NO. 91560

SKIN SUBSTITUTES & SOFT TISSUE GRAFTS

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Policy scope: This policy outlines coverage criteria, limitations, and coding requirements for skin substitutes and soft tissue graft products.

Related policies:

- Platelet Rich Plasma/ Platelet Rich Fibrin Matrix/Autologous Blood-Derived Products/BMAC No. 91553

I. MEDICAL NECESSITY CRITERIA

Medical Necessity Criteria- General Requirements:

Products included in this policy are supported by high-quality, randomized controlled trial–proven evidence demonstrating clinically meaningful benefit, as recommended by society guidelines.

Use of skin and soft tissue substitute products may be considered medically necessary when **all** applicable indication-specific criteria in this policy are met and when all of the following general requirements apply:

a. Documentation of wound characteristics and treatment plan are present prior to skin or soft tissue substitute application.
b. The product is U.S. Food and Drug Administration (FDA) regulated (e.g., PMA, 510(k), HDE, or HCT/P) and used consistent with its regulatory status.
c. The member has no documented hypersensitivity or allergy to any components of the skin substitute.
d. The clinical indication for use is addressed elsewhere in this policy, and the applicable indication-specific medical necessity criteria are satisfied.

A. Breast Reconstruction Surgery:

1. Inclusions: Medical Necessity Criteria (Breast Reconstruction):

The use of an acellular dermal matrix (ADM) may be considered medically necessary as an **adjunct** to implant-based breast reconstruction following **unilateral or bilateral mastectomy,** when **ONE or more** of the following criteria are met:

a. Inadequate pectoralis major muscle or chest wall soft-tissue exists to provide appropriate coverage or support for a tissue expander or implant; **or**
b. Skin flaps are thin, poorly perfused, or otherwise compromised and at increased risk for wound-related complications; **or**
c. The infra-mammary fold and/or lateral mammary fold has been disrupted during mastectomy and surgical re-establishment of these anatomic landmarks is required to support reconstructive outcomes.

2. Eligible Products (Breast Reconstruction):

When the medical necessity criteria in **Section A.1** are met, the following products may be used for this indication. Inclusion of a product in this section does not independently establish medical necessity. Medical necessity is determined solely by satisfaction of the applicable clinical criteria.

Breast Reconstruction		
Product Type	**Product**	**HCPCS Code(s)**
Human Acellular Dermal Matrix	AlloDerm® /AlloDerm Regenerative Tissue Matrix (RTM)	Q4116
Human Acellular Dermal Matrix	Cortiva® (formerly AlloMax®, NeoForm®)	Q4431, Q4432, Q4433/ C9399
Human Acellular Dermal Matrix	DermACELL®	Q4122
Human Acellular Dermal Matrix	DermaMatrix®	Q4431, Q4432, Q4433/ C9399

Human Acellular Dermal Matrix	FlexHD®	Q4128
Xenograft Acellular Dermal Matrix	Strattice™	Q4130
Xenograft Acellular Dermal Matrix	SurgiMend®	C9358/ C9360

3. **Limitations: (Breast Reconstruction):**

   a. Adjunctive Use Only
      i. Acellular dermal matrices (ADM's) are considered medically necessary only **when used as an adjunctive** soft-tissue support or reinforcement as part of implant-based breast reconstruction.
      ii. ADMs are not intended to serve as standalone reconstructive materials.
   b. Non-Covered Uses
      i. The following uses do not meet medical necessity requirements:
         a) Use of ADM's as primary reconstructive materials
         b) Use as load-bearing structural components
         c) Cosmetic, prophylactic, or preference-based enhancements
   c. Investigational or Non-Standard Use
      i. Routine use, cosmetic-only applications, investigational uses, or use under an FDA Investigational Device Exemption (IDE) are not medically necessary, regardless of product inclusion in Section A.2.

4. **Exclusions: (Breast Reconstruction):**

   a. Acellular dermal matrix products **not listed in Section A.2** are considered experimental, investigational, or unproven for breast reconstruction.

B. Burn Related Indications

1. **Inclusions: Medical Necessity Criteria (Burns):**

   The use of skin substitutes may be considered medically necessary for the treatment of thermal burn injuries when standard burn management has been implemented and one or more of the indication-specific clinical criteria below are met.

   General Burn Prerequisites (apply to all B.1 indications)

1. Assessment documented: burn depth, total body surface area (TBSA), anatomic location, and functional risk areas (e.g., hands/joints) are documented.
2. Wound bed appropriate for the requested product: wound is clean with infection controlled (or the product is used only after adequate debridement/excision and infection control, consistent with product intent).
3. Plan of care documented: the record supports why standard therapy alone is insufficient and why the requested product is needed (e.g., temporary coverage, dermal replacement, donor-site protection, donor sparing).
4. Product intent: requested product is used consistent with its U.S. Food and Drug Administration (FDA)-regulated homologous soft tissue/wound coverage intent (where applicable).

Indication-Specific Criteria

a. **Temporary Epidermal or Biosynthetic Coverage (Superficial / Partial-Thickness Burns)**
   Skin substitutes may be medically necessary when:
   - **i.** Temporary wound coverage is required for clean, non-infected superficial or partial-thickness burns (including glove-type coverage for hand burns), and
   - **ii.** Autografting is not indicated.

b. **Partial-Thickness (Second-Degree) Burns- Advanced Wound Matrix Coverage**
   Skin substitutes and/or autologous skin cell suspension (ReCell®) may be medically necessary when:
   - **i.** The member has a partial-thickness (second-degree) thermal burn requiring advanced wound coverage to support healing (e.g., to protect the wound bed, manage exudate, and support epithelialization).

c. **Temporary Wound Coverage Following Surgical Excision of Burns**
   Skin substitutes may be medically necessary when **all** of the following are met:

   - **i.** Full-thickness or deep partial-thickness thermal burns have undergone surgical excision, **and**
   - **ii.** Temporary wound coverage is required prior to definitive autologous skin graft placement as part of a staged burn reconstruction approach.

d. Mid Dermal or Indeterminate- Depth Burns
Skin substitutes may be medically necessary when **all** of the following apply:

- **i.** The member has mid-dermal or indeterminate-depth burns typically requiring debridement, **and**
- **ii.** The burns are expected to heal without autografting, but temporary biologic/biosynthetic coverage is clinically indicated to protect the wound bed and support healing.

e. Deep Dermal or Full-Thickness Burns (Post-Excisional Dermal Reconstruction)
Skin substitutes and/or autologous skin cell suspension (ReCell®) may be medically necessary for extensive deep dermal or full-thickness burns when one or more of the following apply:

- **i.** Burns involving ≥30% total body surface area (TBSA) where dermal or epidermal replacement is clinically indicated, **or**
- **ii.** Autograft is planned in conjunction with a dermal regeneration template, particularly when donor skin is limited or staged management is needed.

f. Severe Burns or Burns with Limited Autograft Options
Skin substitutes and/or autologous skin cell suspension (ReCell®) may be medically necessary when the member has **severe thermal burns** and autologous skin grafting is **limited** because:

- **i.** Available donor skin is insufficient, or
- **ii.** The member is medically unstable or unable to tolerate additional donor-site harvesting.

g. Donor-Site Coverage (Burn-Related Autografting)
Skin substitutes may be medically necessary when **all** of the following apply:

- **i.** The member has undergone **split-thickness skin grafting** for burn treatment, **and**
- **ii.** The product is used for temporary coverage of fresh, clean, non-infected donor site wounds to protect the site and support epithelialization.

h. Reconstructive Burn Surgery (Burn Scars and Contractures)
Skin Substitutes may be medically necessary when **all** of the following apply:

i. The member is undergoing reconstructive surgery for functional impairment related to burn scarring or contracture; **and**

ii. Autologous skin grafting is limited due to:

a) Insufficient available donor skin from prior burns or grafting; **or**

b) Medical conditions, comorbidities, prior graft history, or overall clinical status that preclude additional donor-site harvesting.

2. Eligible Products (Burns):

When the medical necessity criteria in **Section B.1** are met, the following products may be used for the applicable indication. Inclusion of a product in this section does not independently establish medical necessity.

Burns		
Temporary Epidermal or Biosynthetic Coverage (Superficial / Partial-Thickness Burns)		
Product Type	**Product**	**HCPCS Code(s)**
Non-living biosynthetic dressing	BIOBRANE®, per square centimeter	A2043
Non-living biosynthetic dressing	BIOBRANE® Glove, each	A2044
Partial-Thickness (Second-Degree) Burns / General Wound Matrix Coverage		
Dermal Regeneration Template	Integra® Meshed Bilayer Wound Matrix (MBWM)	C9363
Dermal Regeneration Template	Integra® Bilayer Matrix Wound Dressing (BMWD) (Integra® Bilayer Wound Matrix)	Q4104
Autologous skin cell suspension	ReCell®	15011-15018, C8002
Temporary Wound Coverage Following Surgical Excision of Burns		
Product Type	**Product**	**HCPCS Code(s)**
Human fibroblast-derived temporary skin substitute	TransCyte™	Q4182
Mid Dermal or Indeterminate- Depth Burns		
Human fibroblast-derived temporary skin substitute	TransCyte™	Q4182
Deep Dermal or Full-Thickness Burns (Post-Excisional Dermal Reconstruction)		
Dermal Regeneration Template	Integra® Dermal Regeneration Template (IDRT)	Q4105
Autologous skin cell suspension	ReCell®	15011-15018, C8002

Severe Burns with Limited Autograft Options		
Cultured Epidermal Autograft (HDE)	Epicel®	C9399
Autologous skin cell suspension	ReCell®	15011-15018, C8002
Donor-Site Coverage (Burn-Related Autografting)		
Product Type	**Product**	**HCPCS Code(s)**
Cultured Cellular Skin Substitute	OrCel™	C9399
Non-living biosynthetic dressing	BIOBRANE Dressings	A2043
Reconstructive Burn Surgery (Scars and Contractures)		
Product Type	**Skin Substitute Name**	**HCPCS Code(s)**
Dermal Regeneration Template	Integra® Dermal Regeneration Template (IDRT)	Q4105

3. **Limitations (Burns):**

    a. Product listing does not establish medical necessity. Inclusion in a table or list does not independently establish coverage.
    b. Skin substitutes/ acellular dermal matrices (ADMs) meet medical necessity only when used for dermal replacement, reinforcement, or temporary wound coverage consistent with a qualifying burn indication in **B.1.**
    c. They do not meet medical necessity when used as:
        i. Routine dressings for burns manageable with standard wound care,
        ii. Cosmetic/aesthetic/appearance-enhancing applications, or
        iii. Prophylactic use without a qualifying burn indication.
    d. Non-standard or investigational use
        i. Use outside U.S. Food and Drug Administration (FDA)-regulated homologous soft tissue intent (including research protocols) is not medically necessary.

4. **Exclusions (Burns):**

    Skin substitutes/ Acellular Dermal Matrix (ADMs) are considered experimental, investigational, or unproven when used for:
    a. Superficial or partial-thickness burns expected to heal with conventional wound management.
    b. Non-burn wounds (traumatic wounds, surgical wounds, or other non-burn conditions) unless otherwise specified elsewhere in this policy.

C. Diabetic Foot Ulcers (DFU's)

1. Inclusions: Chronic Lower-Extremity Ulcers (Applies to Diabetic Foot Ulcer (DFU) & Venous Leg Ulcer (VLU) - General Medical Necessity Criteria:

The use of a skin substitute/soft tissue graft may be considered medically necessary for a **chronic lower-extremity ulcer** (DFU or VLU) when **ALL** of the following are met:

- **a.** Partial or full-thickness ulcer that does not involve exposed bone, tendon, muscle, or joint capsule.
- **b.** The ulcer has failed to demonstrate meaningful healing (**≥50% area reduction**) after **≥4 weeks** of documented adherence to **standard wound/ulcer care**, including **all** applicable components:
  - **i.** Regular debridement (when indicated)
  - **ii.** Appropriate dressing changes and wound cleansing
  - **iii.** Infection assessment/management (when indicated)
  - **iv.** Etiology-specific foundational therapy must be documented and continued:
    - a) **DFU:** Offloading
    - b) **VLU:** Sustained compression therapy and edema management
- **c.** Adequate arterial perfusion is documented by **ONE** of the following:
  - **i.** Palpable pedal pulses **or** Doppler-confirmed arterial signals; **or**
  - **ii.** Ankle-brachial index (ABI) (ABI) ≥0.70 and ≤1.30 (compressible/valid study); **or**
  - **iii.** If ABI is unreliable (>1.30/non-compressible): Toe pressure ≥30 mmHg or Toe-Brachial Index (TBI) is documented and not consistent with severe ischemia (thresholds vary; commonly ≥0.6–0.7).
- **d.** The skin substitute is used as an **adjunct** to standard care, not a replacement for foundational therapy (offloading/compression, dressings, infection control).
- **e.** Product is U.S. Food and Drug Administration (FDA)-regulated/used consistent with regulatory status (including HCT/P standards where applicable), and wound characteristics/treatment plan are documented prior to application.
- **f.** No contraindications:
  - **i.** No uncontrolled infection in the wound and no hypersensitivity/allergy to product components.

2. DFU-Specific Medical Necessity Criteria (in addition to C.1):

In addition to **C.1**, a skin substitute for diabetic foot ulcer (**DFU)** may be considered medically necessary when **ALL** of the following apply:

- **a.** Member has type 1 or type 2 diabetes
- **b.** Hemoglobin A1c (HbA1c) is assessed within the last 90 days and diabetes management is being optimized;
  - **i.** HbA1c <12% is required; unless clinical documentation supports why wound care cannot be delayed
- **c.** DFU-specific contraindications are absent, including:
  - **i.** Active Charcot deformity or major structural abnormality of the affected foot
  - **ii.** Chronic infection not adequately treated and controlled
  - **iii.** Known or suspected malignancy of the ulcer site

3. Eligible Products and Product-Specific Limitations (DFUs):

When the medical necessity criteria in **Section C.1 and C.2** are met, the following products may be used for the applicable indication. Inclusion of a product in this section does not independently establish medical necessity. Medical necessity is determined solely by meeting the applicable indication-specific clinical criteria.

Diabetic Foot Ulcers (DFUs)		
Product Type: *Human-Derived Acellular Dermal Matrices*		
Product	**HCPCS Code(s)**	**Medical Necessity Criteria:**
AlloPatch Pliable	Q4128	Considered medically necessary when ALL of the following criteria are met: • **Full-thickness** diabetic foot ulcer of greater than **six** weeks duration; When the above medical necessity criteria are met in addition to the general requirements in **C.1 and C.2,** the following utilization guidelines apply: • Initial treatment is limited to **five (5)** applications • Additional applications, for a total of no more than **eight (8)** applications within a 12-week treatment episode per ulcer, may be considered medically necessary when evidence of wound healing is present (e.g., signs of epithelialization and reduction in ulcer size). • Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status.
Combined Human and Animal Grafts		
Apligraf®	Q4101	Considered medically necessary when ALL of the following criteria are met: • **Full-thickness** diabetic foot ulcer of greater **than four (4)** weeks duration When the above medical necessity criteria are met in addition to the general requirements in **C.1 and C.2,** the following utilization guidelines apply: • Initial treatment is limited to **one (1)** application.

		• Additional applications, for a total of no more than **five (5)** in 12 weeks are considered medically necessary when evidence of wound healing is present (e.g., signs of epithelialization and reduction in ulcer size) • Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status.
Acellular/Dermal Replacement from Animal Tissue Source (Xenografts)		
Kerecis™ Omega3 MariGen Shield	A2019	Considered medically necessary when ALL of the following criteria are met: • **Partial or full-thickness**, diabetic foot ulcer of greater than **four** weeks duration When the above medical necessity criteria are met in addition to the general requirements in **C.1 and C.2**, the following utilization guidelines apply: • Initial treatment is limited to **five (5)** applications • Additional applications, for a total of no more than **ten (10)** in 12 weeks are considered medically necessary when evidence of wound healing is present (e.g., signs of epithelialization and reduction in ulcer size) • Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status.
Kerecis™ Omega3 Wound	Q4158	Considered medically necessary when ALL of the following criteria are met: • **Partial or full-thickness**, diabetic foot ulcer of greater than **four** weeks duration When the above medical necessity criteria are met in addition to the general requirements in **C.1 and C.2**, the following utilization guidelines apply: • Initial treatment is limited to five **(5)** applications • Additional applications, for a total of no more than **ten (10)** in 12 weeks are considered medically necessary when evidence of wound healing is present (e.g., signs of epithelialization and reduction in ulcer size) • Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status.
Oasis® Wound Matrix	Q4102	Considered medically necessary when ALL of the following criteria are met: • **Partial or full-thickness**, diabetic foot ulcer of greater than **four** weeks duration When the above medical necessity criteria are met in addition to the general requirements in **C.1 and C.2**, the following utilization guidelines apply: • Initial treatment is limited to **four (4)** applications, one application per week. • Additional applications, for a total of no more than **four (4)** applications within a 12-week treatment episode per ulcer, may be considered medically necessary when evidence of wound healing is present (e.g., signs of epithelialization and reduction in ulcer size). • Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status.
Oasis® Ultra Tri-Layer Matrix	Q4124	Considered medically necessary when ALL of the following criteria are met: • **Partial or full-thickness**, diabetic foot ulcer of greater than **four** weeks duration

		When the above medical necessity criteria are met in addition to the general requirements in **C.1 and C.2,** the following utilization guidelines apply: • Initial treatment is limited to **four (4)** applications. • Additional applications, for a total of no more than **four (4)** applications within a 12-week treatment episode per ulcer, may be considered medically necessary when evidence of wound healing is present (e.g., signs of epithelialization and reduction in ulcer size). • Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status.
Acellular / Dermal Matrix (Synthetic Grafts)		
Integra Omnigraft Dermal Regeneration Matrix	Q4105	Considered medically necessary when ALL of the following criteria are met: • **Partial or full-thickness** diabetic foot ulcer of greater than **six** weeks duration When the above medical necessity criteria are met in addition to the general requirements in **C.1 and C.2**, the following utilization guidelines apply: • Initial treatment is limited to **one (1)** application • Additional applications, for a total of no more than **four (4)** applications within a 12-week treatment episode per ulcer, may be considered medically necessary when evidence of wound healing is present (e.g., signs of granulation tissue formation, epithelialization, or reduction in ulcer size). • Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status.
Combined Natural and Synthetic Grafts		
Dermagraft®	Q4431	Considered medically necessary when ALL of the following criteria are met: • **Full-thickness** diabetic foot ulcer of greater than **six** weeks duration. When the above medical necessity criteria are met in addition to the general requirements in **C.1 and C.2**, the following utilization guidelines apply: • Initial treatment is limited to **five (5)** applications. • Additional applications, for a total of no more than **eight (8)** applications within a 12-week treatment episode per ulcer, may be considered medically necessary when evidence of wound healing is present (e.g., signs of epithelialization and reduction in ulcer size). • Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status.
Human-Derived Cellular/Epidermal and Dermal Grafts		
Theraskin®	Q4121	Considered medically necessary when ALL of the following criteria are met: • **Partial or full-thickness**, diabetic foot ulcer of greater than **four** weeks duration When the above medical necessity criteria are met in addition to the general requirements in **C.1 and C.2**, the following utilization guidelines apply: • Initial treatment is limited to **one (1)** application. • Additional applications, for a total of no more than **four (4)** applications within a 12-week treatment episode per ulcer, may be considered medically necessary when evidence of wound healing is present (e.g., granulation tissue formation, epithelialization, or reduction in ulcer size).

		• Re-application frequency is no more frequent than every 1–2 weeks. • Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status.
Cellular Human Placental-Derived Skin Substitutes		
Grafix® Core and Grafix® PL Core	Q4132	Considered medically necessary when ALL of the following criteria are met: • **Partial or full-thickness** diabetic foot ulcer of greater than **six** weeks duration When the above medical necessity criteria are met in addition to the general requirements in **C.1 and C.2**, the following utilization guidelines apply: • Initial treatment is up to **five (5)** applications, one application per week. • Additional applications may be applied if there is evidence of wound healing and are limited to a maximum of **eight** (**8)** applications in twelve weeks. • Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status.
Grafix® PRIME and Grafix® PL PRIME	Q4133	Considered medically necessary when ALL of the following criteria are met: • **Partial or full-thickness** diabetic foot ulcer of greater than **six** weeks duration When the above medical necessity criteria are met in addition to the general requirements in **C.1 and C.2**, the following utilization guidelines apply: • Initial treatment is up to **five (5)** applications, one application per week. • Additional applications, for a total of no more than **eight (8)** applications within a 12-week treatment episode per ulcer, may be considered medically necessary when evidence of wound healing is present (e.g., signs of epithelialization and reduction in ulcer size). • Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status.
Human Amnion Chorion Membrane Grafts		
AmnioBand ®	Q4151	Considered medically necessary when ALL of the following criteria are met: • **Partial or full-thickness** diabetic foot ulcer of greater than **four** weeks duration When the above medical necessity criteria are met in addition to the general requirements in **C.1 and C.2,** the following utilization guidelines apply: • Initial treatment is limited to **five** applications • Additional applications may be applied once a week if there is evidence of wound healing and are limited to a maximum of **eight (8)** applications in twelve weeks. • Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status.
EpiFix	Q4186	Considered medically necessary when ALL of the following criteria are met: • **Partial or full-thickness** diabetic foot ulcer of greater than **six** weeks duration When the above medical necessity criteria are met in addition to the general requirements in **C.1 and C.2**, the following conditions apply: • Initial treatment is limited to **five (5)** applications

		• Additional applications, for a total of no more than **ten (10)** applications within a 12-week treatment episode, may be considered medically necessary when evidence of wound healing is present (e.g., signs of epithelialization and reduction in ulcer size). • Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status.
Epicord®	Q4187	Considered medically necessary when ALL of the following criteria are met: • **Partial or full-thickness** diabetic foot ulcer of greater than **six** weeks duration When the above medical necessity criteria are met in addition to the general requirements in **C.1 and C.2**, the following utilization guidelines apply: • Initial treatment is limited to **one (1)** application. • Additional applications for a total of no more than **ten (10)** applications within a 12-week treatment episode per ulcer, may be considered medically necessary when evidence of wound healing is present (e.g., signs of epithelialization and reduction in ulcer size) • Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status.
GraftJacket® Regenerative Tissue Matrix-Ulcer Repair	Q4107	Considered medically necessary when ALL of the following criteria are met: • **Partial or full-thickness** diabetic foot ulcer of greater than **six** weeks duration When the above medical necessity criteria are met in addition to the general requirements in **C.1 and C.2**, the following utilization guidelines apply: • **One (1)** application is considered medically necessary • **Additional applications** are considered **not medically necessary**, regardless of wound status.

4. **Limitations (Applies to DFU & VLU):**

   a. Multiple different skin substitutes concurrently or sequentially for the same ulcer are not medically necessary unless there is documented clinical rationale.

   b. Prophylactic use on closed or epithelialized ulcers is not medically necessary.

   c. Maximum utilization:

      i. No more than **ten (10) total** applications per ulcer, with at least 1 week between applications, within a 12-week treatment episode, unless product labeling supports a more restrictive schedule.

   d. Treatment beyond 12 weeks total per ulcer is not medically necessary regardless of product type.

5. **Exclusions (Not Medically Necessary):**

Use of skin substitutes for diabetic foot ulcers is not medically necessary when ANY of the following apply:

- **a.** Ulcers that are infected, ischemic, necrotic, or gangrenous and not yet adequately treated.
- **b.** Failure to meet the general criteria in C.1 and DFU-specific criteria in C.2, including lack of documented adherence to standard care and required perfusion assessment.
- **c.** More than one skin substitute application to the same wound on the same date of service is not medically necessary
- **d.** Known hypersensitivity/allergy to product components or other labeled contraindications
- **e.** Repeat or alternative applications (within 1 year of any given course of grafting) of skin substitute grafts are not considered medically reasonable and necessary when a previous full course of applications was unsuccessful.
    - **i.** Unsuccessful treatment is defined as increase in size or depth of an ulcer or no change in baseline size or depth and no sign of improvement or indication that improvement is likely (such as granulation, epithelialization or progress towards closing) for a period of 4 weeks past start of therapy.
        a) Exception: if the member has a smoking history and has failed a full course of applications, member may be eligible for an attempt with one additional course, if member has documentation of smoking cessation.
- **f.** The member has inadequate control of underlying conditions or exacerbating factors (e.g., uncontrolled diabetes, active infection, and active Charcot arthropathy of the ulcer extremity, vasculitis or continued tobacco smoking).

D. Venous Stasis Leg Ulcers (VLUs)

1. Inclusions: VLU-Specific Medical Necessity Criteria (in addition to C.1):

In addition to **C.1**, a skin substitute/ADM for **VLU** may be considered medically necessary when **ALL** of the following apply:

- **a.** Ulcer is attributable to **chronic (at least 3 months)** venous insufficiency/venous stasis.
- **b.** **Sustained compression therapy** is documented as part of **standard* venous ulcer care** and will be continued throughout

treatment (skin substitutes are not a replacement for compression).

**Standard ulcer therapy includes, but is not limited to regular debridement, appropriate wound dressings, sustained compression therapy, edema management, and off-loading or pressure reduction when indicated.*

2. Eligible Products (VLUs):

When medical necessity criteria for venous leg ulcers in **Section D.1 (including Section C.1)** are met, skin substitutes or acellular dermal matrices that are FDA-regulated and intended for homologous soft-tissue repair, replacement, or reinforcement may be used.

Venous Leg Ulcers (VLUs)		
Product	**HCPCS Code(s)**	**Medical Necessity Criteria**
Apligraf®	Q4101	Considered medically necessary when ALL of the following criteria are met: • **Partial or full-thickness** venous stasis of greater than **four** weeks duration When the above medical necessity criteria are met in addition to the general requirements in **D.1 (and C.1)**, the following utilization guidelines apply: • Initial treatment is limited to **one (1)** applications • Additional applications, for a total of no more than **five (5)** applications within a 12-week treatment episode per ulcer, may be considered medically necessary when evidence of wound healing is present (e.g., signs of epithelialization and reduction in ulcer size). • Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status.
Oasis® Wound Matrix Or Oasis® Ultra Tri-Layer Matrix	Q4102	Considered medically necessary when ALL of the following criteria are met: • **Partial or full-thickness** venous stasis of greater than **four** weeks duration When the above medical necessity criteria are met in addition to the general requirements in **D.1 (and C.1)**, the following utilization guidelines apply: • Initial treatment is limited to up to **four (4)** applications. • Re-application frequency is no more frequent than once weekly. • Additional applications, for a total of no more than **four (4)** applications within a 12-week treatment episode per ulcer, may be considered medically necessary when evidence of wound healing is present (e.g., signs of epithelialization and reduction in ulcer size).

		• Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status.
Theraskin®	Q4121	Considered medically necessary when ALL of the following criteria are met: • **Partial or full thickness** venous stasis ulcer of greater than **four** weeks duration When the above medical necessity criteria are met in addition to the general requirements in **D.1 (and C.1)**, the following utilization guidelines apply: • Initial treatment is limited to **one (1)** application. • Re-application frequency is no more frequent than every one (1) to two (2) weeks. • Additional applications, for a total of no more than **four (4)** applications within a 12-week treatment episode per ulcer, may be considered medically necessary when evidence of wound healing is present (e.g., signs of epithelialization and reduction in ulcer size). • Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status.
AmnioBand®	Q4151	Considered medically necessary when ALL of the following criteria are met: • **Partial or full-thickness** venous stasis ulcer of greater than **four** weeks duration When the above medical necessity criteria are met in addition to the general requirements in **D.1 (and C.1)**, the following utilization guidelines apply: • Initial treatment is limited to up to **five (5)** applications. • Re-application frequency is no more frequent than once weekly. • Additional applications, for a total of no more than **eight (8)** applications within a 12-week treatment episode per ulcer, may be considered medically necessary when evidence of wound healing is present (e.g., signs of epithelialization and reduction in ulcer size). • Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status.
EpiFix® Amniotic Membrane	Q4186	Considered medically necessary when ALL of the following criteria are met: • **Partial or full-thickness** venous stasis of greater than **four** weeks duration When the above medical necessity criteria are met in addition to the general requirements in **D.1 (and C.1)**, the following utilization guidelines apply: • Initial treatment is limited to **one (1)** application. • Additional applications, for a total of no more than **five (5)** applications within a 12-week treatment episode per ulcer, may be considered medically necessary when evidence of wound healing is present (e.g., signs of epithelialization and reduction in ulcer size).

		• Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status.

3. Limitations (VLU-Specific):

a. **See C.4** for general DFU/VLU limitations.
b. For VLU, skin substitutes/ADMs do not meet medical necessity when used:
i. as a replacement for compression therapy**,** or
ii. Prior to an adequate trial of standard venous ulcer care (including sustained compression).

4. Exclusions (VLU's):

Use of skin substitutes or acellular dermal matrices is considered experimental, investigational, or unproven for:
a. Ulcers that are:
i. Superficial (epidermal only), or
ii. Acute and expected to heal with standard wound care, or
iii. Primarily ischemic without successful revascularization (or without meeting the perfusion requirements in Section C.1).
b. Wounds due to etiologies other than venous insufficiency, unless otherwise specified elsewhere in this policy.

E. Dystrophic Epidermolysis Bullosa (DEB)

1. Inclusions: Medical Necessity Criteria (DEB):

The use of OrCel™ may be considered medically necessary for coverage of surgical wounds and/or donor sites associated with recessive dystrophic epidermolysis bullosa (RDEB), when **ALL** of the following criteria are met:
a. The member has confirmed diagnosis of recessive dystrophic epidermolysis bullosa (RDEB).
b. The member has mitten-hand deformity due to RDEB requiring surgical release of hand contractures.
c. OrCel™ is used as an adjunct to standard autograft procedures (e.g., split-thickness skin grafts or flaps) for wound and/or donor site coverage created following surgical release of mitten-hand deformities.
d. Standard wound management and reconstructive approaches have been attempted (and failed), are contraindicated, or are

insufficient to achieve durable wound coverage without adjunctive tissue support.

e. OrCel™ is provided in accordance with the U.S. Food and Drug Administration (FDA) Humanitarian Device Exemption (HDE), including use solely for the FDA-approved humanitarian indication.

2. Eligible Products (Dystrophic Epidermolysis Bullosa):

When the medical necessity criteria in **Section E.1** are met, the following product may be used for the applicable indication. Inclusion of a product in this section does not independently establish medical necessity. Medical necessity is determined solely by meeting the applicable indication-specific clinical criteria.

Dystrophic Epidermolysis Bullosa		
Product Type	**Product**	**HCPCS Code(s)**
Cultured Cellular Skin Substitute	OrCel™	C9399

3. Limitations (Dystrophic Epidermolysis Bullosa):

a. OrCel™ is medically necessary **only** for wounds and/or donor sites created after surgical release of mitten-hand deformities in RDEB and does not meet medical necessity requirements when used for:

- **i.** Routine prophylactic or preventive use in the absence of open wounds
- **ii.** Cosmetic, aesthetic, or non-therapeutic purposes
- **iii.** Use for other DEB wound types (e.g., routine chronic erosions not related to mitten-hand surgical release)

4. Exclusions (Dystrophic Epidermolysis Bullosa):

a. Use of OrCel™ **outside** the FDA-approved humanitarian indication (i.e., not associated with surgical release of mitten-hand deformities in RDEB) is experimental/investigational/unproven.

II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the CMS Online Manual System (IOMs) and Transmittals.
For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to CMS Medicare Coverage Database.

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare Coverage Database website for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

National Coverage Determinations (NCDs)	
NCD – Porcine Skin and Gradient Pressure Dressings (270.5)	
Local Coverage Determinations (LCDs)	
CGS Administrators, LLC	LCD – Wound Application of Cellular and/or Tissue Based Products (CTPs), Lower Extremities (L36690)
First Coast Service Options, Inc.	LCD – Application of Skin Substitute Grafts for Treatment of DFU and VLU of Lower Extremities (L36377)
Wellpoint Federal (formerly National Government Services, Inc.)	Not identified
Noridian Healthcare Solutions	Not identified
Novitas Solutions, Inc.	LCD – Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds (L35041)
Palmetto GBA	Not identified
WPS Insurance Corporation	Not identified

III. BACKGROUND

Skin substitutes (also described as tissue-engineered skin, cellular/tissue-based products, or cellular/acellular/matrix-like products) are a heterogeneous group of biologic and/or synthetic materials intended to temporarily or permanently replace selected functions of skin (e.g., coverage/barrier) and/or provide a scaffold that supports wound repair (e.g., granulation and re-epithelialization) (Vecin & Kirsner, 2023; Kondej et al., 2024).

In clinical practice, these products are typically used as adjuncts to optimized standard wound care when a wound fails to progress despite appropriate foundational management (e.g., debridement when indicated, infection assessment/management,

moisture balance, and etiology-specific measures such as offloading for DFUs or compression for VLUs, plus assessment/optimization of perfusion as clinically appropriate) (Vecin & Kirsner, 2023; Ontario Health, 2021). Because products differ substantially in composition, processing, intended use, and evidence base, clinical outcomes and risks should be interpreted product- and indication-specifically, and the strength of evidence/guideline support varies by wound etiology (Vecin & Kirsner, 2023; Kondej et al., 2024).

Skin substitutes are most commonly evaluated for chronic lower extremity ulcers (especially diabetic foot ulcers and venous leg ulcers) that remain difficult to heal despite standard care, and for burns and complex wounds where coverage is needed and donor site limitations may constrain autografting (Ontario Health, 2021; FDA, 2021). Health technology assessment evidence suggests that, in selected populations, some dermal or multilayer substitutes used adjunctively can increase complete healing compared with standard care alone, while the certainty and magnitude of benefit can vary by ulcer type and product category (Ontario Health, 2021).

Because no single system cleanly captures all products, a multi-axis categorization is most practical and is consistent with Davison-Kotler et al.'s universal classification framework and related classification approaches used across the literature (Ferreira et al., 2011; Kondej et al., 2024). For policy and evidence review purposes, skin substitutes can be described by:

- **Cellularity**
  - Cellular vs acellular
- **Layering /Structure**
  - Epidermal, dermal, or composite/bilayer
- **Origin/materials**
  - Autologous-Skin harvested from the patient
  - Allogeneic (Allografts)-human-derived
  - Xenogeneic/animal-derived
  - Synthetic/biosynthetic/composite- Laboratory-engineered constructs created from cultured skin cells and/or structural components designed to mimic native skin architecture.
- **Durability**
  - Temporary vs permanent/longer-term integration

Acellular matrices (including acellular dermal matrices [ADMs]) are typically decellularized connective-tissue scaffolds derived from human or animal tissues in which cellular components are removed while structural extracellular matrix is retained to support incorporation and host remodeling; manufacturing and decellularization methods can alter ECM composition/architecture and influence host response (Badylak & Gilbert, 2008; Crapo et al., 2011).

Cellular products generally incorporate living cells within a scaffold/construct and may be designed to provide a biologically active matrix; however, constructs vary widely in cellular composition, processing, and intended clinical role (Kondej et al., 2024; Vecin & Kirsner, 2023).

The FDA does not define a single regulatory category called “skin substitutes.” In fact, FDA generally does not use “skin substitutes” as an official class term, and many products commonly grouped under that label enter the market under different statutory/regulatory pathways based on composition, manufacturing, and intended use/claims. Depending on product composition and intended use, these products may be regulated under one of the four following FDA frameworks:

- **Premarket Approval (PMA):** PMA is FDA’s process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices and is the most stringent type of device marketing application. PMA approval is based on FDA’s determination that the application contains sufficient valid scientific evidence to provide reasonable assurance that the device is safe and effective for its intended use(s). The FDA’s public PMA database can be accessed here: Premarket Approval (PMA).

- **Premarket Notification (510(k)):** A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is “substantially equivalent” (i.e., as safe and effective) to a legally marketed predicate device. Evidence requirements for a specific 510(k) vary by device type and claims; the core standard is substantial equivalence to a predicate rather than PMA-level premarket approval. The FDA’s 510(k) database can be accessed here: 510(k) Premarket Notification.

- **Public Health Service (PHS) Act section 361 / 21 CFR Part 1271 (361 HCT/Ps):** Certain human cells, tissues, and cellular and tissue-based products (HCT/Ps) intended for implantation, transplantation, infusion, or transfer into a human recipient are regulated under FDA’s HCT/P framework in 21 CFR Part 1271. An HCT/P may be regulated solely under section 361 of the PHS Act (and 21 CFR Part 1271) only if it meets all criteria in 21 CFR 1271.10(a) (e.g., minimal manipulation and homologous use, among other requirements). Establishments must register and list with FDA and comply with Part 1271 requirements to reduce communicable disease transmission risk; Unlike device PMA/510(k) pathways, HCT/Ps regulated solely under section 361 are not generally subject to FDA premarket review to demonstrate clinical effectiveness. The Human Cell and Tissue Establishment Registration- Public Query can be accessed here: HUMAN CELL AND TISSUE ESTABLISHMENT REGISTRATION (HCTERS) - Public Query.

- **Humanitarian Device Exemption (HDE):** HDE is a marketing application for a Humanitarian Use Device (HUD) intended to benefit patients in the treatment or diagnosis of a disease or condition affecting or manifested in not more than 8,000 individuals per year in the United States (FDA, 2025; 21 CFR Part 814 Subpart H). **HDEs are exempt from PMA effectiveness requirements and are reviewed under a framework based on reasonable assurance of safety and "probable benefit," with additional program requirements and restrictions.** The FDA's public HDE database can be accessed here: Humanitarian Device Exemption (HDE).

Across clinical indications, the proposed rationale for skin substitutes and soft-tissue scaffolds is to (1) provide temporary or definitive coverage, (2) reduce fluid loss and contamination risk, and/or (3) supply a matrix that supports revascularization, granulation, and epithelialization, with the goal of improving the probability and/or time to closure in appropriately selected patients (Vecin & Kirsner, 2023; Kondej et al., 2024). Because product composition, processing, and intended use differ substantially, clinical outcomes and risks should be interpreted product- and indication-specifically, and the availability of high-quality comparative evidence is variable across the category (Vecin & Kirsner, 2023; Kondej et al., 2024).

Breast Reconstruction- ADMs and Soft -Tissue Scaffolds

In implant-based breast reconstruction, biologic meshes, including acellular dermal matrices (ADMs) and related soft-tissue reinforcement scaffolds, are used as adjuncts to help define the implant pocket, provide inferior/lower pole support, and/or provide coverage in dual-plane or prepectoral approaches, including direct-to-implant and contemporary prepectoral techniques (Nahabedian, 2012; Whisker et al., 2021).

Commonly used products include human-derived ADMs (e.g., AlloDerm® SELECT Ready-to-Use) (Allergan Aesthetics, 2025; LifeCell Corporation, 2025) as well as animal-derived matrices used for soft-tissue reinforcement (e.g., SurgiMend® [bovine] and Strattice™ [porcine]) (FDA, 2009; FDA, 2013). ADMs are decellularized extracellular matrix scaffolds, and differences in source tissue and processing (e.g., decellularization approach, sterility level, thickness, and handling properties) may influence intraoperative workflow and early postoperative management (Badylak & Gilbert, 2008; Crapo et al., 2011; Cheng & Saint-Cyr, 2012).

Regulatory communications emphasize that ADM use in implant-based breast reconstruction is commonly off-label and that patients should be counseled regarding uncertainty and potential risks. The U.S. Food and Drug Administration (FDA) issued a safety communication noting that major complication rates differed among certain ADM brands used in implant-based breast reconstruction and reiterated that ADMs/mesh have not been cleared or approved specifically for this indication, reinforcing the need for shared decision-making and brand awareness (FDA, 2021; ASPS, 2021). More broadly, human tissue products may fall under the FDA's framework for human cells, tissues, and

cellular and tissue-based products (HCT/Ps), while some biologic matrices are regulated as devices with 510(k) clearance for soft-tissue reinforcement indications (FDA, n.d.; FDA, 2009; FDA, 2013).

High-quality comparative evidence evaluating ADMs used in implant-based breast reconstruction does not demonstrate consistent, clinically meaningful long-term differences between commonly used products. The BREASTrial Stage III randomized controlled trial, the largest head-to-head RCT comparing two human-derived ADMs (AlloDerm® and DermaMatrix®), found no significant differences in overall complication rates, complication severity, or patient-reported satisfaction through 2 years of follow-up; patient-level factors such as obesity, rather than ADM type, were identified as predictors of complications (Mendenhall et al., 2023).

Contemporary comparative syntheses similarly support a largely product-agnostic interpretation, reporting broadly comparable outcomes across commonly used ADMs while emphasizing substantial heterogeneity in study design, outcome definitions, and surgical technique (Glynou et al., 2024; Tanas et al., 2025). Prospective and observational head-to-head studies may identify differences in selected short-term endpoints; however, these findings should be interpreted cautiously given confounding and variability in operative technique and patient selection (Davison et al., 2024; Israeli, 2012). Earlier systematic reviews also concluded that proposed benefits must be weighed against morbidity and cost, and that evidence quality and comparability limitations restrict strong product-specific conclusions (Sbitany & Serletti, 2011).

Comparative evidence also evaluates ADM versus no-ADM reconstruction strategies. In a multicenter randomized clinical trial, immediate implant-based breast reconstruction with ADM did not reduce reoperation rates at 24 months and was not superior to reconstruction without ADM with respect to patient-reported outcomes (Lohmander et al., 2021). A 2024 meta-analysis pooling randomized trials and prospective comparative studies found no statistically significant differences between ADM and non-ADM cohorts for common postoperative outcomes (including seroma, infection, reoperation, implant loss, and skin necrosis) and noted limited, inconsistently reported patient-reported outcome data (Ng et al., 2024).

In the prepectoral setting, comparative evidence remains limited. A systematic review/meta-analysis of comparative studies reported no significant differences in overall complication rates between prepectoral reconstructions performed with versus without ADM, while emphasizing low/very low certainty due to small numbers of comparative studies and predominantly observational designs (Nolan et al., 2023). Across approaches, complication profiles (e.g., seroma, infection, wound complications, reconstructive failure) have been reported and may be influenced by patient factors, adjuvant therapies (e.g., radiotherapy), and technical variables (Israeli, 2012; Whisker et al., 2021).

Observational and registry/database studies show increasing ADM utilization and suggest small but measurable differences in short-term outcomes in some cohorts; however, these findings are susceptible to confounding by indication and heterogeneity in operative technique (plane, device type, and extent of ADM use). National utilization analyses report increasing ADM adoption over time (Graziano et al., 2023), and nationwide safety analyses in tissue-expander reconstruction have associated complication risk with patient factors and clinical context (Luo et al., 2022). These observational findings should be interpreted cautiously and integrated with higher-quality randomized and prospective comparative evidence (Whisker et al., 2021).

Overall, ADMs and related soft-tissue scaffolds are widely used adjuncts in implant-based breast reconstruction; however, the highest-quality evidence does not consistently demonstrate improved clinical or patient-reported outcomes versus non-ADM approaches, and some data suggest complication profiles may differ by product, processing category, and patient risk factors (Ng et al., 2024; FDA, 2021; Whisker et al., 2021). Accordingly, contemporary guidance emphasizes individualized decision-making, careful patient selection, transparent informed consent (including discussion of uncertainty and FDA safety communications), and ongoing outcomes tracking/audit (Whisker et al., 2021; ASPS, 2021).

Burn Injuries and the Use of Skin Substitutes

Skin substitutes used in burn care serve as temporary wound coverage, dermal regeneration templates, or cellular constructs to support healing when autologous skin grafting is not immediately feasible, insufficient, or contraindicated. Products used for burn treatment are FDA-regulated for wound coverage, dermal replacement, or cellular therapy. Coverage determinations are based on clinical medical necessity and standard burn management principles rather than FDA-labeled indications alone.

Thermal burn injuries represent a significant source of morbidity and mortality worldwide and are associated with prolonged hospitalization, functional impairment, and long-term scarring. Management strategies are guided primarily by burn depth, total body surface area (TBSA), anatomic location, and patient comorbidities, with the overarching goal of achieving timely wound closure to minimize infection risk, fluid loss, and scarring (Greenhalgh, 2019).

Autologous split-thickness skin grafting remains the standard of care for deep dermal and full-thickness burns. However, in patients with extensive burns, donor skin availability may be limited, and repeated harvesting can increase morbidity. In these contexts, skin substitutes—including biosynthetic dressings, dermal regeneration templates, and cellular or tissue-engineered constructs—may be used as temporary wound coverage, dermal replacement, or adjuncts to autografting (van den Bosch et al., 2024).

Skin substitutes may be particularly relevant in:

- Burns involving ≥30% TBSA
- Situations where the patient is medically unstable

- Anatomically or functionally critical areas (e.g., hands, face, joints)
- Post-burn reconstructive settings, including scar revision and contracture release (Iordache et al., 2025)

Among dermal substitutes, Integra® Dermal Regeneration Template is one of the most extensively studied products. A multicenter post-approval clinical trial involving 216 patients with a mean burn size of 36.5% TBSA demonstrated acceptable graft take rates and low rates of invasive infection when Integra was applied to excised burn wounds followed by delayed epidermal autografting (Heimbach et al., 2003). Subsequent observational studies and long-term clinical experience have supported its role in facilitating neodermis formation in patients with extensive burns and limited donor sites.

More recently, a systematic review evaluating indications for dermal substitutes in acute and reconstructive burn care concluded that wound depth and donor site limitation are the primary drivers for use, while emphasizing that clinical heterogeneity limits definitive comparative conclusions across products (van den Bosch et al., 2024).

Cultured epidermal autografts (CEA), commercially available as Epicel®, are authorized under a Humanitarian Device Exemption (HDE) for patients with deep dermal or full-thickness burns ≥30% TBSA when autografting is not feasible. While randomized controlled trials are limited, registry-based data and large cohort analyses demonstrate reasonable graft take rates and survival in severely burned populations (Hickerson et al., 2019). Due to the rarity and severity of these cases, evidence has largely been derived from prospective registries and observational studies rather than large randomized trials.

For partial-thickness burns, randomized controlled evidence suggests that certain biosynthetic or cellular approaches may modestly improve healing outcomes compared with conventional dressings. A randomized controlled pilot trial in second-degree burns found that epidermal cell-based therapy resulted in faster epithelialization and improved scar quality compared with acellular treatments, though sample size was limited (Blome-Eberwein et al., 2023). These findings support selective use of advanced wound coverage in partial-thickness injuries requiring enhanced wound protection.

The American Burn Association (ABA) and the International Society for Burn Injuries (ISBI) provide guidance emphasizing that skin substitutes should be used as adjuncts, not replacements, for standard burn care. Both organizations highlight that selection of skin substitutes should be based on burn depth, wound bed preparation, infection status, and donor site availability, and that no single product is universally appropriate for all burn scenarios (American Burn Association, 2006; ISBI, 2018).

Current ABA clinical practice guidance and consensus documents recognize dermal substitutes and temporary wound coverings as acceptable options when:

- Autografting is delayed or contraindicated
- Temporary coverage is needed following excision
- Dermal replacement may improve functional or reconstructive outcomes

However, these guidelines also caution that evidence quality varies and recommend case-by-case clinical judgment within specialized burn centers. Additional expert consensus on surgical management and use of skin substitutes in burn wound care has been published, reinforcing individualized product selection within comprehensive burn management (Kagan et al., 2013).

ReCell® Autologous Cell Harvesting Device

The ReCell® Autologous Cell Harvesting Device is a point-of-care system that processes a small sample of a patient's own skin to generate a suspension of non-cultured autologous skin cells. This suspension contains keratinocytes, melanocytes, fibroblasts, and other regenerative skin components, which are applied directly to wound beds or used in combination with split-thickness skin grafts (STSG). ReCell is intended to promote epithelial regeneration while reducing donor skin requirements, thereby minimizing donor-site morbidity. The device has been primarily studied in burn care as an adjunct to standard surgical management, with investigational use extending to other complex wounds, including diabetic foot ulcers.

A randomized, within-subject clinical trial demonstrated that RECELL®, when combined with widely meshed STSG, achieved wound healing outcomes comparable to standard STSG while significantly reducing donor skin requirements by 32% in patients with mixed-depth burns. Long-term outcomes, including scarring, pain, patient satisfaction, and adverse events, were similar between treatment groups, supporting RECELL as a safe and effective graft-sparing adjunct. Key limitations included the small sample size, exclusion of burns involving critical anatomical areas, limited generalizability, and potential conflicts of interest related to manufacturer involvement, underscoring the need for larger, independent trials (Holmes et al., 2019).

A systematic review and meta-analysis of nine studies (n = 358) found that autologous skin cell suspensions, including ReCell, were associated with a statistically significant reduction in time to re-epithelialization of approximately 1.7 days compared with standard treatment. However, no significant differences were observed in secondary outcomes such as postoperative pain, scar quality (POSAS or Vancouver Scar Scale), complete healing by four weeks, infection rates, or need for additional interventions. These findings suggest benefit in accelerating epithelial healing without clear superiority in other clinical or cosmetic outcomes (Obeid, 2025).

Another systematic review and meta-analysis including 14 studies (n = 3,362) evaluated ReCell as an adjunct to STSG in burn care and demonstrated a statistically significant reduction in overall complication rates compared with STSG alone. No significant differences were observed in wound infection or graft failure rates. Interpretation was limited by substantial heterogeneity and variable methodological quality across studies, indicating the need for high-quality, large-scale randomized trials to confirm long-term efficacy and define the broader clinical role of ASCS technologies (Daneshi et al., 2026).

A randomized, open-label trial evaluated ReCell in large, adequately vascularized diabetes-related foot wounds and found no significant difference in six-month complete healing rates compared with standard care. Healing outcomes were more strongly associated with patient and wound characteristics, including lower body mass index and non-plantar wound location, rather than treatment type. Although ReCell achieved high overall healing rates, it did not demonstrate superiority over standard care in this population (Manning et al., 2022).

Diabetic Foot Ulcers (DFUs)

Diabetic Foot Ulcers (DFUs) are complex chronic wounds that arise from neuropathy with loss of protective sensation, repetitive mechanical stress, impaired microvascular function, and frequent coexisting infection and/or peripheral arterial disease (PAD), all of which can delay healing and increase complication risk (IWGDF, 2023; Ontario Health, 2021).

Standard DFU management prioritizes optimization of foundational care—regular wound assessment, debridement when indicated, moisture-appropriate dressings/cleansing, and infection evaluation/management when clinically indicated, while maintaining effective offloading as a core requirement throughout treatment (IWGDF, 2023).

A validated clinical decision point for escalation beyond standard care is the ulcer's early healing trajectory; in a large prospective study, percent change in DFU area after 4 weeks strongly predicted complete healing at 12 weeks, supporting reassessment and consideration of adjunctive interventions when a DFU fails to achieve approximately ≥50% area reduction after ≥4 weeks of optimized standard care (Sheehan et al., 2003).

Because adequate perfusion is a prerequisite for DFU healing, objective vascular assessment should be incorporated into patient selection; notably, ABI can be falsely elevated or unreliable in diabetes due to medial arterial calcification, and toe systolic blood pressure (toe pressure) and/or toe-brachial index (TBI) are commonly used in these circumstances (Tehan et al., 2024). Evidence supports toe pressure thresholds around ≥30 mmHg as associated with improved healing likelihood (or lower non-healing risk) in diabetic foot contexts, supporting toe pressure as an objective eligibility criterion when ABI is noncompressible/unreliable (Tay et al., 2018; Linton et al., 2020). For TBI, the literature reports multiple "normal" thresholds (e.g., >0.6, >0.7, >0.75) and overall diagnostic accuracy evidence is limited by heterogeneity and low/very-low certainty, supporting a policy approach that allows reasonable ranges and/or alternate objective tests rather than a single rigid cutoff (Tehan et al., 2024).

Skin substitutes/soft tissue grafts may be used as adjuncts to standard care in selected chronic DFUs to provide a temporary extracellular matrix and/or scaffold intended to support granulation and re-epithelialization; however, products vary substantially in source materials, processing methods, and biologic activity, and effectiveness should

not be assumed across products or classes (Ontario Health, 2021; Vecin & Kirsner, 2023; Haxho et al., 2025; Kondej et al., 2024). Consistent with this evidence-based approach, the ADA Standards of Care—2026 recommend that for chronic DFUs that fail to heal with optimal standard care, clinicians should consider adjunctive treatment with RCT-proven advanced agents, including several skin substitutes, and this recommendation is graded A (American Diabetes Association Professional Practice Committee for Diabetes, 2026).

Randomized and comparative studies report improved outcomes for some advanced wound products in selected DFU populations when used with optimized standard care, though results vary by product and study design (Zelen et al., 2016; Ananian et al., 2018; Tettelbach et al., 2019; Ontario Health, 2021). Economic modeling provides contextual support but does not establish medical necessity; in a Markov model of neuropathic DFUs, adjunctive tri-layer porcine small intestinal submucosa (SIS) was associated with increased ulcer-free time and higher modeled healing probabilities compared with standard care alone under the model assumptions (Guest et al., 2017).

AlloPatch® Pliable is an aseptically processed human reticular acellular dermal matrix (HR-ADM) used as an adjunct to standard care for selected chronic diabetic foot ulcers (DFUs). Product-specific evidence includes a prospective, randomized, controlled multicenter trial evaluating weekly HR-ADM application plus standard of care (SOC) versus SOC alone after a screening/run-in period with offloading and SOC. In the follow-up RCT (n=80), the HR-ADM group demonstrated higher complete closure rates at 6 weeks (68% vs 15%) and 12 weeks (80% vs 30%), with shorter mean time to healing (38 vs 72 days) and no increase in adverse/serious adverse events or graft-related adverse events, supporting effectiveness and safety in appropriately selected chronic DFU patients when used as an adjunct to SOC (Zelen et al., 2018).

While meta-analyses do not evaluate AlloPatch® Pliable exclusively, class-level evidence supports human dermal matrix use as an adjunct to SOC in neuropathic, nonischemic DFUs. A systematic review/meta-analysis of human-derived acellular dermal matrices (H-ADMs) found improved likelihood of complete healing at 12 and 16 weeks and shorter time to closure compared with SOC, with broadly similar performance across commercial H-ADM products (Luthringer et al., 2020). A broader 2024 systematic review/meta-analysis of dermal matrix RCTs similarly reported higher complete healing rates, shorter time to healing, and lower overall and major amputation risk versus SOC alone, without a significant increase in complications, supporting dermal matrix as an effective adjunctive option in appropriate DFU populations (Sui et al., 2024).

EpiCord® (dehydrated human umbilical cord allograft) has Level I product-specific evidence in chronic, nonhealing diabetic foot ulcers (DFUs). In a multicenter, prospective randomized controlled trial conducted at 11 U.S. centers, participants underwent a 14-day run-in with weekly debridement, moist wound therapy, and continued off-loading; those with ≤30% wound area reduction were randomized 2:1 to receive weekly

EpiCord® plus standardized care (n=101) or standardized alginate-based therapy (n=54) for up to 12 weeks (Tettelbach et al., 2019). In the intent-to-treat analysis, DFUs treated with EpiCord® achieved higher complete closure at 12 weeks than controls (70% vs 48%; p=0.0089), with similar superiority in the per-protocol analysis (81% vs 54%; p=0.0013) and no graft-related adverse event signal reported, supporting EpiCord® as an effective adjunct when wounds fail to progress with optimized conservative management (Tettelbach et al., 2019). The corresponding ClinicalTrials.gov record (NCT02844660) corroborates the randomized multicenter design and reports an actual enrollment of 130, supporting trial transparency and design fidelity (ClinicalTrials.gov, 2022). Translational data further support biologic plausibility, showing PURION® PLUS–processed dehydrated human umbilical cord contains extracellular matrix components (including collagen and hyaluronic acid) and a broad proteomic profile with in vitro cellular effects relevant to repair (e.g., fibroblast migration and endothelial progenitor cell vessel formation) (Bullard et al., 2019), while a small case series describing expandable dehydrated human umbilical cord use in stalled lower-extremity wounds in diabetes provides supportive real-world feasibility evidence (Garoufalis & Tettelbach, 2022).

Álvaro-Afonso et al. (2020) performed a structured search of PubMed and the Cochrane databases (May–July 2018) and retrospectively reviewed 28 randomized controlled trials (RCTs) evaluating 17 dermoepidermal skin substitutes for diabetic foot ulcers (DFUs), focusing on complete wound closure rates and time to healing. (Álvaro-Afonso et al., 2020). Across the included RCTs, 12-week healing rates and time to complete closure were heterogeneous, reflecting differences in study populations, ulcer characteristics, and methodologies. (Álvaro-Afonso et al., 2020). In their synthesis of the available RCT data, the highest reported 12-week closure rates were noted among dermal cellular substitutes (e.g., EpiFix 100%, AmnioBand 85%) and dermal acellular substitutes (e.g., AlloPatch 80%, Hyalograft 78.8%). (Álvaro-Afonso et al., 2020). Overall, the authors concluded that dermoepidermal skin substitutes used in conjunction with standard DFU care appear to improve healing compared with standard care alone, while emphasizing the need for more homogeneous trials to clarify effectiveness across ulcer size, duration, and depth, and to better represent patients with more severe comorbidities for real-world generalizability. (Álvaro-Afonso et al., 2020).

An 80-patient multicenter RCT found higher 12-week DFU closure with weekly dHACA **(AmnioBand®)** + SOC (85%) vs SOC alone (33%) and faster mean healing (37 vs 67 days) (DiDomenico et al., 2018).

Mechanistic/translational data support biologic plausibility: PURION® PLUS–processed dehydrated human umbilical cord contains extracellular matrix components (e.g., collagen and hyaluronic acid) and a broad proteomic profile and demonstrated in vitro effects relevant to wound repair (e.g., fibroblast migration and endothelial progenitor cell vessel formation), with biocompatible resorption in an in vivo model (Bullard et al., 2019). Additional real-world evidence from a small case series describes use of expandable dehydrated human umbilical cord allograft in stalled lower-extremity wounds in patients

with diabetes, which is supportive but lower-level evidence compared with the RCT base (Garoufalis & Tettelbach, 2022).

Kerecis

The current body of literature evaluating Kerecis (omega-3 acellular fish skin grafts) for **diabetic foot ulcers (DFUs)** demonstrates consistent improvements in wound healing outcomes compared to standard care, supported by randomized controlled trials and a systematic review, though with important methodological limitations.

In a multicenter RCT of 255 patients with deeper DFUs (including wounds penetrating to tendon, bone, or joint), Dardari et al. (2024) reported significantly higher rates of complete wound closure with fish skin grafts compared to standard care at both 16 weeks (44% vs 26%) and 24 weeks (55% vs 38%), along with a modest reduction in time to healing, although the open-label design, manufacturer funding, and subsequent correction to infection data introduce potential bias.

Similarly, Lantis et al. (2023) demonstrated in a randomized trial of 102 patients with moderate, full-thickness DFUs (excluding exposed deep structures) that fish skin grafts achieved higher healing rates than collagen alginate therapy (56.9% vs 31.4%, p=0.0163) and greater wound area reduction, while Lullove et al. (2021) reported comparable findings in a smaller RCT (n=49), with significantly improved closure rates (67% vs 32%) and wound reduction in the fish skin group.

A 2025 systematic review by Karhana and Khan, which included nine studies of omega-3 fish skin grafts in chronic wounds including DFUs, found that these products were associated with faster healing (approximately 15 weeks for DFUs), reduced pain, and decreased antibiotic use relative to standard therapies, though conclusions were limited by heterogeneity, small sample sizes, and potential publication bias.

Consistent with these findings, a 2025 ECRI Clinical Evidence Assessment concluded that available evidence, including one systematic review and two RCT supports the safety and effectiveness of Kerecis in enhancing DFU healing compared to standard care and collagen/alginate dressings, but characterized the overall strength of evidence as moderate due to limited long-term outcomes and variability in study design (ECRI, 2025). The literature supports improved short-term healing outcomes in DFUs, particularly for non-healing, full-thickness ulcers following standard care, while remaining limited by study size, heterogeneity, and gaps in long-term durability and comparative effectiveness (Dardari et al., 2024; Lantis et al., 2023; Lullove et al., 2021; Karhana & Khan, 2025; ECRI, 2025).

Dystrophic Epidermolysis Bullosa (DEB)

Dystrophic epidermolysis bullosa (DEB) is a rare, inherited skin-fragility disorder caused by pathogenic variants in the *COL7A1* gene, which encodes type VII collagen, a critical structural component of anchoring fibrils at the dermal–epidermal junction. Deficiency or

dysfunction of type VII collagen compromises dermal–epidermal adhesion, resulting in blistering and erosions with minor mechanical trauma, and healing that often occurs with scarring and milia formation (Yadav et al., 2018).

DEB may be inherited in either an autosomal dominant (DDEB) or autosomal recessive (RDEB) pattern, with recessive forms generally associated with more severe disease manifestations. Individuals with moderate-to-severe DEB often experience recurrent blistering, chronic painful wounds, infection risk, pruritus, and progressive fibrotic scarring that can lead to pseudosyndactyly ("mitten-hand" deformities), joint contractures, nutritional compromise, anemia, and extracutaneous complications (e.g., esophageal strictures), as well as a markedly increased risk of aggressive cutaneous squamous cell carcinoma (El Hachem et al., 2025; Vanden Oever & Tolar, 2014).

Management of DEB is supportive and multidisciplinary, emphasizing prevention of trauma, meticulous wound care, infection prevention, and individualized pain and itch management. International consensus guidance highlights atraumatic handling and dressings, and recognizes that advanced wound coverings/skin substitutes may be used as part of comprehensive care in selected patients to reduce shear and repetitive injury to fragile skin (Denyer & Pillay, 2012; Pope et al., 2012).

In dystrophic epidermolysis bullosa, skin grafting using autologous keratinocyte sheets, including genetically corrected grafts, has been used to promote durable wound closure by replacing fragile epidermis and restoring dermal–epidermal attachment; however, its use is limited by the need for specialized manufacturing, surgical application, and restriction of benefit to grafted areas (Osborn et al., 2025).

OrCel™ (Composite Cultured Skin) is authorized under a U.S. Food and Drug Administration (FDA) Humanitarian Device Exemption for use in patients with mitten-hand deformities due to RDEB as an adjunct to standard autograft procedures (e.g., skin grafts or flaps) for covering wounds and donor sites created following surgical release of hand contractures; as a humanitarian device, effectiveness for this use has not been demonstrated (FDA, n.d.; FDA product code definition; n.d.).

While curative therapies are not yet widely available, ongoing advances in gene- and cell-based approaches continue to evolve (Osborn, et al., 2025); however, current standard care remains centered on supportive wound management, prevention of complications, and selected surgical/reconstructive interventions when function is impaired (El Hachem et al., 2025; Vanden Oever & Tolar, 2014).

Venous Leg Ulcers (VLUs)

Venous leg ulcers (VLUs) are chronic open skin lesions of the lower extremity (leg or foot) occuring in the setting of chronic venous disease and venous hypertension, most often in the gaiter region, and often accompanied by edema and characteristic venous skin changes (O'Donnell et al., 2014; WOCN, 2021). The underlying pathophysiology

involves sustained ambulatory venous hypertension (often from venous reflux and/or obstruction) leading to inflammation and microcirculatory dysfunction that can delay healing (O'Donnell et al., 2014; Franks et al., 2016). Because management depends on correct etiology, guidance emphasizes confirming venous disease and evaluating for coexisting arterial insufficiency (e.g., ABI/toe pressures when ABI is unreliable) to identify "mixed" disease and to guide safe compression use (Marston et al., 2016; WOCN, 2021).

First-line VLU care is centered on sustained therapeutic compression to reduce venous hypertension and edema, combined with structured wound care (serial measurement/documentation, moisture-balanced dressings, and debridement when indicated) (O'Donnell et al., 2014; Marston et al., 2016). Skin substitutes/cellular and tissue-based products (CTPs) are considered adjunctive therapies rather than replacements for compression, and guideline-based practice supports considering adjuvant therapies when a VLU fails to demonstrate meaningful improvement after an adequate trial of standard care (commonly ≥4–6 weeks) with appropriate wound bed preparation (O'Donnell et al., 2014; Marston et al., 2016). The evidence base for CTPs in VLUs is product-specific and should not be generalized across the class, with RCT outcomes varying by construct type, ulcer chronicity, and study design (Vecin & Kirsner, 2023; Harding et al., 2013).

Randomized trials support the use of selected products as adjuncts to compression in difficult-to-heal VLUs. For example, a multicenter RCT found that a bilayer living cellular construct (Apligraf®) plus compression improved complete closure versus compression alone in hard-to-heal VLUs (Falanga & Sabolinski, 1999). Another randomized multicenter trial reported higher healing at 12 weeks with porcine small-intestinal submucosa extracellular matrix (OASIS®) plus compression compared with compression alone (Mostow et al., 2005).

Placental-derived allografts also have RCT support, including a multicenter RCT reporting improved healing and faster closure with dehydrated human amnion/chorion membrane (EpiFix®) as an adjunct to multilayer compression compared with standard care alone (Bianchi et al., 2018) and more recent multicenter randomized evidence reporting higher 12-week healing with dehydrated human amniotic membrane (AmnioBand®) added to standard care (Serena et al., 2022).

Not all products demonstrate consistent benefit in primary endpoints; for example, a large RCT of a human fibroblast-derived dermal substitute (Dermagraft®) plus compression did not significantly improve overall 12-week healing versus compression alone, underscoring the importance of patient selection and product-specific evidence (Harding et al., 2013).

Within this context, Grafix® (cryopreserved viable placental membrane; vCPM) and Grafix PL Prime® (lyopreserved; vLPM) are placental-derived allografts designed to

support wound healing through extracellular matrix scaffolding, growth factors, and viable cells. Lyopreserved and cryopreserved formulations have demonstrated comparable clinical performance (Ananian et al., 2019). Evidence evaluating Grafix in VLUs includes a randomized controlled trial, prospective observational studies, retrospective cohort studies, and real-world evidence analyses.

Dhillon et al. (2025) conducted a prospective, randomized, open-label, multicenter trial evaluating lyopreserved placental membrane (Grafix PL Prime) in combination with standard of care compared with standard of care alone in 200 patients with VLUs. The study demonstrated faster wound size reduction and improved healing trajectory, with a statistically significant increase in the probability of complete wound closure observed in wounds ≥3 cm^2 (relative risk 1.72; $p<0.05$). However, the primary endpoint was not statistically significant in the overall intent-to-treat population, and findings were driven by subgroup analyses. Additional limitations include the open-label design and industry sponsorship, introducing potential bias. Overall, this trial provides moderate-quality evidence suggesting potential benefit in larger or more complex VLUs, though results are not definitive (Dhillon et al., 2025).

Farivar et al. (2019) conducted a prospective, single-arm crossover study evaluating cryopreserved placental membrane (Grafix) in 30 VLUs that had failed at least 12 weeks of standard care. The study reported complete wound closure in 53% of ulcers, with an approximate 79% mean reduction in wound size and faster healing compared with prior therapy. Limitations include the absence of a concurrent control group, small sample size, and single-center design. These findings support a potential adjunctive benefit of Grafix in refractory VLUs but do not provide controlled comparative evidence (Farivar et al., 2019).

Ananian et al. (2019) conducted a retrospective, multicenter case series evaluating lyopreserved placental membrane in 98 chronic wounds, including a subgroup of VLUs. The study demonstrated a 47% closure rate in VLUs with a median time to closure of 63 days and comparable outcomes between lyopreserved and cryopreserved formulations. However, limitations include the retrospective design, lack of a control group, and small VLU subgroup, which limits generalizability. These findings suggest moderate effectiveness and support equivalency between formulations but provide limited VLU-specific evidence (Ananian et al., 2019).

Regulski et al. (2013) conducted a retrospective cohort study evaluating cryopreserved placental membrane in 34 VLUs and reported a 67.6% closure rate at 12 weeks with a mean time to closure of approximately 5.8 weeks in wounds that had failed prior advanced therapies. However, the lack of a comparator group, retrospective design, and potential selection bias limit internal validity. These findings suggest relatively high healing rates in refractory wounds but should be interpreted cautiously (Regulski et al., 2013).

Swoboda (2021) evaluated viable placental membrane use in a heterogeneous, real-world population of chronic wounds, including VLUs, and reported a 57% healing rate at 12 weeks in patients with significant comorbidities. While these results suggest that effectiveness observed in controlled settings may translate to routine practice, interpretation is limited by the inclusion of mixed wound types, absence of a control group, and lack of VLU-specific subgroup analysis (Swoboda, 2021).

Johnson et al. (2017) conducted a nonrandomized comparative effectiveness study and reported higher closure rates with cryopreserved placental membrane (Grafix) compared with dehydrated amnion/chorion membrane, including 70.0% versus 7.1% closure in VLUs ($p<0.01$). However, conclusions are limited by the nonrandomized design, single-center setting, and potential confounding.

Padula et al. (2024) conducted a large retrospective claims analysis involving over 120,000 VLU episodes and found that treatment with placental allografts was associated with reduced mortality, recurrence, and adverse outcomes. However, claims-based analyses lack clinical detail and cannot establish causality or isolate product-specific effects.

Overall, evidence evaluating Grafix in VLUs demonstrates moderate rates of wound closure (approximately 47%–67%), improved wound reduction, and potential benefit in chronic or refractory ulcers. However, findings are variable, the evidence base is predominantly observational, and high-quality randomized data remain limited.

Overall, the SVS/AVF guideline reinforces compression as foundational and supports considering adjunctive therapies only after documented inadequate response to standard care, with continued compression throughout treatment (O'Donnell et al., 2014; WOCN, 2021).

Product-Specific Skin Substitutes and Soft Tissue Grafts
The following summarizes product-specific available evidence, recognizing that clinical outcomes of skin substitutes should be interpreted on a product-specific basis due to heterogeneity in composition, processing, and biologic activity.

Foundation Dermal Regeneration Scaffold (DRS) Solo
Foundation Dermal Regeneration Scaffold (DRS) Solo is an FDA 510(k)-cleared, acellular biosynthetic skin substitute composed of a chitosan–chondroitin sulfate matrix designed to function as a biodegradable scaffold that supports cellular infiltration, angiogenesis, and granulation tissue formation within a moist wound environment (U.S. Food and Drug Administration [FDA], 2022; Bionova Medical, 2023). Current evidence is limited, as regulatory clearance was based primarily on bench testing, biocompatibility assessments, and preclinical animal models demonstrating granulation tissue formation and progression toward epithelialization, rather than robust human clinical outcomes (FDA, 2022; Samaritan Biologics, 2025). A randomized controlled trial evaluating DRS

Solo for diabetic foot ulcers is ongoing, but no results are currently available, leaving a critical gap in direct evidence of clinical effectiveness (Samaritan Biologics, 2026). While broader literature on extracellular matrix-based scaffolds supports a biologic rationale for improved wound healing, this evidence is indirect and not product-specific; therefore, the overall quality of evidence for DRS Solo remains very low, and its impact on net health outcomes compared with standard care has not been established.

Myriad Matrix (Ovine Forestomach Matrix, OFM)
Ovine forestomach matrix (OFM; Myriad Matrix) is an acellular extracellular matrix bioscaffold designed to support wound healing; however, the current evidence base is limited and consists primarily of observational studies without robust comparative data. Available literature, including small case series, single-arm observational studies, and retrospective registry analyses suggests potential benefits in granulation tissue formation and wound closure across surgical and chronic wound settings, but findings are constrained by methodological limitations such as lack of control groups, small sample sizes, heterogeneity of patient populations and indications, and potential bias (Chaffin, et al., 2021; Cormican et al., 2023; Lawlor et al., 2024; Bosque et al., 2022; Hsu et al., 2023). The absence of randomized controlled trials and limited long-term outcome data further restrict the ability to determine clinical effectiveness or comparative benefit relative to standard care or other advanced wound products. Accordingly, due to insufficient high-quality evidence demonstrating improved net health outcomes, Myriad Matrix is considered experimental, investigational, and/or unproven for all indications, and additional well-designed randomized controlled trials are necessary to establish its role in evidence-based treatment pathways.

SkinTE / AHSC
SkinTE® (autologous heterogeneous skin construct [AHSC]) is an emerging regenerative therapy derived from a small full-thickness skin harvest and applied to chronic wounds with the intent of promoting healing; however, the current body of evidence remains insufficient to establish its safety, effectiveness, and clinical utility relative to standard wound care.

The available literature is limited to small case series and retrospective, noncontrolled studies, which are inherently subject to bias, lack comparator groups, and do not provide robust, generalizable outcomes (Burgueno-Vega et al., 2023; Mundinger et al., 2020). Additionally, ongoing research includes clinical trials and expanded access programs designed to further evaluate safety and efficacy, indicating that the technology remains in an investigational phase of development (ClinicalTrials.gov, 2025). Although a randomized Phase III trial has been completed, peer-reviewed results are not yet widely available to confirm clinical benefit or long-term outcomes (PolarityBio, 2025).

Furthermore, SkinTE has not received FDA approval and is advancing toward regulatory review, and the associated harvesting and application procedures (CPT codes 1044T–

1049T) are designated as Category III codes, reflecting emerging technologies requiring additional evidence development (AMA CPT/PolarityBio, 2026). In the absence of high-quality comparative studies, guideline endorsement, and established long-term efficacy and safety data, SkinTE and its associated procedures are appropriately classified as investigational and unproven (E/I/U) and therefore considered not medically necessary.

IV. GUIDELINES / POSITION STATEMENTS

Medical/Professional Society	Guideline
American Diabetes Association (ADA)	Retinopathy, Neuropathy, and Foot Care: Standards of Care in Diabetes—2026
American Academy of Family Physicians (AAFP)	Venous ulcers: diagnosis and treatment (2018)
Wound Healing Society (WHS)	WHS guidelines for the treatment of pressure ulcers—2023 update WHS (Wound Healing Society) guidelines update: Diabetic foot ulcer treatment guidelines WHS 2015 update on guidelines for venous ulcers.
The Wound Healing Foundation (WHF)	Chronic wounds: Treatment consensus
International Working Group on the Diabetic Foot (IWGDF)	IWGDF-Guidelines-2023.pdf
Wound, Ostomy and Continence Nurses Society (WOCN)	LE Wounds Due to Venous, Arterial, DM-ND Disease-Clinical Resource Guide (2021)
International Society for Burn Injuries (ISBI) (2016)	ISBI Practice Guidelines for Burn Care ISBI Practice Guidelines for Burn Care, Part 2
American Burn Association (ABA)	Clinical Practice Guidelines: Elevating Burn Care Quality
European Burns Association	EBA-Guidelines-Version-4-2017-1.pdf
The Korean Society of Laryngology, Phoniatrics and Logopedics	ceo-2020-00409.pdf (2020)

Wounds International	Best practice guidelines for skin and wound care in epidermolysis bullosa Skin and Wound Care in Epidermolysis Bullosa (2017)
Agency for Healthcare Research and Quality (AHRQ)	Skin Substitutes for Treating Chronic Wounds (2020)
Dystrophic Epidermolysis Bullosa Research Association of America (DEBRA)	Dystrophic Epidermolysis Bullosa Research Association of America [DEBRA], 2025)
U.S. Clinician Consensus	Consensus Recommendations for Optimizing the Use of Intact Fish Skin Graft in the Management of Acute and Chronic Lower Extremity Wounds (2023)

V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)

Depending on the purpose of the product and how it functions, skin substitutes are regulated by the FDA premarket approval (PMA) process, 510(k) premarket notification process, or the FDA regulations for banked human tissue.

The FDA's public PMA database can be accessed here: Premarket Approval (PMA).

The FDA's 510(k) database can be accessed here: 510(k) Premarket Notification.

The Human Cell and Tissue Establishment Registration- Public Query can be accessed here: HUMAN CELL AND TISSUE ESTABLISHMENT REGISTRATION (HCTERS) - Public Query.

The FDA's public HDE database can be accessed here: Humanitarian Device Exemption (HDE).

Device	Premarket Approval, 513(f)(2)(De Novo), or 510(k) Number	Notice date
Breast Reconstruction:		
Strattice	K130817	04/17/2013
SurgiMend	K071807	08/06/2007
Galaflex	K140533	05/21/2014
GalaShape 3D	K161092	08/23/2016

Galaform 3D	K162922	02/23/2017
Burns:		
BIOBRANEI II GREEN LABEL BIOBRANE II AND RED LABEL BIOBRANE II	K896110 K901369	11/28/1989 06/05/1990
BIOBRANE Temporary Wound Dressing and BIOBRANE Glove	K242146	12/17/2024
Orcel™	P010016	09/20/2001
TransCyte™	P960007	08/14/1998
Integra® Dermal Regeneration Template (IDRT)	P900033	07/18/1996
Integra® Bilayer Matrix Wound Dressing (“Integra® Bilayer Wound Matrix”)	K021792	08/14/2002
Integra Meshed Bilayer Wound Matrix	K081635	12/04/2008
Epicel®	H990002	10/25/2007
Autologous Cell Harvesting Device:		
ReCell®	BP170122	09/20/2018
Diabetic Foot Ulcers:		
Apligraf/Graftskin	P950032A	11/10/1998
Epifix	Epifix (HCT/P)	NA
Oasis® Wound Matrix and Oasis Ultra Tri-Layer Matrix	K061711	07/19/2006
Dermagraft	P000036A	09/28/2001
Integra Omnigraft Dermal Regeneration Matrix	P900033/s042	01/07/2016
Integra Dermal Regeneration Matrix	P900033	03/01/1996
Primatrix	K153690	02/22/2016
Talymed	K102002	07/28/2010

Matristem Wound Matrix	K112409	08/29/2011
Matristem MicroMatrix	K172399	08/08/2017
Kerecis™ Omega3 Wound (formerly known as MeriGen)	K132343	10/23/2013
Kerecis Limited MariGen Wound Extra	K190528	07/10/2019
Kerecis Silicone (Kerecis Limited)	K213231	06/19/2022
Kerecis Parvus	K241080	08/21/2024
Marigen Wound Extra	K190528	07/10/2019
Mirragen™ Advanced Wound Matrix	K161067	12/15/2022
Grafix	Grafix (HCT/P)	NA
Venous Leg Ulcers:		
Apligraf/Graftskin	P950032A P950032/S016	11/10/1998 06/20/2000
TheraSkin®	(HCT/P)	
Epifix	Epifix (HCT/P)	
Oasis® Wound Matrix	K061711	07/19/2006
Primatrix	K153690	02/ 22/2016
Talymed	K102002	07/28/2010
Recessive Dystrophic Epidermolysis Bullosa (RDEB):		
Orcel™	H990013	02/21/2001

VI. CODING

ICD-10 Codes that may support medical necessity

C50.011 – C50.929	Malignant neoplasm of female breast
C79.81	Secondary malignant neoplasm of breast
D05.00 – D05.92	Carcinoma in situ of breast
D48.60 – D48.62	Neoplasm of uncertain behavior of breast
D49.3	Neoplasm of unspecified behavior of breast
T85.44xA – T85.44xS	Capsular contracture of breast implant
N65.0	Deformity of reconstructed breast
N65.1	Disproportion of reconstructed breast
Z85.3	Personal history of malignant neoplasm of breast
Z42.8	Encounter for other plastic and reconstructive surgery following medical procedure or healed injury
Z40.01	Encounter for prophylactic removal of breast
Z42.1	Encounter for breast reconstruction following mastectomy
Z90.10 – Z90.13	Acquired absence of breast and nipple
Z98.82	Breast implant status

T20.20xA – T26.92xS	Burn and corrosion
T30.0 – T32.99	Burns
I83.001 – I83.229	Varicose veins with ulcer
I87.011 – I87.019	Post-phlebitic syndrome with ulcer
I87.311 – I87.319	Chronic venous hypertension with ulcer
I87.331 – I87.339	Chronic venous hypertension (idiopathic) with ulcer and inflammation
I87.2	Venous insufficiency (chronic) (peripheral)
I87.9	Disorder of vein, unspecified
I70.231 – I70.25	Atherosclerosis of native arteries of leg with ulceration
I70.331 – I70.749	Atherosclerosis of bypass graft(s) of leg with ulceration
L97.101- l97.929	Non-pressure chronic ulcer
Q81.2	Epidermolysis bullosa dystrophica
Secondary diagnoses	
E08.40 – E08.610	Diabetes mellitus due to underlying condition with diabetic neuropathy
E09.40 – E09.610	Drug or chemical induced diabetes mellitus with neurological complications
E10.40 – E10.69	Type 1 diabetes mellitus with neurological complications
E11.40 – E11.69	Type 2 diabetes mellitus with neurological complications
E13.40 – E13.69	Other specified diabetes mellitus with neurological complications

CPT/HCPCS Codes

Appropriate Skin Substitute Application code/product combination must be billed on the same claim for the same date of service.

Application of Skin Suspension Autografts (e.g., RECELL ® Autologous Cell Harvesting Device):	
HCPCS Code(s)	**Descriptor**
15011	Harvest of skin for skin cell suspension autograft; first 25 sq cm or less
15012	Harvest of skin for skin cell suspension autograft; each additional 25 sq cm or part thereof (List separately in addition to code for primary procedure)
15013	Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; first 25 sq cm or less of harvested skin

15014	Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; each additional 25 sq cm of harvested skin or part thereof (List separately in addition to code for primary procedure)
15015	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, trunk, arms, legs; first 480 sq cm or less
15016	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, trunk, arms, legs; each additional 480 sq cm or part thereof (List separately in addition to code for primary procedure
15017	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 480 sq cm or less
15018	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 480 sq cm or less
C8002	Preparation of skin cell suspension autograft, automated, including all enzymatic processing and device components (do not report with manual suspension preparation)
	Application of Skin Substitute Products:
HCPCS Code(s)	**Descriptor**
15271	Application of skin substitute graft to **trunk, arms, legs**, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
15272	Application of skin substitute graft to **trunk, arms, legs**, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)
15273	Application of skin substitute graft to **trunk, arms, legs**, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
15274	Application of skin substitute graft to **trunk, arms, legs**, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)
15275	Application of skin substitute graft to **face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits**, total wound surface area up to 100 sq cm; first 25 sq cm or less
15276	Application of skin substitute graft **to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits**, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)

15277	Application of skin substitute graft to **face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits**, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
15278	Application of skin substitute graft to **face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits**, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)
15777	Implantation of biologic implant (eg, acellular dermal matrix) for soft tissue reinforcement (ie, breast, trunk) (List separately in addition to code for primary procedure)

Application of Non-Sheet Form Skin Substitute Grafts:	
HCPCS Code(s)	**Descriptor**
G0681	Application of a premarket approval (pma), 510(k), 361 human cells, tissues or cellular and tissue-based products (hct/p) non-sheet form skin substitute for a wound surface area up to 100 sq cm; first 25 sq cm or less of wound surface area
G0682	Application of a premarket approval (pma), 510(k), 361 human cells, tissues or cellular and tissue-based products (hct/p) non-sheet form skin substitute for a wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure)
G0683	Application of a premarket approval (pma), 510(k), 361 human cells, tissues or cellular and tissue-based products (hct/p) non-sheet form skin substitute graft for a wound surface greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
G0684	Application of a premarket approval (pma), 510(k), 361 human cells, tissues or cellular and tissue-based products (hct/p) non-sheet form skin substitute graft for a wound surface greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area or part thereof, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)

Medically Necessary Skin Substitutes & Soft Tissue Graft Products:

Skin Substitutes & Soft Tissue Graft Products		
HCPCS Code	**Product**	**Notes**
A2019	Kerecis Omega3 MariGen Shield, per sq cm	(add-on, list separately in addition to primary procedure)
A2043	Biobrane, per square centimeter	
A2044	Biobrane glove, each	

C9358	Dermal substitute, native, nondenatured collagen, fetal bovine origin (SurgiMend Collagen Matrix), per 0.5 sq cm	
C9360	Dermal substitute, native, nondenatured collagen, neonatal bovine origin (SurgiMend Collagen Matrix), per 0.5 sq cm	
C9363	Skin substitute (Integra Meshed Bilayer Wound Matrix), per sq cm	
Q4431, Q4432, Q4433/ C9399	Cortiva® (formerly AlloMax®, NeoForm®); DermaMatrix®;	
Q4101	Apligraf, per sq cm	add-on, list separately in addition to primary procedure
Q4102	Oasis wound matrix, per sq cm	add-on, list separately in addition to primary procedure
Q4104	Integra bilayer matrix wound dressing (BMWD), per square centimeter	add-on, list separately in addition to primary procedure
Q4105	Integra dermal regeneration template (DRT) or Integra Omnigraft dermal regeneration matrix, per sq cm	add-on, list separately in addition to primary procedure
Q4107	GRAFTJACKET® (per sq cm)	add-on, list separately in addition to primary procedure
Q4116	AlloDerm, per sq cm	add-on, list separately in addition to primary procedure
Q4121	TheraSkin, per sq cm	add-on, list separately in addition to primary procedure
Q4122	DermACELL, DermACELL AWM or DermACELL AWM Porous, per sq cm	add-on, list separately in addition to primary procedure
Q4124	OASIS® Ultra Tri-Layer Wound Matrix (per sq cm)	add-on, list separately in addition to primary procedure
Q4128	FlexHD, or AllopatchHD, per sq cm	add-on, list separately in addition to primary procedure
Q4130	Strattice, per sq cm	add-on, list separately in addition to primary procedure
Q4132	Grafix Core and Grafix PL Core, per sq cm	add-on, list separately in addition to primary procedure
Q4133	Grafix PRIME, Grafix PL PRIME, Stravix and Stravix PL, per sq cm	add-on, list separately in addition to primary procedure
Q4151	AmnioBand®, Guardian®	add-on, list separately in addition to primary procedure
Q4158	Kerecis® Omega3	add-on; listed separately in addition to primary procedure
Q4182	TransCyte, per sq cm	add-on, list separately in addition to primary procedure
Q4186	Epifix, per sq cm	add-on, list separately in addition to primary procedure
Q4187	Epicord®	add-on, list separately in addition to primary procedure
Q4431	When billed for Dermagraft, per square centimeter	add-on, list separately in addition to primary procedure

Exclusions:

The following are considered exclusions under this policy:

- **Not Medically Necessary:**

  The following are considered not medically necessary under this policy:

  Procedures, services, or products that do not meet the medical necessity criteria outlined in this policy, including those that are excluded, investigational, or unproven (E/I/U), are considered not medically necessary and are **not eligible for coverage.**

Not Medically Necessary Procedures / Services:	
HCPCS code	**Descriptor**
C1763	Connective tissue, nonhuman (includes synthetic)- when utilized for Repair of enterocutaneous fistula of small intestine or colon (excluding anorectal fistula) with plug (e.g., porcine small intestine submucosa [SIS])
Q4200	SkinTE, per sq cm (add-on, list separately in addition to primary procedure)
1044T	Harvest of full-thickness skin for autologous heterogeneous skin-construct graft, including direct closure of donor site; first 5 sq cm or less
1045T	Harvest of full-thickness skin for autologous heterogeneous skin-construct graft, including direct closure of donor site; each additional 5 sq cm, or part thereof (List separately in addition to code for primary procedure)
1046T	Autologous heterogeneous skin-construct graft application, trunk, arms, legs; first 50 sq cm or less, or 0.5% of body area of infants and children
1047T	Autologous heterogeneous skin-construct graft application, trunk, arms, legs; each additional 50 sq cm, or each additional 0.5% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)
1048T	Autologous heterogeneous skin-construct graft application, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 50 sq cm or less, or 0.5% of body area of infants and children
1049T	Autologous heterogeneous skin-construct graft application, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 50 sq cm, or each additional 0.5% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)

- **Not Separately Payable Services:**

  Services, supplies, or products are considered not separately payable when they are not eligible for separate reimbursement. This includes items that are:

- Integral to another procedure or service, or
- Considered not medically necessary due to lack of sufficient high-quality evidence demonstrating independent clinical efficacy; and therefore, do not warrant payment as distinct services.

Items meeting either of the above criteria are excluded from separate reimbursement to ensure consistent application of evidence-based coverage standards and to reduce unnecessary member financial liability when services lack sufficient clinical support.

This list is not exhaustive. Additional products that similarly lack adequate, high-quality clinical evidence to support their use are not eligible for separate reimbursement, even if not explicitly listed below:

The following Products are Not Separately Payable:		
Skin Substitutes & Soft Tissue Graft Products		
HCPCS Code	**Product**	**Notes**
A2001	InnovaMatrix AC (per sq cm)	Not separately payable (add-on code; reported with primary procedure)
A2002	Mirragen Advanced Wound Matrix (per sq cm)	Not separately payable (add-on code; reported with primary procedure)
A2004	XcelliStem (1 mg)	Not separately payable
A2005	Microlyte Matrix (per sq cm)	Not separately payable (add-on code; reported with primary procedure)
A2006	NovoSorb SynPath Dermal Matrix (per sq cm)	Not separately payable (add-on code; reported with primary procedure)
A2007	Restrata (per sq cm)	Not separately payable (add-on code; reported with primary procedure)
A2008	Theragenesis (per sq cm)	Not separately payable (add-on code; reported with primary procedure)
A2009	Symphony (per sq cm)	Not separately payable (add-on code; reported with primary procedure)
A2010	Apis (per sq cm)	Not separately payable (add-on code; reported with primary procedure)
A2011	SUPRA SDRM (per sq cm)	Not separately payable (add-on; reported with primary procedure)
A2012	SUPRATHEL (per sq cm)	Not separately payable (add-on; reported with primary procedure)

A2013	InnovaMatrix FS (per sq cm)	Not separately payable (add-on; reported with primary procedure)
A2014	Omeza Collagen Matrix (per 100 mg)	Not separately payable
A2015	Phoenix Wound Matrix (per sq cm)	Not separately payable (add-on; reported with primary procedure)
A2016	Permeaderm-B (per sq cm)	Not separately payable (add-on; reported with primary procedure)
A2017	Permeaderm Glove (each)	Not separately payable
A2018	Permeaderm-C (per sq cm)	Not separately payable (add-on; reported with primary procedure)
A2020	AC5 Advanced Wound System (AC5)	Not separately payable
A2021	NeoMatriX® (per sq cm)	Not separately payable (add-on; reported with primary procedure)
A2022	InnovaBurn® / InnovaMatrix XL (per sq cm)	Not separately payable (add-on; reported with primary procedure)
A2023	InnovaMatrix PD (1 mg)	Not separately payable
A2024	Resolve Matrix® / XenoPatch® (per sq cm)	Not separately payable (add-on; reported with primary procedure)
A2025	Miro3D (per cc)	Not separately payable (add-on; reported with primary procedure)
A2026	Restrata MiniMatrix (5 mg)	Not separately payable
A2027	MatriDerm® (per sq cm)	Not separately payable (add-on; reported with primary procedure)
A2028	MicroMatrix Flex (per mg)	Not separately payable
A2029	MiroTract Wound Matrix Sheet (per cc)	Not separately payable (add-on; reported with primary procedure)
A2030	Miro3D Fibers (per mg)	Not separately payable
A2031	MiroDry Wound Matrix (per sq cm)	Not separately payable (add-on; reported with primary procedure)
A2032	Myriad Matrix (per sq cm)	Not separately payable (add-on; reported with primary procedure)
A2033	Myriad Morcells (4 mg)	Not separately payable
A2034	Foundation DRS Solo (per sq cm)	Not separately payable (add-on; reported with primary procedure)
A2035	Corplex-P / Theracor-P / AlloCor-P (per mg)	Not separately payable
A2036	Cohealyx Collagen Dermal Matrix (per sq cm)	Not separately payable (add-on; reported with primary procedure)
A2037	G4Derm Plus/Suprello (per mL)	Not separately payable
A2038	MariGen Pacto (per sq cm)	Not separately payable (add-on; reported with primary procedure)
A2039	InnovaMatrix FD (per sq cm)	Not separately payable (add-on; reported with primary procedure)
A2040	Microlyte painguard Matrix with lidocaine, per square centimeter	Not separately payable
A2041	Foundation drs+ duo, per square centimeter	Not separately payable
A2042	Foundation drs+ solo, per square centimeter	Not separately payable
A2045	Novashield or Novogen wound matrix, per square centimeter	Not separately payable
A4100	Non-sheet form skin substitute, NOS (FDA-cleared device)	List in addition to primary procedure; explanatory notes required for unlisted code

A6460	Synthetic resorbable wound dressing, sterile, ≤16 sq in (no adhesive border)	Dressing supply
A6461	Synthetic resorbable wound dressing, sterile, >16 sq in to ≤48 sq in (no adhesive border)	Dressing supply
Q4103	OASIS® Burn Matrix (per sq cm)	Add-on; listed in addition to primary procedure
Q4108	Integra® Matrix (Thin) (per sq cm)	Add-on; listed in addition to primary procedure
Q4110	PriMatrix® (per sq cm)	Add-on; listed in addition to primary procedure
Q4111	GammaGraft® (per sq cm)	Add-on; listed in addition to primary procedure
Q4113	GRAFTJACKET® XPRESS (injectable, 1 cc) Injectable form	
Q4114	Integra® Flowable Wound Matrix (injectable, 1 cc) Injectable / flowable form	
Q4115	AlloSkin® (per sq cm)	Add-on; listed in addition to primary procedure
Q4117	HYALOMATRIX® (per sq cm)	Add-on; listed in addition to primary procedure
Q4118	MatriStem® MicroMatrix (1 mg) Injectable / particulate form	
Q4123	AlloSkin® RT (per sq cm)	Add-on; listed in addition to primary procedure
Q4125	ArthroFlex® (per sq cm)	Add-on; listed in addition to primary procedure
Q4126	MemoDerm®, DermaSpan®, TranZgraft®, IntéguPly® (per sq cm)	Add-on; listed in addition to primary procedure
Q4127	Talymed® (per sq cm)	Add-on; listed in addition to primary procedure
Q4134	hMatrix® (per sq cm)	Add-on; listed in addition to primary procedure
Q4135	MediSkin® (per sq cm)	Add-on; listed in addition to primary procedure
Q4136	EZ-Derm® (per sq cm)	Add-on; listed in addition to primary procedure
Q4137	AmnioExcel®, AmnioExcel® Plus, BioDExcel® (per sq cm)	Add-on; listed in addition to primary procedure
Q4138	BioDFence® DryFlex (per sq cm)	Add-on; listed in addition to primary procedure
Q4139	AmnioMatrix® or BioDMatrix® (injectable, 1 cc) Injectable / flowable form	
Q4140	BioDFence® (per sq cm)	Add-on; listed in addition to primary procedure
Q4141	AlloSkin® AC (per sq cm)	Add-on; listed in addition to primary procedure
Q4142	XCM Biologic Tissue Matrix (per sq cm)	Add-on; listed in addition to primary procedure
Q4143	Repriza® (per sq cm)	Add-on; listed in addition to primary procedure
Q4145	EpiFix® Injectable form (1 mg)	
Q4146	TENSIX®	Add-on; listed in addition to primary procedure

Q4147	Architect®, Architect PX®, Architect FX® ECM	Add-on; listed in addition to primary procedure
Q4148	Neox Cord 1K®, Neox Cord RT®, Clarix Cord 1K®	Add-on; listed in addition to primary procedure
Q4149	Excellagen® Injectable form (0.1 cc)	
Q4150	AlloWrap DS®, AlloWrap Dry®	Add-on; listed in addition to primary procedure
Q4152	DermaPure®	Add-on; listed in addition to primary procedure
Q4153	Dermavest®, Plurivest®	Add-on; listed in addition to primary procedure
Q4154	Biovance®	Add-on; listed in addition to primary procedure
Q4155	Neox Flo®, Clarix Flo® Injectable / particulate form (1 mg)	
Q4156	Neox 100®, Clarix 100®	Add-on; listed in addition to primary procedure
Q4157	Revitalon®	Add-on; listed in addition to primary procedure
Q4159	Affinity®	Add-on; listed in addition to primary procedure
Q4160	NuShield®	Add-on; listed in addition to primary procedure
Q4161	bio-ConneKt® Wound Matrix	Add-on; listed in addition to primary procedure
Q4162	WoundEx® Flow, BioSkin Flow® Flowable / injectable form (0.5 cc)	
Q4163	WoundEx®, BioSkin®	Add-on; listed in addition to primary procedure
Q4164	Helicoll®	Add-on; listed in addition to primary procedure
Q4165	Keramatrix®, Kerasorb®	Add-on; listed in addition to primary procedure
Q4166	Cytal®	Add-on; listed in addition to primary procedure
Q4167	TruSkin®	Add-on; listed in addition to primary procedure
Q4168	AmnioBand®	Injectable / particulate form (1 mg)
Q4169	Artacent® Wound	Add-on; listed in addition to primary procedure
Q4170	Cygnus®	Add-on; listed in addition to primary procedure
Q4171	Interfyl®	Injectable / particulate form (1 mg)
Q4173	PalinGen®, PalinGen Xplus®	Add-on; listed in addition to primary procedure
Q4174	PalinGen®, ProMatrX®	Injectable form (0.36 mg per 0.25 cc)
Q4175	Miroderm®	Add-on; listed in addition to primary procedure
Q4176	NeoPatch®, Therion®	Add-on; listed in addition to primary procedure
Q4177	FlowerAmnioFlo®	Injectable form (0.1 cc)

Q4178	FlowerAmnioPatch®	Add-on; listed in addition to primary procedure
Q4179	FlowerDerm®	Add-on; listed in addition to primary procedure
Q4180	Revita®	Add-on; listed in addition to primary procedure
Q4181	Amnio Wound®	Add-on; listed in addition to primary procedure
Q4183	surgiGRAFT®	Add-on; listed in addition to primary procedure
Q4184	Cellesta®, Cellesta Duo®	Add-on; listed in addition to primary procedure
Q4185	Cellesta® Flowable Amnion Flowable / injectable (25 mg/cc; per 0.5 cc)	
Q4188	AmnioArmor®	Add-on; listed in addition to primary procedure
Q4189	Artacent® AC Injectable / particulate form (1 mg)	
Q4190	Artacent® AC	Add-on; listed in addition to primary procedure
Q4191	Restorigin®	Add-on; listed in addition to primary procedure
Q4192	Restorigin® Injectable form (1 cc)	
Q4193	Coll-E-Derm®	Add-on; listed in addition to primary procedure
Q4194	Novachor®	Add-on; listed in addition to primary procedure
Q4195	PuraPly®	Add-on; listed in addition to primary procedure
Q4196	PuraPly® AM	Add-on; listed in addition to primary procedure
Q4197	PuraPly® XT	Add-on; listed in addition to primary procedure
Q4198	Genesis Amniotic Membrane	Add-on; listed in addition to primary procedure
Q4199	Cygnus® Matrix	Add-on; listed in addition to primary procedure
Q4201	Matrion (per sq cm)	Add-on; listed in addition to primary procedure
Q4202	Keroxx (2.5 g/cc) Injectable form (1 cc)	
Q4203	Derma-Gide (per sq cm)	Add-on; listed in addition to primary procedure
Q4204	XWRAP (per sq cm)	Add-on; listed in addition to primary procedure
Q4205	Membrane Graft / Membrane Wrap (per sq cm)	Add-on; listed in addition to primary procedure
Q4206	Fluid Flow / Fluid GF (1 cc)	Injectable / flowable form
Q4208	Novafix (per sq cm)	Add-on; listed in addition to primary procedure
Q4209	SurGraft (per sq cm)	Add-on; listed in addition to primary procedure
Q4211	Amnion Bio / AxoBioMembrane (per sq cm)	Add-on; listed in addition to primary procedure
Q4212	AlloGen (per cc)	Injectable / flowable form

Q4213	Ascent (0.5 mg)	Injectable / particulate form
Q4214	Cellesta Cord (per sq cm)	Add-on; listed in addition to primary procedure
Q4215	Axolotl Ambient / Axolotl Cryo (0.1 mg)	Injectable / particulate form
Q4216	Artacent Cord (per sq cm)	Add-on; listed in addition to primary procedure
Q4217	WoundFix®, BioWound® (all variants) (per sq cm)	Add-on; listed in addition to primary procedure
Q4218	SurgiCORD (per sq cm)	Add-on; listed in addition to primary procedure
Q4219	SurgiGRAFT-DUAL (per sq cm)	Add-on; listed in addition to primary procedure
Q4220	BellaCell HD / SureDerm (per sq cm)	Add-on; listed in addition to primary procedure
Q4221	Amnio Wrap2 (per sq cm)	Add-on; listed in addition to primary procedure
Q4222	ProgenaMatrix (per sq cm)	Add-on; listed in addition to primary procedure
Q4224	Human Health Factor-10 Amniotic Patch (per sq cm)	Add-on; listed in addition to primary procedure
Q4225	AmnioBind / DermaBind TL (per sq cm)	Add-on; listed in addition to primary procedure
Q4226	MyOwn Skin (includes harvesting/preparation) (per sq cm)	
Q4227	AmnioCore (per sq cm)	Add-on; listed in addition to primary procedure
Q4229	Cogenex Amniotic Membrane (per sq cm)	Add-on; listed in addition to primary procedure
Q4230	Cogenex Flowable Amnion (0.5 cc) Injectable / flowable form	
Q4232	Corplex (per sq cm)	Add-on; listed in addition to primary procedure
Q4233	Surfactor / Nudyn (0.5 cc) Injectable form	
Q4234	Xcellerate (per sq cm)	Add-on; listed in addition to primary procedure
Q4235	AMNIOREPAIR / AltiPly (per sq cm)	Add-on; listed in addition to primary procedure
Q4236	carePATCH (per sq cm)	Add-on; listed in addition to primary procedure
Q4237	Cryo-Cord (per sq cm)	Add-on; listed in addition to primary procedure
Q4238	Derm-Maxx (per sq cm)	Add-on; listed in addition to primary procedure
Q4239	Amnio-Maxx / Amnio-Maxx Lite (per sq cm)	Add-on; listed in addition to primary procedure
Q4240	Corecyte (0.5 cc, topical use only) Injectable / topical	
Q4241	Polycyte (0.5 cc, topical use only) Injectable / topical	
Q4242	Amniocyte Plus (0.5 cc) Injectable form	
Q4245	Amniotext (per cc) Injectable form	
Q4246	Coretext / Protext (per cc) Injectable form	
Q4247	AmnioText Patch (per sq cm)	Add-on; listed in addition to primary procedure

Q4248	Dermacyte Amniotic Membrane Allograft (per sq cm)	Add-on; listed in addition to primary procedure
Q4249	AMNIPLY (topical use only, per sq cm)	Add-on; listed in addition to primary procedure
Q4250	AmnioAmp-MP (per sq cm)	Add-on; listed in addition to primary procedure
Q4251	Vim (per sq cm)	Add-on; listed in addition to primary procedure
Q4252	Vendaje (per sq cm)	Add-on; listed in addition to primary procedure
Q4253	Zenith Amniotic Membrane (per sq cm)	Add-on; listed in addition to primary procedure
Q4254	Novafix DL (per sq cm)	Add-on; listed in addition to primary procedure
Q4255	REGUaRD (topical use only, per sq cm)	Add-on; listed in addition to primary procedure
Q4256	MLG-Complete (per sq cm)	Add-on; listed in addition to primary procedure
Q4257	Relese (per sq cm)	Add-on; listed in addition to primary procedure
Q4258	Enverse (per sq cm)	Add-on; listed in addition to primary procedure
Q4259	Celera Dual Layer / Celera Dual Membrane (per sq cm)	Add-on; listed in addition to primary procedure
Q4260	Signature Apatch (per sq cm)	Add-on; listed in addition to primary procedure
Q4261	TAG (per sq cm)	Add-on; listed in addition to primary procedure
Q4262	Dual-Layer Impax Membrane (per sq cm)	Add-on; listed in addition to primary procedure
Q4263	SurGraft TL (per sq cm)	Add-on; listed in addition to primary procedure
Q4264	Cocoon Membrane (per sq cm)	Add-on; listed in addition to primary procedure
Q4265	NeoStim TL (per sq cm)	Add-on; listed in addition to primary procedure
Q4266	NeoStim Membrane (per sq cm)	Add-on; listed in addition to primary procedure
Q4267	NeoStim DL (per sq cm)	Add-on; listed in addition to primary procedure
Q4268	SurGraft FT (per sq cm)	Add-on; listed in addition to primary procedure
Q4269	SurGraft XT (per sq cm)	Add-on; listed in addition to primary procedure
Q4270	Complete SL (per sq cm)	Add-on; listed in addition to primary procedure
Q4271	Complete FT (per sq cm)	Add-on; listed in addition to primary procedure
Q4272	Esano A (per sq cm)	Add-on; listed in addition to primary procedure
Q4273	Esano AAA (per sq cm)	Add-on; listed in addition to primary procedure
Q4274	Esano AC (per sq cm)	Add-on; listed in addition to primary procedure

Q4275	Esano ACA (per sq cm)	Add-on; listed in addition to primary procedure
Q4276	ORION (per sq cm)	Add-on; listed in addition to primary procedure
Q4278	EPIEFFECT (per sq cm)	Add-on; listed in addition to primary procedure
Q4279	Vendaje AC (per sq cm)	Add-on; listed in addition to primary procedure
Q4280	Xcell Amnio Matrix (per sq cm)	Add-on; listed in addition to primary procedure
Q4281	Barrera SL / Barrera DL (per sq cm)	Add-on; listed in addition to primary procedure
Q4282	Cygnus Dual (per sq cm)	Add-on; listed in addition to primary procedure
Q4283	Biovance Tri-Layer / Biovance 3L (per sq cm)	Add-on; listed in addition to primary procedure
Q4284	DermaBind SL (per sq cm)	Add-on; listed in addition to primary procedure
Q4285	NuDYN DL / NuDYN DL Mesh (per sq cm)	Add-on; listed in addition to primary procedure
Q4286	NuDYN SL / NuDYN SLW (per sq cm)	Add-on; listed in addition to primary procedure
Q4287	DermaBind DL (per sq cm)	Add-on; listed in addition to primary procedure
Q4288	DermaBind CH (per sq cm)	Add-on; listed in addition to primary procedure
Q4289	RevoShield+ Amniotic Barrier (per sq cm)	Add-on; listed in addition to primary procedure
Q4290	Membrane Wrap-Hydro (per sq cm)	Add-on; listed in addition to primary procedure
Q4291	Lamellas XT (per sq cm)	Add-on; listed in addition to primary procedure
Q4292	Lamellas (per sq cm)	Add-on; listed in addition to primary procedure
Q4293	Acesso DL (per sq cm)	Add-on; listed in addition to primary procedure
Q4294	Amnio Quad-Core (per sq cm)	Add-on; listed in addition to primary procedure
Q4295	Amnio Tri-Core Amniotic (per sq cm)	Add-on; listed in addition to primary procedure
Q4296	Rebound Matrix (per sq cm)	Add-on; listed in addition to primary procedure
Q4297	Emerge Matrix (per sq cm)	Add-on; listed in addition to primary procedure
Q4298	AmniCore Pro (per sq cm)	Add-on; listed in addition to primary procedure
Q4299	AmniCore Pro+ (per sq cm)	Add-on; listed in addition to primary procedure
Q4300	Acesso TL (per sq cm)	Add-on; listed in addition to primary procedure
Q4301	Activate Matrix (per sq cm)	Add-on; listed in addition to primary procedure
Q4302	Complete ACA (per sq cm)	Add-on; listed in addition to primary procedure

Q4303	Complete AA (per sq cm)	Add-on; listed in addition to primary procedure
Q4304	GRAFIX PLUS (per sq cm)	Add-on; listed in addition to primary procedure
Q4305	American Amnion AC Tri-Layer (per sq cm)	Add-on; listed in addition to primary procedure
Q4306	American Amnion AC (per sq cm)	Add-on; listed in addition to primary procedure
Q4307	American Amnion (per sq cm)	Add-on; listed in addition to primary procedure
Q4308	Sanopellis (per sq cm)	Add-on; listed in addition to primary procedure
Q4309	VIA Matrix (per sq cm)	Add-on; listed in addition to primary procedure
Q4310	Procenta (per 100 mg) Injectable / particulate form	
Q4311	Acesso (per sq cm)	Add-on; listed in addition to primary procedure
Q4312	Acesso AC (per sq cm)	Add-on; listed in addition to primary procedure
Q4313	DermaBind FM (per sq cm)	Add-on; listed in addition to primary procedure
Q4314	Reeva FT (per sq cm)	Add-on; listed in addition to primary procedure
Q4315	RegeneLink Amniotic Membrane Allograft (per sq cm)	Add-on; listed in addition to primary procedure
Q4316	AmchoPlast (per sq cm)	Add-on; listed in addition to primary procedure
Q4317	VitoGraft (per sq cm)	Add-on; listed in addition to primary procedure
Q4318	E-Graft (per sq cm)	Add-on; listed in addition to primary procedure
Q4319	SanoGraft (per sq cm)	Add-on; listed in addition to primary procedure
Q4320	PelloGraft (per sq cm)	Add-on; listed in addition to primary procedure
Q4321	RenoGraft (per sq cm)	Add-on; listed in addition to primary procedure
Q4322	CaregraFT (per sq cm)	Add-on; listed in addition to primary procedure
Q4323	alloPLY (per sq cm)	Add-on; listed in addition to primary procedure
Q4324	AmnioTX (per sq cm)	Add-on; listed in addition to primary procedure
Q4325	ACApatch (per sq cm)	Add-on; listed in addition to primary procedure
Q4326	WoundPlus (per sq cm)	Add-on; listed in addition to primary procedure
Q4327	DuoAmnion (per sq cm)	Add-on; listed in addition to primary procedure
Q4328	MOST (per sq cm)	Add-on; listed in addition to primary procedure
Q4329	Singlay (per sq cm)	Add-on; listed in addition to primary procedure

Q4330	TOTAL (per sq cm)	Add-on; listed in addition to primary procedure
Q4331	Axolotl Graft (per sq cm)	Add-on; listed in addition to primary procedure
Q4332	Axolotl DualGraft (per sq cm)	Add-on; listed in addition to primary procedure
Q4333	ArdeoGraft (per sq cm)	Add-on; listed in addition to primary procedure
Q4334	AmnioPlast 1 (per sq cm)	Add-on; listed in addition to primary procedure
Q4335	AmnioPlast 2 (per sq cm)	Add-on; listed in addition to primary procedure
Q4336	Artacent C (per sq cm)	Add-on; listed in addition to primary procedure
Q4337	Artacent Trident (per sq cm)	Add-on; listed in addition to primary procedure
Q4338	Artacent Velos (per sq cm)	Add-on; listed in addition to primary procedure
Q4339	Artacent Vericlen (per sq cm)	Add-on; listed in addition to primary procedure
Q4340	SimpliGraft (per sq cm)	Add-on; listed in addition to primary procedure
Q4341	SimpliMax (per sq cm)	Add-on; listed in addition to primary procedure
Q4342	TheraMend (per sq cm)	Add-on; listed in addition to primary procedure
Q4343	Dermacyte AC Matrix (per sq cm)	Add-on; listed in addition to primary procedure
Q4344	Tri-Membrane Wrap (per sq cm)	Add-on; listed in addition to primary procedure
Q4345	Matrix HD Allograft Dermis (per sq cm)	Add-on; listed in addition to primary procedure
Q4346	Shelter DM Matrix (per sq cm)	Add-on; listed in addition to primary procedure
Q4347	Rampart DL Matrix (per sq cm)	Add-on; listed in addition to primary procedure
Q4348	Sentry SL Matrix (per sq cm)	Add-on; listed in addition to primary procedure
Q4349	Mantle DL Matrix (per sq cm)	Add-on; listed in addition to primary procedure
Q4350	Palisade DM Matrix (per sq cm)	Add-on; listed in addition to primary procedure
Q4351	Enclose TL Matrix (per sq cm)	Add-on; listed in addition to primary procedure
Q4352	Overlay SL Matrix (per sq cm)	Add-on; listed in addition to primary procedure
Q4353	Xceed TL Matrix (per sq cm)	Add-on; listed in addition to primary procedure
Q4354	PalinGen Dual-Layer / X-Membrane (per sq cm)	Add-on; listed in addition to primary procedure
Q4355	Abiomend Xplus (per sq cm)	Add-on; listed in addition to primary procedure
Q4356	Abiomend Membrane / Hydromembrane (per sq cm)	Add-on; listed in addition to primary procedure

Q4357	XWRAP Plus (per sq cm)	Add-on; listed in addition to primary procedure
Q4358	XWRAP Dual (per sq cm)	Add-on; listed in addition to primary procedure
Q4359	ChoriPly (per sq cm)	Add-on; listed in addition to primary procedure
Q4360	AmchoPlast FD (per sq cm)	Add-on; listed in addition to primary procedure
Q4361	EPIXPRESS (per sq cm)	Add-on; listed in addition to primary procedure
Q4362	CYGNUS Disk (per sq cm)	Add-on; listed in addition to primary procedure
Q4363	Amnio Burgeon Membrane / Hydromembrane (per sq cm)	Add-on; listed in addition to primary procedure
Q4364	Amnio Burgeon Xplus (per sq cm)	Add-on; listed in addition to primary procedure
Q4365	Amnio Burgeon Dual-Layer (per sq cm)	Add-on; listed in addition to primary procedure
Q4366	Dual-Layer Amnio Burgeon X-Membrane (per sq cm)	Add-on; listed in addition to primary procedure
Q4367	AmnioCore SL (per sq cm)	Add-on; listed in addition to primary procedure
Q4368	AmchoThick (per sq cm)	Add-on; listed in addition to primary procedure
Q4369	AmnioPlast 3 (per sq cm)	Add-on; listed in addition to primary procedure
Q4370	AeroGuard (per sq cm)	Add-on; listed in addition to primary procedure
Q4371	NeoGuard (per sq cm)	Add-on; listed in addition to primary procedure
Q4372	AmchoPlast EXCEL (per sq cm)	Add-on; listed in addition to primary procedure
Q4373	Membrane Wrap-Lite (per sq cm)	Add-on; listed in addition to primary procedure
Q4375	duoGRAFT AC (per sq cm)	Add-on; listed in addition to primary procedure
Q4376	duoGRAFT AA (per sq cm)	Add-on; listed in addition to primary procedure
Q4377	triGRAFT FT (per sq cm)	Add-on; listed in addition to primary procedure
Q4378	Renew FT Matrix (per sq cm)	Add-on; listed in addition to primary procedure
Q4379	AmnioDefend FT Matrix (per sq cm)	Add-on; listed in addition to primary procedure
Q4380	AdvoGraft One (per sq cm)	Add-on; listed in addition to primary procedure
Q4381	Matrix HD Allograft Dermis (per sq cm) Sheet	
Q4382	AdvoGraft Dual (per sq cm)	Add-on; listed in addition to primary procedure
Q4383	Axolotl Graft Ultra (per sq cm)	Add-on; listed in addition to primary procedure
Q4384	Axolotl DualGraft Ultra (per sq cm)	Add-on; listed in addition to primary procedure

Q4385	Apollo FT (per sq cm)	Add-on; listed in addition to primary procedure
Q4386	Acesso TrifACA	Add-on; listed in addition to primary procedure
Q4387	NeoThelium FT	Add-on; listed in addition to primary procedure
Q4388	NeoThelium 4L	Add-on; listed in addition to primary procedure
Q4389	NeoThelium 4L Plus	Add-on; listed in addition to primary procedure
Q4390	Ascendion	Add-on; listed in addition to primary procedure
Q4391	AmnioPlast Double	Add-on; listed in addition to primary procedure
Q4392	GRAFIX® Duo	Add-on; listed in addition to primary procedure
Q4393	SurGraft® AC	Add-on; listed in addition to primary procedure
Q4394	SurGraft® ACA	Add-on; listed in addition to primary procedure
Q4395	Acelagraft	Add-on; listed in addition to primary procedure
Q4396	Natalin	Add-on; listed in addition to primary procedure
Q4397	Summit AAA	Add-on; listed in addition to primary procedure
Q4398	Summit AC, (per sq cm)	Not separately payable
Q4399	Summit FX. (per sq cm)	Not separately payable
Q4400	Polygon3 Membrane, (per sq cm)	Not separately payable
Q4401	Absolv3 Membrane, (per sq cm)	Not separately payable
Q4402	Xwrap 2.0, (per sq cm)	Not separately payable
Q4403	Xwrap Dual Plus, (per sq cm)	Not separately payable
Q4404	Xwrap Hydro Plus, (per sq cm)	Not separately payable
Q4405	Xwrap Fenestra Plus, (per sq cm)	Not separately payable
Q4406	Xwrap Fenestra, (per sq cm)	Not separately payable
Q4407	Xwrap Tribus, (per sq cm)	Not separately payable
Q4408	Xwrap Hydro, (per sq cm)	Not separately payable
Q4409	AmnioMatrix F3X, (per sq cm)	Not separately payable
Q4410	AmchoMatrix DL, (per sq cm)	Not separately payable
Q4411	AmnioMatrix F4X, (per sq cm)	Not separately payable
Q4412	CHORIOFIX®	Add-on; listed in addition to primary procedure
Q4413	Cygnus Solo, (per sq cm)	(add-on, list separately in addition to primary procedure)
Q4414	SimpliChor, (per sq cm)	(add-on, list separately in addition to primary procedure)
Q4415	AlexiGuard SL-T, (per sq cm)	(add-on, list separately in addition to primary procedure)
Q4416	AlexiGuard TL-T, (per sq cm)	(add-on, list separately in addition to primary procedure)

Q4417	AlexiGuard DL-T, (per sq cm)	(add-on, list separately in addition to primary procedure)
Q4418	Biolab membrane wrap flow, per square centimeter	Not separately payable
Q4419	Biolab membrane wrap lite flow, per square centimeter	Not separately payable
Q4420	NuForm, (per sq cm)	Not separately payable
Q4421	Biolab membrane wrap solo, per square centimeter	Not separately payable
Q4422	A/c wrap, per square centimeter	Not separately payable
Q4423	Biolab tri-membrane wrap flow, per square centimeter	Not separately payable
Q4424	Revive ft, per square centimeter	Not separately payable
Q4425	Revive tl, per square centimeter	Not separately payable
Q4426	DermaBind TL + or DermaBind TL X, per sq cm	Not separately payable
Q4427	DermaBind DL N, DermaBind DL +, or DermaBind DL X, per sq cm	Not separately payable
Q4428	DermaBind SL N, DermaBind SL +, or DermaBind SL X, per sq cm	Not separately payable
Q4429	DermaBind CH N or DermaBind CH X, per sq cm	Not separately payable
Q4431	PMA skin substitute product, NOS	List in addition to primary procedure
Q4432	510(k) skin substitute product, NOS	List in addition to primary procedure
Q4433	361 HCT/P skin substitute product, NOS	List in addition to primary procedure
Q4435	Renati membrane, per square centimeter	Not separately payable
Q4436	Renati ac membrane, per square centimeter	Not separately payable
Q4437	Revival ac, per square centimeter	Not separately payable
Q4438	Pretect, per square centimeter	Not separately payable
Q4439	Instagraft, per square centimeter	Not separately payable
Q4440	Curamatrix, per square centimeter	Not separately payable

Collagen, Nerve, and Scaffold Products (HCPCS C-Codes) Not Separately Payable:

HCPCS Code	Product(s)	Billing / use note
C9352	Microporous collagen implantable tube (NeuraGen® Nerve Guide), Per centimeter length	Not separately payable
C9353	Microporous collagen implantable slit tube (NeuraWrap® Nerve Protector), Per centimeter length	Not separately payable
C9354	Acellular pericardial tissue matrix of nonhuman origin (Veritas®), Per square centimeter	Not separately payable
C9355	Collagen nerve cuff (NeuroMatrix®), Per 0.5 centimeter length	Not separately payable
C9356	Tendon porous matrix of cross-linked collagen and glycosaminoglycan (TenoGlide® Tendon Protector Sheet), Per square centimeter	Not separately payable
C9359	Porous purified collagen matrix bone void filler (Integra® Mozaik Osteoconductive Scaffold Putty; Integra® OS Osteoconductive Scaffold Putty), Per 0.5 cc	Not separately payable

C9361	Collagen matrix nerve wrap (NeuroMend® Collagen Nerve Wrap), Per 0.5-centimeter length	Not separately payable
C9362	Porous purified collagen matrix bone void filler (Integra® Mozaik Osteoconductive Scaffold Strip), Per 0.5 cc	Not separately payable
C9364	Porcine implant (Permacol®), per sq cm	Not separately payable

VII. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, devices, services and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service or procedure is medically necessary. For more information, refer to the Priority Health Provider Manual.

Individual case review may allow coverage for care or treatment that is investigational yet promising for the conditions described. Requests for individual consideration require prior plan approval. All determinations of coverage for experimental, investigational, or unproven treatment will be made by a Priority Health medical director or clinical pharmacist. The exclusion of coverage for experimental, investigational, or unproven treatment may be reviewed for exception if the condition is either a terminal illness, or a chronic, life threatening, severely disabling disease that is causing serious clinical deterioration.

VIII. APPLICATION TO PRODUCTS

Coverage is subject to the member's specific benefits. Group-specific policy will supersede this policy when applicable.

- **HMO/EPO**: This policy applies to insured HMO/EPO plans.
- **POS**: This policy applies to insured POS plans.
- **PPO**: This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- **ASO**: For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
- **INDIVIDUAL**: For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- **MEDICARE**: Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.
- **MEDICAID/HEALTHY MICHIGAN PLAN**: For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

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SUMMARY OF CHANGES

Deletions:

- Removed age limitation for RECELL® for burns to align with current FDA indications.

Additions:

- Updated background section with current literature for Grafix Prime® (venous leg ulcers), Foundations® DRS Solo, and Myriad Matrix®.

Changes:

- Reclassified Kerecis® from not medically necessary to medically necessary for diabetic foot ulcers when medical necessity criteria are met.
- Reclassified SkinTE® from "Not Separately Payable" to "Not Medically Necessary."

Clarifications:

- Clarified that coverage includes Grafix PL Core™ and Grafix Prime™ in addition to Grafix Core® and Grafix Prime®, as these products are billed under the same CPT code and differ primarily in processing and storage requirements.
- Updated policy language for clarity and consistency.

Past committee review dates: 12/2008, 08/2009, 08/2010, 08/2011, 08/2012, 04/2013, 05/2014, 05/2015, 05/2016, 05/2017, 05/2018, 05/2019, 05/2020, 05/2021, 05/2022, 05/2023, 05/2024, 05/2025,05/2026,08/2026

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