COALITION OF
Wound
Care
Manufacturers

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Submitted Electronically

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

To Whom This May Concern:

On behalf of the Coalition of Wound Care Manufacturers ("Coalition"), I am submitting the following comments in response to the AHRQ Chronic Venous Ulcers: A Comparative Effectiveness Review of Treatment Modalities. The Coalition represents leading manufacturers of surgical dressings, negative pressure wound therapy, acellular biomaterials and biologics used by physicians and clinicians for the treatment of patients with wounds. Since we recognize that these issues are very complex and the information can be very complicated, we would be pleased to serve as a resource to answer any questions regarding these issues.

Our comments are related to first question.

Question 1- **For patients with chronic venous leg ulcers, what are the benefits and harms of advanced wound dressings (i.e., dressings with active chemical, enzymatic, or antibacterial component(s) compared with standard pressure dressings?**

We have a number of concerns related to this question and will offer recommendation to change the sentence to make it more meaningful. Our concerns include the following:

1. We question if AHRQ intended to use the terms "standard pressure dressings" in reference to those dressings providing compression. Compression therapy is the gold standard of treating venous stasis ulcers as indicated in the AAWC venous ulcer guidelines. Examples include the 2-4 layer compression systems, the Unna's Boot or Duke Boot. We would recommend that the words "standard pressure dressings" be replaced with "compression systems."
2. We also are concerned that the question, as worded implies whether wound **dressings** are used *in lieu* of, rather than in conjunction with appropriate

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compression **therapy**. As stated above, appropriate compression **systems** are ALWAYS indicated for venous ulcer treatment (excepting patients with arterial disease). The wound dressings placed underneath the systems will vary depending upon the needs of the wound. Despite the manner in which clinical trials have been carried out (at the insistence of the FDA), in no case clinically would a single type of dressing be used throughout the course of wound healing. Dressings are changed as the needs of the wound change. Therefore, we would recommend that the sentence state:

For patients with chronic venous leg ulcers, what are the benefits and harms of using advanced wound dressings in conjunction with compression systems as compared with using solely compression systems?

3. A standard **wound** dressings can be one of multiple categories of dressings; collagens, hydrocolloids, foams, absorptive specialty dressings, hydrogel sheet dressings, composite dressings, transparent films, gauze, gauze-based dressings, aqueous hydrogels, etc. Dressings with or without an active chemical, antimicrobial or enzyme are used based on the condition of the wound and often in combination with other dressings. As stated above, rarely is one type of dressing used consistently throughout the full time to healing a wound. Therefore, what would be the 'effectiveness parameters' measured per dressing type, per dressing use, and how would AHRQ intend to evaluate one from another when used together for a period of time in the wound healing cycle?
4. We also have concerns about information included in Table 1. We believe that the table should be broken into three parts:
    - ***Surgical dressings***—all of the dressings should be included in this section. While there is much information about definitions and descriptors of surgical dressings in the literature, we would recommend that AHRQ use definitions that are currently contained the DMEMAC local coverage determination (LCD) for surgical dressings to be consistent. For correct examples of each category, AHRQ can turn to the listings in the Medicare Pricing Data Analysis and Coding (PDAC) website (www.dmepdac.com) . There should be noted that there is a difference within this category between traditional wound care dressings (i.e. gauze) and advanced wound care dressings (all the other categories). The example used in the question (i.e. dressings with active chemical, enzymatic, or antibacterial component(s)] may not really accurately encompass the variety of advanced wound dressing so we are deleting those words. We would also recommend the following:
        - Collagen dressings should be a category by itself—it should not say ECM (which should not include OASIS products)
        - Enzymatic products should be removed from the surgical dressing category since they are biologics (see next section)
        - Contact layers and hydrogels should also be included since they are indicated for the treatment of venous stasis ulcers.

- ***Acellular biomaterials-*** examples include but are not limited to: OASIS Wound Matrix, OASIS Ultra Tri-Layer Matrix (ones that are indicated for venous ulcers)
- ***Biologics-*** examples include but are not limited to: TheraSkin, SANTYL Collagenase ointment, AlloSkin, APLIGRAF (ones that are indicated for venous ulcers)

5. In addition to our recommendations on the reorganization of Table 1, we also have some concerns regarding its accuracy. Our concerns include the following:
    - **a.** We question the need to have the first column addressing functional categories since it may not be relevant to the table (the other columns of types, characteristics, functions and examples seem to be the information that is most important) and the terminology is not accurate. Examples include:
        - **i.** The functional category of Low Water Vapor Transmission Rate (WVTR) does not apply to all hydrocolloids. Additionally, manufacturers measure and indicate WVTR (or more appropriately Moisture Vapor Transmission Rate-MVTR) by various methods and the descriptor "Low" is a relative term and not well defined.
        - **ii.** The term "antibacterial" does not really define the scope of the products that are included in this category. Instead, we would recommend that the term "antimicrobial" be used since this would encompass the categories of antibacterials, antifungals and antiseptics. This terminology could then be included in the category of "type of advanced wound category" instead of functional categories.
    - **b.** In the foam category, we recommend that the words "semi-permeable polyurethane foam" be eliminated under "characteristics" since not all foams have that characteristic. In fact, many are made of products other than polyurethane.
    - c. In the composite category, a waterproof cover should be included in the definition since that is included in the DME MAC surgical dressing LCD.
    - d. In the "characteristics' section of the antibacterial dressing category (which again should be termed "antimicrobial dressing category)," gentian violet, polyvinyl alcohol with methylene blue, cadexomer iodine and chlorhexidine and derivatives should be included. Also the correct spelling for the term PHMB is polyhexamethylene biguanide.

Recommendations: We would suggest that question 1 be broken into three questions and compare advanced surgical dressings, acellular biomaterials, and biologics with compression systems against solely a compression system. Thus, the questions would be:

> ***1A For patients with chronic venous leg ulcers, what are the benefits and harms of using advanced wound dressings in conjunction with compression systems as compared with using solely compression systems?***

1B For patients with chronic venous leg ulcers, what are the benefits and harms of using acelluar biomaterials in conjunction with compression systems as compared with using solely compression systems?
1C For patients with chronic venous leg ulcers, what are the benefits and harms of using biologics in conjunction with compression systems as compared with using solely compression systems?

CONCLUSION

The Coalition appreciates the opportunity to provide AHRQ with our comments. As stated earlier, we would be pleased to serve as a resource to you now or in the future. If you have any questions, or would like further additional information, please feel free to contact me.

Sincerely,

Marcia Nusgart R.Ph.

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Executive Director