Skin and Soft Tissue Substitutes

LOB(s):	State(s):
☒ *Commercial* ☒ *Medicare*	☒ *Idaho* ☒ *Montana* ☒ *Oregon* ☒ *Washington* ☐ *Other:*
☒ *Medicaid*	☒ *Oregon*

Enterprise Policy

PacificSource is committed to assessing and applying current regulatory standards, widely-used treatment guidelines, and evidenced-based clinical literature when developing clinical criteria for coverage determination. Each policy contains a list of sources (references) that serves as the summary of evidence used in the development and adoption of the criteria. The evidence was considered to ensure the criteria provide clinical benefits that promote patient safety and/or access to appropriate care. Each clinical policy is reviewed, updated as needed, and readopted, at least annually, to reflect changes in regulation, new evidence, and advancements in healthcare.

Clinical Guidelines are written when necessary to provide guidance to providers and members in order to outline and clarify coverage criteria in accordance with the terms of the Member's policy. This Clinical Guideline only applies to PacificSource Health Plans PacificSource Community Health Plans, and PacificSource Community Solutions, in Idaho, Montana, Oregon, and Washington. Because of the changing nature of medicine, this list is subject to revision and update without notice. This document is designed for informational purposes only and is not an authorization or contract. Coverage determinations are made on a case-by-case basis and subject to the terms, conditions, limitations, and exclusions of the Member's policy. Member policies differ in benefits and to the extent a conflict exists between the Clinical Guideline and the Member's policy, the Member's policy language shall control. Clinical Guidelines do not constitute medical advice nor guarantee coverage.

Background

Skin and soft tissue substitutes are biologic, synthetic, or biosynthetic materials that may be used temporarily or permanently, eventually replacing damaged skin. Skin substitutes may be used to treat burns, chronic ulcers, or wounds. They may provide temporary coverage of wounds to facilitate healing, help reduce incidence of contracture or infection, either eliminate the need for grafting or as a bridge until the wound is ready for grafting.

The main skin layers treated with skin substitutes are the dermis and epidermis. The epidermis is the outer, thinner layer of skin consisting of layers of stratified squamous epithelium. The epidermis has minimal blood vessels and nerve endings. The dermis is a dense connective tissue layer which lies beneath the epidermis. It is comprised of collagenous fibers, blood vessels, lymph channels, nerves, sebaceous glands, sweat glands and hair follicles.

Wounds may be described as partial-thickness or full-thickness.

Partial thickness wounds have damage to the epidermis and a portion of the dermis.

Full-thickness wounds have damage that extends beyond both the dermis and the epidermis.

Skin and soft tissue substitutes may also be used for repair, reconstruction, and reinforce; tendons, cardiac applications, traumatic injuries, and other surgical procedures.

Special Notes:

- DuraSeal is considered integral to dural repair during spinal surgery and is not separately reimbursed.
- Tisseel is considered integral to the surgery, when used, and is not separately reimbursed.
- TissueMend is considered integral to the surgery, when used, and is not separately reimbursed for the repair or reinforcement of soft tissues repaired by sutures or suture anchors during tendon repair surgery, including reinforcement of the rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons.
- Cryolife BioGlue used in surgery is incidental and not separately reimbursable.

Criteria

Commercial

Prior authorization is required

I. Medical Necessity

A. PacificSource considers skin and soft tissue substitute products medically necessary for wound care when the following general criteria is met:

1. The skin substitute product must be used for one of the medically necessary indications for the specific product listed in **Section II** below:

2. **ALL** of the following criteria is met:

a. The member is 18 years of age or older

b. Attestation noting that the member is tobacco-free, has completed, or is currently enrolled in tobacco cessation program

c. Submission of wound characteristics and treatment plan

3. Additional criteria must also be met for the following conditions:

a. **Diabetic foot ulcer** at least 1 cm^2 in size and **ALL** of the following criteria is met:

- Hgb A1c of less than or equal to 8 or documentation of improving control
- Wound has increased in size or depth or has not changed in baseline size or depth and there is no indication that improvement is likely (e.g., granulation, epithelialization, progress towards closing) after at least six (6) weeks of standard wound care including debridement, standard dressings, compression, and off-loading
- Wound is without evidence of osteomyelitis or infection
- No tendon, muscle, capsule or bone exposure at wound site
- Documentation of adequate circulation in affected extremity by physical examination or imaging (e.g., palpable dorsalis pedis or posterior tibial artery pulse or an ankle brachial index [ABI] of greater than 0.7

b. **Venous Stasis Ulcers** are at least 1 cm^2 in size and **ALL** of the following criteria is met:

- Wound has increased in size or depth or has not changed in baseline size or depth and there is no indication that improvement is likely (e.g., granulation, epithelialization, progress towards closing) after at least six (6) weeks of standard wound care including debridement, standard dressings, compression, and off-loading
- Adequate circulation in affected extremity by physical examination or imaging (e.g., palpable dorsalis pedis or posterior tibial artery pulse or an ankle brachial index [ABI] greater than or equal 0.7)

c. **Partial- or full-thickness thermal burn** wounds when **ALL** of the following criteria is met:

- Severe burns wounds where patients may not have skin to use for autografts or they are too ill to have more wound sites created
- No evidence of infection at burn site
- Excision of the burn wound is complete (e.g., nonviable tissue is removed) and homeostasis is achieved

II. PacificSource considers the following skin and soft tissue substitute products to be medically necessary when meeting the specific criteria for one of the approved indications below.

1. **AlloDerm**
   - **a.** Breast reconstruction surgeries
   - **b.** Partial glossectomy for cancer of the tongue
   - **c.** Surgical repair of complex abdominal wall wounds (e.g., due to infection, fascial defect, etc.)
   - **d.** Ear drum augmentation (tympanoplasty), repair of skull base defect, and temporal bone lining
   - **e.** Nasal septal perforation of less than 2 cm in greatest dimension that had failed conservative treatments (e.g., nasal irrigation, ointments, and silicone septal buttons)
   - **f.** Nasal reconstruction where there is no cartilage and the mucosal flaps are very thin to prevent development of perforation(s)
2. **Allogeneic Human (Cadaver-Derived) Skin Graft**
   - **a.** Traumatic skin wounds or burn wounds that are too large for autograft
3. **AlloPatch**
   - **a.** Partial and full-thickness neuropathic diabetic foot ulcers that are greater than 6 weeks in duration with no capsule, tendon or bone exposed
4. **AlloSkin**
   - **a.** Traumatic skin wounds and burn wounds that are too large for autograft. (Note: not AlloSkin AC or AlloSkin RT, which are different products)

5. **AmnioBand**
    a. Venous partial and full-thickness ulcers of the lower extremity that have failed standard wound therapy of at least 6 weeks duration
    b. Partial and full-thickness diabetic foot ulcers that are greater than 6 weeks in duration
6. **Apligraf (graftskin), a culture-derived human skin equivalent (HSE)**
    a. Full-thickness neuropathic diabetic foot ulcers that have failed conservative measures of greater than 6-weeks duration
    b. Non-infected, partial and full-thickness venous stasis ulcers that have failed conservative measures of greater than 6 weeks duration
7. **Artiss fibrin sealant**
    a. Severe burns
8. **Biobrane Biosynthetic Dressing**
    a. Temporary covering of a partial-thickness burn wound
9. **DermACELL**
    a. Breast reconstruction surgeries
    b. Partial and full-thickness neuropathic diabetic foot ulcers that are greater than 6 weeks in duration
    c. Oro-nasal fistula following cleft palate repair
10. **Dermagraft**
    a. Full-thickness diabetic foot ulcers greater than 6-week duration that extend through the dermis
    b. Dystrophic epidermolysis bullosa wounds
11. **Epicel cultured epidermal autograft**
    a. Partial or full thickness burns comprising a total body surface area of greater than or equal to 30%

Note: Epicel may be used in conjunction with split-thickness autografts, or alone in persons for whom split-thickness autografts may not be an option due to the severity and extent of their burns

12. **Epicord**
    a. Partial and full-thickness neuropathic diabetic foot ulcers that are greater than 6 weeks in duration
13. **EpiFix**
    a. Partial and full-thickness neuropathic diabetic foot ulcers that are greater than 6 weeks in duration
    b. Venous or diabetic partial and full-thickness ulcers have failed standard wound therapy of at least 6-weeks duration

14. Grafix (Grafix Core and Grafix Prime)

- **a.** Partial and full-thickness neuropathic diabetic foot ulcers that are greater than 6 weeks in duration with no capsule, tendon or bone exposed

15. Graftjacket Regenerative Tissue Matrix

- **a.** Full-thickness diabetic foot ulcers greater than 6-weeks
- **b.** Oro-nasal fistula following cleft palate repair

16. Integra Dermal Regeneration Template, Integra Bilayer Wound Matrix, and Integra Meshed Bilayer Wound Matrix (collagen-glycosaminoglycan copolymers)

- **a.** Severe burns wounds where patients may not have skin to use for autografts or they are too ill to have more wound sites created
- **b.** Partial and full-thickness neuropathic diabetic foot ulcers that are greater than 6 weeks in duration

17. Oasis Wound Matrix

- **a.** Partial and full-thickness neuropathic diabetic foot ulcers that are greater than 6 weeks in duration
- **b.** Venous partial and full-thickness ulcers of the lower extremity that have failed standard wound therapy of at least 6 weeks duration

18. Orcel (bilayered cellular matrix)

- **a.** Donor (autograft) site wounds in burn patients
- **b.** Wounds created from hand reconstruction surgery for dystrophic epidermolysis bullosa

19. Strattice Reconstructive Tissue Matrix

- **a.** Surgical repair of complex abdominal wall wounds (e.g., due to infection, fascial defect, etc.)

20. TheraSkin

- **a.** Partial and full-thickness neuropathic diabetic foot ulcers that are greater than 6 weeks in duration
- **b.** Traumatic skin wounds or burn wounds that are too large for an autograft

21. TransCyte (allogeneic human dermal fibroblasts)

- **a.** Temporary wound covering for surgically excised full-thickness and deep partial-thickness burn wounds before autograft placement
- **b.** Burn wounds that typically require debridement and that may be expected to heal without autografting

22. Cryolife BioGlue- (See note above in background section)

III. Continuation of Therapy

PacificSource considers continuation of therapy with skin and soft tissue substitute products medically necessary (unless otherwise specified) for wound care when **ALL** of the following treatment guidelines are met:

1. Skin or soft tissue substitute met original criteria for application for the specific product and shall not exceed 10 applications or treatments per 12-week period of care (Note: EpiFix is limited to one application per week for up to 12 weeks)
2. Progressive wound healing is demonstrated through measurable changes in wound characteristics and wound measurements taken no more than 14 days apart (e.g., granulation tissue, Inflammation, wound dimensions, photographic documentation)

IV. Experimental/ Investigational/Unproven

PacificSource considers the use of **ANY** of the above items experimental, investigational, or unproven for all **other** indications

PacificSource considers Autologous Cell Harvesting and RECELL Device to be to be experimental, investigational, or unproven for all indications. (CPT 15011–15018, HCPC C8002, C1832)

PacificSource considers **ALL OTHER** skin and soft tissue substitute products to be experimental, investigational, or unproven until they are approved for specific indication and added to this policy for coverage.

Medicaid

PacificSource Community Solutions follows the criteria hierarchy described in the Clinical Criteria Used in UM Decisions policy for coverage of Skin and Soft Tissue Substitutes and considers services medically necessary when:

- The condition and service(s) pair on a funded line of the HERC Prioritized List of Health Services, and
- Any relevant Guideline criteria are met, and

Service(s) are medically necessary and appropriate for the specific member. For ancillary services not appearing on the Prioritized List, PCS utilizes Ancillary Services Code Group 6060 and covers these services when:

- Medically necessary and appropriate to provide a funded service; or
- If providing the ancillary service would enable the member to retain or attain the capability for independence or self-care as described in Covered Services OAR 410-141-3820.

Coverage of ancillary services is subject to any applicable Ancillary Guidelines on the Prioritized List.

Additional coverage options for unfunded conditions and services are provided as described in Covered Services OAR 410-141-3820. Service(s) may be limited or excluded in accordance with OARs 410-141-3825 and 410-120-1200, except as otherwise provided in the Covered Services Rule.

PacificSource Community Solutions (PCS) follows EPSDT coverage requirements in OAR 410-151-0000 through 410-151-0003 for EPSDT beneficiaries. Coverage of Skin and Soft Tissue Substitutes is determined through case-by-case reviews for EPSDT Medical Necessity and EPSDT Medical Appropriateness defined in OAR 410-151-0001. Guideline Note 163 may be used to assist in informing a determination of medical necessity and medical appropriateness during the individual case review.

Medicare

PacificSource Medicare follows CMS guidelines and criteria. In the absence of CMS guidelines and criteria, PacificSource Medicare follows the criteria hierarchy described in the “Clinical Criteria Used in UM Decisions” policy for determination of coverage and medical necessity.

Effective January 1, 2026, PacificSource Medicare will follow LCD L39764 and LCA A59628 to determine medical necessity of skin substitutes/grafts/cellular and tissue-based products for the treatment of Diabetic foot ulcers and Venous leg ulcers.

Coding Information

The following list of codes are for informational purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Skin Substitute Grafts: The type of skin substitute graft(s) (Q code) should be requested in conjunction with the application 15271- 15278.

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 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 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 wound surface area

15276 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 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

15777 Implantation of biologic implant (e.g., acellular dermal matrix) for soft tissue reinforcement (e.g., breast, trunk) (List separately in addition to code for primary procedure)

46707 Repair of anorectal fistula with plug (e.g.: porcine small intestine submucosa)

HCPCS	Product

C9250	Human plasma fibrin sealant, vapor-heated, solvent-detergent (Artiss), 2ml
C9363	Skin substitute, Integra Meshed Bilayer Wound Matrix, per sq cm
Q4100	Skin substitute, not otherwise specified
Q4101	Apligraf, per sq cm
Q4102	Oasis Wound Matrix, per sq cm
Q4104	Integra Bilayer Matrix Wound
Q4105	Integra Dermal Regeneration Template (IDRT) or Omnigraft Dermal Regeneration Matrix
Q4106	Dermagraft
Q4107	Graftjacket, per sq cm
Q4115	AlloSkin, per sq cm
Q4116	Alloderm
Q4121	TheraSkin, per sq cm
Q4122	DermACELL, per square centimeter
Q4128	FlexHD, AllopatchHD, or Matrix HD, per sq cm
Q4130	Strattice TM, per sq cm
Q4132	Grafix core, per sq cm
Q4133	Grafix prime, per sq cm
Q4151	Amnioband or guardian, per sq cm
Q4168	Amnioband, 1 mg
Q4182	Transcyte, per square centimeter
Q4186	Epifix, per sq cm
Q4187	Epicord, per sq cm

Related Policies

Bone and Tendon Graft Substitutes

Clinical Criteria Used in UM Decisions

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT)

Gender Affirming Surgery and Related Procedures

New and Emerging Technologies – Coverage Status

Reduction Mammoplasty

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AlloDerm

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Appendix

Policy Number:

Effective: 10/1/2020 **Next review:** 1/1/2027

Policy type: Enterprise

Author(s):

Depts.: Health Services

Applicable regulation(s): OARs 410-120-1200, 410-141-3820, 410-141-3825, 410-151-0000 through 0003.

Commercial OPs: 10/2025

Government OPs: 10/2025