



## Bioengineered Skin Substitutes

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P&P # C.5.25

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### A. Documentation Required

To facilitate the initial authorization process, the referral requests must include **ALL** the following elements in the documentation:

1. Physician detailed physical exam and medical history; **AND**
2. Physician order for the bioengineered skin substitute; **AND**
3. Wound measurements and photographs of ulcers to be treated by appropriate licensed healthcare professional; **AND**
4. Expected outcomes of improvement as a result of the treatment; **AND**
5. Previous conservative treatment(s)/conventional ulcer therapies that have been tried and the response to treatment, including wound bed preparation with debridement of necrotic tissue, moistening wound bed, controlling exudate and avoiding maceration; offloading of pressure, adequate nutritional status, assessment of adequacy of blood flow (ischemia), assessment for infection; compression therapy.

### B. Medical Necessity Criteria for Specific Bioengineered Skin Substitute Products:

**FDA approved bioengineered skin substitute products are considered** medically necessary when they meet the product specific criteria outlined below.

1. **AlloDerm** (Q4116) (LifeCell Corporation)  
AlloDerm Regenerative Tissue Matrix is considered medically necessary for post-mastectomy breast reconstruction surgery. AlloDerm is permanently sutured during the procedure. Reapplication is not medically necessary.
2. **Flex HD** (Q4128) (Mentor Corporation)  
Flex HD Acellular Hydrated Dermis is considered Medically Necessary for post-mastectomy breast reconstruction surgery. Flex HD is permanently sutured in during the reconstruction procedure. Reapplication is not medically necessary.
3. **Apligraf** (Q4101) (Organogenesis Inc.)  
Up to 5 applications of Apligraf per ulcer, without time restrictions between applications, are considered medically necessary in conjunction with conventional ulcer therapy for the treatment of **EITHER** of the following:
  - a. chronic, non-infected, partial and full-thickness venous stasis ulcers that have failed conventional ulcer therapy of greater than 1-month duration; **OR**
  - b. full-thickness neuropathic diabetic foot ulcers of at least 4 weeks duration, which have not adequately responded to conventional ulcer therapy and extend through the dermis but without tendon, muscle, capsule or bone exposure.
4. **Dermagraft** (Q4106) (Organogenesis Inc.)

Up to 8 applications of Dermagraft per ulcer over a twelve-week period, are considered medically necessary in conjunction with conventional ulcer therapy for the treatment of **EITHER** of the following:

- a. Full thickness diabetic foot ulcers that are greater than 6 weeks duration which extend through the dermis, but without tendon, muscle, joint capsule or bone exposure and without sinus tract; **OR**
- b. Wounds related to dystrophic epidermolysis bullosa.

**Dermagraft Continuation of Treatment:** An additional 8 applications of Dermagraft to the same ulcer after the initial twelve weeks of treatment is considered medically necessary if there is measurable signs of healing.

**Dermagraft treatment is limited to a maximum of 16 applications within 6 months.**

5. **Epicel** (Q4100) (Genzyme)

Epicel is considered medically necessary for adult and pediatric patients under the age of 18 years for the treatment of deep dermal or full thickness burns comprising a total body surface area of greater than or equal to 30%. Epicel is solely intended for autologous use.

6. **EpiFix** (Q4131) (MiMedx) (Not the Injectable product which is a drug and biological)

Up to 6 weekly applications of EpiFix per ulcer over a 6-week time period are considered medically necessary in conjunction with conventional ulcer therapy for the treatment of **EITHER** of the following.

- a. diabetic foot ulcers of greater than 4 weeks in duration that have failed conventional ulcer therapy; **OR**
- b. non-infected partial and full thickness venous stasis ulcers.

**EpiFix Continuation of Treatment:**

Up to 6 additional weekly EpiFix applications to the same ulcer are medically necessary after the initial 6 applications if there is evidence of greater than 50% healing of initial ulcer in the first 6 weeks.

**Note:** Medical Necessity of any request for bioengineered skin substitute applications to the same ulcer beyond the limits stated in the criteria above will be determined by the Medical Director if there is documentation that the wound continues to demonstrate measurable signs of healing.

7. **Grafix®** Core and Grafix Prime (Q4132 and Q4133) (Osiris technologies, Inc.)

Initial treatment of up to 4 weekly applications of Grafix is considered medically necessary in conjunction with conventional ulcer therapy for the treatment of **EITHER** of the following:

- a. diabetic foot ulcers of greater than 4 weeks in duration that have failed conventional ulcer therapy; **OR**
- b. non-infected partial and full thickness venous stasis ulcers.

**Grafix Core and Grafix Prime Continuation of Treatment:**

Up to 4 additional weekly Grafix applications to the same ulcer after the initial 4 weeks of treatment is considered medically necessary if there is measurable signs of healing. Requests for continuation of treatment beyond 8 total Grafix applications requires Medical Director approval.

**Note:** Requests for dual therapy with a bioengineered skin substitute in combination with NPWT must be reviewed by the Medical Director and may be considered medically necessary as a therapy of last resort in patients who have failed one or more advanced single therapy modalities and the patient's limb is threatened.

8. **TransCyte** (C9399) (Advanced Tissue Sciences Inc.)  
 TransCyte is considered medically necessary as a temporary wound covering for **EITHER** of the following:
- a. Surgically excised full-thickness and deep partial-thickness thermal burn wounds for patients who require a covering before autograft placement; **OR**
  - b. Mid-dermal to indeterminate depth burn wounds that typically require debridement and may be expected to heal without autografting.

**C. Indications Considered Experimental, Investigational or not Medically Necessary:**

*(Not an all- inclusive list)*

1. Patients that have not had an adequate trial of conventional ulcer therapy to include the following:
  - a. Pressure reduction or off-loading of the ulcer has not occurred;
  - b. Current treatment for infection in the targeted ulcer;
  - c. Evidence of inadequate arterial blood supply to the affected area (i.e. ankle-brachial index ABI <0.65 or impaired pedal perfusion/foot perfusion by toe pressures (<30mmHg) or transcutaneous oxygen measurement (TCO2) <30);
  - d. Inconsistent application of compression garments/dressings for venous ulcers;
  - e. Wound base has necrotic tissue or excessive exudate that would interfere with wound healing or has not been kept moist;
  - f. Poor nutritional status;
  - g. Uncontrolled diabetes with current HbA1c >12%.
2. Patient is not self-sufficient with follow-up care or does not have the required support system to participate in the follow-up care associated with skin substitutes.
3. Treatment for pregnant or lactating women has not been established.
4. Patients under current treatment with high doses of systemic corticosteroids, immunosuppressant drugs including biologic and nonbiologic disease modifying agents antirheumatic drugs, or antimetabolite chemotherapy has not been established.
5. Use of bioengineered skin substitutes named above in children under the age of 18 years  
**(Exception: Epicel which is approved for patients under 18 years)**
6. All other bioengineered skin substitutes not listed in this policy **AND** all other non-indicated uses for the skin substitute products listed above in Section B;
7. Use of the bioengineered skin substitutes named above in patients who are simultaneously undergoing hyperbaric oxygen therapy for the same diabetic lower extremity wound/ulcer, venous stasis ulcer or other condition as applicable

**HCPCS CODES:**

Q4131	Epifix® or epicord, per square centimeter
Q4101	Skin Substitute, Apligraf®, per square centimeter.
Q4106	Skin Substitute, Dermagraft®, per square centimeter
Q4132	Grafix® CORE, per square centimeter
Q4133	Grafix® PRIME, per square centimeter
Q4100	Skin substitute, not otherwise specified (Epicel)
Q4116	Alloderm®, per square centimeter
Q4128	Flex hd, allopatch hd, or matrix hd, per square centimeter

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