August 23, 2023

Dr. Leslie Stevens, Medical Director, Novitas Solutions, Inc.
Dr. Alicia Campbell, Medical Director, First Coast Services Options, Inc.
Dr. Juan Schaening, Medical Director, CGS Administrators, LLC,

Re: LCD - Skin Substitute Grafts/Cellular and/or Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers LCD (L35041) / LCA (A54117), LCD (L36377) / LCA (A57680) and LCD (L36690) / LCA (A56696)

Dear Medicare Administrative Contractors:

As the Officers of the Wound Care Collaborative Community (WCCC), we are compelled to share our collective voice after reviewing the final LCD for Skin Substitute Grafts/Cellular and/or Tissue-Based Products, scheduled to become effective September 17th.

WCCC is a FD A approved 'collaborative community' of over 130 volunteer wound care experts, researchers, government including CMS, medical health systems, payors and industry who are working together to remove barriers to innovation and promote access to evidence-based treatments for patients suffering from wounds, http://www.woundcarecc.org/. We find that the new LCD impedes innovation and access and is counter to our efforts. Therefore, as a collective voice, we are requesting you delay implementation of this LCD coverage policy.

We appreciate the inclusion of language describing treatment of the patient's systemic disease(s) process and standard of care (SOC) that includes thorough assessment, debridement, vascular evaluation, tissue perfusion, and oxygenation evaluation, utilization of appropriate off-loading or compression, management of exudate, nutritional assessment, and maintenance of a moist environment. This aligns with and supports recognized evidence-based care, a core objective of the WCCC.

We understand the designation of an 'episode of skin replacement surgery' as 12 weeks from first application of a CTP/SS graft. However, the policy as written will deny Medicare patients suffering with chronic diabetic foot ulcers and venous/arterial ulcers, necessary and appropriate continued care of their wounds which may lead to additional hospitalizations and procedures, including amputations.

In the policy, under limitations, it states, "*Application of a skin substitute graft product beyond 12-weeks per episode of care"* is considered as *"not medically reasonable and necessary"*. Under coverage, the policy instructions state…*"Additional applications of a skin substitute product beyond the 12-week episode of skin replacement surgery is not expected if the ulcer has responded to the skin replacement surgery with epithelialization and* ***other progression."***

We agree if epithelization has occurred, no additional skin substitute grafts/ CTP applications are required. However, inclusion of the language *"and other progression"* indicates the policy would not cover a second 'episode of skin replacement surgery' if **any progress** is documented, regardless of the percent of progress or medical judgement of the treating clinician. More complex and/or large ulcers, that may be significantly progressing at 12-weeks, but have only reached a 60-75% of closure, not unusual for venous and/ or arterial leg ulcers, need continued CTP treatment to move to closure.

The LCD policy neglected to provide coverage for a second 'episode of skin replacement surgery' for patients with more complex and/or large ulcers, that are often vulnerable to interruption and/ or regression in their healing trajectory. Open wounds can expose patients to dangerous complicating factors (i.e. tissue infection, tissue necrosis, osteomyelitis, amputation, loss of mobility, loss of limb).

The policy's one-episode with a maximum of four skin substitute graft/CTP applications was based on the Armstrong et al.[29] paper referenced in the policy. This single paper reviewed claims data (Oct. 2015-Oct. 2018) for grafts/CTPs applied to diabetic foot ulcers only, which are smaller area wounds. Based on this paper, the diabetic foot ulcers receiving skin substitute graft surgery had an average of 3.7 applications (standard deviation of 3.6). Hence the four-applications in 12 weeks was determined as acceptable. This is not reflective of the full patient population that qualifies for and needs skin substitute graft/CTP surgery. The four-graft application limitation was not based on clinical judgment criteria, or indicators defined in the policy, and is medically unethical and negligent.

The disruption of care for a Medicare patient, that is responding positively to skin graft surgery, should and must be able to continue beyond 12 weeks and 4 grafts applications, to allow for complete closure. As written, this policy will deny patients who are responding positively to applications of a skin substitute grafts, their continued treatments, which could stop progression and endanger patients' lives.

Further, a major concern is the extensive list of CTP products that are now suddenly not included as product choices for clinicians and patients. Most of these products have published clinical evidence yet are now excluded as non-covered. This too needs a second look.

The policy and its implications are a critical issue for the 7% of patients with diabetes in the Medicare population who experience a new DFU each year. Armstrong et.al. looked at a full data set including 9,738,760 patients, of whom approximately 10% had a lower extremity diabetic ulcer.[29] This data reflects only one chronic wound population of Medicare recipients that could be negatively impacted by this restrictive coverage policy. There are millions more who suffer from venous and arterial ulcers, covered in this policy.

A very recent study in the Journal of Medical Economics shows the number of Medicare beneficiaries with chronic wounds increased by 13% between 2014 and 2019, increasing the prevalence to 16.4% of Medicare beneficiaries (10.5 million lives) affected by a wound or ulcer.[1]

We envision working collectively to help construct recommendations for large and /or complex ulcers and other wounds that are progressing significantly at the 12-week point (end of episode), i.e. > 60% at 12-weeks of treatment. These patients should be eligible for continued coverage with skin replacement surgery therapy at shorter 8-week intervals or episodes, if there is documented improvement.

Again, we request that you take a step back and delay activation of this policy, to allow wound care experts to help you develop recommendations that will protect patients and ensure access to their necessary skin graft surgery.

We urge you, as part of the process to schedule meetings for interested parties to engage with you to construct a more relevant, clinically acceptable, and evidence-based policy going forward.

Thank you,

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29. Armstrong DG, Tettelbach WH, Chang TJ, et al. Observed Impact of Skin Substitutes in Lower Extremity Diabetic Ulcers: A Retrospective Analysis of a Medicare LimitedDatabase (2015-2018). 2021
1. Carter MJ, DaVanzo J, Haught R, et al. Chronic wound prevalence and the associated cost of treatment in Medicare beneficiaries: changes between 2014 and 2019. *J Medical Ecom* 2023;21(1):894-901. DOI: 10.1080/13696998.2023.2232256