SUMMARY OF CHANGES

Clarifications:

Deletions:

Additions:

Pg. 2, Section I, A, 8, criteria added for the coverage of 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 ulcer.

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 ≥ 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”)
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™
21. NeuroMatrix™ Collagen Nerve Cuff
22. Neuromed
23. Oasis Burn Matrix
24. Oasis Ultra Tri-Layer Matrix
25. Surgisis® RVP Recto-Vaginal Fistula Plug
26. Talyamed, per sq cm
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](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](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 Michigan Medicaid policy 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), 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)
Q4131 Epifix, per square centimeter
Q4132 Grafix core and GrafixPL Core, per sq cm
Q4133 Grafix prime and GrafixPL Prime, per sq cm
Q4182 Transcyte, per square centimeter

Not Covered:

Q4100 Skin substitute, not otherwise specified (Explanatory notes must accompany claims billed with unlisted codes.)
   Use for billing: NeoForm Dermis™, SurgisisRVP®, Tissuemend®
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 Arthrolflex, 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 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 extracellular matrix, per square centimeter
Q4148  NeoX Cord 1K, NeoX Cord RT, or Clarix Cord 1K, per sq cm
        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, per square centimeter
Q4154  Biovance, per square centimeter
Q4155  Neoxflo or clarixflo, 1 mg
Q4156  Neox 100 pr 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, BioSkin, per sq cm
        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
Q4172  PuraPly or PuraPly AM, per square centimeter
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 (1.1.2018)
Q4177  Floweramnioflo, 0.1 cc (1.1.2018)
Q4178  Floweramniopatch, per square centimeter (1.1.2018)
Q4179  Flowerderm, per square centimeter (1.1.2018)
Q4180  Revita, per square centimeter (1.1.2018)
Q4181  Amnio wound, per square centimeter (1.1.2018)

**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:
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

Unclassified drugs or biologicals

VI. REFERENCES


FDA labeling information @ fda.gov (Retrieved November 18, 2008)


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