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Bioengineered Skin and Soft Tissue Substitutes, Amniotic Membrane and Amniotic Fluid Corporate Medical Policy

File Name: Bioengineered Skin and Soft Tissue Substitutes and Amniotic Membrane and

Amniotic Fluid

File Code: 7.01.VT113 Origination: 09/2016 Last Review: 10/2024 Next Review: 07/2025

Effective Date: 11/01/2024 & Adaptive Maintenance Effective 10/01/2024 Refer to Policy

Implementation Table

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

NOTE: Breast reconstruction involving allogenic acellular dermal matrix products is addressed in the BCBSVT Breast Surgery and Breast Prosthesis Corporate Medical Policy. Refer to this policy for more information.

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

- AlloPatch^{®a}
- Apligraf b ®
- Dermagraft b
- Integra Omnigraft™ Dermal Regeneration Matrix (also known as Omnigraft™) and

Page 1 of 16

Integra Flowable Wound Matrix

- mVASC®
- TheraSkin®
- Affinity[®]
- AmnioBand® Membrane
- Biovance[®]
- EpiCord[®]
- EpiFix®
- Grafix™

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 Templateb.

Human amniotic membrane grafts with or without suture (Prokera®, AmbioDisk™) may be considered **medically necessary** for the treatment of ANY of the following ophthalmic indications:

- Neurotrophic keratitis with ocular surface damage and inflammation that does not respond to conservative therapy;
- Corneal ulcers and melts that do not respond to initial conservative therapy;
- Corneal perforation when there is active inflammation after corneal transplant

Page 2 of 16

^a Banked human tissue.

^b FDA premarket approval.

^c FDA 510(k) clearance.

^d FDA-approved under an HDE

- requiring adjunctive treatment;
- Bullous keratopathy as a palliative measure in patients who are not candidates for curative treatment (eg, endothelial or penetrating keratoplasty);
- Partial limbal stem cell deficiency with extensive diseased tissue where selective removal alone is not sufficient;
- Moderate or severe Stevens-Johnson syndrome;
- Persistent epithelial defects that do not respond within 2 days to conservative therapy;
- Severe dry eye (DEWS 3 or 4) with ocular surface damage and inflammation that remains symptomatic after Steps 1, 2, and 3 of the dry eye disease management algorithm (see Policy Guidelines);
- Moderate or severe acute ocular chemical burn.

Human amniotic membrane grafts with suture or glue may be considered **medically necessary** for the treatment of the following ophthalmic indications:

- Corneal perforation when corneal tissue is not immediately available; OR
- Pterygium repair when there is insufficient healthy tissue to create a conjunctival autograft.

When a service is considered investigational

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

Human amniotic membrane grafts with or without suture are considered **investigational** for all ophthalmic indications not outlined above.

Injection of micronized or particulated human amniotic membrane is considered **investigational** for all indications, including but not limited to treatment of osteoarthritis and plantar fasciitis.

Injection of human amniotic fluid is considered investigational for all indications.

All other human amniotic products (eg, derived from amnion, chorion, amniotic fluid, umbilical cord, or Wharton's jelly) not listed above are considered **investigational** (see policy guidelines).

Use of human amniotic membrane grafts and human amniotic products for all other indications not listed above, including but not limited to treatment of lower-extremity ulcers due to venous insufficiency and repair following Mohs micrographic surgery, is 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™

Page 3 of 16

- AlloSkin™RT
- Apis®
- Aongen™ Collagen Matrix
- Architect® ECM, PX, FX
- ArthroFlex[™] (Flex Graft)
- AxoGuard®Nerve Protector (AxoGen)
- Biobrane®/Biobrane-L
- Bio-ConneK^{t®} Wound Matrix
- CollaCare®
- CollaCare® Dental
- Collagen Wound Dressing (Oasis Research)
- CollaGUARD®
- CollaMend™
- CollaWound™
- Coll-e-derm
- Collexa®
- Collieva®
- Conexa™
- Coreleader Colla-Pad
- CorMatrix[®]
- Cymetra[™] (Micronized AlloDerm)[™]
- Cytal[™] (previously MatriStem[®])
- 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™
- hMatrix[®]
- Hyalomatrix[®]
- Hyalomatrix[®] PA
- Integra™ Bilayer Wound Matrix
- Integra® Matrix Wound Dressing (previously Avagen)
- InteguPly[®]
- Keramatrix®
- Kerecis™ Omega3
- Keroxx™
- MatriDerm[®]
- MatriStem

- Matrix HD™
- MicroMatrix®
- Miroderm[®]
- Mediskin®
- MemoDerm™
- Microderm[®] biologic wound matrix
- MvOwn skin
- Oasis® Burn Matrix
- Oasis® Ultra
- Ologen™ 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 Matrix (previously FortaDerm™)
- PuraPly™ AM (Antimicrobial Wound Matrix)
- Puros[®] Dermis
- RegenePro™
- Repliform®
- ReCell®
- Repriza™
- SkinTE™
- StrataGraft[®]
- Strattice™
- SUPRA SDRM®
- Suprathel®
- SurgiMend®
- Symphony™
- Talvmed®
- TenoGlide™
- TenSIX™ Acellular Dermal Matrix
- TissueMend
- TheraForm™ Standard/Sheet
- **TheraGenesis®**
- TransCyte™
- TruSkin™
- Tutomesh™ Fenestrated Bovine Pericardium
- 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 May 2024. Accessed July 2024.
- 2. Blue Cross and Blue Shield Association Medical Policy MPRM 7.01.149 Amniotic Membrane and Amniotic Fluid. Last reviewed April 2024. Accessed July 2024.

Related Policies

Breast Surgery and Breast Prosthesis

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.

Page 6 of 16

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.	

Page **7** of **16**

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.	
07/2021	Policy name changed from Bioengineered Skin and Soft Tissue Substitutes to Bioengineered Skin and Soft Tissue Substitutes and Amniotic Membrane and Amniotic Fluid. Clarification for ophthalmic indications. References updated. Clarified that services related to all breast surgeries are covered in the separate policy and removed previous references to them from this policy. No material changes in policy statement. Coding Summary: Coding table changes the following codes changed from investigational to requiring prior approval: Q4108, Q4132, Q4133, Q4137, Q4138, Q4139, Q4140, Q4145, Q4148, Q4150, Q4151, Q4153, Q4155, Q4156, Q4157, Q4159, Q4160, Q4162, Q4163, Q4168, Q4169, Q4170, Q4171, Q4173, Q4174, Q4175, Q4185, Q4189, Q4192, Q4195, Q4197, Q4205, Q4206, Q4208, Q4209, Q4210, Q4211, Q4212, Q4213, Q4214, Q4215, Q4216, Q4217, Q4218, Q4219, Q4220, Q4221, Q4226, Q4249, Q4250, Q4254, Q4255.The following codes have be changed from requiring prior approval to investigational: Q4179, Q4182, Q4193, Q4200, Q4202, Q4203. The following code has changed from medically necessary to requiring prior approval: Q4154.	
10/2021	Adaptive Maintenance Effective 10/01/2021: Deleted codes Q4228 & Q4236. Added codes Q4251, Q4252 & Q4253 as Investigational to policy coding table.	
12/2021	Adaptive Maintenance Effective 01/01/2022: Added codes A2001, A2002, A2003, A2004, A2005, A2006, A2007, A2008, A2009, A2010, Q4199 to coding table as investigational.	
03/2022	Adaptive Maintenance Effective 04/01/2022: Added codes: A2011, A2012, Q4224, Q4225, Q4256, Q4257, Q4258 to coding table as requiring prior approval. Added code A2013 to coding table as investigational. Added code A4100 to coding table will suspend for medical review.	
07/2022	Adaptive Maintenance Effective 07/01/2022: A4200 descriptor revised, Added codes Q4259, Q4260, Q4261 as Investigational.	
10/2022	Adaptive Maintenance Effective 10/01/2022: Q4128 descriptor revised, Added codes: A2014, A2015, A2016, A2017, A2018 as investigational.	
12/2022	Adaptive Maintenance Effective 01/01/2023: Deleted code C1849, added codes Q4262, Q4263, Q4264 as investigational.	
03/2023	Adaptive Maintenance Effective 04/01/2023: Added codes A2019, A2020, A2021, Q4265, Q4266, Q4267, Q4268, Q4269, Q4270, Q4271 as investigational to coding table.	

Page **8** of **16** Medical Policy Number: 7.01.VT113

indication for use of human amniotic membrane grafts and human amniotic products for all other indications not listed, including but limited to treatment of lower-extremity ulcers due to venous insuf and repair following Mohs micrographic surgery. Minor changes for and consistency. Adaptive Maintenance Effective 07/01/2023: Added codes Q4272, Q4274, Q4275, Q4276, Q4277, Q4278, Q4280, Q4281, Q4282, Q4283 investigational to coding table. O9/2023 Adaptive Maintenance Effective 10/01/2023: Added codes A2022, A2024, A2025, Q4285, Q4286 as investigational to coding table. Adaptive Maintenance Effective 01/01/2024: Added codes: Q4279, Q4288, Q4289, Q4290, Q4291, Q4292, Q4293, Q4294, Q4295, Q4296, Q4297, Q4298, Q4299, Q4300, Q4301, Q4302, Q4303, Q4304 to the table as investigational. Revised descriptor Q4225. Adaptive Maintenance Effective 04/01/2024: Added codes: A2026, Q4306, Q4307, Q4308, Q4309, Q4310 as investigational to coding table. Adaptive Maintenance Effective 07/01/2024: Deleted codes: Q4210 Q4277 from coding table. Added Codes: Q4311, Q4312, Q4313, Q4315, Q4315, Q4316, Q4317, Q4318, Q4319, Q4320, Q4321, Q4322, Q4324, Q4325, Q4326, Q4327, Q4328, Q4329, Q4330, Q4331, Q4332, Q4324, Q4325, Q4326, Q4327, Q4328, Q4329, Q4330, Q4331, Q4332, Q4324, Q4325, Q4326, Q4327, Q4328, Q4329, Q4330, Q4331, Q4332, Q4324, Q4325, Q4326, Q4327, Q4328, Q4329, Q4330, Q4331, Q4332, Q4324, Q4325, Q4326, Q4327, Q4328, Q4329, Q4330, Q4331, Q4332, Q4324, Q4325, Q4326, Q4327, Q4328, Q4329, Q4330, Q4331, Q4332, Q4324, Q4325, Q4326, Q4327, Q4328, Q4329, Q4330, Q4331, Q4332, Q4324, Q4325, Q4326, Q4327, Q4328, Q4329, Q4330, Q4331, Q4332, Q4324, Q4325, Q4326, Q4327, Q4328, Q4329, Q4330, Q4331, Q4332, Q4324, Q4325, Q4326, Q4327, Q4328, Q4329, Q4330, Q4331, Q4332, Q4324, Q4325, Q4326, Q4327, Q4328, Q4329, Q4330, Q4331, Q4326, Q4327, Q4328, Q4329, Q4330, Q4331, Q4326, Q4327, Q4328, Q4329, Q4330, Q4331, Q4326, Q4327, Q4328, Q4329, Q4330, Q4321, Q4326, Q4327, Q4328, Q4329, Q4330, Q4321, Q4326, Q4327, Q4328, Q4329, Q4330, Q4321, Q4326, Q4327			
A2024, A2025, Q4285, Q4286 as investigational to coding table. 12/2023 Adaptive Maintenance Effective 01/01/2024: Added codes: Q4279, Q4288, Q4289, Q4290, Q4291, Q4292, Q4293, Q4294, Q4295, Q4296, Q4297, Q4298, Q4299, Q4300, Q4301, Q4302, Q4303, Q4304 to the table as investigational. Revised descriptor Q4225. O4/2024 Adaptive Maintenance Effective 04/01/2024: Added codes: A2026, Q4306, Q4307, Q4308, Q4309, Q4310 as investigational to coding table beleted code Q4244 from coding table. O6/2024 Adaptive Maintenance Effective 07/01/2024: Deleted codes: Q4210 Q4277 from coding table. Added Codes: Q4311, Q4312, Q4313, Q4315, Q4316, Q4317, Q4318, Q4319, Q4320, Q4321, Q4322, Q4324, Q4325, Q4326, Q4327, Q4328, Q4329, Q4330, Q4331, Q4332 as investigational. O7/2024 Policy reviewed. Addition of mVASC® and TheraSkin® as requiring pri approval for treatment of chronic, noninfected, full-thickness diabelower-extremity ulcers. Minor formatting changes for clarity. Additinamed investigational products. References updated. Removed codes	/2023	amniotic products for all other indications not listed, including but not limited to treatment of lower-extremity ulcers due to venous insufficiency and repair following Mohs micrographic surgery. Minor changes for clarity and consistency. Adaptive Maintenance Effective 07/01/2023: Added codes Q4272, Q4273, Q4274, Q4275, Q4276, Q4277, Q4278, Q4280, Q4281, Q4282, Q4283, Q4284	
Q4288, Q4289, Q4290, Q4291, Q4292, Q4293, Q4294, Q4295, Q4296 Q4297, Q4298, Q4299, Q4300, Q4301, Q4302, Q4303, Q4304 to the table as investigational. Revised descriptor Q4225. O4/2024 Adaptive Maintenance Effective 04/01/2024: Added codes: A2026, Q4306, Q4307, Q4308, Q4309, Q4310 as investigational to coding to Deleted code Q4244 from coding table. O6/2024 Adaptive Maintenance Effective 07/01/2024: Deleted codes: Q4210 Q4277 from coding table. Added Codes: Q4311, Q4312, Q4313, Q43 Q4315, Q4316, Q4317, Q4318, Q4319, Q4320, Q4321, Q4322, Q4324, Q4325, Q4326, Q4327, Q4328, Q4329, Q4330, Q4331, Q4332 as investigational. O7/2024 Policy reviewed. Addition of mVASC® and TheraSkin® as requiring pri approval for treatment of chronic, noninfected, full-thickness diabelower-extremity ulcers. Minor formatting changes for clarity. Additinamed investigational products. References updated. Removed codes	/2023	Adaptive Maintenance Effective 10/01/2023: Added codes A2022, A2023, A2024, A2025, Q4285, Q4286 as investigational to coding table.	
Q4306, Q4307, Q4308, Q4309, Q4310 as investigational to coding to Deleted code Q4244 from coding table. Adaptive Maintenance Effective 07/01/2024: Deleted codes: Q4210 Q4277 from coding table. Added Codes: Q4311, Q4312, Q4313, Q43 Q4315, Q4316, Q4317, Q4318, Q4319, Q4320, Q4321, Q4322, Q4324 Q4324, Q4325, Q4326, Q4327, Q4328, Q4329, Q4330, Q4331, Q4332 as investigational. Policy reviewed. Addition of mVASC® and TheraSkin® as requiring pri approval for treatment of chronic, noninfected, full-thickness diabelower-extremity ulcers. Minor formatting changes for clarity. Additinamed investigational products. References updated. Removed codes	/2023	Adaptive Maintenance Effective 01/01/2024: Added codes: Q4279, Q4287, Q4288, Q4289, Q4290, Q4291, Q4292, Q4293, Q4294, Q4295, Q4296, Q4297, Q4298, Q4299, Q4300, Q4301, Q4302, Q4303, Q4304 to the coding table as investigational. Revised descriptor Q4225.	
Q4277 from coding table. Added Codes: Q4311, Q4312, Q4313, Q4320, Q4315, Q4316, Q4317, Q4318, Q4319, Q4320, Q4321, Q4322, Q4324, Q4325, Q4326, Q4327, Q4328, Q4329, Q4330, Q4331, Q4332 as investigational. Policy reviewed. Addition of mVASC® and TheraSkin® as requiring pri approval for treatment of chronic, noninfected, full-thickness diabelower-extremity ulcers. Minor formatting changes for clarity. Additinamed investigational products. References updated. Removed codes	/2024	Adaptive Maintenance Effective 04/01/2024: Added codes: A2026, Q4305, Q4306, Q4307, Q4308, Q4309, Q4310 as investigational to coding table. Deleted code Q4244 from coding table.	
approval for treatment of chronic, noninfected, full-thickness diabelower-extremity ulcers. Minor formatting changes for clarity. Additinamed investigational products. References updated. Removed code	/2024	Adaptive Maintenance Effective 07/01/2024: Deleted codes: Q4210 & Q4277 from coding table. Added Codes: Q4311, Q4312, Q4313, Q4314, Q4315, Q4316, Q4317, Q4318, Q4319, Q4320, Q4321, Q4322, Q4323, Q4324, Q4325, Q4326, Q4327, Q4328, Q4329, Q4330, Q4331, Q4332, Q4333 as investigational.	
11/01/2024.	/2024	Policy reviewed. Addition of mVASC® and TheraSkin® as requiring prior approval for treatment of chronic, noninfected, full-thickness diabetic lower-extremity ulcers. Minor formatting changes for clarity. Addition of named investigational products. References updated. Removed code Q4121 from investigational to requiring prior approval. Effective	
A2029, Q4334, Q4335, Q4336, Q4337, Q4338, Q4339, Q4340, Q4341,		Adaptive Maintenance Effective 10/01/2024: Added codes A2027, A2028, A2029, Q4334, Q4335, Q4336, Q4337, Q4338, Q4339, Q4340, Q4341, Q4342, Q4343, Q4344, Q4345 to coding table as investigational. Code A2024 descriptor revised.	

Eligible providers

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

Approved by BCBSVT Medical Directors

Tom Weigel, MD, MBA Vice President & Chief Medical Officer

Tammaji P. Kulkarni, MD Senior Medical Director

Page **9** of **16**

Attachment I Coding Table & Instructions

The following codes will be considered as medically necessary, require prior approval or investigational when applicable criteria have been met.			
Code	Description	Mapping Instructions	
	Implantation of biologic implant (eg, acellular dermal matrix) for soft tissue reinforcement (ie, breast, trunk) (List separately in addition to code		
15777	for primary procedure)	Requires Prior Approval	
A2001	Innovamatrix ac, per square centimeter	Investigational	
A2002	Mirragen advanced wound matrix, per square centimeter	Investigational	
A2004	Xcellistem, 1 mg	Investigational	
A2005	Microlyte matrix, per square centimeter	Investigational	
A2006	Novosorb synpath dermal matrix, per square centimeter	Investigational	
A2007	Restrata, per square centimeter	Investigational	
A2008	Theragenesis, per square centimeter	Investigational	
A2009	Symphony, per square centimeter	Investigational	
A2010	Apis, per square centimeter	Investigational	
A2011	Supra sdrm, per square centimeter	Requires Prior Approval	
A2012	Suprathel, per square centimeter	Requires Prior Approval	
A2013	Innovamatrix fs, per square centimeter	Investigational	
A2014	Omeza collagen matrix, per 100 mg	Investigational	
A2015	Phoenix wound matrix, per square centimeter	Investigational	
A2016	Permeaderm b, per square centimeter	Investigational	
A2017	Permeaderm glove, each	Investigational	
A2018	Permeaderm c, per square centimeter	Investigational	
A2019	Kerecis omega3 marigen shield, per square centimeter	Investigational	
A2020	Ac5 advanced wound system (ac5)	Investigational	
A2021	Neomatrix, per square centimeter	Investigational	
A2022	Innovaburn or innovamatrix xl, per square centimeter	Investigational	
A2023	Innovamatrix pd, 1 mg	Investigational	
A2024	Resolve matrix or xenopatch, per square centimeter	Investigational	
A2025	Miro3d, per cubic centimeter	Investigational	
A2026	Restrata minimatrix, 5 mg	Investigational	
A2027	Matriderm, per square centimeter	Investigational	

Page 10 of 16 Medical Policy Number: 7.01.VT113

A2028	Micromatrix flox por mg	Investigational
AZUZO	Micromatrix flex, per mg	Investigationat
	Mirotract wound matrix sheet, per cubic	
A2029	centimeter	Investigational
	Skin substitute, FDA cleared as a device, not	
A4100	otherwise specified	Suspend for Medical Review
	Acellular pericardial tissue matrix of nonhuman	
C9354	origin (Veritas), per sq cm	Investigational
	Tendon, porous matrix of cross-linked collagen	
	and glycosaminoglycan matrix (TenoGlide Tendon	
C9356	Protector Sheet), per sq cm	Investigational
	Dermal substitute, native, nondenatured	
60350	collagen, fetal bovine origin (SurgiMend Collagen	
C9358	Matrix), per 0.5 sq cm	Investigational
	Dermal substitute, native, nondenatured	
C9360	collagen, neonatal bovine origin (SurgiMend Collagen Matrix), per 0.5 sq cm	Investigational
C 9300	Skin substitute (Integra Meshed Bilayer Wound	Investigationat
C9363	Matrix), per sq cm	Investigational
C9364	Porcine implant, Permacol, per sq cm	Investigational
Q4100	Skin substitute, not otherwise specified	Requires Prior Approval
Q4101	Apligraf, per sq cm	Requires Prior Approval
Q4102	Oasis wound matrix, per sq cm	Requires Prior Approval
Q4103	Oasis burn matrix, per sq cm	Investigational
	Integra bilayer matrix wound dressing (BMWD),	
Q4104	per sq cm	Investigational
	Integra dermal regeneration template (DRT) or	
	Integra Omnigraft dermal regeneration matrix,	
Q4105	per sq cm	Requires Prior Approval
Q4106	Dermagraft, per sq cm	Requires Prior Approval
Q4107	GRAFTJACKET, per sq cm	Requires Prior Approval
Q4108 Q4110	Integra matrix, per sq cm	Requires Prior Approval Investigational
Q4110 Q4111	PriMatrix, per sq cm GammaGraft, per sq cm	Investigational
Q4111	Cymetra, injectable, 1 cc	Investigational
Q4113	GRAFTJACKET XPRESS, injectable, 1 cc	Investigational
Q4114	Integra flowable wound matrix, injectable, 1 cc	Requires Prior Approval
Q4115	AlloSkin, per sq cm	Investigational
Q4116	AlloDerm, per sq cm	Requires Prior Approval
Q4117	HYALOMATRIX, per sq cm	Investigational
Q4118	MatriStem micromatrix, 1 mg	Investigational
Q4121	TheraSkin, per sq cm	Requires Prior Approval
	DermACELL, DermACELL AWM or DermACELL	
Q4122	AWM Porous, per sq cm	Requires Prior Approval
Q4123	AlloSkin RT, per sq cm	Investigational
Q4124	OASIS ultra tri-layer wound matrix, per sq cm	Investigational

Page **11** of **16** Medical Policy Number: 7.01.VT113

Q4125	ArthroFlex, per sq cm	Investigational
	MemoDerm, DermaSpan, TranZgraft or InteguPly,	, .
Q4126	per sq cm	Investigational
Q4127	Talymed, per sq cm	Investigational
Q4128	Flex hd, or allopatch hd, per square centimeter	Requires Prior Approval
Q4130	Strattice TM, per sq cm	Investigational
Q4132	Grafix Core and GrafixPL Core, per sq cm	Requires Prior Approval
	Grafix PRIME, GrafixPL PRIME, Stravix and	
Q4133	StravixPL, per sq cm	Requires Prior Approval
Q4134	HMatrix, per sq cm	Investigational
Q4135	Mediskin, per sq cm	Investigational
Q4136	E-Z Derm, per sq cm	Investigational
	AmnioExcel, AmnioExcel Plus or BioDExcel, per	
Q4137	sq cm	Requires Prior Approval
Q4138	BioDFence DryFlex, per sq cm	Requires Prior Approval
Q4139	AmnioMatrix or BioDMatrix, injectable, 1 cc	Requires Prior Approval
Q4140	BioDFence, per sq cm	Requires Prior Approval
Q4141	AlloSkin AC, per sq cm	Investigational
Q4142	XCM biologic tissue matrix, per sq cm	Investigational
Q4143	Repriza, per sq cm	Investigational
Q4145	EpiFix, injectable, 1 mg	Requires Prior Approval
Q4146	Tensix, per sq cm	Investigational
	Architect, Architect PX, or Architect FX,	
Q4147	extracellular matrix, per sq cm	Investigational
	Neox Cord 1K, Neox Cord RT, or Clarix Cord 1K,	
Q4148	per sq cm	Requires Prior Approval
Q4149	Excellagen, 0.1 cc	Investigational
Q4150	AlloWrap DS or dry, per sq cm	Requires Prior Approval
Q4151	AmnioBand or Guardian, per sq cm	Requires Prior Approval
Q4152	DermaPure, per sq cm	Investigational
Q4153	Dermavest and Plurivest, per sq cm	Requires Prior Approval
Q4154	Biovance, per sq cm	Requires Prior Approval
Q4155	Neox Flo or Clarix Flo 1 mg	Requires Prior Approval
Q4156	Neox 100 or Clarix 100, per sq cm	Requires Prior Approval
Q4157	Revitalon, per sq cm	Requires Prior Approval
Q4158	Kerecis Omega3, per sq cm	Investigational
Q4159	Affinity, per sq cm	Requires Prior Approval
Q4160	Nushield, per sq cm	Requires Prior Approval
Q4161	Bio-ConneKt wound matrix, per sq cm	Investigational
Q4162	WoundEx Flow, BioSkin Flow, 0.5 cc	Requires Prior Approval
Q4163	WoundEx, BioSkin, per sq cm	Requires Prior Approval
Q4164	Helicoll, per sq cm	Investigational
Q4165	Keramatrix or Kerasorb, per sq cm	Investigational
Q4166	Cytal, per sq cm	Investigational
Q4167	Truskin, per sq cm	Investigational
Q4168	AmnioBand, 1 mg	Requires Prior Approval
Q4169	Artacent wound, per sq cm	Requires Prior Approval

Page **12** of **16** Medical Policy Number: 7.01.VT113

Q4170	Cygnus, per sq cm	Requires Prior Approval
Q4171	Interfyl, 1 mg	Requires Prior Approval
Q4173	PalinGen or PalinGen XPlus, per sq cm	Requires Prior Approval
Q4174	PalinGen or ProMatrX, 0.36 mg per 0.25 cc	Requires Prior Approval
Q4175	Miroderm, per sq cm	Requires Prior Approval
Q4176	Neopatch or therion, per square centimeter	Requires Prior Approval
Q4170 Q4177	FlowerAmnioFlo, 0.1 cc	Requires Prior Approval
Q4177 Q4178	FlowerAmnioPatch, per sq cm	Requires Prior Approval
		Investigational
Q4179	FlowerDerm, per sq cm	
Q4180	Revita, per sq cm	Requires Prior Approval
Q4181	Amnio Wound, per sq cm	Requires Prior Approval
Q4182	Transcyte, per sq cm	Investigational
Q4183	Surgigraft, per sq cm	Requires Prior Approval
Q4184	Cellesta or Cellesta Duo, per sq cm	Requires Prior Approval
0.4405	Cellesta Flowable Amnion (25 mg per cc); per 0.5	
Q4185	CC	Requires Prior Approval
Q4186	Epifix, per sq cm	Requires Prior Approval
Q4187	Epicord, per sq cm	Requires Prior Approval
Q4188	AmnioArmor, per sq cm	Requires Prior Approval
Q4189	Artacent AC, 1 mg	Requires Prior Approval
Q4190	Artacent AC, per sq cm	Requires Prior Approval
Q4191	Restorigin, per sq cm	Requires Prior Approval
Q4192	Restorigin, 1 cc	Requires Prior Approval
Q4193	Coll-e-Derm, per sq cm	Investigational
Q4194	Novachor, per sq cm	Requires Prior Approval
Q4195	PuraPly, per sq cm	Requires Prior Approval
Q4196	PuraPly AM, per sq cm	Investigational
Q4197	PuraPly XT, per sq cm	Requires Prior Approval
Q4198	Genesis Amniotic Membrane, per sq cm	Requires Prior Approval
Q4199	Cygnus matrix, per square centimeter	Investigational
Q4200	SkinTE, per sq cm	Investigational
Q4201	Matrion, per sq cm	Requires Prior Approval
Q4202	Keroxx (2.5 g/cc), 1 cc	Investigational
Q4203	Derma-Gide, per sq cm	Investigational
Q4204	XWRAP, per sq cm	Requires Prior Approval
Q4205	Membrane Graft or Membrane Wrap, per sq cm	Requires Prior Approval
Q4206	Fluid Flow or Fluid GF, 1 cc	Requires Prior Approval
Q4208	Novafix, per sq cm	Requires Prior Approval
Q4209	SurGraft, per sq cm	Requires Prior Approval
Q4211	Amnion Bio or AxoBioMembrane, per sq cm	Requires Prior Approval
Q4212	AlloGen, per cc	Requires Prior Approval
Q4213	Ascent, 0.5 mg	Requires Prior Approval
Q4214	Cellesta Cord, per sq cm	Requires Prior Approval
Q4215	Axolotl Ambient or Axolotl Cryo, 0.1 mg	Requires Prior Approval
Q4216	Artacent Cord, per sq cm	Requires Prior Approval
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Page **13** of **16** Medical Policy Number: 7.01.VT113

	WoundFix, BioWound, WoundFix Plus, BioWound	
	Plus, WoundFix Xplus or BioWound Xplus, per sq	
Q4217	cm	Requires Prior Approval
Q4218	SurgiCORD, per sq cm	Requires Prior Approval
Q4219	SurgiGRAFT-DUAL, per sq cm	Requires Prior Approval
Q4220	BellaCell HD or Surederm, per sq cm	Requires Prior Approval
Q4221	Amnio Wrap2, per sq cm	Requires Prior Approval
Q4222	ProgenaMatrix, per sq cm	Investigational
Q.222	Human health factor 10 amniotic patch (hhf10-	estigationat
Q4224	p), per square centimeter	Requires Prior Approval
	Amniobind or dermabind tl, per square	
Q4225	centimeter	Requires Prior Approval
Q4226	ProgenaMatrix, per sq cm	Requires Prior Approval
Q4227	AmnioCoreTM, per sq cm	Requires Prior Approval
Q4229	Cogenex Amniotic Membrane, per sq cm	Requires Prior Approval
Q4230	Cogenex Flowable Amnion, per 0.5 cc	Requires Prior Approval
Q4231	Corplex P, per cc	Requires Prior Approval
Q4232	Corplex, per sq cm	Requires Prior Approval
Q4233	SurFactor or NuDyn, per 0.5 cc	Requires Prior Approval
Q4234	XCellerate, per sq cm	Requires Prior Approval
Q4235	AMNIOREPAIR or AltiPly, per sq cm	Requires Prior Approval
Q4237	Cryo-Cord, per sq cm	Requires Prior Approval
Q4238	Derm-Maxx, per sq cm	Requires Prior Approval
Q4239	Amnio-Maxx or Amnio-Maxx Lite, per sq cm	Requires Prior Approval
Q4240	CoreCyte, for topical use only, per 0.5 cc	Requires Prior Approval
Q4241	PolyCyte, for topical use only, per 0.5 cc	Requires Prior Approval
Q4242	AmnioCyte Plus, per 0.5 cc	Requires Prior Approval
Q4245	AmnioText, per cc	Requires Prior Approval
Q4246	CoreText or ProText, per cc	Requires Prior Approval
Q4247	Amniotext patch, per sq cm	Requires Prior Approval
	Dermacyte Amniotic Membrane Allograft, per sq	
Q4248	cm	Requires Prior Approval
Q4249	AMNIPLY, for topical use only, per sq cm	Requires Prior Approval
Q4250	AmnioAmp-MP, per sq cm	Requires Prior Approval
Q4251	Vim, per square centimeter	Investigational
Q4252	Vendaje, per square centimeter	Investigational
	Zenith amniotic membrane, per square	
Q4253	centimeter	Investigational
Q4254	Novafix DL, per sq cm	Requires Prior Approval
Q4255	REGUaRD, for topical use only, per sq cm	Requires Prior Approval
Q4256	Mlg complete, per square centimeter	Requires Prior Approval
Q4257	Relese, per square centimeter	Requires Prior Approval
Q4258	Enverse, per square centimeter	Requires Prior Approval
	Celera dual layer or celera dual membrane, per	
Q4259	square centimeter	Investigational
Q4260	Signature apatch, per square centimeter	Investigational
Q4261	Tag, per square centimeter	Investigational

Page **14** of **16** Medical Policy Number: 7.01.VT113

	Dual layer impax membrane, per square	
Q4262	centimeter	Investigational
Q4263	Surgraft tl, per square centimeter	Investigational
Q4264	Cocoon membrane, per square centimeter	Investigational
Q4265	Neostim tl, per square centimeter	Investigational
Q4266		Investigational
Q4266 Q4267	Neostim membrane, per square centimeter	Investigational
Q4267 Q4268	Neostim dl, per square centimeter	•
	Surgraft st. per square centimeter	Investigational Investigational
Q4269	Surgraft xt, per square centimeter	
Q4270	Complete sl, per square centimeter	Investigational
Q4271	Complete ft, per square centimeter	Investigational
Q4272	Esano a, per square centimeter	Investigational
Q4273	Esano aaa, per square centimeter	Investigational
Q4274	Esano ac, per square centimeter	Investigational
Q4275	Esano aca, per square centimeter	Investigational
Q4276	Orion, per square centimeter	Investigational
Q4278	Epieffect, per square centimeter	Investigational
Q4279	Vendaje ac, per square centimeter	investigational
Q4280	Xcell amnio matrix, per square centimeter	Investigational
Q4281	Barrera sl or barrera dl, per square centimeter	Investigational
Q4282	Cygnus dual, per square centimeter	Investigational
	Biovance tri-layer or biovance 31, per square	
Q4283	centimeter	Investigational
Q4284	Dermabind sl, per square centimeter	Investigational
Q4285	Nudyn sl or nudyn slw, per square centimeter	Investigational
Q4286	Nudyn sl or nudyn slw, per square centimeter	Investigational
Q4287	Dermabind dl, per square centimeter	Investigational
Q4288	Dermabind ch, per square centimeter	Investigational
	Revoshield + amniotic barrier, per square	
Q4289	centimeter	Investigational
Q4290	Membrane wrap-hydro, per square centimeter	Investigational
Q4291	Lamellas xt, per square centimeter	Investigational
Q4292	Lamellas, per square centimeter	Investigational
Q4293	Acesso dl, per square centimeter	Investigational
Q4294	Amnio quad-core, per square centimeter	Investigational
	Amnio tri-core amniotic, per square	
Q4295	centimeter	Investigational
Q4296	Rebound matrix, per square centimeter	Investigational
Q4297	Emerge matrix, per square centimeter	Investigational
	Amniocore pro, per square	
Q4298	centimeter	Investigational
Q4299	Amnicore pro+, per square centimeter	Investigational
Q4300	Acesso tl, per square centimeter	Investigational
Q4301	Activate matrix, per square centimeter	Investigational
Q4302	Complete aca, per square centimeter	Investigational
Q4303	Complete aa, per square centimeter	Investigational
Q4304	Grafix plus, per square centimeter	Investigational
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Page **15** of **16** Medical Policy Number: 7.01.VT113

	American amnion ac tri-layer, per square	
Q4303 C	centimeter	Investigational
Q4306 A	American amnion ac, per square centimeter	Investigational
	American amnion, per square centimeter	Investigational
	Sanopellis, per square centimeter	Investigational
	/ia matrix, per square centimeter	Investigational
	Procenta, per 100 mg	Investigational
	Acesso, per square centimeter	Investigational
		Investigational
	Acesso ac, per square centimeter	Investigational
	Dermabind fm, per square centimeter	<u> </u>
	Reeva ft, per square cenitmeter	Investigational
	Regenelink amniotic membrane allograft, per	Investigational
	quare centimeter	Investigational
	Amchoplast, per square centimeter	Investigational
	/itograft, per square centimeter	Investigational
	-graft, per square centimeter	Investigational
	anograft, per square centimeter	Investigational
	Pellograft, per square centimeter	Investigational
	Renograft, per square centimeter	Investigational
	Caregraft, per square centimeter	Investigational
	Alloply, per square centimeter	Investigational
	Amniotx, per square centimeter	Investigational
	Acapatch, per square centimeter	Investigational
	Voundplus, per square centimeter	Investigational
	Duoamnion, per square centimeter	Investigational
	Nost, per square centimeter	Investigational
	Singlay, per square centimeter	Investigational
	「otal, per square centimeter	Investigational
	Axolotl graft, per square centimeter	Investigational
	Axolotl dualgraft, per square centimeter	Investigational
	Ardeograft, per square centimeter	Investigational
Q4334 A	Amnioplast 1, per square centimeter	Investigational
	Amnioplast 2, per square centimeter	Investigational
Q4336 A	Artacent c, per square centimeter	Investigational
Q4337 A	Artacent trident, per square centimeter	Investigational
Q4338 A	Artacent velos, per square centimeter	Investigational
	Artacent vericlen, per square centimeter	Investigational
Q4340 S	impligraft, per square centimeter	Investigational
	implimax, per square centimeter	Investigational
Q4342 T	Theramend, per square centimeter	Investigational
	Dermacyte ac matrix amniotic membrane	
	allograft, per square centimeter	Investigational
	ri-membrane wrap, per square centimeter	Investigational
	Natrix hd allograft dermis, per square	
	entimeter	Investigational

Page **16** of **16** Medical Policy Number: 7.01.VT113