ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

July 25, 2014

Dr. James Corcoran
Medical Director
First Coast Service Options, Inc.
532 Riverside Avenue
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Jacksonville, FL 32202

Submitted Electronically to Medical.Policy@FCSO.com

RE: DL35384 - Application of Bioengineered Skin Substitutes for the Treatment of Diabetic and Venous Stasis Ulcers of the Lower Extremities

Dear Dr. Corcoran:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), I am pleased to submit the following comments in response to the First Coast Service Option's ("FCSO") draft LCD, "Application of Bioengineered Skin Substitutes for the Treatment of Diabetic and Venous Stasis Ulcers of the Lower Extremities" (DL35384).

The Alliance is a nonprofit multidisciplinary trade association of health care professional and patient organizations whose mission is to promote quality care and access to products and services for people with wounds through effective advocacy and educational outreach in the regulatory, legislative, and public arenas. These comments were written with the advice of Alliance clinical specialty societies and organizations that not only possess expert knowledge in complex chronic wounds, but also in wound care research. More information about the Alliance which includes a list of our members can be found at www.woundcarestakeholders.org. The Alliance represents every clinical discipline that treats patients with wounds and as such we are very interested in this draft policy.

General Comments

The Alliance would like to applaud First Coast in creating a well-balanced policy. For the most part, the Alliance is in agreement with the policy as written. However, we do have certain areas of concern, as well as questions of clarification, which we have specified in our specific comments below.

The Alliance would also like to point out that there are two active "draft" policies for FCSO. The Alliance recommends that FCSO formally retire the last draft so there is no confusion and we can then be assured we are only working with the recently released "draft" LCD.

Our specific comments follow.

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SPECIFIC COMMENTS

12 Weeks of Treatment and Number of Applications

Concerns: The Alliance has concerns about the timeframe of "only 12 weeks treatment", which may be in conflict with the FDA labeling and clinical practice for many of the CTPs which are only applied every 2-3 weeks to allow incorporation and to see results.

Language in the policy:

It is the expectation that a specific skin substitute graft product will be used for the episode of skin replacement surgery wound care (defined as 12 weeks from the first application of a skin substitute graft) assuming its use is not in conflict with Food and Drug Administration (FDA) assessments and assuming there is one related wound (definitions in CPT).

AND

Utilization of four or more applications of a skin substitute product in an episode of skin replacement surgery wound care, for all indications, may be subject to prepayment medical review.

Issue: The FDA labeling for some products requires reapplication every 7 days, while the FDA labeling for other products requires reapplication every 2-3 weeks. If the LCD limits treatment to 12 weeks, the Alliance is concerned that clinicians would always have to justify utilizing the product chosen to treat their patients – even though they are following FDA labeling. Most of the CTP products are not successful with only 4-6 applications. Therefore, the physicians will always have to overcome the documentation hurdles and will need to further justify why they need to continue to use the product for more than 4 applications.

Recommendation: The Alliance recommends the removal of this statement. A simple statement that the products should be applied in accordance with their FDA labeling places the responsibility on the physician to apply the product correctly.

Retreatment of the Wound

Concerns: This draft policy still contains language regarding retreatment of the wound. The Alliance is concerned with this language as it is hugely problematic as patients can - down the road - develop another ulcer in the same location or can have further breakdown OR can be placed on another type of product after an unsuccessful course of treatment on one type of product. We would like to clarify if the patient down the road develops another ulcer in the same location or has further breakdown that a clinician can treat the patient with the same product to treat the new wound. Similarly, if clinicians treat the patient unsuccessfully with one type of product but believe another product may work to help heal the wound, they should be able to utilize another type of product after an unsuccessful course of treatment of one type of product.

Language in the Policy: Retreatment of an ulcer following an unsuccessful course of treatment is not covered. Retreatment of a successfully treated healed ulcer is not covered.

Recommendations: The Alliance does not agree with the language as drafted in this policy. It is not appropriate to eliminate coverage for Medicare beneficiaries if they have further breakdown after a successful treatment of a wound. Similarly it is not appropriate to eliminate coverage for a Medicare beneficiary if a particular product was tried unsuccessfully and the clinician determines that another product may be used to help heal the wound. We therefore recommend that this language be eliminated from the policy as it is not clinically sound and does not align with FDA labeling of these products.

Issues of Clarification

The Alliance requests clarification of the following:

- Pressure ulcers are not mentioned in the policy. Is there coverage in the FCSO jurisdiction to treat a patient with a pressure ulcer if a product is indicated for this type of wound?

- A number of dermal-based products are indicated for full thickness wounds, DFU, or VLU with exposed bone and tendon. If there are products in the market place that have this indication - will they or can they be covered? It appears that products used to treat these types of wounds would be covered since FCSO is putting the responsibility for appropriate use by FDA indications in the hands of the physicians. As such, we are seeking clarification as to whether treatment of full thickness wounds, DFU or VLU with exposed bone and tendon with CTP products will be covered.

- We are also concerned about the statement - "full thickness ulcers, not involving tendon, muscle, joint capsule or exhibiting exposed bone or sinus tracts" and how this statement would impact Wagner II and III ulcers. We would appreciate clarification on this issue.

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In previous comments, the Alliance had stated our rationale for requesting a change in terminology from "bioengineered skin substitutes" to "cellular and/or tissue based products for wounds (CTPs)". While we understand that FCSO would currently rather follow the CPT®[1] description, we would respectfully point out that other organizations and contractors are beginning to adopt this verbiage. For instance, ASTM is currently revising its nomenclature on its guidance documents on this product sector. In addition, Cigna Government Services is utilizing the term Cellular and/or Tissue Based Products for Wounds as the title for its LCD. Historically, the CPT Editorial Panel would have changed the code descriptor in 2012, but they were afraid that it would affect Medicare payment and coverage for this work. If the MACs begin referring to these products with correct terminology, we can then request a correction to the CPT® code descriptors. We recognize that you may not be inclined to change the terminology at this time, and therefore we would respectfully request at some other point in time to further discuss this issue with you.

[1] CPT is a registered trademark of the American Medical Association

On behalf of the Alliance of Wound Care Stakeholders, we appreciate the opportunity to submit these comments. If you have any questions or would like further information, please do not hesitate to contact me.

Sincerely,

Marcia Nusgart R.Ph.
Executive Director