The Difference Between BLA and non-BLA Skin Substitutes: How it Affects Your Practice

Proper Wound Care Documentation

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Disclosures

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Received grant/research support from: JARALL Medical Management, LLC

Disclosure will be made when a product is discussed for an unapproved use.

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Commercial support was not received for this activity.

Learning Objectives

1. Identify what are BLA and non-BLA Skin Substitutes
2. Analyze the impact these skin substitutes have on clinical practice
3. Demonstrate the differences between BLA and non-BLA Skin Substitutes
4. Discuss proper documentation for wound care

Regulatory and Product Classification

Non-BLA skin substitutes are not FDA-approved biologics (i.e., they do not have a **Biologics License Application**).

Many non-BLA skin substitutes are regulated as 361 HCT/Ps*, medical devices, or human tissue products, which means:

- They are not approved for safety and effectiveness in the same way as BLAs.
- FDA oversight is generally more limited than for drugs/biologics.

CMS coverage is separate from FDA clearance/registration—lack of a BLA does not equal automatic coverage.

*HCT/Ps= Human Cellular Tissue-Based Product

Medicare Coverage of non-BLA skin substitutes

Medicare covers skin substitutes only when reasonable and necessary under existing LCDs, NCDs, and billing guidance.

Coverage is typically limited to:

- Specific wound types (e.g., DFUs, VLUs)
- Defined clinical indications
- Clear failure of standard wound care (**this is the reason for most denials**)

Non-BLA products often face stricter scrutiny due to variable evidence quality.

What Clinical Evidence does CMS look for when evaluating products?

Strong documentation is essential and should clearly show:

- Wound etiology, size, depth, and duration
- Failure of conservative treatment
- Product selection rationale
- Ongoing response to treatment
- Compliance with frequency and application limits

Remember that poor documentation is a primary driver of denials, not product choice.

Utilization Risk

Non-BLA skin substitutes are a high-risk category due to:

- Rapid growth in the number of products
- Significant variation in pricing and use
- History of overutilization and improper billing

This is why they are frequently targeted for:

- Prior authorization
- Pre-payment medical review
- Models like WISeR

Documentation and Medical Necessity

Strong documentation is essential and should clearly show:

- Wound etiology, size, depth, and duration
- Failure of conservative treatment
- Product selection rationale
- Ongoing response to treatment
- Compliance with frequency and application limits

Billing and Coding Considerations

Correct use of:

- HCPCS product codes
- Application CPT codes
- Units and wastage modifiers

Common risk areas:

- Excessive number of applications
- Mismatch between wound size and product billed
- Billing products for non-covered indications

BLA vs non-BLA products

Category	BLA Skin Substitutes	Non-BLA Skin Substitutes
FDA Pathway	Approved under a Biologics License Application (BLA)	Not FDA-approved biologics; often regulated as 361 HCT/Ps or medical devices
FDA Review Standard	Reviewed for safety, purity, and potency	No FDA determination of clinical effectiveness
Clinical Evidence	Typically supported by robust clinical trials	Evidence often limited, variable, or product-specific
Medicare Coverage	Covered when reasonable and necessary per LCD/NCD	Covered only if strict Medicare medical necessity criteria are met
Clinical Indications	Generally clearly defined wound types	Indications often narrow and closely scrutinized

BLA vs non-BLA products

Category	BLA Skin Substitutes	Non-BLA Skin Substitutes
Utilization Risk	Lower historical risk of misuse	Higher risk due to rapid product growth and overutilization history
Documentation Needs	Standard wound care documentation	Enhanced documentation required to justify use
Pricing & Spend	High cost but more predictable utilization	Wide pricing variation; high spend risk if misused
CMS Oversight	Standard claims review	Frequently subject to prior auth or pre-payment review
WISeR Focus	Less likely to be targeted	Common focus of WISeR and program integrity efforts

BLA vs non-BLA products

Feature	BLA Skin Substitutes	Non-BLA Skin Substitutes
Regulatory Pathway	FDA-approved biologic (BLA)	HCT/P, device, or Section 361
Medicare Payment Classification	Biologic (ASP-based)	Incident-to supply (flat rate; waste not paid)
Examples	Apligraf, Dermagraft	AmnioBand, Oasis, Kerecis, PriMatrix, Integra, etc.
Waste Billing	Historically reimbursable	Not reimbursable for non-administered units

BLA vs non-BLA products

Regulatory & Reimbursement Differences

BLA products are treated as biologics for reimbursement, with Medicare paying via biologics pricing formulas, historically allowing separate payment for waste.

Non-BLA products are now predominantly paid as incident-to supplies; only the administered portion is reimbursable — unused/wasted units are not paid.

BLA products

These are biologics regulated under a Biologics License Application (BLA) — highest regulatory review and historically reimbursed as biologics under Medicare Part B.

Key characteristics
Regulated as 301/351 biologics
Have undergone rigorous FDA review for safety/effectiveness
Historically reimbursed under biologics payment methodology (ASP + percentage)

Examples
Apligraf — bioengineered living skin equivalent used for chronic wounds like DFUs and VLUs.
Dermagraft — fibroblast-derived dermal substitute for DFUs.

Note: Some advanced emerging **gene and cell therapies** in wound care (e.g., Vyjuvek, Zevaskyn) are regulated as BLAs but may not classically be called “skin substitutes.”

Non-BLA products

These products do not have a BLA; instead they are regulated as HCT/Ps, medical devices, or under Section 361. Beginning in 2026, most such products are paid as incident-to supplies rather than separate biologics, and Medicare does not reimburse waste/unused portions.

Amniotic / Placental-Derived

- **Affinity**
- **AmnioBand (Guardian)**
- **Epicord**
- **Epifix**
- **Kerecis Omega3 / MariGen Shield**
- **NuShield**

Collagen / Matrix-Derived

- **DermACELL (AWM, porous)**
- **Derma-Gide**
- **Oasis Wound Matrix**
- **PriMatrix**
- **FlexHD / AllopatchHD**
- **GraftJacket**
- **Integra / OmniGraft Dermal Regeneration Template**
- **Theraskin**

What is the practical application of this?

Regulatory & Reimbursement Differences

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Non-BLA products are now predominantly paid as incident-to supplies; only the administered portion is reimbursable — unused/wasted units are not paid.

Coverage Lists Matter

Not all products on the market are covered — e.g., Medicare contractors list **covered** products for specific ulcer types (DFU/VLU), while 100+ products may be non-covered.

FAQs re: non-BLA products

Important point to remember:

These products do not have a BLA; instead they are regulated as HCT/Ps, medical devices, or under Section 361. Beginning in 2026, most such products are paid as incident-to supplies rather than separate biologics, and Medicare does not reimburse waste/unused portions.

CMS has updated its FAQs on the JW and JZ modifiers. These FAQs clearly state that **Medicare fee for service (FFS) does not pay for discarded amounts of "incident to supplies"** (which is how all non-BLA CTPs/skin subs are now classified) and will only pay for the amount of product furnished.

FAQs re: non-BLA products

Q: Should the JW and JZ modifiers be used when billing for separately payable incident-to supplies?

A: The JW and JZ modifiers are only used when billing for drugs and biologicals separately payable under Medicare Part B. The JW and JZ modifiers are not appropriate for billing for incident-to supplies, even if such incident-to supplies are separately payable. In addition, discarded amounts of incident-to supplies are not payable by Medicare.

As a result, non-BLA skin substitutes are no longer payable under Medicare Part B as a drug or biological as of January 1, 2026, and only the administered portion is payable.

FAQs re: non-BLA products

Q: What if I use the entire non-BLA skin substitute from the package or container?

A: For dates of services after January 1, 2026, If a provider or supplier administers an entire non-BLA skin substitute from the package or container (and no units are discarded), the JZ modifier is not appropriate when billing Medicare.

FAQs re: non-BLA products

Q: What if I use a portion of a non-BLA skin substitute from the package or container?

A: For dates of services after January 1, 2026, If a provider or supplier administers a portion of a non-BLA skin substitute from the package or container and a portion is discarded, the provider or supplier may only bill for the units that are administered. It is not appropriate to bill Medicare for such discarded units under any circumstance (that is, such units may not be billed with the JW modifier and such units may not be included when billing for the administered amount).

FAQs re: non-BLA products

Q: What are the reimbursement rates for non-BLA skin substitutes?

A: For dates of services after January 1, 2026, CMS finalized a flat national payment rate of approximately **$127.14–$127.28** per square centimeter for most non-BLA skin substitute products when used in Medicare Part B covered procedures. This applies across settings (physician office, hospital outpatient, ASC) for products classified as incident-to supplies.

FAQs re: non-BLA products

Q: How are non-BLA skin substitutes billed?

A: **HCPCS Product Codes + CPT Procedures**

- The skin substitute product itself is reported with a **HCPCS code** (e.g., A-series codes for synthetic or other products; older Q-codes previously used).
- The skin substitute application procedure is reported with the appropriate **CPT application codes** (e.g., *CPT 15271–15278* series), which have separate physician fees under the Medicare Physician Fee Schedule.

Reimbursement Structure

Product reimbursement: Medicare pays the **$127.xx/cm²** fee *for the amount actually applied* to the wound.

Procedure reimbursement: The CPT codes for application (i.e., the professional service) remain separately payable under the Physician Fee Schedule.

Review of proper wound care documentation

- This is the number 1 way to avoid clawbacks
- Documentation is all about telling a story, whether in words or pictures.
- Auditors reviewing charts/documentation look for certain documentation that is included in the LCD to ensure proper use of the skin sub application in addition to documenting for the proper level of debridement.
  - How the documentation is laid out is just as important.
  - Don’t make an auditor guess or try to find information

Documentation for Wound Care

- Ulcer Location
- Pain and Anesthesia (if needed)
- Sterile Preparation Performed
- Instrumentation
- Selectivity of Debridement: Selective vs. Nonselective
- Tissue Type Removed From Wound Bed: Necrotic (slough), Fibrotic, Granulation Tissue, Devitalized
- Deepest Depth of Tissue Removed: Dermis, Subcutaneous, Muscle, Bone
- Drainage
- Inflammation/Swelling
- Method of Hemostasis (Pressure)
- Post-Debridement Dressing

Documentation for Wound Care

- Purpose of Debridement: (Decrease Bioburden, Decrease Risk of Infection & Promote Healing)
- Ulcer Treatment Goal: (Healing, Palliation, Prevent Infection, Prevent Amputation)
- Ulcer Healing Potential
- Estimated Treatment Duration
- Mode of Offloading
- Tunneling/Undermining
- Antibiotics?
- Culture Obtained?
- Diagnostic Imaging needed?
- Follow Up Scheduled
- Referrals Ordered
- Patient Wound Care Instructions

Documentation for Wound Care

Utilizing terminology found in the LCD “should” help your documentation stand up in an audit.

Think about your wound care documentation like a physical therapist thinks about what they want to do. On your initial visit, document a “**plan of care**”. This plan of care should include any other things you are going to be doing in addition to the wound care: comprehensive medical evaluation, vascular evaluation, orthopedic evaluation, functional evaluation, and metabolic/nutritional evaluation. These things should be reviewed/documented on a periodic basis

Documentation for 97597 vs. 11042

97597: “Selective debridement was medically necessary to remove devitalized tissue impairing wound healing.”

11042: “Excisional debridement of necrotic subcutaneous tissue was required to promote wound healing and reduce infection risk.”
“Debridement extended through the dermis **into** subcutaneous tissue”

Documentation for 97597

Assessment / Medical Necessity

- “The wound contains devitalized tissue including slough and fibrin that is inhibiting granulation and wound healing. Selective debridement is medically necessary to remove non-viable tissue and promote healing.”

Procedure Description

- “Selective debridement was performed using a curette to remove non-viable epidermal and dermal tissue, including slough and fibrin. No subcutaneous tissue was removed.”

Measurements

- “Pre-debridement wound measurements were 3.0 cm × 2.5 cm (7.5 sq cm). Total surface area selectively debrided was 7.5 sq cm.”

Documentation for 97597

Post-Procedure

- “Following debridement, viable tissue was visualized. Minimal bleeding occurred and was controlled with pressure. The patient tolerated the procedure well.”

Plan

- “A sterile dressing was applied. Continued selective debridement is indicated based on wound response.”

Documentation for 11042

Assessment / Medical Necessity

- “The wound contains necrotic subcutaneous tissue that is delaying wound healing and increasing infection risk. Excisional debridement is medically necessary to remove devitalized subcutaneous tissue and promote healing.”

Procedure Description (This Is the Money Paragraph)

- “Excisional debridement was performed using a scalpel and curette. Non-viable tissue was sharply excised through the dermis into the subcutaneous tissue. Necrotic subcutaneous fat was removed.”

Depth & Tissue Statement (Critical)

- “The deepest level of tissue removed was subcutaneous tissue.”

Documentation for 11042

Measurements

- “Pre-debridement wound measurements were 4.0 cm × 3.0 cm (12.0 sq cm). A total of 12.0 sq cm of subcutaneous tissue was excisionally debrided.”

Bleeding / Viability

- “Bleeding occurred, confirming viable tissue, and hemostasis was achieved with pressure.”

Post-Procedure & Plan

- “The patient tolerated the procedure well. A sterile dressing was applied. Repeat excisional debridement may be required based on wound progression.”

Summary

Non-BLA skin substitutes can be covered by Medicare, but because they vary widely in evidence quality and have a history of overutilization, CMS applies heightened scrutiny to ensure use is clinically appropriate, well-documented, and consistent with coverage policy

Thank You!

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