

# CMS to make changes impacting Regenerative Biologic Medicine effective 1/1/26

## Medicare’s Skin Substitute Shake-Up: What Clinicians and Health Systems Need to Know



### Regenerative Biologic Medicine – CMS Changes

**Effective 1/1/2026**  
 CMS has made the following changes to cellular and/or tissue-based products (CTPs) which falls under the Regenerative Biologic Medicine Category.

**Contract Numbers:**

- MS1465
- MS1466
- MS1467
- MS1468
- MS1469
- MS1472
- MS1473
- MS1474
- MS1475
- MS1476
- MS1477
- MS1478
- MS1479

 **Questions/Info**

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### Rising Costs → Rising Scrutiny

Medicare spending on skin substitutes, cellular and/or tissue-based products (CTPs), surged from \$250M in 2019 to over \$10B in 2024, prompting heightened oversight from CMS and the OIG. Reviews have identified unnecessary procedures, inflated utilization, and inaccurate ASP reporting.

CTP use is now a key focus of the OIG Work Plan and the Medicare Fraud Strike Force, signaling a shift toward strict accountability and evidence-based regulation.

### A Unified Coverage Policy: LCD DL35041

The FINAL LCDs titled “Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers”(Skin Substitute LCDs) and scheduled to become effective on January 1, 2026, all seven Medicare Administrative Contractors (MACs); have been withdrawn and delayed until January 1, 2027.

### Implications of the Withdrawal:

**No Changes to Coverage:** With the withdrawal of these LCDs, there will be no changes to skin substitute coverage for Part B Medicare beneficiaries in Calendar Year 2026 Medicare Physician Fee Schedule will remain in effect.

**Active Policies:** Despite the withdrawal, three Part B Medicare Administrative Contractors (MACs), Novitas, CGS, and First Coast, continue to have active skin substitute policies.

**Future Payment Plans:** CMS plans has finalized payment for ski substitute products as incident-to-supplies when used as part of a covered application procedure. This will align with the U.S. Food and Drug Administration (FDA) regulatory status of these products.

## **2026 Payment Reform**

CMS's CY 2026 rule sets site-neutral rates for all FDA-classified CTPs at a max price of \$127.14/cm<sup>2</sup> for PFS, OPPS, and ASC.

CTPs will be billed as "incident-to" supplies, ending separate biologic reimbursement.

New APC groups (6000–6002) will be created after unbundling CTPs from procedures.

Medicare will not pay for CTP / Skin Substitute wastage "Under Any Circumstances"

## **Conclusion**

The alignment of enforcement and payment reform is reshaping CTP utilization. Moving forward, evidence, documentation, and transparency will determine both clinical performance and financial sustainability.

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