By electronic mail to: DMACDraftLCDComments@anthem.com

September 21, 2015

Stacey V. Brennan, M.D., FAAFP
Medical Director, DME MAC, Jurisdiction B
National Government Services
8115 Knue Rd
Indianapolis, IN 46250-1936

Re: PROPOSED/DRAFT Local Coverage Determination (LCD) for Surgical Dressings

Dear Dr. Brennan:

The American Association for Homecare (AAHomecare) submits the following comments on the proposed/draft LCD for Surgical Dressings. The draft LCD proposes to:

- Add a section for collagen dressings
- Add a section for zinc-paste impregnated gauze
- Add a section for dressings comprised of materials not recognized as effective
- Revise requirements for incompatible dressing materials
- Revise requirements for incompatible dressing change intervals, and
- Revise utilization (change interval) requirements.

AAHomecare represents durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers, manufacturers, and others in the homecare community. AAHomecare members include manufacturers, suppliers and clinicians who make these wound care technologies available to Medicare beneficiaries. These comments are informed by their special expertise and experience in working with individuals who need these.

Based on our members' analysis of the draft LCD, AAHomecare requests that the DME MACs withdraw the draft to allow more in-depth opportunities for stakeholders and DME MAC Medical Directors to discuss the proposals' impact on access to these technologies. We believe the draft is inherently flawed because it displaces the clinician's judgment and ability to match a dressing to the wound care needs of a specific patient; withdraws coverage for dressings containing honey; creates inconsistent and confusing standards for the use of primary and secondary dressings and proposes ambiguous utilization standards for collagen dressings. We discuss our concerns in more detail below.

1. A final LCD must include room for clinician judgement in matching a dressing to the specific needs of a patient.

The draft LCD appears to leave no room for clinicians to use their judgment in deciding how to treat wounds based on the specific needs of a patient. This becomes evident upon a close reading of the draft. The terms "usual" or "usually" have been removed through the entire document. For example, under the section "Alginate or Other Fiber Filling Dressing," the DME Mac's have eliminated the term "usually" in connection with the use of these dressings in combination with hydrogels. The draft LCD proposes to make similar changes under the sections for contact layer dressings and foam or wound fillers as well as in other sections throughout the draft.

The effect of these edits is to limit coverage for dressings based on a practitioner's determination of what will work for the patient given the type of wound that is present and the patient's overall medical condition. In the absence of *conclusive* medical evidence that supports noncoverage of a type of dressing under specific circumstances, it is important for Medicare policy to defer to a clinician's judgement on what is best for his or her patient. If the DME MACs intend to limit coverage by restricting clinical judgement, then the contractors must explicitly articulate the data that supports their decision and allow all stakeholders an opportunity to evaluate and comment on the data.

We believe that this fundamental flaw in the proposed LCD supports our recommendation to withdraw the draft LCD.

2. Product Specific Comments

2.1 Collegan Dressings And Wound Fillers

The LCD proposes to add a new section addressing collagen dressing and wound fillers. This section contains new criteria that limit coverage for these to "full thickness" wounds with light-moderate exudate or wounds that have stalled. As a threshold matter, we do not understand why patients should have to wait until their wounds have stalled before being eligible for Medicare coverage of collagen dressings.

More importantly, we again question the basis for these coverage restrictions, especially in light of the DME MAC comments at the LCD meeting that the bibliography they published with the draft is not final. As we noted above, our ability to comment on the proposed revisions is limited without having been fully informed of the clinical studies the MACs propose to support the revisions. Once more, we believe that our concerns support our recommendation that the DME MACs withdraw the draft LCD.

If the contractors reject this recommendation, then we suggest they adopt more explicit utilization guidelines for these products. The draft states that these dressings can "stay in place 7 days depending on the product." To avoid confusion among suppliers, we suggest that they revise the language as follows:

Remove

"They can stay in place up to 7 days, depending on the specific product."

Add

"Dressing change is up to once per day."

2.2 Contact Layer

The section addressing contact layer dressings proposes to limit the use of a contact layer with dressings with all dressings out except gauze-based dressings and limits utilization to one dressing change in seven days. Not all dressings can stay on for 7 days. The condition of the wound is a better benchmark to guide the frequency of wound changes in this situation because high exuding or infected wounds would will need more frequent changes. This is one more example for why it is important that LCD preserve clinicians' ability to use clinical judgment.

2.3 Foam Dressings or Wound Filler

Language changes under this section of the draft limit to only three dressing changes per week instead of letting the physician have flexibility on deciding whether another frequency for changes is more suitable given the specific circumstances of a patient's wound care needs. We reiterate that unless there is explicit data to support noncoverage of a dressing except as stated in the LCD, the DME MACs must permit clinicians to use their judgment to determine what is in a patient's best interest.

2.4 Foam Dressings or Wound Filler

We request that the DME MACs provides definition for "foam." Otherwise, our comments for this section of the LCD are the same as our comments under 2.3 above.

2.5 Hydrocolloid Dressings

Again, the proposal to restrict the frequency of dressing changes to only three times a week is too restrictive and limits a clinician's ability to use his or her judgment in deciding whether a dressing need to be changed more frequently.

2.6 Hydrogel

Again this section limits coverage for these dressings, but we are unclear what, if any, evidence supports this decision.

3. Comments on Miscellaneous Issues

Under the miscellaneous section of the proposed LCD, we recommend that the DME MACs make the following, specific changes to the language of the policy:

Remove

"It is not reasonable and necessary to use a combination of products with differing change intervals. For example, it is not reasonable and necessary to use a secondary dressing with a weekly change frequency over a primary dressing with a daily change interval. Such claims will be denied as not reasonable and necessary"

Add

"Product combinations with different change intervals will be limited to the lesser change frequency of the primary or secondary dressing. It is not reasonable and necessary to use a secondary dressing with a weekly change frequency over a primary dressing with a daily change interval, dressings that exceed the weekly change frequency denied as not reasonable and necessary".

Remove

"It is not reasonable and necessary to use a secondary dressing with primary dressing that contain an impervious backing layer with or without and adhesive border."

Add

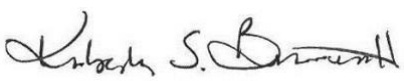
"It is not reasonable and necessary to use a secondary dressing with primary dressing that contains an impervious backing layer with an adhesive border."

4. Conclusion

We reiterate our recommendation that the DME MACs withdraw the draft LCD until they have published a complete bibliography to support their proposal to restrict coverage for surgical dressings. AAHomecare appreciates the opportunity to support these comments.

Please feel free to contact me should you have any questions.

Sincerely,



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