PriorityHealth

MEDICAL POLICY
No. 91560-R9

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**
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. 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.
2. 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.
3. 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.
4. Orcel™ is indicated for the treatment of fresh, clean split-thickness donor site wounds in burn patients.
5. Biobrane Biosynthetic Dressing® for temporary covering of a superficial partial-thickness burn.
6. 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.
7. 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.
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. Acellular dermal matrices (ADMs) as follows: Alloderm®, AlloMax™, Cortiva™, DermACELL™, DermaMatrix™, FlexHD®, Strattice ™ and SurgiMend® when used in association with a medically necessary breast reconstruction.
10. Epicel® cultured epidermal autograft for deep dermal or full thickness burns comprising $\geq$ 30% total body surface area.
11. Oasis® Wound Matrix for chronic, lower extremity, partial or full-thickness, venous or diabetic ulcers, when standard wound therapy has failed.
12. Cymetra when used for treatment of vocal cord paralysis.
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. 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.

B. The following products are considered experimental, investigational or unproven and are **not** a covered benefit. 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 Derm™
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

☐ Required ☒ Not Required ☐ Not Applicable

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); 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: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, 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

ICD-10 Codes that may apply:

C50.011 – C50.929	Malignant neoplasm of female breast
C79.81	Secondary malignant neoplasm of breast
D05.00 - D05.92	Carcinoma in situ of breast
D48.60 - D48.62	Neoplasm of uncertain behavior of breast
D49.3	Neoplasm of unspecified behavior of breast
T85.44xA - T85.44xS	Capsular contracture of breast implant
N65.0	Deformity of reconstructed breast
N65.1	Disproportion of reconstructed breast
Z85.3	Personal history of malignant neoplasm of breast
Z42.8	Encounter for other plastic and reconstructive surgery following medical procedure or healed injury
Z40.01	Encounter for prophylactic removal of breast
Z42.1	Encounter for breast reconstruction following mastectomy
Z90.10 - Z90.13	Acquired absence of breast and nipple
Z98.82	Breast implant status
T20.20xA - T26.92xS	Burn and corrosion
T30.0 - T32.99	Burns
I83.001 - I83.229	Varicose veins with ulcer
I87.011 - I87.019	Postphlebitic syndrome with ulcer
I87.311 - I87.319	Chronic venous hypertension with ulcer
I87.331 - I87.339	Chronic venous hypertension (idiopathic) with ulcer and inflammation
I87.2	Venous insufficiency (chronic) (peripheral)
I87.9	Disorder of vein, unspecified
I70.231 - I70.25	Atherosclerosis of native arteries of leg with ulceration
I70.331 - I70.749	Atherosclerosis of bypass graft(s) of leg with ulceration
L97.101- l97.929	Non-pressure chronic ulcer

Secondary diagnoses

E08.40 - E08.610	Diabetes mellitus due to underlying condition with diabetic neuropathy
E09.40 - E09.610	Drug or chemical induced diabetes mellitus with neurological complications
E10.40 - E10.69	Type 1 diabetes mellitus with neurological complications
E11.40 - E11.69	Type 2 diabetes mellitus with neurological complications
E13.40 - E13.69	Other specified diabetes mellitus with neurological complications

CPT/HCPCS 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™, Cortiva™, AlloMax™
Q4101	Apligraf, per square centimeter
Q4102	Oasis wound matrix, per square centimeter

Q4104 Integra bilayer matrix wound dressing (BMWD), per square centimeter (*Not covered for Priority Medicaid)*
Q4105 Integra dermal regeneration template (DRT), or Integra Omnigraft dermal regeneration matrix, per square centimeter (*Not covered for Priority Medicaid)*
Q4106 Dermagraft, per square centimeter
Q4112 Cymetra, injectable, 1 cc (Cymetra) *(Not covered for Priority Medicaid)*
Q4116 AlloDerm, per square centimeter (*Not covered for Priority Medicaid)*
Q4121 TheraSkin, per sq cm
Q4122 DermACELL, per sq cm (*Not covered for Priority Medicaid)*
Q4128 FlexHD or AllopatchHD or Matrix HD, per sq cm (*Not covered for Priority Medicaid)*
Q4130 Strattice TM, per sq cm (*Not covered for Priority Medicaid)*
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

<u>The following products are not covered and will process as and will process as "not separately payable."</u>

Q4100 Skin substitute, not otherwise specified (Explanatory notes must accompany claims billed with unlisted codes.)
Use for billing: NeoForm Dermis™, SurgisisRVP®, Tissuemend®, Grafix XC
Q4103 Oasis burn matrix, per square centimeter
Q4107 GraftJacket, per square centimeter
Q4108 Integra matrix, per square centimeter
Q4110 Primatrix, per square centimeter
Q4111 GammaGraft, per square centimeter
Q4113 GRAFTJACKET XPRESS, injectable, 1 cc
Q4114 Integra flowable wound matrix, injectable, 1 cc
Q4115 AlloSkin, per square centimeter
Q4117 HYALOMATRIX, per sq cm
Q4118 MatriStem micromatrix, 1 mg

Q4123 AlloSkin RT, per sq cm
Q4124 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
Q4136 Ez-derm, per square centimeter
Q4137 Amnioexcel, AmnioExcel Plus or BioDExcel, per square centimeter
Q4138 BioDfence dryflex, per square centimeter
Q4139 Amniomatrix or biodmatrix, injectable, 1 cc
Q4140 BioDfence, per square centimeter
Q4141 AlloSkin AC, per square centimeter
Q4142 XCM biologic tissue matrix, per square centimeter
Q4143 Repriza, per square centimeter

Q4145	EpiFix, injectable, 1 mg
Q4146	Tensix, per square centimeter
Q4147	Architect , Architect PX, or Architect FX, extracellular matrix, per square centimeter
Q4148	Neox Cord 1K, Neox Cord RT, or Clarix Cord 1K, per sq cm
Q4149	Excellagen, 0.1 cc
Q4150	Allowrap DS or dry, per square centimeter
Q4151	AmnioBand or Guardian, per square centimeter
Q4152	DermaPure, per square centimeter
Q4153	Dermavest and Plurivest, per square centimeter
Q4154	Biovance, per square centimeter
Q4155	Neox Flo or Clarix Flo, 1 mg
Q4156	Neox 100 or Clarix 100, per square centimeter
Q4157	Revitalon, per square centimeter
Q4158	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
Q4163	WoundEx Flow, BioSkin Flow, per square centimeter
Q4164	Helicoll, per square centimeter
Q4165	Keramatrix, per square centimeter
Q4166	Cytal, per square centimeter
Q4167	Truskin, per square centimeter
Q4168	AmnioBand, 1 mg
Q4169	Artacent wound, per square centimeter
Q4170	Cygnus, per square centimeter
Q4171	Interfyl, 1 mg
Q4173	PalinGen or PalinGen XPlus, per square centimeter
Q4174	PalinGen or ProMatrX, 0.36 mg per 0.25 cc
Q4175	Miroderm, per square centimeter
Q4176	Neopatch, per square centimeter
Q4177	FlowerAmnioFlo, 0.1 cc
Q4178	FlowerAmnioPatch, per square centimeter
Q4179	Flowerderm, per square centimeter
Q4180	Revita, per square
Q4181	Amnio Wound, per square centimeter
Q4183	Surgigraft, per square centimeter
Q4184	Cellesta, per square centimeter
Q4185	Cellesta Flowable Amnion (25 mg per cc); per 0.5 cc
Q4187	Epicord, per square centimeter
Q4188	AmnioArmor, per square centimeter
Q4189	Artacent AC, 1 mg
Q4190	Artacent AC, per square centimeter
Q4191	Restorigin, per square centimeter
Q4192	Restorigin, 1 cc
Q4193	Coll-e-Cerm, per square centimeter
Q4194	Novachor, per square centimeter
Q4195	PuraPly, per square centimeter

Q4196 PuraPly AM, per square centimeter
Q4197 Puraply XT, per square centimeter
Q4198 Genesis Amniotic Membrane, per square centimeter
Q4200 Skin TE, per square centimeter
Q4201 Matrion, per square centimeter
Q4202 Keroxx (2.5g/cc), 1cc
Q4203 Derma-Gide, per square centimeter
Q4204 XWRAP, per square centimeter

OP Facility billing only:
(C-codes are not separately payable under APC arrangements)
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®, DermaMatrix™, Cortiva™, AlloMax™

Not Covered/Not separately payable:
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

VI. REFERENCES

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