ALLIANCE OF
Wound
Care
Stakeholders

April 12, 2010

Dr. Charles Haley
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Sent Electronically to Debra.Patterson@trailblazerhealth.com and
Charles.Haley@trailblazerhealth.com

RE: Draft Local Coverage Determination (LCD) for Bioengineered Skin Substitutes - 4S-162AB

Dear Drs. Haley and Patterson:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), I am submitting the following comments in response to the Trailblazer draft Local Coverage Determination (LCD) on Bioengineered Skin Substitutes. I serve as the Executive Director of the 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. These comments were written with the advice of Alliance organizations who possess expert knowledge in complex acute and chronic wounds. This LCD will have a major impact on our Alliance organizations and as such appreciate the opportunity to offer our comments.

As Medicare continues to transition 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:

Indications for Use:

The draft policy states, "*All covered bioengineered skin substitutes must be applied to*

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wounds that have demonstrated a failed or insufficient response to no fewer than four weeks of conservative wound care measures when applied to chronic wounds. 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 less than 30% closure from baseline. For purposes of this LCD conservative measures include, but are not limited to,: elimination of underlying cellulitis, or other infection; elimination of edema; appropriate debridement of necrotic tissue; appropriate non-weight bearing and/or other means for off loading pressure; provision of appropriate wound environment to promote healing."

While the Alliance generally agrees with the statement provided above, we recommend the following changes for clarification. We recommend the above paragraph be modified to read, "**…applied to wounds that have demonstrated a failed or insufficient response to no fewer than four weeks of conservative wound care measures. 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 less than 30% closure from baseline. For purposes of this LCD conservative treatment includes, but is not limited to: reduction or elimination of underlying cellulitis, or other infection; reduction of edema; appropriate debridement of necrotic tissue; appropriate non-weight bearing and/or other means of off-loading pressure; and optimization of wound environment to promote healing**."

The Alliance also questions the evidence supporting 30% closure from baseline in 4 weeks as the basis for a filed response. We are unable to locate any research from where Trailblazer obtained this number. As such, the Alliance would like to request that Trailblazer provide the Alliance with a citation.

Furthermore, your draft policy states, "*All covered bioengineered skin substitutes must be …..applied to wounds of reasonable size given the clinical circumstances. For instance, Medicare would not expect routine use of graft material in treating small wounds (smaller than 1.0 cm2 or 1 cm in smallest diameter) unless the medical record clearly demonstrates the wound to be refractory to conservative treatment but otherwise healable. Use on small wounds that have demonstrated adequate healing by conservative means is not covered*." The Alliance does not agree with this statement 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 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 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.

Limitations for Use

Trailblazer has included language in the LCD which we find troubling. Specifically, "*Retreatment of healed ulcers or ulcers for which an initial course of treatment with skin substitutes was unsuccessful is not indicated. An unsuccessful course of treatment is defined in this case as incomplete healing following maximal numbers of applications and/or maximal duration of treatment time indicated by the FDA label of the individual product and/or this LCD.*" There are times when one product has been used on a patient and based on multiple factors may not have been unsuccessful. However, when another product has been utilized on that same patient, the patient has been healed.

As such, the Alliance believes that Trailblazer is limiting the possibility of healing a patient by utilizing the language provided in the draft policy. As such, the Alliance recommends that Trailblazer modify the language to state, "**Retreatment of healed ulcers or ulcers with the same product for which an initial course of treatment with skin substitutes was unsuccessful is not indicated. An unsuccessful course of treatment is defined in this case as incomplete healing following maximal numbers of applications and/or maximal duration of treatment time indicated by the FDA label of the individual product and/or this LCD."**

The Alliance believes that another portion of the policy is confusing. Specifically, "*Because application of Apligraf, Oasis, GraftJacket and Dermagraft, as well as any subsequently accepted similar product is considered a physician service, these products must be applied by a physician and not by non advanced practice nurses, therapists or medical assistance"*. The Alliance respectfully submits that individual State Practice Acts define a practitioner's scope of practice and therefore the application of bioengineered skin substitutes should be based upon State Practice Acts.

As such, we recommend that the language be modified to read, "**the application of these product, as well as any subsequently accepted similar product is defined by the procedure and the specific applicable scope of practice outlined in State Practice Acts.**"

Within the LCD, Trailblazer provides indications and limitations to Medicare coverage and payment to product specific bioengineered skin substitutes and their related skin substitute application physician services. Within each of these product specific areas, Trailblazer sets forward limitations to the applications permitted in your jurisdiction. We submit that these limitations are not evidence based. There is no clinical evidence showing that most wounds will heal or improve within 2 weeks utilizing skin substitutes– yet, based on the limitations you set forward, Trailblazer is expecting there to be evidence of healing within that time frame.

The Alliance believes that it will take 3 – 4 applications before there will be any visual evidence of improvement. As such, the Alliance recommends that rather than setting limitations on the applications for these products, Trailblazer recognizes, as stated above, 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 failure of visible clinical improvement towards closure after 30 days of application then the skin substitute would no longer be covered.

Skin Substitute Application Procedures (CPT 15330-15331)

The Trailblazer draft policy discusses the use of the KX modifier. Within the description of the KX modifier that Trailblazer is using, the procedure is incorrectly stated/defined. The draft policy states, "*CPT procedure codes listed in this policy describe and are to be used to report skin grafts using bioengineered skin substitutes. Do not report any CPT procedure code listed in this policy when using a bioengineered skin substitutes as an implanted or prosthetic material or otherwise used not as a skin graft.…"*. The policy also states, *"skin graft procedures using bioengineered skin substitutes in which skin substitutes are appropriately handled, applied and mobilized.…*" Utilizing the term "skin grafts" is not correct since both the AMA and CMS do not utilize "skin grafts" in their language, but merely "grafts".

As such, the Alliance recommends that Trailblazer use the same terminology as the AMA and CMS thus modifying the language in this section to **delete "skin" in front of the work "graft" to more appropriately define the procedure**.

Policy Articles

The Alliance also respectfully requests that Trailblazer provide more information in the LCD regarding the use of the JC and JD modifier. This is the first time the use of these modifiers has been provided in your LCD for bioengineered skin substitutes. While information has been provided in the policy articles regarding the JC and JD modifiers, the Alliance would like to point out that Trailblazer utilized the wrong definition in the policy articles to describe the modifiers. As stated above, the AMA and CMS do not utilize the word "skin" in their language, but merely "grafts". Therefore the description should read, "JC – used to report skin substitute used as a graft" and "JD – used to report skin substitute not used as a graft."

Furthermore, the Alliance would like to point out that in the final Outpatient Prospective Payment System regulation (OPPS) issued on November 20, 2009, the Center for Medicare and Medicaid Services (CMS) defined implantable biologics as, "products that are surgically inserted or implanted through a surgical incision or a natural orifice". The Alliance believes that the definition provided by Trailblazer directly conflicts with that provided in the OPPS final rule issued by CMS. It is the opinion of the Alliance that Trailblazer follow the definition provided by CMS and should modify the LCD and

policy articles to reflect the CMS definition. **The JC and JD modifiers should be used when billing for skin substitutes. The difference between them is whether the skin substitute is used as a graft or as a skin covering. The definition of a graft for this purpose is whether the skin substitute is implanted into the wound to be incorporated in the healing of the wound. The JC and JD modifiers should be used when billing for applications of products used as grafts and should not be used for products when used as implants or dressings. An implantable biological are defined as "products that are surgically inserted or implanted through a surgical incision or a natural orifice." Products covered by the Trailblazer LCD which are surgically inserted or implanted through a surgical incision or a natural orifice, should require the JD modifier to the HCPCS code and to the CPT® codes for that product and procedure.**

The Alliance also believes that providers will be confused regarding when to utilize all the modifiers required and for which products – since the definitions are not consistent. As a result, for clarity's sake, the Alliance recommends utilizing the definition provided in the OPPS final rule (as provided above) and also suggests using some examples which would assist providers on when to use the appropriate modifier. We would like to recommend modifying the language on the use of the JC and JD modifiers as follows:

Attach - JC modifier (skin substitute used as a graft) to the covered application codes (15330-15366; 15430-15431) for the graft procedures of covered products performed for covered indications.

If any of the products covered by the LCDs are implanted (surgically inserted or implanted through a surgical incision or a natural orifice), attach – JD (skin substitute not used as as graft) to the HCPCS code.

Clarification

The Alliance would like to seek clarification on the use of all the modifiers in this LCD as well as the policy articles. It is our understanding that providers will be required to use the code being billed along with the JC modifier for a graft, a KX modifier to show that they are following all the requirements of the LCD and product usage, the units being utilized as well as the units for the product, and the modifier for product wastage. It is also our understanding if all of these items are not included on the claim form, the providers will be denied for coverage. Is this correct? If so, the Alliance believes that Trailblazer should be a bit more clear on this information and should provide several examples within the LCD to show the correct use of all the modifiers.

The Alliance appreciates the opportunity to provide our comments on the draft LCD and policy article for Bioengineered Skin Substitutes. I look forward to working with you as

you finalize this policy. If you have any questions or would like more information, please feel free to contact me.

Sincerely,

Marcia Nusgart R.Ph.
Executive Director
Alliance of Wound Care Stakeholders