December 21, 2015

SENT VIA FEDERAL EXPRESS

Ronald Wiesinger, MD
National Medical Director
United Healthcare
9700 Health Care Lane
Minnetonka, MN 55343

Re: Coverage of Vacuum-Pump Systems for Lower-Extremity Amputees

Dear Dr. Wiesinger:

On behalf of the Amputee Coalition and other five undersigned organizations that form the Orthotic and Prosthetic Alliance ("O&P Alliance"), we would like to respond to your correspondence dated October 5, 2015, in which United Healthcare ("UHC") reiterated its position that it considers vacuum-pump systems for lower extremity amputees "experimental and investigational" and, therefore, not a covered service. UHC's October 5th letter responded to our joint letter sent to UHC on September 17, 2015, challenging the non-coverage decision issued on September 7, 2015.

Respectfully, we must take issue with this coverage decision for the following three reasons:

- **Medicare's Coverage Reversal:** UHC acknowledged that it would "reassess [its] position based upon the evolution of published clinical evidence or any future finalized guidance from [Medicare]." Since your October 5, 2015 letter, the Centers for Medicare and Medicaid Services ("CMS") *refused* to finalize the Medicare contractor's "Proposed/Draft Local Coverage Determination (LCD) for Lower Limb Prostheses" and announced that it will convene an Interagency Workgroup to review this policy in 2016. The draft LCD—originally issued for public comment on July 16, 2015—proposed to end ten years of Medicare coverage of vacuum-pump systems with virtually no clinical evidence to support the decision. Since CMS has rejected implementation of this draft LCD, UHC should take this decision into consideration and re-adopt its historically-correct position to cover vacuum-pump systems when medically necessary. Such a coverage decision would be consistent with existing Medicare coverage policy as well as other private insurers (including Aetna, which updated its Coverage Policy Bulletin in July *to cover* vacuum-pump systems).

- **The Incorrect Assertion:** UHC claims in its October 5th letter that "many of the studies referenced in your letter address services other than [vacuum-pump systems], such as microprocessors." Our September 17th letter referenced nine studies. None of them focused on microprocessor-controlled components; every one of them addressed vacuum-

pump systems. UHC's coverage denial of vacuum-pump systems therefore relies on an incorrect reading of the relevant clinical evidence. An appropriate review of the literature justifies covering vacuum-pump systems.

- **The Single Study:** UHC's response pointed to a single study suggesting that "pin suspension" produces better outcomes than vacuum-pump systems. The results of this research stand in stark contrast to the much more substantial body of literature referenced in our September 17th letter to UHC. Moreover, *only five* subjects completed the protocol in the UHC-cited study, all of whom had worn pin systems previously.

I. Medicare has refused to finalize the draft LCD, undercutting the validity of UHC's revised coverage position.

Citing its commitment to "providing high quality care to all beneficiaries, including any beneficiary in need of a prosthesis," CMS acknowledged in a statement issued November 2, 2015 on the Lower Limb Prostheses Draft LCD that both it "and its contractors have heard your concerns about access to prostheses." CMS then expressly refused to adopt the draft LCD in its entirety by stating:

> The Durable Medical Equipment Medicare Administrative Contractors (DME MACs) will not finalize the draft Lower Limb Prostheses Local Coverage Determination (LCD) (DL33787) at this time.

To the extent that UHC relied on the draft LCD as grounds for its sudden reversal in coverage of vacuum-pump systems, Medicare's rejection of that same draft LCD should trigger a review by UHC of its current coverage policy on vacuum-pump systems and prompt a return to coverage of this important prosthetic technology. In its October 5th correspondence to the Amputee Coalition and O&P Alliance, UHC itself acknowledged that it would "reassess [its] position based upon the evolution of published clinical evidence or any future finalized guidance from [Medicare]." Today, the only finalized guidance from Medicare remains the *current* LCD for lower limb prostheses, which expressly covers vacuum-pump systems for lower limb amputees and has done so for nearly a decade.

Put simply, UHC's position with respect to vacuum-pump systems is out of sync with Medicare policy, out of sync with other private payers,[1] and out of sync with the full body of clinical literature discussed more fully in the following sections.

II. UHC incorrectly asserts in its letter that "many" of the studies we referenced apply to microprocessor-controlled devices, not vacuum systems.

Every single study referenced in our previous correspondence to UHC dated September 17, 2015 expressly applies to vacuum-pumps. A cursory review of nothing more than the *titles* of the research publications we previously cited disproves UHC's claim.

[1] In July, for example, Aetna updated its Clinical Policy Bulletin 0630 to include coverage for vacuum-pump systems because it deemed them "medically necessary for use with lower limb prostheses to increase suspension and proprioception and improve gait." *See* http://www.aetna.com/cpb/medical/data/600_699/0630.html. In addition, numerous BCBS plans cover vacuum-pump devices.

- Transfemoral sockets with ***vacuum-assisted suspension*** comparison of hip kinematics, socket position, contact pressure and preference: Ischial containment versus brimless;

- ***Elevated Vacuum Suspension*** Influence on Lower Limb Amputee's Residual Limb Volume at Different Vacuum Pressure Settings;

- Walking in a ***vacuum-assisted socket*** shifts the stump fluid balance;

- A comparison of trans-tibial amputee suction and ***vacuum socket*** conditions;

- The Effects of ***Vacuum-Assisted Suspension*** on Residual Limb Physiology, Wound Healing, and Function: A Systematic Review;

- Outcomes Study of Transtibial Amputees Using ***Elevated Vacuum*** Suspension in Comparison With Pin Suspension;

- Residual limb wounds or ulcers heal in transtibial amputees using an ***active suction socket system***. A randomized controlled study;

- ***Vacuum assisted socket system*** in trans-tibial amputees: Clinical report; and

- Using ***vacuum-assisted suspension*** to manage residual limb wounds in persons with transtibial amputation: A case series.

Given the fact that every one of the studies we referenced expressly applies to vacuum-pump systems, we do not understand UHC's contention that much of the cited research instead focuses on microprocessor-controlled prosthetic components. Moreover, the only microprocessor-controlled devices available to lower extremity amputees are knee joints and ankle-foot devices – *not* vacuum-pump systems.

The fact that UHC supports its change in coverage policy by incorrectly characterizing the substantial body of research disproving its position is troubling. We would respectfully request that UHC review the clinical studies cited above and in our September 17th correspondence, all of which not only focus on vacuum-pump systems, but also document the clinical benefits that vacuum-pump systems provide lower-extremity amputees.

Furthermore, we would like to point out two additional studies were recently published in support of the medical necessity and clinical effectiveness of vacuum-pump systems.

- *Comparative Effectiveness of Electric Vacuum Pumps for Creating Suspension in Transfemoral Sockets*, Major, M.J. et al., JPO, Vol. 27, No. 4 (2015) 149-153. This study relied on previously existing clinical work exhibiting the baseline effectiveness of vacuum-pump systems for lower limb amputees and built upon that assumption to compare systems. Two brands of vacuum-assisted suspension systems were tested to determine their comparative effectiveness, with both systems showing roughly equal effectiveness. This study serves to establish some baseline standard evaluation methods for determining effectiveness of vacuum-pump systems going forward, which can be

used to verify the clinical appropriateness of these systems for use by certain lower limb amputees.

- *Dynamic Effectiveness Evaluation of Elevated Vacuum Suspension*, Gerschutz, M. et al., JPO, Vol. 27, No. 4 (2015), 161-165. In this study, distal displacement during ambulation was measured and the results indicated a significant reduction in vertical displacement (i.e., "pistoning," as described in more detail below) with use of vacuum suspension over suction suspension.[2]

Neither study involved microprocessor-controlled devices, focusing exclusively on the use of vacuum-pump systems by lower limb amputees. The issuance of these two new studies further disproves 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 systems.

III. UHC errantly sought to rebut the overwhelming body of evidence by referencing a single study that is at odds with the rest of the scientific literature.

UHC cites a single research article immediately after the following paragraph in its October 5th letter: "Several of the studies cited in your letter have limitations including one or more of the following: a limited number of participants, lack of long-term follow up and lack of comparison to the pin suspension system." Ironically, the sole study relied upon by UHC in support of its coverage position (a) had only five participants complete the protocol out of 20 originally enrolled in the study ("limited number of participants"); (b) lasted only eight weeks ("lack of long-term follow up"); and (c) each of the five subjects were previous pin system users, suggestive of the fact that they may have been predisposed to prefer their historical socket system to a vacuum-pump system.

To make matters worse, this particular study had an attrition rate of 75%, far in excess of the standard of 20% or less accepted by evidence grading tools from the scientific community. This is a significant flaw in the study cited by UHC. This threat to the study's internal validity must be considered when contemplating the entire body of evidence, which otherwise supports use of this technology.

Separate and apart from these points, UHC's study *supports* the often-verified conclusion that vacuum pumps reduce the amount the patient's residual limb "pistons" in the socket (i.e., moves vertically up and down in the socket due to factors such as excess air in the socket and/or compromised fit). Since pistoning commonly results in pain, residual limb tissue damage, and ulcers, this is a significant finding that UHC should not ignore as it reconsiders its recent decision of non-coverage.

In addition, the results of this study have not been replicated. It stands alone in the literature. Accordingly, giving it more weight than the substantial body of evidence demonstrating the clinical benefits of vacuum-pump systems is both arbitrary and not in the best interests of patients.

[2] We acknowledge that the sample size of this study (five subjects) was small, similar to the final sample size of the UHC-cited study. However, it is telling that both studies concluded that a significant reduction in limb pistoning accompanied use of vacuum-pump systems.

IV. Conclusion

We appreciate you taking the time to respond to our initial letter regarding vacuum-pump systems for lower extremity amputees. However, we have serious concerns about UHC's contentions, as outlined above. Therefore, we request that UHC revisit the decision to classify vacuum-pump systems as experimental and investigational, as the grounds for that decision:

(1) are against the weight of evidence;

(2) rely on incorrect statements of fact regarding the clinical literature;

(3) find support in only a single piece of research that is more noteworthy for the fact that it runs counter to the much larger body of literature supporting vacuum-pump systems than it is for its clinical rigor (only five out of twenty subjects completed it and the study lasted only eight weeks); and,

(4) are now completely at odds with the current and active Medicare policy on this topic, which does provide coverage for vacuum-pump systems for lower extremity amputees, a fact reinforced by the November 2nd announcements by both the White House and CMS that the DME MACs will not finalize the draft LCD.

Thank you and we look forward to your response.

Sincerely,

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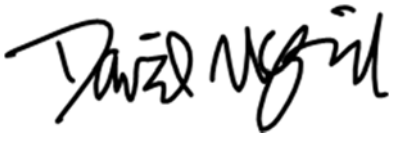

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