve gait. There is insufficient published clinical evidence to support these claims. Claims for L5781 and L5782 will be denied as not reasonable and necessary." (p. 9, paragraph 9)*

The draft LCD's assertion that "insufficient published clinical evidence" exists to support the use of elevated vacuum systems can be disproved with a simple review of readily-available research that establishes the efficacy of vacuum systems across a range of measures:

1. Vacuum users experience less volume fluctuation in their limbs than non-vacuum users, permitting a better fitting socket throughout the day.

   Transfemoral sockets with vacuum-assisted suspension comparison of hip kinematics, socket position, contact pressure and preference: Ischial containment versus brimless, Kahle, J. et al., http://dx.doi.org/10.1682/JRRD.2013.01.0003 (Nov. 2013)

   Elevated Vacuum Suspension Influence on Lower Limb Amputee's Residual Limb Volume at Different Vacuum Pressure Settings, Gerschutz, M. et al., JPO, Vol. 22, No. 4 (2010), 252-256

   Walking in a vacuum-assisted socket shifts the stump fluid balance, Goswami, J. et al., Prosthet. Orthot. Int. (2003) 27:107

   A comparison of trans-tibial amputee suction and vacuum socket conditions, Board, et al., P&O Int'l (2001), 25, 202-09

2. Reduced pistoning in the prosthetic socket.

   Transfemoral sockets with vacuum-assisted suspension comparison of hip kinematics, socket position, contact pressure and preference: Ischial containment versus brimless, Kahle, J. et al., http://dx.doi.org/10.1682/JRRD.2013.01.0003 (Nov. 2013)

   Outcomes Study of Transtibial Amputees Using Elevated Vacuum Suspension in Comparison With Pin Suspension, Ferraro, C, JPO, Vol. 23 No. 2 (2011) 78-81; Board, et al., P&O Int'l (2001)

3. Vacuum users with ulcers are able to walk sooner than non-vacuum users with ulcers.

   Residual limb wounds or ulcers heal in transtibial amputees using an active suction socket system. A randomized controlled study, Traballesi, M. et al., Eur. J. Phys. Rehabil. Med. (2012), 48:613-23

4. Vacuum users with ulcers are able to walk more when compared to non-vacuum users with ulcers.

   Residual limb wounds or ulcers heal in transtibial amputees using an active suction socket system. A randomized controlled study, Traballesi, M. et al., Eur. J. Phys. Rehabil. Med. (2012), 48:613-23

5. Vacuum users experience no more/less pain than non-vacuum users even when walking more.

   Residual limb wounds or ulcers heal in transtibial amputees using an active suction socket system. A randomized controlled study, Traballesi, M. et al., Eur. J. Phys. Rehabil. Med. (2012), 48:613-23

   Vacuum assisted socket system in trans-tibial amputees: Clinical report, Brunelli, S. et al., Orthopadie-Technik Quarterly, II (2009)

6. Vacuum users have higher ambulatory activity scores than non-vacuum users.

   Residual limb wounds or ulcers heal in transtibial amputees using an active suction socket system. A randomized controlled study, Traballesi, M. et al., Eur. J. Phys. Rehabil. Med. (2012), 48:613-23

7. Vacuum users have higher confidence/balance scores than non-vacuum users.

   Outcomes Study of Transtibial Amputees Using Elevated Vacuum Suspension in Comparison With Pin Suspension, Ferraro, C, JPO, Vol. 23 No. 2 (2011) 78-81; Board, et al., P&O Int'l (2001)

In addition, the draft LCD inappropriately designates elevated vacuum devices described by L5781 and L5782 as active suspension systems. These codes, effective since 2003, are explicitly listed as volume management and moisture evacuation systems. More than a decade of Medicare claims data demonstrates that these codes have been eligible for coverage since their implementation and there is no reason why they should not continue to be covered for patients who require limb volume management and moisture evacuation in order to ensure a proper fit of their prosthesis.

For all of the foregoing reasons, this provision of the draft LCD should be deleted.

33. Suction Suspension Restrictions: "*A [suction] suspension socket system is covered for functional level K2-K4." (p. 9, paragraph 10)*

The prohibition on coverage of suction suspension for K1 functional level amputees is discriminatory and without clinical merit. This entire section should be omitted.

34. One-Way Valve Restrictions: *"Codes L5647, L5652, L5781, and L5782 describe a socket design that incorporates a one-way valve into the socket. The one-way air valve that is a part of the suction sockets described by these codes is not a component of a mechanical suspension locking mechanism (L5671). Claims for L5671 in combination with a suction suspension system (L5647, L5652, L5781, L5782) will be denied as incorrect coding." (p. 9, paragraph 11)*

This statement contradicts the following provision of the draft LCD from page 9, paragraph 5: "Some L5671 products incorporate a suction valve (L5647, L5652)." There are locking mechanisms that have a one-way valve incorporated into their design.

Also, the draft LCD's prohibition on multiple suspension systems is inconsistent with the current standard of care. Qualified practitioners commonly use auxiliary suspension when an amputee's activities require additional securing of the prosthesis to their residual limb.

It should be noted that L5781 and L5782 are components which are incorporated into a socket and have, as an integral part of their design, valve systems to prevent the backflow of air.

The draft LCD should not circumvent the clinical decisions of the qualified practitioner treating the beneficiary by prohibiting this type of individualized solution. This section should therefore be clarified with the following language: "*Codes L5647 and L5652 describe a socket design that incorporates a one-way valve into the socket. The one-way air valve that is part of the suction socket described by those codes is not a component of a mechanical suspension system described by L5671*."

35. Suspension Sleeve Restrictions: *"L5685 (ADDITION TO LOWER EXTREMITY PROSTHESIS, BELOW KNEE, SUSPENSION/SEALING SLEEVE, WITH OR WITHOUT VALVE, ANY MATERIAL, EACH) is a sleeve that extends over the socket onto the thigh to form a seal. It is covered for functional level K2-K4."* (p. 10, paragraph 1)

The prohibition on coverage of suction suspension for K1 functional level amputees is discriminatory and without clinical merit. Suction suspension does not typically require advanced prosthetic use in order to be clinically beneficial. This section should be revised to include K1 or deleted entirely.

36. Multiple Suction Suspension Systems: "*Use of multiple suction suspension systems will be denied as not reasonable and necessary (duplicate).*" *(p. 10, paragraph 2)*

See The Alliance's response to Item 30, above.

37. Foot/Ankle Per Prosthesis Restriction: "*One foot/ankle is covered per definitive prosthesis.*" *(p. 10, paragraph 3)*

The draft LCD should additionally state that prosthetic feet and ankles may be billed using one base code along with any appropriate addition codes.

38. New K3 or Higher Foot Code: "*A KXXX1 (ALL LOWER LIMB EXTREMITY PROSTHESES, FOOT, DYNAMIC RESPONSE) is only covered for functional levels K3-K4.*" *(p. 10, paragraph 4)*

The draft LCD's consolidation of existing HCPCS codes L5976, L5980, L5981, and L5987 into a single code described by KXXX1 will severely limit access to prosthetic feet that contain unique features and designs built to meet the specific clinical needs of a wide range of amputees.

In addition, the simple consolidation of four codes into a single generic code describing a "dynamic response foot" ignores the separate and unique function and design features of the individual products that satisfy the requirements of L5976, L5980, L5981, and L5987. All of these codes must remain valid to adequately describe the prosthetic feet that best meet the needs of the individual amputee.

The proposed crosswalk to L5978 does not adequately describe the dynamic response foot that is included in the design of feet currently described by L5979, which describes a combination of a dynamic response foot and a multiaxial ankle. L5979 must remain valid to adequately describe prosthetic feet that provide both of these functions.

Also, through its regulatory authority, the Food and Drug Administration (FDA) has previously deemed prosthetic feet described by HCPCS codes L5976, L5980, L5981, and L5987 as safe and effective. The FDA alone has been delegated responsibility for effectiveness determinations. CMS has been delegated authority on coverage, but has not been delegated to rebut or reverse or otherwise pass judgement on legitimate FDA decisions on the effectiveness of devices. The decision on the safety and effectiveness of prosthetic feet in the draft policy—to simply re-classify unique and different prosthetic feet into a single generic code—may exceed CMS' authority.

Yet another problem with the draft LCD's deletion of multiple codes and collapsing of other codes into new ones is that it usurps the Medicare HCPCS Coding Workgroup's responsibilities. Federal regulation prohibits the DME MACs from eliminating codes or creating new codes for items and services furnished under Medicare Part B.[14] Rather, CMS is tasked with maintaining and distributing HCPCS Level II codes, pursuant to the October 2003 re-delegation from the Secretary, who was authorized to maintain this code set under the Health Insurance Portability and Accountability Act of 1996.[15]

For all of the foregoing reasons, this provision must be deleted in its entirety.

39. New Axial Rotation Unit Code: "*KXXX2 ADDITION TO LOWER EXTREMITY PROSTHESIS, AXIAL ROTATION UNIT, WITH OR WITHOUT ADJUSTABILITY is only covered for functional levels K2-K4." (p. 10, paragraph 9)*

HCPCS code L5986 must be reinstated to properly describe separate multiaxial ankle components that qualified practitioners and manufacturers add to a variety of prosthetic feet. In addition, KXXX2 should be classified as an addition code—not a base code—in the functional level table contained in the draft LCD.

40. L5968 Restrictions: "*An L5968 (ADDITION TO LOWER LIMB PROSTHESIS, MULTIAXIAL ANKLE WITH SWING PHASE ACTIVE DORSIFLEXION FEATURE) is only covered for functional levels K3-K4." (p. 10, paragraph 10)*

The DME MACs provide no clinical support for the summary conclusion that L5968 devices should be available only to K3 or higher amputees. The Alliance contends that coverage for L5968 should not be restricted to K3 and K4 functional level amputees, as K2 patients can also significantly benefit from this feature.

41. Power Assist Foot Restrictions: "*The microprocessor foot or ankle system addition with power assist which includes any type motor (L5969) will be denied as not reasonable and necessary because they do not meet the medical evidence requirements outlined in the Centers for Medicare & Medicaid Services (CMS) Program Integrity Manual (Internet-only Manual 100-08), Chapter 13, §13.7.1." (p. 10, paragraph 11)*

Products described by L5969 should be eligible for coverage based on the fact that the FDA has deemed the predicate product for this code safe and effective.[16]

42. Quick Change Units Restrictions: "*Quick change self-aligning units (L5617) will be denied as not reasonable and necessary." (p. 12, paragraph 2)*

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[14] *See* 42 C.F.R. § 400.202.

[15] Pub. L. No. 104-191. The Health Insurance Portability and Accountability Act of 1996 contains this delegation of authority regarding the HCPCS code set, and on its website the HCPCS Workgroup cites to the October 2003 delegation of this authority to CMS. See Centers for Medicare & Medicaid Services, Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures (rev. Sept. 2012).

[16] See FDA listing for the predicate device for L5969:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?lid=275419&lpcd=ISW

The Alliance disagrees with the draft LCD's determination that quick change self-aligning units are not reasonable and necessary. Products described by HCPCS code L5617 are often clinically appropriate for patients who must temporarily remove components of their prosthesis for medical reasons. This provision of the draft LCD will end up hurting amputees who require these devices for medically necessary reasons.

43. Alignable System Restrictions: ***"An alignable system (L5910, L5920) has movable parts to allow for rotation, height/length adjustment, and linear and angular changes of the prosthesis. This code is a one-time payment with an initial or replacement prosthesis. It is not used with socket replacements. Claims for an alignable system with a socket replacement will be denied as unbundling."*** **(p. 12, paragraph 4)**

The draft LCD's prohibition on using the alignable system codes for a replacement socket will create additional administrative claims work for both the DME MACs and for qualified practitioners. For example, if an amputee has used his/her prosthesis for a year or more, the endoskeletal components (pylon adaptors, set screws, socket adaptors) described by the alignable system codes typically get worn. When qualified practitioners then replace the prosthetic socket for medically necessary reasons, they frequently need to replace these components. That is why the alignable system codes are used during a socket replacement.

If this provision of the draft LCD goes into effect, then repair codes (L7510 and L7520) must be allowed to cover replacement of worn components. We suggest omitting this section.

44. Ultralight Materials Restrictions: "*'Ultralight materials' refer to using the lightest and strongest materials available, such as acrylic resin, carbon fiber, fiberglass, and titanium, etc. (Not all-inclusive). Ultralight materials (L5940, L5950, L5960) are covered when a prosthetic component is individually made and these materials are used in the fabrication process or when specifically included in the Medicare recommended coding for a manufactured item fabricated with these materials." (p. 12, paragraph 5)*

The draft LCD and accompanying Policy Article take an inconsistent approach with respect to ultralight materials. The draft LCD states that ultralight material codes may be used to describe prosthetic components; but the Policy Article provides that ultralight material codes may be used only in connection with claims for prosthetic sockets utilizing those materials. The Alliance recommends that the draft LCD clarify that ultralight material codes should be used to describe only ultralight materials that are incorporated into the prosthetic socket.

45. Protective Outer Surface Covering Systems Restrictions: "*Protective outer surface covering systems (L5962, L5964, and L5966) are specialized covers worn over an existing prosthesis. They are covered when used by a beneficiary who has special needs for protection against unusually harsh environmental situations where it is necessary to protect the lower limb prosthesis beyond the level of that which is afforded by L5704-L5707. They are not covered for cosmetic or convenience reasons, or for everyday usage in a typical environment. This type of product is separate from the covering that is already reimbursed as part of L5704–L5707 and is rarely necessary." (p. 12, paragraph 6)*

The Alliance disagrees with the draft LCD's definitions of these two different types of prosthetic covers. The L5704-L5707-type covers are custom-shaped foam covers that serve two main purposes: (1) to protect the mechanical components from dirt and dust that cause premature wear, and (2) to provide a shape that matches the beneficiary's other limb.

The covers described by L5962-L5966 serve a different purpose. In addition to protecting the prosthetic components, they also protect the custom-shaped foam cover from moisture and abrasions. The draft LCD's conclusion that this type of protective cover is "rarely necessary" reveals a lack of understanding about what these covers do. Any beneficiary who wears their prosthesis while outdoors could benefit from having a protective cover.

In addition, clinical research suggests that a well-shaped, realistic cover can have a significant impact on the psychosocial well-being of the amputee wearing it. Denying amputees access to these protective outer surface coverings, which appear more realistic than foam, may ultimately impact their willingness to wear the prosthesis and live a more active lifestyle.[17]

For all of the foregoing reasons, this section, as well as existing DME MACs' policies that have created an unreasonable limitation for usage of these codes, should be deleted.

LCD: "REHABILITATION PROGRAM" SECTION

46. ***"A prosthetic rehabilitation program is required for a new amputee to ensure successful use of a prosthesis." (p. 12, paragraph 7)***

The draft LCD fails to define key elements of the "prosthetic rehabilitation program," including where it can take place (e.g., Inpatient? Outpatient? Both?), and which kinds of professionals can attest that the amputee has completed the program. This general statement will confuse qualified practitioners who need to understand the specific requirements necessary to qualify the beneficiary for prosthetic treatment. This section must be removed or revised.

A. Rehabilitation Program Elements: ***In a prosthetic rehabilitation program, the beneficiary must: (1) Don and doff the prosthesis without assistance; (2) Transfer without assistance using and without using the prosthesis; (3) Have sufficient wear tolerance to use the prosthesis for a normal day's activities; and (4) 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. (p. 13, paragraph 1)***

The proposed rehabilitation program would hurt amputees by limiting access to many individuals who currently – and *appropriately* – receive a prosthesis. The rehabilitation program criteria listed in the draft LCD are alternately vague, undefined, and inconsistent with accepted standards of care. They also fail to account for the variability in the patient population treated by qualified

[17] *See Delivery of cosmetic covers to persons with transtibial and transfemoral amputations in an outpatient prosthetic practice*, Highsmith et al., Prosthetics and Orthotics Int'l, http://www.ncbi.nlm.nih.gov/pubmed/25575552 (2015).

practitioners, and implicitly oversimplify how those practitioners actually provide prosthetic care and treatment.

Many amputees have one or more comorbidities that, according to the draft LCD's criteria, would disqualify them from using a prosthesis. However, those same individuals are, today, productive, active prosthetic users, who are mobile thanks to their prosthesis. For example, should amputees with comorbidities affecting their upper extremities be denied a limb because they cannot independently don the prosthesis? Should that be the case even when they have in-home assistance from a family member or friend that allows them to effectively don the prosthesis? Under the proposed rule, these hypothetical patients would be consigned to wheelchairs due to their inability to satisfy the arbitrary rehabilitation program criteria.

Other criteria are so vague as to be meaningless. What is "sufficient balance?" What is the standard for "ease of movement?" How would a qualified practitioner document "energy efficiency?" The disconnect between the listed criteria and the world in which qualified practitioners actually fit patients is significant.

As is, the proposed rehabilitation program should be deleted. Alternatively, consistent with the discussion in Item 11, above, qualified professionals should be provided the opportunity to collaborate with the DME MACs – beyond just a four-hour public meeting also devoted to topics other than prosthetics – to discuss the need for and elements of a rehabilitation program before implementation.

B. Rehabilitation Program as Predicate for Preparatory Prosthesis: ***[sic] "Preparatory prosthesis provided to a beneficiary who is not scheduled for, participating in or has not recently (defined as within the previous 90 days) completed a prosthetic rehabilitation program for the affected residual limb will be denied as not reasonable and necessary." (p. 13, paragraph 2)***

Combined with the failings explained in Item 46.A., above, this section creates yet another barrier for new amputees who would benefit from a prosthesis. The currently-accepted standard of care requires a qualified practitioner and ordering physician to consult with the patient and jointly agree on when the amputee is clinically ready for a prosthesis. But the draft LCD's insistence on adding an ill-defined "rehabilitation program" requirement that adds administrative barriers and creates additional costs to both the patient and the Medicare trust fund makes little sense. This section should be deleted.

C. Rehabilitation Program as Predicate for Definitive Prosthesis: "*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." (p. 13, paragraph 3)*

See The Alliance's comment to Item 46.B., above.

LCD: "FUNCTIONAL STATUS (K-LEVEL)" SECTION

47. ***"A beneficiary must meet the following minimal requirements to be functionally successful with a lower extremity prosthesis"***

A. ***"Sufficient trunk control" (p. 13, paragraph 5, 1st bullet point)***

The draft LCD's inclusion of "sufficient trunk control" as a basis for deciding an amputee's functional level does not work on multiple levels. Impaired trunk control is common in many amputees, particularly those with an above-knee or higher level of amputation. For many amputees – particularly those with an above-knee or higher amputation –the prosthesis is *the very tool that allows them to improve trunk stability*. This is analogous to predicating the use of a prosthesis on an amputee's ability to walk *without* the prosthesis: the criterion is actually a symptom that the prosthesis *solves.*

The draft LCD also fails to define what constitutes "sufficient" trunk control.[18] In the total absence of defined standards, criteria like these will hurt amputees by creating a mechanism that allows non-clinical, third-party reviewers virtually unlimited latitude to substitute their own assessments of "sufficiency" in place of the qualified practitioners and ordering physicians actually examining and treating amputees.

This section should be deleted. Alternatively, with respect to this provision and the subsequent criteria for determining "minimal requirements" for successful use of a prosthesis, qualified professionals should be provided the opportunity to collaborate with the DME MACs – beyond just a four-hour public meeting also devoted to topics other than prosthetics – to discuss relevant criteria when assessing an amputee's functional level.

B. ***"Good upper body strength" (p. 13, paragraph 5, 2nd bullet point)***

The draft LCD fails to define what constitutes "good" upper body strength. In the total absence of defined standards, criteria like this will hurt amputees by creating a mechanism that allows non-clinical, third-party reviewers virtually unlimited latitude to substitute their own assessments of "good" upper body strength in place of the qualified practitioners and ordering physicians actually examining and treating amputees.

This section should be deleted.

C. ***"Adequate knee stability with good quadriceps strength and control" (p. 13, paragraph 5, 3rd bullet point)***

The draft LCD fails to define what constitutes "adequate" knee stability and "good" quadriceps strength and control. In the total absence of defined standards, criteria like this will hurt

[18] This is a recurring theme in The Alliance's comments regarding the criteria listed in the draft LCD to assess an amputee's functional level. "Good," "adequate," "sufficient" and similar terms are not standards; they're just words that in this context are so nebulous as to be meaningless. For proof of that proposition, reread each of the proposed criteria and strike out those words: the meaning of the criteria does not change at all.

amputees by creating a mechanism that allows non-clinical, third-party reviewers virtually unlimited latitude to substitute their own assessments in place of the qualified practitioners and ordering physicians actually examining and treating amputees.

Equally troublesome, this criterion fails to acknowledge the reality that there are many different types of amputees. You cannot, for example, measure knee stability for a bilateral above-knee or higher level amputee. Applying this standard to bilateral above-knee amputees would presumably relegate them to lower K level components because they have no knee stability at all.

The draft LCD fails to mention *which knee* should be assessed, for those amputees who have anatomical knees. For a below-knee amputee, is it the sound limb or the knee on the amputated side?

This section should be deleted.

D. *"Good static and dynamic balance or a Tinetti total score of > 24" (p. 13, paragraph 5, 4th bullet point)*

The draft LCD fails to define what constitutes "good" static and dynamic balance. In the total absence of defined standards, criteria like this will hurt amputees by creating a mechanism that allows non-clinical, third-party reviewers virtually unlimited latitude to substitute their own assessments in place of the qualified practitioners and ordering physicians actually examining and treating amputees.

Similarly, there is no statement about what clinical evidence was used to establish the > 24 benchmark for amputees on a Tinetti test, likely because none exists. *There is not a single peer-reviewed publication describing the use of the Tinetti with people with lower limb amputation.* The draft LCD proposes using a tool to assess amputees' functional level that has never been validated for that patient population.[19]

For the foregoing reasons, this section should be deleted.

E. *"Adequate posture" (p. 13, paragraph 5, 5th bullet point)*

The draft LCD fails to define what constitutes "adequate" posture. In the total absence of defined standards, criteria like this will hurt amputees by creating a mechanism that allows non-clinical, third-party reviewers virtually unlimited latitude to substitute their own assessments in place of the qualified practitioners and ordering physicians actually examining and treating amputees.

Equally troublesome, a patient's posture has no clinical bearing on a patient's ability to successfully use a prosthesis. Indeed, prosthetic intervention can *improve* an amputee's overall posture. Also, it is unclear how this specific requirement would affect a bilateral amputee.

[19] Gailey, R. et al., *The Amputee Mobility Predictor (AMP): An Instrument to Assess Determinants of the Lower Limb Amputee's Ability to Ambulate*. Arch Phys Med Rehab 83(5): 613-627 (2002).

For the foregoing reasons, this section should be deleted.

48. Prosthetic Requirements for Functional Level: *"The prosthesis provided must provide:*

- **A. *Stability;***
- **B. *Ease of movement;***
- **C. *Energy efficiency; and***
- **D. *The appearance of a natural gait." (p. 13, paragraph 6)***

The draft LCD fails to define "stability," "ease of movement," "energy efficiency," and "the appearance of natural gait." In the total absence of defined standards, criteria like this will hurt amputees by creating a mechanism that allows non-clinical, third-party reviewers virtually unlimited latitude to substitute their own assessments in place of the qualified practitioners and ordering physicians actually examining and treating amputees.

The Alliance must also register its disbelief that "appearance of natural gait" would ever be listed as a requirement for assessing an amputee's functional status. Many high-functioning amputees walk with noticeable gait deviations not only as a result of their amputations, but because they suffer from one or more additional comorbidities that they nevertheless successfully overcome and manage with the use of a prosthesis. This provision sends a very clear message to amputees: if you walk "badly," Medicare may not approve the kinds of prosthetic devices that might help you walk better. Instead, these individuals will be relegated to lower-functioning, less effective prosthetic devices. Put simply, this proposal is not only offensive; it is a self-fulfilling functional level prophecy that will hurt those amputees who may be in the greatest need of the prosthetic solutions available to higher functional level patients.

49. [sic] "An in-person, comprehensive medical assessment to determine the functional capabilities of the beneficiary must be performed by a licensed/certified medical professional with expertise in the treatment of amputees prior to the provision of any prosthesis." [p. 13, paragraph 8]

See our comments for Item 12.H., above.

50. Elimination of Potential: "*The beneficiary's functional level is based on their overall health status, the objective results of the medical assessment and their documented performance using their immediately previous prosthesis (either preparatory or definitive)." (p. 13, paragraph 9)*

The draft LCD states that the patient's functional level will be based on "documented performance," thereby eliminating the current LCD's language permitting the qualified practitioner and ordering physician to also consider the amputee's "potential." This change could have a catastrophic impact on all lower limb amputees.

The premise of rehabilitation is to invest in the potential of recovering individuals to allow them to regain a measure of their lost abilities after illness or injury. Ignoring amputees' potential will fundamentally compromise their ability to progress and improve their mobility. For example, under this proposal, an amputee who has the capability to be an unlimited community ambulator

(K3) but who is not that today will be limited to K2 components. Those components are less dynamic, less sophisticated, and will ultimately limit the amputee's progress. This will have a significant physical and psychological impact on the individual using the prosthesis.

Under the proposal, access to prosthetic solutions associated with higher functional levels will become a zero-sum, "survival of the fittest" battle of attrition. Instead of receiving medically-necessary prostheses that take into account the patient's expected future capability, Medicare will force amputees to first endure less sophisticated, less medically-appropriate prostheses before they can qualify for the best solution. The end result of the proposed change will be numerous amputees who are limited not by their ability (current and future), but by the draft LCD, which refuses to adequately acknowledge or invest in their potential.

The draft LCD should be amended to reflect the fact that a patient's potential is a legitimate consideration when analyzing a patient's functional level.

51. ***Assessment of the beneficiary's functional capabilities must be based on the following classification levels …***

A. ***"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." (p. 14, 2nd bullet point)***

The clinically unsupported blanket conclusion that use of a walker or crutches automatically consigns an amputee to the K1 functional level is misguided. It fails to acknowledge the fact that some beneficiaries may need assistive devices for very specific activities or for use only part time.

Also, see The Alliance's comments on the need to permit consideration of an amputee's potential in Item 50, above.

This new definition should be deleted.

B. ***"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." (p. 14, 3rd bullet point)***

The clinically unsupported blanket conclusion that use of a cane automatically consigns an amputee to the K2 functional level is misguided. It fails to acknowledge the fact that some beneficiaries may need assistive devices for very specific activities or for use only part time. Moreover, use of a cane does not prevent an amputee from traversing low-level environmental barriers like those described in the draft LCD, nor does it prevent an amputee from functioning

physically within the community independently. Arguably, it *enhances* the amputee's ability to do so.

The draft LCD also provides no definition for what it means to function "psychologically within the community." We are unaware of any clinical research in the bibliography released after this draft LCD's publication that speaks to that point.

Also, see The Alliance's comments on the need to permit consideration of an amputee's potential in Item 50, above.

This new definition should be deleted.

C. ***"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." (p. 14, 4th bullet point)***

See The Alliance's comments on the need to permit consideration of an amputee's potential in Item 50, above.

This new definition should be deleted.

D. ***"K4: has demonstrated sufficient and adequate strength, endurance, range of motion, and coordination for personal independence during ambulation. Exhibiting [sic] recreational demands, high impact activities, or elevated energy levels, typical of the prosthetic utilization for the energetic child, active adult, or athlete. An 'active community ambulator' who not only can walk distances with no difficulty but also run on even ground with little difficulty. Does not require the use of any mobility assistive equipment such as a cane, crutches, walker, or wheelchair." (p. 14, paragraph 1)***

See The Alliance's comments on the need to permit consideration of an amputee's potential in Item 50, above.

The word "Exhibiting" should be "Exhibits."

The statement "can run on even ground with little difficulty" excludes any amputee who is a larger individual and whose vocational activities require prosthetic intervention beyond a typical amputee (e.g., L5930 – high activity knee frame) but who does not have the ability to run with their prosthesis.

This new definition should be deleted.

LCD: "REPAIR AND REPLACEMENT" SECTION

52. ***Repairs and replacement to a beneficiary-owned covered prosthesis are eligible for reimbursement when the criteria described in the NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES section of the related Policy Article are met. (p. 14, paragraph 3 (after bullet points))***

This provision of the draft LCD highlights inconsistent language in the Policy Article. More specifically, the "criteria described in the NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES section" of the policy article are arguably contradictory.

One paragraph of the Policy Article states, "Adjustments to an artificial limb or other appliance required by wear or by a change in the patient's condition (aside from those that are necessary during the first 90 days after delivery) are covered when ordered by a physician." Later, it states, "Adjustments to a prosthesis required by wear or by a change in the beneficiary's condition are covered under the initial physician's order for the prosthesis for the life of the prosthesis." It is therefore unclear whether a new physician's order is required to make an adjustment to a prosthesis.

Another inconsistency exists between the draft LCD and Policy Article with respect to prosthetic maintenance. The draft LCD states that "Medicare payment rules for prosthetic items include all necessary fitting, adjustments, etc. necessary during the 90 days following the date of service." But the Policy article states that "Routine periodic servicing, such as testing, (re)programming, cleaning, and checking of the prosthesis is noncovered." The Policy article therefore indefinitely expands the timeframe that the prosthetist must adjust and maintain the prosthesis indefinitely, without being able to submit a claim for the time and materials used to keep the prosthesis in working order. That is inconsistent with both the historical approach to coverage for this kind of maintenance under the current LCD, and internally inconsistent as between the draft LCD and its related Policy Article.

SECTION III: DOCUMENTATION

LCD: "PRESCRIPTION (ORDER) REQUIREMENTS" SECTION

1. **Dispensing Orders:** ***Equipment and supplies may be delivered upon receipt of a dispensing order except for those items that require a written order prior to delivery. (p. 15, paragraph 2)***

While the draft LCD references "equipment and supplies," this term does not apply to lower limb prostheses. The O&P Alliance recommends replacing "equipment and supplies" with "lower limb prostheses."

In addition, the reference to a "written order prior to delivery" should be deleted, as no lower limb prosthetic device requires a written order prior to delivery.

2. **Items Provided on a Periodic Basis:** ***For items provided on a periodic basis, including drugs, the written order must include: (1) Item(s) to be dispensed, (2) Dosage or concentration, if applicable, (3) Route of Administration, (4) Frequency of use, (5) Duration of infusion, if applicable, (6) Quantity to be dispensed, (7) Number of refill (p. 15, paragraph 8)***

While the draft LCD references "items provided on a periodic basis," this does not apply to lower limb prostheses. This section should be deleted.

3. **Frequency of Use:** ***Frequency of use information on orders must contain detailed instructions for use and specific amounts to be dispensed. Reimbursement shall be based on the specific utilization amount only. Orders that only state "PRN" or "as needed" utilization estimates for replacement frequency, use, or consumption are not acceptable. (PIM 5.9) (p. 16 paragraph 2)***

While the draft LCD references "frequency of use," this does not apply to lower limb prostheses. This section should be deleted.

4. **The detailed description in the written order may be either a narrative description or a brand name/model number. (p. 16, paragraph 3)**

The HCPCS code description is a valid and widely-recognized detailed description of the item or service ordered by the ordering physician. It is reasonable to use the specific HCPCS code description on the written order. The precise language of these descriptors will eliminate confusion when the detailed order, proof of delivery, and claim are compared.

LCD: "MEDICAL RECORD INFORMATION" SECTION

5. ***Suppliers are reminded that:***

- ***Supplier-produced records, even if signed by the ordering physician, and attestation letters (e.g. letters of medical necessity) are deemed not to be part of a medical record for Medicare payment purposes; and***

- ***Templates and forms, including CMS Certificates of Medical Necessity, are subject to corroboration with information in the medical record. (p. 16, paragraph 7)***

While the draft LCD "reminds" the reader that the qualified practitioner's records fall outside the "medical record" for Medicare payment purposes, these individuals are the primary allied health professionals specifically educated and trained to assess, treat and train amputees.[20] The defined scope of practice of qualified practitioners permits the comprehensive functional assessment of amputees and these qualified practitioners have performed them for decades. As a result, their records and documentation should be considered part of the medical record. It is unreasonable to treat as outside of the medical record the documentation created by the healthcare professional critical to the provision of prosthetic limbs.

We are cognizant of the DME MACs' view that qualified practitioners may have a potential conflict of/financial interest. As is already well documented, we strongly disagree with that view. The qualified practitioner's potential conflict of/financial interest is no different than that which exists for any other health care provider who treats beneficiaries and is reimbursed for that treatment. The refusal to consider the qualified practitioner's records part of the official medical record solely on the basis of a *perceived* conflict of interest is discriminatory and should be corrected.

The draft LCD also states that attestations fall outside of the medical record. But attestations are often used to subsequently clarify issues that may be unclear to a reviewer. Indeed, Medicare's contractors at the various level of Medicare claim appeal (e.g., redetermination, reconsideration) *permit attestations* to clarify vague or confusing entries in medical notes. If attestations are permissible as part of the appeal process, they should similarly be admitted into the medical record as part of the claim *submission* process. This draft LCD should delete attestations from the list of items excluded from the medical record.

In addition, while the draft LCD refers to "CMS Certificates of Medical Necessity," this does not apply to lower limb prostheses. This reference should be deleted.

6. Financial Interest in Outcome: ***"Information contained directly in the contemporaneous medical record is the source required to justify payment except as noted elsewhere for prescriptions and CMNs. The medical record is not limited to physician's office records but may include records from hospitals, nursing facilities, home health agencies, other***

[20] Gaunaurd I, et al. *Use of and Confidence Administering Outcome Measures Among Clinical Prosthetists: Results from a National Survey and Mixed-Methods Training Program.* Prosth. Orthot. Intl. (2014).

healthcare professionals, etc. (not all-inclusive). Records from suppliers or healthcare professionals with a financial interest in the claim outcome are not considered sufficient by themselves for the purpose of determining that an item is reasonable and necessary." (p. 16, paragraph 8)

See the first two paragraphs of The Alliance's response to 25, above, regarding the draft LCD's insistence on dismissing qualified practitioners' notes because they fall outside of the medical record for Medicare payment purposes. The Alliance must also point out the fundamental inconsistency in the fact that records from suppliers or healthcare professionals with a financial interest in the claim outcome fall outside of the medical record for claim payment purposes *when exactly the same conflict of interests exists for physicians who submit claims to Medicare for reimbursement.* At a minimum, this provision should be amended to state that qualified practitioners' records are part of the medical record, even if they require corroboration by other health care professionals.

In addition, while the draft LCD refers to "CMS Certificates of Medical Necessity," this does not apply to lower limb prostheses. This reference should be deleted.

7. **Continued Medical Need:** ***"For all Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) items, the initial justification for medical need is established at the time the item(s) is first ordered; therefore, beneficiary medical records demonstrating that the item is reasonable and necessary are created just prior to, or at the time of, the creation of the initial prescription. For purchased items, initial months of a rental item or for initial months of ongoing supplies or drugs, information justifying reimbursement will come from this initial time period. Entries in the beneficiary's medical record must have been created prior to, or at the time of, the initial date of service (DOS) to establish whether the initial reimbursement was justified based upon the applicable coverage policy." (p. 16, paragraph 9)***

For lower limb prostheses, the initial justification for medical need is established at the time the item(s) is first ordered. Therefore, the beneficiary's preliminary medical records demonstrating that the item is reasonable and necessary are created just before or at the time of creation of the initial prescription. Additional information justifying reimbursement may come after this initial time period. Entries in the beneficiary's medical record must be created before or at the time of the date of service (DOS) to establish whether the reimbursement is justified based upon the applicable coverage policy.

The draft LCD provides conflicting guidance on the time frames for the creation of the beneficiary's medical records. It first says that these records must be created "prior to or at the time of the creation of the initial prescription." Two sentences later it provides, "entries in the beneficiary's medical records must be prior to or at the time of the initial date of service." The draft LCD should clarify this inconsistency.

In addition, the draft LCD must address the fact that its proposed in-person medical examination and functional assessment may actually occur *after* the ordering physician issues the initial order.

In addition, while the draft LCD refers to "rental periods," "supplies" and "drugs," none of these terms apply to lower limb prostheses. These references should be deleted.

8. **Supplies & DME Items:** ***For ongoing supplies and rental DME items, in addition to information described above that justifies the initial provision of the item(s) and/or supplies, there must be information in the beneficiary's medical record to support that the item continues to be used by the beneficiary and remains reasonable and necessary. Information used to justify continued medical need must be timely for the DOS under review. Any of the following may serve as documentation justifying continued medical need:***
    - ***A recent order by the treating physician for refills***
    - ***A recent change in prescription***
    - ***A properly completed CMN or DIF with an appropriate length of need specified***
    - ***Timely documentation in the beneficiary's medical record showing usage of the item***

    (p. 17, paragraph 1)

While the draft LCD refers to "CMN's," "supplies" and "rental items," none of these terms apply to lower limb prostheses. These references should be deleted.

9. **Continued Use:** ***Continued use describes the ongoing utilization of supplies or a rental item by a beneficiary. (p. 17, paragraph 3)***

This paragraph and the three paragraphs following it do not apply to lower limb prostheses. All of these paragraphs should be deleted.

10. **Signature Legibility:** ***The signature and date the beneficiary or designee accepted delivery must be legible. (p. 17, paragraph 8)***

The supplier should not bear any responsibility, financially or otherwise, for the legibility of the beneficiary's or designee's signature. An individual's normal signature should be acceptable. As with any legal document, a signature above a printed name is appropriate and the draft LCD should be amended accordingly.

11. **Direct Delivery to the Beneficiary by the Supplier:** ***Suppliers may deliver directly to the beneficiary or the designee. In this case, POD to a beneficiary must be a signed and dated delivery document. The POD document must include …***
    - ***Sufficiently detailed description to identify the item(s) being delivered (e.g., brand name, serial number, narrative description (Note: repetition of HCPCS code narrative verbiage alone is not sufficient.))***

    (p. 18, paragraph 4)

While the draft LCD prohibits qualified practitioners from using HCPCS code verbiage to describe prosthetic item(s) delivered, those Medicare-generated descriptors are a valid and widely-recognized detailed description of the item or service from the ordering physician. It is reasonable to use the specific HCPCS code description on the proof of delivery. The precise

language of these descriptors will eliminate confusion when the detailed order, proof of delivery, and claim are compared.

In addition, the draft LCD's prohibition on "repetition of HCPCS code verbiage alone" is inconsistent with the Program Integrity Manual, which requires only "[a] detailed description of the item being delivered." The HCPCS code verbiage satisfies that standard. The language prohibiting the "repetition of HCPCS code verbiage alone" should therefore be deleted.

The same comments apply to Delivery Methods 2 and 3, described on page 18, paragraph 7 and page 19, paragraph 3 of the draft LCD, respectively.

12. **Nursing Home Use of Prosthesis Confirmation:** ***"Regardless the method of delivery [sic], for those beneficiaries that are residents of a nursing facility, information from the nursing facility showing that the item(s) delivered for the beneficiary's use were actually provided to and used by the beneficiary must be available upon request." (p. 19, paragraph 5)***

This provision of the draft LCD ignores the way prosthetic care and training occurs in a nursing home. In that context, the qualified practitioner provides a well-fitted, appropriately aligned prosthesis. Once the beneficiary has received donning/doffing and basic gait instructions from the prosthetist, therapists and/or other nursing home staff coordinate ongoing care. While the qualified practitioners remain available to modify and adjust the prosthesis as needed, actual utilization is beyond their direct control. The words "and used by" should therefore be deleted from this provision.

13. **Equipment Retained from a Prior Payer:** ***"When a beneficiary receiving a DMEPOS item from another payer (including a Medicare Advantage plan) becomes eligible for the Medicare FFS program, the first Medicare claim for that item or service is considered a new initial Medicare claim for the item. Even if there is no change in the beneficiary's medical condition, the beneficiary must meet all coverage, coding and documentation requirements for the DMEPOS item in effect on the date of service of the initial Medicare claim." (p. 19, paragraph 6)***

This provision relates only to "equipment," not lower limb prostheses, and should therefore be deleted.

Notwithstanding the use of the term "equipment," if the intent of this provision is for it to apply to lower limb prostheses, The Alliance has concerns that this language will prevent amputees from receiving prosthetic care previously deemed medically necessary. The draft LCD also does not clearly address what happens if a single component paid for by a prior payer needs to be repaired or replaced.

LCD: "POLICY SPECIFIC DOCUMENTATION REQUIREMENTS" SECTION

14. ***"When submitting a prosthetic claim, the billed code for knee, foot, ankle and hip (HCPCS codes L5610-L5616, L5710-L5780, L5810-L5840, L5848, L5856, L5857, L5858, L5930,L5961,L5970-L5987) components must be submitted with modifiers K0 - K4, indicating the beneficiary's functional level. This functional ability information must be clearly documented in the medical record and retained in the prosthetist's files. The simple entry of a K modifier in those records is not sufficient. There must be information about the patient's history and current condition which supports the designation of the functional level." (p. 20, paragraph 3)***

See The Alliance's comments about functional levels in Item 50 of Section II.

15. **Motor-Powered Knees: "*For L5859, the medical records should describe the nature and extent of the comorbidity of the spine or the sound limb that is limiting the beneficiary to a household ambulator status. The medical record must clearly document how this feature (L5859) will enable the beneficiary to improve function to that of a community ambulator." (p. 20, paragraph 4)***

While the draft LCD only refers to comorbidities of the spine and sound limb, other neuromuscular or musculoskeletal comorbidities that the technology addressed by this code could improve may limit the beneficiary's functional level. Therefore, the words "of the spine or sound limb" should be deleted from this provision.

Also, see The Alliance's comments about functional levels in Item 50 of Section II.

16. **Custom Fabricated Socket Inserts: "*Custom fabricated socket inserts (L5673, L5679, L5681, L5683) require that there be information in the prosthetic record demonstrating that various coverage requirement are met. Suppliers are reminded that this information must be specific to the individual beneficiary and sufficiently detailed to demonstrate clearly that the relevant requirement(s) has been met and that payment is justified. This information must be available upon request." (p. 20, paragraph 5)***

The draft LCD describes a "prosthetic record," a term that is undefined and that appears nowhere else in the document. That phrase should be replaced with the words, "prosthetist's record." This comment applies equally to use of that term on page 20, paragraph 6 and page 20, paragraph 7 of the draft LCD.

It is unnecessary to indicate that the information must be "specific to the individual beneficiary" as all documentation must relate the individual beneficiary.

Additionally, it is unnecessary to repeat the phrase that "information must be available upon request." That global statement is included in the "Documentation Requirements" and applies to the entire draft LCD.

17. Necessary Documentation: ***The prosthetic record must contain information (1) describing the beneficiary's participation in a rehabilitation program, (2) demonstrating that the beneficiary is sufficiently able ambulate [sic] and manage the use of their preparatory prosthesis, and (3) documenting that the residual limb is sufficiently mature and stable to justify the provision of a definitive prosthesis. (p. 20, paragraph 6)***

See The Alliance's response to Item 11 of Section II, above, regarding the proposed "rehabilitation program" requirement.

The draft LCD fails to define the word "sufficiently. See also The Alliance's response to Item 6 of Section II, above, regarding the term "sufficiently mature."

18. Independent Medical Examination: "*For a definitive lower limb prosthesis to be covered the treating physician must conduct an in-person examination documenting the overall functional abilities and limitations of the beneficiary before writing the order and the supplier must receive a written report of this examination within 45 days after completion of the examination and prior to delivery of the prosthesis." (p. 21, paragraph 1)***

While it is not unreasonable for a physician to perform an in-person examination documenting the beneficiary's functional abilities, the draft LCD should clarify that the *ordering physician* – i.e., the person signing the prescription – is the physician with that responsibility. Any physician meeting the criteria set forth in the draft LCD could therefore be the ordering physician. The term "treating physician" should be replaced with "ordering physician" to provide greater clarity. This same change should be made on page 21, paragraphs 3 and 4 of the Draft LCD.

19. LCMP: ***"The physician may refer the beneficiary to a licensed/certified medical professional, who has experience and training in the functional assessment of beneficiaries with amputations to perform all or part of the in-person functional assessment examination. This person may have no financial relationship with the supplier. (Exception: If the supplier is owned by a hospital, an LCMP working in the inpatient or outpatient hospital setting may perform part of this examination.)" (p. 21, paragraph 3)***

The draft LCD is devoid of guidance regarding the "experience and training" such an individual must have to satisfy the LCMP standard. Also see The Alliance's comments in Item 9 of Section II, regarding issues with the "scope of practice" concept in the draft LCD for LCMPs.

To the extent that this provision requires patients to visit multiple medical professionals beyond the qualified practitioner and ordering physician, The Alliance has concerns that this will expose amputees to longer delays in receiving medically-necessary care and additional out-of-pocket costs. Lengthy delays created by this new requirement will have a direct impact on amputees' physical and psychological rehabilitation.

A more rational, efficient, and cost-effective approach would be for the draft LCD to acknowledge that the qualified practitioner's functional assessment of the patient, when corroborated by the ordering physician, meets all necessary payment requirements. See The

Alliance's comments in Item 5, above, regarding the qualified practitioner's notes being a legitimate part of the medical record for Medicare payment purposes.

20. LCMPs and 45-Day Rule. "***If the beneficiary was referred to the LCMP by the treating physician before being seen by the treating physician, then once the physician has received and reviewed the written report of this examination, the physician must see the beneficiary and perform any additional examination that is needed. The report of the physician's visit must specifically state concurrence or any disagreement with the LCMP examination. If the treating physician agrees with the LCMP assessment, the physician must provide the supplier with a copy of all examination record within 45 days after the in-person with the treating physician. If the treating physician disagrees with all or any part of the LCMP assessment, the treating physician must clearly explain the nature and basis for their disagreement. In addition, the treating physician must specifically document all changes in the functional level-determination that occur as a result of their personal assessment." (p. 21, paragraph 4)***

See The Alliance's response to Item 19, above.

In addition, The Alliance must register its concern with requiring the ordering physician (see Item 18, above) to forward the qualified practitioner a copy of all examination records with days of the in-person assessment. If the ordering physician fails to do so, this could in theory provide a basis for denying the claim after the fact. The qualified practitioner has no ability to control an ordering physician's behavior. Providing a new basis for claim denial that is entirely outside the control of the qualified practitioner is both unfair and will hurt amputees by delaying their access to medically-necessary prostheses as their qualified practitioners await an ordering physician's records.

The Alliance also recommends replacing the word "needed" with "required by this LCD," and deleting the phrase "the nature and basis for."

21. LCMPs and the 45 Day Rule (2): ***If the physician saw the beneficiary to begin the examination before referring the beneficiary to an LCMP, then if the physician sees the beneficiary again in person after receiving the report of the LCMP examination, the 45-day period begins on the date of that second physician visit. However, it is also acceptable for the physician to review the written report of the LCMP examination, to sign and date that report, and to state concurrence or any disagreement with that examination. In this situation, the physician must send a copy of the note from his/her initial visit to evaluate the beneficiary plus the annotated, signed, and dated copy of the LCMP examination to the supplier. The 45-day period begins when the physician signs and dates the LCMP examination. (p. 21, paragraph 5)***

See The Alliance's response to Items 19 and 20, above.

22. Comprehensive Functional Assessment: ***"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 has had an appropriate above or below knee amputation.***
- ***The beneficiary has successfully participated a [sic] rehabilitation program.***
- ***The surgical incision is stable (healed).***
- ***The residual limb has matured.***
- ***The beneficiary is motivated to ambulate using the prosthesis.***
- ***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).”***

(p. 21, paragraph 6)

See The Alliance’s responses to Item 12 of Section II, bullet points 1-7.

In addition, the draft LCD is internally inconsistent to the extent that a “comprehensive functional assessment” does not evaluate the patient’s “overall health status.” Rather, such an assessment is limited to the beneficiary’s ability to use a prosthesis at the time of the examination.

23. K Level Selection: ***“The treating physician or LCMP must explicitly identify what overall functional status to which the beneficiary is assigned based upon the criteria set out in the COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY section of this policy. The applicable K-level must be determined. The selected K-level along with the rationale justifying the selection must be included as part of the examination report.” (p. 22, paragraph 1)***

The Alliance recommends changing this provision as follows: “The ordering physician or LCMP must identify which functional classification is appropriate for the beneficiary based upon the criteria set out in the COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY section of this policy. The examination report must include the specific K-level and the rationale justifying its selection.”

24. Receipt of IME Report: ***A date stamp or equivalent must be used to document the date that the supplier receives the report of the in-person examination. The written report of this examination must be available upon request. (p. 22, paragraph 2)***

The Alliance recommends changing this provision as follows: “The date the qualified practitioner receives the information regarding the in-person examination(s) and/or the functional assessment(s) must be documented on its first page.”

25. Documentation Format of IME: “*The treating physician and the LCMP (if applicable) must document the examination in a detailed record in the beneficiary’s medical record in the same format that they use for other entries. The note must clearly indicate that the*

reason for the visit was a lower limb prosthesis functional assessment." (p. 22, paragraph 3)

The Alliance recommends changing this provision as follows: "The ordering physician and/or the LCMP (when applicable) must document their in-person functional assessment examination in a format that meets the requirements of this policy. The note must indicate that the reason for the visit was for a lower limb prosthesis functional assessment."

As new coverage criteria requirements become established, template-type forms will likely replace the physician or LCMP's normal format to ensure all of the new requirements are captured and reported. The contents of the beneficiary's medical record do not have to be – nor should they be – in the same format as day-to-day patient care records. Specialty reports like the functional assessment examinations require certain specific information. Electronic medical records cannot be easily reprogrammed to meet the demands of this draft language.

26. Related Tests and Prior Records: ***"Physicians shall also provide reports of pertinent laboratory tests, x-rays, and/or other diagnostic tests (e.g., pulmonary function tests, cardiac stress test, electromyogram, etc.) performed in the course of management of the beneficiary. Upon request, suppliers shall provide notes from prior visits to give a historical perspective of the progression of disease over time and to corroborate the information in the face-to-face examination." (p. 22, paragraph 4)***

This provision of the draft LCD fails to recognize the practical realities of how tests and records are recorded and obtained. The physician ordering the prosthesis may not be the same physician who ordered the tests cited in this provision.

If these test results *are* the products of tests ordered by the ordering physician, then they should be made available, but only if relevant to the beneficiary's *current* medical condition.

In addition, it is unreasonable to hold the qualified practitioner accountable for test results that Medicare may or may not have paid for that are not part of the ordering physician's records. The qualified practitioner cannot be the warehouse for all medical documentation detailing an amputee's complete medical history.

Medicare *must* trust the ordering physician to conduct the face-to-face examinations in an honest and straightforward manner and/or refer the beneficiary to a qualified LCMP who possesses the clinical, moral, and ethical qualities necessary to conduct the required examinations. To require the qualified practitioner to compile and retain such documentation is unreasonable.

SECTION IV: APPENDIX OF SUPPORTING MATERIALS

1. "Potential" as a Fundamental Principle in Rehabilitation, but Systematically Dismissed in the Proposed LCD

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

3. Requiring "Demonstrated Performance" with Antiquated Prostheses to Qualify for a Modern Era Prosthesis

4. Tragic Timeline: Required Delays to Individualized Prosthetic Care

5. Raising the Bar while Shortening the Pole: The Conflict of Requiring "Stability, Ease of Movement, Energy Efficiency and a Natural Gait" with a Limited Device

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

7. Unable or Unwilling: Policy Discrimination against Bilateral Amputees and Other More Challenged Patients

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

9. The Proposed/Draft LCD Creates "Improvement Standards" in Direction Violation of Jimmo v. Sebalius

10. Natural Gait: A Reasonable Goal but an Unreasonable Requirement

11. Solving the “Medicare Puzzle” of Increased Prosthetic Foot Costs: 2005-2010

12. An LCMP’S Concern for the New Requirements of LCMPs

“Potential” as a Fundamental Principle in Rehabilitation, but Systematically Dismissed in the Proposed LCD.

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

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Summary

Investments made into rehabilitation assume that a patient has the potential to improve following an insult or injury. When that potential is absent, rehabilitation is replaced with palliative care. Amputation has been put forward as the rehabilitative alternative to the palliative management of the diseased lower extremity.

While the role of potential in amputee rehabilitation is appropriately acknowledged in the current language of the LCD, in the proposed revision, “potential” is replaced with “documented performance” when assigning K-level. The negative impacts of this proposed revision are exacerbated by the timing of K-level assessment and the limited resources available to the patient at that time.

Published observations in the literature suggest significant improvement in gait velocity and environmental obstacle negotiation well after the conclusion of a defined rehabilitation program. To assign K-level at this point in a patient’s recovery is premature and ignores the potential for additional improvements associated with time, training, and healing.

At the proposed time of K-level assessment, most Medicare beneficiaries will be limited to a preparatory device that is both *limited* and *limiting* in its components and performance. Proposed policy language excludes any and all additional items not described in the base codes for preparatory devices. As a result, the preparatory prosthesis would be limited to a 1950’s era SACH foot, no knee mechanism, no interface between the immature limb and the rigid socket, no allowance of a diagnostic test socket, no optimization or alteration to alignment, and no suspension mechanism.

These limitations will fundamentally limit the patient’s ability to attain the documented performance standards required for higher levels of K-level assignment. For example, in the absence of a defined knee mechanism in the descriptors for preparatory prosthesis, it can be reasonably assumed that the single axis knee defined in the base code of a definitive transfemoral prosthesis would be assigned to all preparatory devices. However, a single axis knee has no inherent stability and only allows for ambulation at a constant, slow speed. Limited by this component, many patients will be unable to demonstrate the independent negotiation of environmental obstacles or variable cadence.

The proposed decision to systematically ignore patient potential given adequate time, training, recovery, and prosthetic resources is inconsistent with the intent of physical rehabilitation and would negatively restrict patient’s functional capabilities.

Introduction

Rehabilitation is based on the fundamental premise that following an illness or injury, given adequate time and resources, *people have the potential to improve*. When that potential is absent, the focus of medical efforts and interventions change from rehabilitation to palliative care. This principle is exemplified in the title of a recent publication by Brown and Attinger at the Center for Wound Healing, Georgetown University Hospital, "*The Below Knee Amputation: To Amputate or Palliate*."[1] In their introductory comments, the authors explain:

> Despite advances in vascular surgery and wound healing, our ability to heal a diseased lower extremity remains limited. Our efforts to salvage such extremities are usually associated with a decrease in function. *Advances in prosthetic technology, on the other hand, have significantly increased the quality of life among patients with an amputated lower extremity*. In some patients, *their highest attainable function is often achieved with a properly performed below-knee amputation* (BKA).

Importantly, the authors present a well performed amputation with appropriate access to advanced prosthetic technology as the *rehabilitative* alternative to palliative care. Deciding between these options requires that the medical team consider the *potential* of each patient and whether the nature of the patient's illness or injury warrants palliative care or the additional investments associated with amputation with subsequent rehabilitation. The goal of a lower limb amputation is to help patients return to their highest attainable function, a goal that is best realized when the healthcare system invests in each patient's potential by providing patients with access to appropriate advances in prosthetic technology.

Existing Standard: Potential Functional Ability

This principle has historically been understood and integrated into the classification matrix used to determine a patient's functional level, as reflected in the language of the current LCD.

> "A determination of the medical necessity for certain components/additions to the prosthesis **is based on the beneficiary's potential functional abilities**. **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]

The individual K-level descriptors that follow all begin with a statement mirroring a reasonable understanding of the role of potential in determining likely functional abilities. For example, a K-level 1 is described as someone who has "…**the ability or potential** to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence."[2]

Proposed Revision: Documented Performance

In the proposed revision to the LCD, the principle of potential and Medicare's willingness to invest in that potential is entirely excluded. In its place is an assessment based on *"*documented performance*":*

> "The beneficiary's functional level is based on their overall health status, the objective results of the medical assessment and **their documented performance using their immediately previous prosthesis** (either preparatory or definitive)."[3]

The individual K-level descriptors that follow begin with altered verbiage ignoring any potential improvements in functional capabilities that might be realized with additional time, training, recovery, and resources. For example, in the revised language, a K-level 1 is described as someone who has "… demonstrated the ability to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence." The required standards of *demonstrated ability* increase at each K-level. The effect of such policy language would be to limit available prosthetic components to those patients who cannot perform certain tasks during the early stages of rehabilitation, but might be capable of doing so given adequate resources and training.

Performance Improves with Time and Training

In the language of the proposed LCD revision, patients who experience their amputations as Medicare beneficiaries will be assigned a K-level, according to their documented performance at the conclusion of a mandatory but vaguely defined rehabilitation program. However, the proposal that a patient's performance at the end of a rehabilitation program is representative of his or her longer term abilities is unfounded and contradicted by published observations.

For example, Brooks et al. reported on the 2 minute walk test performance of 290 lower limb amputees at baseline, at the conclusion of a rehabilitation program and again at a three month outpatient follow-up clinic. The mean performances observed at these periods were 30 meters, 41 meters, and 70 meters respectively.[4] Thus, while gait speed increased by an average of 37% between baseline assessment and the conclusion of the rehabilitation program, it increased an additional 71% between the rehabilitation program and the outpatient follow up several months later.[4]

In another study, Barnett et al. reported on the self-selected walking velocities of unilateral transtibial amputees as they negotiated a raised surface walkway designed to replicate the negotiation of stepping onto a curb, walking, turning 180 degrees, returning to, and stepping off of a curb.[5] In examining mean walking speeds during curb descent, speeds increased by 22% between 1 and 3 months post completion of a national health care rehabilitation program. An additional 11% increase in walking velocity was reported between 3 and 6 months after the rehabilitation program.[5] In addition to velocity considerations, ascent and descent strategies changed appreciably during the 6 months after the rehabilitation program, suggesting increased confidence in the prostheses and highlighting continued potential for improvement.[5]

Given the collective roles of community ambulation, environmental obstacle negotiation, and variable cadence in defining functional levels, any assignment of K-level at the conclusion of the rehabilitation programs referenced in these studies would have mischaracterized the true abilities that were ultimately attained by many of the involved amputees.[4-5] Similarly, the current proposal to define K-level based on demonstrated performance at the conclusion of a rehabilitation program is likely to underestimate the ultimate abilities of individual patients given adequate time, recovery, and training.

Both Potential and Subsequent Ability are Further Limited by Restricted Resources

One facet of an individual's potential is the improvement they will experience with time, recovery, and training. A second facet is the improvements that occur when patients are given access to reasonable prosthetic technology. The unjust nature of the "documented performance" requirements are further exacerbated by a thoughtful consideration of the limited resources that would be made available to Medicare beneficiaries at this time in their post-surgical recovery, as illustrated in the language of the proposed LCD below:

> **The beneficiary's functional level is based** on their overall health status, the objective results of the medical assessment and **their documented performance using their immediately previous prosthesis (either preparatory or definitive).**[3]
>
> **Preparatory prostheses use basic prosthetic components**, which provide adjustability and alignment changes as limb maturity occurs. Preparatory prostheses (L5500-L5600) are all-inclusive as described by the code narrative and in the CODING GUIDELINES section in the related Policy Article. **There is no coverage for any additional components, add-ons, upgrades, additions, adjustments, modifications, replacement etc. substitution of components, etc. provided for concurrent use with a preparatory prosthesis. All additional items will be denied as not reasonable and necessary**.[3]

For the sake of brevity, we limit consideration to transfemoral amputees, however similar statements can be said of all amputation levels. The limitations of the device that would be made available to the patient to demonstrate his or her abilities are explained in further detail within the code narrative for a preparatory prosthesis:

> L5590: Preparatory, Above Knee- Knee Disarticulation Ischial Level Socket, Non-alignable system, pylon no cover, SACH foot, laminated socket, molded to model.

Given the strict assertion that "all additional items (including additional components, add-ons, and upgrades) will be denied as not reasonable and necessary," the limitations of this device include:

- A foot developed in the 1950s and described as "for patients whose physical condition precludes ambulating more than a few steps at a time."[6]
- No knee mechanism
- No interface between the healing tissues of the residual limb and the hard socket.
- No use of a test socket to obtain a comfortable socket fit
- No mechanism to align the position of the components relative to the socket
- No suspension mechanism to hold the prosthesis on the limb and prevent movement of the limb within the socket and dislocation of the prosthesis from the person.

Patients cannot be expected to accurately demonstrate their abilities if they are not given access to reasonable technologies.

Restricting Prosthetic Components Limits Demonstrated Abilities

There are a number of ways in which restricting prosthetic components limits a patient's demonstrated ability. This paper will confine itself to a very brief evaluation of the single axis knee. Importantly, the code narrative for a preparatory prosthesis does not include a knee mechanism. However, it can be reasonably assumed that the single axis knee, included in the descriptor for a definitive transfemoral prosthesis, would be included in the preparatory devices mandated by the proposed LCD.

The limitations of the single axis knee are clearly understood and described and must be considered against the requirements for demonstrated performance associated with individual K-levels such as transfers, ambulation, environmental obstacle negotiation, and variable cadence. Quoting from the 3rd edition of the Atlas of Amputations and Limb Deficiencies:

> "Unfortunately, the basic single-axis knee has two major biomechanical deficiencies. First, ***the knee has no inherent stability***, and therefore ***must be carefully controlled*** by the amputee

with every step to prevent collapse of the prosthesis. ***Because the typical new amputee today is an elderly individual with concomitant medical problems, such perfect control of every step is often an unrealistic expectation***.

Equally important, with a free swinging knee, the lower leg is essentially a pendulum with a rate of swing limited by its length. As a consequence, ***the amputee is forced to walk at a constant, slow speed***. Attempts to accelerate result in excessive knee flexion in early swing, which slows cadence even further. Even with the addition of a friction adjustment or a spring extension aid, the ***cadence is still severely restricted***."

The limitations of this single component within the proposed preparatory device must be considered against the requirements associated with the assignment of K-level. These include traversing low-level environmental barriers such as curbs, stairs, or uneven surfaces (K2), functioning physically and psychologically within the community independently (K2), personal independence during ambulation with variable cadence (K3), and demonstrating the ability to traverse most environmental barriers without physical or safety concerns (K3).[3]

Medicare beneficiaries cannot be reasonably expected to demonstrate the abilities described above when they are statutorily confined to a basic knee with no inherent stability, requiring the unrealistic expectation of conscientious control of each step to avoid collapse of the knee; a knee that forces the patient to walk at a constant, slow speed with severe cadence restrictions. Similar arguments could be put forth for the indefensible decision to deny or limit coverage on feet, socket interfaces, and suspension mechanisms when reasonable established technologies exist that facilitate safety and empower the amputee's potential during ambulation and the negotiation of environmental obstacles. A patient's abilities can only be fully attained and realized when they are empowered with the appropriate resources.

Summary

The premise of rehabilitation is to invest in the potential of a recovering individual to allow them to regain a measure of their lost abilities after illness or injury. When a healthcare system is designed to ignore potential rather than invest in it, the individual's rehabilitation is fundamentally compromised. While prior LCD language acknowledged this principle, the proposed LCD dismisses it entirely. This is done by requiring demonstrated performance after a limited rehabilitation period with a *fundamentally limite*d and *fundamentally limiting* prosthesis. The end result of such changes would be a number of Medicare beneficiaries who are limited, not by their ability and potential, but by the policy itself, which refuses to adequately acknowledge or invest in the potential of its beneficiaries.

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

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

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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 prosed 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 in the 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 K1, 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 K2 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 a 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 K4 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:

> K1: 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]
>
> K2: 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]
>
> K3: 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 barriers*."[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 4,000 individuals, assistive devices were reported as the primary means of addressing existing activity limitations.[8] In 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 to 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

Literature establishes the benefits of cane use as an enabler of outdoor walking and for the negotiation of environmental obstacles. Gautheir-Ganon reported that among a cohort of 117 transfemoral amputees, 62% reported active use of their prosthesis in 75% - 100% of their outdoor activities. However, only 15% did so without AD. By contrast, nearly half 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, which is described as "*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 patients 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, as 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 and 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."

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Requiring "Demonstrated Performance" with Antiquated Prostheses to Qualify for a Modern Era Prosthesis

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

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Summary

Over the past few decades, lower limb prostheses have undergone significant technological advances that empower those that require these devices for daily living. However, the proposed changes to the LCD for lower limb prostheses does not acknowledge these improvements and instead forces patients to utilize technology that is at least fifty years old in the beginning of a long and difficult rehabilitation period after a lower limb amputation.

Under the proposed LCD changes, patients would need to demonstrate their K-level functionality with a preparatory prosthesis restricted to an antiquated device using a SACH foot, no liner, no knee mechanism, and without any suspension. For perspective, the SACH foot was introduced in 1956 (Staros, 1957), in the same era as the first implantable cardiac pacemaker developed by Wilson Greatbatch (Aqualina, 2006). It would be unthinkable for Medicare to mandate coverage on modern pacemakers only after patients have *proven* themselves deserving following a cardiac rehabilitation period with Greatbatch's pacemaker. Yet, this would become the case for the prosthetics patient as the current proposed changes to the LCD would modify the practice of prosthetic rehabilitation to a "rewards- based" system which impedes patient access to modern technology.

The current state-of-the-art science regarding the use of the SACH foot rather than newer technologies, such as multi-axial feet, clearly shows worse balance, worse residual limb health, worse utility of the prosthesis, less overall general well-being, reduced walking speed, and worse stair negotiation for low activity ambulators (≤ K2) (Paradisi et al., 2015). For higher activity ambulators, the use of SACH feet when compared against modern Energy Storage and Return (ESAR) feet results in reduced walking speeds (Hafner et al, 2002) and worse energy efficiency where more energy is required to ambulate (Casillas et al., 1995).

The preparatory prosthesis does not have provisions for a knee mechanism. However, it would likely include a friction control, single axis knee (as is specified in the definitive prosthesis base code narrative). The single axis is the most mechanically unstable available prosthetic knee (Uustal and Baerga, 2004), requiring a conscious effort to control the knee from buckling with every step, which is

difficult for the typical elderly amputee as well as individuals with short amputations (Smith, Michael, & Bowker, 2004). Additionally, the knee does not allow for ambulation at different speeds (Mauch, 1968).

Finally, there is no allowance for interface liners to protect the immature residual limb from the hard socket. This is contradicted by evidence that shows gel liners reduce pressures that cause limb ulcers (Boutwell et al., 2012), improve socket comfort (Baars and Geertzen, 2005), and decrease dependency on upper extremity assistive devices to ambulate (Datta et al., 1996).

In conclusion, the proposed changes to the LCD are such that prosthetic practice would become a rewards-based system, whereby patients must prove themselves with antiquated devices before having access to modern technology that better addresses both their individual limitations and capabilities.

Introduction

Significant technological advances have occurred in lower limb prostheses that have empowered users to more fully engage in the challenges and opportunities of daily living. However, the proposed LCD changes would deny access to these improvements during the earliest stages of recovery, forcing patients to begin their long and difficult post-amputation rehabilitation utilizing technology that is over 50 years old. **This document is meant to address the following fundamental flaw within the proposed LCD: Mandatory preparatory prostheses will have defined, unreasonable restrictions that limit prosthetic technology at a very vulnerable period in amputee rehabilitation. These restrictions would preclude access to available safety mechanisms, limit both comfort and performance, and ultimately undermine prosthetic acceptance and ambulation.**

Under the proposed LCD changes, K-level assignment will be based on "demonstrated ability" rather than functional "potential." For new amputees, this will need to be done with their preparatory prosthesis which has been restricted to a device using a SACH foot, no liner, no knee mechanism, and without any suspension. For perspective, the SACH foot was introduced in 1956.[1] In its time, the SACH foot was as revolutionary as other technological inventions of the era including the first implantable cardiac pacemaker developed by Wilson Greatbatch (1958).[2] It is unthinkable for Medicare to mandate coverage on modern pacemakers only after patients have *proven* themselves deserving following a cardiac rehabilitation period with Greatbatch's original pacemaker. **Current proposed changes to the LCD modify the practice of prosthetic rehabilitation to a "rewards-based" system impeding patient access to modern technology.**

Existing Standard: Immediate patient access to appropriate technologies

Currently, the LCD allows for the provision of prosthetic technology and components based on medical necessity consistent with the patient's functionality. It reads:

> "A determination of the **medical necessity for certain components**/additions to the prosthesis is **based on the beneficiary's potential functional abilities**. 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."[3]

The following guidelines pertinent to preparatory prostheses are:[6]

> "When an initial below *above knee prosthesis … or a preparatory below [above] knee prosthesis … is provided, **prosthetic substitutions and/or additions of procedures and components are covered in accordance with the functional level assessment.**"[3]

This language allows the prosthetist and physician to jointly evaluate the patient's history, condition, and medical problems *and select prosthetic components based on both functional abilities and limitations.*

Proposed Revision: Patients rewarded with modern technology only after proving themselves

The draft LCD proposes coverage changes that mandate the initial use of archaic technology and procedures. Under the proposed system, patients would only have access to modern technology after the demonstrated performance of prescribed standards with the severely limited device:

> "**Preparatory prostheses use basic prosthetic components**, which provide adjustability and alignment changes as limb maturity occurs. Preparatory prostheses (L5500-L5600) are all-inclusive as described by the code narrative and in the CODING GUIDELINES section in the related Policy Article. **There is no coverage for any additional components, add-ons, upgrades, additions,** adjustments, modifications, replacement etc. substitution of components, etc. provided for concurrent use with a preparatory prosthesis."

This is followed with mandates on the determination of a patient's functional level:

> "The beneficiary's functional level is based on their overall health status, the objective results of the medical assessment and their **documented performance using their immediately previous prosthesis (either preparatory or definitive)**."

Accordingly, patients will be required to prove their prosthetic abilities with devices that fail to address either their individual capabilities or limitations.

Conflicts Between the Proposed LCD and the State-of-the-Science

The proposed LCD is fundamentally unsound as it denies access to fairly basic and modern era components that would enhance safety, comfort, and performance during this early stage of rehabilitation. These limitations would be seen with archaic feet and knees and the withholding of available interface materials between the residual limb and the socket.

Feet

The SACH foot was introduced in 1956[1] and is among the most studied prosthetic devices. While serving as an advancement over other prosthetic feet of its time, it is now antiquated technology that has proven to be insufficient for numerous aspects of amputee mobility when compared to more modern technologies such as multi-axial and energy-storage-and-return feet (ESAR).

For example, a recent study by Paradisi et al. reported *significant improvements in balance* that occurred when K1 and K2 level walkers were switched from SACH feet to multi-axial feet.[4] Additional observations included *increased mobility, improved residual limb health, improved utility of the prosthesis, improved overall general well-being, increased comfortable walking speed, and improved times to ascend and descend stairs*.[4] These observations strongly suggest that lower functioning patients would have greater success during their rehabilitation program if given access to improved technologies such as multi-axial feet. Additionally, with regard to K-level assignment, the observed

benefits of the multiaxial foot over the SACH foot have obvious implications on a patient's ability to demonstrate the negotiation of environmental obstacles and variable gait speed.

Instead of enabling the patient with such benefits, the proposed LCD changes would force patients to endure a rehabilitation period and subsequently demonstrate their prosthetic abilities with a foot that has been shown to have *poor compliance over uneven ground resulting in greater instability,*[5] and *reduced ability to negotiate inclines and especially declines.*[6] Additionally, the SACH foot has been associated with *reduced walking speeds,*[7] *shorter stride lengths,*[7-8] and *increased self-reported difficulty with walking.*[9]

Even greater separation is observed when the SACH foot is compared against ESAR feet designed for K3-4 level walkers. Within Hafner et al.'s 2002 review of the topic, there is discussion of 9 different studies that all showed *the SACH resulted in reduced walking speeds compared to the ESAR type feet available*.[10] In addition, walking with the SACH foot, as compared to ESAR feet, leads to *reduced energy efficiency* and a gait that *requires more energy to walk*.[11-13] There are negative implications of these limitations on a patient's ability to demonstrate variable cadence ambulation.

Knees

There is currently no provision for a knee mechanism within the code narrative provided for preparatory prostheses and thus it is unclear if the expectation for patients with transfemoral amputations is to rehabilitate without a knee joint. As the proposed LCD carries a general theme of limiting patients to basic, antiquated technology, it can be assumed that the single axis knee, included in the base code for a definitive transfemoral prosthesis, will be similarly defined with the preparatory prosthesis descriptors.

Importantly, the joint configuration of a single axis is mechanically unstable, and when such a prosthetic knee joint is limited to friction controlled damping *it is the most unstable knee configuration available in existing prosthetic technology*.[14] The knee will *not* afford patients with the "ability to traverse most environmental barriers without physical or *safety concerns*" given the inherent mechanical instabilities. This inherent instability requires every step to be consciously and actively controlled to keep the knee from buckling,[15] a difficult feat for the typical new amputee that is an elderly individual with concomitant medical problems. In order to modestly increase mechanical stability, the knee can be set within the prosthesis in a further posterior location.[14] However, this will make it increasingly difficult to initiate swing phase, increasing the difficulty of walking and associated energy expenditure.[14]

In addition, the single axis knee utilizes a constant friction mechanism in its attempts to keep the knee from over-accelerating as the person initiates swing phase. The inherent instabilities associated with a person walking at varying speeds with a friction knee have been documented as far back as 50 years ago.[16] More recently, Hicks et al. demonstrated that adjusting friction in a single axis, constant friction knee has no effect on changing the swing velocity of the knee, noting that a friction knee can only allow for a fixed cadence due to pendulum dynamics.[17] If a patient attempts to increase their walking speed with a friction regulated knee, the knee will be flexed at instances when the patient is transferring weight onto the limb, which will cause the knee joint to buckle and a fall to ensue.

Otherwise stated, the single axis knee that would likely be defined within the base codes of preparatory prostheses *does not permit increased walking speeds*. These limitations were addressed decades ago when pneumatic and hydraulic yielding knees were invented to enable and adapt to increased ranges of walking speeds. Subsequent studies have confirmed that compared to ambulation with a hydraulic or pneumatic knee, walking with a single axis, friction knee results in a *decreased range of walking speeds*, more asymmetric swing and stance phases, and a walking pattern more atypical from healthy, non-amputees.[18] Yet the proposed LCD would require that patients be confined to this component while they attempt to demonstrate variable cadence in order to be classified as a K3 or K4 level walker.

Limb Interfaces

Finally, the proposed LCD prevents the use of gel liners with the preparatory prosthesis. The use of gel liners can reduce pressures on the residual limb,[19] decreases dependency on upper extremity assistive devices,[20] and results in improved comfort.[21] The significance of these related benefits is enhanced by the realization that amputees report comfort as a top factor affecting prosthetic use.[22] In the absence of adequate comfort, many potential prosthetic candidates may abandon their devices.

Conclusion

The proposed changes to the draft LCD are such that prosthetic practice will be a rewards-based system, whereby patients must prove themselves with antiquated devices before having access to modern technology. The unreasonable limitations of these mandated devices would substantially restrict the abilities of individual patients to attain the required documented performance standards proposed for higher K-level assignments. More importantly, by refusing to consider the individual needs and capabilities of individual patients, the policy would ultimately compromise patient safety, participation, and prosthetic acceptance.

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Tragic Timeline: Required Delays to Individualized Prosthetic Care

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Summary

Currently, individualized prosthetic rehabilitation begins shortly after the amputation, with the treating physician and prosthetist evaluating and considering the history, current condition, and co-morbid medical problems of the patient while the residual limb is recovering from the surgery. Under the draft LCD, the early prosthetic care of an individual recovering from amputation would be rationed by the common diagnosis of "amputee," with no initial consideration of individual limitations, abilities, challenges, and environments.

Policy-excused neglect would begin during the use of an immediate prosthesis, when coverage would no longer be available for those patients requiring a replacement of their immediate post-operative socket due to substantial volume loss. It would continue during the mandatory 90 day preparatory prosthetic phase when individual considerations would be soundly ignored in the provision of a uniform, limiting, basic prosthesis.

The LCD would mandate that this training device be used for at least three months regardless of the patient's successes or failures with the prosthesis. At the conclusion of that period, patients would be required to demonstrate minimum competencies to *earn* eligibility for an individualized prosthetic prescription. Those unable to do so would remain in their training device in perpetuity, with no access to definitive prosthetic care.

Those capable of meeting these standards would then begin a series of medical appointments and delays as they move from one professional to the next to satisfy the policy demands of the draft LCD. Throughout this time consuming process, they would remain in their limited training prosthesis, despite having demonstrated their candidacy for a definitive one.

The cumulative effect of the draft LCD policies would be a substantial delay in the time between an amputation and the thoughtful consideration of which prosthetic components are most appropriate for a given individual's physical presentation, environment, and activities. In the best cases, individualized care would be delayed some 6-12 months. In alternate scenarios, patients who could be successfully fit with a prosthesis under the current LCD would become victims of attrition to a process designed to ration prosthetic utilization to the most able individuals with little regard to those facing additional challenges such as weakness, shorter residual limb lengths, and other limiting comorbidities.

Introduction

Existing Standard: Timely Provision of an Individualized Prosthesis

In the current LCD, the individual consideration and provision of the most appropriate prosthesis for a given patient is not subject to policy-mandated delays. Rather, it begins with the collective assessment of the treating physician and prosthetist based on the following:

> "A determination of the medical necessity for certain components/additions to the prosthesis is based on the beneficiary's potential functional abilities. 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**."

Under this model, the unique characteristics of every patient are considered and addressed from the outset of treatment.

Proposed Revisions: A Series of Cumbersome, Restrictive Timelines that Rations Access to Prosthetic Technology and Delays Care

The draft LCD proposes the introduction of arbitrary time frames and waiting periods before determining whether a patient is eligible for individualized prosthetic rehabilitation. Those that are would be encumbered with added visits to doctors or other Licensed/Certified Medical Professionals for in person examinations and the generation of prescriptions. The flow of care from immediate to preparatory to definitive prostheses is largely based on arbitrary, restrictive time frames that fail to consider the individual needs of the patient.

<u>Immediate Prosthesis</u>

In the draft LCD, the immediate prosthesis is "*provided after surgery, while the surgical incision is still healing" to a "beneficiary is motivated to ambulate using the prosthesis.*[1] The draft LCD establishes the time frame of the immediate prosthesis phase to be until the wound heals and the patient is ready for a preparatory prosthesis.

The draft LCD proposes arbitrary restrictions on revisions or replacements of this immediate prosthesis:

> "Medicare payment for prosthetics includes all fitting and adjustments necessary in the 90 days after provision … of the prosthesis, therefore **all additions, adjustments, modifications, replacement** etc. to any components provided as part of the prosthesis and billed separately **during the 90 days after provision of the prosthesis will be denied as unbundling….Socket or other component replacements provided during the 90 days after provision of the immediate prosthesis will be denied as unbundling.**"[1]

The immediate prosthesis phase, or the time required to heal a wound and attain readiness for a preparatory prosthesis, can vary dramatically, from as short as 3 week to as long as 4 months.[2-3] In their recent publication, Ali et al. articulate the need for frequent cast changes with the immediate prosthesis, beginning as early as 1

week and continuing until the fitting of the preparatory prosthesis to account for remolding of the residual limb and to assess wound healing.[2] Such additional cast changes, currently covered by the existing LCD when required, would be precluded from coverage by the draft LCD irrespective of the amount of volume reduction experienced by the limb and the medical necessity for reapplication. In the absence of enabling cast changes as required, the useful period of the immediate prosthesis would be arbitrarily limited by policy, rather than determined by medical evaluation.

Preparatory Prosthesis Phase: **From Wound Healing to 90 days (and well beyond)**

The LCD revisions dictate that the preparatory prosthesis be "*provided after the surgical incision has healed*." During this period the beneficiary must start or be scheduled to start a rehabilitation program.[1] The preparatory phase is characterized by significant shrinking of the residual limb as patients increase their weight bearing and begin ambulation.[3] Modifications are expected as the patient's residual limb remodels, and their functional capacity increases.[3] However, as with the Immediate Prosthesis Phase, the LCD makes no allowances for those individuals who may require substantial changes to their prosthesis during this phase.

Upon receipt of the preparatory prosthesis the LCD asserts that any "additions, adjustments, modifications, replacement etc. to any components provided as part of the prosthesis," billed within 90 days of the patient's receipt of the prosthesis will be denied. In addition, the LCD later states, "[a] replacement preparatory prosthesis provided sooner than 90 days after a previous preparatory prosthesis will be denied…" Finally, the LCD later clarifies that "a definitive prosthesis may not be provided sooner than 90 days after the preparatory prosthesis." **Accordingly, there is ultimately no mechanism to address individual situations in which drastic changes in limb volume are experienced**. Such patients would need to wait 90 days from the receipt of their prosthesis before they would be eligible for a replacement preparatory or definitive prosthesis.

By LCD definition, the preparatory prosthesis is restricted to the most basic prosthetic components, including a 1950's era SACH foot,[4] the single axis knee (*described as the most unstable knee configuration available in existing prosthetic technology*),[5] and an absence of any protective interface between the healing residual limb and the liner (See *Requiring "Demonstrated Performance" with Antiquated Prostheses to Qualify for a Modern Era Prosthesis* at www.saveprosthetics.org). The ability of many patients to tolerate, let alone rehabilitate with such a prosthesis would be very questionable. The LCD addresses such situations stating simply, "*if the patient is unable or unwilling to use the prosthesis, the claim will be denied as not reasonable and medically necessary*." Restated, failures to progress during this 90 day preparatory phase would be viewed as the fault of an unable, unwilling patient, rather than an uncompromising, ration-based coverage policy.

Exceptional patients who are able to progress within the limitations of the coverage policy during this phase would not be eligible for an individualized definitive prosthesis until the conclusion of the policy-based 90 day time frame, irrespective of their limb maturity or functionality.

By severely restricting both the level of prosthetic technology and the prosthetist's ability to revise the preparatory prosthesis to match patient changes, set-backs or improvements, individual progress would be largely determined by the LCD policy rather than the patient.

Definitive Prosthesis Phase: a Cumbersome Process for Those that are Able to Earn It

After the preparatory phase is completed, operationally defined as when a patient presents with a mature residual limb at least 90 days after the receipt of their preparatory prosthesis, the patient enters into a process that will hopefully end in the fitting of an appropriate definitive prosthesis. As the "*definitive prosthesis may not be provided sooner than 90 days after the preparatory prosthesis,*" individualized prosthetic care cannot begin until at least 3 months *after* the surgical incision has healed.

However, the draft LCD states that "*[a]n initial definitive prosthesis is (only) covered for a beneficiary who meets all of the criteria below.*"[1] It then proceeds to describe a series of burdensome and time consuming requirements, the effects of which would range from *inconvenient* to *prohibitive* according to the abilities and limitations of each individual amputee. The cumulative time requirements become increasingly important as preparatory prostheses, which are only meant to be used as a short term gait training tool[6] to meet the continued needs of individual patients as they continue in their attempts to earn access to a definitive prosthesis intended for longer term use.

Hurdle #1: Meeting the rehabilitation goals:

To qualify for a definitive prosthesis, the patient would need to "successfully complete"[1] their rehab during the preparatory prosthesis phase. "Successful completion" dictates that the following goals have been met:

> "…the beneficiary must:
> - 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."

Significantly, the use of a preparatory prosthesis during a rehabilitation program is designed to get the patient **prepared** for the use of a definitive prosthesis, not perfect their gait and function. Under the draft LCD, patients would not have access to their final prosthetic technology during these assessments. Rather, patients would be trying to achieve very difficult goals while using a very basic prosthesis.

While individual patients may be reasonably able to perform some of the goals, others become increasingly unrealistic for many amputees. For example, the research has consistently and clearly shown that lower extremity amputee patients at all levels expend more energy during walking than able-bodied persons.[7] To assume that anyone with a prosthesis will achieve an "ease of movement and energy efficiency" with a rationed prosthesis that limits functionality, and do so within 3 months of the healing of their surgical incision, is both overly ambitious and unsupported by the literature. Yet patients who are unable to do so will have no recourse but to try to meet the demands of daily activity with a training prosthesis intended for short term use.

Hurdle #2: Adding delay – getting to the prescription:

Before qualifying for a definitive prosthesis, patients must see their physician for an in-person, comprehensive specialty examination to assess their readiness for a definitive prosthesis. The examination would be required to include the patient's over-all health status, cognitive capacity, neuromuscular control, cardio-pulmonary function, and global activity.

In metropolitan areas, **the average wait time to see a physician is 18.5 days**.[7] That number is likely higher for people seeking longer appointments with specialists (like physiatrists) or for people accessing a specialist from a rural area. If a 30 day wait time is assumed, the patient is now 4 months removed from the healing of their surgical incision. While a comprehensive evaluation is reasonable and appropriate, the mandate that it occur at the conclusion of the rehabilitation period would serve to further delay the time to individualized prosthetic care and lengthen the time that patients are required to endure the limitations of their training prostheses.

However, the referring physician would also have the option of referring this specialty evaluation to another medical professional with expertise in prosthetic care, such as a Physical Therapist (PT). If this occurs, the process of receiving a definitive prosthesis would be pushed even father out, as many PT clinics have a wait time of 2 weeks or more. If this conservative estimate is used, the patient would now be 4 ½ months removed from the healing of their surgical incision.

The physician would then need to see the patient again if the specialty evaluation was referred out to another medical professional. Conservatively assuming the evaluation report was delivered to the physician within a week and taking into account an average of 3 weeks to get another visit, the wait for individualized prosthetic care has now increased to 5 ½ months.

At this second "post evaluation" visit, the physician can write the prescription to for the prosthesis. The LCD allows the physician 45 days to deliver that prescription and a written report of the examination to the prosthetist. The patient's wait time for individualized, definitive prosthetic care is now up to 7 months from the healing of their surgical incision. Moreover, following the mandatory 3 month trial of the required preparatory prosthesis phase, the patient will have now spent an additional 4 months in a very limiting training prosthesis.

When the prescription is made available, the prosthetist must perform a mandated "in-person evaluation "*…to evaluate prosthetic needs consistent with the overall functional capabilities identified by the medical examination*"[1] and within the limits of the prescription. After this evaluation, the prosthetist will design the best possible system for the patient, order the components and fit and fabricate the device. Typically, the finished definitive prosthesis can be delivered in 3-4 weeks.

Ultimately, within the parameters of the draft LCD, eight months could reasonably lapse between the healing of the patient's surgical incision and receipt of individualized prosthetic care. While the LCD suggests that the preparatory prosthesis phase is a 3 month requirement, the associated delays of multiple appointments with numerous specialists, coupled with inherent delays in the transfer of medical information such as chart notes and evaluations would add several additional months of delay to the receipt of the definitive prosthesis.

Conclusion

The cumulative effect of the draft LCD policies is a substantial delay in the time between and amputation and a thoughtful consideration of which prosthetic components are most appropriate of a given individual's physical presentation, environment, and activities. Under the current LCD, individualized care begins immediately after the amputation. Under the draft LCD, initial care is rationed by the common diagnosis of "amputee." In the best cases, individualized care is delayed some 6-12 months. In alternate scenarios, patients who could be successfully fit with a prosthesis under the current LCD would become victims of attrition to a process that appears to have been designed to ration prosthetic utilization to the most able individuals with little regard to those facing additional challenges such as weakness, shorter residual limb lengths, and other limiting comorbidities.

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Raising the Bar While Shortening the Pole: The Conflict of Requiring "Stability, Ease of Movement, Energy Efficiency and a Natural Gait" With a Limited Device

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

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Summary

The proposed LCD raises the required standards for beneficiaries while restricting the prosthesis they can use to attain these standards to basic, antiquated technology. The duality of these changes, which create new performance standards while restricting prosthetic resources to the minimum available technology, would create a paradigm in which many amputees would be unable to attain their full functional capacity.

Under the current LCD guidelines, the physician and prosthetist collectively consider the individual conditions of the patient and determine the most appropriate initial prosthetic components that are consistent with the patient's assigned K-level. Under the revised LCD, uniform prostheses are provided to all patients irrespective of their individual presentation.

Under the proposed LCD, candidacy for a modern era prosthesis requires that the patient attain each of several benchmark standards, including independent donning and doffing of the prosthesis, independent transfers, daily wear tolerance, and ease of movement and energy efficiency. Each of these new requirements would be challenged to various degrees by the archaic nature of the mandated preparatory prosthesis.

Limitations to basic prosthetic knee and foot technologies could challenge or prohibit independent transfers among newer transfemoral amputees. Daily wear tolerance would be challenged by the prohibition against any protective interface between the healing residual limb and the rigid prosthetic socket. Finally, component restrictions would prevent many lower limb amputees from ever attaining "ease of movement and energy efficiency."

Medical consensus has defined several prosthetic components that enable safer transfers, such as axial feet allowing more surface to be in contact with the ground, knee technologies with inherent stability, and suspension liners allowing partial donning before entire body weight placed on prosthesis. Liner interfaces help to reduce limb pressures (Boutwell et al., 2012), decrease dependency on upper extremity assistive devices (Datta et al., 1996), and result in improved comfort (Baars and Geertzen,

2005), all of which would contribute to the objective of daily wear tolerance. While foot solutions exist the would facilitate “ease of movement and energy efficient gait,” patients are relegated to the use of SACH feet; known to compromise balance even for low activity individuals (Paradisi et al., 2015) and increasing energy expenditure for more active users (Casillas et al., 1995). Thus patients are denied access to the very components that might facilitate their attainment of elevated performance standards.

Ultimately, the proposed LCD creates a number of performance requirements for new amputees and their preparatory prostheses. However, within the same document there are regulations that prevent the provision of individualized prostheses equipped to accomplish these goals. Ultimately, performance standards should be based on the limitations and abilities of the individual patient who is provided with a prosthesis designed to facilitate, rather than undercut, their ability to reach that level of success.

Introduction

The proposed LCD raises the required standards for beneficiaries while restricting the prosthesis they can use to accomplish such standards. The attainability of these standards for many patients would be questionable if they were given access to reasonable prosthetic technology. However, the LCD further mandates that these standards can be attained at the conclusion of a rehabilitation program in which the prosthesis made available to new amputees is both limited and limiting, with only the most basic prosthetic components. The duality of these changes, which create new performance standards while restricting the prosthesis to antiquated prosthetic technology, would create a paradigm in which many amputees would be unable to attain their full functional capacity.

Existing Standard: Personalized prosthetics where decisions, practices, and expected outcomes recognize 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 capability 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."

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

> "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."

Under these guidelines, the physician and prosthetist have been able to 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 had a short residual limb that would likely preclude his or her ability to safely utilize a single axis knee, the physician and prosthetist could select an alternative knee joint that would provide mechanical stability to reduce the likelihood of the knee buckling.[1]

Proposed Revision: "Cookbook prosthetics" where all individuals are expected to accomplish the same performance standards using the same simple, archaic prosthetic componentry

In the revised language of the proposed LCD, a series of standards are introduced to "ensure successful use of a prosthesis." At the conclusion of a 90 day rehabilitation program, the patient must:

- "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"

Failure to do so results in non-coverage for any advanced in prosthetic care:

> "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."

Thus, candidacy for a modern era prosthesis would require that the patient attain each of the capabilities outlined above. Yet each of these new requirements would be challenged to various degrees by the archaic nature of the mandated preparatory prosthesis. Limitations to basic prosthetic knee and foot technologies, currently viewed as both reasonable and medically necessary, could challenge or prohibit independent transfers among newer transfemoral amputees. Daily wear tolerance would be challenged by the prohibition against any protective interface between the healing residual limb and the rigid prosthetic socket. Finally, component restrictions would prevent many lower limb amputees from ever attaining "ease of movement and energy efficiency."

Mandatory use of a disabling prosthesis

For many patients, the augmented performance standards would only be realistic when they are provided with the proper prosthetic tools. However, this is precluded by language elsewhere in the proposed LCD. The severe limitations of the preparatory prostheses made available to patients in their attempts to reach the prescribed performance standards are described below:

> "preparatory prostheses use **basic prosthetic components**, which provide adjustability and alignment changes as limb maturity occurs. Preparatory prostheses (L5500-L5600) are all-inclusive as described by the code narrative and in the CODING GUIDELINES section in the related Policy Article. **There is no coverage for any additional components, add-ons, upgrades, additions, adjustments, modifications, replacement etc. substitution of components, etc. provided for concurrent use with a preparatory prosthesis**."

Under these mandates, preparatory prostheses will constitute a hard socket with a solid-ankle-cushioned heel (SACH) foot and no knee mechanism if a patient has a transfemoral or proximal amputation. The preparatory prosthesis base code narratives do not include any suspension, and the inability to add L5910 and L5920 will remove the ability of the preparatory prosthesis to "provide adjustability and alignment changes" as defined within the proposed LCD. As the proposed LCD stands currently, patients would be unable to utilize interface liners of any sort including gel, silicone, urethane, or foam. They will also be required to utilize the SACH foot which was first introduced in 1956.[2]

Elevated standards of performance

Don and Doff the prosthesis without assistance

The ability to independently don and doff the prosthesis is constrained by the limited nature of the prosthesis. In the absence of any prescribed method of suspension, the reasonableness of this requirement is uncertain as suspension type affects the patient's mobility.[3] Suspension refers to the method used to create a linkage between the prosthesis and the residual limb. If there is no suspension,

then the prosthesis will not stay on the residual limb unless the person uses his or her hands to hold the prosthesis onto the residual limb. Bending over to hold the prosthesis onto the residual limb creates a highly unstable position, as well as a difficult movement strategy that is highly inefficient and lacks any sort of natural gait appearance. If the patient does not hold the prosthesis onto the residual limb with his or her hands, there is a highly unstable scenario with the patient's first step as the prosthesis will no longer be under the patient to accept weight transfer.

The long held industry standards for suspension generally involve an interface liner, the use of which is precluded by the restrictive definition of the preparatory prosthesis. Thus, until a suspension mechanism is defined for the various levels of amputation, the ability of patients of various abilities to independently don their prosthesis is uncertain.

Independent transfers

Limitations to basic prosthetic knee and foot technologies could challenge or prohibit independent transfers among newer amputees. Medical consensus has defined several prosthetic components that enable safer transfers. Locking liners allow patients to partially don their prosthesis in sitting and then fully seat their limb in weight bearing. Axial feet allow the entire surface of the foot to come in contact with the floor during transfers and through-out each step. This consideration is especially relevant to transfemoral amputees as such mechanisms reduce the instabilities that would otherwise be experienced around the knee. A number of knee technologies with inherent safety mechanisms have been designed and accepted in recent decades, including weight activated stance control knees that increase their resistance to flexion when loaded, and polycentric knees that position the functional axis of rotation proximal and posterior to the physical joint, making it easier for the user to control the relative extension of the knee. All of these readily available technologies could assist patients in reaching the new standards of the LCD. However, the preclusion of suspension liners, axial feet, and knees with inherent stability will severely limit the abilities of many newer amputees to demonstrate this ability.

Daily wear tolerance

As stated earlier, the language of the LCD precludes the use of interface liners. The use of gel liners can reduce pressures on the residual limb,[4] decrease dependency on upper extremity assistive devices,[5] and result in improved comfort.[6] The significance of these related benefits is enhanced by the realization that comfort is reported by amputees as a top factor affecting prosthetic use.[7] In the absence of adequate comfort, many potential prosthetic candidates may abandon their devices. In short, the utilization of interface liners, well-established as a reasonable standard of care in modern prosthetics, is restricted by the proposed LCD, undermining the abilities of many amputees to attain the new standard of demonstrating daily wear tolerance.

Ease of movement and energy efficiency

Furthermore, all individuals are expected to reach the same benchmark standards of "sufficient balance and stability to ambulate with ease of movement and energy efficiency." This stipulation is as ridiculous and short sighted as mandating that all patients in a weight loss program must lose 100 pounds regardless of the patient's weight or any individual consideration of what level of weight loss would improve quality of life and functionality.

In terms of gait and mobility, stability is difficult with antiquated technology for both active individuals and lower activity individuals. Paradisi et al.[8] showed for lower activity individuals (19 K2, 1 K1), the use of a multi-axial foot as opposed to the SACH foot resulted in *significantly improved balance*. Paradisi et al. also reported *increased mobility*, *improved residual limb health*, improved utility of the prosthesis, and overall *improved general well-being* as well as *increased comfortable walking speeds* and improved times to ascend and descend stairs using the multi-axial foot. Yet these benefits would be unavailable to patients during the rehabilitation phase as they attempt to meet the standards of "ease of movement and energy efficiency."

Instead, the LCD language mandates that new patients must use a SACH foot, making it nearly impossible for a prosthesis to provide "stability, ease of movement, and a natural gait." The rigidity of the SACH foot causes problems with increased time for foot flat in early stance after the heel contacts the ground.[9] The non-compliance of the SACH foot then creates problems with conforming to uneven ground.[10] Such limitations undermine the notion of demonstrating "ease of movement." The rigidity of the SACH creates increased difficulty with inclines and especially declines.[11] It is important to remember that walking outside in the community will always present inclines, declines, and uneven terrain as the world is not flat.

For more active patients, achieving an energy efficient gait with "ease of movement" could be facilitated by the use of well-established energy-storage-and-return feet (ESAR). Snyder et al.[12] reported *increased walking speed* when patients used an energy-storage-and return (ESAR) type foot compared to a SACH foot. This was likely due to the reported increased stride length with the ESAR foot[12]. Powers et al.[13] also reported *increased stride length* with an ESAR foot compared to SACH feet. Macfarlane et al.[14] found that patients walking with an ESAR type foot reported *less difficulty with movement*. Hafner et al.'s review[15] discusses 9 different studies that all showed *increased self-selected walking speed* with ESAR type feet compared to SACH, reinforcing the reality that the SACH foot simply does not provide "ease of movement." Regarding energy efficiency and energy cost, multiple studies have found patients walk with *improved energy efficiency with ESAR feet* compared to SACH feet.[16-18] Hsu et al.[17] and Casillas et al.[16] reported *improved energetic cost with ESAR feet*. Yet this technology, widely understood, accepted, and utilized in modern prosthetics, would be unavailable to patients as they are required to demonstrate "ease of movement and energy efficiency."

Patients with amputations proximal to the knee joint will face further difficulties achieving rehabilitation goals. There is no knee mechanism specified in the preparatory prosthesis base code, however the definitive prosthesis base code narrative includes a constant friction, single axis knee. For a patient that will walk at different speeds, not having a knee joint with a fluid medium (e.g. hydraulic or pneumatic) will compromise stability as the knee joint itself is unable to increase its swing velocity to allow ambulation at faster speeds. Mauch[19] detailed the inherent instabilities from a friction knee for a person walking at varying speeds nearly 50 years ago. If a patient changes walking speed, a knee that utilizes friction for yielding purposes will be flexed at instances when the patient is transferring weight onto the limb, which will cause the knee joint to buckle and a fall to ensue. This is hardly conducive to "ease of movement and energy efficiency," and yet it would potentially be the only knee joint available to new amputees at the very time when ease and efficiency are required.

Conclusion

The proposed LCD mandates that individuals demonstrate independent donning and transfers along daily wear tolerance to qualify for a definitive prosthesis. Similarly, the preparatory prosthesis must

provide stability, ease of movement, energy efficiency, and the appearance of a natural gait. Within the same document, however, there are regulations that prevent the provision of a prosthesis reasonably equipped to accomplish these goals. Ultimately, performance standards should consider the individual patient along with their limitations and abilities. Further, any such standards must allow for the provision of prosthetic technology that enables the attainment of such standards.

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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?

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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, i.e., "*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 et al., 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, Prvu-Bettger et al. observed that 43 percent of 4,720 veterans with lower limb amputation had pre- existing neurological conditions (Prvu-Bettger, 2009). However, compromised neuromuscular control

does not preclude success with a prosthesis. In their study of transfemoral amputees 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 that 58 percent (Herbert et al., 2012).

Compromised cardiovascular compromise is ubiquitous among lower limb amputees with 82 percent of amputations in the United States 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 percent ambulated within one level of their pre-amputation status at a two 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 Bertand, 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*"[1] 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 cardio-pulmonary 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."[2]

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, "a licensed/certified medical professional who has experience and training in the functional assessment of beneficiaries with amputations"[1] determines the patient's abilities and limitations through an examination:

> "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); and
> - The **beneficiary has sufficient cardio-pulmonary capacity** to effectively use the prosthesis at the determined functional level (K0–K4)."[1]

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 use 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.[3] The patients' co-morbidity data was recorded with commonly encountered conditions including peripheral vascular disease (PVD), cardiac conditions, stroke, and mental health conditions.[3] 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[4] which can be a contributing factor for all these co-morbid conditions.[5] Importantly, **the prevalence of all these cognitive, neuromuscular and cardio-pulmonary conditions was higher in the prosthetic users than in the non-users**.[2]

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.[6] 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." [7] 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 rehabilitation programs.[5] 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.[8]

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 percent.[9] Accordingly, such neuromuscular conditions are not uncommon in patients who undergo lower-extremity (LE) amputation. **In their retrospective study of 4,720 veterans with lower limb amputation, Prvu-Bettger et al. found that 43 percent had pre-existing neurological conditions at the time of their amputation,** the most common of which were peripheral nerve injuries and hemiplegia.[10] While few studies have thoroughly examined the impact of these conditions on the prognosis for prosthetic rehabilitation,[9-10] 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.[9] **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 two crutches, 11 used a cane, and two subjects ambulated without any assistive device at all.[9] **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.[11] 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 percent) of amputations in the United States, and the incidence is expected to rise as rates of co-morbid diseases such as peripheral vascular disease and diabetes continue to increase.[4] 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 two year follow-up.[12] Their results showed that at two 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**.[12]

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.[13] 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.[13] 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 of 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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Unable or Unwilling: Policy Discrimination against Bilateral Amputees and Other More Challenged Patients

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

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Summary

Within the draft LCD, three types of prosthesis are defined: Immediate, Preparatory, and Definitive. In the coverage criterion for each type, the LCD asserts "**If the beneficiary is *unable* or *unwilling* to use the prosthesis, the claim will be denied as not reasonable and necessary**." However, an analysis of the LCD suggests several policy changes that seem designed to subvert the *ability* and *willingness* of individual patients to succeed with limited prosthetic resources. This is especially true of individuals presenting with greater levels of difficulty. If the standards of "*reasonable"* and *"necessary"* are to be applied to prosthetic coverage determinations, they should also be applied to the proposed policies themselves. However, especially with regard to amputees facing greater challenges and limitations, the proposed LCD is neither reasonable nor necessary and would leave many previously capable patients as either unable or unwilling to succeed with a prosthesis.

The policies outlined within the draft LCD initially deny access to both enabling prosthetic technologies and adequate time and training to fully utilize the prosthesis before amputees' functional abilities are fairly assessed. Rather, under the proposed LCD, patients would be given access to only the most basic prosthetic technologies and given only 90 days to train with them before their prosthetic abilities and function are placed on trial. To be able and willing to wear such a prosthesis in this early and vulnerable stage of rehabilitation would be challenging for many healthy unilateral amputees, and impossible for those with additional challenges such as bilateral amputation and high level amputations through the pelvis.

Rather than aiding and enabling those individuals with increased disability and physical challenges, the proposed LCD will increase the barriers to success. As a result, individuals with bilateral amputation, more proximal amputations at the pelvis level, and those with other comorbidities will fail to reach their true potential.

Introduction

Within the draft LCD, three types of prosthesis are defined: Immediate, Preparatory, and Definitive. In the coverage criterion for each type, the LCD asserts "**If the beneficiary is *unable* or *unwilling* to use the prosthesis, the claim will be denied as not reasonable and necessary**." However, an analysis of the LCD suggests several policy changes that seem designed to subvert the *ability* and *willingness* of individual patients to succeed with limited prosthetic resources. This is especially true of individuals presenting with greater levels of difficulty, including patients with bilateral amputation, those with amputations at the level of the pelvis, and those with co-morbid injuries and illness. If the standards of "*reasonable"* and *"necessary"* are to be applied to prosthetic coverage determinations, they should also be applied to the proposed policies themselves. However, especially with regard to amputees facing greater challenges and limitations, the proposed LCD is neither reasonable nor necessary and would leave many previously capable patients as either unable or unwilling to succeed with a prosthesis.

Existing Standard: Individual Evaluation, Consideration, and Definition of Functional Potential

Under the current LCD, prosthetic rehabilitation begins with an individual evaluation that is used to determine individual potential functional abilities. This evaluation includes past history, current presentation, and other medical problems:

> "A determination of the medical necessity for certain components/additions to the prosthesis **is based on the beneficiary's potential functional abilities**. **Potential functional ability is based on the reasonable expectations of the prosthetist and treating physician**, who consider 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."

Based on that evaluation, the rehabilitation team determines a functional state that can be reasonably expected of the individual. Individualized prosthetic coverage is made available to a patient who will reach that individually defined functional state:

> "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."

Proposed Revisions: Uniform Minimal Standards of the Patient and Prosthesis Regardless of Individual Presentation and Limitations

Under the proposed LCD, this standard would be drastically altered by the provision of a uniform, basic prosthesis at the time the amputation wound has healed. This preparatory prosthesis would not consider individual variations in patient presentation, nor would it allow for the incorporation of any prosthetic technologies beyond the most limited components. At the conclusion of a 90 day

rehabilitation program with the Spartan device, both the patient and the prosthesis would be held to minimal performance standards, irrespective of patient presentation.

The following are requirements of the patient, irrespective of their presentation:

> "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"

The following are requirements of the prosthesis, irrespective of the patient's presentation:

> "The **prosthesis provided must provide**:
> - Stability,
> - Ease of movement,
> - Energy efficiency, and
> - The appearance of a natural gait"

The following are requirements of the patient with their prosthesis, irrespective of their presentation:

> "In the prosthetic rehabilitation program, **the beneficiary must**:
> - 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"

Under the proposed LCD, failure to meet any of these requirements indicates that a patient will not be successful with a definitive prosthesis, and would therefore be ineligible for long term prosthetic care. As articulated elsewhere in the LCD, **the patient is now considered "unable and unwilling to use the prosthesis," and prosthetic coverage is no longer "reasonable and necessary."**

The Self-fulfilling Prophesy Fulfilled

The policies outlined within the draft LCD would ultimately create a self-fulfilling prophesy in which patients are initially denied access to both enabling prosthetic technologies and adequate time and training to fully utilize the prosthesis before their functional abilities are fairly assessed. Rather, they would be given access to only the most basic prosthetic technologies and given only 90 days to train with them before their prosthetic abilities and function are placed on trial. To be able and willing to wear such a prosthesis in this early and vulnerable stage of rehabilitation would be challenging for many healthy unilateral amputees, and impossible for those with additional challenges. Individuals with bilateral limb loss would be especially challenged to meet this criterion.

Prevalence of Bilateral Amputees

The minimal requirements that would be established would be difficult for a large number of Medicare beneficiaries that are sadly forsaken and forgotten within the proposed LCD. Taylor et al. looked at functional outcomes after major lower limb amputation in a cohort of 553 patients, reporting 23.6% resulted in bilateral amputation (Taylor et al., 2005). In their convenience sample of 201 dysvascular amputees, Kulkarni et al. reported that 24% presented with bilateral transtibial amputations (Kulkarni, 2006). However, these numbers may actually be an underestimation on the number of bilateral amputees given that up to 55% of persons with diabetes who have a lower extremity amputation will require amputation of the contralateral leg within 2-3 years (Pandian, Hamid, & Hammond, 1998). By conservative estimates, roughly one quarter of the amputees who are covered by Medicare have bilateral limb loss.

The Impact of Minimal Functional Requirements on Bilateral Amputees

Many bilateral amputees would be challenged to meet the minimal performance standards established by the LCD. For example, in the absence of a sound side limb, most bilateral amputees would be unlikely to perform the Tinetti balance assessment without a walker or cane 3 months after their amputation, and would therefore fail to demonstrate "adequate static and dynamic balance" as it is not possible to score above the threshold of 24 set in the proposed LCD if assistive devices are used (Tinetti, 1986). Similarly, ease of movement with a pair of 1950's era prostheses would be challenging as would any pretense of energy efficiency. DuBow et al. reported energy expenditure for bilateral transtibial amputees to be 123% of that measured in similar non-amputees (DuBow et al., 1983). Energy efficiency is inherently even poorer when the amputation is due to vascular disease rather than trauma (Waters and Mulroy, 2004). Likewise, the ability of such individuals to don and doff their prostheses independently, particularly early in the rehabilitation process might be suspect. Finally, their ability to demonstrate sufficient daily wear tolerance would be challenging in the absence of cushioning gel liners to protect tissues of the residual limb. Specifically, while unilateral amputees shift loads to the sound limb to off-load their residual limb when they experience limb soreness because of increased demands (Michael and Jorge, 2013), bilateral amputees are unable to do so. Uellendahl (2004) provides the following practice guideline for bilateral amputees "transtibial amputees benefit from soft interface materials such as silicone, urethane, or thermoplastic gel liners that, along with appropriate socket design, spread forces evenly over the greatest possible area."

Current Prosthetic Utilization by Bilateral Amputees

Importantly, under the current LCD, bilateral amputees can and do attain levels of prosthetic proficiency, even among the most challenged and at-risk populations. In their report on the long term mobility and mortality of patients with peripheral arterial disease following bilateral amputation, 45% of those patients amputated bilaterally below the knee retained the ability to walk, as did 30% of those with a single preserved anatomic knee joint (Inderbitzi, Buettiker, & Enzler, 2003). Taylor et al. (Taylor et al., 2005) similarly reported 43% of the bilateral dysvascular amputees were ambulatory 1 year after their amputation.

The mandates from the proposed LCD conflict with published practice guidelines. In the most recent edition of the *Atlas of Amputations and Limb Deficiencies: Surgical, Prosthetic, and Rehabilitation Principles*, Uellendahl (2004) states for bilateral amputee prosthetic fittings, "foot and ankle components that provide good shock absorption" should be used. He asserts the best practice includes "modern foot and ankle components that offer compliance and some measure of dynamic response". Uellendahl (2004) also states "a more flexible foot is generally preferred over one that is rigid." **Despite the LCD's high regard for the *Atlas of Amputations and Limb Deficiencies: Surgical, Prosthetic, and Rehabilitation Principles*, as evidenced by 26% of the references utilized to formulate the proposed LCD coming from the Atlas**, these practice guidelines provided by Uellendahl are not upheld. Rather, similar to all patients, bilateral amputees would be forced to use a rigid SACH foot with poor shock absorption in their preparatory prosthesis. Then, *if* they can clear the unreasonable hurdles to get a definitive prosthesis, they will similarly find that the consolidation of foot codes has eliminated their potential for feet with vertical shock absorption (L5987), which are a lighter alternative to a prosthetic foot with an additional shock absorbing pylon component added.

Further mandates include a vague and unclear directive regarding the suspension used with the preparatory prosthesis. The LCD mandates no add-ons to the preparatory prosthesis base code, but there is no suspension within the base code narrative. Uellendahl (2004) further states "Suspension of a prosthesis is always critical and assumes even more importance for the bilateral amputee. Any amount of pistoning in the socket will increase the effective length of the prosthesis during swing phases and the bilateral amputee cannot actively vault to compensate." Uellendahl (2004) clearly specifies "Suction suspension is recommended whenever possible, for all cases and levels of [bilateral] amputation." Suction suspension, however, is not possible in the above- knee application for a maturing residual limb that will quickly reduce in volume unless a silicone or gel liner is used. Within the proposed LCD, the use of a silicone or gel liner will be considered custom and will not be covered for patients in any prosthesis unless a foam liner is unable to be effective.

What Happens When LCD Standards Are Not Met?

While the LCD allows patients with bilateral amputation to receive a very basic preparatory prosthesis, there is high likelihood these patients will not meet the standards to qualify them for provision of a definitive prosthesis. The policies of the LCD assume that amputees that are unable to meet these minimal functional requirements will simply abandon prosthetic use. Tragically, because of the Spartan nature of the mandated preparatory prosthesis, this would likely be the case for many bilateral amputees. However, others would continue to function with their prostheses, albeit at a level dismissed by the LCD. As the draft LCD has no mechanism for patients who fail to meet the minimal functional requirements to receive ongoing, long term prosthetic care, these patients would have no alternative but to attempt to derive long term utilization from preparatory prostheses designed for short term use.

While their general health is often compromised, bilateral dysvascular amputees are reported to have as high as 67% 5-year survival rate and 42% 10-year survival rate (Kulkarni, Pande, & Morris, 2006). Inderbitzi et al. report an average life expectancy after the second amputation of 3.2 years while 31% lived longer than 5 years (Inderbitzi, Buettiker, & Enzler, 2003). These tenures are far beyond the

reasonable lifespan of a preparatory prosthesis, especially an antiquated, simple device intended for a 90 day period prior to functional evaluation. It is not clear how these individuals who are not eligible for ongoing prosthetic care with a definitive prosthesis will be managed. Furthermore, the economics of the situation are questionable when Inderbitzi et al. (Inderbitzi, Buettiker, & Enzler, 2003) reported 82% of the individuals they reviewed that were ambulatory with prostheses returned to their individual homes as compared to 63% of those who were mobile with a wheelchair.

From Unilateral to Bilateral

Finally, the high standards and mandate on preparatory prostheses will severely hinder the 55% of patients that have the other leg amputated within 2-3 years as they will now be faced with the possibility of walking with a more modern technology definitive prosthesis received with their initial amputation, and a completely different prosthetic setup for their preparatory prosthesis. This is analogous to walking all day with a high heel and a tennis shoe, and goes against the practice guidelines from Michael & Jorge (Michael and Jorge, 2013) that state "The prosthetist should consider both prostheses together rather than simply generate a 'right-side' and a 'left-side' prescription recommendation."

Impact on Other Forgotten Patients

Bilateral amputees are not the only individuals with increased disability that will be discriminated against. Patients with hip disarticulation and transpelvectomy constitute a small percentage of lower limb amputees, with incidence reported as high as 3.0% (Michael and Jorge, 2013). Yet, they do exist and a small percentage ambulate. These individuals will similarly fail to meet the high standards established, forcing them into wheelchairs. There are also aging polytrauma patients with upper extremity amputation to accompany their lower extremity amputation. This population will also face increased scrutiny and likelihood that their devices will not be available in their Medicare years due to high standards. The patients and their providers are not allowed to determine for each individual what constitutes prosthetic success.

Conclusion

The proposed LCD will deny claims as "not reasonable and necessary" for cases when the beneficiary is "is *unable* or *unwilling* to use the prosthesis." However, an analysis of the LCD includes several policy changes that disregard the *ability* and *willingness* of individual patients to succeed with limited prosthetic resources. Rather than aiding and enabling those individuals with increased disability and physical challenges, the proposed LCD will have increased barriers to success. As a result, individuals with bilateral amputation, more proximal amputations at the pelvis level, and those with other comorbidities will fail to reach their true potential.

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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 Prostheses (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 the patient 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 (Gautheir-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.[1] However, *accurately predicting* walking capability following prosthetic rehabilitation has proven elusive.[2] 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.[3-5] 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.[6] 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.[4] In absence of a more precise instrument, classification via the MFCL system remains largely subjective.[4]

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."[2]

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."[7] The LCD draft additionally proposes a set of "minimum requirements to be functionally successful with a lower limb prosthesis"[7]:

> "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[7]

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 a prerequisite to success with a prosthesis displays a general ignorance of the test itself, it's 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**.[8] 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.[9] 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,[10] and "*adequate*" for patients with Parkinson's disease.[11] 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**, <u>the Tinetti has never been tested in an amputee population</u>**. 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-of 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.[11-15] These cut-off scores have been established for older adults,[13,15] for people with stroke,[14] and for people with Parkinson's disease.[11-12] However, these cut-off scores range from 17.5[12] to 21.[15] 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).[16] **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, Gautheir-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.[17] 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.[17] 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*.[18] Similarly, the SACH foot included in the preparatory prosthesis has been associated with *greater instability*[19] and *increased self-reported difficulty with walking*.[20] 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 with elevated fall 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," indicates 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 utilizing the technologies that could augment their safety and engagement in society.

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

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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, sufficient balance and stability to ambulate with ease of movement, and energy efficiency.

The majority of patients who fail to meet these "improvement standards" would otherwise benefit from an individualized prosthetic prescription which 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. These technologies are of particular value to amputees with limited capabilities.

The proposed 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 or well-being of the individual. Denying patients access to reasonable prosthetic components that would assist them 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 acknowledges 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 and 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 to keep 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, the medical consensus 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 consideration 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 mechanisms, 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 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. A patient who is unable to attain sufficient wear tolerance for a normal day's activities is given access to an interface liner that protects the fragile tissues of the residual limb. However, 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 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.

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Natural Gait: A Reasonable Goal but an Unreasonable Requirement

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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 has 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 that 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 he or she is in his or her mandated preparatory prosthesis or prefers 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,[1] "*…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 patients 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[2] reported that an amputee's satisfaction with his or her prosthesis correlates with his or her self-reported ambulation skill, the utility of his or her 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[2]:

> "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.[3] 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 [4] 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 him or her better balance. They conclude:[4]

> "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.[5] had similar findings, showing transtibial amputees successfully utilize an asymmetric force

distribution between the prosthetic and sound limbs to effectively maintain balance. Again, the study highlights 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 and Kogler [6] 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 [7] 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.[8] 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.[8] 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 his or her 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.[9]

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 to modern prosthetic technologies. Other deviations are simply the result of patient habit and preference,[8] 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 on 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 prosthetists’ reimbursement to factors beyond their control.

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Solving the "Medicare Puzzle" of Increased Prosthetic Foot Costs: 2005-2010

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

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Summary

The tone of the draft LCD for lower limb prostheses is based on rationing prosthetic technology to the most able amputees while restricting it from the remainder of that community. While changes to an LCD should be based on scientific evidence, the draft LCD in question seems to be more influenced by economic motives. Chief among these motives is the uninformed speculation included in a 2012 magazine article that misrepresents changes in Medicare spending on prosthetic feet in 2005 and 2010. The majority of the increases in spending within the magazine article can be justified by a proper understanding of allowed versus reimbursed payments, annual increases in the Medicare fee schedule, and the introduction of a new, expensive billing code associated with new technology that carries low utilization rates. The remainder of the differential reflects changes in Medicare's demographics as beneficiaries became younger. Any changes in LCD policies should be driven by peer-reviewed, published evidence in the scientific literature, rather than uninformed speculations in the popular press.

Introduction

The prevailing tone in the draft LCD for Lower Limb Prostheses **(DL33787),** released by CMS in July 2015 is one of rationing modern era prosthetic components to the most able lower limb amputees while restricting access to such technology from the remainder of the amputee population. The motivation for this approach to the new prosthetic coverage policy is unclear. However, the first reference appearing at the top of the LCD Bibliography may suggest the undertones within this magazine article may have strongly influenced the authors of the proposed LCD.

Medicare's Provider Integrity Manual is clear as to the types of evidence that should support changes in coverage LCD's. According to section 13.7.1 – "*Evidence Supporting LCDs*:"

> "Contractor LCDs shall be based on **the strongest evidence available**. The extent and quality of supporting evidence is key to defending challenges to LCDs. The initial action in gathering evidence to support LCDs shall always be a **search of published scientific literature** for any available evidence pertaining to the item or service in question.
>
> In order of preference, LCDs should be based on:
>
> - Published authoritative evidence derived from definitive **randomized clinical trials** or other **definitive studies**, and
> - General acceptance by the **medical community** (standard of practice), as supported by sound **medical evidence** based on:
>   - **Scientific data** or **research studies** published in **peer-reviewed medical journal**s;
>   - Consensus of **expert medical opinion** (i.e., recognized authorities in the field); or
>   - Medical opinion derived from consultations with **medical associations** or other **health care experts**."

Nowhere within this list are magazine news articles written by freelance journalists. It is unfortunate to note however, within these stated guidelines the first reference cited to support the proposed changes of the draft LCD was not a randomized clinical trial, a peer-reviewed research study from a respected medical journal, expert medical consensus, nor any form of published scientific literature. Rather, the LCD cites an Associated Press (AP) news article written by a freelance author:

> *Alonso-Zalvidar R. Medicare puzzle: Big rise in artificial feet costs. AP Mobile News. February 16, 2012*.

Failing any reasonable standard for published scientific literature, the foundations and conclusion of the article are both misleading and inaccurate, lacking any reasonable awareness of the prosthetic profession. The article was not peer-reviewed by knowledgeable experts in the field nor did the author have the knowledge, credentials, or qualifications to reasonably render any relevant or applicable insights into the complexities of Medicare's reimbursement of prosthetic feet. Furthermore, as will be detailed here, it can be seen that the writer was careless with his investigation into Medicare spending.

The premise of the article is summarized in the author's statement below:

"Medicare paid $94 million for artificial feet in 2010, according to research conducted for The Associated Press. That was nearly $35 million more than in 2005, even though in 2010, Medicare covered about 1,900 fewer such prostheses."

This conclusion is unfortunately inaccurate and fails to fully account for numerous influencing factors. These issues include reimbursed versus allowed charges, gradual increases in Medicare's fee schedule due to inflation, the creation of new billing codes to reflect newly developed technologies, and a shift in the demographics of Medicare beneficiaries that occurred during the cited 5 year period to reflect a younger and more active population.

Allowed vs Reimbursed Charges

The reported $94 million paid by Medicare in 2010 is a striking figure that must have captured the targeted reading audience. However, Medicare data shows this spuriously glamourized number is misleading and inaccurate. Medicare did not pay $94 million. That figure represents the allowed charges for prosthetic feet during 2010. The actual payments during that period were substantially less, at just over $74 million. Thus, 20 million dollars' worth of public outrage was based on this error alone (Table 1).

	2005			2010		
HCPCS	ALLOWED SERVICES	ALLOWED CHARGES	PAYMENT	ALLOWED SERVICES	**ALLOWED CHARGES**	**PAYMENT**
L5970	1,332	$ 230,473	$ 182,428	629	$ 125,755	$ 100,132
L5970	0	$ -	$ -	137	$ 27,330	$ 21,146
L5974	3,455	$ 740,792	$ 588,306	1,626	$ 389,411	$ 307,697
L5972	7,512	$ 2,386,458	$ 1,893,929	6,680	$ 2,402,820	$ 1,913,863
L5975	1,461	$ 548,029	$ 436,651	1,013	$ 426,672	$ 340,710
L5978	1,451	$ 384,001	$ 302,236	603	$ 178,540	$ 141,750
L5973	0	$ -	$ -	200	$ 3,054,545	$ 2,411,472
L5976	4,650	$ 2,318,445	$ 1,836,149	2,291	$ 1,286,647	$ 1,013,362
L5979	4,648	$ 9,200,315	$ 7,276,402	2,243	$ 4,970,747	$ 3,931,629
L5980	4,793	$ 15,348,236	$ 12,073,149	5,248	$ 18,967,559	$ 14,974,401
L5981	7,265	$ 18,400,974	$ 14,467,171	11,345	$ 32,163,083	$ 25,364,886
L5987	1,636	$ 9,370,792	$ 7,323,451	4,626	$ 29,943,555	$ 23,518,357
L5990	446	$ 645,661	$ 509,984	142	$ 233,046	$ 184,008
Total	38,649	$59,574,175	$46,889,857	36,783	**$94,169,709**	**$74,223,415**

Table 1: Medicare's "allowed charges" and "payments" for prosthetic feet in 2005 and 2010.

Based on Medicare's data shown above, the increase from 2005 to 2010 was not $35 million but just over $27 million.

Increases in the Fee Schedule

The reporter's next oversight was a failure to account for increases in the Medicare fee schedule during the intervening 5 year period. This consideration accounts for an additional 8.2 million dollars of unwarranted public outrage. **Had the prosthetic feet provided in 2010 been reimbursed under the 2005 fee schedule, Medicare would have only paid $66 million (or roughly $30 million less than the $94 million stated within the cited article)** (Table 2).

	2005			2010			
HCPCS	ALLOWED SERVICES	PAYMENT	2005 Payment Per Device	ALLOWED SERVICES	PAYMENT	2010 Payment Per Device	2010 payments at 2005 pricing
L5970	1,332	$ 182,428	$ 136.96	629	$ 100,132	$ 159.19	$86,146
L5971	0	$ -	$ -	137	$ 21,146	$ 154.35	$ 21,146
L5974	3,455	$ 588,306	$ 170.28	1,626	$ 307,697	$ 189.24	$276,870
L5972	7,512	$ 1,893,929	$ 252.12	6,680	$ 1,913,863	$ 286.51	$1,684,165
L5975	1,461	$ 436,651	$ 298.87	1,013	$ 340,710	$ 336.34	$302,757
L5978	1,451	$ 302,236	$ 208.29	603	$ 141,750	$ 235.07	$125,602
L5973	0	$ -	$ -	200	$ 2,411,472	$ 12,057.36	$ 2,411,472
L5976	4,650	$ 1,836,149	$ 394.87	2,291	$ 1,013,362	$ 442.32	$904,649
L5979	4,648	$ 7,276,402	$ 1,565.49	2,243	$ 3,931,629	$ 1,752.84	$3,511,396
L5980	4,793	$ 12,073,149	$ 2,518.91	5,248	$ 14,974,401	$ 2,853.35	$13,219,255
L5981	7,265	$ 14,467,171	$ 1,991.35	11,345	$ 25,364,886	$ 2,235.78	$22,591,887
L5987	1,636	$ 7,323,451	$ 4,476.44	4,626	$ 23,518,357	$ 5,083.95	$20,707,997
L5990	446	$ 509,984	$ 1,143.46	142	$ 184,008	$ 1,295.83	$162,372
Foot Total	38,649	46,889,857		36,783	74,223,415		66,005,713

Table 2: Medicare's payments for prosthetic feet in 2005 and 2010 with an additional column showing Medicare's 2010 reimbursement had they been paid under the 2005 fee schedule.

Simply by taking into account the difference between allowable and reimbursed costs and fee schedule increases, the $35 million increase in prosthetic foot costs is reduced to under $20 million.

Introduction of a New Prosthetic Foot

The AP article also failed to observe that on January 1, 2010, Medicare introduced a new billable foot code, L5973. This code provided coverage for new technology that was not available in 2005. The code is used to reimburse for prosthetic feet with microprocessor control. With an average reimbursement of over $12,000 per unit, the cost of such feet is more than 5 times more expensive than the most commonly used foot reimbursed by Medicare, the L5981. The reimbursement of a comparatively small number of such feet, 200 units, accounts for an additional $2.4 million of the cost increases observed between 2005 and 2010. Alternatively, 200 out of 36,783 total units (0.5%) accounted for 12.6% of the remaining $19.1 million increase. Provision of 200 out of 36,783 total units highlights very selective use of these expensive devices on patients. Despite the undertones of the magazine article, prosthetists are in fact very diligent and aware of cost and spending and do not over utilize expensive devices.

Changing Medicare Population

The majority of the $35 million cost increase put forward in the cited article is explained by the three considerations of actual reimbursement, fee schedule increases, and the introduction of a new very expensive but rarely provided foot type. The remainder requires a consideration of the altered demographics of Medicare beneficiaries during the time period in question.

Medicare statistics indicate that between 2005 and 2010 the greatest growth in number of beneficiaries was in the 65-69 age category and under 65 category. Viewed collectively, **the growth in the number of Medicare beneficiaries under 69 years old (+21%) was more the three times that of those 70 years and**

older (+6%) (Table 3). Thus, during the 5 year period in question, the average age of Medicare beneficiaries became younger. The reduced age will encompass increased activity levels.

	Medicare Age Distribution Number in Thousands*						
	Total	**Under65 Years**	**65-69Years**	**70-74Years**	**75-79Years**	**80-84Years**	**85 Years or Over**
2005	42,500	6,723	9,905	8,352	7,251	5,493	4,777
2010	47,664	8,033	12,096	9,138	7,169	5,617	5,612
		1,310	2,191	786	-82	124	835
		3,501		**1,663**			

Table 3: Age distribution of Medicare beneficiaries between 2005 and 2010.

Shift in Prosthetic Foot Types

Between 2005 and 2010, the number of Medicare beneficiaries over the age of 70 increased by 1.6 million. By contrast, there was an addition of 3.5 million new beneficiaries under the age of 70. Given this shift, it is reasonable to expect a similar shift in the activity levels of the amputees.

More active amputees require prosthetic feet designed to facilitate a more active lifestyle. Unsurprisingly, the foot type most conducive to the active lifestyles that often characterize relatively younger amputees (ie, younger than 65 years old) experienced greater utilization (Table 4).

	2005			2010			
HCPCS	ALLOWED SERVICES	PAYMENT	2005 Payment Per Device	HCPCS	ALLOWED SERVICES	PAYMENT	2010 Payment Per Device
L5987	1,636	$ 7,323,451	$ 4,476.44	L5987	4,626	$ 23,518,357	$ 5,083.95

Table 4: Utilization of the L5987 foot code in 2005 and 2010.

So while there was a nominal decrease in the *number* of feet provided (<5%), there was a substantial shift in the *types* of feet provided, consistent with changes in Medicare demographics. Similar, though less pronounced increases were observed in the provision of related carbon fiber feet (L5980 and L5981). Furthermore, it should be highlighted that the L5987 code is for prosthetic feet that incorporate a vertical shock absorbing feature, which from the reference cited within the LCD Bibliography, (Gard and Konz, 2003), has been shown in a research study to provide benefits to the amputee user. Thus, the utilization of these feet stands on sound scientific justification. Viewed collectively, the increased utilization of these prosthetic foot types to meet the needs of younger beneficiaries accounts for the remainder of the cited increases in Medicare spending for prosthetic feet.

Conclusion

According to Medicare's Policy Integrity Manual, changes to an LCD should be based on sound evidence taken from published scientific literature. Unfortunately, the tone of the draft LCD seems to be more based on the careless observations of a journalist who misinterpreted Medicare data that he was not qualified to reasonably and accurately interpret. Accusations of a 60% increase in prosthetic foot costs over a 5 year period are quickly corrected by taking into account the differences between allowed and reimbursed costs, Medicare's own fee schedule increases, and the creation of a new billing code to accompany a new technology that is rarely utilized but has a

high reimbursement. The remainder of this differential is explained by a shift in Medicare beneficiary demographics to a younger, more active population. Changes to LCD policies should be motivated by scientific evidence rather than the uninformed speculations of the popular media.

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An LCMP's Concern for the New Requirements of LCMPs

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

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Summary

The proposed LCD mandates that individuals with an amputation are required to receive an evaluation and prosthetic recommendation by a Licensed/Certified Medical Professional (LCMP) prior to the receipt of a definitive prosthesis. Albeit an attempt by the DME MACs to reduce spending, this stipulation will create increased burden on LCMPs and patients, creating a burden that will ultimately serve as a barrier to access to prosthetic care. This increased burden and reduced access can be expected to yield decreased utilization and reduced success in prosthetic rehabilitation.

The mandate of a required evaluation and prosthetic recommendation creates several major concerns that fail to be acknowledged. First, the competencies of LCMPs to perform an evaluation and prosthetic recommendation should be addressed. The definition of LCMPs excludes prosthetists. There are some LCMPs that have taken particular interest in amputee care and taken it upon themselves to increase their expertise in the area, however, the more common LCMP will be restricted to the few hours of didactics received in the formal education. Second, access to competent LCMPs will be an additional hurdle and barrier to care. And finally, the proposed LCD adds patient evaluation costs to the healthcare system and to beneficiaries.

Healthcare policy and practice changes should try to accomplish the goals of the Triple Aim: better outcomes, greater patient satisfaction, and lower costs of care. Of those three, it is quite apparent that the draft proposal is only focused on lowering costs of care at the potential sacrifice of outcomes and patient satisfaction. Furthermore, the efforts of the proposed LCD to lower costs of care is questionable in light of the impact of certain directives focused on increased burden to other members of the rehabilitation team.

Introduction

The proposed LCD mandates that individuals with an amputation are required to receive an evaluation and prosthetic recommendation by a Licensed/Certified Medical Professional (LCMP) prior to the receipt of a definitive prosthesis. Albeit an attempt by the DME MACs to reduce spending, this stipulation **will create increased burden on LCMPs and patients**, creating a burden that will ultimately serve as a barrier to access to prosthetic care. As greater utilization and prosthetic success is dependent upon ease of access to proper care (Pasquina, Carvalho, & Sheehan, 2015), thus decreased utilization and reduced success can be expected.

The mandate of a required evaluation and prosthetic recommendation creates several major concerns that fail to be acknowledged. First, the competencies of LCMPs to perform an evaluation and prosthetic recommendation should be addressed. The definition of LCMPs excludes prosthetists. There are some LCMPs that have taken particular interest in amputee care and taken it upon themselves to increase their expertise in the area, however, the more common LCMP will be restricted to the few hours of didactics received in the formal education. Second, access to competent LCMPs will be an additional hurdle and barrier to care. And finally, the proposed LCD adds patient evaluation costs to the healthcare system and to beneficiaries.

Existing Standard: The Prosthetist Assists with Determination of Potential Function and Prosthetic Utilization

The current LCD states:

> "A determination of the medical necessity for certain components/additions to the prosthesis is based on the beneficiary's potential functional abilities. **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."

Although the current LCD is restrictive in its recognition of the prosthetist's abilities, the prosthetist is still regarded as an important member of the rehabilitation team who, along with the treating physician, is responsible for determining the patients' potential functional level.

Proposed Revision: Increased Burden on Other Members of the Rehabilitation Team

Within the proposed LCD, a LCMP must perform an evaluation and determination of the patient's functional level. LCMPs include physical therapists (PT), occupational therapists (OT), physician assistants (PA), nurse practitioners (NP), and physicians with training and expertise in the functional evaluation of amputees. The healthcare providers included in the definition of LCMP are inconsistent within the proposed LCD (page 3 and page 6, with only the physicians and PTs appearing in both definitions). Notably excluded from this list is the prosthetist whose schooling and training entirely revolves around the patient with limb loss.

The proposed LCD regarding the required evaluation by LCMP states:

> "This specialty evaluation must:
> - Evaluate and document the beneficiary's over-all health status taking into consideration factors related to the amputation and prosthesis use as well the effect of co-morbidities on potential function. The evaluation must include a complete physical examination including an objective neuromuscular evaluation, cardio-pulmonary capacity evaluation and cognitive evaluation.
> - Determine a global activity level as described by the functional level modifiers. (K-levels)."

The proposed LCD further states:

> "An in-person, comprehensive medical assessment to determine the functional capabilities of the beneficiary must be performed by a licensed/certified medical professional with expertise in the treatment of amputees prior to the provision of any prosthesis.
>
> The beneficiary's functional level is based on their overall health status, the objective results of the medical assessment and their documented performance using their immediately previous prosthesis (either preparatory or definitive)."

The proposed LCD further explains:

> "If a prosthesis that exceeds the beneficiary's functional capabilities (K-level) is provided, it will be denied as not reasonable and necessary.
>
> If the patient's functional capability is K0, the prosthesis will be denied as not reasonable and necessary."

Issue 1. Licensed/ Certified Medical Professional (LCMP) amputee evaluation competency

The proposal includes a very robust and ambitious patient evaluation including (minimally) neuromuscular, cardio-pulmonary, cognitive, and functional assessments. However, the draft fails to address LCMP competencies, qualifications, or certifications. Having physicians, physician assistants, nurse practitioners, physical therapists, and occupational therapists determine the capacity of an amputee to use (and obtain) a prosthetic device in the absence of having the demonstrated qualifications to do so is misguided. This proposal is contrary to the training, testing, and certification process used by organizations that regulate certain rehabilitation assessment outcomes measures. For example, as the name implies, the commonly used and well-tested *Functional Independence Measure (FIM)* requires training, testing, and certification for use, and yet it is limited only to assessing function and does not include the other evaluation categories in the proposal. Adding an amputee evaluation certification requirement for the proposed LCMPs would be a very expensive and time-consuming proposition for whoever developed and administered such a program.

By not taking amputee patient evaluation competency into account, the proposal assumes that

the average physician, physician assistant, nurse practitioner, physical therapist, and occupational therapist is experienced in the treatment of amputees, prosthetic lower limbs, and the many prosthetic components addressed in the draft. In fact, the actual time spent on amputee and prosthetic education in medical, nursing, physical therapy, and occupational therapy schools is very short, and a small percentage of these practitioners regularly work with amputees and prosthetic legs. Therefore, capable and experienced providers are sorely lacking. Ironically, if a college/university medical, nursing, or therapy educational program does include a section on prosthetics, a considerable majority of those programs use prosthetists as adjunct faculty to provide the education, the very licensed/certified medical professionals excluded in this proposal from evaluating and assessing amputees. Furthermore, in the United States, occupational therapists traditionally limit their practice to upper extremity function, either by choice and/or state board definitions and requirements. In light of that, including occupational therapists as a LCMP in a lower limb prosthetic LCD is illogical and unwise.

In addition, this physical therapist is unaware of research that has investigated and reported on the correlations between K-Levels and the integrity/ capacity of the neuromuscular, cardio-pulmonary, and cognitive systems. Assuming that an LCMP was able to provide a valid and reliable comprehensive amputee patient evaluation, in the absence of definitive research findings, the therapist would have to speculate on the capacity of a patient in regard to a corresponding K-Level.

Furthermore, there is an issue of real-time versus future physiological and functional capacity. Per CMS, in the *Artificial Legs, Arms and Eyes benefit (Social Security Act §1861(s)(9),* it specifically states, "*a beneficiary is placed at one of the five potential functional levels based on the reasonable expectations of the supplier and the referring physician."* K-Levels are designed and used only to predict future prosthetic limb use. Therefore, a patient's 'current' status predicts prosthetic use only very vaguely.

Finally, the *purpose* of an amputee obtaining a prosthesis is primarily to improve physical function. Testing a patient's functional and physical structure in the absence of an artificial limb and using those performance scores (e.g., Tinetti POMA) to determine his/her capacity to use a limb, or an enhanced device is illogical; **the new or replacement prosthesis is required for patients to achieve their highest levels of function.**

Issue 2: Access to a competent evaluator

As discussed in Issue #1, few physicians, physician assistants, nurse practitioners, physical therapists, and occupational therapists actually have the education, experience, and qualifications to adequately and accurately evaluate an amputee patient per the proposal. Therefore, a typical healthcare market would be lacking LCMP's to adequately evaluate and assess amputee patients in keeping with the lofty requirements and expectations of this proposal. If high-quality, experienced evaluations and assessments are the true goal of the proposal, it is very likely that a substantial percentage of patients would need to travel considerable distances to obtain a proper, qualified, and fair prosthetic assessment. In turn, those practitioners who were qualified would likely be in demand and likely would not be able to meet the demand within a given market, available appointments would be limited, and patients could experience extended wait times.

Finally, for residents of skilled nursing facilities, it is likely that in that setting, a competent LCMP would not be present on the premises, thereby requiring a majority of patients to be transported to another healthcare facility for proper evaluation/ assessment.

Issue 3. The cost of evaluative services for beneficiaries

Currently, the cost of a prosthetist evaluating a patient for the appropriateness for, and the level of, an artificial limb, is included in the cost of the prosthesis. Requiring a patient to visit a qualified licensed/certified medical professional (LCMP) for an evaluation would add to the cost of care to NHIC, the government, the taxpayer, and if co-pays are required, the beneficiary as well. It should be noted that poverty is a known risk factor for amputation (Fisher, Goodman, & Chandra, 2008).

Conclusion

Healthcare policy and practice changes should try to accomplish the goals of the Triple Aim: better outcomes, greater patient satisfaction, and lower costs of care. Of those three, it is quite apparent that the draft proposal is only focused on lowering costs of care at the potential sacrifice of outcomes and patient satisfaction. Furthermore, the efforts of the proposed LCD to lower costs of care is questionable in light of the impact of certain directives focused on increased burden to other members of the rehabilitation team.

References

1. Fisher, E.S., Goodman, D.C., Chandra, A., 2008. Geography Is Destiny: Differences in Health Care among Medicare Beneficiaries in the United States and California. 2015.
2. Pasquina, P.F., Carvalho, A.J., Sheehan, T.P., 2015. Ethics in Rehabilitation: Access to Prosthetics and Quality of Care Following Amputation. American Medical Association Journal of Ethics. 17, 535-546.