April 28 Open meeting skin substitute draft LCD speaking points

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Proposed LCD - Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers (DL36377)

* I will introduce myself and share that I practice in the First Coast jurisdiction.
* I will share the number of patients we serve per year in our hospital clinics in the United States.
* I will share a few key findings from a recent publication of our outcomes:
* Recent publication of our outcomes revealed of the 620,000 wounds - approximately 36% of them are secondary to diabetes and 23% of them are venous leg ulcers.
* Therefore nearly 60% of all patients treated in our wound care centers might be candidates for skin substitute products.
* I will review the following elements:
* The proposed LCD provides detailed review of the literature to support an evidence-based approach to the coverage determinants.
* It is for this reason that we are surprised by the limitation of two applications of a specific skin substitute, despite most of the quoted articles describing more than two applications being required to achieve the intended benefit.
* I will speak to the two studies described in the LCD where more than two applications were utilized.
* Finally, I will close by reinforcing our position:
* Placing a cap of two applications on this advanced wound healing modality is overly restrictive and limits access to care. It appears that the LCD has taken a narrow view of the number of applications in articles cited when the preponderance of literature utilized more applications in their treatment groups with positive results compared to SOC. The number and frequency of applications should remain at the discretion of the clinician, understanding indication requirements as well as critical utilization review. As a physician seeing and caring for these patients with challenging wounds and comorbidities, every tool is necessary to achieve favorable outcomes.