Organogenesis

Empowering Healing

Novitas/FCSO Open Meetings on Proposed LCD – Skin Substitutes of the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers

Proposed Skin) Substitute LCDs (DL35041 and DL36377)

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Presenter

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Topics Covered

We agree with Novitas and First Coast Service Options (FCSO) on the following issues:

- Need to harmonize the Novitas and FCSO LCDs on application of skin substitutes
- Need for appropriate documentation to demonstrate that wounds are responding to application of skin substitutes

We disagree on the:

- Limitation to two applications of a skin substitute to a wound per episode of care
- Prohibition on switching from one skin substitute to another during an episode of care
- Improper assignment of PuraPly products to the Group 3 Non-covered code list

We are continuing to review the proposed LCDs and may raise additional points in our comment letters

Novitas/First Coast Proposes to Limit the Number of Skin Substitute Applications in a 12-Week Period to 2

Proposed LCDs state that the following are not considered reasonable and necessary:

> "Greater than two applications of a specific skin substitute graft product within the episode of skin replacement surgery for wound care (defined as 12 weeks from the first application of a skin substitute graft).
>
> - The expectation is treatment will consist of the fewest repeat applications and amount of product to heal the wound. It is expected that products are used per the labeling. It is not expected that every ulcer, in every patient will require the maximum number of applications listed on the product label. This utilization pattern may be subject to focused medical review." (p. 6)

Clinical Guidelines Do Not Include a Limit on Skin Substitute Applications

- Guidelines for both VLU and DFU focus on evaluation intervals and assessment of any intervention, including standard treatment, use of skin substitutes or any other modality
  - Guidelines are silent on the frequency and timing of skin substitute applications
  - Applying skin substitutes 3 or more times is within the guidelines if the wound meets guideline criteria for improvement

VLU Guidelines

- Wound Healing Society[1]

  Guideline #5.6

  Selectively use adjuvant agents (topical, device, and/or systemic) after evaluating individual patient/ulcer characteristics and when there is a lack of healing progress in response to more traditional therapies. If significant wound improvement does not occur within 3-6 weeks of initiating a tx plan, **reevaluation of the patient and consideration of other tx options should be considered.** (Level I)

[1] Marston W, Tang J, Kirsner RS, Ennis W. Wound Healing Society 2015 update on guidelines for venous ulcers. Wound Repair Regen. 2016 Jan-Feb;24(1):136-44. doi:10.1111/wrr.12394.

DFU Guidelines

Wound Healing Society[1]

Guideline #4.4. There should be an ongoing consistent documentation of wound history, recurrence, and characteristics (location, size, base, exudates, condition of the surrounding skin, staging, and pain) to evaluate wound bed preparation. The rate of wound healing should be evaluated to determine whether treatment is optimal. (Level II)

Principle: Ongoing evaluations of wound bed preparation are necessary; if the ulcer is not healing at the expected rate, **interventions for wound bed preparation need to be reassessed.** The longer the duration of the ulcer, the more difficult it is to heal. If an ulcer is recurrent, etiology, patient education, or issues of prevention and long term maintenance need to be reassessed.

Guideline #4.5: Patients who fail to show a reduction in ulcer size by 50% or more after 4 weeks of therapy should be reevaluated and other treatments should be considered. (Level II)

Principle: Percent change in wound area of DFUs over four weeks of treatment is a good predictor of effectiveness of therapy and likelihood of healing.

Society of Vascular Surgery, American Podiatric Medical Association, Society for Vascular Medicine[2]

Recommendation 1: We recommend frequent evaluation at 1- to 4-week intervals with measurements of diabetic foot wounds to monitor reduction of wound size and healing progress (Grade 1C).

Evidence. Percentage reduction in wound size is an early predictor of treatment outcome. Wound area reduction of 10% to 15% per week or 50% area reduction in 4 weeks results in increased likelihood of healing with decreased complications of infection and amputation. Although there are no studies that evaluated the benefit and utility of different wound check intervals, studies that monitored healing progression of DFUs strongly correlated 50% healing at 4 weeks with final full healing by 16 weeks. By measuring wounds at 1- to 4-week intervals, the clinician documents healing progress and **identifies the basis for treatment modification**

1 Lavery LA, Davis KE, Berriman SJ, et al. WHS guidelines update: Diabetic foot ulcer treatment guidelines. Wound Repair Regen. 2016 Jan-Feb;24(1):112-26. doi:10.1111/wrr.12391.
2Hingorani A, LaMuraglia GM, Henke P, et al. The management of diabetic foot: A clinical practice guideline by the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine. J Vasc Surg. 2016 Feb;63(2 Suppl):3S-21S. doi:10.1016/j.jvs.2015.10.003.

Only Basis for Limiting the Number of Skin Substitute Applications Should be Medical Necessity

- Physicians should be allowed to apply skin substitutes when **medically necessary** to achieve wound healing
- There is no clinical basis for limiting the number of applications to 2 or any number
  - Novitas/FCSO themself agree that skin substitutes should be used according to their FDA labels
  - Labeled indications for almost all products do not limit the number of applications
    - Labels are silent on the number of applications for 510(k) and HCT/P products
- The evidentiary reviews conducted by Novitas/FCSO do not support any limitation on the number of applications
  - None of the professional society guidelines or clinical trial results or other evidence cited (including the AHRQ report) support any limitation on the number of uses
  - Moreover, there are many additional published clinical trials not cited by Novitas/FCSO and we are not aware of any that support a limitation on the number of applications
- Any limitation on the number of applications, aside from having no clinical basis, is inappropriate given the heterogeneity of DFUs and VLUs and the diversity of skin substitute products

Switching Skin Substitute Products in a 12-Week Period Should Be Permitted

Proposed Skin Substitute LCDs state that the following is not considered reasonable and necessary:

> "Switching skin substitute graft products in a 12-week episode of skin replacement surgery for wound care. Exceptions should be rare and may be considered on appeal when the medical necessity of the change is clearly documented in the medical record."

- We disagree with this limitation. A patient's lack of clinical response to one product may require switching to another product, especially to a product that is technologically different
  - In such a case, switching may result in fewer overall skin substitute applications

Puraply Products Are Improperly Assigned to Group 3

- Novitas/FCSO stated in the draft LCDs: “Coverage will be provided for products in the associated billing and coding guideline meeting the necessary FDA regulatory requirements as of publication”
- There are skin substitutes listed in Group 3 that meet the Novitas/FCSO criterion and should be reassigned to Group 2
  - **Specifically, PuraPly, PuraPly AM, and PuraPly XT are products that should be reassigned to Group 2**
- PuraPly products are cleared by the FDA under 510(k)s under the name FortaDerm – the name was changed to PuraPly after commercialization

Product	510(K)	Date	Original Name
PuraPly	K011026	6/12/2001	FortaDerm
PuraPly AM	K051647	11/8/2005	FortaDerm Antimicrobial
PuraPly XT	K051647	11/8/2005	FortaDerm Antimicrobial

PuraPly, PuraPly AM, and PuraPly XT Should be Reassigned to Group 2

- PuraPly, PuraPly AM, and PuraPly XT are indicated for use in patients with diabetic foot ulcers and venous stasis ulcers
  - They are legally marketed for these indications
- PuraPly AM, and PuraPly XT are the only skin substitutes containing polyhexamethylene biguanide hydrochloride (PHMB) which provides an effective antimicrobial barrier
- The predicate device for PuraPly was Oasis (Q4102) and Puraply (as Fortaderm) was listed as a predicate for Integra BMWD (Q4104) and Integra (Q4108); Oasis, Integra BMWD, and Integra are appropriately marketed as skin substitutes and assigned to Group 2
- Novitas and First Coast should reassign all PuraPly products to Group 2