

November 5, 2015

Jackie Dunn Union Trust Building Suite 600 501 Grant St Pittsburgh, PA 15219

Submitted electronically to: jackie.dunn@novitas-solutions.com

RE: DRAFT Local Coverage Determination (LCD) for Strapping (DL36423)

Dear Ms. Dunn:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), I am pleased to submit the following comments in response to the Novitas draft LCD regarding Strapping (DL36423). The Alliance is a nonprofit multidisciplinary trade association of health care professional and patient organizations 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. These comments were written with the advice of Alliance clinical specialty societies and organizations that not only possess expert knowledge in complex chronic wounds, but also in wound care research. A list of our members can be found at www.woundcarestakeholders.org.

The basis of our comments is to seek clarification on two points:

- 1. Novitas' draft policy identifies Unna Boots and the application of multi-layer compression system. Your draft policy strangely mentions Unna boots and the application of multi-layer compression system, yet indicates that it does not apply to wound care. As such, we would like you to ensure that this policy does not apply to Unna boots and the application of multi-layer compression system when used to treat patients with wounds.
- 2. There is conflicting language in the policy as it relates to the utilization of Unna boots. In the coverage section, the draft states, "the cast should be left in place for 4 to 7 days." However, in the utilization guidelines the draft language states, "For Unna boot (Procedure code 29580): It is not expected that Unna boot application would be done more often than once per seven days."

This discrepancy needs to be clarified prior to finalizing the policy. It is not uncommon to change an Unna's boot after 48 hours on the first application because with rapid edema reduction the cast will slip down. Additionally, when used over draining ulcers, an Unna boot may have to be changed more often than once per week due to soiling from the draining wounds. Usual clinical practice is to change the

Unna's boot two or 3 times per week, which would be every 3rd or every 4th day. As such, the Alliance would recommend language allowing the Unna's boot to be changed every 3rd or 4th day. Should Novitas decide not to adopt our recommendation — which is based on clinical practice - then at the very least Novitas needs to be consistent with the verbal description and clear up the inconsistency. The language therefore should say every 4 to 7 days.

On behalf of the Alliance of Wound Care Stakeholders, we appreciate the opportunity to submit these comments. If you have any questions or would like further information, please do not hesitate to contact me.

Sincerely,

Marcia Nusgart R.Ph.

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Executive Director