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COMMENTARY

Expert guidance for a pragmatic, evidence-based framework for skin substitutes (CTPs/CAMPs) across all chronic wound types

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Summary

- The problem is systemic. Rapid biotechnological growth in "skin substitutes"—more accurately, cellular and tissue based products (CTPs) or cellular–acellular matrix like products (CAMPs)—has collided with a legacy reimbursement framework not designed to accommodate scale, complexity, or heterogeneity of modern wound care. The result has been fiscal volatility, practice uncertainty, uneven patient access, in addition to fraud, waste, and abuse.
- Blunt instruments harm patients and providers. The current policy reaction—flat rate cuts, broad audits, and overly restrictive coverage —threatens access to limb saving therapies while failing to distinguish good practice from waste and fraud.
- A comprehensive framework can exist. We propose inclusive Local Coverage Determination (LCD)/ National Coverage Determination (NCD) guidance that extends beyond diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs) to pressure injuries, open (surgical/trauma/other) wounds, and revascularized arterial ulcers, anchoring coverage in objective clinical entry criteria, etiology specific standard of care, documentation rigor, and technical standards (e.g., graft thickness, negative pressure wound therapy (NPWT) compatibility) that reflect real world biology.
- Align incentives with evidence. A tiered reimbursement structure tied to randomized controlled trials (RCTs) and real world evidence (RWE) protects innovation and differentiates clinically effective products—ensuring excellent therapies aren't crowded out by a one price fits all payment that only incentivizes use of the least expensive products to manufacture.

- Stop subsidizing inefficiency; A practical wastage policy, medically unnecessary edit (MUE) standardization, and volume aware sizing rules reduce inadvertent waste and outright abuse—without undermining appropriate coverage or clinical judgment.
- Provider and payor trust is a policy objective. Transparent criteria, consistent documentation requirements, and a defined "safe harbor" for adherence to evidence based care re enable clinicians to treat confidently—and Medicare Administrative Contractors (MACs) to adjudicate consistently.

Why this commentary—and why now

The sector historically called "skin substitutes" has outgrown both the term and the regulatory scaffolding built to manage it. Clinicians now handle a diverse ecosystem of CTPs/CAMPs that can be decisive in converting stalled, complex wounds into durable healing. Yet, within barely five years, Medicare Part B expenditures for wound care have swelled from an estimated $250 million (2019) to > $22 billion (projected 2025)[1]—a trajectory driven by expanded access and innovation, but also by systemic inefficiencies, documentation variability, and exploitable payment mechanics that enabled avoidable waste, non-medically necessary utilization, and fraudulent billing.

Unsurprisingly, this fueled intense scrutiny. Department of Justice (DOJ) and Office of Inspector General (OIG) investigations, audits, and False Claims Act actions concentrated on outlier utilization patterns. While many cases rightly targeted abuse, the policy reflex—swift cuts to reimbursement, sweeping medical review, and a restrictive DFU/VLU LCD that was poised to roll out across MACs—risked withdrawing medically necessary therapies from patients with complex wounds. The draft LCD's late withdrawal left a guidance vacuum—with four of seven national MACs operating without any skin substitute LCD at all, creating a patchwork of expectations that providers must navigate at their peril.

This is an untenable equilibrium: it undermines patient outcomes, erodes provider confidence, and weakens the policy goal of accountable, value based care. The purpose of this commentary is to offer a pragmatic, field tested framework—crafted by a multidisciplinary group with >200 years of combined clinical and research experience and hundreds of thousands of wound-patient visits annually—to stabilize the space.

The authors represent a broad spectrum of academic, non-academic, clinic-based, private practice, and mobile care providers – therefore a wide variety of care and reimbursement algorithms. In this commentary, we present key elements that should be included in a LCD/NCD policy that is etiology inclusive, clinically specific, and economically rational.

The case for a unified, etiology inclusive approach

Historically, coverage policies have oscillated between narrow scope (e.g., DFU/VLU only LCDs) and over generalization that treats different wound types as interchangeable. Neither stance reflects clinical reality. Chronic, non-healing wounds share common impediments—inflammation, bioburden, senescent tissue, protease imbalance, ischemia, mechanical stress—yet differ profoundly in root cause, required standard of care (offloading, compression, nutrition, debridement cadence), and timing and selection of advanced therapies.

An inclusive policy must therefore do two things:

1. Anchor coverage to shared clinical logic

Require ≥30 days of standard of care (SOC) with documented failure to respond (e.g., <50% reduction in area or volume), adequate perfusion, rigorous wound bed preparation, and infection control as universal entry criteria.

2. Respect etiology specific standards

Define SOC expectations by wound type (DFU, VLU, pressure injury, open/surgical/trauma, arterial ulcer).
This dual structure does not limit innovation; it requires discipline. It protects patients by ensuring CTP/CAMPs are deployed when healable potential exists and upstream causes have been addressed.

Three core policy objectives

1. Maintain patient access to best possible care

Patients with limb- and life-threatening wounds cannot be collateral damage of fiscal repair. Coverage must remain

available for partial and full thickness ulcers, including those exposing tendon, muscle, or bone, provided granulation is present, bioburden is controlled, and healing prerequisites (perfusion, offloading/compression, nutrition) are met. This includes pressure injuries (stage III/IV),open/surgical/trauma wounds, and arterial ulcers which constitute a large fraction of the U.S. burden but are often under addressed in DFU/VLU-centric policies.

2. Protect innovation from regulation

A tiered evidence model would ensure that new and effective technologies progress along a predictable pathway to reimbursement.

3. Restore provider trust with clear rules

Clinicians must not operate under perpetual fear that today's medically necessary decision becomes tomorrow's audit citation. Explicit entry criteria, documentation minimums, and technical standards create a defensible practice standard. If providers follow the evidence and document accordingly, reimbursement should be secure.

Documentation: rigor that enables, not punishes

A clear documentation standard raises quality and defends necessity.
This standardization rewards good care by making it legible and reduces denial risk without micromanaging clinical judgment.

Getting sizing, overlap, and "wastage" right

Sheet based matrices require anchoring/fixation to healthy margins to avoid shear, desiccation, and edge lift. In practice, clinicians must overlap onto intact skin and excise surplus for irregular shapes. Interpretations that demand an exact Length x Width graft fit at the surface of the skin defy biology and lead to undertreatment of the true three-dimensional wound bed area.

An LCD/NCD should cover the need for up to 0.5 cm overlap onto intact skin on all sides, as well as issues of irregular shape. Graft size should be chosen using wound base area (reflecting 3D-area contour into depth of wound)—not just skin surface length × width area. In deeper wounds, L x W skin surface area metrics can significantly underestimate required graft size.

Medically unnecessary edit standardization

We suggest a default cap: 300 cm² per application. If >300 cm² documentation of medical necessity, clinical rationale, and an explicit bridge to surgery plan should be required unless significant response to CTP/CAMP is proven during the episode or surgery is contraindicated or refused. Use of >300 cm² for 10 applications without surgical consideration is not expected; selective exceptions would be allowed with documented significant improvement. This approach curbs excess yet protects appropriate multidisciplinary overlap and deep wound realities.

Thickness matters—especially under NPWT

Biology and mechanics converge at graft thickness. Thicker matrices often provide greater ECM volume, substrate content, and durability, especially under NPWT; ultra thin constructs risk rapid dissolution in draining or deep wounds, particularly under NPWT suction.

Evidence tied reimbursement: incentivizing what works

Flat rate payment solves none of the core problems: it doesn't reward products with better outcomes, invites manipulation of the reimbursement system based solely on profit, and penalizes evidence generation. A tiered model—agnostic to regulatory pathway—reconnects payment to proof:

1. Covered products (top tier): Completed and published peer-reviewed RCT (quality per GRADE) + RWE → highest per cm² rate (TBD).
2. Coverage with evidence development: Completed and published peer reviewed RWE only and/or ongoing RCT research → lower rate (TBD).
3. New technology add on (NTAP like): Up to +50% for 2–3 years for products demonstrating new clinical evidence in a new population/severity/etiology and costs exceeding flat rate.
4. No research: No reimbursement after Jan 1, 2028.

By Jan 1, 2028, we believe reimbursement should be wound type specific, determined by completed peer reviewed, IRB approved studies.

This approach preserves innovation while ensuring payers fund outcomes, not just inputs.

Implementation roadmap

For CMS/MACs

1. Adopt a unified, etiology inclusive LCD/NCD structure with both universal wound eligibility and etiology specific SOC.
2. Codify the 0.5 cm fixation overlapping edge, wound base area sizing, .
3. Set MUE default at 300 cm^2; require pre approval >300 cm^2 with bridge to surgery planning when possible
4. Define combination NPWT + thickness guidelines and documentation for depth ≥2 cm and/or exposed deep structures.
5. Publish the research evidence tiering timeline with wound type specific research required by 1/1/2028.
6. Standardize documentation elements nationwide to reduce variance and audit ambiguity.

For health systems and clinicians

1. Operationalize SOC checklists by etiology; embed tissue perfusion, infection, debridement, offloading/ compression, and nutrition prompts in the EHR.
2. Measure volume, not just area; record manual depth and use validated tools (including FDA cleared digital measurement) where available. Determine contoured wound bed area whenever possible.
3. Match thickness to wound biology, particularly under NPWT.
4. Right size grafts; Train teams on overlapping fixation edges and irregular shape trimming.
5. Document progress every 1–2 weeks.
6. Maintain a surgical plan for very large wounds; treat CTP/CAMP use as a bridge whenever possible, not an endless loop.

For manufacturers

1. Align product portfolios to include sizes that minimize wastage.
2. Generate GRADE quality RCTs and RWE by the stated deadlines; design studies by wound type.
3. Publish thickness specifications and compatibility guidance with NPWT.
4. Pursue New Technology Add-on Payment (NTAP)-like indications for new populations/severity where data justify.

Conclusion

The window for coherent policy is open—but not indefinitely. If we default to extremes—over restriction that denies needed care or over permissiveness that fuels waste—we will lose the clinical and fiscal ground gained over the past decade. We urge:

- CMS and MACs to adopt a unified, etiology inclusive framework with clear clinical criteria, documentation standards, practical wastage rules, and evidence tiered reimbursement on the timeline proposed.
- Clinicians and health systems to implement check-listed SOC, volume aware measurement, and thickness informed selection, treating CTP/CAMPs as decisive tools within a disciplined pathway.
- Manufacturers to produced graft sizes to allow providers to minimize waste, publish thickness specifications, and invest in RCTs + RWE that will elevate the entire field.

We suggest targeted review by March 1, 2026 at a national forum—or sooner if CMS/MAC policy shifts. The operational details (e.g., exact per cm^2 rates) properly reside in payment rules (e.g., the Physician Fee Schedule); our proposals here provide a clinical economic scaffold to inform those determinations.

The objective is simple and non-negotiable: salvage limbs, restore lives, and do so with transparent, evidence aligned stewardship of public funds. With this framework, we can replace chaos with clarity—and ensure that innovation in wound care translates into predictable healing for the patients who need it most.

Conflicts of interest

The authors have no conflicts of interest to declare.

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