

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 continued concerns related to the January 22nd DME MAC Correct Coding Article for Surgical Dressings Containing Non-Covered Components and your recent response dated April 28, 2015. We respectfully disagree with several points made in your response letter. 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 believe that coding and coding verification is not a transparent process and this is just another example of such a process breakdown.

The Coalition maintains that there was a fundamental change in how medical grade honey impregnated dressings are coded and covered. In your April 28 letter, you stated that it was not a fundamental change and you were simply providing clarification. Yet the coding and coverage change was not a simple clarification, since the coding decision revoked coverage for nearly an entire group of products and should have been subject to a notice and comment period. As manufacturers we are very concerned about this point. When a standard has been set and products are measured against that standard for

coverage and coding for nearly ten years, any change to that standard IS a change in policy. Medical grade honey impregnated dressings have been a covered code and have been covered as part of the surgical dressing policy for years. The determining factor has been the **clinically** predominant component. Yet there is no mention of the clinically predominant component in your response letter. You stated that the decision was based on the predominant component. This too is a change in how these products have been measured.

Another point of concern that we have is that you stated in your letter that “a manufacturer prompted this request to reclassify this product and thus the DMEMAC issued a joint publication soliciting comments” – to which we did respond. As a result of the review, the DMEMAC did in fact issue the results of the review as you mentioned in your letter. What you neglected to state and address was the fact that the DMEMAC decided that medical grade honey would continue to be covered. So, to repeat, in the September 2014 DMEMAC notice, the DMEMACs stated,

Historically medical honey has not been considered as a separate, covered surgical dressing component by Medicare. Dressings incorporating honey have been assigned HCPCS coding based upon the underlying covered elements. For example, an alginate dressing with honey is put into the same HCPCS codes as an alginate dressing without honey.

The DME MAC Medical Director Workgroup reviewed the clinical literature and other evidence in consideration of whether medical honey should be considered as a separate, covered component in surgical dressings. The workgroup determined that 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.

Yet four months later, without warning, notice or any evidence, the DMEMACs issued a new coverage standard on January 22nd and the PDAC then applies that standard to downgrade multi-component dressings impregnated with honey to a non-covered code on January 30th. This determination of downgrading medical grade honey impregnated dressings ultimately resulted in non coverage by the DMEMAC – thus eliminating coverage to products that were covered in the past – one in which the DMEMAC, only a few short months ago stated that they would continue to cover. Again, not only is this not very transparent it IS a change in coverage policy and should have been subject to public notice and comment.

You have also cited the Program Integrity Manual for when you are permitted to avoid a notice and comment period. However, there are other sections of the Program Integrity Manual which suggest that once a product is covered – as medical grade honey impregnated dressings have been for nearly a decade– and the MAC makes a decision to

limit, or eliminate, that products' coverage in its LCD – they must put it forward for public notice and comment. Specifically section 13.7.2 of the Medicare Program Integrity Manual states that, Contractors shall provide for both a comment period and a notice period in the following situations: 1) All new LCDs 2) Revised LCDs that restrict existing LCDs - examples - adding non covered indications to an existing LCD; deleting previously covered ICD-9 codes 3) revised LCD that make substantive correction - if the contractor identifies an error published in an LCD that substantively changes the reasonable and necessary intent of the LCD then the contractor shall extend the comment/ad/or notice period by an additional 45 calendar days.” It is clear that the criteria by which medical grade honey was judged in the recent decision - significantly changed from when this product was covered previously. When this significant change occurs thus impacting coverage, we respectfully disagree with your notion that it does not have to go through the public notice and comment period. The revisions that you made did restrict an existing LCD.

The Coalition is extremely concerned regarding this process issue and the lack of public notice and comment before making this change in coverage. Manufacturers can not afford to continue operating when CMS and their contractors make such arbitrary decisions and do not follow the process by which they are mandated.

As such –we continue to request that the DMEMACs rescind the January 22nd DME MAC Correct Coding Article for Surgical Dressings Containing Non-Covered Components and instead issue it in a format for notice and comment since it had such fundamental changes. 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 medical grade honey impregnated dressings prior to the January 22 article and January 30 PDAC decision.

Thank you for your consideration.

Sincerely,



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