COALITION OF

Wound Care Manufacturers

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Dear Drs. Brennan, Hoover, Mamuya, Moynihan and Hughes,

On behalf of the Coalition of Wound Care Manufacturers ("Coalition"), we are addressing our concerns related to the January 22nd DME MAC Correct Coding Article for Surgical Dressings Containing Non-Covered Components. The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds including surgical dressings that is subject to this correct coding article. The Coalition has had a long history of working both with the DME MAC medical directors as they have developed medical policy and especially the surgical dressing policy since its creation and the PDAC as it addresses processes for coding and coding verification.

We have two major concerns:

1. We understand that the DMEMACs have stated that this article is a simple clarification of how non-covered components should be coded. After having clarity of coverage for multi-component surgical dressings in the LCD based on the identity of the "clinically predominant component", we submit that such a fundamental change in how these products are coded and covered is more than just a simple clarification and should have been subject to a notice and comment period.
2. The consequence of this article is that the PDAC took no time in changing the coding of surgical dressings containing medical grade honey to a non-covered

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code. We disagree that these products should be non-covered. The process by which the PDAC reviewed and then changed honey impregnated dressings from a covered HCPCS code to a non-covered code was far from transparent, predictable, accurate, or understandable and leaves us confused and concerned.

In terms of our first concern, for over a decade, surgical dressing manufacturers have created surgical dressings with the knowledge of clear coding, coverage and payment guidelines that if they manufactured a product with multicomponent product, it would be coded based on the substrate—i.e. the clinically predominant component. However, now without any notice or comment, the DME MACs have stated that when the non-covered components comprise 50% or more of the dressing (which is an undefined metric), that the functionality of the whole dressing is viewed as not medically necessary by the DME MAC medical directors for the Medicare beneficiary. We completely disagree. Not only are we astounded by this new interpretation, it is a major shift in policy and is unacceptable to have this type of fundamental policy change without notice and comment.

We question the rationale for not covering a surgical dressing whose medical necessity has been established such as a hydrocolloid, hydrogel or alginate and that its functional properties are the primary reason for the clinicians to use them; yet, simply because there is a "non-covered" component in 50% or more of the dressing, it will now not be covered.

In addition, we are seeking clarification of how the DMEMACs and PDAC will define 50% of the dressing. We have concerns about how it will be determined (weight, volume, density) and will the same methodology be used for each surgical dressing and components?

In terms of our second concern, we do not understand why surgical dressings containing medical grade honey are now non-covered. On July 13, the Coalition submitted comments in response to the DMEMACs' request for evidence to support the use of honey-impregnated dressings. On September 11, after reviewing all the evidence, the DMEMACs issued a joint notice that stated, "there is insufficient evidence to justify the conclusion that medical honey should be considered as a separate, covered component in surgical dressings. HCPCS coding for honey containing surgical dressings will continue as it has been in the past i.e. HCPCS coding is based upon the underlying covered components". We agreed with this decision and believed that this issue was resolved. Yet three short months later, the PDAC issued a non-covered code for these dressings and the DME MACs issued their correct coding article on this issue.

We believe that the decision was arbitrary and are very concerned that the processes which should be in place to prevent such an egregious act, failed. Coverage and coding of honey impregnated dressings have been in place for 10 years based on the guideline that multicomponent dressings are based on the **clinically predominant component**. Yet

the article that was issued on January 22 was a material change to the coverage policy by eliminating the fundamental "clinically predominant component" element of the coverage analysis. Furthermore, the advisory statement did not specify how the percentage of a non-covered component was to be measured. As such, the process was flawed. A material change in coverage took place, with out notice and comment. There was and continues to be no transparency regarding the metric that was utilized to make this decision. If there was, it was not public, transparent or otherwise disclosed. The PDAC nor the DMEMAC should be making any ill-willed decisions without justification, nor should they tout a fundamental change in policy as clarification.

Therefore, we are requesting that the DMEMACs rescind the January 22nd DME MAC Correct Coding Article for Surgical Dressings Containing Non-Covered Components and if the DME MAC feels compelled to have a policy like this in place, then they should reissue in a manner subject to public notice and comment. We also request that the DMEMACs and PDAC immediately reverse its recent decision classifying medical grade honey as non-covered and restore the HCPCS codes that were in place for honey dressings prior to the January 22 article and January 30 PDAC decision.

Sincerely,

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