

July 30, 2014

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Re: Request for Information: Medical Grade Honey as a Surgical Dressing Component

Submitted Electronically to NHICdmedraftlcdfeedback@hp.com

## Dear Medical Directors:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), I am pleased to submit the following comments in response to the Durable Medical Equipment Medicare Administrative Contractor's (DME MAC) request for evidence to support the use of honey-impregnated dressings. The Alliance is a nonprofit multidisciplinary trade association of health care professional 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. Our clinical specialty societies and organizations not only possess expert knowledge in complex chronic wounds, but also in wound care research. A list of our members can be found at <a href="https://www.woundcarestakeholders.org">www.woundcarestakeholders.org</a>.

The DMEMAC is requesting relevant clinical evidence discussing the accepted uses of medical grade honey in wound care. As you are aware, 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 agrees with the current surgical dressing policy and believes that honey impregnated dressings should continue to be classified according to the substrate material to which the honey is an added component.

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.

One of our clinical association members, AAWC, has submitted comments to the DME MAC regarding this issue. Within their comments they highlight some of the available data from randomized, controlled studies that support the clinical use of wound dressings containing medical grade honey. These studies, which we have included below have demonstrated statistical significant results compared to other comparative wound dressings for a variety of wound types and we support the DMEMAC review of these studies. They include:

- Al Waili 1999, Infected Surgical Wounds (50), Yemeni Honey Gauze vs Povidone I -70% ethanol gauze
- Gethin 2009, Venous Ulcers (108), Honey + foam dressing vs. Hydrogel + foam dressing
- Gulati 2012, Venous Ulcers (45), Honey film dressing vs. Povidone I film dressing
- Kamaratos 2012, Diabetic Foot Ulcers (63), Medihoney Tulle vs. gauze dressings
- Song 2012, Radiation mucositis minor to severe (3 RCT:120), Honey dressing vs. Lignocaine
- Subrahmanyam 1993, Mixed acute, chronic wounds healing by 2<sup>nd</sup> intention (100), Honey gauze vs. Silver sulfadiazine (SSD) gauze
- Wasiak 2013, Partial-thickness burns (169), Honey gauze vs. Silver Sulfadiazine
- Weheida 1991, Pressure Ulcers (40), Honey Gauze v Saline Gauze
- Wijisinghe 2009, Burns partial-thickness or mixed partial and full- thickness
  (8 RCT:624), Honey gauze vs. SSD gauze, Film dressing Amniotic membrane, tulle gauze, air, boiled potato peel
- Yapucu Gunes 2007, Pressure Ulcers (26), Honey gauze vs. Nitrofurazone gauze

In additional to the studies above, 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.

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. We are in agreement with the DME MAC process and multiple reviews conducted by the PDAC and

their policy of classifying products based on the clinically predominant dressing component as well as the current classification of these products within the current surgical dressing policy.

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,

Marcia Nusgart, R.Ph

Marcia Rusgart R.PL

**Executive Director**