9700 Health Care Lane
Minnetonka, Minnesota 55343

October 5, 2015

Susan Stout
President & Chief Executive Officer
Amputee Coalition & Alliance

Re: Medical Policy on Prosthetics and Vacuum Assisted Suspension Systems

Dear Ms. Stout:

Thank you for your recent letter regarding UnitedHealthcare Insurance Company's medical policy on Vacuum Assisted Suspension System (VASS) in the management of prosthetic lower limb devices for amputees and the request to change UnitedHealthcare's medical policy.

UnitedHealthcare provides benefit coverage for services that prevent, diagnose, or treat sickness or injury unless we conclude they are investigational, unproven, cosmetic, custodial or explicitly excluded from coverage.

Our medical policy defines *unproven* as services and medications that are determined not to be effective for treatment of the medical condition and/or not to have a beneficial effect on health outcomes because of insufficient and inadequate clinical evidence from well-conducted randomized controlled trials or cohort studies in current published peer-reviewed medical literature. These are further defined as follows:

- *Well-conducted randomized controlled trials:* two or more treatments are compared to each other, and the patient is not allowed to choose which treatment is received;
- *Well-conducted cohort studies*: patients who receive treatment are compared to patients who receive standard therapy, and the comparison group is nearly identical to the treatment group.

The UnitedHealthcare Medical Technology Assessment Committee, comprised of internal physicians in a range of medical and surgical subspecialties, including internal medicine, orthopedics, and physical medicine, reviewed our medical policy on prosthetics and VASS and concluded that 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.

The comparative studies available did not assess patient-relevant health outcomes, such as functional capabilities and quality of life, following use of these systems. Professional society guidelines addressing this technology were also unavailable.

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.

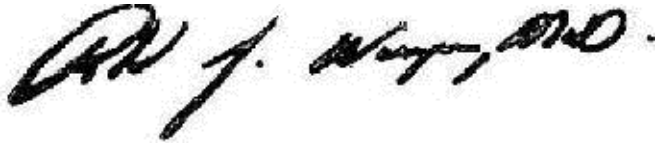
Notably, in the research published by Klute et al. (2011), patients reported better overall outcomes with the pin suspension system than with VASS. The authors noted that the clinical relevance of the result of the "small but statistically significant difference" of improved socket fit was "difficult to discern."

Many of the other studies referenced in your letter address services other than VASS, such as microprocessors. UnitedHealthcare has a separate medical policy that provides the coverage criteria for microprocessors.

We will review new clinical evidence supporting the use of VASS annually and reassess our position based upon the evolution of published clinical evidence or any future finalized guidance from the Centers for Medicare & Medicaid Services.

Please feel free to forward additional clinical information for further review. If you have questions, please contact me at 952-202-2502 or ronald_wiesinger@uhc.com. Thank you.

Sincerely,



Ronald Wiesinger, MD
National Medical Director

cc: Richard Migliori, MD