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(319) 354-1150

August 26, 2015

Stacey V. Brennan, MD, FAAFP
Medical Director, DME MAC, Jurisdiction B
National Government Services
8115 Knue Rd.
Indianapolis, IN 46250-1936

Dear Dr. Brennan

I am writing to provide comments on the proposed revisions to the Medicare Local Coverage Determination (LCD) and Policy Article for Lower Limb Prosthetics published on July 16, 2015. I am an orthopaedic oncologist and, after discussion with many prosthetists, I am concerned about recent policy initiatives that would affect my Medicare patients. Occasionally an ablative surgery is necessary to control a tumor or infection, and in such a scenario, access to a durable and functional prosthesis in an expeditious and simple manner is critical to the recovery and eventual outcome of these patients.

The proposed changes are the most far-reaching re-write of lower limb prosthetic policy in the history of Medicare. Unfortunately the proposals lack any evidence to support the changes. These proposals if implemented would dramatically reduce access to the current standard of prosthetic care and force Medicare patients to accept 1970's technology. Because many of the proposals involve major changes to the Uniform Code Set, these changes have the potential to impact all amputees who receive prosthetic care.

As I understand it, the proposed revisions would:

- Alter the HCPCS coding system whereby "base" prosthetic codes are augmented with "add-on" codes. The add-on system ensures the most appropriate combination of techniques, materials and technology.

- Create multiple new barriers that will delay, and in some cases, deny care to beneficiaries with limb loss. These barriers include the requirement to undergo a rehabilitation program before being eligible for coverage, obtain detailed documentation from a newly designated set of providers known as "LCMP's", and establish other prerequisites to be met before a prosthetist can even interact with the patient.

- Abolish coverage of numerous prosthetic knees, feet and ankle that have had widespread use for years and make patients accept technology that is outdated and not consistent with the current standard of care.

PROFESSOR OF ORTHOPAEDIC SURGERY - UNIVERSITY OF IOWA, COLLEGE OF MEDICINE
DIPLOMATE - AMERICAN BOARD OF ORTHOPAEDIC SURGERY
FELLOW - AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
FELLOW - AMERICAN COLLEGE OF SURGEONS
PRESIDENT - CERVICAL SPINE RESEARCH SOCIETY (1991-1992)

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- Eliminate years of precedent by barring consideration of a patients potential when determining functional level classification. This issue is especially critical to recent amputees who are progressing through their prosthetic rehabilitation. Limiting coverage to only allow consideration of a patient's current status, rather than considering what they can achieve through the provision of appropriate prosthetic components will lead to poor patient outcomes, and hinder the patient's ability to achieve their maximum level of functionality.

- Eliminate coverage of some of the most effective suspension techniques that are in widespread use today. Patients should not be limited to prosthetic suspension techniques that are not clinically appropriate for their needs.

- Eliminate access to certain prosthetic components if the patient has an assistive device. Patients may have a mobility aid (cane, crutches, walker, etc.) for nighttime bathroom access, or periodic situations of soreness or skin irritation from greater than normal activity. They should not be penalized for having a mobility aid available for these instances.

- Eliminates the licensed/certified prosthetist when determining an amputee's functional capabilities/deficiencies. The proposal creates a new system where physicians, therapists, nurse practitioners, and physician assistants, but not prosthetists, will be required to conduct functional assessments and prepare significant documentation.

- Include a long set of requirements a patient must satisfy before being eligible to receive prosthetic care. The requirements include upper body strength, adequate posture, cognitive capability, sufficient neuromuscular control, sufficient cardio-vascular capacity, appearance of a "natural gait", and numerous other prerequisites. These requirements are overly broad, not medically supported and appear to be an effort to use the existence of a condition to withhold coverage of more advanced care, or perhaps any care.

- Reiterates ill-advised policy that prohibits a prosthetist's clinical documentation from being considered as part of the medical record. The continued failure to recognize the prosthetist's notes for purposes of establishing medical necessity and to consider the prosthetist as simply a "supplier" with a vested interest in payment is offensive when considering their extensive education, training, knowledge, and expertise.

In conclusion I would like to point out that the bibliography that was released several days after the proposals were published was an assortment of references of which the overwhelming majority lacked any scientific evidence. The references included an Associated Press newspaper article, numerous DME MAC publications, proposed legislation that was not enacted, and an outdated and irrelevant article published nearly 50 years earlier. The majority of items listed in the bibliography do not relate to, or support the changes put forth in the proposed LCD. It should also be noted that several of the authors whose works are referenced in the bibliography have stated they cannot support the proposed policies, nor the use of their publications as germane to these proposals.

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It is always difficult to anticipate the real-world outcome after a policy change. While I am sympathetic to the necessity to streamline care and maintain fiscal accountability, I believe it should not come at the expense of reliable interventions that clearly optimize the care of individuals.

Thank you for the opportunity to comment on the proposed revisions.

Sincerely,

Charles R. Clark

Charles Clark, MD
Professor of Orthopaedic Surgery
University of Iowa

August 23, 2015

Dear Dr. Brennan,

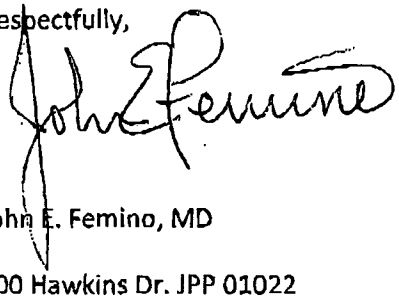
I am an Orthopaedic Surgeon practicing at the University of Iowa Hospitals and Clinics. I am writing regarding the *Local Coverage Determination Regulations* (DL33787). I am not writing in any official capacity of this institution but as a licensed medical doctor in the state of Iowa. I have read this ~40 page document and I respectfully request that the document be rescinded in total. As an orthopaedic foot and ankle surgeon I care for this patient population who are often medically complicated. The recommendations pertaining to the future care and payment for this group will certainly make prosthesis delivery more delayed and technically inappropriate.

This new regulation of care regimens forces a return to outmoded 1950's technology, which will have a negative impact on the eventual level of function of many of our amputee patients. Additionally, obscure words and phrases in this document do not add anything positive to our patient's outcomes.

Care options for amputees need to be **flexible**. 90 percent of these patients have diabetes and/or peripheral vascular disease, and they therefore have numerous co-morbidities that add to the complexity of their care. The notion that rigid care regimens with limited – outdated components offer either time or money savings is without basis. In many cases, once an attainable functional level is lost, it may not be regained.

I urge you to please rescind these regulations and empower a group of recognized experts in surgery, rehabilitation and prosthetics who are experienced with amputee care assist you in developing different rules that will be positive and beneficial to patient outcomes; rules based on modern treatment practices and technology, which are grounded in scientific evidence where appropriate, and expert opinion by consensus where such evidence is not available. The American Academy of Orthopaedic Surgeons has a process whereby appropriate use recommendations are made and I urge you to look at that process as a potential model to base these recommendations on.

Respectfully,



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31 August 2015

Stacey V. Brennan, M.D., FAAFP
Medical Director, DME MAC,
Jurisdiction B National Government Services
8115 Knue Rd.
Indianapolis, IN 46250-1936
By email: DMAC_Draft_LCD_Comments@anthem.com

Re: Proposed/Draft LCD on Lower Limb Prostheses (DL33787)

Dear Dr. Brennan:

This letter is a response of the government request for comments on the above cited coverage document.

First, let me introduce myself. I am a 77 year old, now mostly retired, academic physician (Professor Emeritus of Internal Medicine (Nephrology) at the U. Iowa College of Medicine), and myself for the last 5.5 years myself a right above knee amputee. I have both considerable professional experience with government policy issues and with issues of bundling in provision of dialysis and transplant care, and also a personal stake in the outcome of the revisions to this document. I am strongly supportive of many of the revisions proposed in this policy, but I believe that there are some areas where revisions of this proposed policy are needed to assure that the Medicare covered individual has access to prostheses appropriate to his/her general medical status and potential for ambulatory rehabilitation.

First, I strongly support the move to a "bundled" approach to the coverage for lower extremity prostheses, to replace the current "fee for service" approach. As you well know, nephrologists have lived productively with increasing bundling of dialysis services over the years. Our most recent experience was with inclusion of epoetin and

other injectables in the dialysis bundle. This change in coverage policy has led to a 30 – 50% reduction in the total dose of epoetin prescribed, with substantial savings both for CMS and for the dialysis provider, and with no meaningful change in the fraction of dialysis patients in the US meeting hemoglobin targets. Freed of being tied to compensation for specific doses of epoetin, we found equally effective and less expensive ways to achieve the same medical goals.

I expect that introduction of bundling into the provision of durable medical equipment such as prostheses will similarly lead to more circumspect selection of equipment for each individual patient, will simplify bookkeeping, will free the prosthetist from perverse economic pressures, and ultimately lead to cost savings. While I believe that most prosthetists are fully professional individuals, a fee for service approach has built in perverse incentives that may lead to provision of a more expensive prosthesis than can be used effectively by the recipient.

However the move from a fee for service compensation plan to a plan for bundled compensation comes with a need for assurances that the bundling does not lead to "cherry picking," with skimping on equipment needed for the patient that may benefit from a more advanced prosthesis or to outright refusal to service such patients. Similarly, to win the cooperation of prosthetists and prosthetic firms, it is important that the payment for the bundle includes adequate payment for the bundled components and for the professional services that will need to be provided in the proposed 90 coverage period. I recognize that these issues of actual payments for specific services and of fair access and quality assurance are not immediately germane to the proposed coverage policy. But I suspect that public CMS clarity on these two issues would provide considerable reassurance to the amputee who needs prosthetics service and to the prosthetists that serve us.

With respect to specific proposed coverage decisions, let me address two issues: the decision not to cover negative pressure socket systems and some limitations on prosthetic feet available to the amputee at a lower K rehabilitation level.

First, I am one of those amputees that has had a major problem with volume changes of my stump over the course of a day wearing my prosthesis. Each day I don my prosthesis with a traditional vacuum socket. In the morning the socket fits fine. By noon, the socket regularly loses its vacuum when I sit down. By the evening I have substantial difficulty in keeping the leg from falling off. I have had two prosthetists try to help manage this problem, I have added stump socks, and I have had pads placed in my socket. But nothing has worked well to date. This is a safety issue as well as a nuisance, as frequently I find that my leg has fallen off when I try to take a step forward and my leg doesn't follow me. The theory is that a negative pressure socket, by maintaining a negative pressure even during stance phase, will help retain fluid in the residual limb and prevent stump shrinkage. One published study (Biel TL et al J Rehabil Res Dev 2002; 39:693-700) provides objective data supporting this theory. The general experience of the prosthetics community is that this problem of volume loss is best managed with a negative pressure vacuum system, and the two independent prosthetist with whom I have worked both recommended that I be fitted with a version of this system. I would love to tell you whether this approach has now worked for me, but I am still awaiting the new leg that I have just been fitted with.

Surely it is not every amputee that needs a negative pressure socket system. But some (including me) do. I believe that the coverage document should not be so absolute in its statement that such systems will not be covered. In parallel with the way in which borderline indications like this in medicine are often managed, the possibility of coverage should be offered with the provision of clear historical evidence that simpler solutions have not worked, and after confirmation of the indication by a second financially disinterested prosthetist (a prosthetic second opinion).

With respect to prosthetic feet, I am pretty convinced as a doctor that a SACH foot is an inappropriate foot for anyone using a lower limb prosthesis for anything beyond simple transfer. The absence of "toe push off" at the end of the stance phase causes the user of a SACH

foot to have the contralateral, sound, foot slap down leading to repetitive trauma to the forefoot. Given that the majority of lower limb amputees are dysvascular and neuropathic diabetics, I believe that this gait pattern puts them at risk for contralateral Charcot joints, 1st metatarsal head ulcers, and ultimately contralateral amputations. I would strongly favor coverage of a dynamic response foot for any lower limb amputee using the limb for more than transfers. (As an additional thought, it might be mentioned that the SACH foot does NOT favor a "natural gait," the standard for appropriate prosthetic fitting cited elsewhere in the proposed coverage document).

I should like to suggest revisions in two other places of this document. First, the document suggests that use of a walking aid such as a crutch is inconsistent with a diagnosis of K3 or K4 rehabilitation status. This is correct if one means *habitual* use of such a walking aid. I am a K3 bordering on K4 prosthetic user. I wear my prosthesis every day and I'm pretty active. But I *do* use my crutches at night, and occasionally during the day during periods of stump soreness, etc. The use of a walking aid on an occasional basis is NOT a bar to diagnosis of K3 or K4 rehabilitation status, and the suggestion that prior CMS payment for crutches or a cane would disqualify someone for coverage of a K3 or K4 level prosthesis is completely inappropriate.

Finally, concern has been expressed in the amputee community about the statement that:

" The prosthesis must provide:

- Stability
- Ease of movement
- Energy efficiency, and
- The appearance of a natural gait"

I strongly support this statement as the goals of prosthetic rehabilitation. But some in the amputee community have expressed concern that an "advanced" prosthetic would be denied someone that could not be expected to achieve "the appearance of a natural gait."

This would be inappropriate. Take, for instance, the hip disarticulation amputee. The way in which such an individual throws his (prosthetic) leg forward is totally different from the way in which an amputee with a reasonable length of AK stump will do it. It is impossible to achieve in a hip disarticulate "the appearance of a natural gait." The same may be said for other AK amputees with contractures. But these individuals may be even more in need of an "advanced prosthesis" than the patient with a simple BK amputation. This section should be reworded to emphasize what I take to be its meaning, that the prosthetic prescription should aim to optimize the function of the amputee to the above stated goals – not to imply loss of funding for such prostheses unless "the appearance of a natural gait" can be assured.

Many thanks for the opportunity to comment on this proposed CMS coverage policy.

Sincerely yours,

L. G. Hunsicker, M.D.
Professor (Emeritus) of Internal Medicine
U. of Iowa Carver College of Medicine

cc:
Andrew Slavitt, Acting Administrator
Centers for Medicare and Medicaid Services
United States Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201
(By email: Andy.Slavitt@cms.hhs.gov)

UNIVERSITY of IOWA HEALTH CARE

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*Benjamin J. Miller, M.D., M.S.*
*Assistant Professor*
*Department of Orthopaedic Surgery*
*Leader, Sarcoma Multidisciplinary Oncology Group*
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August 26, 2015

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Thank you for the opportunity to comment on the proposed revisions.

Sincerely,

Benjamin J. Miller, MD, MS

August 26, 2015

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8115 Knue Rd.
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Submitted Electronically to: DMAC_Draft_LCD_Comments@anthem.com

Dear Dr. Brennan

I am writing to provide comments on the proposed revisions to the Medicare Local Coverage Determination (LCD) and Policy Article for Lower Limb Prosthetics published on July 16, 2015. As a prosthetist and physical therapist, I am deeply concerned about the impact these changes would have on my ability to provide quality prosthetic care to my Medicare patients.

The proposed changes are the most far-reaching re-write of lower limb prosthetic policy in the history of Medicare. Unfortunately the proposals lack any evidence to support the changes. These proposals if implemented would dramatically reduce access to the current standard of prosthetic care and force Medicare patients to accept 1958 technology. Because many of the proposals involve major changes to the Uniform Code Set, these changes have the potential to impact all amputees who receive prosthetic care.

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- Ignores the written notes of the licensed/certified prosthetist when determining an amputee's functional capabilities/deficiencies. The proposal creates a new system where physicians, therapists, nurse practitioners, and physician assistants, but not prosthetists, will be required to conduct functional assessments and prepare significant documentation.

- Include a long set of requirements a patient must satisfy before being eligible to receive prosthetic care. The requirements include upper body strength, adequate posture, cognitive capability, sufficient neuromuscular control, sufficient cardio-vascular capacity, appearance of a "natural gait", and numerous other prerequisites. These requirements are overly broad, not medically supported and appear to be an effort to use the existence of a condition to withhold coverage of more advanced care, or perhaps any care. Such undefined terms and phrases will offer post fitting auditors more opportunities to reject the claim.

- Reiterates ill-advised policy that prohibits a prosthetist's clinical documentation from being considered as part of the medical record. The continued failure to recognize the prosthetist's notes for purposes of establishing medical necessity and to consider the prosthetist as simply a "supplier" with a vested interest in payment is offensive when considering their extensive education, training, knowledge, and expertise.

My first 20 years of practice dealt with the treatment of amputees as a physical therapist. During that time I worked closely with many physicians and surgeons caring for all ages and types of amputees. Since then I have worked with amputees as a prosthetist.

Once these new rules are approved, amputees of all ages and levels will suffer.

Please rescind these rules and empower a group of experienced professionals to rewrite rules which will allow patients to achieve their best outcome in as short a time as possible. Please focus on flexibility in these rules so amputees may progress at their own pace. Flexible rules also will provide managing professionals the opportunity to move patients along using their best professional judgement, consistent with modern technology.

Thank you.

Donald G. Shurr CPO,PT

Donald G. Shurr CPO,PT
North Liberty, Iowa

Dear Dr. Brennan,

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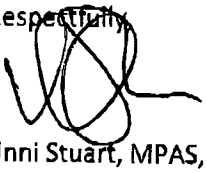

Unni Stuart, MPAS, PA-C