DermaBind
A LEVARIS BRAND

30-Day Pathway

Clear Medical Necessity

Covering application details
dermabind.com/application

DermaBind
A LEVARIS BRAND

Before you start

You already know your patient needs advanced care. This pathway documents the clinical reality you've been managing so that when you escalate, your decision is supported by clear records.

It is a documentation tool that tracks the 30 days of standard of care required by CMS LCDs for graft eligibility.

TIME INVESTMENT

5 minutes per visit over 4 weeks,
and 10 minutes on day 30 to wrap up.

Part 1: Set the Baseline (Day 1)

Patient Name ..... Date of Birth .....

Pathway start date .....

Wound type: ☐ DIABETIC FOOT ULCER ☐ VENOUS LEG ULCER ☐ OTHER: .....

Initial wound measurements

Length ..... cm X Width ..... cm X SA ..... cm^2

Length ..... cm X Width ..... cm X Depth ..... cm = Volume ..... cm^3

Pre-Flight Checklist

(Complete these before starting the 30 days)

DermaBind
A LEVARIS BRAND

Pre-Flight Item	Done
Perfusion and vascular assessment ABI ..... (L) ..... (R) Date ..... If ABI is unreliable or borderline, confirm perfusion with arterial Doppler or alternative vascular assessment before proceeding. ABI <0.60 or Toe Pressure ≤30 mmHg without vascular intervention = not yet eligible. **Do not start the 30-day pathway.** In the case of VLU: Use Venous Duplex to confirm insufficiency and CEAP classification.	☐
A1C documented (if diabetic) Result ..... Date ..... If uncontrolled, document the optimisation plan and managing provider.	☐
Infection status confirmed ☐ **CLEAR** ☐ **TREATING — PLAN**	☐
Patient counselled on the following • Type of offloading ..... • Compression minimum 20mmHg for VLU and edema • Compression minimum 20mmHg or pneumatic compression • Type of compression ..... • Smoking cessation (if applicable) • Attendance • Compliance • Current medication list reviewed • Active diagnoses documented, including underlying conditions contributing to wound chronicity • Wound history documented, including duration and reasons prior treatments have not produced adequate response	☐
Wound meets graft eligibility criteria • Wound surface area ≥ 1.0 cm^2 • Partial or full thickness wound documented • No exposed bone, muscle, tendon, ligament, joint capsule, or sinus tract • No osteomyelitis • Exudate controlled • No necrotic tissue present • No infection	☐

Part 2:
The 30 Days

DermaBind
A LEVARIS BRAND

The goal is to have **consistent documentation of attempting standard of care.**

Complete your full wound assessment in your EHR at each visit. Use this column to note the visit reference, key finding, or reason for progression decision.

Visit frequency: Weekly visits are the minimum expected, unless the wound is unstable. A treatment plan needs to be documented with each visit in addition to a plan if standard of care fails.

Debridement: record the technique (sharp, enzymatic, autolytic) in your clinical note and check the box here.

Clinical narrative examples (what you observed and why): "Wound dimensions unchanged at 2.3 × 1.8 cm despite consistent moist wound environment and weekly sharp debridement." | "Wound edges remain non-adherent. Compression therapy ongoing per plan. No signs of infection." | "No changes in wound measurements, granulation tissue, epithelial tissue."

* Surface area reduction

Week	Date	Size (L×W×D cm)	Debridement	% SAR*	Progress	Clinical Narrative	Photo taken
1	__ / __	___ X ___ X ___ Surface area in cm^2 _____ Volume in cm^3 _____	☐ Yes ☐ No		☐ Improved ☐ No change ☐ Worse		☐
2	__ / __	___ X ___ X ___ Surface area in cm^2 _____ Volume in cm^3 _____	☐ Yes ☐ No		☐ Improved ☐ No change ☐ Worse		☐
3	__ / __	___ X ___ X ___ Surface area in cm^2 _____ Volume in cm^3 _____	☐ Yes ☐ No		☐ Improved ☐ No change ☐ Worse		☐
4	__ / __	___ X ___ X ___ Surface area in cm^2 _____ Volume in cm^3 _____	☐ Yes ☐ No		☐ Improved ☐ No change ☐ Worse		☐

Part 2:
The 30 Days

DermaBind
A LEVARIS BRAND

Week	Date	Size (L×W×D cm)	Debridement	% SAR*	Progress	Clinical Narrative	Photo taken
5	__ / __	___ X ___ X ___ Surface area in cm^2 _____ Volume in cm^3 _____	☐ Yes ☐ No		☐ Improved ☐ No change ☐ Worse		☐
6	__ / __	___ X ___ X ___ Surface area in cm^2 _____ Volume in cm^3 _____	☐ Yes ☐ No		☐ Improved ☐ No change ☐ Worse		☐
7	__ / __	___ X ___ X ___ Surface area in cm^2 _____ Volume in cm^3 _____	☐ Yes ☐ No		☐ Improved ☐ No change ☐ Worse		☐
8	__ / __	___ X ___ X ___ Surface area in cm^2 _____ Volume in cm^3 _____	☐ Yes ☐ No		☐ Improved ☐ No change ☐ Worse		☐
9	__ / __	___ X ___ X ___ Surface area in cm^2 _____ Volume in cm^3 _____	☐ Yes ☐ No		☐ Improved ☐ No change ☐ Worse		☐
10	__ / __	___ X ___ X ___ Surface area in cm^2 _____ Volume in cm^3 _____	☐ Yes ☐ No		☐ Improved ☐ No change ☐ Worse		☐

Part 2:
The 30 Days

DermaBind
A LEVARIS BRAND

Standard of care interventions used over 30 days

- [ ] Moist wound environment
- [ ] Compression (venous)
- [ ] Offloading (DFU or pressure injury)
- [ ] Negative pressure
- [ ] Debridement:
  - [ ] Sharp [ ] Enzymatic [ ] Autolytic [ ] Mechanical
- [ ] Diabetic education / nutrition counselling
- [ ] Infection control
- [ ] Weekly follow-up maintained
- [ ] Other .....

Part 3:
Day 30 Assessment

DermaBind
A LEVARIS BRAND

Final wound measurements

Length ..... cm X Width ..... cm X SA ..... cm^2

Length ..... cm X Width ..... cm X Depth ..... cm = Volume ..... cm^3

Change from baseline

- [ ] Reduced by ..... %
- [ ] About the same
- [ ] Larger

Ready for advanced care (all boxes checked)

- [ ] 30+ days documented
- [ ] Adequate perfusion confirmed
- [ ] A1C optimised (if diabetic)
- [ ] No active infection
- [ ] Patient compliant and engaged
- [ ] Non smoker
- [ ] Offloading implemented
- [ ] Exudate controlled
- [ ] Edema controlled
- [ ] Plan in place for allograft procedure

Clinical conclusion

- [ ] Wound is progressing with Standard of Care
- [ ] Wound hasn't responded adequately to 30 days of standard of care
- [ ] Wound remains stalled/chronic despite consistent intervention

Not yet ready — address first

- [ ] .....

.....

.....

.....

.....

Part 4:
Provider attestation

I attest that

This patient received 30 consecutive days of appropriate standard of care as documented above. Medical necessity and provider best clinical judgement for advanced wound care has been established per CMS LCD guidelines. **Patient would benefit from advanced wound care treatment with DermaBind as a protective wound covering at this time given failed conservative treatment listed above.** This documentation is accurate and maintained in the patient's medical record.

Provider .....

Date (DD/MM/YY) ..... Signature .....

Supported Peer Reviewed Published Findings — DermaBind TL and FM

A peer-reviewed case series published in the Journal of Wound Care (2025) documented findings across 27 patients and 36 wounds, including diabetic foot ulcers, venous leg ulcers, pressure ulcers, full-thickness trauma injury and full-thickness post-necrotizing fasciitis. The wound did not demonstrate meaningful improvement despite a minimum of four weeks of standard-of-care management.

The use of a skin substitute in this case is supported by peer-reviewed, published data describing the product's characteristics, clinical rationale, and observed performance in comparable patient populations. These published findings align with and are consistent with real-world clinical presentations similar to this patient's case, supporting the medical necessity of selecting this therapy as part of the treatment plan.

Observed findings

- 69.1% average surface area reduction across all wounds
- 6.7 weeks average treatment duration
- No adverse events reported across all patient cases

Mendivil et al., Journal of Wound Care, 2025. Full citation available on request.

DermaBind
A LEVARIS BRAND

When to **stop** and refer

- Patient's perfusion is inadequate and vascular surgery is warranted. Don't start the 30 days pathway until perfusion is addressed
- Wound is improving with standard of care (SOC). Continue current treatment and follow up as scheduled.
- Osteomyelitis is present and not currently under active treatment. Refer or treat.

ONGOING REFERRAL CONSIDERATIONS

Good wound outcomes depend on active management of the whole patient. Consider involvement of the following throughout the pathway as clinical need warrants:

- Primary Care Provider, for optimisation of underlying comorbidities including diabetes, nutrition, and vascular health.
- Podiatry, for routine foot and nail care where this falls outside the treating providers scope.
- General surgery, where surgical intervention may be indicated.
- Infectious disease, where complex or recurrent infection requires specialist input.

LCD Quick Reference

DermaBind
A LEVARIS BRAND

Consent required to proceed	Do not apply graft if
☑ 30+ days of failed standard of care, documented. Include interventions used with dates and response	☒ Active infection
☑ Weekly visits with wound measurements and photos	☒ ABI <0.60 without vascular intervention
☑ Adequate perfusion (ABI ≥ 0.60)	☒ Patient non-compliant or lost to follow-up
☑ Glycaemic control optimised (diabetic patients)	☒ Fewer than 30 days of standard of care documented
☑ Infection treated and resolved before graft	☒ Wound showing steady improvement with standard of care
☑ Patient compliance documented throughout	☒ Uncontrolled diabetes (A1C)
☑ Wound eligibility criteria confirmed (see Pre-Flight Item 5)	☒ Exposed bone, muscle, tendon, ligament or joint capsule, or sinus tract
☑ Medication list, diagnoses, and treatment history documented in EHR	☒ Wound starting size <1cm2
☑ Graft selection rationale completed (see Part 3)	☒ Tobacco use
☑ Non-tobacco use	☒ Edema not managed with adequate compression therapy
	☒ Uncontrolled exudate
	☒ Necrotic tissue

DermaBind
A LEVARIS BRAND

Auditors check for:

1. 30-day trial with consistent measurements (a significant source of industry clawbacks)
2. Perfusion documented with supporting testing
3. A1C documented with actual value (diabetic patients)
4. Visit-by-visit measurements demonstrating stalled progress
5. Debridement attempted and technique recorded in clinical note
6. If there is supporting peer reviewed data, wound photos, appropriate usage and wastage with justification*
7. Infection and smoking status

Documentation tips

USE

"As a protective wound covering"

"Failed to respond to 4 weeks of moist wound environment and weekly debridement"

"Despite consistent compression therapy and offloading, wound remains stalled"

"Standard of care measures exhausted without adequate healing response"

LANGUAGE WE CAN USE (REFINED)

Protective barrier

Functions as a protective wound covering

Intended for homologous use

Serves as a protective covering

Biologic matrix

AVOID

"Patient requested graft"

"Trying advanced care to see if it works"

"Using DermaBind to heal the patients wound"

LANGUAGE WE CANNOT USE

Healing, healed

Supporting the healing cascade

Promoting/supporting a healing environment

Aiding in healing

Wound closure

Supporting an environment to aid in the body's own healing process

Helps with inflammation or scar reduction

1. **Documentation aid disclaimer:** This tool supports clinical record-keeping, LCD compliance, and best practices documentation with an EHR. It does not constitute medical advice, establish standards of care, or replace clinical judgment. Providers are responsible for ensuring all documentation meets applicable LCD requirements and accurately reflects care provided.

2. **Section 361 product notice:** DermaBind is regulated as a Section 361 HCT/P. This documentation tool supports medical necessity determination consistent with CMS guidelines and does not make claims regarding therapeutic outcomes. The provider determines medical necessity and needs to fully understand product intended use, review the instructions for use (IFU) and understand the LCD guidelines.

3. **Audit Protection Notice:** Completion of this pathway does not guarantee reimbursement or audit approval. Providers should ensure all documentation is accurate, complete, consistent with clinical findings, and follows LCD guidelines, product intended use and instruction for use.