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 will make 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
james.wilcox@vizientinc.com

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
Effective January 1, 2026, all MACs will implement LCD DL35041, Medicare's first nationally aligned coverage
standard for CTP use in diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs).

Key Provisions
- Evidence-based eligibility: Only CTPs supported by strong, peer-reviewed studies qualify.
- SOC requirement: ≥4 weeks of documented standard care, offloading, debridement, infection control, moisture balance, with <50% improvement prior to CTP use.
- Restricted product list: 17 CTPs covered for DFUs; 5 for VLUs; 200+ excluded for insufficient evidence.
- Usage limits: Up to 8 applications in 16 weeks, with KX-modifier justification after the 4th.

2026 Payment Reform
CMS's CY 2026 rule sets site-neutral rates for all FDA-classified CTPs at $127.14/cm² for both PFS and OPPS.
- 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.

Balancing Oversight and Innovation
LCD DL35041 and the new payment model aim to reduce waste, prevent fraud, and reinforce evidence-based care, while tightening clinical and financial expectations.

Action Steps for Hospitals

1. Strengthen documentation to meet SOC and audit requirements.
2. Review formularies to confirm covered CTPs and identify alternatives.

Conclusion

The alignment of enforcement, unified coverage, and payment reform is reshaping CTP utilization. Moving forward, evidence, documentation, and transparency will determine both clinical performance and financial sustainability. Purchasing capital equipment requires a substantial financial commitment.

List of Medicare Approved CTPs with Vizient Contract Numbers

LCD (DL35041) Effective date of 01/01/2026. Medicare covered CTPs/skin subs for Diabetic Foot Ulcers (DFU**)** and Venous Leg Ulcers (VLU) only.

Application limit is 8 CTPs/skin subs during a 16-week period. Must use the KX-modifier to attest medical necessity for use over 4 applications. To qualify for a CTPs/skin subs the DFU/VLU must receive documented SOC for 4 weeks with less than 50% healing. When CTPs/skin subs are applied over exposed muscle, tendon, or bone, the CTPs/skin subs must be approved for this indication.

For other wound types, the use of CTPs "must meet the reasonable and necessary threshold for coverage and the products must be used in accordance with their intended use as approved/regulated by the FDA." It is up to the discretion of the individual MACs how these other wound types will be handled.

HCPCS Codes	Manufacture	Products on Vizient Contracts	Product Name	Source	Approved Usage
Q4105	Integra LifeSciences	MS1468	Dermal Regeneration Template Omnigraft Dermal Regeneration Matrix (Brand names for the same product)	A bilaminate sheet of cross-linked bovine tendon collagen and glycosaminoglycans (GAG) from shark cartilage with a silicone sheet cover.	DFU
Q4110	Integra LifeSciences	MS1468	Primatrix	Fetal bovine dermis	DFU
A2019	Kerecis/Coloplast	MS1469	MariGen Shield	Fish-Skin Graft and Silicone Cover	DFU
Q4158	Kerecis/Coloplast	MS1469	Omega3	Fish-Skin	DFU
Q4121	LifeNet Health	MS1472	Theraskin	Human Split-thickness Skin	DFU
Q4122	LifeNet Health	MS1472	Dermacell AWM & Dermacell AWM Porou (Like Products, one porous)	Human acellular dermal matrix	DFU
Q4186	MiMedx	MS1473	Epifix	Human placental membrane amnion and chorion layer	DFU & VLU
Q4187	MiMedx	MS1473	Epicord	Human umbilical cord tissue	DFU
Q4128	MTF Biologics	MS1474	Flex HD & AlloPatch HD (Brand names for the same product)	Human allograft skin	DFU
Q4151	MTF Biologics	MS1474	Amnioband/Guardian (Brand names for the same product)	Human placental membrane amnion and chorion layer	DFU & VLU
Q4101	Organogenesis	MS1475	Apligraft	living cells derived from human neonatal foreskin	DFU & VLU
Q4106	Organogenesis	MS1475	Dermagraft *(Not available until mid-2026)*	Human fibroblast cells derived from human neonatal foreskin	DFU & VLU
Q4159	Organogenesis	MS1475	Affinity	Human placental membrane amnion only	DFU
Q4160	Organogenesis	MS1475	Nushield *(No longer available)*	Human placental membrane amnion and chorion layer	DFU
Q4133	Smith & Nephew (was Osiris Therapeutics)	MS1478	Grafix (cryopreserved) Grafix PL (Lyopreserved) Stravix (cryopreserved) Stravix PL (Lyopreserved)	Grafix - Human placental membrane chorion layer only Stravix – Human umbilical cord Tissue	DFU
Q4102	Smith & Nephew	MS1478	Oasis Wound Matrix (owned by Cook Biotech, not on contract, but courtesy pricing is available for members through S&N)	Porcine small intestinal submucosa	DFU & VLU
Q4203	StimLabs	MS1479	Derma-Gide (Not on Contract at this time)	Porcine collagen	DFU
Q4107	Stryker		GraftJacket	Human dermal tissue	DFU