

CAPITOL STREET

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Mixed Bag for Skin Substitutes in Final Medicare LCD

Products Grouped into Three Categories for Coverage, Non-Coverage, and Status Quo

Relevant Companies



»» Our Take & Next Up

In our view, CMS is taking a reasonable, measured approach on Medicare coverage of skin substitutes in a final Local Coverage Determination ([here](#)), effective Jan. 1, 2026. Under the new policy, 18 products meet the evidence threshold for coverage beginning Jan. 1, 2026 (IART, MDXG, ORGO, SNN, SYK), while 158 other products do not (ABBV, CTEC, IART, JNJ, MDT, MDXG, ORGO, SNN, TAK, ZBH). Meanwhile, 154 products will be given another year to build evidence to support coverage (BNTX, CTEC, ENOV, IART, MDXG, ORGO, SNN).

»» Key Points

A final Medicare LCD on skin substitutes will be implemented on Jan. 1, 2026, with products grouped into three categories. CMS [announced](#) yesterday that implementation will move forward on a Local Coverage Determination (LCD) on Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers. According to CMS, skin substitute products will be categorized into three groups under the new policy:

- **Coverage (18 products).** These products meet the evidence threshold outlined in the LCD and will be covered by Medicare beginning Jan. 1, 2026 (includes IART, MDXG, ORGO, SNN, SYK).
- **Non-Covered (158 products).** These products do not have adequate evidence that their products meet the reasonable and necessary standard or identified any ongoing relevant research (includes ABBV, CTEC, JNJ, MDT, MDXG, ORGO, SNN, TAK, ZBH).
- **12-Month Status Quo Period (154 products).** These products have published interim results, published or submitted protocols, have an assigned clinical trial number, or demonstrated ongoing clinical trial or peer-reviewed investigational research published between the posting date of the proposed LCD and Nov. 1, 2025 (includes BNTX, CTEC, ENOV, IART, MDXG, ORGO, SNN).

The updated final LCD does not establish a coverage policy for the products in the 12-month status quo category. According to CMS, products in this category can be paid for at the MACs' discretion, while the product sponsors complete their studies. At the conclusion of the 12-month status quo period, the MACs will initiate a reconsideration of the LCD, reviewing any evidence received by Dec. 31, 2026. The MACs will also reconsider

coverage for products non-covered under the LCD if sponsors submit additional evidence that demonstrates that the product is reasonable and necessary for the Medicare population. The reconsideration of the LCD is scheduled for release in early 2027.

Stakeholders have limited options once the final LCD is implemented. Manufacturers with non-covered or status quo products will have to build evidence to support Medicare coverage. Other options for recourse would likely entail months-long processes, including requesting an LCD reconsideration/challenge ([here](#)), lobbying for Congressional action, or taking legal action.

Recall, all seven Medicare Administrative Contractors (MACs) postponed implementation of the final skin substitutes LCD ([here](#)) from April 13, 2025 to January 1, 2026, while requesting new evidence from stakeholders ([here](#)). This was the second implementation delay of the skin substitutes LCD as it was originally a Biden-era regulation subject to regulatory freeze by the Trump Administration. CMS received evidence submissions for 66 skin substitute products by the Nov. 1, 2025, deadline.

Skin substitutes have been a target for the Trump Administration. The Trump Administration has frequently pointed to skin substitutes as a major area of fraud, waste, and abuse and recently touted \$19.6 B in savings in 2026 from paying for certain skin substitute products as supplies in the final CY26 Physician Fee Schedule. In that rule, CMS set payment rates using three categories based on FDA regulatory pathways (PMAs, 510(k)s, and 361 HCT/Ps). For 2026, CMS finalized the use of a single payment rate (\$127.28) to reflect the highest average for the three categories of skin substitute products. CMS will propose different payment rates in future years (our take [here](#)).

BACKGROUND

The skin substitutes LCD outlines Medicare coverage for products used for diabetic foot and venous leg ulcers. The final policy took into account feedback during the public comment period, but still introduces frequency and utilization limits on skin substitutes. According to the Medicare Access to Skin Substitutes Coalition, the policy would have denied coverage for over 200 skin substitute products, leaving only 15 covered products to serve Medicare beneficiaries nationwide and substantially reducing the number of therapies allowed per patient.

The draft LCD received a groundswell of opposition from stakeholders including:

- Alliance for Wound Care Stakeholders ([here](#))
- American Professional Wound Care Association ([here](#))
- Medicare Access to Skin Substitutes Coalition ([here](#))
- American Podiatric Medical Association ([here](#))

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