COALITION OF
Wound
Care
Manufacturers

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Comments Submitted Electronically to policydmedraft@noridian.com

Re: DMEMAC Draft Surgical Dressings Local Coverage Determination (DL33831) and Policy Article (A54563)

Dear Dr. Moynihan,

On behalf of the Coalition of Wound Care Manufacturers ("Coalition"), I am pleased to submit the following comments in response to the DMEMAC draft surgical dressing LCD (DL33831) and policy article (A54563). The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds including those products that are subject to provisions contained in this draft LCD and policy article. In addition, many of our members had worked with the original DMERC medical directors when creating the original surgical dressing policy in the 1990's. Therefore, we have a vested interest in ensuring that our comments are taken into consideration by the DMEMAC medical directors.

General Comments

The Coalition appreciates that the DMEMAC has revised the surgical dressing draft LCD. We were eagerly awaiting a balanced, new policy that definitely needed revision. However, as the DMEMAC and the rest of the audience heard repeatedly during the public meeting on August 26, 2015, this draft LCD is problematic and needs to be withdrawn. There are multiple issues with the draft LCD from a lack of clarity to a lack of clinical evidence to support the proposed language. The draft policy, as it is written, will eliminate coverage of products that have been used by clinicians to help treat patients with chronic non-healing wounds and which have become part of their clinical protocols.

Furthermore, by eliminating the terms "usual" or "usually" throughout the entire document, the policy as written has taken away any flexibility in clinical judgment that clinicians have when treating patients with chronic non-healing wounds based on their individual wound care needs. As drafted, the finality in the utilization parameters is often

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contrary to not only the manufacturers' instructions for use (IFU), but also clinical practice.

Our recommendation is to request that the DMEMAC medical directors withdraw this draft LCD and work with all stakeholders to establish a policy that is clinically relevant, transparent, and conforms to current clinical practice guidelines.

Our specific comments follow.

Specific Comments

DMEMAC Medical Directors Are Exceeding The Scope of Their Authority in Draft LCD

First, the contractors are exceeding the scope of their authority to promulgate an arbitrary weight-based coverage standard to deny access to multi-component dressings. The Social Security Act authorizes CMS to pay for items and services considered to be medically reasonable and necessary for the Medicare population. The statute defines items, in part, as finished medical devices. The items we are dealing with here are multi-component surgical dressings. Neither CMS nor its contractors have the authority to judge the medical necessity of an item by evaluating the medical necessity of the item's ingredients or in this case materials. The proposed LCD leaps from the term "item" to the term "materials" without any legal basis.

The materials identified in the draft policy that the DMEMAC considers to be reasonable and necessary, ARE in fact the items. That is, substrate-only dressings that have historically been recognized as the clinically predominant component in multi-component dressings.

Furthermore, the DMEMAC has provided a list of ingredients included in multicomponent dressings which lack sufficient evidence of safety and effectiveness. When manufacturers submit their surgical dressing products to the FDA to gain FDA approval/clearance, they are not receiving clearance on the individual items of the surgical dressing rather, the FDA approves products containing these ingredients for safety and effectiveness – products which have been used by clinicians to treat their patients with wounds for years.

If CMS's contractors acted within the scope of their authority, then they would rely upon the FDA's clearance of the finished item – again a medical device in FDA terms – to accept the fact that multi-component dressings are safe and effective for their intended use.

Acting outside the scope of its statutory authority, the DMEMAC is putting misplaced emphasis on the safety and effectiveness of the ingredients added to multi-component dressings, rather than on the finished product in order to eliminate existing coverage.

For this reason alone, the proposed LCD should be rescinded.

Multicomponent Dressing Coding and Coverage Violation -

A second reason why this draft LCD should be rescinded is that it actually has been in effect since mid-June. Since that time, several honey-impregnated dressings were assigned code A4649 and, now, miscellaneous codes are proposed in the draft policy article for honey and other multi-component dressings. The DMEMAC is also proposing that claims submitted with A4649 will be denied because these dressings are not proven to be reasonable and necessary. However, claims submitted with A4649 have already been denied on this basis.

The implementation of this proposal, therefore, violates chapter 13.7.4.2 and 7.4.3 of the Medicare program integrity manual. The rules require that the public comment period be open for 45 days and **after** those comments have been considered and the LCD has been finalized there be a minimum 45 day notice period **before it is effective**. The DMEMAC has gone through the formality of issuing a draft LCD and policy article, however, the effects of the policy regarding multicomponent dressings have already been implemented.

To remedy both of these legal deficiencies, the Coalition recommends that the DMEMAC withdraw this proposed LCD, reinstate the codes these products had in place before they were improperly taken away on January 30th, and rely upon the 2005 policy as clarified on September 11, 2014 and again on June 12, 2015.

If, however, the contractors and CMS are determined to redefine the coverage and coding landscape to eliminate Medicare beneficiary access to multi-component surgical dressings, then to be in full compliance with its own legal requirements, the Coalition would expect any proposed LCD to:

- Clearly explain the basis for restricting current coverage of multi-component dressings as required by chapter 13.4 of the program integrity manual
- Not exceed its scope of authority as defined by the Social Security Act
- And truly be proposed – which requires CMS to reinstate the codes that were originally taken away January 30th for the reasons being proposed in this policy.

Concerns with 50% by Weight Metric

50% Metric for Multicomponent Dressing is an Arbitrary Standard Not Supported by Clinical or Scientific Evidence

The Coalition is extremely concerned by the manner in which the DMEMAC has drafted this policy and the lack of transparency used to establish new criteria in which multicomponent dressings are being "judged" and specifically we have two concerns:

1. It is unclear how the DMEMACs established the 50% by weight standard proposed in this policy.
2. Neither manufacturers or the SADMERC staff historically have used weight as an absolute metric in completing the coding verification application

First, it is unclear how the DMEMACs established the 50% by weight standard proposed in this policy. There certainly is no clinical or scientific evidence to support the 50% or this metric. There has been no transparency in terms of how this weight standard was developed or why. This standard is a significant departure from the clinically predominate metric that has been utilized for years and therefore the DMEMAC should be providing information to stakeholders regarding how this metric has been established, how this information will be verified and how it will be applied, uniformly to all products.

Weight has not been used historically as an absolute by manufacturers or by the SADMERC when submitting coding verification applications. When manufacturers submit code verification applications, the information provided on their application to show the composition of their product is based on whatever metric the manufacturer chooses to place on the application. To date, there has never been a requirement on the application that the composition of a surgical dressing be based on weight and most manufacturers have not used weight as the standard used to answer this question on the code verification application.

To verify this information, the Coalition did the following: First, we conducted an informal poll of our members and asked them how they answered the question on the PDAC verification form relating to listing the exact amounts of each component of the dressing and the percent of each component. The members always used percentages but they came by them in various ways—by circumference, thickness, drawings, volume, and weight. The majority however did not use weight. If they did, it was by choice and not because it was a requirement.

Second, we contacted a former manager of the SADMERC, Jennifer Hutter, to confirm historically whether the coding verification forms included weight as the standard. Ms. Hutter stated the following: "The coding verification application asks for percentage of the product and it is up to the manufacturer to state it. I know that the clinically predominant component of a dressing has not always been decided by weight. It has always been determined by percentage of the component. The percentage can be calculated by measurement (square inches), volume, or weight." Ms. Hutter has also submitted comments to this draft LCD and we recommend that they be taken under consideration.

Thus, the Coalition questions how the DMEMAC has arrived at the 50% by weight standard as the means by which coverage for certain products will be determined. It

appears that 50% is an arbitrary number without any specific justification. There certainly is no scientific or clinical evidence to support the 50% weight as a standard to be used. In fact, the Coalition requests that the DMEMAC provide the evidence used to establish this metric. The information in the bibliography provided by the DMEMAC did not provide any evidence to support this new metric.

The standard is and has always been based on the clinically predominant component. The Coalition recommends that the DMEMAC continue to use the clinically predominant component standard and provide the evidence by which they arrived at the 50% standard so in good faith manufacturers can see the transparency in your actions.

Concerns Relating to Miscellaneous Coding if No Single Material Comprises a Minority

The draft LCD states that the DMEMACS are planning to potentially move many products to a miscellaneous code if no single material comprises a majority, defined in this policy as 50.1% or greater in weight. There are several multicomponent dressings, which have 3 or more components within the dressing. By definition, then it is likely that no single component will weigh greater than 50.1%. So, it appears that the DMEMAC will be moving any product that does not contain 50.1% of one component into a miscellaneous code. This is very disconcerting to us and we do not understand the rationale behind this provision.

Enforcement of the 50% Weight by the PDAC Is Too Complicated to Implement

The Coalition also has concerns about how this new metric of weight will be enforced. Will the PDAC be re- code verifying all multicomponent dressings and request that the products not be sold until they are re-code verified? Will patients be taken off these dressings and then clinicians have to select other dressings to use? How will the agency verify that the information they receive from the manufacturer is correct? What type of standardized testing will the PDAC use to know whether a product meets the 50% by weight standard?

Concerns that the Correct Coding Article has Implemented 50% by Weight Standard before Draft LCD is Final

Finally, with respect to the 50% standard, the Coalition has a significant process issue. A Correct Coding Article was posted by the DMEMAC August 13, 2015. The same language included in the policy article (referred to in the proposed LCD) - which is currently open to public comment until September 21, 2015 – is also contained in the Correct Coding Article which has already been put into effect. We are concerned that the Correct Coding Article has been issued establishing the 50% standard prior to this LCD being finalized. The 50 % standard is a new proposed standard by which multicomponent dressings will be judged should that language be placed in the final

policy and by placing this standard in the Correct Coding Article, the DMEMACs are validating this standard even before the public notice and comment period runs its course and the LCD process is completed. Coverage and coding are supposed to be separate and distinct processes, however, it appears that this is not the case with respect to these products.

The Coalition recommends that the Correct Coding Article be withdrawn until the LCD has been finalized and any dressings currently submitted to the DMEMAC for coverage should be based upon the current policy and not on a standard which has yet to be finalized.

Concerns with Incomplete List of Dressings With Materials Not Recognized as Effective

The DMEMAC has provided a list of dressings with materials not recognized as effective. However, there is a caveat – the DMEMAC has also stated that the list is not exhaustive. This is extremely troublesome to manufacturers as it is impossible to develop new products without having an understanding of whether there will be coverage for these products. This will stifle innovation in the surgical dressing field. A full list of dressings that contain materials that are not recognized as effective should be provided in this policy. This is another area in which the draft policy is incomplete and is lacking in transparency.

Grandfather Provision

While the Coalition does not believe that the DMEMACs should be moving forward with the 50% by weight metric, if the DMEMACs do decide to move forward with this arbitrary and capricious standard then they should do so in a prospective manner and not retrospectively. As such, the Coalition highly recommends that the DMEMACs grandfather this provision of the LCD. This will allow for manufacturers to know what to expect moving forward so they can appropriately place the weight on their application for coding. However, since currently there is no requirement to place weight on the applications, the DMEMAC should provide for the grandfathering of these products.

Bibliography

During the August 26, 2015 public meeting, the DMEMAC medical directors indicated that the bibliography included in the proposed policy was incomplete and additional references were consulted as resources for the proposed LCD. The process of developing an LCD should be transparent and information forthcoming. If in fact the DMEMAC consulted additional resources, those resources should have been identified in the released draft policy. The public has a right to review the resources and without access to

that information, this draft policy is incomplete. As stated previously, this this policy should be rescinded as a result of the incompleteness of the draft policy.

Clinical Issues

The Coalition is a non-voting member of the Alliance of Wound Care Stakeholders, 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. The Alliance submitted clinical comments to this proposed LCD and policy article. We support the issues and recommendations that were submitted by them and ask that the DMEMAC implement their recommendations.

Conclusion

The Coalition appreciates the opportunity to provide you with our comments on this important draft policy. Should you have any questions or require any additional information, please do not hesitate to contact me.

Thank you for your consideration.

Sincerely,

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