

Skin Substitutes for Wound Care

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| Origination: 12/13/04 | Revised: 10/10/07 | Annual Review: 12/15/11 |
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Purpose:

The Medical Technology Assessment Committee will review published scientific literature and information from appropriate government regulatory bodies (when available) related to Skin Substitutes for Wound Care in order to determine inclusion in the benefit plan.

Compliance Status:

- Centers for Medicare & Medicaid Services (CMS)

Recommendation:

A recommendation was made by the MTAC following discussion by committee members based on current literature:

Definition

- Metabolically Active Human Dermal/Epidermal Replacements (MAHD/ER) are bioengineered dermal tissues, which contain the characteristics of dermis, or both dermis and epidermis. MAHD/ER are manufactured under aseptic conditions using human fibroblast, or fibroblast and keratinocytic cells derived from newborn male foreskin tissue. These cells are tested and found free from human and animal viruses. Human dermal and/or epidermal replacements do not contain macrophages, lymphocytes, blood vessels or hair follicles. Several types of dermal and/or epidermal (substitute) tissues of human or non-human origin, with or without bioengineered processed elements, are available for a variety of conditions.¹

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Recommendation, continued:

Examples of Skin Substitutes and their indications include the following

- **Apligraf[®] (Organogenesis, Inc.)**
Apligraf[®] is supplied as a living, bi-layered skin substitute. Like human skin, Apligraf[®] consists of living cells and structural proteins. The lower dermal layer combines bovine type 1 collagen and human fibroblasts (dermal cells), which produce additional matrix proteins. The upper epidermal layer is formed by promoting human keratinocytes (epidermal cells) first to multiply and then to differentiate to replicate the architecture of the human epidermis. Unlike human skin, Apligraf[®] does not contain melanocytes, Langerhans' cells, macrophages, and lymphocytes, or other structures such as blood vessels, hair follicles or sweat glands. **Apligraf[®] is indicated for use along with standard compression therapy in venous ulcers of at least 1 month in duration that have not adequately responded to conventional ulcer therapy. Apligraf[®] is also indicated for use with conventional diabetic foot ulcer care for the treatment of full-thickness neuropathic diabetic foot ulcers of greater than three weeks duration which extend through the dermis but without tendon, muscle, capsule or bone exposure.** The persistence of Apligraf[®] cells on the wound and the safety of this device in venous ulcer patients beyond 1 year and in diabetic foot ulcer patients beyond six months has not been evaluated.²

The safety and effectiveness of Apligraf[®] have not been established for patients receiving more than five (5) device applications.

- **Dermagraft[®]**
Dermagraft[®] is a single layered cryopreserved human fibroblast-derived dermal substitute composed of fibroblasts, extracellular matrix, and a bioabsorbable scaffold. During the manufacturing process, the human fibroblasts are seeded onto a bioabsorbable polyglactin mesh scaffold. The fibroblasts proliferate to fill the interstices of this scaffold and secrete human dermal collagen, matrix proteins, growth factors and cytokines to create a three-dimensional human dermal substitute containing metabolically active living cells. Dermagraft[®] does not contain macrophages, lymphocytes, blood vessels or hair follicles. It is supplied frozen containing one piece, approximately 2" x 3" for a single-use application. **Primary indication is for the treatment of full-thickness diabetic foot ulcers greater than 6 weeks duration that extend through the dermis but without tendon, muscle, joint capsule or bone exposure. Dermagraft[®] should be used in conjunction with standard wound care treatment in patients with adequate blood supply to the foot.**³

The use of Dermagraft[®] is limited to no more than eight (8) applications per treatment site over a 12 week period.

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Recommendation, continued:

Examples of Skin Substitutes and their indications include the following, continued

- **Integra®**
Integra® Bilayer Matrix Wound Dressing is a tissue-engineered matrix comprised of a porous matrix of cross-linked bovine tendon collagen and glycosaminoglycan and a semi-permeable polysiloxane (silicone) layer. The semi-permeable silicone membrane controls water vapor loss, provides a flexible adherent covering for the wound surface and adds increased tear strength to the device. The collagen-glycosaminoglycan biodegradable matrix provides a scaffold for cellular invasion and capillary growth. Although Integra® indicates coverage for multiple wound management, Medicare will consider Integra® medically reasonable and necessary for post-excisional treatment of life-threatening full-thickness or deep partial-thickness thermal injuries where sufficient autograft is not available at the time of excision or not desirable due to the physiological condition of the patient.⁴
- **OASIS® Wound Matrix**
The OASIS® Wound Matrix is a biologically derived extracellular matrix-based wound product that is compatible with human tissue. Unlike other collagen-based wound care materials, OASIS® is unique because it is a complex scaffold that provides an optimal environment for a favorable host tissue response, a response characterized by restoration of tissue structure and function. OASIS® is comprised of porcine-derived acellular small intestine submucosa (SIS) material. OASIS® is indicated for use in all partial and full thickness wounds, diabetic ulcers, venous ulcers, pressure ulcers, chronic vascular ulcers, trauma wounds, draining wounds and surgical wounds.⁵
- **OrCel® (Ortec International)**
OrCel® is a bilayered cellular matrix in which normal human epidermal keratinocytes and dermal fibroblasts are cultured in two separate layers onto a Type I bovine collagen sponge. The bovine sponge serves as an absorbable biocompatible matrix that provides a favorable environment for host cell migration. Ortec has FDA approval for use of a non-frozen version of OrCel® in the treatment of Epidermolysis Bullosa and donor sites in burn patients.⁶

The use of OrCel® is limited to a single, one time application per donor site. No more than eight (8) pieces of OrCel® should be utilized per donor site.

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Recommendation, continued:

Examples of Skin Substitutes and their indications include the following, continued

- **TransCyte[®]**
TransCyte[®] is a human fibroblast-derived temporary skin substitute. The product consists of a polymer membrane and newborn human fibroblast cells cultured under aseptic conditions in vitro on a nylon mesh. TransCyte[®] is indicated for use as a temporary wound covering for surgically excised full-thickness and deep partial-thickness thermal burn wounds in patients who require such a covering prior to autograft placement. The product is also indicated for the treatment of mid-dermal to indeterminate depth burn wounds that typically require debridement and that may be expected to heal without autografting.⁷

Exclusion

- The safety and effectiveness of re-treatment of a single wound using Apligraf[®], Dermagraft[®], or OrCel[®] has not been established and is not covered.⁸

References:

1. 1 & 8. Medicare Local Coverage Database, LCD for Skin Substitutes (L13832) Local Carrier First Coast Service Options, Inc. Revision effective date on or after 1/1/2007.
2. Novartis Pharmaceuticals Apligraf[®] information (verified 10/07).
3. Advanced BioHealing, Inc. 2007.
4. Integra Lifesciences Corporation 2006.
5. OASIS[®] is a registered trademark of Cook Biotech, Inc. 2004; Oasis[®] Wound Matrix is exclusively marketed and distributed by Healthpoint, Ltd. 2007.
6. Ortec International, Inc. 2006.
7. Advanced BioHealing, Inc 2007.

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Disclaimer Information:

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions using these guidelines, along with the Member's benefit document. The use of this guideline is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed for selected therapeutic or diagnostic services found to be safe, but proven 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 AvMed Health Plans service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations.

Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change.