Appendix 1

Additional Evidentiary Concerns

This Appendix identifies additional evidentiary concerns where the Future LCD adopted noncoverage determinations that are inconsistent with the available evidence and established standards of practice. Despite the existence of substantial evidentiary support for the reasonable and necessary use of dressings containing silver and honey, the LCD did not take that evidence into consideration, and the Comment and Response Summary did not address the evidence provided by stakeholders during the comment process. In addition, despite concerns over an apparent limitation restricting use of collagen dressings to once per seven days, the Future LCD failed to clarify or revise this coverage restriction. These issues further demonstrate the need for a delay in the LCD's implementation until a full evaluation of the evidence can be developed to support appropriate coverage limitations.

I. THE FUTURE LCD'S NONCOVERAGE DETERMINATIONS FOR DRESSINGS CONTAINING SILVER AND HONEY CONFLICT WITH AVAILABLE EVIDENCE.

Because neither the Future LCD nor the Comments and Response Summary respond to the comments and evidence commenters submitted demonstrating that silver and honey are effective components of surgical dressings, the Future LCD must be delayed. While the DME MACs recognized in the Comments and Response Summary the submission of "[m]ultiple comments that there is sufficient evidence that honey, silver, copper, and iodine dressings are safe and efficacious," the DME MACs did not address this evidence, instead choosing to discuss manufacturer compliance with FDA requirements and statutory provisions that exclude coverage for antiseptics, antimicrobials, and other substances from coverage as surgical dressings. Where dressings containing silver or honey do not make such antiseptic or antimicrobial claims, this reference is irrelevant to coverage of dressings containing these substances—which have been demonstrated to improve wound healing. The absence of a meaningful presentation of evidence demonstrating honey or silver are not effective in surgical dressings is particularly concerning because both silver and honey-impregnated surgical dressings have become the standard of care for treating certain wounds.

The clinical effectiveness of surgical dressings impregnated with honey is supported by published, peer-reviewed evidence demonstrating its ability to enhance the clinical function of surgical dressings by decreasing the wound healing time of chronic wounds treated with surgical dressings.[1] In one randomized controlled trial, the mean healing time was significantly shorter for wounds treated with honey-impregnated dressings when compared to conventional

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[1] *See e.g.*, Molan *et al.*, *Honey: A Biologic Wound Dressing,* 27 WOUNDS 141 (2015); Robson *et al.*, *Standardized antibacterial honey (Medihoney) with standard therapy in wound care: randomized clinical trial*, 65 J. ADVANCED NURSING 565 (Mar. 2009); Smith *et al.*, *Topical Leptospermum Honey (Medihoney) in recalcitrant venous leg wounds: A preliminary case series,* 22 ADVANCES IN SKIN & WOUND CARE 68 (2008); Acton, *Medihoney: a complete wound bed preparation product*, 17 BRITISH J. NURSING S46 (2008).

dressings.[2] A 2015 Cochrane Review focused primarily on honey dressings identified numerous peer-reviewed, randomized trials that demonstrated the improved rate of wound healing for dressings containing honey.[3]

Similarly, there is extensive published clinical literature that suggests surgical dressings that incorporate silver improve wound healing and improve patients' quality of life. A number of studies, including RCTs, have found silver dressings to have positive effects on wound healing parameters.[4] For example, a 2010 prospective, randomized controlled trial published in the journal *Wounds* found that infected venous ulcers treated with silver foam dressings had a significantly greater healing rate compared to infected venous ulcers treated with nonadhesive foam alone.[5] Specifically, 81% of ulcers treated with silver dressings healed within 9 weeks of treatment, while only 48% of ulcers treated with non-silver dressings healed within that time period. Similarly, a meta-analysis published in the *Journal of Clinical Nursing* incorporated data from 1,399 study participants in eight RCTs to find that silver dressings significantly improved wound healing, reduced odor and pain related symptoms, decreased wound exudates, and had a prolonged dressing wear time when compared to alternative wound management approaches.[6] Neither the RCT published in *Wounds* nor the meta-analysis published in the *Journal of Clinical Nursing* was included in the Future LCD's "Sources of Information and Basis for Decision," nor were 12 of the 13 articles that the Alliance of Woundcare Stakeholders (the "Alliance") included in their comment to the Draft LCD.

The DME MACs are required by the CMS Program Integrity Manual to respond to comments either individually or via a comment/response document, and where appropriate, the DME MACs must incorporate the comments into the final LCD itself.[7] In this case, neither the LCD nor the Comments and Response Summary respond to these studies, and the absence of these articles from the Future LCD's Sources of Information and Basis for Decision suggests that they were not meaningfully considered—if considered at all—in the development of the Future LCD. The Coalition urges the DME MACs delay implementation of the LCD until they have complied with CMS requirements to meaningfully review and respond to this evidence and incorporate it into the Future LCD.

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[2] Kamaratos *et al*., *Manuka honey-impregnated dressings in the treatment of neuropathic diabetic foot ulcers*, 11 INT. WOUND J. 259 (June 2014).

[3] *See* Jull *et al*., *Honey as a topical treatment for wounds (Review)*, Cochrane Database of Systematic Reviews (2015) (citing Gethin & Cowman, *Manuka honey vs. hydrogel – a prospective, open label, multicentre, randomised controlled trial to compare desloughing efficacy and healing outcomes in venous ulcers*, 18 J. OF CLINICAL NURSING 466 (2009) (finding that 44.4% of venous leg ulcers treated with Manuka honey dressings had healed at 12 weeks compared with 33.3% of venous leg ulcers treated with hydrogel dressings).

[4] *See, Appropriate Use of Silver Dressings in Wounds*, 9 INT. WOUND J. 461 (Oct. 2012); Muangman P. *et al*., *A prospective, randomized trial of silver containing Hydrofiber dressing versus 1% silver sulfadiazine for the treatment of partial thickness burns*, 7 INT. WOUND J. 271 (2010); Dimikakos E. *et al*., *Infected venous leg ulcers: management with silver-releasing foam dressing*, 21 WOUNDS 4 (2009).

[5] *See* Dimikakos E. *et al.*, *Infected venous leg ulcers: management with silver-releasing foam dressing*, 21 WOUNDS 4 (2009).

[6] Lo *et al*., *The effectiveness of silver-releasing dressings in the management of non-healing chronic wounds: a meta-analysis*, 18 J. CLINICAL NURSING 716 (Feb. 12, 2009).

[7] *See* CMS, PIM, Ch. 13, Sec. 13.7.4.

II. THE LIMITATION ON COLLAGEN DRESSING CHANGES IS INCONSISTENT WITH DRESSINGS' INSTRUCTIONS FOR USE AND CLINICAL STANDARDS.

In addition, the Future LCD suggests that collagen dressings will not be considered reasonable and necessary if changed more frequently than every seven days—a limitation that is inconsistent with the standard of care and manufacturers' specific instructions regarding the appropriate use of these dressings. For example, the instructions for use of Acelity's PROMOGRAN collagen dressing instructs, "[a]fter initial application, reapply PROMOGRAN® Dressing to the wound every 72 hours depending upon the amount of exudate." Similarly, Medline instructs for its Puracol Plus collagen dressing that "[d]ressing change frequency will depend on amount of drainage." The standard of care dictates that the frequency of dressing changes will necessarily vary based on a variety of factors, including the level of exudate of the wound.

While unclear in its application, the LCD suggests that these instructions and clinical considerations have been disregarded in the LCD's language stating collagen dressings may last "up to seven days." To avoid a significant negative impact on clinician's wound healing practices and beneficiary's health, the LCD must be limitation must be revised to adhere to current clinical practice.