Bioengineered Skin and Soft Tissue Substitutes
Corporate Medical Policy

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®
- Apligraf®
- Dermagraft®
- Epifix
- Integra® Omnipatch™ Dermal Regeneration Matrix (also known as Omnipatch™) 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®
- Epifix
- Oasis™ Wound Matrix.

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])

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)
- Integra® Dermal Regeneration Template.

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:

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

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<td>09/2016</td>
<td>New Policy. Adopted BCBSA MPRM# 7.01.113.</td>
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<td>Effective 01/01/2018: Q4176, Q4177, Q4178, Q4179, Q4180, Q4181, Q4182 requiring prior approval</td>
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<td>10/2018</td>
<td>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 &amp; C9349 deleted 01/01/2017, added HCPCS codesQ4166, Q4167, Q4168, Q4169, Q4170, Q4171, Q4172, Q4173, Q4174, Q4175 effective 01/01/2017, investigational. Added -JC, -JD modifiers to table to reflect content within medical policy. Added CPT® Code 15777 require prior authorization. Added related policy section.</td>
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<td>Review 2019 Code changes effective 01/01/2019 with the following: Q4131 &amp; 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.</td>
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<td>Revised codes Q4165, Q4184 &amp; 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.</td>
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<td>Adaptive Maintenance updates: Added codes Q4249, Q4250, Q4254, Q4255 as Investigational. Simplified introduction. No change to policy statement.</td>
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Eligible providers

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

Approved by BCBSVT Medical Directors

| Joshua Plavin, MD, MPH, MBA |
| Date Approved |
| Chief Medical Officer |

| Kate McIntosh, MD, MBA, FAAP |
| Senior Medical Director |

Medical Policy Number: UM.SURG.16
## Attachment I

**Coding Table & instructions**

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<th>Description</th>
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<tr>
<td>HCPCS Q4155</td>
<td>Neox Flo or Clarix Flo 1 mg</td>
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<tr>
<td>HCPCS Q4156</td>
<td>Neox 100, per sq cm</td>
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<td>HCPCS Q4157</td>
<td>Revitalon, per sq cm</td>
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<tr>
<td>HCPCS Q4158</td>
<td>Marigen, per sq cm</td>
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<tr>
<td>HCPCS Q4159</td>
<td>Affinity, per sq cm</td>
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<tr>
<td>HCPCS Q4160</td>
<td>Nushield, per sq cm</td>
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<td>HCPCS Q4161</td>
<td>Bio-ConneKt wound matrix, per sq cm</td>
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<tr>
<td>HCPCS Q4162</td>
<td>AmnioPro Flow, BioSkin Flow, BioRenew Flow, WoundEx Flow, Amniogen-A, Amniogen-C, 0.5 c</td>
<td>Investigational</td>
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<tr>
<td>HCPCS Q4163</td>
<td>AmnioPro, BioSkin, BioRenew, WoundEx, Amniogen-45, Amniogen-45</td>
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<tr>
<td>HCPCS Q4164</td>
<td>Helicoll, per sq cm</td>
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<tr>
<td>HCPCS Q4165</td>
<td>Keramatrix, per square centimeter</td>
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<td>HCPCS Q4166</td>
<td>Cytal, per square centimeter</td>
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<tr>
<td>HCPCS Q4167</td>
<td>Truskin, per square centimeter</td>
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<tr>
<td>HCPCS Q4168</td>
<td>Amnioband, 1mg</td>
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<tr>
<td>HCPCS Q4169</td>
<td>Artacent wound, per square</td>
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<tr>
<td>HCPCS Q4170</td>
<td>Cygnus, per square centimeter</td>
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<tr>
<td>HCPCS Q4171</td>
<td>Interfyl, 1mg</td>
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<tr>
<td>HCPCS Q4173</td>
<td>PalinGen or PalinGen XPlus, per square centimeter</td>
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<tr>
<td>HCPCS Q4174</td>
<td>PalinGen or ProMatrX, 0.36mg per</td>
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<tr>
<td>HCPCS Q4175</td>
<td>Miroderm, per square centimeter</td>
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<td>HCPCS Q4195</td>
<td>Puraply, per square centimeter</td>
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<tr>
<td>HCPCS Q4196</td>
<td>Puraply am, per square centimeter</td>
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<tr>
<td>HCPCS Q4197</td>
<td>Puraply xt, per square centimeter</td>
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<tr>
<td>HCPCS Q4205</td>
<td>Membrane graft or membrane wrap, per sq</td>
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<td>HCPCS Q4206</td>
<td>Fluid Flow or Fluid GF, 1 cc</td>
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<td>HCPCS Q4208</td>
<td>Novafix, per sq cm</td>
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<td>HCPCS Q4209</td>
<td>SurGraft, per sq cm</td>
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<td>HCPCS Q4210</td>
<td>Axolotl Graft or Axolotl DualGraft, per sq</td>
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<td>HCPCS Q4211</td>
<td>Amnion Bio or AxoBioMembrane, per sq cm</td>
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<td>HCPCS Q4212</td>
<td>AlloGen, per cc</td>
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<td>HCPCS Q4213</td>
<td>Ascent, 0.5 mg</td>
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<td>HCPCS</td>
<td>Code</td>
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<td>HCPCS</td>
<td>Q4214</td>
<td>Cellesta Cord, per sq cm</td>
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<td>HCPCS</td>
<td>Q4215</td>
<td>Axolotl Ambient or Axolotl Cryo, 0.1 mg</td>
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<tr>
<td>HCPCS</td>
<td>Q4216</td>
<td>Artacent Cord, per sq cm</td>
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<td>HCPCS</td>
<td>Q4217</td>
<td>WoundFix, BioWound, WoundFix Plus,</td>
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<td>HCPCS</td>
<td>Q4218</td>
<td>SurgiCORD, per sq cm</td>
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<td>HCPCS</td>
<td>Q4219</td>
<td>SurgiGRAFT-DUAL, per sq cm</td>
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<tr>
<td>HCPCS</td>
<td>Q4220</td>
<td>BellaCell HD or Surederm, per sq cm</td>
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<td>HCPCS</td>
<td>Q4221</td>
<td>Amnio Wrap2, per sq cm</td>
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<td>HCPCS</td>
<td>Q4222</td>
<td>ProgenaMatrix, per sq cm</td>
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<td>HCPCS</td>
<td>Q4226</td>
<td>MyOwn Skin, includes harvesting and preparation procedures, per sq cm</td>
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<tr>
<td>HCPCS</td>
<td>Q4249</td>
<td>Amniply, for topical use only, per square centimeter</td>
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<td>HCPCS</td>
<td>Q4250</td>
<td>Amnioamp-mp, per square centimeter</td>
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<td>HCPCS</td>
<td>Q4254</td>
<td>Novafix dl, per square centimeter</td>
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<td>HCPCS</td>
<td>Q4255</td>
<td>Reguard, for topical use only, per square centimeter</td>
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</table>

**Modifier-JC**  
Skin substitute used as a graft

**Modifier-JD**  
Skin substitute not used as a graft