Medica Coverage Policy

**Policy Name:** Skin and Soft Tissue-Engineered Substitutes for Wound and Surgical Care  
**Effective Date:** 3/20/2019

### Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

### Coverage Policy

Postmastectomy breast reconstructive surgery is **COVERED** when using any of the following tissue-engineered skin substitutes:

- AlloDerm®
- AlloMax™
- AlloMend®
- Cortiva®
- DermACELL™
- DermaMatrix™
- FlexHD®
- Graftjacket®
- hMatrix®
- Neoform™

Treatment of (1) non-infected wounds, or (2) non-infected chronic ulcers (diabetic or venous insufficiency) of the lower-extremity, either of which have not adequately responded to conventional therapy, is **COVERED** when using any of the following tissue-engineered skin substitutes:

- Apligraf®
- Dermagraft®
- EpiFix®
- Integra®: Omnit graft Dermal Regeneration Matrix (also known as Omnitraft), Dermal Regeneration Template, Wound Matrix, and Bilayer Matrix Wound Dressing (excludes flowable wound matrix)
- Graftjacket® Regenerative Tissue Matrix
- Oasis® Wound Matrix
Treatment of deep dermal or full thickness burns (2nd or 3rd degree burns) is **COVERED** when using any of the following tissue-engineered skin substitutes:

- Epicel® (humanitarian device exemption [HDE])
- Integra® Dermal Regeneration Template™
- OrCel™ (HDE)
- TranCyte®
- Biobrane®

Treatment of Stevens-Johnson syndrome and toxic epidermal necrolysis is **COVERED** when using:

- Biobrane®

Treatment of dystrophic epidermolysis bullosa is **COVERED** when using:

- OrCel™ (HDE)

All other uses of the tissue-engineered skin substitutes not listed above are investigative and unproven and therefore **NOT COVERED**. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

All other tissue-engineered skin substitutes not listed above are investigative and therefore **NOT COVERED** for all indications. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

**Note:** The FDA has granted a humanitarian device exemption (HDE) for certain tissue-engineered skin substitutes (e.g., Dermagraft®, OrCel™, and Epicel®). Medica considers an FDA-approved HDE device medically necessary when all of the FDA-required criteria are met. For a current list of HDE-approved devices, refer to the FDA HDE Database at: [https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfHDE/hde.cfm](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfHDE/hde.cfm)

**Description**

Tissue-engineered skin substitutes are used to provide temporary wound coverage, assist in wound closure, reduce healing time, minimize post-operative contractures, and improve functional abilities and overall quality of life.

Tissue-engineered skin substitutes may be cellular or acellular, biological or biosynthetic. Cellular products contain living cells such as fibroblasts and keratinocytes within a matrix, and may be allogenic, obtained from another individual, or autogenic, from the same individual. Some products are derived from other species (e.g., bovine, porcine) and are referred to as xenografts. Acellular (i.e., cadaveric human dermis with cellular material removed) products contain a matrix or scaffold composed of materials such as collagen, hyaluronic acid, and fibronectin. Biological products contain no synthetic components. Examples: AlloDerm, Epicel, Graftjacket, Oasis, and PriMatrix. Biosynthetic products contain both biological and synthetic components, such as silicone. Examples include Biobrane, Apligraf, Dermagraft, and Integra. Manufacturing processes of tissue-engineered skin substitutes products vary by company in a number of ways including additives (e.g., antibiotics, surfactants, proteins and growth factors), hydration (wet, freeze dried) and required preparation (e.g., multiple rinses, rehydration).

Skin substitutes have been proposed for a variety of conditions and procedures including breast reconstruction, ocular defects, plantar fasciitis, hernia repair, chronic wounds, surgical wounds and treatment of severe burns.

**FDA Approval**

Products regulated as human tissue are regulated by the American Association of Tissue Banks (AATB) and are therefore not subject to FDA approval. These products include, but are not limited to, Arthroflex, AlloDerm®, and Graftjacket.
Other products are primarily used to protect wounds and provide scaffolding for healing. These products are approved by the FDA 510(k) process and include (but are not limited to) Oasis® Wound Matrix (Cook Biotech), and Primatrix™ (TEI Biosciences).

Products classified by the FDA as interactive wound and burn dressings are approved under the PMA process as class III, high risk devices and include, but are not limited to, Dermagraft® (Advanced Tissue Sciences), Apligraf® (Organogenesis Inc.), and OrcelTM (Bilayered Cellular Matrix).

Prior Authorization
Prior authorization is not required. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.

Coding Considerations
Use the current applicable CPT/HCPCS code(s).

Original Effective Date: 4/1/2013
Re-Review Date(s): 1/20/2016
6/28/2016 – administration update
2/20/2019
3/16/2020 – administrative update; format
12/15/2020 – administrative update; title change