February 10, 2016

VIA FEDERAL EXPRESS

Alan M. Muney, MD, MHA
Chief Medical Officer
Cigna Corporate Headquarters
900 Cottage Grove Road
Bloomfield, CT 06002

RE: Cigna's Coverage Policy Number 0194 Regarding Coverage for Residual Limb Volume Management and Moisture Evacuation Systems

Dear Dr. Muney:

In its Coverage Policy 0194, effective September 15, 2015, Cigna restated its conclusion that it considers residual limb volume management and moisture evacuation systems, such as vacuum-assisted socket systems ("VASS"), "experimental, investigational, or unproven." Cigna characterizes such vacuum pump systems[1] for lower extremity amputees as unproven and not medically necessary, claiming that "Evidence in the published, peer-reviewed scientific literature is insufficient and does not substantiate the effectiveness of the VASS device in maintaining limb volume."

Based on the evidence available to justify the medical necessity and effectiveness of this technology, the Amputee Coalition[2] and the Orthotic & Prosthetic Alliance[3] (the "O&P Alliance") have serious concerns with this coverage policy. We write this letter to request that Cigna:

(1) Rescind this coverage policy as expeditiously as possible; and

[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.

(2) Provide us the opportunity to meet with you to discuss the establishment of a more evidence-based coverage policy for residual limb volume management and moisture evacuation systems.

The Prosthetic Limb Technology at Issue

Body fluid volume change is a known physiologic reality occurring in all humans. The rate of change is dependent upon the body's homeostatic efficiency. All amputees' homeostatic efficiency is reduced immediately and directly as a function of amputation. Because the amputee's residual limb is contained within the socket of the prosthesis, even small changes in volume will affect the relationship (i.e., the "fit") between the residual limb and the socket of the prosthesis (the socket is the receptacle in which the residual limb is contained).

The percent fluid volume change in the lower limbs during daily activity cycles of walking, standing, and sitting varies greatly from morning to afternoon and from day-to-day based on the efficiency of the body's homeostatic efficiency. These changes significantly alter pressure distribution to the residual limb within the prosthetic socket, which in turn leads to increased pressure over smaller areas that can cause skin and tissue breakdown with pain, pressure ulcers, and blisters. The ultimate result is reduced prosthetic use and less activity and function for the amputee prosthetic user. Vacuum pump systems, developed in the late 1990s, have provided distinct clinical benefits for patients, improving the fit of the socket by modulating volume fluctuations and 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]

Cigna's Coverage Policy

Cigna's coverage policy currently prohibits coverage of two HCPCS codes – L5781 and L5782. This policy is flawed in two major respects.

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

Cigna's assertion that "[e]vidence in the published, peer-reviewed scientific literature is insufficient and does not substantiate the effectiveness of the VASS device in maintaining limb

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

volume" is consistent with the body of evidence on this technology 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.

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 movement of the residual limb in the socket during ambulation;

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

[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.
[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.

- 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 skin ulcers are also able to walk sooner and longer—with no increase or even a decrease in pain—than non-vacuum system users with skin 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 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.

Furthermore, the most recently published studies on vacuum pump systems also support the medical necessity and clinical effectiveness of such components.

- *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

[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). We disagree with Cigna's characterization of the results of the Traballesi study as inappropriate for generalization, especially in combination with the pre-existing scientific support for the study's conclusions.
[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).
[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.

used to ensure that covered systems are, in fact, clinically appropriate for use by 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") with use of vacuum suspension over suction suspension.

In response, Cigna might point to the report from the Washington State Department of Labor and Industries cited in its medical policy. However, that report is not in accord with the significant body of research that reaches a different conclusion regarding the effectiveness of VASS. For that reason, we believe that the Washington State Department of Labor and Industries' conclusions should be disregarded as now unpersuasive.[12]

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 covered by Cigna. In fact, it suggests the motivation for the new policy may be based primarily on the short term cost-effectiveness of denying coverage. Indeed, Cigna's analysis of the relevant clinical literature omits ten 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.

In light of the strong evidence base that justifies coverage of vacuum socket technology, we strongly encourage you and your colleagues at Cigna to reconsider the decision to not cover vacuum pump systems and, instead, publish a reasonable coverage determination that grants coverage for amputees in need of this prosthetic technology.

[12] Cigna might also reference the proposed omission of Medicare coverage of vacuum pump technology in the July 2015 DME MAC Draft Local Coverage Determination ("LCD"). However, reaction to that proposal since its release, via both oral testimony at the August 26, 2015 public session and in the written record, has demonstrated its very serious deficiency in terms of not being supported well, if at all, by any credible weight of scientific research or evidence. In fact, CMS has declined to finalize the LCD and has initiated a completely new process for considering changes to coverage guidance for lower limb prostheses. Any reliance on such a widely discredited draft would be profoundly misplaced.

Conclusion

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 Cigna about the "insufficiency" of such evidence are unfounded and the coverage guidance based upon that alleged lack of evidence should be rescinded as expeditiously as possible.

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 Cigna. 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,

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Advancement of C

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