



## Skin and Soft Tissue Substitutes

<b>LOB(s):</b> <input checked="" type="checkbox"/> Commercial <input checked="" type="checkbox"/> Medicare <input checked="" type="checkbox"/> Medicaid	<b>State(s):</b> <input checked="" type="checkbox"/> Idaho <input checked="" type="checkbox"/> Montana <input checked="" type="checkbox"/> Oregon <input checked="" type="checkbox"/> Washington <input type="checkbox"/> Other: <input checked="" type="checkbox"/> Oregon <input type="checkbox"/> Washington
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## Enterprise Policy

*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** – 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.

## Criteria

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**Prior authorization is required for external applications of skin substitutes.**

### **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

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

### **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

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.

### **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

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

#### **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 conservative 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

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

#### **Medicaid**

PacificSource Community Solutions (PCS) follows 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) follows Guideline Note 172 of the Oregon Health Plan (OHP) Prioritized List of Health Services for coverage of the associated CPT code 15777 to have unclear benefits versus other effective therapies; increased risk of adverse events.

#### **Medicare**

PacificSource Medicare follows MCG Skin Substitute, Tissue-Engineered (Human Cellular), for Diabetic Foot Ulcer and Venous Ulcer ACG: A-0326 (AC).

#### **Experimental/ Investigational/Unproven:**

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PacificSource considers skin substitutes, which include but are not limited to the following, to be experimental, investigational, or unproven:

- Affinity
- AmnioExcel (BioDexcel)
- Amniofix.
- AmnioFlex Fluid Injection
- Amniotic Membrane Allograft (e.g., Axolotl Ambient, Axolotl Cryo, Axolotl Dual Graft, Axolotl Graft, Cygnus, Cygnus Matrix, AmnioWrap 2, Dermacyte)

- Apis
- ArthroFlex Decellularized Dermal Allograft
- Biobrane/Biobrane-L
- Biodesign® Surgisis® AFP™ Anal Fistula Plug, GORE BIO-A® Fistula Plug and SIS Fistula Plug
- BioDExCel/
- BioDFactor/BioDFence
- BioDfence Dryflex or BioD DryFlex
- BioDmatrix
- BioDOptix
- CLARIX Flo
- Clarix Regenerative Matrix
- Corplex P and Corplex
- Cortiva® (formerly AlloMax)
- DuraGen
- Dura-Guard (Dural Repair Patch)
- DuraMatrix
- Durapair
- Epicel
- Epicord
- E\_Z Derm (Porcine Xenograft (Mesh))
- FlexHD
- Flower AmnioFlow Injection
- Gammagraft
- Grafix Core
- Grafix Prime
- GraftJacket.
- GraftJacket Express
- Hyalomatrix
- InnovaMatrix AC
- InnovaMatrix FS
- Kerecis (Mirragen wound matrix3)
- Lyoplant

- MatriStem
- Mediskin
- MyOwn Skin Substitute
- NEOX Flo
- NuCel Bioactive Amniotic Suspension
- Oasis Burn Matrix and Oasis Wound Matrix
- OrCel
- Primatrix
- PuraPly or Puraply am
- Repriza
- Strattice Reconstructive Tissue Matrix
- Stravix
- Stravix PL
- Suprathel
- SurgiMend
- TheraSkin
- TissueMend
- Transcyte
- Viaflow and Viaflow C Flowable Placental Tissue Matrices
- Vendaje
- Xelma

## Coding Information

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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
A2001	InnovaMatrix® AC
A2010	Apis, per sq cm
A2012	Suprathel
A2013	InnovaMatrix® FS
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
Q4100	Skin substitute, not otherwise specific
Q4101	Apligraf
Q4102	Oasis Wound Matrix
Q4103	Oasis Burn Matrix
Q4104	Integra Bilayer Matrix Wound
Q4105	Integra Dermal Regeneration Template (IDRT)
Q4105	Integra Omnigraft Dermal Regeneration Matrix
Q4106	Dermagraft
Q4107	Graftjacket
Q4108	Integra Matrix Wound
Q4110	Primatrix, per sq cm

Q4111	GammaGraft, per sq cm
Q4113	GraftJacket Xpress
Q4114	Integra Flowable Wound Matrix, injectable, 1 cc
Q4115	Alloskin, per square centimeter
Q4116	Alloderm
Q4117	Hyalomatrix, per sq. cm
Q4118	MatriStem micro matrix, 1 mg
Q4121	TheraSkin, per square centimeter
Q4122	DermACELL, per square centimeter
Q4123	Alloskin RT, per sq. cm
Q4124	Oasis ultra tri layer matrix, per sq cm
Q4125	ArthroFlex, per sq cm
Q4126	Memoderm, dermaspan, tranzgraft or integuply, per square centimeter.
Q4127	Talymed®, per sq. cm
Q4128	FlexHD Allopatch HD, or Matrix HD, per sq cm
Q4130	Strattice/StrataGraft
Q4132	Grafix core, per square centimeter
Q4133	Grafix prime, per square centimeter
Q4134	Hmatrix, per square centimeter
Q4135	MediSkin
Q4136	Ez-derm, per square centimeter
Q4137	AmnioExcel or BioDexcel
Q4138	Biodfence dryflex,
Q4139	Amniomatrix or biodmatrix, injectable, 1 cc
Q4140	Biodfence
Q4141	Alloskin
Q4142	Xcm biologic tissue matrix,
Q4143	Repriza,
Q4145	Epifix, injectable, 1 mg
Q4146	TenSIX
Q4147	Architect, Architect PT, Architect Fx, extracellular matrix
Q4148	Neox Cord 1k, Neox Cord RT, Clarix Cord1k
Q4149	Excellagen, 0.1 cc
Q4150	Allowrap® ds or dry, per square centimeter
Q4151	Amnioband or guardian, per square centimeter
Q4152	Dermapure, per square centimeter
Q4153	Dermavest or Plurivest per square centimeter
Q4154	Biovance, per square centimeter
Q4155	Neox Flo or clarix Flo, 1 mg
Q4156	Neox 100 or Clarix, per square centimeter
Q4157	Revitalon, per square centimeter
Q4158	Kerecis Omega3
Q4159	Affinity, per square centimeter

Q4160	Nushield, per square centimeter
Q4161	Bio-connekt wound matrix, per square centimeter
Q4162	BioSkin Flow, WoundEx Flow
Q4163	BioSkin, WoundEx,
Q4164	Helicoll, per square centimeter
Q4165	Keramatrix or Kerasorb, per square centimeter
Q4166	Cytal, per square centimeter
Q4167	Truskin, per square centimeter
Q4168	Amnioband, 1 mg
Q4169	Artacent wound, per square centimeter
Q4170	Cygnus, per square centimeter
Q4171	Interfyl, 1 mg
Q4177	Flower AmnioFlo, 0.1 cc
Q4184	Cellesta or Cellesta Duo, per sq cm
Q4185	Cellesta Flowable Amnion (25 mg per cc); per 0.5 cc
Q4186	EpiFix, per sq cm
Q4187	Epicord, per sq cm
Q4188	AmnioArmor,
Q4189	Artacent AC, 1 mg
Q4190	Artacent AC, per sq cm
Q4191	Restorigin, per sq cm
Q4192	Restorigin, 1 cc
Q4193	Coll-e-Derm, per sq cm
Q4194	Novachor, per sq cm
Q4195	PuraPly, per sq cm
Q4196	PuraPly AM, per sq cm
Q4197	PuraPly XT, per sq cm
Q4198	Genesis Amniotic Membrane, per sq cm
Q4199	Cygnus Matrix
Q4200	SkinTE, per sq cm
Q4201	Matrion, per sq cm
Q4202	Keroxx (2.5 g/cc), 1 cc
Q4203	Derma-Gide, per sq cm
Q4204	XWRAP, per sq cm
Q4210	Axolotl Graft, Cygnus
Q4215	Axolotl Ambient, Axolotl Cryo, Axolotl Dual Graft
Q4221	AmnioWrap 2
Q4226	MyOwn Skin, per sq cm
Q4231	Corplex P, per cc
Q4232	Corplex, per square centimeter
Q4248	Dermacyte
Q4252	Vendaje, per sq cm



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HCPCS® codes, descriptions and materials are copyrighted by Centers for Medicare and Medicaid Services (CMS).

## Related Policies

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New and Emerging Technologies – Coverage Status

Bone and Tendon Graft Substitutes

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## Appendix

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**Policy Number:**

**Effective:** 10/1/2020

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**Policy type:** Enterprise

**Author(s):**

**Depts.:** Health Services

**Applicable regulation(s):**

**Commercial Ops:** 8/2023

**Government Ops:** 9/2023