The Graft That Was Never Supposed to Be Applied: Medical Necessity in Skin Substitute Cases

Our last post looked at skin substitute fraud where every graft was real and the fraud was in the price. This one looks at the other side of the ledger: grafts that should never have been applied at all.

Medicare does not pay for a skin substitute simply because a wound exists. It pays when a wound has failed standard care, when the patient is a candidate for healing, and when the treating practitioner has documented both. Those conditions are spelled out in the Medicare coverage rules, and a graft applied without meeting them is not a covered service. When a practice bills for it anyway, and knows or should know that the conditions were never met, the claim is false. This post explains what those rules require, what a violation looks like in a patient's chart, and who is in a position to recognize it.

What Medicare requires before a graft goes on

Medicare pays only for items and services that are "reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395y(a)(1)(A). For skin substitutes, the Medicare Administrative Contractors have translated that standard into local coverage determinations. The most widely applied is Novitas LCD L35041, *Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds*.

The LCD sets out a sequence. A graft is covered only after conservative care has been tried and has failed, and only when the wound bed is actually ready to accept it:

- **Conservative care first.** For example, a diabetic foot ulcer must have failed more than four weeks of documented standard wound care. A venous leg ulcer must have been present for at least three months and unresponsive to at least thirty days of care.
- **"Failed" has a definition.** Standard care has failed when the wound has increased in size or depth, or has not changed from baseline. A wound that is shrinking on its own is responding, and a graft is not indicated.
- **The wound bed must be prepared.** Necrotic tissue must be debrided. Infection and osteomyelitis must be ruled out or resolved. Diabetic foot ulcers require offloading; venous leg ulcers require compression therapy and edema control.
- **There are limits.** No more than ten applications per wound per episode of care, and an episode of care generally does not exceed twelve weeks. A wound that

requires retreatment within a year is a treatment failure, not a reason for another round.
- **It must all be in the chart.** The record must document the wound's measurements, the conservative care that was provided and when, the reason it failed, and the clinical rationale for each application.

See CMS Medicare Coverage Database, LCD L35041 (Novitas Solutions). (In late 2025 the MACs withdrew replacement LCDs that would have tightened these rules further, so L35041 remains the operative standard for the conduct now under investigation.)

The common thread is that a graft is the end of a documented process, not the beginning of one. Practices that skip the process and go straight to the graft are not treating wounds. They are billing for them.

What it looks like in the chart

Medical necessity fraud in this space tends to leave the same fingerprints. Anyone who has worked in or around a wound care practice will recognize most of these.

- **No conservative care, or conservative care on paper only.** The first visit note already calls for a graft. Or the chart recites four weeks of offloading and dressing changes that nobody actually provided, in language identical from patient to patient.
- **Wounds that were healing anyway.** Measurements show the wound shrinking week over week, and the graft goes on regardless. Under the LCD, a responding wound is not a failed wound.
- **Every patient gets the same thing.** The same product, the same size, the same schedule, no matter the wound. Treatment protocols that do not vary by patient are a sign that the decision was made before the patient was seen.
- **Grafts far larger than the wound.** A two-square-centimeter ulcer treated with a sixteen-square-centimeter graft, billed in full, with the excess discarded or, worse, used on another patient and billed again.
- **Applications past the limit.** More than ten applications to the same wound, episodes that run far past twelve weeks, or a new "episode" started the moment the old one hit its cap.
- **Patients who are not candidates.** Hospice patients. Patients with untreated osteomyelitis or active infection. Patients whose wounds have no realistic prospect of closing, selected because they have Medicare and a wound, not because a graft will help.
- **The wrong setting.** Grafts applied in a patient's home or a facility, documented as if performed in the office so that the higher office-based rate applies.
- **Templated documentation.** Preprogrammed text that drops the required findings into every note with one click: wound bed prepared, infection ruled out, conservative care failed. The words are there. The care is not.

The *Vohra* complaint, filed in 2025 in the Southern District of Florida, alleges a version of this pattern at scale: a nationwide wound care physician group whose providers performed surgical debridements under production quotas, regardless of whether the wound called for them. *See* Complaint, *United States v. Vohra Wound Physicians Management, LLC*, No. 1:25-cv-21570 (S.D. Fla. 2025). And in the Apex Medical case in Arizona, the government alleged that untrained sales representatives selected patients, many of them in hospice, and that grafts were applied to wounds that did not need them, were not measured, or in some instances did not exist. *See* DOJ Press Release, *Wound Graft Company Owners Sentenced in $1.2B Health Care Fraud and Agree to Pay $309M to Resolve Civil Liability* (2026).

As always, allegations in a complaint or indictment are only allegations. But the patterns they describe are the ones a potential whistleblower should be watching for.

Why it is a false claim

A Medicare claim for a skin substitute is an implied representation that the service was reasonable and necessary. Every provider certifies as much when it enrolls and when it bills. *See* 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 424.516(f). A graft applied without meeting the coverage criteria is not reasonable and necessary within the meaning of the statute, and a claim for it is false under 31 U.S.C. § 3729(a)(1)(A). Where a chart is padded with templated findings to make the graft look covered, the records themselves support a separate false-record theory under § 3729(a)(1)(B).

Two elements get the most attention in these cases.

Materiality. The False Claims Act reaches only misrepresentations that would matter to the government's decision to pay. *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 192–94 (2016); 31 U.S.C. § 3729(b)(4). The LCD criteria are not a formality. They are the conditions under which Medicare agrees to pay at all, and the MACs enforce them through prepayment review and audit. A graft that skipped conservative care is not a technical violation. It is a service Medicare would have denied on its face.

Scienter. The Act requires actual knowledge, deliberate ignorance, or reckless disregard. 31 U.S.C. § 3729(b)(1). The government does not need to prove that a practitioner set out to defraud Medicare. It needs to show that the practice knew what the coverage rules required and billed anyway, or that it structured its operations so that nobody would look. Templated notes, uniform treatment protocols, production quotas, and sales representatives choosing patients all speak to that. So does a sudden surge in graft volume with no change in the patient population. *See United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 749–50 (2023) (scienter turns on the defendant's own knowledge and subjective beliefs).

One caution we have offered before applies here too. Medical necessity cases can turn into a battle of experts over whether a particular wound warranted a particular graft. The strongest cases do not depend on second-guessing individual clinical judgments. They rest on patterns that no legitimate clinical judgment produces: every patient, every time, the same product, the same size, regardless of the wound.

Who sees it

Unlike a pricing scheme, which lives in invoices and rebate agreements, medical necessity fraud lives in the exam room and the chart. The people who see it are clinical and administrative staff:

- Nurses and medical assistants who measured wounds that were closing and watched grafts go on anyway
- Nurse practitioners and physician assistants told to apply a product on a fixed schedule, or handed a patient list assembled by a sales representative
- Coders and billers who noticed that every note contained the same conservative-care language, or that graft sizes never matched wound measurements
- Hospice, nursing home, and assisted living staff who saw outside wound care vendors treat residents who had no prospect of healing
- Practitioners recruited into a wound care company who realized the protocol they were handed had nothing to do with the LCD

Under the False Claims Act, a whistleblower whose case leads to a recovery receives between 15% and 30% of what the government collects, 31 U.S.C. § 3730(d), and the statute protects employees from retaliation for lawful efforts to stop a violation, 31 U.S.C. § 3730(h). A complaint is filed under seal, and the first-to-file rule, 31 U.S.C. § 3730(b)(5), means the person who comes forward first is the one whose case proceeds.

If what is described here sounds like a practice you have worked in, we may be able to help. Pollock Cohen represents whistleblowers in False Claims Act matters nationwide, and consultations are confidential and without charge. You can reach us at (646) 290-8261.

This post is for general informational purposes and does not constitute legal advice. Allegations in indictments and complaints are allegations only, and defendants are presumed innocent unless and until proven guilty.