Skin and Soft Tissue Substitutes

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

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.

Skin consists of two main layers, the dermis, and the 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. Partial-thickness wounds may heal spontaneously if kept clean and protected; however, contractures formed by scar tissue may result.

Full-thickness wounds have damage that extends through both the dermis and the epidermis. Full-thickness wounds usually require excision followed by split-thickness grafts of varying thickness. Split-thickness grafts contain only small portions of dermis which is why skin substitutes may be elected for the treatment of larger surface area burns.

Deep partial thickness burns – These burns extend into the deeper dermis and are characteristically different from superficial partial-thickness burns. Deep burns damage hair follicles and glandular tissue. They are painful to pressure only, almost always blister (easily unroofed), are wet or waxy dry, and have variable mottled colorization from patchy cheesy white to red.

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

- 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.

Criteria

Commercial

Prior authorization is required

I. Skin Substitutes for Breast Reconstruction Surgery

PacificSource considers the following products to be medically necessary when used in an approved breast reconstruction surgery:

A. AlloDerm

B. DermACELL

II. Skin Substitutes for Full Thickness or Deep Partial Thickness Burns

PacificSource considers **Integra Bilayer Matrix Wound Dressing, Integra Dermal Regeneration Template, and Integra Matrix** to be medically necessary for the post excisional treatment of full-thickness or deep partial-thickness burns when **EITHER** of the following criteria is met:

A. There is a limited amount of the patient's own skin to use for autografts

B. The member is too ill for autografting

III. Skin Substitutes for Diabetic Plantar Surface Foot Ulcers

PacificSource considers the use of **Dermagraft** to be medically necessary for treatment of diabetic plantar surface foot ulcers when **ALL** of the following criteria is met:

A. The plantar surface ulcer has been present more than 3 weeks

B. The ulcer has failed to respond to standard therapy (e.g., moist-wound therapy with alginates, foams, hydrocolloids, or hydrogels)

C. There is no tendon, muscle, capsule, or bone exposed in ulcer

IV. Skin Substitutes for Venous Stasis Leg Ulcers and Diabetic Foot Ulcers:

PacificSource considers the use of **Apligraf** or the **sheet form of EpiFix** medically necessary for the treatment of venous stasis leg ulcers when **ALL** of the following criteria is met:

A. The venous stasis ulcer has been present for more than one month

B. The ulcer is not infected

C. The ulcer has failed to respond to standard treatment prior to Apligraf or EpiFix application (e.g., compression dressings, Unna boot)

PacificSource considers the use of **Apligraf** or the **sheet form of EpiFix** medically necessary for the treatment of diabetic foot ulcers when **ALL** of the following criteria is met:

A. The diabetic foot ulcer is full thickness

B. The ulcer has been present more than 3 weeks

C. The ulcer has failed to respond to standard therapy (e.g., moist-wound therapy with alginates, foams, hydrocolloids, or hydrogels)

D. There is no tendon, muscle, capsule, or bone exposed in the ulcer bed

Medicaid

PacificSource Community Solutions (PCS) follows OARs 410-141-3820 to 3830, 410-151-0000 to 0003, & and 410-120-1200 for coverage of Skin and Soft Tissue Substitutes and Guideline Note 163 of the Oregon Health Plan (OHP) Prioritized List of Health Services for coverage of Skin and Soft Tissue Substitutes.

PacificSource Community Solutions (PCS) considers implantation of acellular dermal matrix for soft tissue reinforcement (15777) to be medically necessary when performed as part of an approved breast reconstruction surgery. For all other indications, PCS follows Guideline Note 172 of the Oregon Health Plan (OHP) Prioritized List of Health Services which considers this service to have an increased risk of adverse events and unclear benefits versus other effective therapies. Additionally, for members under the age of 21, PacificSource Community Solutions (PCS) follows OARs 410-151-0000 through 0003 for coverage of services.

Medicare

PacificSource Medicare follows CMS guidelines and criteria. In the absence of CMS guidelines and criteria, PacificSource Medicare will follow internal policy for determination of coverage and medical necessity.

Experimental/ Investigational/Unproven

PacificSource considers the use of AlloDerm and DermACELL to be to be experimental, investigational, or unproven for all other indications.

PacificSource considers the use of Integra Bilayer Matrix Wound Dressing, Integra Dermal Regeneration Template, and Integra Matrix to be to be experimental, investigational, or unproven for all other indications.

PacificSource considers the use of Dermagraft to be to be experimental, investigational, or unproven for all other indications.

PacificSource considers the use of Apligraf and EpiFix to be to be experimental, investigational, or unproven for all other indications.

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

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
Q4104	Integra Bilayer Matrix Wound
Q4105	Integra Dermal Regeneration Template (IDRT)
Q4105	Integra Omnigraft Dermal Regeneration Matrix
Q4106	Dermagraft
Q4108	Integra Matrix Wound
Q4114	Integra Flowable Wound Matrix, injectable, 1 cc

Q4116	Alloderm
Q4122	DermACELL, per square centimeter

Related Policies

New and Emerging Technologies – Coverage Status

Bone and Tendon Graft Substitutes

Gender Affirming Surgery and Related Procedures

Reduction Mammoplasty

References

AlloDerm

Australia and New Zealand Horizon Scanning Network (ANZHSN). (February 2007). Alloderm for deep superficial and full-thickness burns. Horizon Scanning Prioritizing Summary.

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Alloderm / Strattice

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Apligraf

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Appendix

Policy Number:

Effective: 10/1/2020 **Next review:** 1/1/2026

Policy type: Enterprise

Author(s):

Depts.: Health Services

Applicable regulation(s): OAR 410-141-3820 through 3830, 410-151-0000 through 0003.

Commercial OPs: 12/2024

Government OPs: 01/2025