September 17, 2015

VIA FEDERAL EXPRESS

Richard Migliori, M.D.
Executive Vice President, Medical Affairs
and Chief Medical Officer
United Health Group, Inc.
9900 Bren Road
Minnetonka, MN 55343

RE: United Healthcare's October 1, 2015 Medical Policy Update Eliminating Coverage for "Vacuum Pump" Prosthetic Limb Systems

Dear Dr. Migliori:

Last week, United HealthCare (UHC) issued its Medical Policy for "Omnibus Codes." In that document, UHC characterizes vacuum pump systems[1] for lower-extremity amputees as unproven and not medically necessary, claiming "insufficient clinical evidence of safety and/or efficacy in published peer-reviewed medical literature." The Amputee Coalition[2] and the Orthotic & Prosthetic Alliance[3] (the "Alliance") have serious concerns with this proposed change, which is scheduled to take effect on October 1, 2015. We write you to request that UHC:

(1) Immediately rescind this proposed change to the medical policy; and

(2) Provide us the opportunity to meet with you to discuss this important issue in detail.

[1] Referred to interchangeably as "vacuum pump" or "vacuum" systems or devices in this letter.
[2] The Amputee Coalition is the nation's leading organization representing individuals with limb loss and dedicated to enhancing the quality of life of amputees and their families, improving patient care, and preventing limb loss.
[3] The O&P Alliance is 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, each of which is listed at the conclusion of this letter.

The Prosthetic Limb Technology at Issue

Changes in volume in an amputee's residual limb throughout the course of a day's use of a prosthetic leg are a frequent cause of poor fit, which leads to pain, blisters, tissue breakdown, and ultimately, reduced prosthetic use. Vacuum pump systems were developed in the late 1990s to improve the fit of the residual limb in the prosthetic socket, a critical factor in amputees' ability to successfully use their prostheses and reclaim healthy, active, and independent lifestyles. Among other clinical benefits, reduced volume fluctuation and improved fit of the prosthesis throughout the course of a day's use result from the function of these devices, actively removing air and moisture from the prosthetic socket.

For more than a decade, vacuum systems have been an accepted standard of clinical care in the treatment of lower extremity amputees. Indeed, the Centers for Medicare and Medicaid Services (CMS) amended the HCPCS code set in 2002 (effective January 1, 2003) by adding new billing codes and coverage policy for vacuum pump devices for Medicare beneficiaries. The HCPCS codes comprise the Uniform Code Set, which is also used by commercial payers. Since the creation of this code, Medicare has approved more than 15,000 claims for vacuum devices consistent with both the prescriptions of licensed physicians and the recommendations of the licensed/certified prosthetists providing prosthetic care and treatment to those patients.[4]

UHC's Medical Policy Update

UHC's update to its medical policy will eliminate coverage for two HCPCS codes—L5781 and L5782. This change in coverage appears to stem from the publication of a recently released Proposed/Draft Local Coverage Determination (LCD) on Lower Limb Prostheses (DL33787) by four Medicare contractors known as the Durable Medical Equipment Medicare Administrative Contractors (the "DME MACs"). The draft LCD states:

> 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.

Proposed/Draft Local Coverage Determination for Lower Limb Prostheses, DL33787 (issued in draft form on July 16, 2015).

The public comment period for this change in coverage by the DME MACs closed on August 31, 2015. On September 8, 2015, the undersigned organizations learned that UHC issued the following coverage guidelines for vacuum systems for residual limb volume management and

[4] Medicare Claims Data, Allowed Services for L5781 and L5782, 2003-2013.

moisture evacuation systems among amputees (HCPCS codes L5781 and L5782) to indicate a coverage determination similar to the Medicare draft LCD:

> The use of vacuum pumps for residual limb volume management and moisture evacuation systems among amputees is *unproven and not medically necessary due to insufficient clinical evidence of safety and/or efficacy in published peer-reviewed medical literature.*

UHC Medical Policy Update Bulletin (August 2015) at p. 27 (emphasis added).

Whether or not UHC's new coverage restrictions on vacuum pump devices emanated from Medicare's draft LCD, the fact is that the new coverage policy is flawed in two major respects.

1. Numerous clinical studies demonstrate and validate the efficacy provided by vacuum systems.

UHC's assertion that "insufficient clinical evidence of safety and/or efficacy in published peer-reviewed medical literature" exists to support the use of vacuum pump devices puts it in lockstep with the DME MACs' draft LCD. This assertion, however, is incorrect and is readily disproved by reviewing available research establishing the efficacy of these systems across a range of measures.

Multiple sources of clinical evidence demonstrate that users of vacuum pump systems experience less volume fluctuation in their residual limbs than non-vacuum pump users, permitting a better fitting socket throughout the course of a day's use. A sample of this clinical evidence is cited below:

- *Transfemoral sockets with vacuum-assisted suspension comparison of hip kinematics, socket position, contact pressure and preference: Ischial containment versus brimless*, Kahle, J. et al., JRRD, Vol. 50, No. 9 (Nov. 2013) 1241-1252.[5]

- *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., P&O Int'l (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.

[5] This study was also revised and republished in an updated form by two of its original authors: *Transfemoral interfaces with vacuum-assisted suspension comparison of gait, balance, and subjective analysis: Ischial containment versus brimless*, Kahle, J., Highsmith, J., Gait & Posture 40 (2014) 315-320.

In addition, researchers recently published a systematic review—the highest level of evidence—on the subject of vacuum pump device use.[6] This provides Level 2 evidence (i.e., randomized, controlled trials) that active suction components control residual limb volume changes, giving amputees better function during walking.

Other medical benefits exist from the use of vacuum pumps, which is clearly evidenced in published clinical studies and reviews, including the systematic review referenced above. *The Effects of Vacuum-Assisted Suspension on Residual Limb Physiology, Wound Healing, and Function: A Systematic Review* includes:

- A Grade B recommendation that vacuum pump systems reduce pistoning and socket movement that can damage the residual limb;

- Level 2 evidence that vacuum devices favorably distribute pressure across the residual limb;

- Level 2 evidence that vacuum pump systems improve functional performance (e.g., walking quality and balance confidence) when compared to prostheses that do not utilize these components; and

- Level 2 evidence that vacuum devices are equivalent to non-prosthetic alternative wound care interventions (e.g., soft dressings).

Other research shows that vacuum pump systems result in reduced pistoning of the residual limb within the prosthetic socket.[7] Vacuum device users with ulcers are also able to walk sooner and longer—with no increase or even a decrease in pain—than non-vacuum system users with ulcers.[8] In addition, vacuum pump system users have higher ambulatory activity scores[9] and have higher confidence and balance scores than non-vacuum pump systems users.[10] Finally, use of vacuum devices may have a beneficial effect on wound healing. This allows the continued use

[6] *See The Effects of Vacuum-Assisted Suspension on Residual Limb Physiology, Wound Healing, and Function: A Systematic Review*, Kahle, J. et al., Technology & Innovation, Vol. 15 (2014) 333-341.
[7] *See Transfemoral sockets with vacuum-assisted suspension comparison of hip kinematics, socket position, contact pressure and preference: Ischial containment versus brimless*, Kahle, J. et al., JRRD, Vol. 50, No. 9 (Nov. 2013) 1241-1252; *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).
[8] *See 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; *see also Vacuum assisted socket system in trans-tibial amputees: Clinical report*, Brunelli, S. et al., Orthopadie-Technik Quarterly, II (2009).
[9] *See 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.
[10] *See 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).

of a prosthetic limb even when a wound on the residual limb exists[11] that would otherwise be exacerbated by pistoning of the residual limb within the socket in a prosthesis that does not utilize a vacuum pump device.

2. Vacuum devices are a clinically-accepted standard of care in the treatment of lower-extremity amputees.

The technology used in vacuum pump systems for limb prostheses has existed since the mid-1990s. As noted above, Medicare has approved more than 15,000 claims over the last 12 years for these components. The Food and Drug Administration has also approved the manufacture, distribution, and use of this technology, signaling that it vouches for, at minimum, the safety of the components.

To counter this evidence and deny amputees access to a clinically-accepted standard of care on the summary conclusion that insufficient clinical evidence exists compromises the medical well-being of individuals with limb loss. In fact, it suggests the motivation for the new policy may be based primarily on the short term cost-effectiveness of denying coverage. Indeed, UHC's analysis of the relevant clinical literature omits nine studies referenced in this letter alone, all of which add to the nearly-universal body of literature establishing that patients using vacuum systems derive distinct clinical benefits not offered by prostheses lacking this capability.

And to the extent that UHC's change in coverage rests on the DME MACs publication of the draft LCD, we must emphasize that that document *is only a proposed draft*. Clinical reaction to the lack of evidence cited for this policy change by the DME MACs has been swift and unanimous. Indeed, the DME MACs offer nothing in their LCD's bibliography that in any way buttresses their conclusion regarding vacuum pump devices. Perhaps most telling, virtually the entire community of prosthetic researchers quoted in that bibliography have written a letter to the DME MACs *disavowing* the citation of their studies for any of the propositions for which they are cited. This letter, and others questioning multiple aspects of Medicare's draft LCD, has been included as attachments to this letter.

Simply put, the DME MACs have not implemented any provisions of the draft LCD—only published them for public comment. And given the widespread opposition to this proposed policy and the utter lack of valid clinical evidence supporting it, we believe it highly unlikely that the DME MACs will implement the draft LCD without significant changes or wholesale revision. We strongly encourage you and your colleagues at UHC to do the same.

Conclusion

[11] *See The Effects of Vacuum-Assisted Suspension on Residual Limb Physiology, Wound Healing, and Function: A Systematic Review*, Kahle, J. et al., Technology & Innovation, Vol. 15 (2014) 333-341; *Using vacuum-assisted suspension to manage residual limb wounds in persons with transtibial amputation: A case series*, Hoskins, R. et al., P&O Int'l, Vol. 38, No. 1 (2013) 68-74.

As set forth above, ample clinical evidence exists supporting the clinical efficacy and medical necessity of vacuum pump systems as components in lower limb prostheses. The assertions made by UHC (and the DME MACs) about the "insufficiency" of such evidence are unfounded and the coverage guidance based upon that alleged lack of evidence should be immediately rescinded.

In addition, the Amputee Coalition and the Alliance request a meeting with you to further discuss this issue and its impact on amputee patients covered by UHC. Please contact Peter Thomas at 202-455-6550 or Peter.Thomas@ppsv.com with any questions you may have about our concerns and to facilitate our requested meeting. Thank you for your consideration of our views and we look forward to speaking with you about this issue in greater depth in the near future.

Sincerely,

Sue Stout
President/CEO
Amputee Coalition

M. Jason Highsmith, PT, DPT, PhD, CP, FAAOP
President
American Academy of Orthotists and Prosthetists

James L. Hewlett, BOCO
Chair, Board of Directors
Board of Certification/Accreditation (BOC)

Charles H. Dankmeyer, CPO
President
American Orthotic & Prosthetic Association

James H. Wynne, CPO, FAAOP
President
American Board for Certification in Orthotics, Prosthetics and Pedorthics, Inc.

David McGill
President
National Association for the Advancement of Orthotics and Prosthetics

Enclosures

Douglas G. Smith, MD
Professor of Orthopaedic Surgery
University of Washington
Past-President Orthopaedic Rehabilitation Association

August 21, 2015

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

RE: Draft Lower Limb Prosthetics LCD
REQUEST TO REMOVE MY NAME AND LITERATURE I HAVE PUBLISHED FROM YOUR DRAFT

Dear Dr. Brennan:

I am writing to express my extreme disappointment, and strong views against the Draft Lower Limb Prosthetics LCD. My initial intention was to comment on the draft policy in its entirety, but after review, it is not possible to do so because of the failures of this draft are simply too numerous, and the harm it will cause to amputees is overwhelming.

I believe you have misused my name, by the way you cite literature to support your draft. I strongly request you remove literature that bears my name from your citations supporting your changes. I do not believe you have not cited this literature appropriately. I find your use of this literature very offensive, misleading, and not an accurate use of the literature.

The proposed changes described in DL#33787, in my opinion, would diminish both the quality and access to prosthetic care across our nation. I wish to go on record as strongly opposing the draft LCD. I look forward to working with CMS in the development of a more scientifically based approach to policymaking as outlined in the PIM.

We should remember that "Patients are First" requires timely access for care that meets community and national standards. Your proposals would be very harmful to amputees, and it does not meet current standards for our patients.

Douglas G Smith, MD
Professor of Orthopaedic Surgery
University of Washington and Harborview Medical Center
Seattle, WA dgsmith@u.washington.edu

MAYO CLINIC

200 First Street SW
Rochester, Minnesota 55905
507-284-2511

Kenton R. Kaufman, Ph.D., P.E.
Director, Orthopedics Biomechanics Laboratory
W. Hall Wendel, Jr, Musculoskeletal Research Professor
507-284-2262, Fax 507-266-2227

August 28, 2015

Stacey Brennan, MD
National Government Services, Inc.
DME MAC
P.O. Box 6036
Indianapolis, Indiana 46206-6036

Re: Draft LCD Lower Limb Prostheses (L33787)

Dear Dr. Brennan:

Mayo Clinic respectfully provides the following comments on the draft local coverage determination for Lower Limb Prostheses (L33787) published on July 16, 2015.

Mayo Clinic has a Core Value that "The needs of the patient come first." We believe that we share this core value with CMS in that all patients needing prosthetic devices deserve the highest quality and clinically appropriate care. We are writing to share some data that we hope will be valuable when you consider the LCD. Supporting the clinical needs of the patient with limb loss is a primary goal of the clinicians at Mayo Clinic.

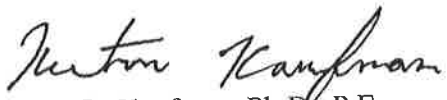
Based on research we have conducted, there is a clinical need for expanded coverage of Microprocessor-controlled knee prosthesis (MPK) (HCPCS L5828-5859). Microprocessor-controlled knee prosthesis (MPK) (HCPCS L5828-5859) help optimize the functional quality of life while minimizing risk to the beneficiary. With respect to Medicare coverage of MPK, there are 4 outcomes to be considered: function, quality of life, cost, and morbidity/mortality. Based on our research, patients receiving a MPK have improved function, (i.e. increased mobility) (Kaufman, 2008), improved quality of life (Kaufman, 2008), and decreased morbidity due to improved balance (Kaufman, 2007).

Individuals with leg amputations have a greater risk of falling than the general public. The reported incidence of falls for a lower extremity amputee is 52% compared with 33% for older adults. In addition, individuals with a transfemoral amputation are 1.4 times more likely to fall within one year than those with a transtibial amputation. A prospective study of community-dwelling amputees also demonstrated a high fall-related injury rate. Of the amputees who fell, 50% sustained some form of soft tissue injury. Further, 7% sustained bony injury necessitating hospital treatment. MPKs have been shown to reduce falls. The incremental cost of a MPK over a mechanical knee is approximately $22K in 2014 Medicare dollars. We have retrospectively reviewed the costs of falls in patients with an above knee amputation requiring either an emergency room visit or hospitalization. We have found the mean six-month direct medical costs of falls for 6 hospitalized adults with an above knee amputations was $25,652. The mean cost for the 10 adults admitted to the emergency department was $18,091. Thus, the cost savings

due to the cost of a fall are about the same as the incremental cost of providing a MPK (Mundell, manuscript submitted for publication). Given that a person typically gets a new prosthesis every 3 years, the data suggests that providing a high tech prosthesis results in savings of down-stream medical expenses. This agrees with the Dobson DaVanzo Retrospective Cohort Study of the Economic Value of Orthotic and Prosthetic Services among Medicare Beneficiaries (July 2013) which has shown that appropriate use of technology actually reduces the overall cost of care for amputees. http://mobilitysaves.org/docs/Dobson_Davanzo_Study_on_Cost_Effectiveness.pdf

Based on this data, we respectfully disagree with the draft policy as written and petition the Durable Medical Equipment (DME) Medicare Administrative Contractors (MAC) to rescind the draft policy. It contains significant revisions that will have adverse effects on Medicare beneficiaries that use prostheses. The current Lower Limb policy allows for adequate coverage and should not be replaced with the highly restrictive draft policy. Mayo Clinic seeks a uniform coverage for lower limb prostheses that would benefit all beneficiaries with limb loss by promoting the highest functional quality of life. Should you need additional information, please do not hesitate to contact me directly at 507-266-0136.

Sincerely,



Kenton R. Kaufman, Ph.D., P.E.
W. Hall Wendel Jr. Musculoskeletal Research Profess
Professor of Biomedical Engineering
Consultant, Departments of Orthopedic Surgery, Physiology and Biomedical Engineering

cc. Don Hertel
Mollie Brooks

References

1. K.R. Kaufman, J.A. Levine, R.H. Brey, B.K. Iverson, S.K. McCrady, D.J. Padgett, M.J. Joyer. Gait and balance of transfermoral amputees using passive mechanical and microprocessor-controlled prosthetic knees. Gait and Posture 26. 2007: 489-493
2. K.R. Kaufman, J.A. Levine, R.H. Brey, S.K. McCrady, D.J. Padgett, M.J. Joyer. Energy Expenditure and activity of transfermoral amputees using mechanical and microprocessor-controlled prosthetic knees. Arch Phys Med Rehabil Vol 89, July 2008: 1380-5
3. A. Dobson, A. El-Gamil, M. Shimer, J.E. DaVanzo. Retrospective cohort study of the economic value of orthotic and prosthetic services among Medicare beneficiaries. July 2013 Final Report

August 24, 2015

SUBMITTED VIA ELECTRONIC MAIL

Stacey Brennan, M.D.
DME MAC Region B Medical Director
National Government Services
8115 Knue Road
Indianapolis, Indiana 46250
DMAC_DRAFT_LCD_Comments@anthem.com

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

Dear Dr. Brennan:

We are writing today as concerned, independent researchers regarding the latest CMS draft LCD (DL #33787) for provision of Lower Limb Prostheses. It is important to note that we are not collectively affiliated with any organization, but are writing as individual researchers and authors.

It has recently come to light that the bibliography that was associated with the decision-making process for this draft LCD included papers that we had authored.

We would like to go on record as stating that the works referenced do not support any of the changes outlined in the CMS proposal. In addition, many of the citations in the CMS bibliography are not peer reviewed, are not current, or are not true citations in accordance with referencing standards by recognized entities.

We are extremely concerned that the CMS Draft LCD was not based at all on the current literature and science associated with the provision of prosthetic care.

According to the PIM the (Provider Integrity Manual), 13.7.1 – Evidence Supporting LCDs (Rev. 473, Issued: 06-21-13, Effective: 01-15-13, Implementation: 01-15-13):

> 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:

o Scientific data or research studies published in peer-reviewed medical journals;

o Consensus of expert medical opinion (i.e., recognized authorities in the field); or

o Medical opinion derived from consultations with medical associations or other health care experts.

The articles referenced by CMS claimed to support the LCD, actually have no bearing on any of the policy changes described in the proposed LCD. In fact, many of the citations could be used to refute the proposed changes. Further, these selected references do not support the significantly diminished quality of care that beneficiaries would receive if the proposed changes were implemented. It is also clear that some of the articles referenced in the bibliography are not accessible for evaluation and comment, calling into greater question the quality of the science behind CMS's proposed decision making when drafting the LCD proposal.

The current standard of practice is fully supported by sound, (peer- reviewed) scientific evidence. The changes proposed are not consistent with the current standard of practice and not derived from consultation with any of the referenced authors. As CMS has used our works in the preparation of this ill-conceived proposal, we are led to question why we, as health care experts in this field, were not consulted.

The proposed changes described in DL#33787, in our expert opinion, would diminish both the quality and access to prosthetic care across our nation. We, as the experts cited in this document, wish to go on record as strongly opposing the draft LCD.

We look forward to working with CMS in the development of a more scientifically based approach to policymaking as outlined in the PIM.

Ultimately, we should remember where our collective focus should be: on the beneficiary. We are all working to ensure people with limb loss receive appropriate care that is supported by science.

Sincerely,

M. Jason Highsmith, PT, DPT, PhD, CP, FAAOP
Associate Professor
School of Physical Therapy & Rehabilitation Sciences
Morsani College of Medicine
University of South Florida
President, American Academy of Orthotists and Prosthetists

Brian M. Kelly, D.O.
Professor
Medical Director, Division of Orthotics and Prosthetics
Assistant Program Director, Residency Training Department of Physical Medicine and Rehabilitation
University of Michigan Health Systems

Steven A. Gard, PhD
Executive Director
Northwestern University Prosthetics-Orthotics Center

Don Cummings CP (LP) FAAOP
Director: Prosthetics, Texas Scottish Rite Hospital for Children

Susan Kapp, M.Ed., CPO, LPO, FAAOP
Associate Professor and Director
UT Southwestern School of Health Professions
Prosthetics-Orthotics Program

John W. Michael, MEd, CPO/L
Fellow, ISPO
Fellow, AAOP
Assistant Professor of Physical Medicine & Rehabilitation
Northwestern University, Feinberg School of Medicine
Director, Northwestern University Prosthetics-Orthotics Center

Lisa U. Pascual, M.D.
Clinical Professor
Department of Orthopaedic Surgery
University of California, San Francisco

Robert S. Gailey, Jr., PhD, PT
Professor
Department of Physical Therapy
Miller School of Medicine
University of Miami

Robert S. Kistenberg, MPH, L/CP, FAAOP
Author, Outcome Measures in Lower Limb Prosthetics
http://www.oandp.org/olc/lessons/html/SSC_06/section_06.asp?frmCourseSectionId=07

Subj: **Draft Lower Limb Prosthetics LCD**
Date: 8/31/2015 3:43:49 P.M. Eastern Daylight Time
From: Beckerjimc@aol.com
To: DMAC_DRAFT_LCD_Comments@anthem.com

Dr Brennan,

Last week at the Public Hearing I expressed significant concern over the quality of the evidence that had been used to support the changes described in DL#33787.

At the hearing I read from a letter sent to you by Dr Douglas Smith, Professor of Orthopaedic Surgery at the University of Washington, in his letter to you Dr Smith, requested that you remove literature that bears his name from your citations, he found the use of this literature offensive and misleading.

In addition I referenced letters that had been sent to you by eleven of the cited experts, in the opinion of these subject matter experts the articles selected by CMS claimed to support the LCD actually have no bearing on any of the policy changes described in the proposed LCD. In fact, many of the citations could be used to refute the proposed changes.

Please find attached the letter signed by Dr John Bowker. Because of his status and his contribution to the field of amputation surgery and prosthetic care his opposition to the proposed LCD is notable.

Most of his contemporaries have retired but at age 84, orthopaedic surgeon John H. Bowker proudly remains on the job, treating patients two days a week at Miami's Jackson Memorial Medical Center. One day each week, Bowker sees "a large number of mostly indigent-care patients in clinics that alternate, with one devoted to preventive and therapeutic management of foot problems of diabetics, and one dedicated to the care of persons with amputations, including the provision and maintenance of prosthetic limbs. These clinics emphasize a team approach. The second day is my surgery schedule; I address the serious problems seen in the clinics, ranging from function-preserving amputations within the foot to major lower-limb amputations."

Bowker, who works with the Orthopaedic Rehabilitation Association and The International Society for Prosthetics and Orthotics, is a member of Technical Committee 168 of the International Organization for Standardization (ISO). He has served as an editor for the last three editions of Levin and O'Neal'sThe Diabetic Foot (Elsevier Publishing), "the leading interdisciplinary work on management of diabetic foot problems for over 30 years," as well as for the most recent editions of the Atlas of Amputations and Limb Deficiencies, published by the American Academy of Orthopaedic Surgeons.

More than five decades into his career, Bowker considers his work in the clinics, in "improving the quality of both amputation surgery techniques and the lifelong prosthetic management of persons with amputation," and in "training literally hundreds of orthopaedic residents in the principles of care for these patients," highly rewarding.

The draft LCD and associated bibliography contain numerous errors and multiple inconsistencies, including those attributed to Dr Bowker, however the misrepresentation of content is even more alarming than the serious administrative errors that relate to the accuracy of cited references.

Bowker describes the goal of restoring functional independence and the variability across amputees, he describes the restoration of body image, the role of prosthetic rehabilitation with the emphasis placed on the team approach. In contrast the draft LCD attempts to create required minimum rehabilitation goals; it dismisses individual variation in functional capacity and essentially removes

the prosthetist from the clinic team.

All payers' are driving towards outcomes focused metrics, however the heightened, and often misguided, scrutiny of the value and cost of prosthetic (and orthotic) interventions in coverage decisions are impacting not only what we can provide but more importantly they are also negatively impacting the quality of the life for the people who receive care.

In response to this demand from payers, as a member of the AOPA Board of Directors and the incoming President of AOPA I have been deeply involved in our "Survival Imperatives" initiative relating to Episodes of Care, Practice Standards and Evidence Based Practice. We are making good progress; I am very appreciative of the level of interest and engagement we have seen across the clinical and scientific community as we work collaboratively to develop and strengthen our evidence base. The rapid drive towards cost-efficient, evidence-based and outcome-driven orthotic and prosthetic care is not slowing down, it is of the upmost importance and urgency to me to advance and support O&P research initiatives, at all levels, that demonstrate the true value and positive outcome of the care we provide.

I know that given the opportunity myself and scientists and clinicians across the Prosthetic community would be delighted to work with you to establish an appropriate evidence and scientific base to policymaking.

I urge you to reconsider this proposal and to rescind the Draft Lower Limb Prosthetics LCD.

Respectfully,

James H Campbell PhD CO FAAOP
Becker Orthopedic
635 Executive Drive,
Troy, MI 48083

Dear CMS Medical Directors and Deputy Directors,

We are writing today regarding the latest CMS draft LCD (DL #33787) for provision of Lower Limb Prostheses.

It has recently come to light that the bibliography that was associated with the decision making process for this draft LCD included papers that we had authored.

We would like go on record as stating that the works referenced do not support any the changes outlined in the CMS proposal. In addition, many of the citations in the CMS bibliography are not peer reviewed, are not current, or are not true citations.

We are extremely concerned that the CMS Draft LCD was not based at all on the current literature and science associated with the provision of prosthetic care.

> According to the PIM the (Provider Integrity Manual), 13.7.1 - Evidence Supporting LCDs (Rev. 473, Issued: 06-21-13, Effective: 01-15-13, Implementation: 01-15-13):
>
> 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:
>
> o Scientific data or research studies published in peer-reviewed medical journals;
>
> o Consensus of expert medical opinion (i.e., recognized authorities in the field); or
>
> o Medical opinion derived from consultations with medical associations or other health care experts.

The articles referenced by CMS as supposedly supporting the LCD have no bearing on any of policy changes described in LCD. Indeed, many of them could be used to refute the proposed changes. Further, these references do not support the significantly

diminished quality of care that beneficiaries would receive if the proposed changes were implemented. It is also clear that some of the articles referenced in the bibliography are not accessible for evaluation and comment, calling into greater question the quality of the science behind CMS' proposed decision making.

The current standard of practice is fully supported by sound (peer reviewed) scientific evidence. The changes proposed are not consistent with the current standard of practice and not derived from consultation with any of the referenced authors. As CMS has used our works in the preparation of this ill-conceived proposal, we are lead to question why we, as health care experts in this field, were not consulted.

The proposed changes described in DL#33787, in our expert opinion, would diminish both the quality and access to prosthetic care across our nation. We, as the experts cited in this document, wish to go on record as strongly opposing the draft LCD.

We look forward to working with CMS in the development of a more scientifically based approach to policymaking as outlined in the PIM.

Ultimately, we should remember where our collective focus should be: on the beneficiary. We are all working to ensure people with limb loss receive appropriate care.

Sincerely;

John H. Bowker M.D. 8/31/15
Professor Emeritus
Dept. of Orthopaedics
Miller School of Medicine
Director of Amputee and
Diabetic Foot Services
Jackson Memorial Medical Center
Miami, Florida

The University of Oklahoma
Health Sciences Center
Department of Biostatistics and Epidemiology

August 17, 2015

Wendy Fischl Beattie, CPO, FAAOP
Clinical and Program Director
Orthotics & Prosthetics Master's Program
Eastern Michigan University
221 Warner Building
Ypsilanti, MI 48197

Ms. Beattie:

I appreciate your communication, and your invitation that I comment on the Local Coverage Determination (LCD) on lower limb prostheses (DL33787), which the Centers for Medicare and Medicaid Services (CMS) issued recently.

The LCD lists, in the document's bibliography, a brief essay that I posted online in 2001 (http://moon.ouhsc.edu/dthompso/gait/pobmk/amrehab1.htm). I was motivated to research and author the essay out of frustration that my physical therapy students at the University of Oklahoma could find no authoritative source to help them judge patients' rehabilitation potential. I constructed the posting without executing what we now recognize as a systematic review, nor did I submit the document for publication or to peer review.

Reading the document now, fifteen years later, I regard it as judicious, but limited by more than its obvious age. Policy makers can find within it sentences that justify limitations on funding for prosthetic components. They can just as easily find support for *expanding* resources, especially for people with trans-tibial amputations. I propose that Robert Gailey's research, also listed in the bibliography but still nearly a decade old, found parallel evidence that persons with trans-tibial amputations may have functional potential that exceeds the prosthetic resources we provide to them.

Policy decisions that affect people with amputations should be served by responsible health services research. I dedicated time over the last week to review current literature, and a gap still exists regarding functional outcomes among users of lower limb prostheses. Existing databases, including those maintained by CMS, can provide data that are more contemporary than many of the sources listed in the LCD's bibliography. CMS might support an exploration of these data.

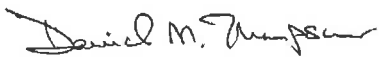
My contributions to people with amputations have been as a physical therapist and not as a prosthetist. Consequently, I want to close by commenting on the DL33787's

College of Public Health PO Box 26901 • 801 NE 13th Street, Room 309 • Oklahoma City, Oklahoma 73126-0901 • (405) 271-2229 • (405) 271-2068 (fax)

definitions of functional levels K2 and K3. In particular, I regard the definition of the K3 level as internally inconsistent. Specifically, *use of a cane can permit a person to be an unlimited community ambulatory*, able to "traverse most environmental barriers without physical or safety concerns" and to engage in "vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond typical environmental barriers." Use of a cane while using a prosthesis should not preclude a K3 classification. I have had the pleasure of providing physical therapy to numerous users of prostheses who achieved this level of function.

I appreciate the opportunity to share these comments with my clinical colleagues and with the architects of responsible public policy.

Sincerely,



David M. Thompson PT, PhD
Associate Professor of Biostatistics and Epidemiology

College of Public Health PO Box 26901 • 801 NE 13th Street, Room 309 • Oklahoma City, Oklahoma 73126-0901 • (405) 271-2229 • (405) 271-2068 (fax)