Patient Access to Skin Substitutes

The Association for Advancing Tissue and Biologics (AATB) requests that Congress support the following language in the fiscal year 2027 Labor, Health and Human Services, Education, and Related Agencies report:

Skin Substitutes—The Committee recognizes the significant increase in Medicare Part B payments for skin substitutes between 2019 and 2025 and appreciates the agency's commitment to reducing spending in this area. We are concerned, however, that patient access to these products is threatened by the agency's decision to finalize flawed policies for the payment of skin substitutes in office and outpatient hospital settings for 2026 onward, including to move payments for these important products when furnished in the office setting into the Medicare Physician Fee Schedule as incident to supplies and to use a non-representative data set to establish a payment rate of $127.14/cm^2 for 2026. The Committee is further concerned that this payment rate could be further reduced due to the agency's plan to use the most recently available calendar quarter(s) of average sales price data to set the rates for future years. The Committee encourages the agency to reverse the decision to pay for skin substitutes under the Medicare Physician Fee Schedule and to consult with stakeholders to develop a sustainable payment approach for skin substitutes across office and outpatient hospital settings that more accurately reflects the costs associated with acquiring and processing allograft tissue used as skin substitutes in order to preserve access to these important medical products for patients who need them. Such an approach should consider historic spending for skin substitutes in both the physician office and outpatient hospital setting prior to the effectuation of the 2026 changes. The Committee further encourages the agency to report to Congress within six months of passage of this bill on any new authorities that may be needed to establish a more sustainable payment model for skin substitutes in future years.

Background. Pioneered in the late 1800s, skin grafting was one of the first allografts, or tissues grafted from one human to another. Since then, application of "skin substitutes" has become a common way to treat patients with a variety of conditions, including diabetic foot ulcers and chronic wounds. Skin substitutes are used in nearly every hospital in the United States and have demonstrated significantly improved clinical outcomes for chronic wounds compared with standard of care alone. In fact, data from multiple systematic reviews and Medicare-based analyses demonstrate a 60-110 percent higher likelihood of wound closure, faster healing, and reduced wound size when skin substitutes are used – without increased safety risks. The use of skin substitutes is also associated with meaningful downstream benefits, including fewer amputations, emergency department visits, hospitalizations, and reduced short-term mortality rates.[1,2,3]

AATB recognizes that Medicare spending on skin substitutes has increased significantly in recent years.[4] However, recent efforts by the Centers for Medicare and Medicaid Services (CMS) to reduce spending on this category of

[1] Tettelbach W, Tucker T, Kot K. Real-world outcomes of a placenta-based tissue product versus standard of care for lower extremity diabetic ulcers: a Medicare cohort study. *J Wound Care*. 2025;34(Sup11):S25-S30. doi:10.12968/jowc.2025.0496

[2] Armstrong DG, Tettelbach WH, Chang TJ, et al. Observed impact of skin substitutes in lower extremity diabetic ulcers: lessons from the Medicare Database (2015-2018). *J Wound Care*. 2021;30(Sup7):S5-S16. doi:10.12968/jowc.2021.30.Sup7.S5

[3] Guo X, Mu D, Gao F. Efficacy and safety of acellular dermal matrix in diabetic foot ulcer treatment: A systematic review and meta-analysis. *Int J Surg*. 2017;40:1-7. doi:10.1016/j.ijsu.2017.02.008

[4] https://oig.hhs.gov/reports/all/2025/medicare-part-b-payment-trends-for-skin-substitutes-raise-major-concerns-about-fraud-waste-and-abuse/

products is limiting access for those who need them most; stifling innovation; and will ultimately lead to an increase in preventable amputations and death. Companies that produce skin substitutes have already had to lay off employees, defund critical innovation projects, and implement other cost-saving measures as a result of changes to skin substitute payment policy in the Calendar Year (CY) 2026 Medicare Physician Fee Schedule (PFS) Final Rule (i.e., PFS Final Rule).

Unsustainably low payment rate for allograft tissue used for skin substitutes. The PFS Final Rule, along with the CY 2026 Medicare Hospital Outpatient Prospective Payment System (OPPS) Final Rule, established a payment rate of $127.14/cm^2 for skin substitutes furnished in office and outpatient hospital settings, which is an unsustainably low number that was calculated using the wrong data. In particular, AATB is concerned that CMS chose to adopt a flat payment rate using utilization data from only hospital outpatient department settings. Payment for skin substitutes in that setting has historically been bundled and capped, leading to disincentives to treat patients with large wounds, and making payment in that setting an unrepresentative data set for the true costs physicians bear in the private office site of service. To set a payment rate for both sites of care, data from both the facility and non-facility settings should be incorporated into the calculation of skin substitute payment rates based on the costs physician offices may bear.

AATB is also concerned that CMS plans to update rates annually through rulemaking using one or more recently available calendar quarters of average sales price (ASP) data to set the rates. We expect this will result in downward pricing pressure on the market, which will further limit product availability and patient access. An annual inflationary update would instead control price increases, while also enabling tissue banks to recoup their costs and continue to offer these products. The agency's final policy to geographically adjust payments for skin substitutes furnished in non-facility settings in the PFS Final Rule, as required by statute, will further limit access to skin substitutes for patients in rural and underserved areas and underscores a key challenge with incorporating payment for these products into the PFS.

The finalized CY 2026 policies have already resulted in employee layoffs and other cost-saving measures. AATB members have had to reduce output, suspend clinical studies, and pull back on research and development that could result in new and innovative products. And we are concerned that patients who previously could not receive care in hospital outpatient settings may find out that they can no longer receive care in physicians' offices either. In fact, on February 3rd, 2026, the House Energy and Commerce Subcommittee on Oversight and Investigations held a hearing titled "*Common Schemes, Real Harm: Examining Fraud in Medicare and Medicaid*," where one witness (Stephen W. Nuckolls, CEO, Coastal Carolina Health Care and former Board Chair, National Association of Accountable Care Organizations (NAACOs)) stated in response to a question asking if the artificially low reimbursement rate risks restricting access for legitimate patients and providers, *"I can tell you that no one will give skin substitutes. Patients will not receive skin substitutes based on the current regulations that were passed by the Secretary and HHS."* A lack of access to skin substitutes will almost certainly result in an increase in preventable amputations and death.

Rather than continuing the flawed policies under the CY 2026 PFS and OPPS final rules, AATB believes CMS should work with stakeholders to determine a path forward that both reasonably limits federal spending on skin substitutes but also preserves access for patients who need these important products. Such an approach should more accurately reflect the costs associated with acquiring and processing allograft tissue used as skin substitutes and should consider historic spending for skin substitutes in both the physician office and outpatient hospital setting prior to the effectuation of the 2026 changes. The report language on the previous page would help accomplish this goal. CMS may require additional authorities to accomplish this goal, so the report language encourages the agency to report to Congress within six months if CMS needs new authority to establish a more sustainable payment model for skin substitutes in future years.

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