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EDITORIAL

Update: CMS Final DFU/VLU CAMP LCDs Effective January 1, 2026: Covered, Cut, Status Quo, and Emerging Collateral Statutory Constraints

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On December 15, 2025 (updated December 16, 2025), Centers for Medicare & Medicaid Services (CMS) announced that all the Medicare Administrative Contractors (MACs) will issue updated "Final" Local Coverage Determinations (LCDs) for cellular, acellular and matrix-like products (CAMPs) used to treat diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs), with an effective date of January 1, 2026. Importantly, CMS states these LCDs are indication-limited: they apply to DFU/VLU and "do not impact payment ... for other uses" (e.g., pressure injuries, surgical wounds, etc.), while also describing frequency and utilization limits intended to promote safety and reasonable use.

Why this "final" update is happening now

CMS frames the current action as the endpoint of a delayed implementation process. In an April 11, 2025 press release, CMS stated it was reviewing coverage policies and therefore delayed the effective date of the then-final LCDs until January 1, 2026, and asked stakeholders to submit "peer-reviewed publications and high-quality findings" by November 1, 2025 for MAC review. In the December 2025 fact sheet, CMS reiterates that an additional evidence window was granted and reports evidence submissions for 66 products by the November 1, 2025 deadline.

The core policy structure: "Covered, Cut, and Status Quo"

CMS/MACs organized products into three evidence-status groups that will drive coverage outcomes beginning January 1, 2026.

1. Covered

Products meeting the LCD evidence threshold will be covered by Medicare beginning January 1, 2026. CMS reports the MACs identified 18 covered products (18 HCPCS codes). The "covered" list includes widely used products such as Apligraft (Q4101), Dermagraft (Q4106), Oasis Wound Matrix (Q4102), Grafix Prime (Q4133), TheraSkin (Q4121), GraftJacket (Q4107), DermACELL (Q4122) and others listed in CMS's Table 1.[1]

2. Non-covered (“Cut”)

Products without adequate evidence and without ongoing relevant research identified by the MACs fall into the Non-Covered group. CMS’s Table 3 lists 158 non-covered products (158 HCPCS codes), the single most disruptive element operationally because it creates a bright-line “do not cover” posture for DFU/VLU. CMS’s newly added FAQ underscores the practical headline: “what is notable” about the updated LCDs is “the 158 products that will no longer be covered.”[1]

3. 12-month “Status Quo/MAC Discretion”

The third category is the major nuance, and the focus of CMS’s FAQ clarification. CMS describes the 12-Month Status Quo Period as products with indications of ongoing evidence generation (e.g., published interim results, protocols, a trial number, or ongoing clinical trial/peer-reviewed investigational research within the specified period). CMS’s Table 2 lists 154 “MAC Discretion” products (154 HCPCS codes).[1]

Crucially, CMS emphasizes that the updated final LCDs do not establish a positive or negative coverage policy for products in the status-quo bucket. The FAQ makes this explicit: if a product is on the MAC Discretion list, coverage has not changed as of January 1, 2026; these products “will continue to be paid as they have been previously.” CMS further clarifies that the LCDs “will not make product-specific changes that affect payment” for items on the MAC Discretion list during the 12-month period.

That said, CMS also reminds stakeholders what “status quo” is (and is not): products without an affirmative LCD determination must still meet the statutory “reasonable and necessary” requirement under SSA §1862(a)(1)(A) and all applicable coding/billing rules, and MACs will make individual claim determinations (i.e., claim-by-claim discretion). Operationally, “status quo” means continued possibility of payment, not guaranteed payment, so variability across MAC adjudication and documentation scrutiny remains a central risk.

Evidence pathway and what CMS says about Grafix Prime

CMS provides a useful window into how it applied its evidence rubric. It states that among the 66 submissions, the MACs identified eight as reports of interventional randomized controlled trials (RCTs); of those, Grafix Prime met the evidence threshold and was added to the covered group, with the RCT published April 16, 2025 (plus corroborating evidence). Even if stakeholders disagree with the thresholds or conclusions, this explanation signals that the MACs are positioning the LCDs as a comparative evidence gate, and that RCT design alone is not sufficient if it does not align with the LCD’s evidence expectations. Hopefully, these evidence expectations will also be further clarified soon.

What happens after the 12-month status quo period

CMS’s stated intent is to preserve beneficiary access while studies are completed, but with a firm timeline. CMS explains that many sponsors could not complete and submit final results by November 1, 2025, and that the “status quo” category was designed to avoid cutting off access while evidence is generated, while still issuing non-coverage for products the MACs believe should not be covered.

At the end of the 12-month period, the MACs plan to initiate reconsideration of the LCDs, reviewing evidence received by December 31, 2026, with the reconsidered LCDs scheduled for release in early 2027. CMS also notes that MACs will reconsider coverage for currently non-covered products if sponsors later submit evidence demonstrating the product is reasonable and necessary for the Medicare population.

Practical implications for providers, health systems, and manufacturers

A. Immediate formulary and workflow bifurcation (effective January 1, 2026)

Wound programs treating DFU/VLU will need an operational split among: (a) covered products (lowest administrative friction), (b) status quo products (potentially payable but documentation, and MAC-behavior-sensitive), and (c) non-covered products (high denial likelihood for DFU/VLU).

B. Documentation and medical-necessity discipline become even more consequential

CMS explicitly ties status-quo payment to the longstanding statutory “reasonable and necessary” standard and “all other applicable Medicare coverage, coding, and billing requirements,” with claim-by-claim MAC discretion. In practice, this increases the premium on: clear DFU/VLU diagnosis, wound chronicity/severity documentation, standardized baseline care, and precise product selection rationale, especially for status-quo products.

C. "Status quo" products will behave like a documentation- and MAC-variance problem, not a coverage expansion

Although the 154 MAC Discretion products are not newly covered or non-covered, programs should expect greater variability in claim outcomes across jurisdictions and heightened need for tight DFU/VLU eligibility documentation, standard of care failure documentation, and product-selection rationale, because payment remains subject to §1862(a)(1)(A) and MAC claim-by-claim adjudication during 2026.

D. The LCD change is occurring amid CMS's broader "skin substitute spend" narrative

CMS has publicly linked the CAMP policy environment to rapid spending growth and concerns about waste, fraud and abuse. For example, CMS stated in an October 31, 2025 press release that Medicare spending on CAMPs rose sharply over the past 5 years and described CY 2026 PFS policies intended to reduce "unnecessary use" and spending on CAMPs. Even though LCDs are coverage policy (not payment methodology), this broader framing signals an environment of heightened program-integrity scrutiny that will likely amplify audit sensitivity around DFU/VLU skin substitute use.

E. Florida - collateral effects of the national CAMP spend and program-integrity narrative

While Florida's advanced practice registered nurse (APRN) scope-of-practice and supervision statutes[2] were not drafted specifically as "CAMP legislation", they operate in a policy environment shaped by rapid Medicare CAMP spending growth and increasing focus on non-facility outliers. Claims analyses summarized in the *International Journal of Tissue Repair* consensus document found that in 2024, fewer than 3% of non-facility providers accounted for 47% of total Medicare CAMP spending ($3.4B of $7.2B billed), with markedly higher application frequency and graft size than other providers.[3] Among the top 100 highest-spending providers, APRNs were the most frequently represented specialty (37 of 100), and outlier care patterns showed heavy reliance on home-based and other non-facility sites, including mobile unit (POS 15) and home-based care (POS 12).[3] In that context, state-level supervision/structure requirements may function as collateral constraints on legitimate wound-care delivery models, even when the underlying target is inappropriate utilization by a narrow subset of billers.

Bottom line

CMS's clarification can be summarized as: "Covered" products proceed under affirmative LCD coverage; 158 products are affirmatively "non-covered" for DFU/VLU; and 154 products are in a 12-month "status quo/MAC discretion" lane where no new LCD determination is made, but claims remain subject to longstanding medical-necessity standards and MAC claim-by-claim discretion. The next decisive inflection point is the reconsideration cycle, evidence submitted through December 31, 2026, with revised LCDs expected early 2027, making 2026 the critical year for beneficiary-access advocacy, study completion, and operational tightening around documentation and utilization.

Conflicts of interest

The author declares no conflicts of interest.

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