ALLIANCE OF

Wound Care Stakeholders

April 13, 2009

Trailblazer
Debra Fulfer
8330 LBJ Freeway
Dallas, TX 75243

RE: Bioengineered Skin Substitutes (4S-157AB [DL2955]

Dear Ms. Fulfer:

I serve as the Executive Director of the Alliance of Wound Care Stakeholders ("Alliance"), 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.

On behalf of the Alliance, I am submitting the following comments in response to the Trailblazer draft Local Coverage Determination (LCD) on bioengineered skin substitutes. These comments were written with the advice of the following Alliance organizations who possess expert knowledge in complex acute and chronic wounds: Association for the Advancement in Wound Care, Wound Healing Society, American Professional Wound Care Association, American Association of Wound Care Management, American College of Certified Wound Specialists, Undersea and Hyperbaric Medical Society, National Association for the Support of Long Term Care, and the Coalition of Wound Care Manufacturers. This LCD will have a major impact on our Alliance organizations and as such appreciate the opportunity to offer our comments.

As a general comment, as Medicare is transitioning to the Medicare Administrative Contractors (MACs), the MACs are reissuing LCDs. While we understand, for consistency sake, the MACs are required to reissue LCDs that are coming under their jurisdiction, many MACs are substantively changing existing LCDs. Some of these changes are significant and are impacting coverage – without the ability of the provider community to offer their comments. We appreciate that Trailblazer has issued its LCD with the ability to provide our comments.

Specifically, we would like to address these areas of concern:

1. The requirement for application of skin substitutes to only be considered covered procedures if they are sutured or stapled;
2. Non-coverage of skin substitute application to a wound smaller than 1.0 sq cm; and
3. Non-coverage of Q4102 Skin Substitute.

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4. Definition of "Failed Response"

All of these areas pose a problem for our Alliance members and are a change from current practice.

Skin substitutes covered only if they are sutured or stapled

In its draft policy, Trailblazers has deviated significantly from the current CPT Code Manual on this issue. The draft LCD suggests that skin substitutes will be covered procedures only if they are sutured or stapled. The Alliance disagrees with this change. The draft language is based on the 2006 CPT code manual – which is no longer current or accurate. The application of a skin substitute is a surgical procedure (15330-15431) whether or not the application involves surgical fixation using sutures or staples. The surgeon has several options for fixation of the skin substitutes other than surgical fixation with sutures or staples. The surgeon's choice of fixation does not determine whether or not the application of the skin substitute is or is not a "graft." The view that the application of a skin substitute product using fixation other than sutures or staples is not reportable under codes CPT® 15330-15431 is an inaccurate interpretation of current CPT® coding.

The Alliance recommends that Trailblazers use the 2009 CPT coding manual language instead of the current draft language as noted above.

Non coverage of skin substitute application to a wound smaller than 1.0 sq cm

In the draft LCD, Trailblazers put forward a new coverage determination—that they would no longer cover skin substitute application to wounds smaller than 1.0 sq cm. The Alliance does not agree with this determination since it is not evidence based. As larger chronic wounds progress towards closure, they may become smaller but could still require support with skin substitutes to support healing towards final closure.

As such, the Alliance recommends that in order to continue coverage of skin substitutes, there should be evidence of visible clinical improvement towards closure. This would support continued use of skin substitutes. If there is a failure of visible clinical improvement towards closure after 30 days of application then the skin substitute would no longer be covered.

The Alliance believes that the current LCD more accurately reflects current clinical practice and should not be changed. The way this draft is written, Trailblazer is only taking into consideration the size of the wound when determining coverage. However, wound size should not be the sole determinant. Wound edge physiology – irrespective of size – has similar requirements throughout the healing process.

Non coverage of Q4102 Skin Substitute

In the draft LCD, Trailblazer has changed their current coverage policy as it relates to Q4102 – Oasis Wound Matrix. Trailblazer, in their draft LCD, has decided to no longer cover this product. The Alliance disagrees with this non coverage decision. It is our clinical opinion that the Oasis Wound Matrix is both clinically and cost effective. There are ample studies to support this statement. In a time where the health care system is moving towards evidence based medicine, the Alliance believes that there is sufficient published data such as the following to support the coverage of this product:

- O'Donnell TF, Lau J. A systemic review of randomized controlled trials of wound dressings for chronic venous ulcers. *J Vascular Surgery* 2006;44(5):1118-1125.
- Landsman A, et. al. Living cells or collagen matrix; which is more beneficial in the treatment of diabetic foot ulcers. *Wounds* 2008;20(5):111-116.
- Werier J, et.al. Model of radiation-impaired healing of a deep excisional wound. *Wound Repair and Regeneration* 2006;14:498-505.
- Barendse-Hohmann MG, et. al. Extracellular matrix prevents split-skin grafting in selected cases. *J Wound Care* 2007;16(10).
- Hodde JP, Allam R. Small intestinal submucosa wound matrix for chronic wound healing. *Wounds* 2007;19(6):157-162.

The Alliance recommends that Trailblazer continue to cover Q4102 – Oasis Wound Matrix.

Definition of "Failed Response"

The Trailblazers' draft policy adds the definition of 'failed response" for wounds eligible for skin substitute therapy by stating "For initial applications of skin substitutes/replacements, a "failed response" to conservative measures is defined as an ulcer that has increased in size or depth or for which there has been no change in baseline size or depth and no sign of improvement or no indication that improvement is likely (such as granulation or epithelialization and no progress toward closing)."

We have concerns regarding this definition since we question if a wound that has had minimal progress with traditional therapy for several weeks or months, will this definition exclude the wound from coverage with skin substitute treatment?

The Alliance appreciates the opportunity to provide Trailblazer with our comments on the draft LCD for bioengineered skin substitutes. We look forward to working with you as you finalize this policy. If you have any questions or would like additional information, please feel free to contact me.

Sincerely,

Marcia Nusgart
Executive Director