ALLIANCE OF

Wound Care Stakeholders

September 28, 2008

Submitted electronically

Dr. Barry Straub
Centers for Medicare and Medicaid Services
Coverage and Analysis Group
7500 Security Blvd
Baltimore, Maryland

Dear Dr. Straub;

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), I am pleased to present comments regarding CMS' request for comments on a list of potential topics for future National Coverage Determinations (NCD). The Alliance is a multidisciplinary consortium of over 15 physician, clinical, provider, manufacturer and patient organizations whose mission is to promote quality care and patient access to wound care products and services. Many of the physician and clinical organizations who participate in the Alliance have many members that also conduct clinical research in the areas of wound care. These comments were written with the advice of the following Alliance organizations who possess expert knowledge in complex acute and chronic wounds as well as in wound care research. These include: Association for Advancement of Wound Care, American Professional Wound Care Association, the American College of Hyperbaric Medicine, American College of Certified Wound Specialists, and American Association of Wound Care Management.

On July 30, 2008, the Centers for Medicare & Medicaid Services (CMS) released a list of potential topics for future National Coverage Determinations (NCDs). While many topics were identified in that document, the Alliance is particularly interested in the question, *"Is the evidence for any specific modalities adequate to demonstrate improved health outcomes for selected wound patients while avoiding side effects seen with other growth hormones?"*

Our comments revolve around these issues: clarification of the topic, evaluation and the CMS process for quarterly posting of potential NCD topics on the coverage website.

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Needed Clarification Regarding Issues on This Topic

In order to submit comments that are relevant to the questions asked, the Alliance would like clarification on the following points regarding this topic:

- Specifically, what types of wound care patients are CMS referring to?
- What type(s) of biologic therapy are CMS referring to?
- Is CMS trying to address growth factors and autologous growth factors? The Alliance participants are confused by the question, as it appears CMS is only addressing biologic therapies that have growth hormones - such as Regranex®. Is this a correct assumption? If not, what products is the Agency trying to address in this NCD proposed topic?

The Alliance would like to point out that there are several components to biological therapies for the treatment of chronic wounds. There are biological skin substitutes and there are biological growth factors. Biological skin substitutes do not have growth hormone effects since they are varied by layers of dermis, epidermis or a cellular matrix that support the natural scaffolding structures of the body's own cells to resurface wounds. The Alliance believes that the LCD process is working well for bioengineered skin substitutes.

Since it is unclear what CMS is seeking and more information needs to be ascertained before stakeholders can provide adequate, objective feedback, the Alliance recommends that CMS not issue an NCD for biologic therapies for the treatment of chronic wounds at this time. Furthermore, the Alliance submits that it would be premature for CMS to consider this issue under a NCD until clarification has been provided on these questions to all stakeholders in this arena.

While the Alliance does not agree with biologic therapies for the treatment of chronic wounds as a topic for an NCD at this time, if CMS considers moving forward, the Alliance recommends that the Agency consider evaluating biologics as follows:

- Categorize the types (i.e. – skin or tissue matrix, topical gel, human or xeno, living or non living) as well as the delivery methods of biologics used to treat chronic wounds.
- What is the route of administration – is the biologic administered by the physician or the patient?
- Focus on the Food and Drug Administration (FDA) indications for use and chronic wound type.

In addition, the Alliance would like to address an item the Agency put forward in your topic question – specifically regarding the safety of biological therapies. While the Alliance is not addressing any specific growth hormone products, the safety record of biological therapies has been well established through the FDA

approval and clearance process as well as from clinical practice. Safety should not be an issue.

Concerns Regarding CMS Process for Quarterly Posting of Potential NCD Topics on its Coverage Website.

The Alliance also has the following concerns from a stakeholder perspective regarding this process:

- Will CMS be updating the list of topics quarterly?
- Will CMS be collating and responding to the specific comments received by interested stakeholders?
- Will CMS be publishing what the next steps will be?

These aspects are just a few that we have identified in which CMS needs to address.

Conclusion

The Alliance thus recommends that CMS not move forward with an NCD for biological therapies for the treatment of chronic wounds at this time. CMS must clarify what they are seeking in the earlier question posed and, once clarified, issue a revised draft for further discussion and comment.

The Alliance appreciates the opportunity to provide our comments and looks forward to working with the Agency to address the issues discussed in this letter. We are happy to serve as resource for you to discuss wound care issues such as these in the future. Please contact me directly if you have any questions or concerns.

Sincerely,

Marcia Nusgart R.Ph.

Marcia Nusgart R.Ph.
Executive Director