ALLIANCE OF

Wound
Care
Stakeholders

Summary of Marcia Nusgart's Presentation
July 9, 2009 CMS HCPCS Public Meeting for Negative Pressure Wound Therapy (NPWT) Devices

My name is Marcia Nusgart and I serve as Executive Director for the Alliance of Wound Care Stakeholders ("Alliance"). The Alliance is a multidisciplinary consortium of over 15 physician, clinical, provider, manufacturer and patient organizations whose mission is to promote quality care and patient access to wound care products and services. A list of these organizations can be found on the Alliance's website—www.woundcarestakeholders.org. I receive no compensation from any of the organizations who participate in the Alliance's activities.

Since most of the Alliance physician, clinician or patient organizations either use or benefit clinically from the use of NPWT, appropriate coding, coverage and payment of these devices is seen as being very important and having immense implications to their practices. The Alliance has previously commented on today's issue most notably in our February 2, 2009 letter to both CMS and AHRQ where we made a number of requests concerning the process for the evaluation of the NPWT HCPCS codes. We appreciate that the Agency implemented many of our recommendations, most notably having a separate HCPCS public meeting for NPWT in order to allow sufficient time for all interested stakeholders to address issues of importance.

Similarly, today, while we are not taking a stand on the HCPCS Workgroup's preliminary coding decision, we do want to comment on the process and data that was used to make this decision. It is our understanding that since there were no head-to-head comparison studies, AHRQ relied on indirect comparisons which consisted solely of randomized controlled clinical trials (RCTs) to base their decisions.

While the Alliance understands that CMS was simply following what Congress had mandated through the MIPPA law for evaluating the existing HCPCS codes for NPWT, we have concerns that in the future, this approach may be too narrow for CMS to follow in subsequent coding, coverage or payment evaluations of wound care technologies. Moreover, we hope that this process was an isolated request and does not set a precedent that a "technology assessment" is performed when a request for an evaluation for a HCPCS code is made. Such action, we believe, would be unnecessary, expensive, and time consuming in a situation that already exists where under the current HCPCS coding process, determinations often include the review of clinical evidence similar to information used to determine coverage policies. To have a technology assessment performed every time a HCPCS request is made would have a chilling effect on new and existing wound care technologies thus hindering their appropriate commercialization.

To that end, the Alliance offers to serve as a resource working with both CMS and AHRQ to address the value of alternate forms of wound care evidence and surrogate endpoints that the Agency and other policymakers can use in making coding and coverage decisions of wound care technologies in the future.

The Alliance appreciates CMS' consideration of these comments.

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