# Medical Necessity Guideline

| Medical Necessity Guideline (MNG) Title: Skin Substitutes (Epifix) | | |
|---|---|---|
| **MNG #: 044** | **☒SCO ☒One Care** | **Prior Authorization Needed? ☒Yes ☐No** |
| **Clinical: ☒** | **Operational: ☐** | **Informational: ☐** |
| **Medicare Benefit: ☒Yes ☐No** | **Approval Date:** 8/5/2020 | **Effective Date:** 12/18/2020 |
| **Last Revised Date:** 6/7/2020; 07/01/2021;9/13/2021; 10/14/2021 | **Next Annual Review Date:** 8/5/2021; 07/01/2022;9/13/2022; 10/14/2022 | **Retire Date:** |

**OVERVIEW:**
Skin substitutes are cellular and tissue-based products that may be derived from human tissue (autologous or allogeneic), non-human tissue (xenogeneic), synthetic materials, or a composite of these sources to replicate the functional and structural characteristics of human skin. They are becoming important adjuncts in the management of acute and *chronic wounds*, specifically for partial- and full-thickness skin loss in neuropathic *diabetic ulcers*, *chronic venous ulcers,* and *pressure injuries*.

Skin substitutes have demonstrated benefits (in reduced healing time, pain, and post-operative contractures) in these conditions, and situations where conservative treatment may appear insufficient to provide complete healing. To achieve these positive outcomes, skin substitutes donate growth factors and provide the scaffolding for deficit reduction, wound re-vascularization, cell proliferation, and epithelial growth. Though skin substitutes are not capable of replacing the patient's own skin, they can (1) cover skin deficits temporarily, (2) promote tissue healing, and (3) regenerate lost tissue, without the need for more extensive treatments. Consequently, skin substitutes have improved the appearance, functional abilities, and overall quality of life in these patients.

**DEFINITIONS:**
**Apligraf**: A permanent skin substitute that is produced from non-human tissue (specifically, bovine collagen) and cells derived from human tissue (specifically, human fibroblasts and keratinocytes). The composition of this cellular bi-layered human-skin equivalent allows it to provide wound protection and foster new epithelial growth. It is indicated for use with standard care for full-thickness neuropathic diabetic foot ulcers (of greater than three weeks duration) and partial- or full-thickness skin ulcers due to venous insufficiency (of greater than one-month duration).

**Chronic Wounds**: Wounds that do not respond to standard wound treatment following four (4) weeks of conservative therapy and optimization. These wounds fail to pass through the normal healing process in an orderly and timely manner. They tend to remain in the inflammatory phase.

**Complete Healing of Chronic Wounds or Healed Ulcers:** Wounds that are marked by re-epithelialization of the epidermis and repair of the dermis. This is evidenced by wounds that are ≤ 0.5 sq cm and a size reduction of ≥ 75%.

**Dermagraft**: A temporary skin substitute that is manufactured from human tissues (e.g. fibroblasts, extracellular matrix, and bioabsorbable scaffold). It is a biosynthetic dermal matrix with cells that can secrete growth factors,

collagen, and matrix proteins to create a three-dimensional human dermal substitute. It is indicated for use with standard care for the treatment of full-thickness diabetic foot ulcers (of greater than six weeks duration).

**Diabetic Foot Ulcer**: An ulceration in the foot of a patients with diabetes as a result of neuropathy, pressure, and/or ischemia.

**Epicel®**: An aseptically processed wound dressing that is manufactured from human (e.g. keratinocytes) and non-human (e.g. murine or mouse fibroblasts). It is indicated for use in adult and pediatric patients who have deep dermal or full thickness burns that comprise a total body surface area of ≥ 30%.

**Epifix**: A skin substitute that is dehydrated, minimally manipulated, and made of non-viable cellular human amniotic membrane. Epifix is composed of a single layer of epithelial cells, basement membrane, and avascular connective tissue matrix. It preserves and delivers extracellular matrix proteins, growth factors, cytokines and other specialty proteins found in the amniotic tissue to help regenerate soft tissue.

**Failure to Respond (in the context of wound care)**: Situation where despite the application of appropriate standard wound care measures, an ulcer or skin deficit has increased in size or depth, or has not changed in baseline size or depth, and there is no indication that improvement (in terms of granulation, epithelialization, or progression towards closing) is likely.

**Integra® (Bilayer matrix wound dressing, dermal regeneration template)**: A collagen-glycoasminoglycan copolymer or bi-layered membrane system that is made of non-human collagen tissue (purified bovine) that acts as the dermis and a layer of silicone rubber that acts as a temporary epidermis. The first collagen layer is used to combine with the wound to form a vascular neodermis. The silicone layer provides immediate wound coverage and helps to control moisture loss. Integra is indicated for use with standard care for the treatment of full-thickness or deep partial-thickness thermal injuries and full-thickness diabetic foot ulcers (of greater than six weeks duration).

**Measurable Signs of Healing**: The measurable signs of healing include diminishing wound size or depth, decreased amount of exudate, and reduction in necrotic tissue.

**Oasis™ Wound Matrix**: A biological extracellular matrix made from non-human tissue (porcine small intestinal submucosa) for dermal regeneration. This skin substitute product functions as a single-layer, extracellular matrix to provide a natural scaffold for tissue growth. It is intended for one-time use and is incorporated or absorbed into the wound environment. Oasis™ wound matrix is indicated for the management of partial- and full-thickness wounds: pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled, undermined wounds, surgical wounds, trauma wounds (second-degree burns), and draining wounds.

**Pressure injuries**: Pressure ulcers that result from local trauma to the skin and/or underlying tissues due to shearing, frictional forces, or unrelieved pressure.

**Standard of Care (in the context of wound care)**: Standard treatment of lower extremity ulcers or skin loss would include: Infection and edema control, mechanical offloading (for diabetic foot ulcers), mechanical compression or limb

elevation (for venous leg ulcers), debridement of necrotic or infected tissue, maintenance of moisture balance (to control exudate), and management of concomitant medical issues (e.g. blood glucose control and tobacco use cessation).

**TransCyte**: A temporary skin substitute that is made from human tissue (human fibroblasts). It acts as a biosynthetic dressing that is used as a temporary wound covering for surgically excised full-thickness or deep partial-thickness thermal burn wounds.

**Venous Stasis Ulcers**: Shallow open lesions caused by venous hypertension or insufficiency. They tend to weep serous fluid and are located on the lower leg near the ankles.

**DECISION GUIDELINES:**
**Clinical Coverage Criteria:**
Commonwealth Care Alliance may cover **Apligraf, Dermagraft, Epifix, Integra® (bilayer matrix wound dressing, dermal regeneration template),** and **Oasis™ (Wound Matrix)** for the treatment of chronic neuropathic diabetic foot ulcers, when all the following criteria are met:

- Documentation that supports the medical necessity for skin substitute application and the specific product for the diagnosis,
- Documented failure to respond to standard wound care with at least four (4) weeks of standard treatment,
- The member has been compliant with the standard wound treatment and recommendations,
- There is no evidence of underlying osteomyelitis, nidus of infection, and/or active Charcot disease,
- The ulcer is of partial- or full-thickness and does not involve the tendon, muscle, joint capsule, or exhibit exposed bone or sinus tract,
- The ulcer is clean and free of necrotic tissue or eschar,
- The skin deficit is at least one (1) square centimeter (cm) in size,
- There is evidence of adequate circulation/oxygenation to support tissue growth and wound healing by having a clean granular base, an Ankle-Brachial Index (ABI) of no less than 0.60 and toe pressure greater than 30 millimeters of mercury (mmHg), AND
- The member does not smoke, has ceased smoking, or have refrained from systemic tobacco intake for at least four (4) weeks during standard wound treatment

Commonwealth Care Alliance may cover **Apligraf**, **Epifix**, and **Oasis™ (Wound Matrix)**, for the treatment of chronic partial- or full-thickness venous stasis ulcers, when all the following criteria are met:

- Documentation that supports the medical necessity for skin substitute application and the specific product for the diagnosis,
- Documented presence of a venous stasis ulcer for at least three (3) months,
- Documented failure to respond to standard wound care with at least 30 days of standard treatment,
- The member has been compliant with the standard wound treatment and recommendations,
- There is no evidence of underlying osteomyelitis, nidus of infection, and/or active Charcot disease,
- The ulcer is of partial- or full-thickness and does not involve the tendon, muscle, joint capsule, or exhibit exposed bone or sinus tract,

- The ulcer is clean and free of necrotic tissue or eschar,
- The skin deficit is at least one (1) square centimeter (cm) in size,
- There is evidence of adequate circulation/oxygenation to support tissue growth and wound healing by having a clean granular base, an Ankle-Brachial Index (ABI) of no less than 0.60 and toe pressure greater than 30 millimeters of mercury (mmHg), AND
- The member does not smoke, has ceased smoking, or have refrained from systemic tobacco intake for at least four (4) weeks during standard wound treatment

**LIMITATIONS/EXCLUSIONS:**

Commonwealth Care Alliance will limit the following:

- All skin substitutes used for the episode of wound care must be in compliance with the U.S. Food and Drug Administration Guidelines for the specific product for a maximum of five (5) weekly applications or treatment. After such time it is recommended to resume routine wound care, and to identify risk factors and treat other reversible causes of the wound. If the wound does not present with measurable signs of healing thereafter, review from a medical director will be required to determine the medical necessity of further skin substitute therapy,
- Use of one (1) skin substitute product for the episode of the wound, unless there is consultation with an appropriate specialist, and documentation can be provided for the medical necessity of a different product,
- Treatment of any chronic skin wound or ulcer will be limited to 12 weeks per episode of care

Commonwealth Care Alliance will not cover, but not limited to, the following:

- Skin substitutes without the appropriate applicable documentation submitted by the treating provider,
    - Documentation required, at a minimum, include: Medical record documentation that supports the medical necessity for the need for skin substitute application and specific product; wound characteristics at baseline (size, location, stage, duration, presence of infection); current wound treatment plan (interventions and response to treatment); medication history; review of pertinent medical problems; conditions that have been treated and resolved (e.g. control of edema, infection, smoking cessation, etc.), planned wound treatment plan (skin replacement surgery, choice of skin substitute graft product)
- The simultaneous use of more than one (1) product for the episode of the wound,
- Repeat or alternative applications of skin substitute grafts when a previous full course of applications was unsuccessful,
- Retreatment or continued treatment of healed ulcers,
- The use of skin substitutes in members with inadequate control of underlying conditions or exacerbating factors,
    - This includes: Uncontrolled diabetes, exudate consistent with heavy bacterial contamination, active infection, active Charcot arthropathy of the ulcer extremity, vasculitis, or continued tobacco smoking despite medical team's attempt to affect smoking cessation.
- For ulcers with partial thickness loss and retention of epithelial appendages,
- Repeat use of surgical preparation services in conjunction with skin substitute application,
- Retreatment within one year of any given course of skin substitute for a chronic, non-infected lower extremity skin ulcer (e.g. diabetic neuropathic foot ulcer or venous stasis ulcer), AND

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Skin substitutes not specifically referenced in this MNG may be considered experimental and investigational therapies per *MNG 010 Experimental and Investigational Services*, and therefore not medically necessary for the treatment of chronic diabetic foot ulcers and venous stasis ulcers.

**AUTHORIZATION:**
The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not signify that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. This Medical Necessity Guideline is subject to all applicable Plan Policies and Guidelines, including requirements for prior authorization and other requirements in Provider's agreement with the Plan (including complying with Plan's Provider Manual specifications).

| HCPCS Code | Description |
|---|---|
| Q4101 | Apligraf, per square centimeter |
| Q4106 | Dermagraft, per square centimeter |
| Q4186 | Epifix, per square centimeter |
| Q4104 | Integra bilayer matrix wound dressing (BMWD), per square centimeter |
| Q4105 | Integra dermal regeneration template (DRT) or integra omnigraft dermal regeneration matrix, per square centimeter |
| Q4102 | Oasis wound matrix, per square centimeter |

**REGULATORY NOTES:**
Medical Necessity Guidelines are published to provide a better understanding of the basis upon which coverage decisions are made. CCA makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the servicearea who are medical experts in the appropriate field, review of FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions. If at any time a CMS Local or National Coverage Determination (LCD or NCD) is published that conflicts with the criteria set forth herein, the NCD or LCD criteria shall supersede these criteria.

**Disclaimer:**
This Medical Necessity Guideline is not a rigid rule. As with all of CCA's criteria, the fact that a member does not meet these criteria does not, in and of itself, indicate that no coverage can be issued for these services. Providers are advised,

however, that if they request services for any member who they know does not meet our criteria, the request should be accompanied by clear and convincing documentation of medical necessity. The preferred type of documentation is the letter of medical necessity, indicating that a request should be covered either because there is supporting science indicating medical necessity (supporting literature (full text preferred) should be attached to the request), or describing the member's unique clinical circumstances, and describing why this service or supply will be more effective and/or less costly than another service which would otherwise be covered. Note that both supporting scientific evidence and a description of the member's unique clinical circumstances will generally be required.

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**ATTACHMENTS:**

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| **EXHIBIT A:** | |
| **EXHIBIT B** | |

**REVISION LOG:**

| REVISION DATE | DESCRIPTION |
|---|---|
| 9/13/2021 | Added in Exclusions: Skin substitutes that are not mentioned in this MNG are experimental, investigational, and not medically necessary. |
| 6/7/2021 | Proposed a change to the title of the MNG from Dehydrated Human Amniotic Membrane MNG to *Skin Substitutes*. Expanded coverage of the MNG to include more skin substitutes: *Apligraf, Dermagraft, Epifix, Integra (Bilayer matrix wound dressing and dermal regeneration template), Oasis (Wound matrix)*. Added limitations of how many treatments per week, how many skin substitutes will be covered per episode of care, and the duration of treatment covered. Added exclusions of coverage to the MNG. |

# Medical Necessity Guideline

**APPROVALS:**

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|---|---|
| Douglas Hsu, MD, MPH | Vice President, Medical Policy and Utilization Review |
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|  | 8/5/2020 |
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