COALITION OF

Wound
Care
Manufacturers

COMMENTS AT AUGUST 26, 2015 SURGICAL DRESSING LCD PUBLIC MEETING

My name is Karen Ravitz and I serve as the senior policy advisor to the Coalition of Wound Care Manufacturers ("Coalition"). 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 DME MAC medical directors as they have developed medical policies including helping to create the original surgical dressing policy. While the Coalition will be submitting formal comments to the draft surgical dressings LCD, we are highlighting today some significant areas of concern both within it and the policy article.

We appreciate that the DMEMAC has issued a new draft LCD, 20 years after the original surgical dressing policy was issued. However, there are several areas where we have concerns and would request. For the purposes of this public meeting, I have divided our concerns into three distinct areas:

1. Need for clarification of contradictory and confusing language,
2. Concerns regarding multicomponent dressings, and
3. Concerns regarding the publishing of the August 2015 correct coding article

We would have hoped not only that we would have been granted more than three minutes to present our concerns with this draft policy but also that this public meeting or another public venue would have provided the opportunity for the DMEMACs to give us and others clarification of these issues so that our written comments could be more focused on your intent of the policy. Instead, we are simply guessing on what you meant in writing the LCD and policy article.

Our first concern is there is conflicting language in the draft policy and article. For example, if one compares the language used in both the policy article and the LCD regarding coverage for such ingredients as medical

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grade honey and silver it is unclear whether the DMEMAC will cover any dressing which contains them in a multi component dressing if the amount is under 50% by weight

The language in the LCD states:

Dressings containing multiple components are classified based upon the clinically predominant component. Multi- component dressings predominantly comprised of materials not recognized as effective are not considered reasonable and necessary even if there is some minor proportion of effective materials included in the composition of the complete product. Claims for surgical dressings composed predominantly of materials not listed as reimbursable in the policy will be denied as not reasonable and necessary

Yet the policy article states,

Products where a single material comprises greater than 50% (by weight) of a product's composition are coded based upon the applicable specific HCPCS code for that material. If a specific HCPCS code does not exist for the predominant component, HCPCS code A4649 is used

So, if a multi component dressing has an ingredient such as medical grade honey, silver or PHMB component that is less than 50% and is being coded with the applicable specific HCPCS code for that material, will these dressings be reimbursed? Furthermore, if a multicomponent dressing has an ingredient such as medical grade honey or silver that is less than 50 % and there is a component that is more than 50 % that is a covered component will the dressing be reimbursable? We have had multiple conference calls with our members and other clinicians, and no one has a definitive answer with the language that is used.

Another example of language that needs to be clarified is collagen dressings. The language in the policy states, “a collagen dressing can stay in place up to 7 days, depending on the specific product”. Does this mean that only 1 collagen dressing can be used in a 7 day period? In their instructions for use, collagen products have ranges from daily dressing changes to once every 7 days. According to your language, the providers have the flexibility to

submit claims based on the products' instructions for use. The provision is not clear in this regard and as such, we question if this is the intent of the policy language. We have heard from our members' customers that perhaps they may like more specific utilization guidelines and either we or they will provide them to you in the formal written comments.

We also would like to have clarification on the definition of foam . The definition reads in part that "It has a nonadherent property over the wound site." we seek clarity on whether this means that there is a nonadherent layer

There are several other examples of this type of confusing or contradictory language which we will be providing in our comments and hope the DMEMAC will provide clarity prior to finalizing this LCD.

With respect to multicomponent dressings, we have three concerns. The 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 this metric.

Second, the DMEMAC is 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 don't understand the rationale behind this provision.

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, we did two things. First, we did an informal poll of our members and asked them how they answered the question on the PDAC verification form. 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.

Our members sometimes but not always used weight when providing the composition of their dressing. 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."

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 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.

Third, as a practical matter, 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 is the standardization method for the PDAC to know whether a product meets the 50% by weight standard.

Finally, with respect to the 50% standard, the Coalition has a significant process issue. A Correct Coding Article was posted August 13, 2015. The same language included in the policy article which is referred to in the proposed LCD - which is 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 standard by which multicomponent dressings will be judged and by placing this new standard in the correct coding article, the DMEMAC is validating this standard even before the public notice and comment period runs its course and the LCD process is completed. 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.

Thank you for the opportunity to provide some of our issues with your draft policy. As stated, the Coalition will be submitting more in depth formal comments.