BlueCross BlueShield of Vermont
An Independent Licensee of the Blue Cross and Blue Shield Association.

Bioengineered Skin and Soft Tissue Substitutes
Corporate Medical Policy

File Name: Bioengineered Skin and Soft Tissue Substitutes
File Code: UM.SURG.16
Origination: 09/2016
Last Review: 10/2020
Next Review: 10/2021
Effective Date: 01/01/2021

Description/Summary

Bioengineered 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. Acellular dermal matrix (ADM) products are also being evaluated for soft tissue repair.

Policy

Coding Information

Click the links below for attachments, coding tables & instructions.
Attachment I – Coding Table & Instructions

When a service may be considered medically necessary

Breast reconstructive surgery using allogeneic acellular dermal matrix productsa (including each of the following: AlloDerm®, AlloMend®, Cortiva®, AlloMax™, DermACELL™, DermaMatrix™, FlexHD®, FlexHD®, Pliable™, Graftjacket® may be considered **medically necessary:**

- when there is insufficient tissue expander or implant coverage by the pectoralis major muscle and additional coverage is required,
- when there is viable but compromised or thin postmastectomy skin flaps that are at risk of dehiscence or necrosis, **or**
- the inframammary fold and lateral mammary folds have been undermined during mastectomy and reestablishment of these landmarks is needed.

*NOTE: Refer to Corporate Medical policy for breast surgery for criteria and guidelines.

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

- AlloPatch®[a]
- Apligraf®[b]
- Dermagraft®[b]
- Epifix
- Integra® Omnigraft™ Dermal Regeneration Matrix (also known as Omnigraft™) and Integra Flowable Wound Matrix.

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

- Apligraf®[b]
- Epifix
- Oasis™ Wound Matrix[c].

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

- OrCel™ (for the 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 U.S. Food and Drug Administration [FDA])[d].

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

- Epicel® (for the treatment of deep dermal or full-thickness burns comprising a total body surface area ≥30% when provided in accordance with the HDE specifications of the FDA)[d]
- Integra® Dermal Regeneration Template[b].

[a] Banked human tissue.
[b] FDA premarket approval.
[c] FDA 510(k) clearance.
[d] FDA-approved under an HDE

When a service is considered investigational

All other uses of the bioengineered skin and soft tissue substitutes listed above are considered **investigational.**

All other skin and soft tissue substitutes not listed above are considered **investigational**, including, but not limited to:

- ACell® UBM Hydrated/Lyophilized Wound Dressing
- AlloSkin™
- AlloSkin™ RT
- Amnioamp-mp
- Amniply
- Aongen™ Collagen Matrix
- Architect® ECM, PX, FX
- ArthroFlex™ (Flex Graft)
- Atlas Wound Matrix
- Avagen Wound Dressing
- AxoGuard® Nerve Protector (AxoGen)
- Biobrane®/Biobrane-L
- CollaCare®
- CollaCare® Dental
- Collagen Wound Dressing (Oasis Research)
- CollaGUARD®
- CollaMend™
- CollaWound™
- Collexa®
- Collieva®
- Conexa™
- Coreleader Colla-Pad
- CorMatrix®
- Cymetra™ (Micronized AlloDerm™
- Cytal™ (previously MatriStem®)
- Dermadapt™ Wound Dressing
- DermaPure™
- DermaSpan™
- DressSkin
- Durepair Regeneration Matrix®
- Endoform Dermal Template™
- ENDURAGen™
- Excellagen
- ExpressGraft™
- E-Z Derm™
- FlexiGraft®
- GammaGraft
- Graftjacket® Xpress, injectable
- Helicoll™
- Hyalomatrix®
- Hyalomatrix® PA
- hMatrix®
- Integra™ Bilayer Wound Matrix
- Keramatrix®
- Kerecis™
- MariGen™/Kerecis™ Omega3™
- MatriDerm®
- Matrix HD™
- Mediskin®

- MemoDerm™
- Microderm® biologic wound matrix
- NeoForm™
- Norafix dl
- NuCel
- Oasis® Burn Matrix
- Oasis® Ultra
- Pelvicol®/PelviSoft®
- Permacol™
- PriMatrix™
- PriMatrix™ Dermal Repair Scaffold
- PuraPly™ Wound Matrix (previously FortaDerm™)
- PuraPly™ AM (Antimicrobial Wound Matrix)
- Puros® Dermis
- Reguard
- RegenePro™
- Repliform®
- Repriza™
- StrataGraft®
- Strattice™ (xenograft)
- Suprathel®
- SurgiMend®
- Talymed®
- TenoGlide™
- TenSIX™ Acellular Dermal Matrix
- TissueMend
- TheraForm™ Standard/Sheet
- TheraSkin®
- TransCyte™
- TruSkin™
- Veritas®Collagen Matrix
- XCM Biologic® Tissue Matrix
- XenMatrix™ AB.

Policy Guidelines

Clinical input has indicated that the various acellular dermal matrix products used in breast reconstruction have similar efficacy. The products listed are those that have been identified for use in breast reconstruction. Additional acellular dermal matrix products may become available for this indication.

Reference Resources

1. Blue Cross and Blue Shield Association Medical Policy MPRM 7.01.113 Bioengineered Skin and Soft Tissue Substitutes. Last reviewed June 2020.

Related Policies

Breast Surgery

Document Precedence

Blue Cross and Blue Shield of Vermont (BCBSVT) Medical Policies are developed to provide clinical guidance and are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. The applicable group/individual contract and member certificate language, or employer's benefit plan if an ASO group, determines benefits that are in effect at the time of service. Since medical practices and knowledge are constantly evolving, BCBSVT reserves the right to review and revise its medical policies periodically. To the extent that there may be any conflict between medical policy and contract/employer benefit plan language, the member's contract/employer benefit plan language takes precedence.

Audit Information

BCBSVT reserves the right to conduct audits on any provider and/or facility to ensure compliance with the guidelines stated in the medical policy. If an audit identifies instances of non-compliance with this medical policy, BCBSVT reserves the right to recoup all non-compliant payments.

Administrative and Contractual Guidance

Benefit Determination Guidance

Prior approval may be required and benefits are subject to all terms, limitations and conditions of the subscriber contract.

Incomplete authorization requests may result in a delay of decision pending submission of missing information. To be considered compete, see policy guidelines above.

NEHP/ABNE members may have different benefits for services listed in this policy. To confirm benefits, please contact the customer service department at the member's health plan.

Federal Employee Program (FEP): Members may have different benefits that apply. For further information please contact FEP customer service or refer to the FEP Service Benefit Plan Brochure. It is important to verify the member's benefits prior to providing the service to determine if benefits are available or if there is a specific exclusion in the member's benefit.

Coverage varies according to the member's group or individual contract. Not all groups are required to follow the Vermont legislative mandates. Member Contract language takes precedence over medical policy when there is a conflict.

If the member receives benefits through an Administrative Services Only (ASO) group, benefits may vary or not apply. To verify benefit information, please refer to the member's employer benefit plan documents or contact the customer service department. Language in the employer benefit plan documents takes precedence over medical policy when there is a conflict.

Policy Implementation/Update information

09/2016	New Policy. Adopted BCBSA MPRM# 7.01.113.
01/2018	Effective 01/01/2018: Q4176, Q4177, Q4178, Q4179, Q4180, Q4181, Q4182 requiring prior approval
10/2018	Policy updated with literature review through November 6, 2017; references 4-5, 7, 9, 15, 20, 29, 35, and 54 added; references 59 and 61 updated. DermACELL and FlexHD Pliable added to medically necessary statement on breast reconstructive surgery. Integra Flowable Wound Matrix added to medically necessary statement on use of Integra Dermal Regeneration Template for diabetic lower extremity. Q4105 updated descriptor, Q4131 updated descriptor, C9349 code deleted 01/01/2017. Q4119, Q4120 Deleted effective 01/01/2017, Q4129 & C9349 deleted 01/01/2017, added HCPCS codesQ4166, Q4167, Q4168, Q4169, Q4170, Q4171, Q4172, Q4173, Q4174, Q4175 effective01/01/2017, investigational. Added –JC, -JD modifiers to table to reflect content within medical policy. Added CPT® Code 15777 require prior authorization. Added related policy section.
01/2019	Review 2019 Code changes effective 01/01/2019 with the following: Q4131 & Q4172 deleted. Q4183, Q4184, Q4186, Q4187, Q4188, Q4190, Q4191, Q4193, Q4194, Q4198, Q4200, Q4201, Q4202, Q4203, Q4204 require prior approval effective 01/01/2019. Q4195, Q4196, Q4197 are considered investigational effective 01/01/2019.
10/2019	Revised codes Q4165, Q4184 &Q4122 descriptors updated. Q4154 removed from investigational to medically necessary. Added codes Q4205, Q4206, Q4208, Q4209, Q4210, Q4211, Q4212, Q4213, Q4214, Q4215, Q4216, Q4217, Q4218, Q4219, Q4220, Q4221, Q4222, Q4226 as considered investigational.
10/2019	Policy Updated. Formatting Changes. Policy Statements unchanged.
10/2020	Adaptive Maintenance updates: Added codes Q4249, Q4250, Q4254, Q4255 as Investigational. Simplified introduction. No change to policy statement.

Eligible providers

Qualified healthcare professionals practicing within the scope of their license(s).

Approved by BCBSVT Medical Directors — Date Approved

Joshua Plavin, MD, MPH, MBA
Chief Medical Officer

Kate McIntosh, MD, MBA, FAAP
Senior Medical Director

Attachment I
Coding Table & instructions

Code Type	Number	Description	Policy Instructions
The following codes will be considered as medically necessary when applicable criteria have been met.			
CPT®	15777	Implantation of biologic implant (eg, acellular dermal matrix) for soft tissue reinforcement (ie, breast, trunk) (List separately in addition to code for primary procedure)	Prior Approval Required
HCPCS	Q4100	Skin substitute, not otherwise specified	Prior Approval Required
HCPCS	Q4101	Apligraf, per sq cm	Prior Approval Required
HCPCS	Q4102	Oasis wound matrix, per sq cm	Prior Approval Required
HCPCS	Q4105	Integra dermal regeneration template (DRT), or integra omnigraft dermal regeneration matrix per sq cm	Prior Approval Required
HCPCS	Q4106	Dermagraft, per sq cm	Prior Approval Required
HCPCS	Q4107	GRAFTJACKET, per sq cm	Prior Approval Required
HCPCS	Q4114	Integra flowable wound matrix, injectable,	Prior Approval Required
HCPCS	Q4116	AlloDerm, per sq cm	Prior Approval Required
HCPCS	Q4122	Dermacell, per square centimeter	Prior Approval Required
HCPCS	Q4128	FlexHD, AllopatchHD, or Matrix HD, per sq cm	Prior Approval Required
HCPCS	Q4154	Biovance, per sq cm	No Prior Approval Required
HCPCS	Q4176	Neopatch, per square centimeter	Prior Approval Required
HCPCS	Q4177	Floweramnioflo, 0.1 cc	Prior Approval Required
HCPCS	Q4178	Floweramniopatch, per square	Prior Approval Required
HCPCS	Q4179	Flowerderm, per square centimeter	Prior Approval Required
HCPCS	Q4180	Revita, per square centimeter	Prior Approval Required
HCPCS	Q4181	Amnio wound, per square centimeter	Prior Approval Required
HCPCS	Q4182	Transcyte, per square centimeter	Prior Approval Required
HCPCS	Q4183	Surgigraft, per square centimeter	Prior Approval Required
HCPCS	Q4184	Cellesta, per square centimeter	Prior Approval Required
HCPCS	Q4186	Epifix, per square centimeter	Prior Approval Required
HCPCS	Q4187	Epicord, per square centimeter	Prior Approval Required

HCPCS	Q4188	Amnioarmor, per square centimeter	Prior Approval Required
HCPCS	Q4190	Artacent ac, per square centimeter	Prior Approval Required
HCPCS	Q4191	Restorigin, per square centimeter	Prior Approval Required
HCPCS	Q4193	Coll-e-derm, per square centimeter	Prior Approval Required
HCPCS	Q4194	Novachor, per square centimeter	Prior Approval Required
HCPCS	Q4198	Genesis amniotic membrane, per square centimeter	Prior Approval Required
HCPCS	Q4200	Skin te, per square centimeter	Prior Approval Required
HCPCS	Q4201	Matrion, per square centimeter	Prior Approval Required
HCPCS	Q4202	Keroxx (2.5g/cc), 1cc	Prior Approval Required
HCPCS	Q4203	Derma-gide, per square centimeter	Prior Approval Required
HCPCS	Q4204	Xwrap, per square centimeter	Prior Approval Required
The following codes will be denied as Investigational			
HCPCS	C9354	Acellular pericardial tissue matrix of nonhuman origin (Veritas), per sq	Investigational
HCPCS	C9356	Tendon, porous matrix of cross-linked collagen and glycosaminoglycan matrix (TenoGlide Tendon Protector Sheet), per sq cm	Investigational
HCPCS	C9358	Dermal substitute, native, nondenatured collagen, fetal bovine origin (SurgiMend Collagen Matrix), per 0.5 sq cm	Investigational
HCPCS	C9360	Dermal substitute, native, nondenatured collagen, neonatal bovine origin (SurgiMend Collagen Matrix), per 0.5 sq cm	Investigational
HCPCS	C9363	Skin substitute (Integra Meshed Bilayer Wound Matrix), per square cm	Investigational
HCPCS	C9364	Porcine implant, Permacol, per sq cm	Investigational
HCPCS	Q4103	Oasis burn matrix, per sq cm	Investigational
HCPCS	Q4104	Integra bilayer matrix wound dressing (BMWD), per sq cm	Investigational
HCPCS	Q4108	Integra matrix, per sq cm	Investigational
HCPCS	Q4110	PriMatrix, per sq cm	Investigational
HCPCS	Q4111	GammaGraft, per sq cm	Investigational
HCPCS	Q4112	Cymetra, injectable, 1 cc	Investigational

HCPCS	Q4113	GRAFTJACKET XPRESS, injectable, 1cc	Investigational
HCPCS	Q4115	AlloSkin, per sq cm	Investigational
HCPCS	Q4117	HYALOMATRIX, per sq cm	Investigational
HCPCS	Q4118	MatriStem micromatrix, 1 mg	Investigational
HCPCS	Q4121	TheraSkin, per sq cm	Investigational
HCPCS	Q4123	AlloSkin RT, per sq cm	Investigational
HCPCS	Q4124	OASIS ultra tri-layer wound matrix, per	Investigational
HCPCS	Q4125	ArthroFlex, per sq cm	Investigational
HCPCS	Q4126	MemoDerm, DermaSpan, TranZgraft or InteguPly, per sq cm	Investigational
HCPCS	Q4127	Talymed, per sq cm	Investigational
HCPCS	Q4130	Strattice TM, per sq cm	Investigational
HCPCS	Q4132	Grafix Core, per sq cm	Investigational
HCPCS	Q4133	Grafix Prime, per sq cm	Investigational
HCPCS	Q4134	HMatrix, per sq cm	Investigational
HCPCS	Q4135	Mediskin, per sq cm	Investigational
HCPCS	Q4136	E-Z Derm, per sq cm	Investigational
HCPCS	Q4137	AmnioExcel or BioDExCel, per sq cm	Investigational
HCPCS	Q4138	BioDFence DryFlex, per sq cm	Investigational
HCPCS	Q4139	AmnioMatrix or BioDMatrix, injectable,	Investigational
HCPCS	Q4140	BioDFence, per sq cm	Investigational
HCPCS	Q4141	AlloSkin AC, per sq cm	Investigational
HCPCS	Q4142	XCM biologic tissue matrix, per sq c	Investigational
HCPCS	Q4143	Repriza, per sq cm	Investigational
HCPCS	Q4145	EpiFix, injectable, 1 mg	Investigational
HCPCS	Q4146	Tensix, per sq cm	Investigational
HCPCS	Q4147	Architect, Architect PX, or Architect FX, extracellular matrix, per sq cm	Investigational
HCPCS	Q4148	Neox 1k, per sq cm	Investigational
HCPCS	Q4149	Excellagen, 0.1 cc	Investigational
HCPCS	Q4150	AlloWrap DS or dry, per sq cm	Investigational
HCPCS	Q4151	AmnioBand or Guardian, per sq cm	Investigational
HCPCS	Q4152	DermaPure, per sq cm	Investigational
HCPCS	Q4153	Dermavest and Plurivest, per sq cm	Investigational

HCPCS	Q4155	Neox Flo or Clarix Flo 1 mg	Investigational
HCPCS	Q4156	Neox 100, per sq cm	Investigational
HCPCS	Q4157	Revitalon, per sq cm	Investigational
HCPCS	Q4158	Marigen, per sq cm	Investigational
HCPCS	Q4159	Affinity, per sq cm	Investigational
HCPCS	Q4160	Nushield, per sq cm	Investigational
HCPCS	Q4161	Bio-ConneKt wound matrix, per sq cm	Investigational
HCPCS	Q4162	AmnioPro Flow, BioSkin Flow, BioRenew Flow, WoundEx Flow, Amniogen-A, Amniogen-C, 0.5 c	Investigational
HCPCS	Q4163	AmnioPro, BioSkin, BioRenew, WoundEx, Amniogen-45, Amniogen-	Investigational
HCPCS	Q4164	Helicoll, per sq cm	Investigational
HCPCS	Q4165	Keramatrix, per square centimeter	Investigational
HCPCS	Q4166	Cytal, per square centimeter	Investigational
HCPCS	Q4167	Truskin, per square centimeter	Investigational
HCPCS	Q4168	Amnioband, 1mg	Investigational
HCPCS	Q4169	Artacent wound, per square	Investigational
HCPCS	Q4170	Cygnus, per square centimeter	Investigational
HCPCS	Q4171	Interfyl, 1mg	Investigational
HCPCS	Q4173	PalinGen or PalinGen XPlus, per square centimeter	Investigational
HCPCS	Q4174	PalinGen or ProMatrX, 0.36mg per	Investigational
HCPCS	Q4175	Miroderm, per square centimeter	Investigational
HCPCS	Q4195	Puraply, per square centimeter	Investigational
HCPCS	Q4196	Puraply am, per square centimeter	Investigational
HCPCS	Q4197	Puraply xt, per square centimeter	Investigational
HCPCS	Q4205	Membrane graft or membrane wrap, per sq	Investigational
HCPCS	Q4206	Fluid Flow or Fluid GF, 1 cc	Investigational
HCPCS	Q4208	Novafix, per sq cm	Investigational
HCPCS	Q4209	SurGraft, per sq cm	Investigational
HCPCS	Q4210	Axolotl Graft or Axolotl DualGraft, per sq	Investigational
HCPCS	Q4211	Amnion Bio or AxoBioMembrane, per sq cm	Investigational
HCPCS	Q4212	AlloGen, per cc	Investigational
HCPCS	Q4213	Ascent, 0.5 mg	Investigational

HCPCS	Q4214	Cellesta Cord, per sq cm	Investigational
HCPCS	Q4215	Axolotl Ambient or Axolotl Cryo, 0.1 mg	Investigational
HCPCS	Q4216	Artacent Cord, per sq cm	Investigational
HCPCS	Q4217	WoundFix, BioWound, WoundFix Plus,	Investigational
HCPCS	Q4218	SurgiCORD, per sq cm	Investigational
HCPCS	Q4219	SurgiGRAFT-DUAL, per sq cm	Investigational
HCPCS	Q4220	BellaCell HD or Surederm, per sq cm	Investigational
HCPCS	Q4221	Amnio Wrap2, per sq cm	Investigational
HCPCS	Q4222	ProgenaMatrix, per sq cm	Investigational
HCPCS	Q4226	MyOwn Skin, includes harvesting and preparation procedures, per sq cm	Investigational
HCPCS	Q4249	Amniply, for topical use only, per square centimeter	Investigational
HCPCS	Q4250	Amnioamp-mp, per square centimeter	Investigational
HCPCS	Q4254	Novafix dl, per square centimeter	Investigational
HCPCS	Q4255	Reguard, for topical use only, per square centimeter	Investigational
Modifier-JC		Skin substitute used as a graft	
Modifier-JD		Skin substitute not used as a graft	