



May 9, 2015

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

On behalf of the Alliance of Wound Care Stakeholders (“Alliance”), I am responding to your April 28, 2015 response to our February 25, 2015 letter regarding the “Correct Coding of Surgical Dressings Containing Non-covered Components.” The Alliance of Wound Care Stakeholders is a nonprofit multidisciplinary trade association of health care professional specialty societies and 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 has significant concerns with your response and respectfully disagrees with several of your points.

Our overarching concern is the problematic comingling in this instance of a coverage and coding decision which, as we all know, are processes that should be made independently of each other. The process by which the January DMEMACs and PDAC decisions were made – were not independent or transparent. More specifically, the Alliance addresses below the following additional concerns from points raised in your letter.

First of all, we agree that the decision to cover or not to cover a product is within the purview of the DMEMACs. However, once a product is covered – as medical grade honey impregnated dressings have been for nearly a decade– and the DMEMACs make a decision to limit, or eliminate, that products’ coverage –but place it in a coding article rather than in an LCD obviates the opportunity for public comment as there should have been in this instance. It is clear that the criteria by which medical grade honey impregnated dressings were judged in the recent decision - significantly changed from when these products were covered previously. When this significant change occurs thus impacting coverage, we respectfully disagree with your notion that it should not have had to go through a notice and comment period.

Secondly, your letter stated that a manufacturer prompted this request to reclassify this product and thus the DMEMACs issued a joint publication soliciting comments. The Alliance did submit them in July 2014. As a result of the review, the DMEMACs did in fact issue its results as was stated in your letter. What your letter neglected to state and address was the fact that the DMEMACs decided that medical grade honey impregnated dressings 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 in the guise of a coding article on January 22nd and the PDAC then applied that standard to downgrade many medical grade honey impregnated dressings to a non-covered code on January 30th. Again, the wound care clinical community expects more from the DMEMACs and PDAC in terms of transparency and soliciting input than what was shown by these actions.

The last and most important point is that your letter completely dismissed a critical aspect of this whole issue: how to identify the “**CLINICALLY**” predominant component. For over 10 years, the DMEMACs and PDAC have provided coverage and coding based on clinical evidence of the clinically predominate component. Literature consistently supports the conclusion that the clinically predominant component is the substrate in a multi-component dressing. The DMEMACs recognized this point in their September 2014 release when they indicated they would continue to cover medical grade honey impregnated dressings based upon the underlying covered component. Yet, in the letter sent to the Alliance, it shifts to discussing the predominant component without any regard to the “**clinical predominance**”.

Once more, we emphasize that coverage and coding decisions should NOT be comingled. They should be made independently of one another. The process by which your decisions were made, were not independent or transparent. Unfortunately, the information in the coding article did serve as coverage criteria which instead should have been placed in a LCD since the changes were material and significant and thus should have been subject to notice and comment.

As we stated previously, none of the clinical associations whom we represent were afforded the right to offer comments prior to this change being implemented. According to our members who care for patients with wounds, the DMEMACs and PDAC’s decision have not only negatively impacted patient care but also have

created a financial burden to the Medicare beneficiaries that our clinical members treat. Thus, the change has caused, and continues to cause, a disruption in care for those Medicare beneficiaries, and the Medicare system and its patients have, as a result, incurred unnecessary expenses.

We again are urging the PDAC to immediately reverse its decision classifying many of the medical grade honey impregnated dressings as non-covered. Furthermore, we urge the DMEMACs to rescind their Correct Coding Article as it contains significant changes to the current policy without the ability for us to provide comment.

We look forward to hearing from you on this very important matter.

Sincerely,



Marcia Nusgart R.Ph.
Executive Director

cc: Laurence Wilson
Liz Richter