Bio-Engineered Skin and Soft Tissue Substitutes

DESCRIPTION

Bio-engineered skin and soft tissue substitutes may be derived from human tissue (autologous or allogeneic), nonhuman tissue (xenographic), synthetic materials, or a composite of these materials. Bioengineered skin and soft tissue substitutes are being evaluated for a variety of conditions, including breast reconstruction and healing lower-extremity ulcers and severe burns. The gold standard for surgical wound repair is to use a skin graft harvested from the patient’s own skin (autograft). However, autologous tissue grafting is an invasive and painful procedure, and the extent of damaged skin can be too large to be covered by an autologous graft alone.

While there are many proposed applications for these products the evidence on any single product is extremely limited. FDA approval is obtained as premarket approval, 510(k) clearance, humanitarian device exemption (HDE) or regulated as banked human tissue depending on the source of the product.

POLICY

- Bioengineered skin and soft tissue substitutes are considered **medically necessary** if the medical appropriateness criteria are met. (See Medical Appropriateness below.)

- All other uses of bio-engineered skin and soft tissue substitutes are considered **investigational**.

- All other skin and soft tissue substitutes, including, but not limited to the following, are considered **investigational**:
  - ACell® UBM Hydrated Wound Dressing
  - Affinity™
  - AlloSkin™
  - AlloSkin™ AC
  - AlloSkin™ RT
  - Allowrap™ DS
  - AMNIOEXCEL®
  - Amniofix®
  - AmnioGraft®
  - AMNIOMATRIX®
  - AmnioPro
  - AmnioPro Flow
  - Aongen™ Collagen Matrix
  - Architect® ECM, PX, FX
  - ArthroFlex™ (FlexGraft)
  - Atlas Wound Matrix
  - Avagen Wound Dressing
  - Avaulta™ / Avaulta Plus™
  - AxoGuard® Nerve Protector / Avance® Nerve Graft
  - Biobrane®
  - bio-ConneKt Wound Matrix
  - BioDDryflex®
  - BioDfence®
  - BioDfactor®
  - CellerateRX® / CRXa™
  - CLARIX®

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Medical Policy Manual

Approved: Do Not Implement Until 7/8/17

- CLARIX® Flo Regenerative Matrix / Neox® Flo
- CollaCare®
- CollaCare® Dental
- Collagen Wound Dressing (Oasis Research)
- CollaGUARD®
- CollaMend™
- CollaWound™ Collagen Granules
- Collexa®
- Collieva®
- Conexa™
- Colla-Pad (Corleader)
- CorMatrix®
- CRXa™ / CellerateRX®
- Cymetra® Micronized AlloDerm® Tissue, injectible
- Cytal™
- DermADAPT™ Wound Dressing
- DermACELL AWM™
- Dermapure™
- DermaSpan™
- Dermavest™
- DressSkin™
- Durepair® Regeneration Matrix
- Endoform Dermal Template™ ENDURAGen™
- EpiFix®, injectible
- Excellagen
- ExpressGraft™
- E-Z Derm™
- FlexiGraft®
- FortaDerm™ Wound Dressing / Puraply™
- GammaGraft
- GraftJacket® Xpress, injectable
- GUARDIAN
- HA Absorbent Wound Dressing
- Helicoll™
- Hyalomatrix® Tissue Reconstruction Matrix
- Hyalomatrix® PA
- hMatrix® PR
- Integra™ Bilayer Wound Matrix
- Integra™ Flowable Wound Matrix
- Integra™ Matrix
- Keramatrix
- Kerecis™ Omega3 Wound
- Laserskin®
- MariGen™ Omega3 Wound
- MatriDerm®
- MatriStem® Burn Matrix / Cytal™ Burn Matrix
- MatriStem® Micromatrix
- MatriStem® Wound Matrix / Cytal™ Wound Matrix
- MediSkin®
- MemoDerm™
- MIRODERM® (Microderm Biologic Wound Matrix)

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Any product utilized for this procedure must have FDA approval specific to the indication, otherwise it will be considered investigative.

See also: Amniotic Membrane and Amniotic Fluid Injections

MEDICAL APPROPRIATENESS

- Bioengineered skin and soft tissue substitutes are considered medically appropriate if ANY ONE of the following criteria are met:
Treatment for breast reconstructive surgery using allogenic acellular dermal matrix products including each of the following: AlloDerm® Regenerative Tissue Matrix; AlloMax™ Surgical Graft; AlloMend®; DermMatrix™; FlexHD®, or GraftJacket® if ANY ONE of the following criteria are met:
- There is insufficient tissue expander or implant coverage by the pectoralis major muscle and additional coverage is required
- There are viable but compromised or thin postmastectomy skin flaps that are at risk of dehiscence or necrosis
- The infra-mammary fold and lateral mammary folds have been undermined during mastectomy and re-establishment of these landmarks is needed

Treatment of chronic, non-infected, full-thickness diabetic lower extremity ulcers using ANY ONE of the following tissue-engineered skin substitutes:
- AlloPatch® Pliable
- Apligraft®
- Dermagraft®
- Integra® Dermal Regeneration Template
- The following human amniotic membrane graft products: AmnioBand® Membrane, Biovance®; Epifix®; GrafixCore™; or GrafixPrime™

Treatment of chronic, non-infected, partial- or full-thickness lower extremity skin ulcers due to venous insufficiency, which have not adequately responded following a 30 day period of conventional ulcer therapy, using ANY ONE of the following tissue-engineered skin substitutes:
- Apligraft®
- Oasis™ Wound Matrix

Treatment of dystrophic epidermolysis bullosa using OrCel™ for individuals with mitten-hand deformity when ALL of the following criteria are met:
- Standard wound therapy has failed
- Provided in accordance with the Humanitarian Device Exemption (HDE) specifications of the FDA

Treatment of second- and third-degree burns using ANY ONE of the following tissue-engineered skin substitutes:
- Epicel® when ALL of the following criteria are met:
  - For the treatment of deep dermal or full-thickness burns comprising a total body surface area of greater than or equal to 30%
  - Provided in accordance with the Humanitarian Device Exemption (HDE) specifications of the FDA
- Integra Dermal Regeneration Template™
- TransCyte™

IMPORTANT REMINDERS

- Any specific products referenced in this policy are just examples and are intended for illustrative purposes only. It is not intended to be a recommendation of one product over another, and is not intended to
represent a complete listing of all products available. These examples are contained in the parenthetical e.g. statement.

- We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits, or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member’s health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

**ADDITIONAL INFORMATION**

Overall, the number of bio-engineered skin and soft-tissue substitutes is large, but the evidence is limited for any specific product. Relatively few products have been compared with the standard of care (SOC), and then only for some indications. Therefore, many of these products remain investigational.

**SOURCES**


Frykberg, R., Gibbons, G., Walters, J., Wukich, D., and Milstein, F. (2016) A prospective, multicentre, open-label, single-arm clinical trial for treatment of chronic complex diabetic foot wounds with exposed tendon and/or bone:

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positive clinical outcomes of viable cryopreserved human placental membrane. *International Wound Journal* ISSN 1742-4801. (Level 2 evidence)


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