

Wound Care Manufacturers

July 25, 2014

Dr. James Corcoran
Medical Director
First Coast Service Options, Inc.
532 Riverside Avenue
ROC 19T
Jacksonville, FL 32202

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 Coalition of Wound Care Manufacturers (CWCM), I am pleased to we are 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 Coalition is a non clinical member of the Alliance of Wound Care Stakeholders. We understand that the Alliance has submitted comments to FCSO on this draft LCD. In their comments they recommended the following:

- Recommendation that FCSO remove the following language from the policy 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.

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.

- Recommend that FCSO remove the following language from the policy as it is not clinically sound and does not align with FDA labeling of these products:

Retreatment of an ulcer following an unsuccessful course of treatment is not covered. Retreatment of a successfully treated healed ulcer is not treated.

The Coalition is in agreement with these recommendations and encourage FCSO to adopt them prior to the draft policy becoming final. We appreciate the opportunity to provide our comments. If you need more information or have any questions, please do not hesitate to contact me.

Karen Ravitz, JD
Senior Policy Advisor
Coalition of Wound Care Manufacturers
Karen.ravitz@comcast.net
301 807-5296