

Wound Care Manufacturers

June 22, 2017

Wisconsin Physician Services
Cheryl Ray, D.O., MBA, FACN
1717 W. Broadway
Madison, WI 53701-1787

Submitted Electronically to policycomments@wpsic.com

RE: Draft LCD – Wound Care (DL37228)

Dear Dr. Ray,

The Coalition of Wound Care Manufacturers (“Coalition”) is submitting the following comments in response to WPS draft LCD on Wound Care. The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds including but not limited to Negative Pressure Wound Therapy (NPWT) which is one of many areas contained in this draft policy. As such, we have a particular interest in this draft document.

NPWT refers to the application of negative pressure across a wound and can come in the form of traditional as well as disposable systems. The aim of NPWT is to facilitate wound healing, promote granulation of the wound bed, and provide a bridge to surgical closure. NPWT is ideal for chronic wounds that are “stuck” and unable to progress. NPWT is cost effective by helping certain wounds progress through the healing process which in turn reduces the hospital readmission rates and overall healthcare expenditures. While the Coalition is pleased with the coverage in this draft policy for both traditional and disposable NPWT, we do have some concerns surrounding the language in this draft policy.

NEGATIVE PRESSURE WOUND THERAPY

Language in Policy – (p. 6) *No more than 6 NPWT services in a four month period will be considered reasonable and necessary.*

Concern – The utilization parameter WPS has set for NPWT is arbitrary and WPS has not provided any supportive clinical evidence or standard clinical practice guidelines to substantiate the utilization parameters contained in this draft policy. The evidence utilized in making any changes to medical policy must be provided in the bibliography so stakeholders can review the literature reviewed and the evidence needs to substantiate the

changes made. However, WPS has not been transparent and has not provided such evidence in the bibliography.

The Coalition questions whether **parameters even need to be set**. NPWT dressings should be changed based upon the condition of the wound as well as the manufactures recommendation in their instructions for use. The proposed utilization parameters are completely arbitrary and can result in increased risk of infection and worsen outcomes.

Furthermore, when WPS refers to NPWT services within the policy what does WPS mean – dressing changes? There is a level of uncertainty with the words “NPWT services” so the Coalition is seeking clarification on what WPS means by using that phrase.

Recommendation – The Coalition recommends that WPS eliminate the utilization parameters set forth in this draft policy for NPWT. There is no basis in the clinical evidence to support setting these parameters and the limitation conflicts with existing Medicare coverage policies.

LACK OF TRANSPARENCY FOR THE CHANGES MADE IN THE DRAFT LCD

Over the years, the Coalition has had concerns in the manner in which the MACs have developed new draft LCDs or revised existing ones. The process of developing a draft LCD should be transparent and information forthcoming to any stakeholder interested in the policy. This allows for meaningful comments on the policy being drafted. The information that a MAC utilizes in creating or revising an LCD should all be contained in the *Sources of Information and Basis for Decision* bibliography in order for stakeholders to review that information to better understand how the MAC substantiated the language placed in the LCD created or revised. The information should be transparent and accessible. If in fact WPS consulted additional resources, those resources should have been identified in the released draft policy.

The public has a right to review the resources and without access to that information, a draft policy is incomplete. We have addressed our concerns regarding the articles in the bibliography and the fact that they do not for the most part correspond to the changes made in the draft LCD. In summary, WPS has not been transparent in their policy making efforts and we request that WPS provide all the evidence used to impact the policy language contained in this draft LCD.

CONCLUSION

While the Coalition appreciates the efforts of WPS to create a well-balanced policy, it would be helpful to work with stakeholders in order to ensure that the policy is based on evidence and not arbitrary and unsubstantiated parameters. In addition to the comments and recommendations that the Coalition has submitted, the Coalition is a non-voting member of the Alliance of Wound Care Stakeholders. The Alliance submitted more detailed clinically oriented comments, which we support. We would like to recommend that WPS review the Alliance comments and adopt their recommendations. The Coalition appreciates the opportunity to provide you with our specific

comments as well and look forward to a continuing dialogue with you as you address our comments and our concerns. If you have any questions, please do not hesitate to contact me.

Sincerely,

A handwritten signature in grey ink, appearing to read "Karen S. Ravitz".

Karen S. Ravitz, JD
Senior Policy Advisor
Coalition of Wound Care Manufacturers
301 807 5296