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October 13, 2017

Marcia Nusgart, R.Ph.
Alliance of Wound Care Stakeholders
5225 Pooks Hill Road, Suite 6275
Bethesda, MD 20814-2052
Via email to marcia@woundcaresatkeholders.org

Re: Nusgart/AWCS Response to September 11, 2017 letter

Dear Ms. Nusgart,

The Durable Medical Equipment Medical Directors have reviewed your September 11, 2017 letter sent on behalf of the Alliance of Wound Care Stakeholders asking for assistance in clarifying issues in the LCD that may create confusion. Our response to the questions that you raised in that letter is contained below.

Collagen Dressings

Your letter comments that the coverage criteria for collagen dressings in the new LCD have created confusion among clinicians, manufacturers, and suppliers about utilization limits and the scope of wounds that covered.

You specifically cite the LCD sentence which reads “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.”. You ask if this means that the following wound types are included:

1. full-thickness wounds;
2. wounds with light to moderate exudate; and
3. wounds that have stalled or not progressed toward a healing goal.

We understand your point to be an inquiry attempting to discern whether only wounds with all three characteristics are covered versus whether each is an independent criterion that justifies coverage. The latter interpretation is correct. Each of the specified wound types are independent criteria that can justify coverage.

Your letter also states that the LCD creates confusion by stating that collagen dressings can “stay in place up to 7 days, depending on the specific product”. You ask if the following represents the intended interpretation of this passage:

1. 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
2. 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.

Both statements of interpretation are correct. The DMDs understand that these dressings have change frequencies that may vary from as little as once per day to once per seven days depending upon the wound characteristics. We are unaware of any common clinical scenario where these dressings being changed less frequently than weekly. Please note, all collagen dressings are equally subject to this requirement. Change frequency for any dressing is determined by the clinical needs of the wound. Some have misinterpreted the passage, "…*depending on the specific product",* to mean that the change frequency is determined by the manufacturer instructions for a specific dressing. For Medicare policy purposes, all products described by a HCPCS code are equivalent and interchangeable. Choice of an individual product is controlled by the product specified by the ordering physician if they have a preference. If the ordering physician does not specify a product, the supplier should defer to the product choice of other clinicians (not associated with the supplier) providing care to the beneficiary, or beneficiary preference.

Wound Staging

Your letter also comments on the inclusion of the NPUAP Wound Staging System. You note that inclusion of this staging system creates confusion since it is the only wound staging system referenced in the LCD, and that this staging system is only applicable to pressure ulcers.

The NPUAP wound stage system in the current LCD is the updated version of the staging system, published by the NPUAP in 2016. The NPUAP staging system was referenced in the prior versions of the LCD. The versions included in prior LCDs were the most current version of the staging system in effect at the time of the prior LCD publication. The update that was done in the current LCD merely reflects inclusion of the most up-to-date version of this wound staging system.

The NPUAP wound staging system has been accepted as the standard to be used for pressure wound staging for a significant period of time. We are also aware that there are other grading/staging systems that may be used in defining surgical wounds, including the Wagner Scale that you mention, all of which have some degree of acceptance and clinical utility. However, unlike the NPUAP system, none has emerged to be the "gold standard" for wound staging and none appear to have gained broad-based acceptance among the clinical community. It is important to note that the LCD neither mandates nor proscribes the use of the NPUAP staging system. This system continues to be included as a useful reference.

Finally, you cite the LCD coverage criteria statement on hydrogel dressings being covered when used on "full-thickness wounds (e.g. stage III or IV ulcers) with minimal or no

exudate". You note that hydrogel dressings are not reasonable and necessary for "stage II ulcers". You offer 3 alternative interpretations of this hydrogel passage and ask which, if any, is the correct interpretation. Your choices were (renumbered for ease of reference):

1. 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; or,
2. 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; or,
3. 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).

Interpretation 2 is correct. Hydrogel dressing are covered on any full thickness wound that has minimal or no exudate. You will note that the reference to staging is listed as a parenthetical example (e.g). The non-coverage passage that references "stage II" is intended to indicate that partial thickness wounds, of any type, will not justify coverage of a hydrogel dressing. We apologize for any confusion.

We hope these responses adequately address your questions regarding the surgical dressing LCD.

Sincerely,

Peter J. Gurk, M.D.
On behalf of

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