ALLIANCE OF

Wound Care Stakeholders

December 17, 2010

Dr. James Strong
Cahaba GBA MAC A & B
Comments for Draft LCDs - J10LCD
P.O. Box 13384
Birmingham, AL 35202-3384

Sent electronically to Comment@cahabagba.com

RE: Draft Local Coverage Determination (LCD) for Bioengineered Skin Substitutes (DL 31428)

Dear Dr.Strong:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), I am submitting the following comments in response to the Cahaba draft Local Coverage Determination (LCD) on Bioengineered Skin Substitutes (DL 31428.) 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. These comments were written with the advice of Alliance organizations. This LCD will have a major impact on our Alliance organizations and, as such, appreciate that Cahaba has issued its LCD with the ability to offer our comments.

It is our understanding that Medicare is transitioning to the Medicare Administrative Contractors (MACs), who are reissuing LCDs. We recognize that some MACs are required to reissue LCDs that are coming under their jurisdiction, while others are substantively changing existing LCDs. Over the past few years, the Alliance has had the opportunity to comment on many draft LCDs. In our comments below, we have recommended that Cahaba adopt language used by other MACs (i.e., First Coast, NHIC) in their similar LCDs and policy articles which may be helpful to you in finalizing the draft policy.

We have divided our following comments into two sections: General Comments and Specific Comments.

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General Comments

Recommendation Regarding Restructuring the LCD Format

The Alliance recommends that Cahaba utilize the same format as some of the other LCDs on this topic and provide the guidelines for each covered brand (hcpcs code) separately. Because the covered products differ in their source of origin and their cellularity, they have different FDA indications.

Therefore, the Alliance recommends that the final LCD should list the indications and guidelines for each covered brand separately. We propose that Cahaba use the NHIC Corp Articles (A48910, A48911, A49162, A50483) attached to the NHIC LCD L29867 as an example to follow. The brand specific guidelines include the following: the covered indications, limitations, documentation requirements, utilization guidelines, and coding guidelines. Including this information in this easy to follow format will help explain the coverage and limitations and allow clinicians to better understand Cahaba's policy and the parameters surrounding the products contained within.

Recommendations Regarding Terminology within the LCD

The Alliance has concerns regarding the following terms that are included within the LCD:

1. **The term "skin substitute" should be eliminated both in the definitions of the products and in the title of the LCD.** We recommend that Cahaba eliminate the term "skin substitute" when listing the various products in the "Limitations" section so as to reflect the current HCPCS coding recommendations by Centers for Medicare & Medicaid Services (CMS) HCPCS Workgroup for calendar year 2011. The CMS HCPCS Workgroup recommended deletion of the term "skin substitute" from the definition of the product specific HCPCS codes and only use the product name and the size. These recommendations became final in November 2010 and will be included in the 2011 HCPCS codes.

   Therefore, the Alliance recommends using the term "bioengineered and biologically active products" instead of skin substitutes in the title of the LCD and throughout the LCD itself. The Alliance suggests that the title of the LCD be changed to: ***DRAFT LCD for Bioengineered and Biologically Active Product Use in Lower Extremities Chronic Wounds*** **(DL 31428)**

   In addition, the Alliance proposes that Cahaba add an introductory paragraph under **Indications and Limitations of Coverage and/or Medical Necessity** for clarification purposes. This paragraph is similar to what is contained in the First Coast Policy and defines the types of products covered under this draft LCD. The **Alliance recommends the language should read as follows:**

This LCD applies to payment for bioengineered and biologically active products physician/non-physician services associated with the application of such products to lower extremity wounds. Biologically active products are either bioengineered or natural human skin products that have living cells and provide growth factors, cytokines, and an extracellular matrix to the wound to promote healing. Bioengineered products and biologically active (i.e., human skin equivalents, dermal substitute tissues, biologically active allografts) are human cellular and tissue based products that use living cells (e.g., fibroblasts or keratinocytes) or other collagen-derived or biologically-derived extracellular matrix in a scaffold of natural, biodegradable or synthetic matrices to support wound healing. The scaffold provides a stable framework that guides tissue integration and development. The scaffold is also able to bind autologous proteins which influence cell migration and adherence. Bioengineered and biologically active products are indicated in the management of wounds that have not responded to aggressive conventional wound therapy or as outlined in the indications given below.

In the rest of our comments, we will be using the term "bioengineered and biologically active products" instead of skin substitutes when applicable.

2. The LCD uses the words "ulcer" and "wound" interchangeably. To be consistent, the **Alliance recommends the use of the word "wound" throughout the LCD**.

3. To further clarify the products that are/not covered by this LCD, the **Alliance recommends Cahaba add the following to the Limitations section of the LCD:**

Products that have been assigned HCPCS codes (A6000-A6549) are covered as surgical dressings, not as bioengineered products. Application of a "surgical dressing" is included in the payment for the e/m service and should not be billed separately, even when the service is on the same or previous day.

This information should also be used in the Definition section to define a "surgical dressing".

4. Throughout the policy, Cahaba indicates that the application of bioengineered and biologically active products is a physician service. The Alliance notes that the application of these products is defined by the procedure and the specific applicable scope of practice outlined in state practice acts. Therefore, the Alliance believes that Cahaba needs to recognize that state law governs the application of bioengineered and biologically active products and modify the language throughout the policy to reflect this. Specifically, the **Alliance recommends using the following language – as has been used in many other LCDs (i.e. NHIC):** ***The application of all covered products is limited to***

physicians and non-physician practitioners and is defined by the procedure and the specific applicable scope of practice outlined in State Practice Acts.

Specific Comments

The Alliance would like to offer the following specific comments on the draft LCD:

Indications and Limitations of Coverage and /or Medical Necessity

Indications

1. FAILED RESPONSE (FIRST INDICATION IN DRAFT LCD)

***DRAFT LCD STATES*:** "All covered BSS must be: Applied to partial –or full-thickness ulcers of the lower extremities (see individual product information for labeled indications) that have demonstrated a failed or insufficient response to at least four weeks of conservative wound care measures when applied to chronic ulcers. 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."

COMMENTS: The Alliance generally agrees with the statement provided above, however, we question the evidence supporting 30% closure from baseline in 4 weeks as the basis for a failed response. We are unable to locate any research that identifies 30% closure as a valid clinical marker for the types of chronic wounds that are reflected in this coverage policy. Furthermore, there is no definition of conservative measures provided in your draft policy.

***RECOMMENDATIONS**:*

1. The Alliance requests that Cahaba provide the Alliance with a citation for this policy.
2. The Alliance would also like to provide information for what is considered conservative measures. For purposes of the Cahaba LCD the Alliance recommends that Cahaba adopt the following language: "*conservative measures include, but are not limited to: elimination of underlying cellulitis, osteomyelitis 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.*"

2. PARAMETERS FOR ADEQUATE CIRCULATION/OXYGENATION (THIRD INDICATION IN DRAFT LCD)

***DRAFT LCD STATES*:** "All Covered BSS must be only applied to ulcers of the lower extremity with adequate circulation/oxygenation to support tissue/ulcer healing as evidenced by physical examination, e.g., presence of acceptable peripheral pulses

(dorsalis pedis and/or posterior tibial), and/or Doppler toe signals, and/or Ankle-Brachial Index (ABI) of no less than 0.65"

COMMENTS: The Alliance believes, as is noted in many research citations, ankle brachial indexes (ABIs) are unreliable particular in patients with diabetes. Therefore, a patient could have an abnormally high ABI and yet have local tissue ischemia. As such, ABIs are not reflective of the microvascular perfusion, particularly in the distal portion of the foot. Furthermore, many patients have significant edema or pain where a good pulse, waveform or oxygen measurement cannot be determined. In such patients, clinical documentation of capillary refill, skin temperature / color and quality can be provided as a clinical documentation to support adequate circulation for bioengineered products. In other cases, blood flow may be poor but the patient may not be an operative candidate due to morbid risk factors. In such cases, wounds may fail conservative healing methods and bioengineered products can be considered. Currently, there is no single stand alone assessment that can be used and those recommended as part of an algorithm are noted-palpable pulses, ABI and toe Doppler perfusion pressures. The Alliance would like to point out however, that most wound care studies use TcPO2 values of 20 mmHg or greater for enrollment. Therefore, the Alliance believes this measurement should also be listed in the Cahaba policy. Similarly, distal perfusion assessments such as PPG and PVR are far more indicative than perhaps even digital doppler. The Alliance believes that these should also be included in the types of assessments accepted by Cahaba in their policy.

RECOMMENDATIONS:

1. The Alliance recommends that Cahaba modify the language for this provision as follows: "Applied only to wound with adequate perfusion to support tissue growth/wound healing as evidenced by physical examination with presence of palpable peripheral pulses, Doppler toe signals, ankle–brachial index (ABI) of no less than 0.65, PPG, PVR or TcPO2 values of 20 mmHg or greater".
2. Furthermore, while the Alliance believes the value of the ABI of "no less than 0.65" is reasonable, we are requesting information why this value was chosen over some other value.
3. The Alliance would like to recommend that Cahaba add PPG, PVR and TcPO2 values of 20 mmHg or greater as alternative measurements.

Limitations

1. PRODUCTS COVERED UNDER THE LCD (THIRD LIMITATION)

DRAFT LCD STATES: Cahaba discusses the products that will not be covered under this LCD and state the products identified (Q4100-14111, Q4115, Q4116 and C9363) will be considered biologic wound dressings.

COMMENTS: The Alliance has significant concerns that Cahaba classifies the above Q codes as biologic wound dressings and not bioengineered and biologically active products. This is in direct conflict with how both the FDA and other MAC LCDs classify

these products. None of the products that are included in the above Q codes have been cleared by the FDA as wound or surgical dressings; instead they have all been cleared as biologicals. Furthermore, in other MAC LCD and policy articles such as NHIC policy article A49162, the MAC clearly makes a distinction between those products in that surgical or wound dressings have "A " codes and those that are covered as biologics have been assigned "Q" codes by brand. This was stated in reference to which products should have JC or JD modifiers as noted below:

> *o Products that may be covered as biologics have been assigned skin substitute HCPCS codes by brand (Q4102-Q4116). Attach –JC modifier to the products covered by this Article and all other Articles affiliated with LCD 29867.*
> *o Products that may be covered as wound dressings have been assigned HCPCS codes A6000-A6549. Do not attach –JC modifier to these products.*

RECOMMENDATIONS:
The Alliance recommends that Cahaba eliminate the first paragraph under point 3 of this section and instead include guidelines for coverage for each brand product Q4100-14111, Q4115, Q4116, C9363 and new 2011 HCPCS Q codes (Q4118, Q4119, Q4121) in the format stated under our first General Comment section.

2. JC AND JD MODIFIERS (THIRD LIMITATION)

COMMENTS: Generally the Alliance agrees with the information provided regarding the JC and JD modifiers.
RECOMMENDATIONS: To further clarify when to use the JC and JD modifiers, the Alliance recommends that Cahaba modify the language on the use of the JC and JD modifiers to add the following language which is also used in other MAC LCDs such as NHIC:

The JC and JD modifiers should be used when billing for bioengineered and biologically active products. The difference between them is whether the bioengineered and biologically active products are used as a graft, an implant, or a skin covering. The definition of a graft for this purpose is whether the bioengineered and biologically active product is applied onto the wound surface to be incorporated in the healing of the wound. If the bioengineered and biologically active product is used to cover a wound, to protect it from contamination or fluid loss, then it is not a graft, but a dressing. The JC modifier should be used when billing for applications of products used as grafts. The JD modifier should be used for products when used as implants or dressings. Implantable biologics are products that are surgically inserted or implanted through a surgical incision or a natural orifice" Those products covered by the Cahaba 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.

Bioengineered products, HCPCS codes Q4102-Q4116, are examples of products that may be covered as biologics. The JC modifier should be attached to the products currently covered by this policy.

The JC modifier should not be utilized when utilizing products that may be covered as surgical dressings (HCPCS codes A6000-A6549).

Coverage Instructions

In the specific coverage directions for Apligraf and Oasis, the Alliance believes Cahaba should remove the word "neuropathic" because these two products are indicated for all types of diabetic foot wounds and therefore should not limit coverage for solely neuropathic wounds.

List of Covered ICD-9 codes

The Alliance believes that Cahaba inadvertently left out ICD-9 code 440.23 Atherosclerosis of the extremities from the list of covered ICD-9 codes. The Alliance would like to recommend that Cahaba add this code to the list of covered ICD-9 codes in this policy before it becomes final.

Utilization Guidelines

The guidelines provided in this draft LCD are not consistent with the 2011 CMS Medicare Physician Fee Schedule final rule or with the FDA package inserts for Apligraf, Oasis and Dermagraft – which state they can be utilized every 7 days if needed. Furthermore, Graftjacket is only supposed to have one application. The Alliance believes that Cahaba should ensure that the language provided in this LCD is consistent with both CMS and the FDA and recommends doing so before the policy becomes final.

Conclusion

The Alliance appreciates the opportunity to provide our comments. As Cahaba finalizes its LCD, we would like to offer the Alliance as a resource to you and your staff due to our expertise in this subject. 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