Bio-Engineered Skin and Soft Tissue Substitutes

I. Policy

University Health Alliance (UHA) will reimburse for treatment of bio-engineered skin and soft tissue substitutes when determined to be medically necessary and within the medical criteria guidelines (subject to limitations and exclusions) indicated below.

II. Background

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. Bio-engineered skin and soft tissue substitutes are being evaluated for a variety of conditions, including breast reconstruction and healing lower-extremity ulcers and severe burns. Acellular dermal matrix (ADM) products are also being evaluated for soft tissue repair. The following policy addresses specific commercially available bio-engineered skin and soft tissue substitutes that have substantial relevant evidence on efficacy.

III. Criteria/Guidelines

A. Breast reconstructive surgery: Allogeneic acellular dermal matrix products (i.e., AlloDerm®, AlloMax™, AlloMend®, DermaMatrix™, FlexHD®, Graftjacket®) or Strattice are covered (subject to Limitations/Exclusions and Administrative Guidelines) in breast reconstructive surgery when one of the following criteria is met:

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

B. Shoulder tendon repair: The use of allograft products is covered (subject to Limitations and Administrative Guidelines) for shoulder tendon repair.

C. Diabetic ulcers: AlloPatch®, Amnioband membrane, Apligraf®, Dermagraft®, Apligraf, Dermagraft, Integra® Dermal Regeneration Template, Amniotic Membrane Graft (e.g., Biovance, Epifix, Grafix) are covered (subject to Limitations/Exclusions and Administrative Guidelines) for the treatment of chronic, **non-infected**, full-thickness diabetic lower extremity ulcers when all of the following criteria are met:

1. The ulcers have not adequately responded after six weeks of standard wound therapy*; and
2. The patient is on a comprehensive diabetic management program; and
3. Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities; and
4. Products are used only within the manufacturers indication for use

D. Skin ulcers due to venous insufficiency: Apligraf® or Oasis™ Wound Matrix is covered (subject to Limitations / Exclusions and Administrative Guidelines) for the treatment of chronic, non-infected, partial or full-thickness lower extremity skin ulcers due to venous insufficiency when all of the following criteria are met:

1. The ulcers have not adequately responded after six weeks of standard wound therapy*; and
2. Compression bandages and/or graduated compression garments have been consistently applied; and

3. Leg elevation and exercise have been encouraged.

E. Dystrophic epidermolysis bullosa: OrCel™ is covered (subject to Limitations / Exclusions and Administrative Guidelines) for the treatment of dystrophic epidermolysis bullosa.

F. Burns: Treatment of second- and third-degree burns using the following tissue-engineered skin substitutes is covered (subject to Limitations and Administrative Guidelines).

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

*Within this policy, standard wound therapy includes:

- Evaluation of wound with documentation of measurements (length, width, and depth) at baseline and at least weekly by a licensed medical professional
- Application of moist topical dressings
- Debridement of necrotic tissue, if present
- Treatment of infection, if present
- Evaluation and provision of adequate nutrition
- Management of diabetes mellitus, if applicable
- Evaluation and management of peripheral artery disease, if applicable

IV. Limitations/Exclusions

A. Bio-engineered skin and soft tissue substitutes have not been shown to improve health outcomes for all other conditions not listed under Criteria/Guidelines and therefore are not covered.

B. All other bio-engineered skin and soft tissue substitutes not listed under Criteria/Guidelines are not covered as their use is not known to improve health outcomes. These include, but are not limited to:

ACell® UBM Hydrated Wound Dressing	HA Absorbent Wound Dressing
ACell® UBM Lyophilized Wound Dressing	Helicoll
Affinity™	Hyalomatrix® (Laserskin®)
AlloSkin™	Hyalomatrix® PA
AlloSkin™ RT	hMatrix®
AlloWrap™	Integra™ Flowable Wound Matrix
Alphaplex™ with MariGen Omega3™	Integra™ Bilayer Wound Matrix
AmnioFix®	Jaloskin®
Aongen™ Collagen Matrix	MariGen
Arthroflex™ (Flex Graft)	MatriDerm®
Atlas Wound Matrix	MatriStem® Burn Matrix
Atracent	MatriStem® Micromatrix
Avagen Wound Dressing	Matrix Collagen Wound Dressing
Avaulta Plus™	Matrix HD™
Biobrane®	MediHoney®
BioDfence/BioDfactor	Mediskin®
CellerateRX®	MemoDerm™
Clarix® Flo	Microderm
Collagen Sponge (Innocoll)	Neox® Flo
Collagen Wound Dressing (Oasis Research)	NuShield™
CollaGUARD®	Oasis® Burn Matrix
CollaSorb™	Oasis® Ultra Tri-Layer Matrix

CollaWound™	Permacol™
Collexa®	PriMatrix™
Collieva®	PriMatrix™ Dermal Repair Scaffold
Conexa™	PuraPly
Coreleader Colla-Pad	Puros® Dermis
CorMatrix®	Repliform®
CRXa™	Repriza™
Cymetra®	Revitalon™
Cystal	SIS Wound Dressing II
Dermadapt™ Wound Dressing	SS Matrix™
DermaPure™	Stimulen™ Collagen
DressSkin	StrataGraft®
Dermavest™	Suprathel®
Durepair Regeneration Matrix®	SurgiMend®
Endoform Dermal Template™	Talymed®
ENDURAGen™	TenoGlide™
Excellagen	TheraForm™ Standard/Sheet
E-Z Derm™	TheraSkin®
GammaGraft	TruSkin
Graftjacket® Xpress, injectable	Veritas® Collagen Matrix
GUARDIAN	

NOTE:

This UHA payment policy is a guide to coverage, the need for prior authorization and other administrative directives. It is not meant to provide instruction in the practice of medicine and it should not deter a provider from expressing his/her judgment.

Even though this payment policy may indicate that a particular service or supply is considered covered, specific provider contract terms and/or member's individual benefit plans may apply, and this policy is not a guarantee of payment. UHA reserves the right to apply this payment policy to all UHA companies and subsidiaries.

UHA understands that opinions about and approaches to clinical problems may vary. Questions concerning medical necessity (see Hawaii Revised Statutes §432E-1.4) are welcome. A provider may request that UHA reconsider the application of the medical necessity criteria in light of any supporting documentation.

V. Administrative Guidelines

A. Prior authorization is required for the application of Apligraf, Dermagraft, Epicel, OrCel, Integra Dermal Regeneration Template, Amniotic Membrane graft (e.g., Biovance, Epifix, Grafix), TransCyte, and Oasis Wound Matrix. The following documentation must be submitted:

1. Clinical notes documenting patient's compliance with a diabetic management program
2. The exact location of the ulcer and initial ulcer size
3. Duration and description of the standard treatments that were tried and failed
4. Documentation of the presence of dystrophic epidermolysis bullosa if this is the indication
5. Imaging studies and colored photographs, if applicable

B. Prior Authorization is not required for acellular dermal matrix products or Strattice when used in breast reconstruction surgery.

C. UHA reserves the right to perform retrospective reviews using the above criteria to validate if services rendered met payment determination criteria.

D. The application of these products outside of the guidelines and standard appropriate use criteria for hospitalized patients' wounds will result in denial of claims.

E. To request prior authorization, please submit via UHA's online portal.

F. This policy may apply to the following codes. Inclusion of a code in the table below does not guarantee that it will be reimbursed.

Applicable HCPCS Codes:

HCPCS Code	Description
Q4100	Skin substitute, not otherwise specified
Q4101	Apligraf, per square centimeter
Q4102	Oasis wound matrix, per square centimeter
Q4105	Integra dermal regeneration template (DRT) or Integra Omnigraft dermal regeneration matrix, per square centimeter
Q4106	Dermagraft, per square centimenter
Q4107	GRAFTJACKET, per square centimeter
Q4116	AlloDerm, per square centimeter
Q4122	DermACELL, per square centimeter
Q4124	OASIS ultra tri-layer wound matrix, per square centimeter
Q4128	FlexHD, AllopatchHD, or Matrix HD, per square centimeter
Q4130	Strattice TM, per square centimeter
Q4132	Grafix Core and GrafixPL Core, per square centimeter
Q4133	Grafix Prime and GrafixPL Prime, per square centimeter
Q4145	EpiFix, injectable, 1 mg
Q4151	AmnioBand or Guardian, per square centimeter
Q4154	Biovance, per square centimeter
Q4186	Epifix, per square centimeter

HCPCS Codes that do not meet payment determination criteria:

HCPCS Code	Description
C9354	Acellular pericardial tissue matrix of nonhuman origin (Veritas), per square centimeter
C9356	Tendon, porous matrix of cross-linked collagen and glycosaminoglycan matrix (TenoGlide Tendon Protector Sheet), per square centimeter
C9358	Dermal substitute, native, non-denatured collagen, fetal bovine origin (SurgiMend Collagen Matrix), per 0.5 square centimeter
C9360	Dermal substitute, native, non-denatured collagen, neonatal bovine origin (SurgiMend Collagen Matrix), per 0.5 square centimeter
C9363	Skin substitute (Integra Meshed Bilayer Wound Matrix), per square centimeter
C9364	Porcine implant, Permacol, per square centimeter
Q4103	Oasis Burn Matrix, per square centimeter
Q4104	Integra Bilayer Matrix Wound Dressing (BMWD), per square centimeter
Q4108	Integra Matrix, per square centimeter
Q4110	PriMatrix, per square centimeter
Q4111	GammaGraft, per square centimeter
Q4112	Cymetra, injectable, 1 cc
Q4113	GRAFTJACKET XPRESS, injectable, 1 cc
Q4114	Integra Flowable Wound Matrix, injectable, 1 cc
Q4115	AlloSkin, per square centimeter
Q4116	AlloDerm, per square centimeter
Q4117	HYALOMATRIX, per square centimeter

Q4118	MatriStem micromatrix, per square centimeter
Q4121	TheraSkin, per square centimeter
Q4123	AlloSkin RT, per square centimeter
Q4125	Arthroflex, per square centimeter
Q4126	Memoderm, Dermaspan, Transgraft or Integuply, per square centimeter
Q4127	Talymed, per square centimeter
Q4134	hMatrix, per square centimeter
Q4135	Mediskin, per square centimeter
Q4136	E-Z Derm, per square centimeter
Q4137	AmnioExcel or BioDExCel, per square centimeter
Q4138	BioDFence DryFlex, per square centimeter
Q4139	AmnioMatrix or BioDMatrix, injectable, 1 cc
Q4140	BioDFence, per square centimeter
Q4141	AlloSkin AC, per square centimeter
Q4142	XCM biologic tissue matrix, per square centimeter
Q4143	Repriza, per square centimeter
Q4146	Tensix, per square centimeter
Q4147	Architect, Architect PX, or Architect FX, extracellular matrix, per square centimeter
Q4148	Neox Cord 1K, Neox Cord RT, or Clarix Cord 1K, per square centimeter
Q4149	Excellagen, 0.1 cc
Q4150	AlloWrap DS or dry, per square centimeter
Q4151	AmnioBand or Guardian, per square centimeter
Q4152	DermaPure, per square centimeter
Q4153	Dermavest and Plurivest, per square centimeter
Q4155	Neox Flo or Clarix Flo 1 mg
Q4156	Neox 100 or Clarix 100, per square centimeter
Q4157	Revitalon, per square centimeter
Q4158	Kerecis Omega3, per square centimeter
Q4159	Affinity, per square centimeter
Q4160	Nushield, per square centimeter
Q4161	Bio-ConneKt wound matrix, per square centimeter
Q4162	WoundEx Flow, BioSkin Flow, 0.5 cc
Q4163	WoundEx, BioSkin, per square centimeter
Q4164	Helicoll, per square centimeter
Q4165	Keramatrix, per square centimeter
Q4169	Artacent wound, per square centimeter

VI. Policy History

Policy Number: MPP-0090-120918

Current Effective Date: 08/21/2019

Original Document Effective Date: 09/18/2012

Previous Revision Dates: 08/08/2018

PAC Approved Date: 09/18/2012

Previous Policy Title: Tissue-Engineered Skin Substitutes