

Wound Care Manufacturers

March 15, 2021

Policy Drafts
Noridian Administrative Services, LLC
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Submitted electronically to policydraft@noridian.com

RE: Noridian Draft Local Coverage Determination (LCD) – Wound Care (DL38902) and Local Coverage Article: Billing and Coding Wound Care (DA58565)

Dear Dr. Clark,

On behalf of the Coalition of Wound Care Manufacturers (“Coalition”), I am submitting the comments that were addressed by Karen Ravitz at the recent Noridian public meeting on these issues. We recognize that Noridian provides a written transcript of this public meeting and we thought it might be helpful to you to provide these comments in a written format also.

The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds including those that are the subject of this public meeting. The Coalition has had a long history of working with the A/B and DME MAC medical directors as they have developed medical policies. The Coalition is a non-clinical association member of the Alliance of Wound Care Stakeholders and thus we support their submitted written comments. We respectfully request that you also take into consideration their recommendations which may be updated from what is stated below.

There are two issues we ask that Noridian consider to change in its final LCD and policy that we addressed in our oral remarks: definition of “advanced dressings” and consistency between the LCD and the LCA.

Definition of Advanced Dressings

The first is regarding the definition that Noridian has used regarding advanced dressings under the section: Dressing changes for wound debridement. The draft LCD states:

Advanced dressings: Used with increasing frequency to provide gentle debridement in the treatment of acute wounds, chronic venous, diabetic and pressure ulcers.

We have concerns with this definition since the way it is written is incorrect. Not all advanced dressings debride. Advanced dressings are very diverse such as: collagen, composite, contact layers, foam, hydrocolloid, hydrogels, alginates, fiber gelling products, specialty absorptive and transparent film.

Just as their technologies are different, so are their functions and/or mechanisms of action- which include but are not limited to:

- Absorbs drainage
- Hydrates dry tissue/provides a moist environment
- Maintains moisture or protects tissue
- Conforms to depth or contours
- Provides active bacterial control
- Provides odor control
- Enables autolytic debridement
- Helps w/deposition & organization of new collagen fibers and granulation tissue formation

Advanced wound care treatments revolve around the principle of moisture therapy, which provides adequate moisture to the wound to encourage natural cell repair, while at the same time allowing the wound room to breathe. Film dressings are designed to adhere firmly to the skin surrounding a wound without sticking to the wound itself. This moist environment helps prevent necrosis, which is death of cells/tissue through disease or injury. Hydrogels are designed to keep dry wounds moist; they're especially useful for deeper wounds; hydrocolloid dressings contain hydrophilic substances such as cellulose and gelatin, which absorb dirt, fluids, bacteria, which form a protective gel mass.

In the past, MAC policies referred mostly to advanced dressings' autolytic properties in order to qualify for coverage under the *surgical* dressing benefit. The expansion of the definition of debridement in 1994 beyond surgical debridement to include autolytic was what allowed the Surgical Dressing Policy to expand coverage to include advanced wound dressings and not just standard or traditional gauze dressings

Taking all of this into consideration, we ask that Noridian considers the following definition for advanced dressings in place of what is in the draft LCD:

Advanced dressings: ones with composition and structure designed to create an optimal wound environment by helping to remove dead tissue through autolysis or other debridement mechanisms, creating and maintaining a moist wound environment, and providing a bacterial and/or viral barrier to the outside environment.

(Note: Please note the updated recommendation below in the Alliance final comments which we support)

The revised language should read: *Advanced dressings should create an optimal environment for moist wound healing by facilitating autolytic debridement; controlling moisture levels; controlling bacterial levels; providing thermal insulation and/or physical protection; aiding in wound healing by having a positive impact on the various phases of wound healing; and/or as a delivery mechanism for medications or antiseptic agents.*

Categories of advanced dressings include the following, but are not limited to: alginates and/or other gelling fiber dressings, collagen dressings, composites, foams, super absorbent dressings, hydrocolloids, hydrogel dressings, specialty absorptive dressings, transparent films, compression bandages and gradient compression, and impregnated gauzes.

Consistent Language between the LCD and the LCA

It is not common for the documentation and utilization section to be contained in both the LCD and LCA as Noridian does for this Wound Care LCD. However, if Noridian wishes to place these sections in both, the language should be exactly the same – which currently it is not. The LCA

contains one additional requirement in the documentation section which is not present in the LCD. That language reads, “When the documentation, or lack thereof, does not meet the criteria for the service rendered or the documentation does not establish the medical necessity for the services, such services will be denied as not reasonable and necessary. Again, any language in one document should be mirrored in the other in the event that Noridian takes this unusual step.

There is also language in the LCA that acts like a utilization parameter – which is not only inappropriate, that same language is not contained in the LCD. Specifically, in the section discussing surgical debridements – which as an aside has inaccurate and outdated language – the policy states the following: *This A/B MAC allows payment for an aggregate total of one independent tissue debridement on a given day of service. **Any number greater than the aggregate total of four for one or both feet per date of service will result in a denial which may be appealed with documentation justifying the additional services.** Once debridement is properly done repeat debridement is not expected for several days afterward.*

The CPT clearly identifies what 11042-11047 are and, how they are defined. But Noridian is trying to go a step further and in its own description it appears a limitation is being placed within the policy article which is not appropriate. Utilization parameters go to the very heart of coverage and therefore this language should not be placed in the LCA, especially when it is not contained in the LCD itself.

Thank you for the opportunity to provide these issues with the draft LCD/LCA.

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Dr. Clark—we are submitting this to address the issues that are important to the members of the Coalition of Wound Care Manufacturers and to show our support of the similar comments submitted by the Alliance of Wound Care Stakeholders. We are happy to speak with you about any of these issues in more detail.

Sincerely,



Marcia Nusgart R.Ph.
Executive Director