ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

September 11, 2017

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RE: Application of New Provisions of Surgical Dressings LCD (L33831)

Dear Drs. Mamuya, Hoover, Brennan, and Gurk

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), we write on behalf of our members to request your assistance in clarifying certain issues contained in the recently implemented Surgical Dressing LCD (L33831) that have created confusion among physicians, clinicians, patients, surgical dressing manufacturers, and DMEPOS suppliers. While we appreciate your letter dated August 18, 2017, which addressed some of the questions raised by our stakeholders and the September 7, 2017 DMEMAC articles, we continue to confront important requests for clarifications that are critical to treating physicians, patients, and suppliers. Since the publication of the final effective LCD, the questions listed below have been posed by Alliance physician medical specialty societies and clinical specialty societies, whose members include wound care physicians and clinicians who possess expert knowledge in complex chronic wounds and in wound care research. Despite these stakeholders' and our best efforts to interpret the new language of the LCD, there continues to be significant disagreement and confusion over how the LCD provisions apply. Unfortunately, inconsistent interpretations have led to direct impacts on patient care.

We anticipate the questions can be answered quickly and directly by you, but without any other explanation available beyond the language of the LCD, no one else has been able to do so. As complications related to the LCD continue to mount, we ask for and very much appreciate your prompt attention to these questions. To the extent these questions would be better addressed on a call with one or more medical directors, we would be more than happy to schedule a time in the near term to discuss these issues.

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1. Collagen Dressings

The coverage criteria applied to collagen dressings in the new LCD have created significant confusion among physicians, clinicians, manufacturers and suppliers regarding the scope of wounds covered and utilization limits that apply. The relevant language is copied here:

> *A collagen-based dressing or wound filler is covered for full thickness wounds (e.g., stage III or IV ulcers) wounds with light to moderate exudate, or wounds that have stalled or have not progressed toward a healing goal. They can stay in place up to 7 days, depending on the specific product. Collagen based dressings are not covered for wounds with heavy exudate, third-degree burns, or when an active vasculitis is present.*

The first sentence appears to identify three different types of wounds for which collagen-based dressings or wound fillers will be covered: (1) full-thickness wounds; (2) wounds with light to moderate exudate; and (3) wounds that have stalled or not progressed toward a healing goal. This coverage statement would be consistent with clinical evidence demonstrating the safety and effectiveness of collagen dressings for use in all these wound types. We would appreciate your clarification of this three-pronged interpretation of the sentence, and whether it is consistent with your intent.

With regard to the frequency of dressing change, the LCD appears to recognize that collagen dressings must be changed on a regular basis, depending on healing progression and the stage of the wound (as well as instructions of the dressing manufacturer), but in some cases may stay in place for a maximum of 7 days. The statement that dressings can stay in place "up to 7 days, depending on the specific product," however, has created confusion among suppliers and distributors, who are more familiar with the traditional format of utilization limits set out in the LCD for other dressings (e.g., limiting transparent film changes to "up to 3 times per week" or contact layer dressings "up to once per week"). To clarify this statement, we ask that you provide clarification as to whether the following statements are consistent with the LCD:

- The LCD suggestion that collagen dressings may stay in place up to 7 days, depending on the specific product, does **not** impose a one-dressing-per-week utilization limit for collagen dressings; and

- That collagen dressings may be changed as frequently as indicated by the condition of the patient and wound and the clinical judgement of the treating physician.

2. Wound Staging

Since the surgical dressings identified in the LCD could be applied to a variety of wounds types, the references to wound stages in the LCD—combined with the inclusion of the 2016 Revision of the National Pressure Ulcer Advisory Panel (NPUAP) definitions of pressure ulcer staging—create confusion over what types of wounds will support Medicare coverage. The NPUAP stages relate only to pressure wounds. Yet throughout the LCD, the coverage criteria reference stages for wounds of different etiologies (i.e., wounds that are not pressure injuries). There are other staging criteria that apply to these wounds, such as the Wagner staging criteria applicable to diabetic foot ulcers. The inclusion of only the NPUAP staging system, combined with references to wound stages for wounds that are not pressure injuries, creates significant confusion as to the application of the staging criteria.

Although the use of different staging systems does create confusion among physicians and suppliers, the characterization of a wound as "partial thickness" or "full thickness" can be applied universally among all types of wounds. We ask that you clarify which areas of the LCD are intended to address only pressure injuries, if any.

For instance, in the coverage criteria applied to hydrogel dressings, the LCD states "hydrogel dressings are covered when used on full thickness wounds ***(e.g., stage III or IV ulcers)*** with minimal or no exudate. Hydrogel dressings are not reasonable and necessary for ***stage II ulcers***." While a stage II pressure ulcer under the NPUAP system would not generally qualify as a full-thickness wound, under certain other wound staging systems (such as the Wagner scale), a stage II ulcer can be a full thickness ulcer extending to ligament, tendon, joint capsule, or deep fascia. In light of this example of the other references to stages of wounds in the policy, we would appreciate feedback on the following interpretations:

- That hydrogel dressings are reasonable and necessary for use in treatment of full thickness wounds with minimal or no exudate, even if that wound is identified as "stage II" under a non-NPUAP staging system;

- When the wound is not a pressure ulcer, the LCD's characterization of a wound as "full thickness" or "partial thickness" applies for purposes of coverage, rather than the NPUAP wound staging definitions that apply only to pressure injuries; and

- That hydrogel dressings are only noncovered for use in treatment of NPUAP stage II pressure ulcers (i.e., partial thickness wounds), as opposed to full-thickness wounds that would be characterized as "stage II" wounds (e.g., Wagner Grade II).

* * *

The Alliance greatly appreciates your consideration of these questions and your prompt clarifications. I would be happy to discuss any of these issues in greater detail. Please do not hesitate to contact me at 301-530-7846 or marcia@woundcarestakeholders.org.

Sincerely,

Marcia Nusgart R.Ph.
Executive Director