COALITION OF

Wound Care Manufacturers

May 23, 2015

Dr. James Corcoran
Medical Director
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Medical Policy
532 Riverside Ave
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Jacksonville, FL 32202

Submitted electronically to: Medical.Policy@fcso.com

RE: DRAFT Local Coverage Determination (LCD) for Application of Skin Substitute Grafts for Treatment of DFU and VLU of Lower Extremities (DL36013)

Dear Dr. Corcoran:

The Coalition of Wound Care Manufacturers ("Coalition") is submitting the following comments in response to the FCSO draft LCD policy" Application of Skin Substitute Grafts for Treatment of DFU and VLU of Lower Extremities (DL36013) **".** The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds including those products that are subject to provisions contained in this Guidance. As such we have a particular interest in this draft document. For your reference, throughout our comments, we refer to "Skin Substitutes" as Cellular and/or Tissue Based Products for Wounds (CTPs) as it is a more clinically appropriate term and has widely been accepted in the clinical community when referring to these types of products.

Our specific comments follow.

Clinical Evidence

As manufacturers, we are especially troubled by the provision in the draft policy in which FCSO states that "specific products may be listed as non covered in the future based on clinical literature that establishes inferiority". While Coalition members have and will continue to support evidence based medicine as well as the investigation of our technologies including but not limited to randomized controlled trials, case studies and white papers, we do not support a policy in which we do not know what evidence will be

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required in order to maintain coverage and what criteria will be used to show inferiority. As an ethical concern, comparing one advanced tissue to another may not always be appropriate as each has specific indications, application intervals that may be different and may be more applicable for a particular patients' wound, thereby complicating this 'inferiority' comparison that is fair and clinically relevant. Does FCSO intend to require a specific amount or types of evidence compared to specific products in the future?

The Coalition believes that evidence can be established for coverage not only through RCTs but also through Registry data, retrospective clinical studies (includes populations of patients with multiple comorbid conditions that are commonly eliminated in most RCTs), scientific evidence and expert knowledge. This approach is consistent with the widely accepted definition of evidence-based medicine but also adopted by the newly created important organization Patient Centered Outcomes Research Institute (PCORI). **We believe that payers should cover these CTPs if the manufacturers provide clinical evidence in peer reviewed journals showing positive outcomes of their products without regard of how they are regulated by the FDA—Class II, III or HCT/Ps nor how they compare to other products in the marketplace**.

The Coalition would like to know what type of evidence will FCSO be reviewing when making a non coverage determination? Furthermore, how will the non-coverage decision be made? It is unclear how FCSO will use this literature to make non-coverage decisions. It seems as though one minute a product can be covered and then based on the clinical literature of a competitor- which may or may not include bias – a product may be placed in a non-coverage policy.

The draft language in the policy gives the appearance that FCSO will allow expanded treatment options for clinicians based upon providers clinical decision-making by including more CTPs. The Coalition supports this medical decision making approach. However, the language is conflicting and makes statements such as "specific products may be considered non-covered based on clinical literature that establishes inferiority in head to head studies with other products" and "overall body of published evidence regarding the safety and efficacy of bioengineered skin substitutes is limited and does not clearly demonstrate established or reproducible benefits of these products compared with optimal wound care". These statements lead us to believe that if a product does not have adequate studies then FCSO will not cover the product despite the clinicians' decision making. Furthermore, it is unclear how new products will be treated and if a competitor issues a comparator study showing their product is more effective than another, then FCSO may stop coverage of a product as a result. This leaves some level of uncertainty for our clinical community as to what will/will not actually be covered under this policy.

The Coalition recommends that FCSO provide the criteria by which they will be making any non coverage determinations. This will allow for a more transparent process for manufacturers when submitting a CTP for coverage. We further urge FCSO to issue a document for comment prior to any changes in coverage status and not simply place a

product in the non-coverage policy and publish in the newsletter updates.

It is unclear how FCSO will judge the supportive clinical evidence for each product used. As such, the Coalition highly recommends that FCSO clearly identify what evidence they are seeking and if a product meets those criteria – then it would be covered.

Conclusion

The Coalition is a non-clinical, non-voting member of the Alliance of Wound Care Stakeholders. We are aware that they submitted comments on the clinical inaccuracies in this draft policy. We support their comments and request that FCSO implement their recommendations prior to this policy becoming final.

We appreciate the opportunity to provide you with our comments on this important draft policy. Should you have any questions or require any additional information, please do not hesitate to contact me.

Thank you for your consideration.

Sincerely,

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