ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

COMMENTS AT AUGUST 26, 2015 SURGICAL DRESSING LCD PUBLIC MEETING

My name is Kara Couch and I am a family nurse practitioner and certified wound specialist, representing the Alliance of Wound Care Stakeholders ("Alliance"). The Alliance is a nonprofit multidisciplinary trade association of physician medical specialty societies and clinical associations whose mission is to promote quality care and access to products and services for people with wounds through effective advocacy and educational outreach in the regulatory, legislative, and public arenas. All of the members use surgical dressings in their practices and thus have a vested interest in ensuring patient access to these important supplies. We appreciate the opportunity to speak today but would have welcomed an opportunity to engage in a conversation with you before the policy have been released to take advantage of our expertise, which could have perhaps resolved some of our concerns.

I have been working in wound care and limb salvage for the past 12 years and been a representative to the Alliance for many years. My early background is in diabetic limb salvage while working at MedStar Georgetown University Hospital and I then worked at Walter Reed National Military Medical Center on our war wounded. Currently I am working in the Department of Rheumatology in the Wound Healing and Limb Preservation Center at George Washington University Hospital. I speak locally and nationally on wound care topics and have authored or co-authored numerous publications in peer-reviewed journals. Over the past few years, I have been focusing on wound care guidelines and policy and how it impacts our patients and outcomes. I am the current co-chair of the International Consensus Venous Ulcer Guideline for the Association for the Advancement of Wound Care and have also been on the guidelines committee for the past 7 years. Just recently, I was one of the clinicians representing the Alliance at an FDA meeting addressing the updating of the Agency's 2006 Wound care guidance document.

While I am speaking on behalf of the Alliance of Wound Care Stakeholders, many of my comments are based on my own personal clinical experiences treating patients with wounds.

When I initially reviewed the draft policy on surgical dressings, I was very concerned as I believe there is a lack of understanding of the wound care products and how they are utilized on patients. From my understanding, the draft policy is an update to policy that was written over 20 years ago. Much has changed in wound care and surgical dressings over that time frame. We have become "smarter" with our products and are able to have a single dressing serve multiple functions for the wound, (i.e., exudate management, debridement, odor control, bioburden management, and atraumatic removal.) This follows the "keep it simple" principle as the burden for wound care is often left to the patients and their caregivers and a complicated dressing regimen is not typically advised.

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The Alliance's concerns regarding the LCD include but are not limited to:

- Removal of clinical judgement in the LCD language
- New Coverage criteria
- Lack of clarity which leads to confusion
- Bibliography

Our comments will be more detailed but here are some examples of our concerns:

As a clinician, my first obligation is to my patient and it is important that I have the flexibility to use the wound care products and procedures appropriately to heal my patient's wound. Typically, my decision to use a product is based on the wound appearance and its characteristics as well as my goals for healing. Clinicians need to have the ability to use their clinical judgement in cases to change the dressing on the wound depending on how it is healing. Therefore, we have concerns that the DMEMACs have eliminated the term "usual" in describing many of the utilization parameters such as in specialty absorptive and transparent film and request that this term be included in the final LCD.

We also have concerns with the new coverage criteria for some of the dressings. For example:

Composite dressings are listed as being covered for moderately to highly exudative wounds. However, the dressing change frequency is up to three times per week. This is contradictory when you are treating a highly exudative wound that typically requires daily dressing changes. Similar language exists for foam dressings. This is contradictory to the language used for alginates which allows for daily dressing changes although foams and alginates are used for exudates management and can have similar absorption capabilities.

In addition, there is unclear language in the LCD which must be clarified. For instance, on our Alliance calls, we have had discussions based on our interpretation of the LCD and new policy articles whether multi component dressings that include the non-covered items of silver, honey and other products are covered and reimbursed. In addition, we don't understand how the 50% by weight issue was determined by the DMEMACs. We would appreciate it if these issues could be clarified today so we can focus on the correct issues when we write our comments.

The Alliance clinicians would be very concerned if both honey and silver dressings are no longer being covered and reimbursed according to this LCD and policy article.

Quite frankly, I have no idea what I would have used to treat my military wounded patients if they were Medicare beneficiaries without iodine, honey and silver. Their infections were so severe, they needed a multimodal approach to heal their wounds. Just last week, I had a patient with a dehisced abdominal wound have a positive wound culture for carbapenem resistant E.coli. She is being treated with an iodine based dressing since I have no systemic options for her. This is not going to change in the future. This is one of many examples where a product that the LCD has listed as being non covered has helped a patient. I can give you many other examples of other products using honey, silver as surgical dressings to reduce the bioburden in the

wounds. The ability to apply a silver impregnated alginate or honey-impregnated alginate on a wound should be based on my judgment as a clinician and not dictated by a policy which doesn't allow for appropriate therapy based on some arbitrary designation of components. In addition, I don't believe that I have ever given any thought to the "weight" of a product's composition until I read this draft. I have written numerous papers on dressing selection and this is simply not a factor in clinical decision making.

Finally, the Alliance members have reviewed the bibliography and question how the articles support the language in the LCD.

Overall, the language in this draft policy does not reflect real life for wound care clinicians and the challenges that we face to treat surgical wounds. Clinicians need to be able to have flexibility to treat the wounds that we see. In wound care, we don't often deal in absolutes, i.e. "dressing change is up to three times a week. We try to be cost conscious and utilization thrifty by using one dressing for multiple functions but this draft takes away that ability in many instances and seriously negatively impacts patients who already have issues with wound healing.

We appreciate the opportunity to speak today and will be sending you more details in our written comments. Thank you.