Bioengineered Skin and Soft Tissue Substitutes

Summary

Injuries and damage to the skin or underlying soft tissue can occur through a number of different mechanisms. Common causes may include severe burns, accidents, surgical procedures, and ulcers (e.g., diabetic or venous stasis ulcers). In most cases, conservative treatment, such as optimizing blood flow, preventing or treating infections, keeping the tissue moist, and clearing any dead tissue is adequate. However, some wounds require more advanced techniques to promote wound healing in the presence of other comorbidities or due to the extent of the damage. In such cases, biologic or synthetic skin/tissue products may be grafted to the wound. These skin/tissue products can provide living cells and/or a scaffold to encourage wound closure, promote tissue regeneration, or provide structural support. They can be "donated" from another site on the member's body or bioengineered depending on the specific indication. Such procedures are often part of a multidisciplinary wound care treatment plan.

This guideline outlines the clinical criteria, indications, and exclusions for bioengineered skin and soft tissue substitutes. This document does *not* address cosmetic or reconstructive skin procedures, blood-derived products for chronic wound healing, hyperbaric oxygen therapy, negative pressure wound therapy, suction devices, infrared or electrical stimulation, or other types of wound management.

Certain skin and soft tissue substitutes may be considered as part of medically necessary breast reconstruction as per the Plan Clinical Guideline: Breast Procedures (CG036).

Definitions

"Allograft (Allogeneic transplant)" is the transfer of tissue from a genetically non-identical donor of the same species.

"Bioengineered Skin Substitutes," also referred to as "Human Skin Equivalents (HSE)," are engineered, "artificial skin" products or combinations of skin products and other materials. They can be acellular or cellular, as defined below, and can be contained within a framework called a matrix, which can be synthetic or natural.

"Cellular Dressing" refers to a bioengineered skin substitute containing at least one layer of live cells (e.g., fibroblasts, keratinocytes, epidermal cells, dermal cells, etc). The cells can be derived from the member's own body (i.e., autologous), a human donor (i.e., allogeneic), or from another species (i.e., xenographic). They can also be derived from different tissues other than skin, such as placenta, intestine, or synthetic/composite materials. Cellular dressings provide a framework for the member's own body to begin wound healing as well as other growth factors and cells to facilitate this process. Some examples are, but not limited to:

- AmnioBand/Guardian (Q4151) - an allograft placental matrix comprised of donated human amnion and chorion.
- Apligraf (Q4101) - a living, bilayered (epidermal and dermal) skin substitute derived from human keratinocytes and fibroblasts
- Dermagraft (Q4106) - a human fibroblast-derived dermal substitute
- Epicel (Q4100) - a cultured epidermal autograft
- Epifix (Q4186) - a multilayer biologic allograft derived from human amniotic membrane
- Grafix Core and Grafix PRIME (Q4132-Q4133) - extracellular matrix containing growth factors designed as allografts with endogenous mesenchymal stem cells; Grafix Core is derived from chorionic placental tissue and Grafix PRIME is derived from the amniotic membrane of placental tissue
- OrCel (Q4100) - a bilayered skin substitute consisting of epidermal keratinocytes and dermal fibroblasts in two layers of bovine collagen
- StrataGraft (Q4100) - is a bi-layered construct made from allogeneic (human) cultured keratinocytes and dermal fibroblasts in murine (rodent) collagen
- Theraskin (Q4121) - a biologically active epidermal and dermal skin substitute consisting of cryopreserved human skin allograft, fibroblasts, keratinocytes, and extracellular matrix
- TransCyte (Q4100) - a biosynthetic dressing consisting of allogeneic human dermal fibroblasts

"Acellular Dressing" refers to a bioengineered skin substitute containing matrix or scaffold materials (e.g., collagen, hyaluronic acid) but without any living cells. Acellular matrix provides a foundation for the member's cells to begin building upon to aid in wound healing. Some examples are, but not limited to:

- Allopatch (Q4128)- a hydrated allograft acellular dermal matrix uniquely derived from human tissue processed to remove epidermal and dermal cells
- Biobrane/Biobrane-L (Q4100) - a biosynthetic wound dressing constructed from a silicon film with nylon impregnated into the dressing
- Cortiva (Allomax/NeoForm) (Q4100), Alloderm (Q4116), FlexHD (Q4128)
- DermACELL (Q4122) - human acellular dermal matrix with ≥97% of donor DNA removed.
- Integra Bilayer Matrix Wound Dressing (Q4104), Integra Meshed Bilayer Wound Matrix (C9363 or Q4105), and Integra Dermal Regeneration Template (Q4105) or Integra Omnigraft Dermal Regeneration Matrix (Q4105) - cross-linked bovine tendon collagen and glycosaminoglycan and a semi-permeable polysiloxane (silicone) layers
- Graftjacket Regenerative Tissue Matrix (Q4107) - a cadaveric dermal and epidermal skin substitute
- Oasis Wound Matrix (Q4102) - an extracellular matrix material derived from the submucosal layer of porcine small intestine

"Grafting" is when a material (whether organic or synthetic) is transplanted to cover an injury or wound. There are several graft types:

- "Autologous" grafting (i.e., autograft) refers to a graft derived from the patient's own skin/tissue, and can be referred to as partial- or split-thickness depending on how it is harvested.
- "Allogeneic" grafting (i.e., allograft) refers to a graft derived from another human other than the member (e.g., cadaver).
- "Xenographic" grafting refers to a graft derived from non-human organisms (e.g., cows, pigs, etc.).
- "Synthetic" grafting refers to a graft that is derived from man-made materials.
- "Composite" grafting refers to a graft derived from various materials or organisms that can be interlinked to create a final product, such as a combination of human cells and synthetic matrix.

"Epidermolysis Bullosa (EB)" is a rare disease characterized by fragile skin and recurrent blisters resulting from minor irritation or trauma, typically presenting in early childhood. The resulting blisters may form large, painful wounds that resemble severe burns, and may require extensive grafting. Epidermolysis Bullosa can be categorized as Epidermolysis Bullosa Simplex (most common type with majority of mutations in the keratin genes KRT5 and KRT14), Junctional Epidermolysis Bullosa (majority of mutations in the laminin-332 genes), and Dystrophic Epidermolysis Bullosa (mutations in the COL7A1 gene).

Clinical Indications

General Criteria

In addition to the product-specific criteria outlined below, ALL of the following criteria must be met:

1. The procedure is performed by a licensed practitioner per state and federal law; *and*
2. Members using tobacco products have received cessation counseling and been informed of the impact of smoking on surgical outcomes prior to the procedure; *and*
3. Medical records document ALL of the following (unless the review of request is upon prior auth and wound characteristics are not available until after surgery, the surgery must meet medical necessity and the planned brand of tissue must be identified in request):
    a. Medical necessity for the skin/tissue substitute; *and*
    b. Wound characteristics, including the size, location, depth, underlying conditions; *and*
    c. Previous methods, response, and duration of conservative therapy; *and*
    d. Full treatment plan that accompanies the bioengineered skin/tissue substitute.
4. The duration and frequency of the treatment plan is ordered as follows:
    a. Treatment is limited to one initial application; *and*
    b. Additional applications may occur at a minimum of 1 week intervals up to a maximum of 12 weeks (specific number of treatments may vary) *and* only when there is evidence of wound healing (e.g., reduced ulcer size, increasing epithelialization).

Product-Specific Criteria

Alginate or other fiber gelling dressing (A6196 - A6199)

Alginate or other fiber gelling dressing (A6196 - A6199) is considered medically necessary when the following criteria is met:

1. For moderate to heavy exudating partial and full thickness wounds (e.g., pressure ulcers, venous ulcers, diabetic ulcers, donor and graft sites, traumatic and surgical wounds, and 1st and 2nd degree burns).

AmnioBand/Guardian (Q4151), AlloPatch (AllopatchHD) (Q4128)

AmnioBand/Guardian (Q4151) or AlloPatchHD (Q4128) are considered medically necessary when the following criteria are met:

2. For diabetic foot ulcers, when the following characteristics are present:
    a. The ulcer has no evidence of infection; *and*
    b. Full thickness (i.e., extends through the dermis) neuropathic diabetic foot ulcer; *and*
    c. The ulcer does not expose bone, tendon, muscle, or joint capsule; *and*
3. A minimum of 4 weeks of appropriate conventional therapy has failed or been ineffective, as defined by standard dressing changes, debridement as necessary, and off-loading of pressure/weight: *and*
4. The member has a current diagnosis of type 1 or type 2 diabetes, and the hemoglobin A1C is less than 12%; *and*
5. The member must have adequate circulation to the affected extremity, and may be defined by one or more of the following:

a. Transcutaneous oxygen test (TcPO2) ≥30 mmHg; *or*
b. Ankle-brachial index (ABI) between 0.7 and 1.2; *or*
c. Triphasic or biphasic doppler arterial waveforms at the ankle of the affected leg; *or*
d. Palpable foot pulses (e.g., dorsalis pedis or posterior tibial pulses).

Artiss (C9250)

Artiss (C9250) is considered medically necessary when the following criteria are met:

1. Members age 1 or older with severe burns undergoing autologous skin grafting; *and*
2. Body surface area of burn(s) is not more than 40%

Breast Reconstructive Surgery

Cortiva (AlloMax/NeoForm) (Q4100), Alloderm/Alloderm RTU (Q4116), DermACELL (Q4122), or FlexHD (Q4128) are considered medically necessary when the following criteria are met:

1. For use in members when in conjunction with a medically necessary breast reconstructive surgery*; and*
2. The member had completed discussion with the provider about the risks and benefits of implant-based breast reconstruction with or without these acellular dermal matrices. (Note: In general, the FDA has provided a safety communication that acellular dermal matrix products have not been approved/cleared for breast reconstruction. These matrices above can be ordered for members unless explicitly stated in a black box warning or contraindication).

Biobrane/Biobrane-L (Q4100)

Biobrane/Biobrane-L (Q4100) is considered medically necessary when ONE of the following criteria are met:

1. Biobrane: For the temporary covering of superficial, partial-thickness thermal injury; *or*
2. Biobrane-L: Covered when the criteria for Biobrane are met AND the dressing is used as an adjunct to a meshed autograft.

Dermagraft (Q4106)

Dermagraft (Q4106) is considered medically necessary when the following criteria are met:

1. Dermagraft is not being used in conjunction with Dakin's solution, chlorhexidine, polymyxin/nystatin, or any other cytotoxic solution due to breakdown and loss of effectiveness as demonstrated in clinical studies; *and*
2. Dermagraft is not ordered for members under the age of 18, pregnant women, members receiving immunosuppressive therapy (e.g., steroids, chemotherapy), or members with ulcers overlying Charcot's deformity; *and*
3. Treatment strictly adheres to FDA labeling guidelines, as documented by the 24-step procedure; *and*
4. For dystrophic epidermolysis bullosa wounds; *or*
5. For diabetic foot ulcers, when the following characteristics are present:
    a. Full thickness (i.e., extends through the dermis) neuropathic diabetic foot ulcer; *and*

b. The ulcer does not expose bone, tendon, muscle, or joint capsule; *and*
c. The ulcer has no evidence of infection or a sinus tract; *and*
d. The member must have adequate circulation to the affected extremity, and may be defined by one or more of the following:
    i. Transcutaneous oxygen test (TcPO2) ≥30 mmHg; *or*
    ii. Ankle-brachial index (ABI) between 0.7 and 1.2; *or*
    iii. Triphasic or biphasic doppler arterial waveforms at the ankle of the affected leg; *or*
    iv. Palpable foot pulses (e.g., dorsalis pedis or posterior tibial pulses).
e. A minimum of 6 weeks of appropriate conventional therapy has failed or been ineffective, as defined by standard dressing changes, debridement as necessary, and off-loading of pressure/weight; *and*
f. The member has a current diagnosis of type 1 or type 2 diabetes, and the hemoglobin A1C is less than 12%.

DermACELL (Q4122)

DermACELL (Q4122) is considered medically necessary when the following criteria are met:

1. For diabetic foot ulcers, when ALL the following characteristics are present:
    a. Full thickness (i.e., extends through the dermis) diabetic foot ulcer; *and*
    b. The ulcer does not expose bone, tendon, muscle, or joint capsule; *and*
    c. The ulcer has no evidence of infection or a sinus tract; *and*
    d. The member must have adequate circulation to the affected extremity, and may be defined by:
        i. Transcutaneous oxygen test (TcPO2) ≥30 mmHg; *or*
        ii. Ankle-brachial index (ABI) between 0.8 and 1.2; *or*
        iii. Triphasic or biphasic doppler arterial waveforms at the ankle of the affected leg; *or*
        iv. Palpable foot pulses (e.g., dorsalis pedis or posterior tibial pulses).
    e. A minimum of 4 weeks of appropriate conventional therapy has failed or been ineffective, as defined by standard dressing changes, debridement as necessary, and off-loading of pressure/weight; *and*
    f. The member has a current diagnosis of type 1 or type 2 diabetes, and the hemoglobin A1C is less than 12%.

Epicel (Q4100)

Epicel (Q4100) is considered medically necessary per FDA-approved Humanitarian Device Exemption (HDE) when ONE of the following criteria are met:

1. For deep-dermal or full-thickness burns reaching a total body surface area (BSA) ≥ 30%; *or*
2. For use in conjunction with split-thickness autografts or alone in members who are not candidates for autografting given the severity and/or extent of the thermal injury or the instability of the current overall condition.

Epifix (Q4186) Dehydrated Human Amnion/Chorion Membrane (dHACM)

Epifix (Q4186) is considered medically necessary when the following criteria are met:

1. The ulcer has no evidence of infection or malignancy; *and*
2. The member does not have an autoimmune connective tissue disease; *and*
3. The patient is not being treated with radiation, chemotherapy, or COX-2 inhibitors; *and*
4. For diabetic foot ulcers, when the following characteristics are present:
    a. Full thickness (e.g. extends through the dermis) neuropathic diabetic foot ulcer; *and*
    b. The ulcer does not expose bone, tendon, muscle, or joint capsule; *and*
    c. A minimum of 4 weeks, and a maximum of 52 weeks, of appropriate conventional therapy has failed or been ineffective, as defined by standard dressing changes, debridement as necessary, and off-loading of pressure/weight: *and*
    d. The member has a current diagnosis of type 1 or type 2 diabetes, and the hemoglobin A1C is less than 12%; *and*
    e. The member must have adequate circulation to the affected extremity, and may be defined by:
        i. Transcutaneous oxygen test (TcPO2) ≥30 mmHg; *or*
        ii. Ankle-brachial index (ABI) between 0.7 and 1.2; *or*
        iii. Triphasic or biphasic doppler arterial waveforms at the ankle of the affected leg; *or*
        iv. Palpable foot pulses (e.g., dorsalis pedis or posterior tibial pulses).
    f. The wound is between 1cm^2 and 25cm^2.
5. For venous insufficiency skin ulcers, when the following characteristics are present:
    a. Ulcer must be chronic, non-infected, partial- or full-thickness and due to venous insufficiency; *and*
    b. A minimum of *4 weeks* of appropriate conventional therapy has failed or been ineffective; *and*
    c. Conventional therapy must have included at least 14 days of standard therapeutic compression; *and*
    d. The member must have adequate circulation to the affected extremity, and may be defined by:
        i. Transcutaneous oxygen test (TcPO2) ≥30 mmHg; *or*
        ii. Ankle-brachial index (ABI) between 0.7 and 1.2; *or*
        iii. Triphasic or biphasic doppler arterial waveforms at the ankle of the affected leg; *or*
        iv. Palpable foot pulses (e.g., dorsalis pedis or posterior tibial pulses).
    e. The wound is between 2cm^2 and 20cm^2; *and*
    f. If the member has diabetes, the hemoglobin A1C is less than 10%; *and*
    g. The ulcer is not on the dorsum of the foot or at least 50% of the ulcer is below the malleolus.

Grafix Core and Grafix PRIME (Q4132-Q4133) or Graftjacket Regenerative Tissue Matrix (Q4107)
Grafix Core and Grafix PRIME (Q4132-Q4133) or Graftjacket Regenerative Tissue Matrix (Q4107) is considered medically necessary when the following criteria are met:

1. For Grafix Core and Grafix PRIME, the ulcer has no evidence of infection; *and*
2. For Graftjacket Regenerative Tissue Matrix, treatment is limited to ONE application; *and*
3. For diabetic foot ulcers, when the following characteristics are present:
    a. Full thickness (i.e., extends through the dermis) neuropathic diabetic foot ulcer; *and*
    b. The ulcer does not expose bone, tendon, muscle, or joint capsule; *and*
    c. A minimum of 4 weeks of appropriate conventional therapy has failed or been ineffective, as defined by standard dressing changes, debridement as necessary, and off-loading of pressure/weight: *and*
    d. The member has a current diagnosis of type 1 or type 2 diabetes, and the hemoglobin A1C is less than 12%; *and*
    e. The member must have adequate circulation to the affected extremity, and may be defined by:
        i. Transcutaneous oxygen test (TcPO2) ≥30 mmHg; *or*
        ii. Ankle-brachial index (ABI) between 0.7 and 1.2; *or*
        iii. Triphasic or biphasic doppler arterial waveforms at the ankle of the affected leg; *or*
        iv. Palpable foot pulses (e.g., dorsalis pedis or posterior tibial pulses).

Integra Bilayer Matrix Wound Dressing (Q4104), Integra Meshed Bilayer Wound Matrix (C9363 or Q4105), Integra Dermal Regeneration Template (Q4105) or Integra Omnigraft Dermal Regeneration Matrix (Q4105)
Integra Bilayer Matrix Wound Dressing (Q4104) or Integra Meshed Bilayer Wound Matrix (C9363 or Q4105), Integra Dermal Regeneration Template (Q4105) or Integra Omnigraft Dermal Regeneration Matrix (Q4105) are considered medically necessary when the following criteria are met:

1. Hemostasis must be obtained prior to application, as blood products may interfere with application; *and*
2. Integra Bilayer Matrix Wound Dressing or Integra Meshed Bilayer Wound Matrix:
    a. For deep partial and full-thickness thermal injury (i.e., second and third degree burns), when applied on the day of excision and when ONE of the following characteristics are present:
        i. There is inadequate remaining skin to perform autografting; *or*
        ii. The member is too ill for further autografting; *or*
    b. For chronic pressure ulcers, venous ulcers, trauma wounds, or surgical wounds that have been treated for a minimum of *6 weeks* with appropriate conventional therapy that has tried and failed or been ineffective, as defined by standard dressing changes, debridement as necessary, and off-loading of pressure/weight; *and*
        i. The ulcer does not expose bone, joint capsule, or tendon; *or*
    c. For diabetic ulcers when ALL of the following characteristics are present:

i. Partial and full thickness (e.g. extends through the dermis) diabetic ulcer; *and*
ii. The ulcer does not expose bone, tendon, muscle, or joint capsule; *and*
iii. The member must have adequate circulation to the affected extremity, as defined by:
    1. Transcutaneous oxygen test (TcPO2) ≥30 mmHg; *or*
    2. Ankle-brachial index (ABI) between 0.7 and 1.2; *or*
    3. Triphasic or biphasic doppler arterial waveforms at the ankle of the affected leg; *or*
    4. Palpable foot pulses (e.g., dorsalis pedis or posterior tibial pulses).
iv. A minimum of *6 weeks* of appropriate conventional therapy has failed or been ineffective, as defined by standard dressing changes, debridement as necessary, and off-loading of pressure/weight; *and*
v. The member has a current diagnosis of type 1 or type 2 diabetes, and the hemoglobin A1C is less than 12%.

3. Integra Dermal Regeneration Template or Integra Omnigraft Dermal Regeneration Matrix:
    a. For deep partial and full-thickness thermal injury (i.e., second and third degree burns), when applied on the day of excision and when ONE of the following characteristics are present:
        i. There is inadequate remaining skin to perform autografting; or
        ii. The member is too ill for further autografting; *or*
    b. For diabetic foot ulcers when ALL of the following characteristics are present:
        i. Full thickness (e.g. extends through the dermis) neuropathic diabetic foot ulcer; *and*
        ii. The ulcer does not expose bone, tendon, muscle, or joint capsule; *and*
        iii. The member must have adequate circulation to the affected extremity, as defined by:
            1. Transcutaneous oxygen test (TcPO2) ≥30 mmHg; *or*
            2. Ankle-brachial index (ABI) between 0.7 and 1.2; *or*
            3. Triphasic or biphasic doppler arterial waveforms at the ankle of the affected leg; *or*
            4. Palpable foot pulses (e.g., dorsalis pedis or posterior tibial pulses).
        iv. A minimum of *6 weeks* of appropriate conventional therapy has failed or been ineffective, as defined by standard dressing changes, debridement as necessary, and off-loading of pressure/weight; *and*
        v. The member has a current diagnosis of type 1 or type 2 diabetes, and the hemoglobin A1C is less than 12%.

OrCel (Q4100)

OrCel (Q4100) is considered medically necessary when ONE of the following criteria are met:

1. To close and heal wounds in children with dystrophic epidermolysis bullosa who are undergoing hand surgery, including donor sites; *or*
2. To be applied to donor sites in members who have been burned and required autografting.

StrataGraft (Q4100)

StrataGraft is considered medically necessary when the following criteria are met:

1. The member is an adult with deep partial-thickness burns; *and*
2. The member does not have a known allergy to any similar or specific implanted material in this product.

Apligraf (Q4101), Oasis Wound Matrix (Q4102), or Theraskin (Q4121)

Apligraf (Q4101), Oasis Wound Matrix (Q4102), or Theraskin (Q4121) is considered medically necessary when the following criteria are met:

1. Apligraf is not being used in conjunction with Dakin's solution, chlorhexidine, polymyxin/nystatin, or any other cytotoxic solution due to breakdown and loss of effectiveness as demonstrated in clinical studies; *and*
2. For diabetic foot ulcers, when all of the following characteristics are present:
    a. Full thickness (e.g., extends through the dermis) neuropathic diabetic foot ulcer; *and*
    b. The ulcer does not expose bone, tendon, muscle, or joint capsule; *and*
    c. The member must have adequate circulation to the affected extremity, and may be defined by:
        i. Transcutaneous oxygen test (TcPO2) ≥30 mmHg; *or*
        ii. Ankle-brachial index (ABI) between 0.7 and 1.2; *or*
        iii. Triphasic or biphasic doppler arterial waveforms at the ankle of the affected leg; *or*
        iv. Palpable foot pulses (e.g., dorsalis pedis or posterior tibial pulses).
    d. Appropriate conventional therapy has failed or been ineffective, as defined by standard dressing changes, debridement as necessary, and off-loading of pressure/weight
        i. For Apligraf, a minimum of 3 weeks; *or*
        ii. For Oasis Wound Matrix or Theraskin, a minimum of 4 weeks; *and*
    e. The member has a current diagnosis of type 1 or type 2 diabetes, and the hemoglobin A1C is less than 12%.
3. For venous insufficiency skin ulcers, when all of the following characteristics are present:
    a. Ulcer must be chronic, non-infected, partial- or full-thickness and due to venous insufficiency; *and*
    b. A minimum of *4 weeks* of appropriate conventional therapy has failed or been ineffective; *and*
    c. The member must have adequate circulation to the affected extremity, and may be defined by:

i. Transcutaneous oxygen test (TcPO2) ≥30 mmHg; *or*
ii. Ankle-brachial index (ABI) between 0.7 and 1.2; *or*
iii. Triphasic or biphasic doppler arterial waveforms at the ankle of the affected leg; *or*
iv. Palpable foot pulses (e.g., dorsalis pedis or posterior tibial pulses).

d. Conventional therapy must have included standard therapeutic compression.

TransCyte (Q4182)

TransCyte (Q4182) is considered medically necessary when ONE of the following criteria are met:

1. For deep partial- and full-thickness thermal injury (i.e., second and third degree burns) after surgical excision has been performed, in members who need temporary wound covering prior to autografting; *or*
2. For mid-dermal burns or those of an indeterminate depth that are expected to heal without autografting.

Experimental or Investigational / Not Medically Necessary

Wound applications beyond 12 weeks of therapy are not considered medically necessary. Retreatment of a successfully treated, healed ulcer is generally not medically necessary.

Intra-abdominal and pelvic adhesion prevention (including gynecologic adhesion prevention) with biologic or bioengineered materials is considered experimental or investigational (some examples are, but not limited to: amniotic, placental, stem cell) have not been shown scientifically to be of clinical significance. This does not apply to hyaluronic acid or cellulose derived adhesion barrier films, gels, or liquids.

3D bioprinted skin substitutes are considered experimental or investigational, as there is insufficient scientific evidence to evaluate its clinical safety and efficacy.

Skin/tissue substitutes or wound care treatments ordered for any indication not listed in the clinical indications or general criteria are considered investigational and/or experimental. The following skin/tissue substitutes or other wound care treatments are considered investigational and/or experimental (not all inclusive):

- Affinity™
- AlloMend™
- Alloskin™
- Alloskin™ AC
- AlloSkin™ RT
- AlloWrap®
- AlloWrap™ Dry
- AlloWrap™ DS
- Alphaplex™ with MariGen Omega3™
- AmnioArmor®
- AmnioCare®
- AmnioCore, AmnioCore Pro, AmnioCore Pro+
- AmnioClear®
- AmnioExcel®, BioDExcel™ (trade

name for AmnioExcel), AmnioExcel Plus
- AmnioFix®
- AmnioGraft® for any indication other than ocular surgery
- Amniomatrix® or BioDMatrix™
- Amnio-Maxx™
- AmnioMTM™
- AmnioShield®
- Amnio wound
- Aongen™ Collagen Matrix
- Architect® Stabilized Collage Matrix (ECM), Architect PX, or Architect FX
- Artacent® wound, Artacent AC, Artacent AC powder
- Artacent AC Cord
- Artacent Connect®
- Artacent Flex®
- Artacent Trident
- Artacent Velos
- Artacent Vericlen
- Artelon® (CMC and TMC)
- ArthroFLEX™ (FlexGraft®)
- Atlas Wound Matrix
- Avance® Nerve Graft
- Avaulta Plus™
- AxoGuard® nerve connector
- Axolotl Graft or Axolotl DualGraft
- AxoGuard nerve protector®
- Belladerm®
- Bio-ConneKt®
- BioDDryFlex® Amniotic Tissue Membrane
- BioDfactor®
- BioDfence®
- BioDOptix™
- BioFiber™
- BioVance® Amniotic Membrane Allograft
- Biovance Tri-layer, Biovance 3L
- CellerateRX®
- Cellesta® Cord
- Cellesta® or Cellesta® Duo
- Cellesta® Flowable Amnion
- CG CryoDerm™ or CGDerm™
- CLARIX® 100 Quick-Peel Wound Matrix
- CLARIX® Cord 1k
- CLARIX™ FLO
- CollaFix™
- CollaGUARD®
- Collamend™
- CollaSorb™
- CollaWound™
- Coll-e-Derm RT™
- Collexa®
- Conexa™
- CorMatrix®
- CorPatch® Epicardial Repair
- C-QUR™
- CRXa™
- CryoSkin®
- Cuffpatch™
- Cymetra®
- Cygnus® Dual
- Cygnus® Matrix
- Cygnus Max or Cygnus Max XL
- Cygnus® or Cygnus® Solo
- Cytal® (formerly Matristem) Wound Matrix, Cytal® Burn Matrix
- DeNovo® NT Graft
- Dermadapt™ Wound Dressing
- Derma-Gide™
- DermaPure™
- DermaSpan™
- Dermavest™
- Dermavest 2™
- Duraform™
- Duragen™ Plus
- Duragen® XS
- DuraMatrix™
- Durepair® Regeneration Matrix
- Endobon® Xenograft Granules
- Endoform™
- ENDURAgen™
- EpiBurn®
- EpiCord®
- EpiDex®
- EpiFix™, particulate or injectable form
- Excellagen®
- E-Z Derm™
- FloGraft™
- FlowerAmnioFlo™ or FlowerFlo™
- FlowerAmnioPatch™ or FlowerPatch™

- FlowerDerm™
- Fortiva™Porcine Dermis
- GalaFLEX™ Scaffold, GalaFLEX LITE™ Scaffold, GalaFLEX 3D™ Scaffold, GalaFLEX 3DR™ Scaffold
- Gammagraft™
- Genesis Amniotic Membrane
- GORE BIO-A® Fistula Plug
- Graftjacket™ Xpress injectable
- GraftRope™
- Hyaluronic acid Absorbent Wound Dressing
- Helicoll™
- hMatrix®
- Hyalomatrix®
- Inforce®
- InnovaMatrix AC or InnovaMatrix FS (Triad Life Sciences Inc.)
- Integra™ Matrix Wound Dressing
- Integra Flowable Wound Matrix™
- InteguPly™ (formerly known as TranzGraft)
- Jaloskin®
- Kerecis MariGen®, Kerecis Shield® Adhesive (formerly MariGen Omega3)
- Keroxx™
- LiquidGen™
- Matriderm®
- Matrion™
- MicroMatrix by Integra LifeSciences (formerly known MatriStem®)
- Gentrix Surgical Matrix (formerly known MatriStem®)
- Matrix HD™
- Medeor™
- MediHoney®
- Mediskin®
- Memoderm™
- Menaflex™ Collagen Meniscus Implant
- Meso BioMatrix™
- Microlyte Matrix (Imbed Biosciences)
- Nanofactor™ Flow
- Nanofactor™ Membrane
- NeoPatch™
- NEOX® 100 Quick-Peel Wound Matrix
- NEOX® 1k Wound Matrix
- NEOX®FLO
- Neuragen®
- NeuraWrap™
- Neuroflex™
- NeuroMatrix™
- NeuroMend™
- Novachor™
- NovoSorb® BTM, NovoSorb SynPath
- NuCel®
- NuShield®
- OrthADAPT™
- OsseoGuard®
- Ovation®
- OviTex, Reinforced Tissue Matrix (TELA Bio mesh)
- PalinGen Flow™
- PalinGen Hydromembrane
- PalinGen Membrane
- PalinGen XPlus Hydromembrane
- PalinGen XPlus Membrane
- Pelvicol®
- Pelvisoft®
- Peri-Guard® Repair Patch
- Peri-Strips Dry®
- Permacol™
- Phasix Mesh™
- Phasix™ ST Mesh, Phasix™ Plug and Patch
- Preclude® Pericardial Membrane
- Preclude® Vessel Guard
- Primatrix™ (formerly known as DressSkin)
- Procenta®
- PTFE felt
- Puracol®
- Puraply™
- PureSkin™ or PureSkin XL
- Puros® Dermis
- PX50® and PX50® Plus
- Repliform®
- Repriza™

- Restore® Orthobiologic Soft Tissue Implant
- Restorigin Amnion Patch, Restorigin Amniotic Fluid Therapy™
- Restrata®
- Restrata® MiniMatrix™
- Revita
- Revitalon™
- Seamguard®
- SERI® Surgical Scaffold
- Signature APatch
- SIS Wound Dressing II
- SJM™ Pericardial Patch
- SkinTE™
- SportMatrix
- SportMesh™
- SS Matrix™
- Sterishield II Amnion Patch
- Stimulen™ Collagen
- Strattice™
- Stravix® / StravixPL
- Suprathel®
- SurgiGRAFT™, SurgiGRAFT nano, SurgiGRAFT-Dual
- SurgiMend®
- Surgisis® (including Surgisis® AFP™ Anal Fistula Plug, Surgisis® Gold™ Hernia Repair Grafts, and Surgisis®Biodesign ™)
- Symphony (Aroa Biosurgery)
- Talymed ™
- TenoGlide™
- TenSIX™
- TEXAGEN™ Amniotic Membrane Allograft
- TheraForm™ Standard/Sheet
- TheraGenesis (Bioventus LLC)
- TissueMend®
- Tornier® BioFiber Absorbable Biological Scaffold
- Tutomesh™ Fenestrated Bovine Pericardium
- Tutopatch™ Bovine Pericardium
- Unite™
- Vascu-Guard®
- Veritas® Collagen Matrix
- VIM Amniotic Membrane (Cook Biotech)
- WoundEx® Flow
- WoundEx® Membrane
- XCelliStem Wound Powder (Stemsys)
- XCM Biologic™
- Xelma®
- XenMatrix™ Surgical Graft
- XenoSure® Biologic
- X-Repair
- XWRAP® (Hydro, DRY, and ECM)

Applicable Billing Codes (CPT/HCPCS/ICD-10 Codes)

Table 1	
CPT/HCPCS Codes considered medically necessary if criteria are met:	
Code	*Description*
15002-15003	Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, trunk, arms, legs; first 100 sq cm or 1% of body area of infants and children. Or each additional 100 sq cm.

15004-15005	Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet and/or multiple digits; first 100 sq cm or 1% of body area of infants and children. Or each additional 100 sq cm.
15100-15101	Split-thickness autograft, trunk, arms, legs; first 100 sq cm or less, or 1% of body area of infants and children (except 15050). Or each additional 100 sq cm.
15120-15121	Split-thickness autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1% of body area of infants and children (except 15050). Or each additional 100 sq cm.
15220-15221	Full thickness graft, free, including direct closure of donor site, scalp, arms, and/or legs; 20 sq cm or less. Or each additional 20 sq cm.
15240-15241	Full thickness graft, free, including direct closure of donor site, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands, and/or feet; 20 sq cm or less. Or each additional 20 sq cm.
15260-15261	Full thickness graft, free, including direct closure of donor site, nose, ears, eyelids, and/or lips; 20 sq cm or less. Or each additional 20 sq cm.
15271-15278	Application of skin substitute
15760	Graft; composite (eg, full thickness of external ear or nasal ala), including primary closure, donor area
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)
A6196 - A6199	Alginate or other fiber gelling dressing, wound cover, sterile
C5271 - C5274	Application of low cost skin substitute graft to trunk, arms, legs
C5275 - C5278	Application of low cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits
C9250	Human plasma fibrin sealant, vapor-heated, solvent-detergent (Artiss), 2ml
C9363	Skin substitute, Integra Meshed Bilayer Wound Matrix, per square centimeter
Q4100	Skin substitute, not otherwise specified ● Due to multiple products represented by this CPT/HCPCS code, specific indications are provided: ● When this code is billed for Orcel®, Biobrane Biosynthetic Dressing®, Epicel®, Cortiva® (AlloMax/NeoForm), or Stratagraft, it is considered medically necessary

Q4101	Apligraf, per sq cm
Q4102	Oasis Wound Matrix, per sq cm
Q4104	Integra Bilayer Matrix Wound Dressing (BMWD), per sq sm
Q4105	Integra Dermal Regeneration Template (DRT), per sq cm
Q4106	Dermagraft, per sq cm
Q4107	Graftjacket, per sq cm
Q4116	Alloderm, per square centimeter
Q4121	TheraSkin, per sq cm
Q4122	DermACELL, DermACELL AWM or DermACELL AWM Porous, per sq cm
Q4128	FlexHD,Allopatch HD, per sq cm
Q4132	Grafix core, per sq cm
Q4133	Grafix PRIME, GrafixPL PRIME, Stravix and StravixPL, per sq cm • Due to multiple products represented by this CPT/HCPCS code, specific indications are provided: • When this code is billed for Grafix PRIME or GrafixPL PRIME, it is considered medically necessary.
Q4151	Amnioband or guardian, per sq cm
Q4182	Transcyte, per square centimeter
Q4186	Epifix, per square centimeter

Table 2	
CPT/HCPCS codes considered experimental, investigational	
Code	*Description*
A2001	InnovaMatrix AC, per sq cm
A2004	XCelliStem, 1 mg
A2005	Microlyte Matrix, per sq cm
A2006	NovoSorb SynPath dermal matrix, per sq cm
A2007	Restrata, per sq cm
A2008	TheraGenesis, per sq cm

A2009	Symphony, per sq cm
A2012	SUPRATHEL, per sq cm
A2013	Innovamatrix FS, per sq cm
A2019	Kerecis Omega3 MariGen Shield, per sq cm
A2026	Restrata MiniMatrix, 5 mg
A2027	Matriderm, per square centimeter
A2028	Micromatrix flex, per mg
C9352	Microporous collagen implantable tube (NeuraGen Nerve Guide), per cm length
C9353	Microporous collagen implantable slit tube (NeuraWrap Nerve Protector), per cm length
C9354	Acellular pericardial tissue matrix of nonhuman origin (Veritas), per sq cm
C9355	Collagen nerve cuff (NeuroMatrix), per 0.5 cm length
C9356	Tendon, porous matrix of cross-linked collagen and glycosaminoglycan matrix (Tenoglide Tendon Protector Sheet), per square centimeter
C9358	Dermal substitute, native, non-denatured collagen (SurgiMend Collagen Matrix), per 0.5 square centimeters
C9360	Dermal substitute, native, non-denatured collagen, neonatal bovine origin (SurgiMend Collagen Matrix), per 0.5 square centimeters
C9361	Collagen matrix nerve wrap (NeuroMend Collagen Nerve Wrap), per 0.5 cm length
C9364	Porcine implant, Permacol, per square centimeter
G0428	Collagen meniscus implant procedure for filling meniscal defects (e.g., CMI, collagen scaffold, Menaflex)
Q4100	Skin substitute, not otherwise specified *(use assigned code for covered product)*
Q4103	Oasis Burn Matrix, per sq cm
Q4108	Integra Matrix Wound Dressing
Q4110	PriMatrix, per sq cm
Q4111	GammaGraft, per sq cm
Q4112	Cymetra, injectable, 1 cc
Q4113	GRAFTJACKET XPRESS, injectable, 1cc
Q4114	Integra Flowable Wound Matrix, injectable, 1 cc
Q4115	AlloSkin, per square centimeter

Q4117	HYALOMATRIX, per sq cm
Q4118	MatriStem micromatrix, 1 mg
Q4123	AlloSkin RT, per square centimeter
Q4124	OASIS ultra tri-layer wound matrix, per sq cm
Q4125	Arthroflex, per sq cm
Q4126	MemoDerm, DermaSpan, TranZgraft or IntéguPly, per square centimeter
Q4127	Talymed, per sq cm
Q4130	Strattice, per sq cm
Q4133	Grafix PRIME, GrafixPL PRIME, Stravix and StravixPL, per sq cm ● Due to multiple products represented by this CPT/HCPCS code, specific exclusions are indicated: ● When this code is billed for Stravix and StravixPL, it is considered experimental or investigational.
Q4134	hMatrix, per sq cm
Q4135	Mediskin, per sq cm
Q4136	E-Z Derm, per sq cm
Q4137	AmnioExcel, AmnioExcel Plus or BioDExcel, per sq cm
Q4138	Biodfence dryflex, per sq cm
Q4139	Amniomatrix or bioDMatrix, injectable, 1 cc
Q4140	Biodfence, per sq cm
Q4141	AlloSkin AC, per square centimeter
Q4142	XCM biologic tissue matrix, per sq cm
Q4143	Repriza, per sq cm
Q4145	Epifix, injectable, 1 mg
Q4146	TENSIX, per sq cm
Q4147	Architect, architect PX, or architect FX, extracellular matrix, per sq cm
Q4148	Neox Cord 1K, Neox Cord RT, or Clarix Cord 1K, per sq cm
Q4149	Excellagen, 0.1 cc
Q4150	Allowrap DS or dry, per sq cm
Q4152	Dermapure, per sq cm
Q4153	Dermavest and Plurivest, per sq cm

Q4154	Biovance, per sq cm
Q4155	Neoxflo or clarixflo 1 mg
Q4156	Neox 100, per sq cm
Q4157	Revitalon, per sq cm
Q4158	Kerecis Omega3, per sq cm
Q4159	Affinity, per sq cm
Q4160	Nushield, per square centimeter
Q4161	Bio-connekt wound matrix, per square centimeter
Q4162	WoundEx Flow, BioSkin Flow, 0.5 cc
Q4163	WoundEx, BioSkin, per sq cm
Q4164	Helicoll, per square centimeter
Q4165	Keramatrix, 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
Q4173	Palingen or Palingen XPlus, per square centimeter
Q4174	Palingen or Promatrix, 0.36 mg per 0.25 cc
Q4175	Miroderm, per square centimeter
Q4176	NeoPatch, per sq cm
Q4177	FlowerAmnioFlo, 0.1 cc
Q4178	Floweramniopatch, per square centimeter
Q4179	FlowerDerm, per sq cm
Q4180	Revita, per sq cm
Q4181	Amnio wound, per square centimeter
Q4183	Surgigraft, per sq cm
Q4184	Cellesta or Cellesta Duo, per sq cm
Q4185	Cellesta Flowable Amnion (25 mg per cc); per 0.5 cc

Q4187	Epicord, per sq cm
Q4188	AmnioArmor, per sq cm
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, per sq cm
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
Q4214	Cellesta Cord, per sq cm
Q4216	Artacent Cord, per sq cm
Q4219	SurgiGRAFT-Dual, per sq centimeter
Q4227	AmnioCore, per sq cm
Q4239	Amnio-Maxx or Amnio-Maxx Lite, per sq cm
Q4251	Vim, per sq cm
Q4260	Signature apatch, per square centimeter
Q4282	Cygnus Dual, per sq cm
Q4283	Biovance Tri-Layer or Biovance 3L, per sq cm
Q4298	AmniCore Pro, per sq cm
Q4299	AmniCore Pro+, per sq cm
Q4310	Procenta, per 100 mg

Q4331	Axolotl Graft, per sq cm
Q4332	Axolotl DualGraft, per sq cm
Q4336	Artacent c, per square centimeter
Q4337	Artacent trident, per square centimeter
Q4338	Artacent velos, per square centimeter
Q4339	Artacent vericlen, per square centimeter
Q4345	Matrix hd allograft dermis, per square centimeter
S9055	Procuren or other growth factor preparation to promote wound healing

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