BILLING & CODING GUIDE

FastSkin® Patch

Autologous Blood-Derived Wound Care — Medicare Reimbursement Reference 2026

The FastSkin® Patch is an FDA 510(k)-cleared autologous blood-derived wound care product (cleared November 7, 2025; 510(k) BK251174). It is classified by the FDA as a **peripheral blood processing device for wound management** (Class II, product code PMQ). It is NOT a skin substitute. It is billed under **G0465** (diabetic chronic wounds) or **G0460** (non-diabetic chronic wounds) and falls under **NCD 270.3** — Blood-Derived Products for Chronic Non-Healing Wounds. FastSkin® Patch is substantially equivalent to the predicate device ActiGraft® RD2 Ver.02 (RedDress Ltd).

QUICK REFERENCE

Item	Detail
Product	FastSkin® Patch — MimiX AWC
FDA clearance	510(k) cleared — November 7, 2025 (BK251174)
FDA classification	Peripheral blood processing device for wound management (Class II, PMQ)
Predicate device	ActiGraft® RD2 Ver.02 — RedDress Ltd
Coverage	Medicare NCD 270.3 — Blood-Derived Products for Chronic Non-Healing Wounds
Primary HCPCS code	G0465 — Diabetic chronic wounds (national coverage under NCD 270.3)
Secondary HCPCS code	G0460 — Non-diabetic chronic wounds (MAC-determined coverage)
Standard protocol	Up to 20 applications per patient (up to 20 weeks)
Beyond 20 weeks	Modifier -KX required; coverage determined by local MAC

1. G0465 vs G0460 — Choosing the Correct Code

Two HCPCS codes describe autologous blood-derived products for chronic wound care. The correct code is determined solely by whether the patient has a documented diagnosis of diabetes mellitus. Code descriptors were updated by CMS effective July 1, 2023 to allow reporting for blood-derived products beyond PRP specifically.

	G0465	G0460
Full CMS descriptor (as of July 1, 2023)	Autologous platelet rich plasma (PRP) or other blood-derived product for **diabetic** chronic wounds/ulcers, using an FDA-cleared device for this indication (includes, as applicable: administration, dressings, phlebotomy, centrifugation or mixing, and all other preparatory procedures, per treatment)	Autologous platelet rich plasma (PRP) or other blood-derived product for **non-diabetic** chronic wounds/ulcers (including as applicable: phlebotomy, centrifugation or mixing, and all other preparatory procedures, administration and dressings, per treatment)
Patient population	Patients with documented diabetes mellitus (DFU, VLU in diabetic patients, other diabetic chronic wounds)	Patients WITHOUT diabetes mellitus (VLU, pressure ulcers, other chronic non-healing wounds)
FDA-cleared device required?	**Yes — explicitly required** FastSkin® Patch is FDA-cleared (BK251174)	Not explicitly required by descriptor; however FastSkin® Patch is FDA-cleared
Coverage type	**National — NCD 270.3** CMS national coverage for diabetic wounds	**MAC-determined** Local coverage only; no national NCD coverage
2026 PFS rate (Non-Facility / Office)	**$1,069.80** per application (31.87 total RVUs × 2026 CF)	**Contractor Priced** Rate set by local MAC; varies by jurisdiction
2026 OPPS rate (Hospital Outpatient)	**$2,107.97** per application (APC 5054, Status Indicator T)	**$2,107.97** per application (APC 5054, Status Indicator T)

Source: 2026 CMS PFS Final Rule, CMS-1832-F, Addendum B; 2026 CMS OPPS/ASC Final Rule, CMS-1834-FC, Addenda AA and B. Rates are estimates. Actual payment subject to geographic adjustment and MAC determination.

Critical rule — VLU in diabetic patients: A venous leg ulcer (VLU) in a patient with documented diabetes mellitus must be billed under **G0465**, not G0460. Under NCD 270.3, any chronic wound in a diabetic patient qualifies as a diabetic chronic wound. Billing G0460 for a diabetic VLU results in incorrect coding, potential underpayment, and compliance risk.

ICD-10 Diagnosis Code Requirements for G0465 (Effective July 1, 2023)

Per CMS requirements effective July 1, 2023, claims reporting G0465 must include **both** of the following ICD-10 diagnosis codes. Claims missing either code may be denied.

Requirement	Example ICD-10 Code	Description
Diabetes mellitus diagnosis (required)	E11.621 (use most specific E10.xx or E11.xx)	Type 2 diabetes mellitus with foot ulcer. Use the most specific diabetes code available for the patient.

Chronic ulcer diagnosis (required)	L97.xxx	Non-pressure chronic ulcer of lower extremity. Specify anatomic site and wound severity.
VLU in diabetic patient	I83.009 + E11.xx	Varicose veins with ulcer (unspecified leg) + appropriate diabetes mellitus diagnosis code. Bill under G0465.

Consult your MAC's local coverage article for the complete list of covered ICD-10 diagnosis codes. Use the most specific code available. Unspecified codes increase denial risk.

Covered Places of Service (NCD 270.3)

Per NCD 270.3 and CMS Transmittal R11214CP, the following POS codes are covered for G0465 claims. G0460 coverage by POS is MAC-determined.

POS	Setting	G0465 Coverage	G0460 Coverage
11	Office (Private Practice)	National — $1,069.80	MAC-determined (Contractor Priced)
22	On-campus Hospital Outpatient	National — $2,107.97	$2,107.97 (APC 5054)
19	Off-campus Hospital Outpatient	National — $2,107.97	$2,107.97 (APC 5054)
49	Independent Clinic	National — verify with MAC	MAC-determined
12	Home	National — verify with MAC	MAC-determined
31	Skilled Nursing Facility (SNF)	National — verify with MAC	MAC-determined

Source: NCD 270.3; CMS Transmittal R11214CP. Rates shown are 2026 national rates. Verify applicable rate with your MAC for POS 12, 31, and 49.

2. Patient Eligibility Criteria — NCD 270.3 & LCD L38935

The following criteria must be documented in the patient record to support coverage under NCD 270.3. Non-diabetic wound coverage under G0460 is subject to MAC-specific LCD criteria — verify with your local MAC before treatment.

G0465 — Diabetic Foot Ulcer (DFU)	G0465/G0460 — Venous Leg Ulcer (VLU)
✓ Documented diagnosis of diabetes mellitus (ICD-10 E10.xx or E11.xx)	✓ Venous insufficiency documented (duplex ultrasound or clinical assessment)
✓ Chronic wound persisting ≥30 days despite appropriate standard care	✓ Chronic wound persisting ≥3 months despite appropriate standard care
✓ Standard care ≥4 weeks: debridement, appropriate dressings, offloading	✓ Compression therapy ≥30 mmHg applied ≥4 weeks — dates documented
✓ <50% reduction in wound size after 4 weeks of standard care	✓ ABI documented to exclude significant arterial disease (ABI ≥0.7 recommended)
✓ Vascular assessment: ABI or toe pressure documented (adequate perfusion)	✓ Patient compliance with compression and leg elevation documented
✓ Glycemic assessment: HbA1c or glucose documented	✓ <50% reduction in wound size after 4 weeks of standard care
✓ No active uncontrolled infection at wound site	✓ No active uncontrolled infection at wound site
✓ FDA-cleared device used for blood product preparation	■ Diabetic VLU → use G0465 (national coverage); non-diabetic VLU → G0460 (MAC-determined)

✓ Required criterion ■ Important note / conditional — review with MAC

3. Documentation Checklist — Pre-Submission

Important: This checklist is a reference tool only. It does not guarantee coverage or reimbursement. Healthcare providers are solely responsible for accurate documentation, coding, and medical necessity determination. Final coverage decisions are made by the applicable payer.

1. Patient Eligibility Documentation	
☐	Wound type documented in chart (DFU / VLU / other chronic non-healing wound)
☐	Diabetic status documented: diabetes mellitus diagnosis with ICD-10 code (E10.xx or E11.xx)
☐	Wound duration documented: ≥30 days for DFU/other; ≥3 months for VLU
☐	Standard care failure documented: wound has not responded despite appropriate treatment
☐	Wound size measured and recorded (length × width × depth in cm)
☐	<50% wound size reduction after ≥4 weeks standard care — documented in chart

2. Standard of Care Documentation	
☐	DFU: Debridement performed (≥4 weeks) — dates, type, and provider documented
☐	DFU: Wound dressings: type, frequency, and duration documented
☐	DFU: Offloading device prescribed; patient compliance documented
☐	DFU: Glycemic assessment: HbA1c or fasting glucose value documented
☐	VLU: Compression therapy ≥30 mmHg applied for ≥4 weeks — dates documented
☐	VLU: Patient compliance with compression therapy and leg elevation documented
☐	All wounds: ABI (Ankle-Brachial Index) or toe pressure measured and recorded
☐	All wounds: Adequate arterial perfusion confirmed (ABI ≥0.7 or toe pressure ≥40 mmHg)
☐	All wounds: Active infection ruled out or treated prior to application

3. Product Application Documentation	
☐	FastSkin® Patch applied — date of service recorded
☐	Lot number of FastSkin® Patch kit: _____
☐	Wound bed prepared (debrided) prior to application — documented
☐	20 mL blood draw performed — documented per IFU
☐	Application performed per FastSkin® Patch Instructions for Use
☐	Patient tolerated procedure — any adverse events noted

☐	Post-application dressing applied — type documented
☐	Next scheduled application date recorded (if applicable)

4. Billing Documentation	
☐	HCPCS code selected: G0465 (diabetic patient) or G0460 (non-diabetic patient)
☐	G0465 claims: both ICD-10 codes present (diabetes mellitus + chronic ulcer code)
☐	Place of Service (POS) code matches actual treatment setting
☐	Date of first blood-derived product service recorded (required for 20-week protocol tracking)
☐	If date of service is >20 weeks from first service: modifier -KX appended to claim
☐	If 2 kits applied same date of service: G0465 or G0460 billed ×2 (note: MPPR applies — 2nd unit reimburses at 50%)
☐	Treating physician signature on procedure note with date of service
☐	Prior authorization obtained if required by applicable payer (Medicare Advantage, Medicaid, commercial)
☐	ABN (Advance Beneficiary Notice) issued if coverage uncertain — signed by patient

4. Billing FAQ

Q: What is the -KX modifier and when is it required?

A: The -KX modifier must be appended to G0465 or G0460 when the date of service is more than 20 weeks from the date of the **first** blood-derived product service for that patient. It signals to the MAC that the treating physician has documented continued medical necessity beyond the standard NCD 270.3 coverage period. Claims for dates of service beyond week 20 submitted without -KX will be automatically denied. Coverage beyond 20 weeks is at MAC discretion. **Example:** if first service is January 6, the -KX modifier is required for all claims dated May 27 or later.

Q: What is MPPR and when does it apply?

A: The Multiple Procedure Payment Reduction (MPPR) applies when two units of G0465 or G0460 are billed on the same date of service (e.g., for wounds >25 cm² or multiple wounds requiring separate applications). CMS reduces payment on the second unit to 50% of the standard rate. **Private Office example (G0465):** Unit 1 = $1,069.80 + Unit 2 = $534.90 = $1,604.70 total. Note: RedDress Medical has formally requested that CMS remove MPPR for G0465 — verify current MPPR status with your MAC before billing multiple units.

Q: Can G0465 and G0460 be billed together for the same patient on the same date?

A: No. Only one HCPCS code applies per patient per date of service. Code selection is based exclusively on diabetic status. A patient with documented diabetes mellitus always uses G0465 regardless of wound type. A patient without diabetes always uses G0460. Never bill both codes for the same patient on the same date of service.

Q: Is G0460 covered nationally under NCD 270.3?

A: No. NCD 270.3 provides national Medicare coverage only for the treatment of **chronic non-healing diabetic wounds** using an FDA-cleared device (G0465). Coverage of autologous blood-derived products for non-diabetic chronic wounds (G0460) is determined solely by local Medicare Administrative Contractors (MACs). There is no national NCD coverage for G0460. Verify G0460 coverage with your MAC before treating non-diabetic patients.

Q: What happens when a patient's coverage is uncertain beyond 20 weeks?

A: Issue an Advance Beneficiary Notice (ABN) to the patient before treatment when coverage is uncertain — including for treatments beyond 20 weeks, non-diabetic wound treatments, or any scenario where MAC coverage has not been confirmed. The ABN allows the patient to choose to receive treatment and accept financial responsibility if Medicare denies the claim. Never provide treatment with uncertain coverage without a signed ABN.

Q: Is prior authorization required for FastSkin® Patch?

A: Traditional Medicare (Fee-For-Service) generally does not require prior authorization for G0465 claims under NCD 270.3 for diabetic wounds within 20 weeks. However, **Medicare Advantage plans, Medicaid, and commercial payers may require prior authorization**. Always verify prior authorization requirements with the specific payer before initiating treatment. Failure to obtain required prior authorization is a leading cause of claim denial.

Disclaimer

Key references: NCD 270.3 (cms.gov); CMS Pub 100-04; CMS Transmittal R11214CP; CMS MM12403; 2026 CMS PFS Final Rule CMS-1832-F; 2026 CMS OPPS/ASC Final Rule CMS-1834-FC; FDA 510(k) BK251174 (FastSkin Patch); AHA Coding Clinic for HCPCS, Q3 2023.