



February 25, 2015

Stacey Brennan, MD
National Government Services Inc.
P.O. Box 6036
Indianapolis, Indiana 46206-6036

Robert D. Hoover, Jr., MD,
CGS
Two Vantage Way
Nashville, TN 37228

Fred Mamuya, MD
NHIC Corp
75 Sgt. William B. Terry Drive
Hingham, MA 02043

Eileen M. Moynihan, MD
Noridian, LLC
PO Box 6747
Fargo, ND 58108-6747

Paul J. Hughes, MD
Pricing, Data Analysis and Coding
PO Box 6757
Fargo ND 58108-6757

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

The Alliance of Wound Care Stakeholders (“Alliance”), is providing this letter in response to the January 22nd DME MAC Correct Coding Article for Surgical Dressings Containing Non-Covered Components and the subsequent decision by the PDAC to no longer code surgical dressings containing medical grade honey as covered. This PDAC decision has had an immediate negative impact on patient care and the elimination of products which were part of the treatment algorithm in our members’ established practices. In this letter we are requesting that the PDAC immediately reverse its recent decision classifying dressings containing medical grade honey as non-covered. Furthermore, we request the DMEMAC rescind its Correct Coding Article since such substantial changes that have created a significant change to our members’ practice should have sought our physician and clinician members’ input, so that any substantive change to coverage would have been based on their input.

We have concerns and questions regarding both the DMEMAC article and the PDAC coding decision. The Alliance submitted comments on July 13, 2014 in response to the DME MACs’ request for evidence to support the use of honey-impregnated dressings. Specifically, the DMEMAC requested relevant clinical evidence discussing the accepted uses of medical grade honey in wound care. In the Alliance comments, we stated that medical grade honey is only a component of wound dressings similar to surgical dressings which contain silver. In both cases, the dressings’ substrates are impregnated with a secondary component. Since the evidence is inconclusive with respect to both silver and honey – these impregnated surgical dressings are classified simply as surgical dressings. The Alliance agreed with the current surgical dressing policy and believed that honey impregnated dressings should continue to be classified according to the substrate material to which the honey is an added component.

On September 11, 2014, based on the Alliance comments and others, the DME MACs 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 continued to provide this treatment option to our patients.

In regards to the PDAC, it has conducted multiple reviews in the past regarding this product category and has continued to place these products in covered HCPCS codes in the surgical dressing policy. Yet on January 22, only three months after the DME MAC issued its decision to cover this product the PDAC--without any warning, notice, request for information or published rationale-- decided to undertake a coding review and issued new codes for these products which are non-covered under the Medicare program.

The Alliance is extraordinarily concerned that the DME MAC article lacks any specificity on which components are defined as non-covered and the process for defining what non-covered components are. To our knowledge, there is nothing published. So how did the PDAC determine that this product that has been covered for 10 years, by which the DME MAC just conducted a review and determined it is a covered product just 3 short months ago is now non-covered? We would be interested in knowing what new information came to light – as we are unaware of any.

Unfortunately, once this decision was made, the PDAC immediately removed the surgical dressings containing medical grade honey from covered codes to the non-covered A9270 code even though they were covered for nearly a decade under the previous coverage standard. Not only is the PDAC decision a material change to coverage but now eliminating a group of products from our members’ treatment tool box without due notice or ability to offer comment has immediate implications for patient care.

First of all, it has eliminated a product category which our members have relied on for years. The first consideration from a clinician’s standpoint in treating a wound is how they manage the wound care environment and exudate. That drives their selection of the surgical dressing that contains the appropriate substrate and medical grade honey is supportive in its role.

Secondly, the elimination of this product category will cause an interruption of treatment protocols which, by DME MAC requirements, state in order to change an order the patient must be seen by a clinician. This will cost the Medicare program money as well as the patient (e.g., every time they are seen they are required to pay a copayment). We understand that an appeals has been filed. Therefore, the Alliance recommends that during the appeal process, the original code should remain until all levels of appeal have been exhausted. This would allow for clinicians to transition patients to other products if indeed a non-covered code is subsequently implemented.

Furthermore, the medical literature provides abundant data supporting the use of dressings incorporating medical grade honey for the management of a wide variety of wounds. However, the evidence is inconclusive concerning the independent beneficial effect of honey. Since honey is always combined with a dressing material, the benefit of the honey component has not been clearly distinguished from the salutary effects of the dressing products themselves. There are published guidelines for the treatment of chronic wounds including those published by NPUAP, AHRQ and AAWC. It is important to note that despite the existence of clinical

practice guidelines, wound care professionals tailor care protocols based on the needs of a particular patient or wound.

The Alliance is further concerned that the PDAC process was not an open, transparent process with defined processes. This is hugely problematic as the PDAC decisions impact our daily practices and the patients we serve.

In conclusion, the evidence supports wound dressings that incorporate medical grade honey as appropriate dressing choices for the management of a wide variety of wounds, but is inconclusive concerning the independent contribution of honey separate from the salutary effect of the dressing itself in managing wound exudate.

However, we are not in agreement with the latest decision by the PDAC and question its rationale for making this change just months after the DMEMAC issued their decision to continue to cover these products. We therefore urge the PDAC to immediately reverse its recent decision classifying dressings containing medical grade honey as non-covered and for the DMEMACs to rescind the correct coding article and revert back to classifying surgical dressings based on the clinically predominant dressing component.

Thank you for the opportunity to provide you with our comments. If you have any questions or would like any additional information, please do not hesitate to contact me.

Sincerely,

A handwritten signature in black ink that reads "Marcia Nusgart R.Ph." in a cursive script.

Marcia Nusgart R.Ph.
Executive Director

c.c. Director Laurence Wilson