



June 8, 2024

Novitas Solutions, Inc.
2020 Technology Parkway, Suite 100
Mechanicsburg, Penn. 17050-9411

RE: Proposed Local Coverage Determination: Skin Substitute Grafts (DL35041)

Thank you for the opportunity to comment on the proposed local coverage determination for Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers (DL35041).

NAACOS is a member-led and member-owned nonprofit of more than 430 ACOs in Medicare, Medicaid, and commercial insurance working on behalf of health systems and physician provider organizations across the nation to improve quality of care for patients and reduce health care cost. NAACOS represents over 9 million beneficiary lives through Medicare’s population health-focused payment and delivery models, including the Medicare Shared Savings Program (MSSP) and the ACO Realizing Equity, Access, and Community Health (REACH) Model, among other alternative payment models (APMs). Our comments below reflect concerns of our members and their employed or aligned clinicians.

NAACOS supports the proposed LCD as it would align with existing LCDs for “Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers” across MAC jurisdictions and develop automated edits to enforce reasonable and necessary requirements. coverage of open skin wounds. The aim of skin substitutes is to replicate the properties of normal skin. Skin substitutes are an important adjunct in the management of acute or chronic wounds. However, our members have reported a rapid increase in the use of biological skin substitutes that do not align with clinical needs. ACOs are responsible for the total cost of care and outcomes for patients. Accordingly, CMS provides ACOs with full claims data for attributed beneficiaries. Upon reviewing the increased expenditures, our members were able to review full patient records and determine that some use of biological skin substitutes was abuse or potentially fraudulent. For example, members have reported:

- Using skin substitute products in patients without control of underlying conditions or exacerbating factors. Members have reported that skin substitutes who have been provided to patients who are poor candidates for specialty wound care, including hospice patients receiving significant wound care in the last 3 days of life, patients with inability to off-load pressure or transport without force, and patients who are unable to maintain adequate nutrition.
- Exceeding recommended treatment minimums and continuing to treat wounds that are not improving. Members have reported that the number of units are increasing over time, indicating that the wound is not healing. Additionally, there is lack of use of the JW modifier indicated the number of discarded units, this would assume that the number of units are billed perfectly.

We believe this LCD will address potential overutilization and abuse reported by our members as it clarifies the covered indications and limitations under which the skin substitutes are not considered medically reasonable and necessary.

Thank you for your consideration of our comments. If you have any questions, please contact Aisha Pittman, senior vice president, government affairs at aisha_pittman@naacos.com.

Sincerely,

A handwritten signature in black ink, appearing to read 'Clif Gaus', with a long horizontal flourish extending to the right.

Clif Gaus, Sc.D.
President and CEO
NAACOS