September 28, 2012

Via Electronic Mail
AHRO
Scientific Resource Center, Oregon EPC
Mail code: BICC
3181 S.W. Sam Jackson Park Road
Portland, Oregon 97239-3098

Re: Draft Research Review: Chronic Venous Ulcers: A Comparative Effectiveness Review of Treatment Modalities

Dear Scientific Resource Center Review Team:

AdvaMed appreciates the opportunity to offer comments in response to the draft report on Chronic Venous Ulcers: A Comparative Effectiveness Review of Treatment Modalities. While AdvaMed appreciates AHRQ's interest in improving treatment and raising awareness through evaluating the modalities used to treat chronic venous ulcers, we have some concerns related to the structure of the abstract as well as the review methods and result findings. Our comments appear below.

AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. We are committed to ensuring patient access to life-saving and life-enhancing devices and other advanced medical technologies in the most appropriate settings.

Report Structure
The current structure of the CER document does not fully reflect contemporary treatment practices involving the use of compression therapy. Consequently, AdvaMed is concerned that the method of comparison proposed in the draft report will not provide any conclusive evidence regarding the effectiveness of any of the modalities being evaluated.
Moreover, AdvaMed is concerned that the objective guiding the report may not be adequate to fully evaluate the range of modalities available to treat chronic venous ulcers. The objective identified in the Structured Abstract section of the paper (see page vi) states that AHRQ will conduct a systematic review of whether “advanced wound dressings, systemic antibiotics, or venous surgery” enhance the healing of venous ulcers over the use of adequate venous compression. However, for many years the clinician, provider, and manufacturer communities have recognized the application of some type of compression therapy, either prior to or in conjunction with the other treatments identified in the report, in treating venous ulcers. For example, an article in Wound Repair and Regeneration stated that, “Wound dressings, including advanced dressings, should always be administered to chronic venous leg ulcers as part of a protocol of care that includes effective compression therapy.”

Data and Results
AdvaMed is concerned with the draft reports reliance on HCPCS code descriptors as the basis for classifying and identifying the characteristics associated with the use of the various technologies that were evaluated. HCPCS codes are broad groupings of products with similar ingredients or components, but not necessarily products with similar function or uses. Choice of secondary ingredients/components, material quality and construction, manufacturing methods, and clinical performance are among the factors that contribute to differences in performance and clinical indications of products within each HCPCS category. While HCPCS categories provide a framework for payment, they are not reflective of the use or performance of the various devices that may be grouped together nor are they intended for use in scientific research. Lia Van Rijswijk wrote about this problem in 2006 stating that, “Wound dressings are classified according to their ingredients, but in many cases dressings within the same group have different recommended uses and even ingredients. Should future classifications be based on dressing functions?” It is not appropriate to use reimbursement categories to describe results that measure efficacy.

AdvaMed also believes that the methods and published literature selected by AHRQ for inclusion in their review may have resulted in the omission of a large body of evidence related to the use of compression therapy in the treatment of chronic venous ulcers. Because the use of some type of compression therapy in the treatment of venous ulcers has been the standard for many years, it is difficult to find studies that do not include use of compression. Additionally, it is not always clear based on an analysis of the results whether the compression products used in a study were standardized.

Finally, AdvaMed has concerns regarding the draft report’s reliance on Randomized Controlled Trial (RCT) data in reaching its conclusion. The low number of RCTs related to the use of compression therapy in chronic venous ulcer management does not adequately represent the lives of actual patients living with this condition. Compliance with treatment recommendations is a major problem within this patient population. Additionally, the rates of compliance associated with patients in an RCT setting can skew the effectiveness results for some of these therapies. To address this concern, AdvaMed recommends that the draft report also consider data from observational studies.

**Conclusion**
We are pleased to provide AHRQ with our input on the draft comparative effectiveness review and encourage the organization to continue to seek stakeholder input and feedback, as similar documents are drafted in the future.

We hope that you find our comments useful. Should you have additional questions please feel free to contact DeChane Dorsey at 202-434-7218 or ddorsey@advamed.org. Thank you.

Sincerely,

Ann-Marie Lynch  
Executive Vice President, Payment and Health Care Delivery