Patient Access to Skin Substitutes

The American Association of Tissue Banks (AATB) and AATB Tissue Policy Group (TPG) request that Congress:

1. Direct the Centers for Medicare and Medicaid Services (CMS) to:
    a. Delay implementation of the Local Coverage Determinations for "Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers (DFUs) and Venous Leg Ulcers (VLUs)" ("skin substitute LCDs") **by at least one year;** and
    b. Establish a new process for expedited review of products that meet evidentiary requirements, in place of LCD Reconsideration.
2. Direct CMS to abandon its plans to treat skin substitute products as "incident to supplies" under the Medicare Physician Fee Schedule (PFS) and to work with Congress and stakeholders to develop a more appropriate payment methodology for these products, including through public comment opportunities.
3. Enact payment reform for skin substitute products, ensuring that payment for such products:
    a. Accounts for differential costs of different raw materials used to manufacture the various products;
    b. Accounts for the volume of product use based on the size of the wound; and
    c. Allows for annual payment updates that account for inflation and are not subject to budget neutrality requirements.

Background. Pioneered in the late 1800s, skin grafting was one of the first allografts, or tissues grafted from one patient to another. Since then, skin grafts, or "skin substitutes," have become a common way to treat patients with a variety of conditions, including burns, diabetic foot ulcers, and chronic wounds. Skin substitutes are used in nearly every hospital in the United States; in fact, it is estimated that over 160,000 skin grafts are performed per year across the country on patients with severe burns alone.

AATB recognizes that Medicare spending on skin substitutes has increased significantly in recent years.[1] However, recent efforts by CMS and the Medicare Administrative Contractors (MACs) to reduce spending on this category of products would limit access for those who need them most; stifle innovation; and lead to an increase in preventable amputations and death, as described below.

Skin Substitute LCDs. In November 2024, all seven MACs issued final skin substitute LCDs that, when implemented on April 13, 2025, will restrict coverage to a small number of products based on new evidentiary requirements, excluding many products that have historically been covered and that are currently being used consistent with Food and Drug Administration (FDA) requirements.

AATB has significant concerns with the final LCDs and has asked the MACs to delay implementation for at least one year to address those issues.[2] In particular, AATB believes that skin substitute manufacturers should be given additional time to conduct clinical trials and publish the required evidence for coverage a in peer-reviewed

[1]https://www.medpac.gov/wp-content/uploads/2024/07/July2024_MedPAC_DataBook_SEC.pdf
[2]https://www.aatb.org/sites/default/files/2023/Federal%20Advocacy%20Letters/AATB%20December%2010%20Skin%20Substitutes%20Town%20Hall%20Statement.pdf

publication before their products are excluded from coverage; that the MACs should address whether they will restrict coverage of skin substitutes for non-DFU or VLU wounds to the same limited set of products allowed for DFUs and VLUs; and that CMS should establish an **expedited** process (in lieu of LCD Reconsideration) for moving products from the noncovered list to the covered list when sufficient evidence has been collected to reduce the burden on both the product manufacturers and the MACs.

Given these concerns, AATB requests that members of Congress – or Congressional staff – urge CMS to delay the date of implementation of the LCDs by at least one year and to establish an expedited process for adding new products with sufficient evidence to the covered products list.

Treatment of skin substitute products as "incident to supplies." AATB is also concerned that CMS is considering treating skin substitute products as "incident to supplies" under the PFS and bundling the costs of these products into the physician payment rates for the underlying procedures, specifically by including the products as inputs used in establishing the practice expense relative value units (PE RVUs) for each applicable procedure code. CMS proposed such changes in the Calendar Year (CY) 2023 PFS proposed rule, and while CMS did not finalize its proposals, CMS has repeatedly expressed interest in pursuing changes of this nature through future rulemaking, most recently in the CY 2025 PFS final rule. Treating skin substitute products as "incident to supplies" would be a drastic departure from the current treatment of these products, since skin substitutes administered in physicians' offices are paid separately, generally at the average sales price plus 6 percent (ASP + 6%).

Should CMS decide to implement these or similar policies, patient access to skin substitutes could be significantly curtailed due to the impact of the policies on payment rates. By moving skin substitutes into PE RVUs, CMS would subject these products to the constraints that apply under the PFS. This includes budget neutrality requirements that apply both to the pool of PE RVUs as well as to the overall PFS conversion factor. Additionally, PFS updates are not meaningfully tied to inflation; rather, the PFS receives zero or little inflationary updates based on current law. These features of the PFS would result in payments for physician services not keeping pace with increases in costs of skin substitutes over time. They would also result in payment differentials between office settings (paid under the PFS) and outpatient hospital settings (paid under the Medicare Outpatient Prospective Payment System), which could restrict access in office settings and shift services to outpatient hospital settings that already struggle with insufficient payment for these products.

Most importantly, the changes CMS is contemplating regarding reimbursement for skin substitutes would harm patients and likely lead to an increase in preventable amputations and death. The greatest impact would be to patients with large wounds, which are more expensive to treat and for which payments would be least likely to cover expenses. Racial and ethnic minority populations—who are disproportionately affected by foot ulcers in the United States—would also be significantly harmed by this policy.

Payment Methodology Reform. To address excess spending growth on skin substitutes while avoiding the pitfalls of the CMS and MAC strategies, AATB believes a new payment methodology is needed to create appropriate incentives for the medically appropriate use of skins substitutes. Such an approach should prioritize aligning payments with costs, including based on the product type used and the volume required, and in a manner that allows for annual updates to keep up with inflation.

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