Bioengineered Skin

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Approved By:	Highmark Health Options – Market Leadership
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Products:	Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 8

Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under medical surgical benefits of the Company's Medicaid products for medically necessary bioengineered skin.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan Plus members.

Bio-engineered Skin – Soft tissue substitutes may be derived from human tissue (autologous or allogeneic), nonhuman tissue (xenographic), synthetic materials, or a composite of these materials. Bio-engineered skin and soft tissue substitutes are utilized in the treatment for breast reconstruction, healing of lower extremity ulcers and severe burns. Acellular dermal matrix (ADM) products are utilized in the repair of a variety of soft tissues.

PROCEDURES

A prior authorization is required for this procedure.

Breast reconstructive surgery using ONE of the following allogeneic ADM products may be considered medically necessary for any ONE of the following indications:

1. Product(s):

    - AlloDerm®; or
    - AlloMax™; or
    - AlloMend®; or
    - DermaMatrix™; or
    - DermACELL®; or
    - FlexHD®; or
    - GraftJacket®

2. Indication(s):

    - When there is insufficient tissue expander or implant coverage by the pectoralis major muscle and additional coverage is required; or
    - When there is viable but compromised or thin post-mastectomy skin flaps that are at risk of dehiscence or necrosis; or
    - The infra-mammary fold and lateral mammary folds have been undermined during mastectomy and re-establishment of these landmarks is needed.

Services that do not meet the above criteria will be considered not medically necessary.

Treatment of chronic, noninfected, full-thickness diabetic lower extremity ulcers using any ONE of the following tissue-engineered skin substitutes may be considered medically necessary:

- AlloPatch®; or
- Apligraf®; or
- Dermagraft®; or
- Integra® Dermal Regeneration Template or
- Oasis® Ultra Tri-Layer Matrix or
- Oasis Wound Matrix

Services that do not meet the above criteria will be considered not medically necessary.

Treatment of chronic, noninfected, partial- or full-thickness lower extremity skin ulcers due to venous insufficiency, which have not adequately responded following a one (1) month period of conventional ulcer therapy, using any ONE of the following tissue-engineered skin substitutes may be considered medically necessary:

- Apligraf; or
- Oasis™ Wound Matrix or
- Oasis® Ultra Tri-Layer Matrix

Services that do not meet the above criteria will be considered not medically necessary.

Treatment of dystrophic epidermolysis bullosa using the following tissue-engineered skin substitutes may be considered medically necessary for ALL of the following indications:

1. Product(s):

    - OrCel™

2. Indication(s):

    - Treatment of mitten-hand deformity when standard wound therapy has failed; **and**
    - When provided in accordance with the Humanitarian Device Exemption (HDE) specifications of the Food and Drug Administration (FDA).

Services that do not meet the above criteria will be considered not medically necessary.

Treatment of second- and third-degree burns using any ONE of the following tissue-engineered skin substitutes may be considered medically necessary.

- Epicel®
    - Treatment of deep dermal or full-thickness burns comprising a total body surface area greater than or equal to 30% when provided in accordance with the HDE specifications of the FDA; or
- Integra Dermal Regeneration Template™; or
- TransCyte™.

Services that do not meet the above criteria will be considered not medically necessary.

TheraSkin® may be considered medically necessary for any ONE of the following indications:

- In conjunction with standard therapeutic compression for the treatment of chronic, noninfected, partial or full-thickness skin ulcers due to venous insufficiency greater than one (1) month duration and which have not adequately responded following a one (1) month period of conventional ulcer therapy (i.e., standard dressing changes, standard therapeutic compression, etc.); or
- In conjunction with standard diabetic foot ulcer care for the treatment of full-thickness neuropathic diabetic foot ulcers greater than one (1) month duration which have not adequately responded following at least four (4) weeks of conventional ulcer therapy (i.e., surgical debridement, complete off-loading and standard dressing changes, etc.) which can extend through the dermis, including tendon, muscle, joint capsule or bone exposure; or
- Other uses supported by clinical results and clinical literature include pressure sores, skin cancer excision (e.g., Mohs Surgery), large surgical wounds (i.e., club release, etc.), radiation compromised wounds and necrotizing fasciitis.

Services that do not meet the above criteria will be considered not medically necessary.

ALL other skin and soft tissue substitute not listed above are considered experimental/investigational and, therefore noncovered because the safety and/or effectiveness cannot be established by the available published peer-reviewed literature. This includes, but is not limited to:

- ACell® UBM Hydrated Wound Dressing; and
- ACell® UBM Lyophilized Wound Dressing; and
- ActiveMatrix®; and
- AlloSkin™; and
- AlloSkin™ RT; and
- Alphaplex with MariGen Omega3; and
- Aongen™ Collagen Matrix; and
- Architect Extracellular Matrix; and
- ArthroFlex™ (FlexGraft); and

- Atlas Wound Matrix; and
- Avagen Wound Dressing; and
- Avaulta Plus™; and
- BellaCell HD or Surederm; and
- Biobrane®; and
- CellerateRX®; and
- Collagen Sponge (Innocoll); and
- Collagen Wound Dressing (Oasis Research); and
- Collaguard; and
- CollaSorb™; and
- CollaWound™; and
- Coll-E-Derm; and
- Collexa®; and
- Collieva®; and
- Conexa™; and
- Coreleader Colla-Pad; and
- CorMatrix®; and
- CRXa™; and
- Cymetra®; and
- Cytal; and
- Dermadapt™ Wound Dressing; and
- DermaGide; and
- DermaMatrix Acellular Dermis; and
- DermaPure™; and
- Derm-maxx; and
- DressSkin; and
- Durepair Regeneration Matrix®; and
- Endoform Dermal Template™; and
- ENDURAgen™; and
- Excellagen; and
- E-Z Derm™; and
- FlowerDerm; and
- FlowerPatch™; and
- FortaDerm™ Wound Dressing; and
- GammaGraft; and
- GraftJacket® Regenerative Tissue Matrix; and
- GraftJacket® Xpress, injectable; and
- HA Absorbent Wound Dressing; and
- Helicoll; and
- Hyalomatrix® (Laserskin®); and
- Hyalomatrix® PA; and
- hMatrix®; and
- Integra™ Flowable Wound Matrix; and
- Integra™ Bilayer Wound Matrix; and
- Integra™ Matrix; and
- Kerrox; and
- MatriDerm®; and
- MatriStem® Burn Matrix; and
- MatriStem® Micromatrix; and
- MatriStem® Wound Matrix; and
- Matrix HD™; and

- MediHoney®; and
- Mediskin®; and
- MemoDerm™; and
- Miroderm; and
- MyOwnSkin; and
- Neox®; and
- Oasis® Burn Matrix; and
- Permacol™; and
- PriMatrix; and
- Primatrix™ Dermal Repair Scaffold; and
- Progenamatix; and
- Puraply; and
- Puraply AM; and
- Puraply XT; and
- Puros® Dermis; and
- Repliform®; and
- SS Matrix™; and
- Skin TE; and
- Stimulen™ Collagen; and
- StrataGraft; and
- Strattice™ (xenograft); and
- Suprathel®; and
- SurgiMend®; and
- Talymed®; and
- TenoGlide™; and
- Tensix™; and
- TheraForm™ Standard/Sheet; and
- Truskin; and
- Unite® Biomatrix; and
- Veritas® Collagen Matrix; and
- Xcm Biologic Tissue Matrix

POST-PAYMENT AUDIT STATEMENT

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

PLACE OF SERVICE: OUTPATIENT

Experimental/investigational (E/I) services are not covered regardless of place of service.

The application of bio-engineered skin and soft tissue substitutes is typically an outpatient procedure which is only eligible for coverage as an inpatient procedure in special circumstances, including, but not limited to, the presence of a comorbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

CODING REQUIREMENTS

CPT code	Description
15150	Tissue cultured skin autograft, trunk, arms, legs; first 25 sq cm or less.

15151	Tissue cultured skin autograft, trunk, arms, legs; additional 1 sq cm to 75sq cm (list separately in addition to code for primary procedures).
15152	Tissue cultured skin autograft, trunk, arms, legs; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedures).
15155	Tissue cultured skin autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 25 sq cm or less.
15156	Tissue cultured skin autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; additional 1 sq cm or 75 sq cm (list separately in addition to code for primary procedures).
15157	Tissue cultured skin autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedures).
15271	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area.
15272	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; each additional 25 sq cm or less wound surface area, or part thereof (list separately in addition to code for primary procedure).
15273	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm or less wound surface area, or 1% of body area of infants and children.
15274	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure).
15275	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area.
15276	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area or part thereof (list separately in addition to code for primary procedure).
15277	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm or less wound surface area, or 1% of body area of infants and children.
15278	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure).
15777	Implantation of biologic implant (e.g., acellular dermal matric) for soft tissue reinforcement (i.e., breast, trunk) (list separately in addition to code for primary procedure).
19357	Tissue expander placement in breast reconstruction, including subsequent expansion(s).
19361	Breast reconstruction; with latissimus dorsi flap.
19364	Breast reconstruction; with free flap (e.g., ftram, diep, siea, gap flap).
19367	Breast reconstruction; with single-pedicled transverse rectus abdominis myocutaneous (tram) flap.

19368	Breast reconstruction; with single-pedicled transverse rectus abdominis myocutaneous (tram) flat, requiring separate microvascular anastomosis (supercharging).
19369	Breast reconstruction, with bepedicled transverse rectus abdominis myocutaneous (tram) flat.
19380	Revision of reconstructed breast (e.g., significant removal of tissue, re-advancement and/or re-inset of flaps in autologous reconstruction or significant capsular revision combined with soft tissue excision in implant-based reconstruction).

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

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POLICY UPDATE HISTORY

10/27/2021	Approved in Medical Policy Committee
11/2021	Approved in QI/UM
12/28/2022	Annual review; approved in Medical Policy Committee
01/03/2023	Approved in QI/UM