August 31, 2015

VIA EMAIL (DMAC_Draft_LCD_Comments@anthem.com)
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National Government Services
8115 Knue Road
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Re: Draft Local Coverage Determination for Lower Limb Prostheses

Dear Dr. Brennan:

I would like to thank you for the opportunity to submit comments regarding the draft LCD for Lower Limb Prostheses published by the DME MACs in July.

Who I Am

My name is David McGill[1] and I am 45 years old. I became an amputee three weeks before Christmas in 1996. I got crushed between two cars while trying to push a young woman's stranded vehicle into a gas station less than 20 yards away. A few hours later, my wife – the only witness to the accident as she watched it unfold in front of her from the side of the road – faced a horrific choice: have doctors try to save my knee, which would have necessitated extensive and repeated surgeries and carried a high risk of infection; or have them amputate above the knee, which would place a ceiling on my overall mobility relative to a successful trans-tibial amputation. She instructed doctors to amputate above the knee.

I have no memory of the accident itself; only driving into the intersection around midnight and commenting to Cara that someone should help the woman standing next to a broken car in the middle of a dark and sleet-covered road. I awoke in the ICU to learn that I was now "disabled," an amputee.

[1] In the interest of transparency, I want to disclose the following affiliations, past and present: (1) as an attorney from 1996-2001, I represented insurance companies and defended doctors and hospitals in medical malpractice litigations at the request of insurance companies; (2) I co-founded and co-owned a prosthetic facility in New York from 2001-2006, specializing in reimbursement and insurance issues; (3) I was a Board member of the Amputee Coalition from 2003-2011 and served as Chairman of the Board for most of that time; (4) since 2006 I have been employed by Össur Americas, a prosthetic component manufacturer and distributor as Vice President of Reimbursement & Compliance; (5) I have been an AOPA Board Member since 2012, filling a slot allotted to orthotic and/or prosthetic device manufacturers; and (6) I am currently President of the National Association for the Advancement of Orthotics and Prosthetics, an organization that I have been on the board of since 2007. While I have worn and continue to wear a number of different hats related to prosthetics, I submit these comments individually as one of the approximately two million Americans living with limb loss in the United States today.

I share this story with you before delving into the intricacies of the draft Local Coverage Determination proposed by the DME MACs because I need to emphasize just how significant the prospect of wearing a prosthesis is to a new amputee. As I lay in the bed in ICU, *all I could see* as I looked at myself in the bed was the space where my knee, ankle and foot should have been. As I began to ambulate before receiving a prosthesis using only crutches, the emptiness below my left thigh felt more tangible and real than my remaining limbs – I certainly thought about it more than the body parts I had left.

While I knew nothing about prosthetic limbs then, the fact that I knew they existed gave me hope at the moment I most desperately needed it. I held onto the belief that I would soon be walking again, living a productive and independent life.

Thanks to the quality of the prosthetists who treated me and the devices available to me, I was able to return to work full-time only 90 days after my accident. I was able to complete a 10k road race – not running, but walking and "hop-skipping" – almost four months to the day after walking into that intersection. But I was only able to do those things because of the access I had to timely, high-quality prosthetic care. I'm sorry to say that if in 1996-97 I had been forced to leap over the various hurdles the draft LCD places in front of all amputees, I wouldn't have been able to celebrate those achievements.

My Confusion about the Draft LCD's "Origin Story"

I've read the draft LCD in its entirety over the last 5 weeks more times than I can count. I don't understand where it came from or the rationale behind it.

I attended and spoke at the Open Comment Meeting hosted by the DME MACs on Wednesday, August 26th in Linthicum Maryland, hoping to get an explanation for the rationale underlying the draft LCD. I got none. That fact alone gives me and every amputee in the United States reason for concern: how do you provide constructive feedback about the draft LCD when you have no idea what its authors were trying to achieve?

In the absence of that information, the only thing I have to offer you are my thoughts about how this proposal will affect amputees in the United States; not just Medicare beneficiaries – *all* amputees.

So let's start there: why should you listen to a 45 year-old amputee currently insured by Aetna in a discussion about a draft LCD that purportedly applies only to Medicare beneficiaries?

1. The draft LCD will ultimately – and quickly – affect nearly all amputees in the United States – not just Medicare beneficiaries.

If you examine the prosthetic medical policies for the major private insurance companies in the United States, you can see just how embedded the DME MACs' LCDs are in the private insurance world. These payers follow the DME MACs' guidance when it comes to (a) assessing

amputees' functional level, (b) processing claims using Medicare's codes, and (c) limiting access to certain types of components based on the patients' K level. [2]

History also shows that private insurers swiftly update their own medical policies when the DME MACs update their LCDs. Lag time is commonly less than 12 months, and it is rare to see delays in implementation beyond 18 months.[3] Why the congruence between private insurance medical policies and the LCDs?

First, it makes sense for private payers to adopt some of the LCD's core elements because the HCPCS codes used for every prosthetic claim submission in the United States are controlled by and originate with Medicare's HCPCS Coding Workgroup. To the extent that those codes, their reimbursement and their linkage to patient functional levels are intertwined, it is administratively efficient for private payers to remain aligned with Medicare policy.

Second, research regarding each of the DME MACs reveals that several of them – perhaps as many as three out of four – operate as subsidiaries of or are otherwise related to private insurance companies.[4] In that context, it is not surprising that information coming from a DME MAC might get quickly transmitted to a sister private insurance company or "affiliate."

Third, given the fact that every proposed change related to coding in the Draft LCD has the effect of *decreasing* overall reimbursement for lower limb prostheses, private payers have a huge financial incentive to follow Medicare's lead in this instance. There is no economic argument – literally none – in favor of *not* adopting the provisions of the LCD if you operate a private insurance company.

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[2] *See, e.g.*, **Aetna Clinical Policy Bulletin 0578** *(eff. 3/13/15)*, adopting (1) the HCPCS codes for lower limb prostheses listed in the DME MACs' Local Coverage Determinations, (2) the DME MACs' Local Coverage Determination functional level definitions (K0-K4), (3) the DME MACs' functional level guidelines for mechanical prosthetic feet, mechanical knees, non-motorized microprocessor-controlled knees, and prosthetic sockets, and (4) listing an earlier version of the DME MACs' Local Coverage Determination as a reference; **Cigna Medical Coverage Policy 0194** *(eff. Sep. 15, 2014)*, adopting (1) the HCPCS codes for lower limb prostheses listed in the DME MACs' Local Coverage Determinations, (2) the DME MACs' Local Coverage Determination functional level definitions (K0-K4), and (3) the DME MACs' functional level guidelines for mechanical prosthetic feet, mechanical knees, non-motorized microprocessor-controlled knees, and prosthetic sockets; **UnitedHealthcare CDG.018.03** *(eff. Feb. 1, 2015)* adopting (1) the HCPCS codes for lower limb prostheses listed in the DME MACs' Local Coverage Determinations, (2) the DME MACs' Local Coverage Determination functional level definitions (K0-K4), and (3) the DME MACs' Local Coverage Determination functional level guidelines for prosthetic knees and microprocessor-controlled feet; **Humana Medical Coverage Policy CLPD-0331-016** *(eff. 5/28/15)* adopting (1) the HCPCS codes for lower limb prostheses listed in the DME MACs' Local Coverage Determinations, (2) the DME MACs' Local Coverage Determination functional level definitions (K0-K4), and (3) the DME MACs' functional level guidelines for all prosthetic feet, all prosthetic knees and prosthetic sockets.

[3] For example, Medicare created code L5969, effective January 1, 2014. Today, every payer's medical policy listed in the preceding footnote makes an explicit reference to that code. This demonstrates private payers' regular monitoring of the DME MACs' Local Coverage Determination for Lower Limb Prostheses and their willingness to update their own policies accordingly.

[4] For example, the email I received from a National Government Services representative confirming my online registration for the Open Comment Meeting last week was from Stacie.McMichel@anthem.com. Similarly, if you go to the Anthem "Provider" webpage, it lists National Government Services, the DME MAC for Jurisdiction B, as an Anthem "Affiliate." https://www.anthem.com/home-providers.html

Thus, to act as if changes to the current LCD will somehow remain cordoned off from the broader private insurance market would be naïve, in direct conflict with historical precedent, and economically inconsistent with private payers' short-term interests. The draft LCD does not potentially affect just amputees covered by the Medicare program; it will directly affect virtually all amputees in the United States. For people like me who depend on a prostheses every second of every day to navigate the world, the stakes here could not be higher.

With that, I would like to focus on how the draft LCD would affect amputees if implemented "as is." Rather than walk through the draft LCD line-by-line, as I am sure many other commenters have, I will try to describe the practical effect of the proposed changes by comparing the prosthesis and related care I received nearly 20 years ago to what would happen to an above-knee amputee like me if the draft LCD "went live" today.

2. The Draft LCD hurts new amputees, preventing them from getting medically-necessary components by rigidly defining "preparatory prosthesis."[5]

The Draft LCD would preclude me from receiving the type of prosthesis I got *19 years ago*. The proposed definition of a "preparatory prosthesis" would rigidly limit me to the following:

A. a "non-alignable" system – meaning that it could not be adjusted after initial fitting for changes in my gait and capabilities – that

B. lacks a knee unit (a definitive above-knee prosthesis only qualifies for a "pylon no cover"), and

C. a SACH foot (Solid Ankle Cushioned Heel), an antiquated,[6] non-dynamic, non-energy-storing foot.[7]

Even if my prosthetist *wanted* to give me the knee or foot that I actually received in early 1997, the Draft LCD would require the DME MACs to deny those components:

> "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*

[5] The draft LCD implicitly suggests that every new amputee progresses through the following types of prostheses in succession: (1) an "immediate prosthesis," (2) a "preparatory prosthesis," and finally (3) a "definitive prosthesis." In the interest of efficiency I will not discuss immediate prostheses beyond this footnote. But it is important to note that while immediate prostheses are delivered to some patients, they are far from a standard post-amputation protocol. The draft LCD ignores this fact, implicitly presenting a world in which immediate prostheses are the clinical rule, not the exception.

[6] The SACH foot was created in 1956.

[7] See draft LCD, p. 5, paragraph 5, and draft LCD p. 26 (listing preparatory prosthesis codes (L5500-L5600) and their descriptions).

> *components*, etc. provided for concurrent use with a preparatory prosthesis. *All additional items will be denied as not reasonable and necessary*."[8] (emphasis added)

Imagine waking up in a bed missing one of your limbs above the knee, as I did. Think about the fear, the displacement, the fundamentally *alien* nature of what that would feel like. The thing you want most in the world (besides your biological limb back) is the knowledge that you will receive a prosthesis that allows you to walk normally again.

Now imagine that for your first prosthesis, you instead receive something that (a) lacks a knee joint, with a rigid steel tube connecting your socket to your foot, making your gait visibly abnormal, and (2) includes a prosthetic foot from the mid-1950's that by its very nature impairs a normal walking pattern and requires you to expend significantly more energy than any other foot available today.

This makes no sense.

It makes no sense *clinically* because the one thing all amputees need to be doing from the first time they try to ambulate with a prosthesis is to learn how to balance and walk in a way that prevents overuse and cumulative trauma to their sound limb. A knee that doesn't bend and a foot that amputees in the United States were using nearly *a decade before the Vietnam War* do exactly the opposite.

It makes no sense from a *training and education perspective* because denying amputees definitive components with their preparatory prosthesis forces them to relearn how to walk twice. Instead, the Draft LCD locks patients into antiquated components (and an antiquated way of thinking about prosthetic rehabilitation) for *three full months* before they can even gain access to the devices that will actually allow them to navigate the world effectively.

It makes no sense *economically* because the Draft LCD forces Medicare to pay for two full prostheses in their entirety. In contrast, the clinically-accepted, modern approach would only require Medicare to pay for the prosthetic knee and foot once, because amputees would have the opportunity to use definitive components from their first day wearing a prosthesis.

And last but certainly not least, it makes no sense *psychologically* because teaching amputees to walk on ancient, non-alignable components that force them to walk with visible and significant gait deviations will have a profoundly negative impact on their state of mind. If you believe I'm overstating this point or that it is not a "medically necessary" consideration for Medicare coverage purposes, I'd ask you to answer the following questions:

- Would you willingly walk completely stiff-legged in a public place for even 30 minutes?
- How would you sit in a chair – especially at a desk – with a fused knee? How would you get into or sit in a car? How would you tie the laces on the shoe covering your prosthetic foot?

[8] *See* Draft LCD, p. 5, paragraph 5.

- How do you think your sound foot, ankle, knee, your hips and your back would feel after a single day of walking like this? How about if you were forced to walk like this for *90 days*, as the draft LCD requires?

I would hazard a guess that being forced to navigate and interact with the world with a fused knee joint – particularly when other clinically-accepted options exist – would have a profound effect on your "motivation to ambulate,"[9] your self-perception, and ultimately your overall health. Contrast the proposed approach with what I received 20 years ago (and what Medicare correctly makes available to amputees today) and the differences are startling.

My prosthetist started me on a hydraulic knee and an energy-storing foot. As result, I only had to learn how to walk once – no need to learn how to use a knee joint after walking on a non-bending pylon for 90 days.

In addition, because my prosthesis was "alignable," my prosthetist could adjust my preparatory prosthesis based on my day-to-day progress. At the end of 90 days in that system, I had gone from walking at one speed between parallel bars to walking independently at different speeds in the real world. But a prosthesis with no knee and a SACH foot would never have allowed me to make the gains I did during that critical initial period of rehabilitation.

My rehabilitation was built on the *possibility of what might be*, what I was capable of achieving. I cannot say strongly enough just how transformative this was for me both physically and mentally. In contrast, what the DME MACs are proposing has the effect of constantly *capping* an amputee's performance, forcing him to push through significant limitations actively imposed on him by the draft LCD in order to *attempt* to qualify for the next best thing months later.

3. The Draft LCD hurts new amputees by delaying (and potentially denying altogether) their access to an "initial definitive prosthesis."

In order for amputees to transition from a "preparatory prosthesis" to a "definitive prosthesis," they must satisfy 11 unique factors listed in the draft LCD.[10] When you then take into account additional criteria embedded in those 11 factors – primarily in the "functional level determination" and "rehabilitation program" requirements – the number balloons to 26.[11]

If we were talking about 26 "yes/no" or "check the box" questions, this might not be a barrier to timely amputee care. But if you examine the requirements in detail, it becomes clear that the Draft LCD has proposed 26 requirements that (1) often lack any definition, (2) in the absence of definition, provide virtually unlimited authority to the DME MACs to interpret those terms in a manner that could deny amputees coverage, and (3) increase the number of hurdles an amputee must clear in order to qualify for a definitive prosthesis.

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[9] One of the requirements to receive a prosthesis in both the current and draft LCDs.
[10] *See* draft LCD, Section IV. DEFINITIVE PROSTHESIS, pp. 5-6;
[11] *See* draft LCD, Section VII. FUNCTIONAL STATUS (K LEVEL), pp. 13-14, and INDEPENDENT MEDICAL EXAMINATION, pp. 20-22.

For example:

1. 14 of the 26 standards use nebulous terms like "appropriate," "successfully," "sufficient," "good," "adequate," "ease of movement," "energy efficiency," and "appearance of natural gait." None of these standards has a specific metric associated with it that permits objective assessment of whether an amputee has met the standard. This means that individual claims reviewers working for a DME MAC could apply their independent judgment without limitation to *legitimately* deny coverage for a definitive prosthesis because more than half of the "standards" that are a prerequisite to this kind of device are entirely – 100% – subjective.

2. In order to receive an initial definitive prosthesis, amputees must now "successfully complete a rehabilitation program."[12] The elements of this rehabilitation program are, again, often nebulous, sometimes inconsistent with accepted standards of care, and more troubling, inherently at odds with the purpose of a definitive prosthesis. For example (and this is a non-inclusive list of rehabilitation program requirements):

    a. The amputee must be able to don and doff the prosthesis "without assistance."[13] This fails to account for the fact that many amputees today successfully use prostheses even though family members or nurses assist with donning and doffing Should people who walk successfully today be denied the right to do so tomorrow because they need help putting the prosthesis on and taking it off? Should the DME MACs prevent amputees from gaining all-day mobility with a prosthesis because they need two minutes of help putting it on and taking it off? I am unaware of any clinical data that supports denying an amputee access to a prosthesis on this basis.

    b. The amputee must be able to transfer without assistance "using *and without using* the prosthesis."[14] (emphasis added) This ignores the fact that for many amputees, *the prosthesis itself is what permits them to transfer successfully.* This requirement has the effect of placing amputees in an untenable catch-22: if they cannot transfer without a prosthesis, the draft LCD prohibits them from getting one, even if that device would then allow them to transfer and gain mobility and independence. Again, I am unaware of any clinical data that supports denying an amputee access to a prosthesis on this basis.

    c. The amputee must have "sufficient wear tolerance"[15] to use the prosthesis for a normal day's activities. Again, the DME MACs offer no guidance on how to define or ascertain "sufficient wear tolerance." The absence of metrics leaves the door wide open to claims reviewers denying amputees definitive prostheses.

[12] *See* draft LCD, p. 5, 2nd bullet point.
[13] Draft LCD, p. 13, 1st bullet point.
[14] Draft LCD, p. 13, 2nd bullet point.
[15] Draft LCD, p. 13, 3rd bullet point.

3. The Draft LCD also requires amputees to undergo a face-to-face examination with the treating physician.[16] While few people would disagree with the proposition that it's reasonable for physicians to confirm that their amputee patients are physically capable of using a prosthesis, the underlying "independent medical examination" requirements, as drafted, again act as a barrier to timely prosthetic care. The IME has 8 distinct elements, many of which a general practitioner might not be comfortable or competent to address.

   If I had gone to my primary care physician – an internist – in 1997 and told him that he needed to document that (a) I'd had an "appropriate" above-knee amputation, (b) had "successfully" completed a rehabilitation program, (c) my surgical incision was "stable," (d) my residual limb was "mature," (e) I was motivated to ambulate, (f) I was cognitively capable of using the prosthesis, (g) I had sufficient neuromuscular control to use the prosthesis, and (h) I had sufficient cardiopulmonary capacity to use the prosthesis at the identified functional level,[17] he would have smiled thinly at me and asked a series of questions.

   I suspect he would have asked me why he had to document things like my cognitive capability when I had no history of cognitive disability and no traumatic brain injury from my accident. Similarly, he would have inquired why performing neuromuscular control tests were necessary when literally the only injury I had suffered in my life other than the amputation of my left leg were minor fractures of my nose and my right fibula in the same accident. And I'm certain he would have laughed at the need to record the fact that I was "motivated to ambulate," as he would have correctly concluded that the fact I was at his office seeking a prescription for an above-knee prosthesis implicitly proved the point. Then he would have told me that some of these requirements needed a specialist's input, and referred me to a physical medicine and rehabilitation specialist.

   At this point, I would have had to call the PM&R physician's office to schedule an appointment as a new patient. I would likely have waited at least two or three weeks – maybe longer – for an appointment. In addition, I would have had to reach into my own pocket for the copayment and any related coinsurance associated with this second visit. (Medicare, incidentally, would now also have to pay for two physician visits – the first to my internist, the second to the PM&R – instead of one.)

I could continue this hypothetical for several more pages but I think the point is clear: whatever its intent, the draft LCD's practical impact on amputees is to, at a minimum, delay how long it takes them to receive a definitive prosthesis, and for some individuals, to act as an outright barrier to ever obtaining one.

Contrast this with the more rational approach when I received my prosthesis in 1997. I visited my internist. He had received a detailed letter from my prosthetist explaining my clinical condition, my readiness for a prosthesis, and the reasons for selecting the specific components he suggested. My internist documented that he had seen me and signed a detailed written order, implicitly endorsing my prothetist's findings.

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[16] *See* draft LCD, p. 6, 2nd bullet point.
[17] *See* draft LCD, pp. 5-6, bullet points.

One in-person physician visit for the amputee; corroboration by that physician that my prosthetist's findings and recommendations were consistent with what he was observing; a timely and clinically-validated transition into an appropriate prosthesis – this isn't some fantastical medical Avalon beyond the reach of amputees and payers in the United States. *It's what we had in 1997!*

I suspect that one possible rebuttal of the "back to the future" scenario I just presented is that it fails to acknowledge the reality that the DME MACs have some responsibility for making sure not only that claims get processed and paid, but that they get processed and paid only for *legitimate* claims.

I will be the first person to acknowledge that fraud and abuse are legitimate concerns. But creating vague and clinically irrelevant "standards" that rope off amputees from a prosthesis isn't the right mechanism to deal with those issues. The draft LCD's approach in this regard is analogous to a department store attempting to address the problem of its *own employees* stealing merchandise by forcing all customers leaving its premises to undergo a full-body pat-down and bag search.

Separate and apart from all the foregoing issues with the draft LCD, one final point merits mention. The draft LCD states that

> Definitive prosthesis [sic] (L5000 through L5341) are 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.[18]

If the DME MACs actually intend to implement this provision, it will have the effect of preventing amputees from *ever* receiving anything beyond the items described in the base code.[19] I am assuming that this language was included in the "Definitive Prostheses" section of the draft LCD in error, but in the interest of completeness, I raise it here and request that this language be stricken from this section of the draft LCD.

4. The Draft LCD reduces the number of solutions available to amputees.

In addition to delaying and denying care to new amputees, the draft LCD hurts all amputees – new and old – by eliminating coverage of both (a) entire classes of prosthetic devices, and (b) certain devices for specific patient populations. None of these changes find support in either the bibliography produced by the DME MACs weeks after the draft LCD's publication, or in the peer-reviewed clinical literature.

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[18] Draft LCD, p. 6, 5th paragraph from bottom of page.

[19] This would mean even definitive prostheses get treated exactly the same way proposed for preparatory prostheses as discussed in the preceding section of this letter.

For example, the DME MACs take the position that there is "insufficient published clinical evidence" in support of elevated vacuum suction systems, rendering them medically unnecessary.[20] First, that is simply untrue. Plenty of peer-reviewed, published research exists supporting the efficacy of elevated vacuum. Second, the DME MACs have chosen to reach this new conclusion *more than a decade after* Medicare's HCPCS Coding Workgroup created the codes describing elevated vacuum. Tens of thousands of Medicare amputees have received these devices since these codes went into effect. They have used them to control the volume of their residual limbs, to remove excess moisture, and to assist in wound healing.

The most bizarre element of this decision is that more evidence supporting the use of elevated vacuum exists today than existed in 2003. To deny amputees the right (1) to continue to use what they have consistently and successfully used for more than a decade, and (2) to access this type of technology at all moving forward, even when clinically appropriate, defies easy explanation. This is especially true in light of the fact that the DME MACs have failed to cite any clinical evidence in support of their conclusion.

The DME MACs also summarily propose that mechanical plantar flexing and dorsiflexing ankles – devices historically available to K2 and higher functional level amputees –now be "only covered for functional levels K3-K4."[21] The benefits of dorsiflexion cannot be overstated – it allows the prosthetic toe to lift up during swing phase in the gait cycle, creating greater foot-ground clearance. This reduces the chance that amputees will catch the toe of their prosthetic foot on the ground, helping avoid trips and falls. This becomes particularly important when K2 amputees navigate an everyday environmental aide designed to *help* them: a handicapped ramp. But despite the obvious benefits these components provide, the DME MACs will deny K2-level amputees access to them. And again, the DME MACs' bibliography contains no support for limiting access to this kind of component to only higher-functioning individuals.

5. The draft LCD prevents prosthetists, doctors, and other health care professionals from considering an amputee's potential when conducting a functional assessment, a change that will prevent amputees from receiving the most clinically-appropriate prostheses.

Perhaps the most far-reaching and damaging aspect of the draft LCD is its proposed elimination of the concept of "potential" from the K level analysis. Currently, the DME MACs' Local Coverage Determinations require prosthetists and physicians to jointly consider an amputee's potential functional abilities, but the draft LCD would change that.

The concept of rehabilitation without regard to patient potential is oxymoronic. An example is illustrative of the point.

Assume that I have been using my above-knee prosthesis for several years. The various components are outside the manufacturer's warranty and the socket no longer fits me

[20] Draft LCD, p. 9, 3rd paragraph from bottom of page.
[21] Draft LCD, p. 10, 4th paragraph from bottom of page.

appropriately due to the fact that I have lost 15 pounds and the circumference of my residual limb has changed as a result. I was undisputedly a K3 ambulator with this prosthesis.[22] However, because of significant pain and skin breakdown on my residual limb, for the last month I have only been able to walk at a fixed speed, and over the last two weeks I have been using a cane for extra stability. My prosthetist has administered me the AMP PRO and 6-Minute Walk Test, both of which validate that I am currently a "limited community" (K2) ambulator.[23]

The fact that over the preceding 3 years I have walked at different speeds without any assistive device as an unlimited community ambulator – and that I have the *potential* to do so again as soon as I get a well-fitting socket and new components – now counts for nothing. The DME MAC claims reviewer could legitimately conclude that I am a K2 patient, thereby limiting me to components inappropriate for someone of my age, activity level and lifestyle. After all, my "documented performance using [my] immediately previous prosthesis"[24] shows that I do not satisfy the K3 functional level requirements.

I am now restricted to the wrong components, forced to use a prosthetic knee and foot that will limit me and prevent me from returning to my previously-higher functional level. If I do end up persevering, soldiering through the limitations of the inferior components and ultimately establishing that I do meet the K3 level requirements, presumably the DME MACs will approve new components for me. But, that will happen only after either (a) I have been wearing those components for some (an extended?) period of time, and (b) the DME MACs pay *twice* – once for the K2 components, and then again for the K3 devices.

Alternatively, faced with this unappealing scenario, many amputees will likely just give up. They'll submit to the K2 components and the reduced mobility and less independent lifestyle forced upon them by a DME MAC coverage policy focused on cost control at the expense of amputees' mobility.

Alternatively, the DME MACs could continue to provide prostheses in the current (and rational) way that it does today. Using the above scenario, understanding that my limitations were only temporary, my prosthetist and physician could reasonably consider my future capabilities – my potential – and provide me with the components most likely to promote a healthy and independent lifestyle.

To the extent that the DME MACs are trying to address the problem of potential fraud or abuse, eliminating the concept of "potential" from amputees' functional assessments is the wrong way to solve it. Again, as discussed in Section 3 of this letter,[25] amputees are not the source of that problem (to the extent it actually exists). Yet, the proposed solution primarily affects them while doing little to clamp down on the people creating those problems.

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[22] See Draft LCD, p. 14, 4th bullet point.
[23] *See* draft LCD, p. 14, 3rd bullet point.
[24] Draft LCD, p. 13, second-to-last paragraph on page.
[25] *See* p. 9.

CONCLUSION

I am requesting that the DME MACs rescind the draft LCD immediately. Alternatively, any effort to somehow salvage or rewrite the draft LCD should only happen after appropriate consultation with amputees, prosthetists, physicians, and other members of the amputee rehabilitation team. I would happily volunteer to be part of such a collaborative effort.

Because of timely access to high-quality prosthetic care, hundreds of thousands of people with limb loss in the United States live mobile, healthy, independent lives – especially in comparison with the alternative (i.e., crutches, wheelchairs). I am one of the people who has enjoyed a full and rewarding life since my accident in 1996 thanks to both the prosthesis I use and the people who fabricate it for me.

At the same time, I recognize that the DME MACs have multiple responsibilities, including making sure that claims get paid properly. Neither I nor any other amputee *wants* to see unscrupulous individuals take advantage of the Medicare program.

But in the final analysis, the draft LCD throws a staggering number of obstacles in the way of amputees seeking timely and appropriate prosthetic care. It does so without regard to established, undisputed, and accepted standards of modern prosthetic care. It does so without regard to the glaring inadequacies of the bibliography allegedly supporting the draft LCD. And it does so without regard to the available clinical evidence that *does* exist.

The draft LCD sacrifices amputees on the altar of economic and administrative efficiency. Surely, my right – *all* amputees' fundamental right to mobility – outweighs that.

Sincerely,

David McGill
Amputee
Greenlawn, NY