MEDICAL POLICY No. 91560-R10

SKIN SUBSTITUTES & SOFT TISSUE GRAFTS

 Effective Date: July 1, 2018
 Review Dates: 12/08, 8/09, 8/10, 8/11, 8/12, 4/13, 5/14, 5/15, 5/16, 5/17, 5/18, 5/19, 5/20, 5/21, 5/22, 5/23, 5/24

 Date Of Origin: December 10, 2008
 Status: Current

I. POLICY/CRITERIA

- A. The following products are a covered benefit when used for FDA approved indications:
 - 1. Acellular dermal matrices (ADMs) when used in association with a medically necessary breast reconstruction:
 - a. Alloderm
 - b. AlloMax
 - c. Cortiva
 - d. DermACELL DermaMatrix
 - e. FlexHD
 - f. Strattice
 - g. SurgiMend
 - 2. Apligraf® (graftskin) for either of the following:
 - a. In conjunction with standard therapy for the treatment of non-infected partial and full-thickness skin ulcers due to venous insufficiency of greater than one month duration without adequate response to conventional ulcer therapy.
 - b. In conjunction with standard diabetic foot ulcer care for full-thickness neuropathic diabetic foot ulcers of greater than three weeks duration without adequate response to conventional ulcer therapy and which extend through the dermis but without tendon, muscle, capsule or bone exposure.
 - 3. Biobrane Biosynthetic Dressing® for temporary covering of a superficial partial-thickness burn.
 - 4. Cymetra when used for treatment of vocal cord paralysis.
 - 5. Dermagraft® when used for full-thickness diabetic foot ulcers greater than six weeks duration which extend through the dermis, but without tendon, muscle, joint capsule, or bone exposure. It is intended for use in conjunction with standard wound care and in patients that have adequate blood supply to the involved foot.
 - 6. Epicel[®] cultured epidermal autograft for deep dermal or full thickness burns comprising $\geq 30\%$ total body surface area.

- EpiFix membrane for a diabetic foot ulcer or a venous stasis ulcer that has failed to respond to at least one month of conservative treatment. Coverage is limited to 5 applications per ulcer.
- 8. Grafix® CORE Multipotent Cellular Repair Cryopreserved Chorion Matrix and Grafix® PRIME Multipotent Cellular Repair Cryopreserved Amnion Matrix for use in the treatment of partial and full-thickness neuropathic diabetic foot ulcers when all of the following apply:
 - a. Ulcer is greater than six weeks in duration.
 - b. There is no capsule, tendon or bone exposed.
 - c. Used in conjunction with standard diabetic ulcer care
 - d. Hemoglobin A1c (HbA1C) no greater than 12%.
 - e. Treated foot has adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.70 .
- 9. Integra[®] Dermal Regeneration Template ("IDRT"), Integra[®] Omnigraft Dermal Regeneration Matrix ("Omnigraft"), Integra[®] Bilayer Matrix Wound Dressing ("Integra[®] Bilayer Wound Matrix"), and Integra Meshed Bilayer Wound Matrix for either of the following:
 - a. Severe burns where there is a limited amount of skin for autografts, or patient is too ill to have more wound graft sites created.
 - b. Reconstructive surgery for burn scars where there is a limited amount of skin for autografts or patient is too ill to have more wound graft sites created.
- 10. Integra Dermal Regeneration Template ("IDRT) and Integra Omnigraft Dermal Regeneration Matrix ("Omnigraft") for use in the treatment of partial and full-thickness neuropathic diabetic foot ulcers when all of the following apply:
 - a. Ulcer is greater than six weeks in duration.
 - b. There is no capsule, tendon or bone exposed.
 - c. Used in conjunction with standard diabetic ulcer care
 - d. Hemoglobin A1c (HbA1C) no greater than 12%.
 - e. Treated foot has adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.70 .
- 11. Oasis[®] Wound Matrix for chronic, lower extremity, partial or full-thickness, venous or diabetic ulcers, when standard wound therapy has failed.
- 12. Orcel[™] is indicated for the treatment of fresh, clean split-thickness donor site wounds in burn patients.
- 13. Theraskin[®] for partial or full-thickness diabetic foot ulcer or venous stasis ulcer of greater than four weeks duration that have failed standard wound care. There must be evidence of adequate blood supply to the involved

foot. For diabetic foot ulcers, the HbA1C cannot exceed 12%. Coverage is limited to up to 12 weeks of Theraskin application at FDA-approved intervals.

- 14. Transcyte® for either of the following:
 - a. As a temporary wound covering for surgically excised full-thickness and deep partial-thickness thermal burn wounds in patients who require such a covering prior to autograft placement, *or*
 - b. For the treatment of mid-dermal to indeterminate depth burn wounds that typically require debridement and that may be expected to heal without autografting.
- B. The following products are considered experimental, investigational or unproven. There is insufficient evidence to support their clinical effectiveness. Non-coverage may apply to other products and may not be limited to the following:
 - 1. Acellular dermal matrices (with the exception of those listed above which are only covered when used in association with a medically necessary breast reconstruction)
 - 2. Allopatch HD
 - 3. Alloskin
 - 4. AlloSkin RT, per sq cm
 - 5. Arthroflex, per sq cm
 - 6. Endoform Dermal Template[™]
 - 7. EpiFix, injectable or powderized, or any form other than membrane; or any indication not listed in A12 above
 - 8. E-Z DermTM
 - 9. Gammagraft
 - 10. Graftjacket Express
 - 11. GraftJacket® Regenerative Tissue Matrix
 - 12. Hyalomatrix
 - 13. Integra[®] Matrix Wound Dressing ("Integra[®] Wound Matrix")
 - 14. Integra[®] Wound Matrix Thin ("Integra[®] Thin")
 - 15. Integra[®] Neurawrap[™]
 - 16. Integra[®] Flowable Wound Matrix ("Flowable")
 - 17. MatriStem micromatrix, MatriStem wound matrix and MatriStem burn matrix
 - 18. MemoDerm, per sq cm
 - 19. NeoForm Dermis[™]
 - 20. NeuraGen® Nerve Guide
 - 21. NeuroMatrix[™] Collagen Nerve Cuff
 - 22. Neuromend
 - 23. Oasis Burn Matrix
 - 24. Oasis Ultra Tri-Layer Matrix
 - 25. Surgisis® RVP Recto-Vaginal Fistula Plug



- 26. Talymed, per sq cm
- 27. TenoGlide[™] Tendon Protector Sheet
- 28. TissueMend®
- 29. Unite biomatrix, per sq cm
- 30. Veritas® Collagen Matrix

II. MEDICAL NECESSITY REVIEW

Prior authorization for certain drug, services, and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service, or procedure is medically necessary. For more information, please refer to the Priority Health Provider Manual.

III. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- **HMO/EPO:** *This policy applies to insured HMO/EPO plans.*
- ***** POS: This policy applies to insured POS plans.
- PPO: This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- ASO: For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
- INDIVIDUAL: For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- MEDICARE: Coverage is determined by the Centers for Medicare and Medicaid Services (CMS) and/or the Evidence of Coverage (EOC); if a coverage determination has not been adopted by CMS, this policy applies.
- MEDICAID/HEALTHY MICHIGAN PLAN: For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: <u>http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html</u>. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: <u>http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html</u>, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.



IV. DESCRIPTION

Tissue-engineered human skin substitutes are products that use living cells within a natural or synthetic matrix to enhance wound healing. The skin substitutes are classified as dermal, epidermal or composite (both epidermal and dermal cells).

Skin substitutes are used to provide temporary wound coverage or complete wound closure, and may reduce healing time, pain, and contractures. They may obviate the need for more extensive treatments (e.g., grafting, amputation), as well as improve aesthetic results and functional abilities.

Numerous skin substitute products are available with FDA approval for various indications.

V. CODING INFORMATION

<u>y</u> apply:
Malignant neoplasm of female breast
Secondary malignant neoplasm of breast
Carcinoma in situ of breast
Neoplasm of uncertain behavior of breast
Neoplasm of unspecified behavior of breast
Capsular contracture of breast implant
Deformity of reconstructed breast
Disproportion of reconstructed breast
Personal history of malignant neoplasm of breast
Encounter for other plastic and reconstructive surgery following
medical procedure or healed injury
Encounter for prophylactic removal of breast
Encounter for breast reconstruction following mastectomy
Acquired absence of breast and nipple
Breast implant status
Burn and corrosion
Burns
Varicose veins with ulcer
Postphlebitic syndrome with ulcer
Chronic venous hypertension with ulcer
Chronic venous hypertension (idiopathic) with ulcer and
inflammation
Venous insufficiency (chronic) (peripheral)
Disorder of vein, unspecified
Atherosclerosis of native arteries of leg with ulceration
Atherosclerosis of bypass graft(s) of leg with ulceration
Non-pressure chronic ulcer

Secondary diagnoses

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Soft Tissue GraftsE08.40 - E08.610Diabetes mellitus due to underlying condition with diabetic
neuropathyDiabetes mellitus due to underlying condition with diabetic
neuropathyE09.40 - E09.610Drug or chemical induced diabetes mellitus with neurological
complicationsType 1 diabetes mellitus with neurological complicationsE10.40 - E10.69Type 1 diabetes mellitus with neurological complications

E10.40 - E10.69Type 1 diabetes mellitus with neurological complicationsE11.40 - E11.69Type 2 diabetes mellitus with neurological complicationsE13.40 - E13.69Other specified diabetes mellitus with neurological complicationscomplicationscomplications

CPT/HCPCS Codes:

Appropriate Skin Substitute Application code/product combination must be billed the same claim for the same date of service.

High Cost Application Codes: 15271-15277

Low Cost Application Codes: C5271-C5278

Not Covered:

- 15011 Harvest of skin for skin cell suspension autograft; first 25 sq cm or less
- 15012 Harvest of skin for skin cell suspension autograft; each additional 25 sq cm or part thereof (List separately in addition to code for primary procedure)
- 15013 Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; first 25 sq cm or less of harvested skin
- 15014 Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; each additional 25 sq cm of harvested skin or part thereof (List separately in addition to code for primary procedure)
- 15015 Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, trunk, arms, legs; first 480 sq cm or less
- 15016 Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, trunk, arms, legs; each additional 480 sq cm or part thereof (List separately in addition to code for primary procedure)
- 15017 Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 480 sq cm or less
- 15018 Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 480 sq cm or part thereof (List separately in addition to code for primary procedure)

Product Codes:

Q4100	Skin substitute, not otherwise specified
	(Explanatory notes must accompany claims billed with unlisted codes.)
	- Use for billing: Orcel [®] , Biobrane Biosynthetic Dressing [®] , Epicel [®] ,
	DermaMatrix TM , Cortiva TM , AlloMax TM
Q4101	Apligraf, per square centimeter

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- Q4102 Oasis wound matrix, per square centimeter
- Q4104 Integra bilayer matrix wound dressing (BMWD), per square centimeter
- Q4105 Integra dermal regeneration template (DRT), or Integra Omnigraft dermal regeneration matrix, per square centimeter
- Q4106 Dermagraft, per square centimeter
- Q4112 Cymetra, injectable, 1 cc (Cymetra)
- Q4116 AlloDerm, per square centimeter
- Q4121 TheraSkin, per sq cm
- Q4122 DermACELL, per sq cm
- Q4128 FlexHD or AllopatchHD or Matrix HD, per sq cm
- Q4130 Strattice TM, per sq cm
- Q4132 Grafix core and GrafixPL Core, per sq cm
- Q4133 Grafix prime and GrafixPL Prime, Stravix and StravixPL, per sq cm
- Q4182 Transcyte, per square centimeter
- Q4186 Epifix, per square centimeter

The following products are not separately payable.

- A2001 Innovamatrix ac, per sq cm
- A2002 Mirragen adv wnd mat per sq
- A2004 XCelliStem, 1 mg
- A2005 Microlyte matrix, per sq cm
- A2006 Novosorb synpath per sq cm
- A2007 Restrata, per sq cm
- A2008 Theragenesis, per sq cm
- A2009 Symphony, per sq cm
- A2010 Apis, per square centimeter
- A2011 Supra SDRM, per sq cm
- A2012 SUPRATHEL, per sq cm
- A2013 Innovamatrix FS, per sq cm
- A2014 Omeza collagen matrix, per 100 mg
- A2015 Phoenix wound matrix, per square centimeter
- A2016 Permeaderm b, per square centimeter
- A2017 Permeaderm glove, each
- A2018 Permeaderm c, per square centimeter
- A2019 Kerecis Omega3 MariGen Shield, per sq cm
- A2020 AC5 Advanced Wound System (AC5)
- A2021 NeoMatriX, per sq cm
- A2022 Innovaburn or innovamatrix xl, per square centimeter
- A2023 Innovamatrix pd, 1 mg
- A2024 Resolve Matrix or XenoPatch, per sq cm
- A2025 Miro3d, per cubic centimeter
- A2026 Restrata minimatrix, 5 mg
- A2027 Matriderm, per square centimeter
- A2028 Micromatrix flex, per mg
- A2029 Mirotract wound matrix sheet, per cubic centimeter
- A4100 Skin substitute, FDA-cleared as a device, not otherwise specified
 - (Explanatory notes must accompany claims billed with unlisted codes.)
- A6460 Synthetic resorbable wound dressing, sterile, pad size 16 sq in or less, without adhesive border, each dressing

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A6461 Synthetic resorbable wound dressing, sterile, pad size more than 16 sq in but less than or equal to 48 sq in, without adhesive border, each dressing O4100 Skin substitute, not otherwise specified (Explanatory notes must accompany claims billed with unlisted codes.) Use for billing: NeoForm Dermis[™], SurgisisRVP®, Tissuemend®, Grafix XC Oasis burn matrix, per square centimeter Q4103 O4107 GraftJacket, per square centimeter Q4108 Integra matrix, per square centimeter Q4110 Primatrix, per square centimeter O4111 GammaGraft, per square centimeter Q4113 GRAFTJACKET XPRESS, injectable, 1 cc Q4114 Integra flowable wound matrix, injectable, 1 cc Q4115 AlloSkin, per square centimeter O4117 HYALOMATRIX, per sq cm O4118 MatriStem micromatrix, 1 mg Q4123 AlloSkin RT, per sq cm O4124 OASIS ultra tri-layer wound matrix, per sq cm Q4125 Arthroflex, per sq cm Q4126 MemoDerm, Dermaspan, Tranzgraft or Integuply, per square centimeter Q4127 Talymed, per sq cm Q4134 hMatrix, per square centimeter Q4135 Mediskin, per square centimeter O4136 Ez-derm, per square centimeter O4137 Amnioexcel, AmnioExcel Plus or BioDExcel, per square centimeter O4138 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 O4143 Repriza, per square centimeter O4145 EpiFix, injectable, 1 mg Q4146 Tensix, per square centimeter Architect, Architect PX, or Architect FX, extracellular matrix, per square Q4147 centimeter Q4148 Neox Cord 1K, Neox Cord RT, or Clarix Cord 1K, per sq cm Q4149 Excellagen, 0.1 cc O4150 Allowrap DS or dry, per square centimeter O4151 AmnioBand or Guardian, per square centimeter O4152 DermaPure, per square centimeter Q4153 Dermavest and Plurivest, per square centimeter Q4154 Biovance, per square centimeter Q4155 Neox Flo or Clarix Flo, 1 mg O4156 Neox 100 or Clarix 100, per square centimeter Revitalon, per square centimeter O4157 Q4158 Kerecics 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 Page 8 of 15

O Priorit	y Health	MEDICAL POLICY No. 91560-R10	Skin Substitutes & Soft Tissue Grafts
Q4163	WoundEx Flo	ow, BioSkin Flow, per square	e centimeter
Q4164		square centimeter	
Q4165	Keramatrix, per square centimeter		
Q4166		are centimeter	
Q4167		quare centimeter	
Q4168	AmnioBand,		
Q4169	· · · · · · · · · · · · · · · · · · ·	nd, per square centimeter	
Q4170		quare centimeter	
Q4171	Interfyl, 1 mg		
Q4173	PalinGen or F	alinGen XPlus, per square co	entimeter
Q4174	PalinGen or F	ProMatrX, 0.36 mg per 0.25 c	cc
Q4175	Miroderm, pe	r square centimeter	
Q4176		square centimeter	
Q4177	FlowerAmnic		
Q4178		Patch, per square centimeter	
Q4179		per square centimeter	
Q4180	Revita, per sq		
Q4181		d, per square centimeter	
Q4183		r square centimeter	
Q4184		square centimeter	
Q4185		able Amnion (25 mg per cc);	; per 0.5 cc
Q4187	Epicord, per square centimeter		
Q4188		, per square centimeter	
Q4189	Artacent AC,		
Q4190		per square centimeter	
Q4191		er square centimeter	
Q4192	Restorigin, 1		
Q4193		per square centimeter	
Q4194	-	r square centimeter	
Q4195	• •	equare centimeter	
Q4196 Q4197	•	per square centimeter	
Q4197 Q4198		per square centimeter iotic Membrane, per square c	pontimator
Q4198 Q4199	Cygnus matri		centimeter
Q4199 Q4200		square centimeter	
Q4200 Q4201		square centimeter	
Q4201 Q4202	Keroxx (2.5g	-	
Q4202 Q4203		per square centimeter	
Q4203 Q4204		square centimeter	
Q4204 Q4205		raft or Membrane Wrap, per	sa cm
Q4205 Q4206		Fluid GF, 1 cc	or one
Q4208	Novafix, per		
Q4208 Q4209	SurGraft, per	-	
Q420) Q4211	-	or AxoBioMembrane, per sq	cm
Q4212	AlloGen, per		
Q4212 Q4213	Ascent, 0.5 m		
Q4214	Cellesta Cord	-	
Q4215		ent or Axolotl Cryo, 0.1 mg	
Q4216	Artacent Cord	• •	
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Q4217	WoundFix B	ioWound WoundFix Plus F	BioWound Plus, WoundFix Xplu
X1217		l Xplus, per sq cm	
Q4218	SurgiCORD,		
Q4219	•	DUAL, per sq cm	
Q4220	-	or Surederm, per sq cm	
Q4221	Amnio Wrap		
Q4222	ProgenaMatri	ix, per sq cm	
Q4224	Human Healt	h Factor 10 Amniotic Patch ((HHF10-P), per sq cm
Q4225	AmnioBind o	r dermabind tl per sq cm	
Q4226			paration procedures, per sq cm
Q4227		er square centimeter	
Q4229		niotic membrane, per square o	centimeter
Q4230	•	vable amnion, per 0.5 cc	
Q4231	Corplex p, pe		
Q4233		nudyn, per 0.5 cc	
Q4234	· .	er square centimeter	
Q4235		or altiply, per square centime	eter
Q4237	•	er square centimeter	
Q4238		per square centimeter	
Q4239		or amnio-maxx lite, per squa	are centimeter
Q4240		topical use only, per 0.5 cc	
Q4241		topical use only, per 0.5 cc	
Q4242	Amniocyte pl		
Q4245	Amniotext, p		
Q4246	Coretext or p	· •	
Q4247		tch, per square centimeter	
Q4248	•	nniotic membrane allograft,	
Q4249		topical use only, per square of	centimeter
Q4250	·	np, per square centimeter	
Q4251	Vim, per sq c		
Q4252	Vendaje, per Zonith Amnie		
Q4253		otic Membrane, per sq cm	
Q4254 Q4255	· •	er square centimeter	centimeter
Q4255 Q4256	MLG-Comple	topical use only, per square of	
Q4230 Q4257	Relese, per sq		
Q4257 Q4258	Enverse, per sq		
Q4238 Q4259		ayer or Celera Dual Membra	ane ner sa cm
Q4239 Q4260		atch, per sq cm	
Q4260 Q4261	TAG, per sq c		
Q4261 Q4262		npax membrane, per square c	pentimeter
Q4263		r square centimeter	
Q4263 Q4264		orane, per square centimeter	
Q4265	NeoStim TL,		
Q4265 Q4266		brane, per square centimeter	
Q4267		er square centimeter	
Q4267 Q4268	-	er square centimeter	
Q4269		er square centimeter	
Q4270		per square centimeter	
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O Priorit		DICAL POLICY No. 91560-R10	Skin Substitutes & Soft Tissue Grafts
Q4271	Complete ft, per squa	are centimeter	
Q4272	Esano a, per square c		
Q4273	Esano aaa, per squar		
Q4274	Esano ac, per square		
Q4275	Esano aca, per square		
Q4276	Orion, per square cer		
Q4278	Epieffect, per square		
Q4279	Vendaje ac, per squa		
Q4280	• • •	per square centimeter	
Q4281		dl, per square centimet	ter
Q4282	Cygnus dual, per squ	are centimeter	
Q4283	Biovance tri-layer or	biovance 31, per squar	e centimeter
Q4284	Dermabind sl, per sq	uare centimeter	
Q4285	Nudyn dl or nudyn d	l mesh, per square cen	timeter
Q4286		w, per square centime	ter
Q4287	Dermabind dl, per so	uare centimeter	
Q4288	Dermabind ch, per so	quare centimeter	
Q4289	Revoshield + amniot	ic barrier, per square c	entimeter
Q4290	· · ·	ro, per square centime	ter
Q4291	Lamellas xt, per squa		
Q4292	Lamellas, per square		
Q4293	Acesso dl, per square		
Q4294	Amnio quad-core, pe	-	
Q4295		otic, per square centim	eter
Q4296	Rebound matrix, per		
Q4297	Emerge matrix, per so	-	
Q4298	Amnicore pro, per sq		
Q4299	Amnicore pro+, per s		
Q4300	Acesso tl, per square		
Q4301	Activate matrix, per s	•	
Q4302	Complete aca, per squ		
Q4303	Complete aa, per squa		
Q4304	Grafix plus, per squar		ntimaton
Q4305 Q4306		tri-layer, per square ce per square centimeter	
Q4300 Q4307	American amnion, pe	A A	
Q4307 Q4308	Sanopellis, per square	-	
Q4309	Via matrix, per square		
Q430) Q4310	Procenta, per 100 mg		
Q4310 Q4311	Acesso, per square ce		
Q4312	Acesso ac, per square		
Q4312 Q4313	Dermabind fm, per se		
Q4313 Q4314	Reeva ft, per square c		
Q4315		membrane allograft, p	er square centimeter
Q4315 Q4316	Amchoplast, per squa		
Q4317	Vitograft, per square		
Q4317 Q4318	E-graft, per square ce		
Q4319	Sanograft, per square		
Q4320	Pellograft, per square		
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P riori	ity Health	MEDICAL POLICY No. 91560-R10	Skin Substitutes & Soft Tissue Grafts			
Q4321	Penograft per	square centimeter				
Q4321 Q4322	0	quare centimeter				
Q4323	Alloply, per squ					
Q4323 Q4324		quare centimeter				
Q4324 Q4325	-	quare centimeter				
Q4325 Q4326	I / I	r square centimeter				
Q4327		r square centimeter				
Q4327 Q4328	-	-				
Q4328 Q4329	· • •	Most, per square centimeter				
Q4329 Q4330	Singlay, per square centimeter					
Q4330 Q4331	Total, per square centimeter					
· ·		Axolotl graft, per square centimeter				
Q4332	Axolotl dualgraft, per square centimeter					
Q4333		Ardeograft, per square centimeter				
Q4334	Amnioplast 1, per square centimeter					
Q4335	Amnioplast 2, per square centimeter					
Q4336	Artacent c, per square centimeter					
Q4337		, per square centimeter				
Q4338		per square centimeter				
Q4339		en, per square centimeter				
Q4340		square centimeter				
Q4341	A · A	square centimeter				
Q4342	Theramend, per square centimeter					
Q4344		wrap, per square centimeter				
Q4345	-	raft dermis, per square centi	meter			
Q4346		x, per square centimeter				
01217	D (11)	• ,• ,				

- Q4347 Rampart dl matrix, per square centimeter
- Q4348 Sentry sl matrix, per square centimeter
- Q4349 Mantle dl matrix, per square centimeter
- Q4350 Palisade dm matrix, per square centimeter
- Q4351 Enclose tl matrix, per square centimeter
- Q4352 Overlay sl matrix, per square centimeter
- Q4353 Xceed tl matrix, per square centimeter

OP Facility billing only:

(*C*-codes are not separately payable under *APC* arrangements) C1832 Autograft suspension, including cell processing and application, and all system components (payable for Medicare & Medicaid) C9358 Dermal substitute, native, non-denatured collagen (SurgiMend Collagen Matrix), per 0.5 square centimeters C9363 Skin substitute, Integra Meshed Bilayer Wound Matrix, per square centimeter C9364 Porcine implant (Permacol), per square cm C9399 Unclassified drugs or biologicals These C-codes reportable by outpatient facility only; using rev code 0636 - Use for billing: Orcel®, Biobrane Biosynthetic Dressing®, Epicel®, DermaMatrixTM, CortivaTM, AlloMaxTM

Not separately payable:

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- C9352 Microporous collagen implantable tube (NeuraGen Nerve Guide), per cm length
- C9353 Microporous collagen implantable slit tube (NeuraWrap Nerve Protector), per cm length
- C9354 Acellular pericardial tissue matrix of nonhuman origin (Veritas), per square centimeter
- C9355 Collagen nerve cuff (NeuroMatrix), per 0.5 centimeter length
- C9356 Tendon, porous matrix of cross-linked collagen and glycosaminoglycan matrix (TenoGlide Tendon Protector Sheet), per square centimeter
- C9359 Porous purified collagen matrix bone void filler (Integra Mozaik Osteoconductive Scaffold Putty, Integra OS Osteoconductive Scaffold Putty), per 0.5 cc
- C9360 Dermal substitute, native, nondenatured collagen, neonatal bovine origin (SurgiMend Collagen Matrix), per 0.5 square cm
- C9361 Collagen matrix nerve wrap (NeuroMend Collagen Nerve Wrap), per 0.5 cm length
- C9362 Porous purified collagen matrix bone void filler (Integra Mozaik Osteoconductive Scaffold Strip), per 0.5 cc

Not Covered

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- C9796 Repair of enterocutaneous fistula small intestine or colon (excluding anorectal fistula) with plug (e.g., porcine small intestine submucosa [sis])
- C8002 Preparation of skin cell suspension autograft, automated, including all enzymatic processing and device components (do not report with manual suspension preparation)

V. **REFERENCES**

- 1. Ananian CE, Dhillon YS, Van Gils CC, Lindsey DC, Otto RJ, Dove CR, Pierce JT, Saunders MC. A multicenter, randomized, single-blind trial comparing the efficacy of viable cryopreserved placental membrane to human fibroblast-derived dermal substitute for the treatment of chronic diabetic foot ulcers. Wound Repair Regen. 2018 May;26(3):274-283. Epub 2018 Aug 27. PMID: 30098272.
- 2. Baldursson BT, Kjartansson H, Konrádsdóttir F, Gudnason P, Sigurjonsson GF, Lund SH. Healing rate and autoimmune safety of full-thickness wounds treated with fish skin acellular dermal matrix versus porcine small-intestine submucosa: a noninferiority study. Int J Low Extrem Wounds. 2015 Mar;14(1):37-43
- 3. Barber FA, Burns JP, Deutsch A, Labbé MR, Litchfield RB. A prospective, randomized evaluation of acellular human dermal matrix augmentation for arthroscopic rotator cuff repair. Arthroscopy. 2012 Jan;28(1):8-15.
- 4. Beale EW, Hoxworth RE, Livingston EH, Trussler AP. The role of biologic mesh in abdominal wall reconstruction: a systematic review of the current literature. Am J Surg. 2012 Oct;204(4):510-7.

- Becker S, Saint-Cyr M, Wong C, Dauwe P, Nagarkar P, Thornton JF, Peng Y. AlloDerm versus DermaMatrix in immediate expander-based breast reconstruction: a preliminary comparison of complication profiles and material compliance. Plast Reconstr Surg. 2009 Jan;123(1):1-6; discussion 107-8.
- 6. Bejjani GK, Zabramski J; Durasis Study Group. Safety and efficacy of the porcine small intestinal submucosa dural substitute: results of a prospective multicenter study and literature review. J Neurosurg. 2007 Jun;106(6):1028-33.
- Bellows CF, Shadduck P, Helton WS, Martindale R, Stouch BC, Fitzgibbons R. Early report of a randomized comparative clinical trial of StratticeTM reconstructive tissue matrix to lightweight synthetic mesh in the repair of inguinal hernias. Hernia. 2014 Apr;18(2):221-30.
- Brooke, S., Mesa, J. Complications in tissue expander breast reconstruction: A comparison of AlloDerm, DermaMatrix, and Flex HD accellular inferior pole dermal slings. Annals of Plastic Surgery, Vol. 69, No. 4, October 2012 pp. 347-349.
- 9. Cheng A, Saint-Cyr M. Comparison of different ADM materials in breast surgery. Clin Plast Surg. 2012 Apr;39(2):167-75.
- Cigna Medical Coverage Policy. Policy Number 0068.Tissue-Engineered Skin Substitutes and Growth Factors, Available at https://static.cigna.com/assets/chcp/pdf/coveragePolicies/medical/mm_0068_cove ragepositioncriteria woundhealing.pdf (Retrieved April 5, 2023).
- 11. Hayes, Inc. AlloDerm[®] (LifeCell Corp.) for Post-Mastectomy Breast Reconstruction, Search & Summary. October 2008.
- 12. Hayes, Inc. Biosynthetic Tissue-Engineered Skin Substitutes for Wound Healing, January 14, 2010 & annual updates February 2014.
- 13. Hayes, Inc. Biological Tissue-Engineered Skin Substitutes for Wound Healing January 28, 2010, Update January 2011.
- 14. Hayes, Inc. EpiFix for Treatment of Nonhealing Wounds, March 26, 2015.
- 15. Hayes, Inc. Skin Substitutes for Wound Healing, February 2004 and Updated Searches February 2008.
- 16. Israeli R. Complications of acellular dermal matrices in breast surgery. Plast Reconstr Surg. 2012 Nov;130(5 Suppl 2):159S-72S.
- 17. Nahabedian MY. Acellular dermal matrices in primary breast reconstruction: principles, concepts, and indications. Plast Reconstr Surg. 2012 Nov;130(5 Suppl 2):44S-53S.
- Sbitany H, Serletti JM. Acellular dermis-assisted prosthetic breast reconstruction: a systematic and critical review of efficacy and associated morbidity. Plast Reconstr Surg. 2011 Dec;128(6):1162-9.
- Tettelbach W, Cazzell S, Sigal F, Caporusso JM, Agnew PS, Hanft J, Dove C. A multicentre prospective randomised controlled comparative parallel study of dehydrated human umbilical cord (EpiCord) allograft for the treatment of diabetic foot ulcers. Int Wound J. 2019 Feb;16(1):122-130. Epub 2018 Sep 24. PMID: 30246926; PMCID: PMC7380046.
- 20. Winters CL, Brigido SA, Liden BA, Simmons M, Hartman JF, Wright ML. A multicenter study involving the use of a human acellular dermal regenerative

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tissue matrix for the treatment of diabetic lower extremity wounds. Adv Skin Wound Care. 2008 Aug;21(8):375-81.

21. Zelen CM, Serena TE, Gould L, Le L, Carter MJ, Keller J, Li WW. Treatment of chronic diabetic lower extremity ulcers with advanced therapies: a prospective, randomised, controlled, multi-centre comparative study examining clinical efficacy and cost. Int Wound J. 2016 Apr;13(2):272-82.

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