

A Compliance-First Clinical Pathway to Heal Chronic Wounds

Use smart antianionic dressings before considering any skin substitute.

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Abstract

Background: Federal scrutiny of high-cost skin substitutes/cellular and tissue-based products (CTPs) has intensified, with the Department of Justice (DOJ) announcing large-scale healthcare fraud takedowns, including alleged schemes involving unnecessary wound grafting and CTP billing. Simultaneously, the Centers for Medicare & Medicaid Services (CMS) and the HHS Office of Inspector General (OIG) have highlighted rapid growth and pricing concerns in the skin-substitute category.¹

Federal scrutiny of high-cost skin substitutes/cellular and tissue-based products (CTPs) has intensified.

Objective: Provide a practical, auditable protocol—aligned with current guidelines and coverage expectations—to help practices demonstrate that lower-cost, evidence-informed, non-cytotoxic “smart dressing” strategies have been exhausted and optimized before any skin-substitute/CTP use.

Methods/Design: We outline a stepwise pathway grounded in guideline-concordant standard of care (SOC) for diabetic foot ulcers (DFU), venous leg ulcers (VLU), pressure injuries, and mixed-etiology wounds (vascular/ischemic), integrating consistent debridement, off-loading or compression, infection/biofilm control, moisture/ionic balance, and documentation standards. The protocol embeds measurable checkpoints at 2, 4, and 6–8 weeks to determine response and appropriateness of escalation while creating a defensible record for payers.

Results (conceptual): The pathway standardizes “pre-CTP optimization,” prioritizes lower-cost smart dressings (including ionically active hydrogels) that can be used longitudinally, and defines objective “failure-to-improve” thresholds, data capture, and audit trails.

Conclusions: Implementing this protocol enables clinicians to meet guideline and coverage expectations, improve healing efficiency and cost stewardship, and cleanly justify escalation to CTPs only when clinically necessary

and properly documented—precisely the posture CMS and DOJ expect.²

Background and Regulatory Landscape

High-priced skin substitutes/CTPs face intensifying government scrutiny. DOJ’s 2025 national healthcare fraud takedown charged 300+ defendants and specifically described wound graft-related misconduct among other schemes. Regional cases (e.g., Houston) similarly alleged medically unnecessary “second skin” procedures with extensive Medicare exposure.¹

For its part, CMS has repeatedly signaled the need for substantial evidence and appropriate use. After multiple proposed LCDs for DFU/VLU, CMS announced in April 2025 that implementation of updated coverage determinations for skin substitute grafts/CTPs would be delayed until January 1, 2026, as part of an administration-level review—explicitly emphasizing maintenance of access for products with high-quality evidence and the importance of documentation. CMS OIG has separately flagged ASP reporting problems and sharply rising Part B expenditures for skin substitutes, highlighting risk for audits and recoupments. Office of Inspector General Legal and coding advisories have also warned that the new policies (as drafted regionally) tighten covered product lists and documentation rigor.³

Implication for clinics: The safest posture is to (1) maximize guideline-concordant, lower-cost wound optimization; (2) capture meticulous, auditable documentation; and (3) escalate to a CTP only after the record clearly shows SOC

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New Concepts and Studies

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failure despite appropriate advanced (but non-CTP) measures (Figure 1).

Guiding Clinical Principles

- **Adhere to disease-specific SOC.**
- **DFU:** aggressive debridement, infection control, and knee-high off-loading (preferably non-removable); evaluate perfusion; address glycemic control.⁴

- **VLU:** high-quality compression as first-line, sustained local wound care, debridement, and treatment of venous hypertension.⁵

- **Pressure injuries/arterial/mixed:** off-loading/pressure redistribution; evaluate and treat ischemia per WHS updates.⁶

- **Objective measurements at set intervals prove that SOC has been applied correctly and consistently** for a meaningful window (commonly ≥ 4 weeks for DFU/VLU in many LCDs).⁷

- **Use advanced “smart” dressings before CTPs**—for example, non-cytotoxic, ionically active hydrogels that modulate moisture, pH/ORP, ionic balance, and biofilm while protecting viable cells. (Examples in the market include hydrogels such as BioClense®, BioRelease and AgFresh®, and similar non-cytotoxic ionically active systems.) The mechanism-of-action rationale aligns with guideline calls to correct local wound physiology and with payer expectations to exhaust reasonable, lower-cost options first.⁸

The Pre-CTP Smart-Dressing Protocol

Goal: Create a standardized, evidence-aligned, auditable care pathway that maximizes healing probability and can demonstrate to CMS and auditors that all reasonable, cost-effective measures were exhausted before any skin substitute.

Step 0: Intake, Eligibility, and Risk Stratification (Day 0)

1. **Establish wound etiology** (DFU, VLU, pressure, arterial/mixed).
2. **Perfusion assessment** (ABI/TBI, Doppler, vascular consult when indicated) and glycemic control for DFU.⁹
3. **Baseline documentation:**
 - Wound photography (with scale), location, staging/classification.
 - Validated measurements: length \times width \times depth and area (cm²).
 - Tissue type (% granulation/slough/eschar), exudate volume/character.
 - Pain score, odor, periwound condition, edema score.

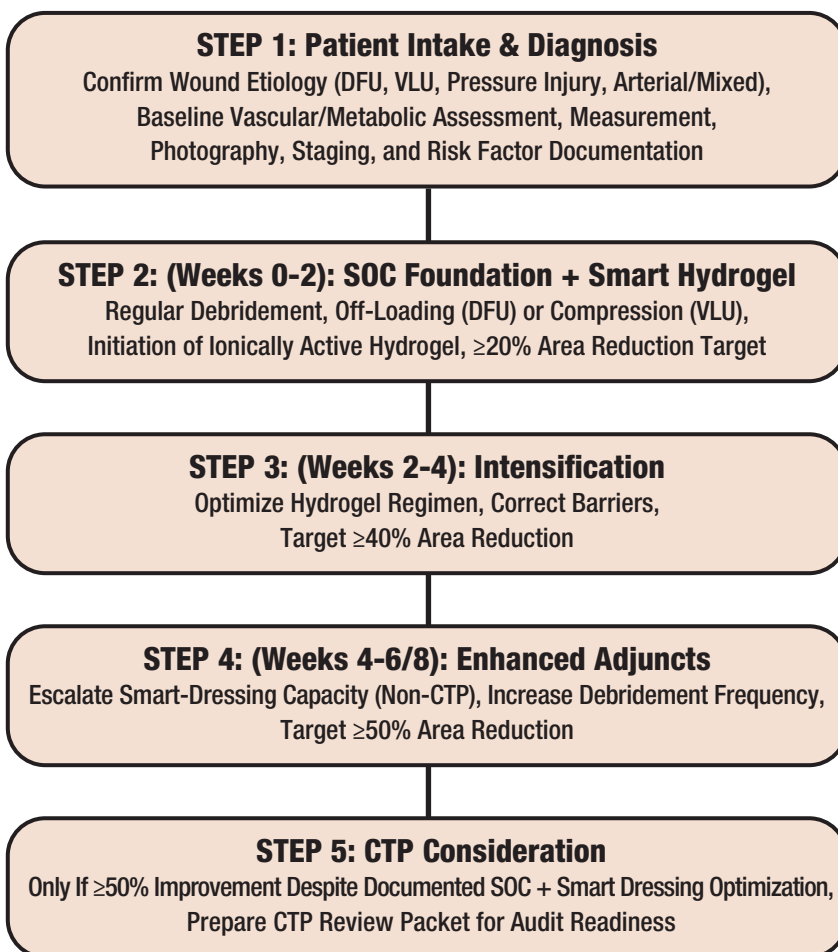


Figure 1: Pre-CTP Optimization Pathway for Chronic Wounds

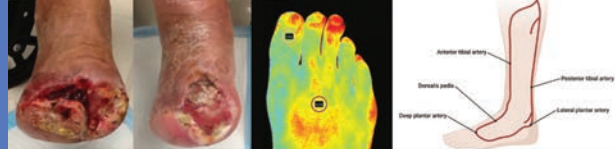
- Functionally relevant data: off-loading/compression capacity, adherence risk, social determinants (transport, home support).

4. **Informed consent** for longitudinal protocol and data use for QI.

Step 1: Foundational SOC (Week 0–2)

- **Debridement** (sharp/enzymatic/adjunct) to disrupt biofilm and slough; record method, extent, and tolerance.¹⁰
- **Infection/Biofilm:** culture if clinically infected; treat per IDSA/IWGDF infection guidance; avoid indiscriminate cytotoxic topicals and replace with ion-balancing products.¹¹
- **Off-loading (DFU):** Prefer non-removable knee-high device; if contraindicated, document reason and alternative.¹¹
- **Compression (VLU):** Initiate graduated compression with documented pressure range; address venous reflux/edema.⁵
- **Moisture and microenvironment:** Start a non-cytotoxic smart hydrogel regimen (see Step 2) to optimize moisture/ionic balance and protect viable tissue.

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• **Nutrition/glycemic control support** and smoking cessation counseling as indicated.

Checkpoint (end of Week 2): Expect $\geq 20\%$ area reduction (typical early-response target) or evidence of qualitative improvement (granulation, exudate control). If not met, proceed to Step 2 intensification and address barriers (device adherence, compression tolerance, perfusion issues).

Step 2: Smart-Dressing Optimization + Intensified SOC (Week 2–4)

- **Continue scheduled debridement** (weekly or as indicated) with biofilm control.¹³
- **Antianionic, non-cytotoxic hydrogel layer** (e.g., BioClense® for irrigation and microbial load management;

the smart-dressing domain (not to CTP yet), unless clear indications justify earlier CTP.

Why 4 weeks? Multiple MAC LCDs and OIG materials reflect the long-standing expectation that DFU/VLU generally should receive ≥ 4 weeks of SOC before CTPs are considered. Meticulous documentation of that interval is key to audit defensibility.⁷

Step 3: Enhanced Adjuncts While Staying Pre-CTP (Week 4–6)

- **Re-debride**; consider more frequent debridement for heavy biofilm.¹²
- **Escalate smart-dressing strategy** (still non-CTP):
 - Continue ionically active hydrogels with protocolized frequency.

FIGURE 2

Root-Cause Barrier Review Checklist

Barrier Category	Examples	Documentation Requirements	Corrective Actions
Device Non-Adherence	Off-Loading Not Worn, Compression Removed	Patient Statement, Staff Notes	Fit Adjustment, Irremovable Device
Edema Management	Persistent Swelling, Lymphedema	Edema Scoring, Limb Measurement	Adjust Compression, Referral
Perfusion Issues	ABI < 0.8 or > 1.3	Vascular Testing Results	Vascular Consult, Revascularization
Infection/Biofilm	Malodor, Purulence	Wound Culture, Clinical Signs	Targeted Antimicrobials, Debridement
Nutritional Deficiency	Low Albumin	Lab Values, Diet History	Nutritional Referral, Supplementation
Glycemic Control	HbA1c $> 8\%$	Lab Value	Endocrinology Referral
Social Barriers	Transportation, Cost	Social Work Notes	Arrange Support, Telehealth Follow-up

BioRelease® for sustained moisture/ionic modulation). AgFresh® for sustained cation release to balance wound electrolytes and eliminate biofilms.

– Purpose: support autolysis, manage exudate, buffer ionic imbalance, and maintain a pro-healing microenvironment that is gentle to host cells (especially important in ischemic/fragile beds and around exposed structures).

– Application: Per manufacturer's IFU, record frequency/volume and combine with secondary absorptive dressings as needed.

• Device adherence:

– DFU—confirm off-loading use through wear-time logs; consider rendering the device irremovable when practical.¹³

– VLU—optimize multilayer compression fit, document mmHg range, and patient tolerance.⁵

• **Edema & systemic factors:** diuretic/lymphedema referrals as appropriate; diabetes/vascular co-management.

Checkpoint (end of Week 4):

• **Primary threshold:** $\geq 40\%$ area reduction or trajectory consistent with closure by 12–16 weeks.

• **If $< 40\%$ reduction**, execute a Root-Cause Barrier Review (Figure 2) and proceed to Step 3 escalation within

– Add higher capacity absorptives/foams if exudative; protect periwound.

– Consider topical antianionics that are non-cytotoxic to viable tissue when bioburden is suspected, document clinical rationale and duration.

• **DFU:** Re-assess off-loading (device fit, patient factors) and consider total contact casting or rendering removable walkers irremovable if feasible.¹⁴

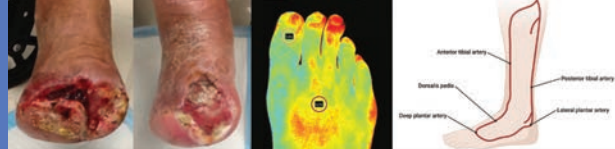
• **VLU:** Confirm duplex results and optimize compression class; consider a referral for venous intervention if non-responsive under compression.⁵

• **Arterial/mixed:** Address vascular work-up and revascularization pathways (documented).¹⁵

Checkpoint (Week 6–8):

- Proceed to CTP evaluation *only* if the chart shows:
 1. Correct diagnosis/etiology work-up,
 2. Consistent SOC (debridement + off-loading/compression + infection management),
 3. Documented trial of smart, non-cytotoxic advanced dressings, and
 4. Objective non-response (e.g., $< 50\%$ area reduction by Week 6–8) despite correction of barriers, or compelling

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clinical indications (e.g., tendon/bone exposure with a clean, well-vascularized bed that still fails to advance). The record must also show patient adherence efforts and education.

Documentation, Audit Readiness, and Billing Alignment

Core Documentation Elements (every visit)

1. **Measurements & photography with scale** (stored in EHR; date-stamped).
2. **Debridement details** (type, extent, rationale).¹⁶
3. **Device status** (off-loading/compression parameters, tolerance). IWGDF Guidelines⁵
4. **Dressing regimen** (smart hydrogel brand/generic class, frequency, response).
5. **Infection/biofilm assessment** (signs, cultures if indicated, antibiotics rationale/duration).¹¹
6. **Barriers & actions** (edema control, glycemic optimization, vascular plans).
7. **Patient education & adherence interventions** (teach-back; written plan).

The “4-Week Packet” (to justify any CTP consideration)

- Etiology confirmation and perfusion status.
- SOC summary: schedule of debridements; off-loading/compression fidelity.

Adherence-critical measures (off-loading/compression) are the strongest healing drivers in DFU/VLU and must be optimized alongside any dressing choice.¹⁹

- Smart antianionic dressing log: start date, materials, change frequency, responses.
- Objective metrics: % area change at weeks 2 and 4; granulation trends.
- Barriers addressed (transport, device tolerance, edema, glycemia).
- Physician statement: “Despite compliant SOC and advanced smart-dressing therapy, the wound failed to achieve the expected improvement; escalation to CTP is medically reasonable and necessary.”

FIGURE 3

EHR Flowsheet Template for Audit-Proof Documentation

Field	Details/Options
Visit Date	Date of Clinic Visit
Wound # / Location	Unique Wound ID and Anatomical Location
Etiology	DFU / VLU / Pressure / Arterial / Mixed
Measurements (cm)	Length x Width x Depth; Area; % Change
Tissue Type	% Granulation / Slough / Eschar
Exudate	Volume, Type, Odor
Debridement Performed	Y / N; Type: Sharp / Enzymatic / Autolytic / Mechanical
Off-Loading / Compression Status	Device Type, Wear Time, Pressure mmHg
Smart Dressing Used	Product Name, Frequency, Duration
Infection / Biofilm Status	Clinical Signs, Culture Results
Barriers Noted	List Identified Barriers
Corrective Actions Taken	List Corrective Actions
Patient Education Provided	Y / N; Topics Covered
Next Checkpoint Date	Date for Next Protocol Checkpoint

Compliance context: CMS’s review of the LCDs and OIG’s focus on pricing/reporting reinforces the expectation that CTPs be reserved for documented, appropriate cases, with rigorous evidence of prior optimization.¹⁷

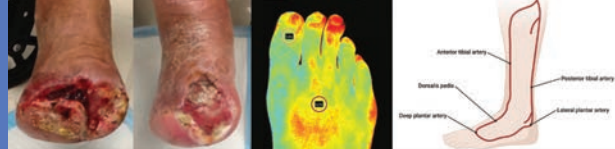
Coding/Policy Awareness (high-level)

- Track your MAC’s current LCDs and articles; national policy timing remains dynamic (implementation of updated LCDs delayed to Jan 1, 2026, per CMS). Keep screenshots/PDFs of policy versions in the compliance file.¹⁷
- Avoid arrangements that resemble volume-driven CTP use, rebates, or quid-pro-quo; recent advisories highlight such risks.³

Mechanistic Rationale for Smart, Non-Cytotoxic Dressings Before CTPs

- **Correcting micro-environmental derangements** (excess proteases, pH/ORP/CEC shifts, ionic imbalance, and exudate management) is central to chronic wound conversion back to acute-like healing. The 2023 IWGDF wound-healing guideline emphasizes optimizing wound physiology as a precondition for advanced interventions.¹⁹
- **Non-cytotoxic, ionically active hydrogels** can maintain moisture balance, support autolytic debridement, modulate ionic gradients, and aid bioburden control

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without harming viable cells—a crucial distinction given the regulatory focus on “medical necessity” and cost-effective measures before CTPs. (Mechanistic alignment; specific product evidence should be summarized separately if submitting brand data.)¹⁹

• **Adherence-critical measures (off-loading/compression)**

are the strongest healing drivers in DFU/VLU and must be optimized alongside any dressing choice.¹⁹

Outcomes and Data Collection Plan

Primary endpoint: % area reduction at 4 and 8 weeks.

Secondary endpoints: time to closure, pain, exudate volume, dressing change frequency, device adherence, infection-related events, and need for escalation to CTP.

Data capture: structured EHR forms (Figure 3), auto-calculated % change, and a “CTP eligibility” checklist that unlocks only after 4-week SOC fields are complete (reduces documentation gaps if audited).

Quality dashboard: monthly charts of healing rates, time-to-closure, and CTP use per 100 wound episodes; variance analysis on cases escalated to CTP before Week 4 with clinical rationale attached.

Sample Clinic Algorithm (Textual Figure)

1. **Diagnose & stage** → *Perfusion/etiology confirmed* → enroll in protocol.
2. **Week 0–2:** SOC (debridement + device + smart hydrogel).
 - If $\geq 20\%$ area reduction, continue; else, intensify.
3. **Week 2–4:** Intensified SOC + optimized smart hydrogel regimen.
 - If $\geq 40\%$ area reduction, continue; else, barrier audit.
4. **Week 4–6/8:** Enhanced adjuncts (still pre-CTP).
 - If $< 50\%$ area reduction and barriers corrected → CTP review packet ready.
5. **CTP consideration** only with complete documentation, patient consent, and payer policy alignment.

Implementation Tips and Pitfalls

• **Make devices wearable.** The best off-loading/compression plan fails if patients can’t function. Render removable walkers irremovable when feasible; tailor compression to tolerance and document the “why” behind any deviation.¹⁴

• **Debridement discipline.** Regular, appropriate debridement is a cornerstone; note when debridement is not

indicated (e.g., dry stable eschar in critical ischemia) and document the clinical reasoning.⁵

• **Avoid cytotoxic over-treatment.** Be cautious with agents that can damage viable tissue; payers scrutinize non-healing wounds treated with repetitive cytotoxic topicals absent a clear indication.¹¹

**These guidelines ensure that
when a CTP is used, the chart already
tells the story—making the care
defensible and compliant.**

• **Be policy-literate.** Assign a staff lead to monitor MAC LCDs and CMS updates, and archive copies with dates to your CTP Oversight Binder.¹⁸

• **Create an audit trail in real time.** If it isn’t documented, it didn’t happen. Build flowsheets/templates that force entry of SOC, smart-dressing usage, and adherence coaching before allowing a “CTP referral” order (Figure 4).

Ethical, Legal, and Compliance Considerations

Recent DOJ actions illustrate the criminal exposure associated with medically unnecessary procedures, falsified documentation, or kickbacks involving high-cost wound materials. Clinics should maintain: (1) a formal CTP policy tied to this protocol; (2) vendor-neutral selection criteria based on published evidence and cost; and (3) an internal review committee that reviews any pre-Week-4 CTP use.²⁰

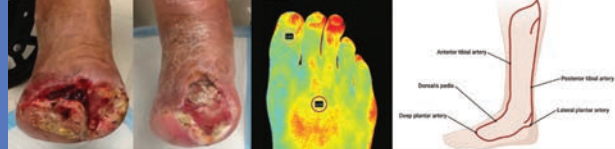
OIG’s concerns regarding pricing and reporting further increase the likelihood of retrospective reviews and statistical extrapolation in overpayment audits. A defensible file will show serial measurements, corrected barriers, and smart-dressing trials before CTP exposure.¹⁷

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FIGURE 4

Compliance Toolkit

Component	Description
Policy Archive Log	Store Copies of All Applicable LCDs and Coverage Articles with Dates, MAC Region, Link to CMS/OIG policy, and Notes on Effective Date / Changes
Vendor-Neutral CTP Criteria	Documented: ≥ 4 Weeks SOC + Smart Dressing Optimization, Barrier Correction Attempts $< 50\%$ Improvement Despite Adherence, Patient Informed Consent for CTP
Patient Education Handouts	Handouts: “Why We Start with Smart Dressings Before Skin Substitutes” and “Your Role in Wound Healing: Off-Loading and Compression”
Internal Review Committee Form	Summarizes Case, Criteria Checklist, Committee Decision, and Rationale for Approving or Deferring CTP Use



Discussion

This protocol operationalizes what guidelines and payers have implicitly demanded: fix the fundamentals first, instrument the wound carefully, use non-cytotoxic, cost-conscious advanced dressings to push physiology toward healing, and only then consider CTPs when trajectory remains unsatisfactory. Not only is this clinically sound (off-loading/compression and serial debridement remain the strongest single levers), but it is policy-aligned given CMS's ongoing review of CTP coverage and DOJ's posture on medically unnecessary grafting.²⁰

The framework does not foreclose timely CTP use for appropriate indications (e.g., optimized yet stagnant wounds or complex exposures). Instead, it ensures that when a CTP is used, the chart already tells the story—making the care defensible and compliant.

Limitations

- Condition-specific nuance (e.g., severe ischemia, vasculitis, malignancy) may justify earlier deviation; document thoroughly.
- Product-specific evidence for various smart hydrogels differs; practices should maintain a local evidence compendium (IFUs, peer-reviewed data) and disclose conflicts of interest per journal policy.
- The 4-week SOC convention reflects LCD expectations for DFU/VLU, but not every wound type; use clinical judgment and your MAC's current policies.⁷

Conclusion

In an era of heightened enforcement and policy scrutiny, a standardized, auditable pre-CTP protocol is the safest, most patient-centered, and fiscally responsible approach. By documenting guideline-concordant SOC, optimizing non-cytotoxic smart dressings (e.g., antianionic, cationic electrolyte hydrogels such as BioClense®/BioRelease®/AgFresh®), and applying objective “failure-to-improve” thresholds, practices can both accelerate healing and prove to payers and regulators that CTPs are reserved for the right patients at the right time. **PM**

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