



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 to facilitate healing of lower-extremity ulcers and severe burns. The gold standard for surgical wound repair is to use a skin graft harvested from the individual'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.

Note: Please see [Human Amniotic Membrane Grafts and Amniotic Fluid Injections](#) medical policy for all products using human amniotic membrane or amniotic fluid.

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
 - AlloSkin™
 - AlloSkin™ RT
 - Apsis®
 - Aongen™ Collagen Matrix
 - Architect® ECM, PX, FX
 - ArthroFlex™ (FlexGraft)
 - AxoGuard® Nerve Protector / Avance® Nerve Graft
 - Biobrane®
 - bio-ConneKt® Wound Matrix
 - CollaCare®
 - CollaCare® Dental
 - Collagen Wound Dressing (Oasis Research)
 - CollaGUARD®
 - CollaMend™
 - CollaWound™
 - Coll-e-derm
 - Collexa®
 - Collieva®
 - Conexa™
 - Colla-Pad (Corleader)



- CorMatrix®
- Cymetra® Micronized AlloDerm® Tissue, injectible
- Cytal™
- Dermadapt™ Wound Dressing
- Derma-gide
- Dermapure™
- DermaSpan™
- DressSkin
- Durepair® Regeneration Matrix
- Endoform Dermal Template™
- ENDURAGen™
- Excellagen®
- ExpressGraft™
- E-Z Derm™
- FlowerDerm™
- GammaGraft
- Geistlich Derma-Gide™
- GraftJacket® Xpress, injectable
- Helicoll™
- Hyalomatrix®
- Hyalomatrix® PA
- hMatrix®-PR
- Integra™ Bilayer Wound Matrix
- Integra® Matrix Wound Dressing (previously Avagen)
- InteguPly®
- InnovaMatrix®
- Keramatrix®
- Kerecis™ Omega3 Wound
- Keroxx™
- MatriDerm®
- ⇌ MatriStem
- Matrix HD™ Allograft / Matrix HD™ Allograft Fenestrated
- MediSkin®
- MemoDerm™
- MIRODERM® (Microderm Biologic Wound Matrix)
- Microlyte matrix®
- MyOwn skin
- Novosorb™ Biodegradable Temporizing Matrix (BMT)
- Oasis® Burn Matrix
- Oasis® Ultra
- Olagen™ Collagen Matrix
- Omega3 Wound (originally Merigen wound dressing)
- Omeza® Collagen Matrix
- Permacol™
- PermeaDerm® B
- PermeaDerm® C
- PermeaDerm® Glove
- Phoenix™ Wound Matrix
- PriMatrix™
- Primatrix™ Dermal Repair Scaffold



- Progenamatrix®
- Puracol® and Puracol® Plus Collagen Wound Dressings
- PuraPly™ Wound Dressing / FortaDerm™
- PuraPly™ Antimicrobial
- Puros® Dermis
- ReCell®
- RegenePro™
- Repliform®
- Repriza™
- Restrata®
- SkinTE™
- StrataGraft®
- Stratice™ Reconstructive Tissue Matrix
- SUPRA SDRM®
- Suprathel®
- SurgiMend®
- Symphony™
- Talymed®
- TenoGlide™
- TenSIX™ Acellular Dermal Matrix
- TheraForm™ Standard/Sheet
- TheraGenesis®
- TissueMend
- TransCyte™
- TruSkin™
- Tutomesh™ Fenestrated Bovine Pericardium
- Veritas® Collagen Matrix
- Xcellistem®
- XCM BIOLOGIC® Tissue Matrix
- XenMatrix™ AB

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

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 (i.e., AlloDerm® Regenerative Tissue Matrix;-Cortiva®, [AlloMax™ Surgical Graft]; AlloMend®; DermACELL™; DermMatrix™; FlexHD®; FlexHD Pliable®; 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



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- 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
 - Apligraf®
 - Dermagraft®
 - Integra® Dermal Regeneration Template or
 - Integra Omnigraft™ Dermal Regeneration Matrix
 - Integra® Flowable Wound Matrix
 - mVasc®
 - TheraSkin®
- Treatment of chronic, non-infected, partial- or full-thickness lower extremity skin ulcers and **ALL** of the following:
 - Skin ulcers are due to venous insufficiency
 - Conventional wound therapy has failed after a 30-day period
 - Tissue-engineered skin substitute to be used is **ANY ONE** of the following:
 - Apligraf®
 - Oasis™ Wound Matrix
- Treatment of dystrophic epidermolysis bullosa when **ALL** of the following criteria are met:
 - Individual with mitten-hand deformity
 - Tissue-engineered skin substitute being used is OrCel™
 - 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™

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



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Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program 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.

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