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. Transeyte® 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. Orceᵀᴹ 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, Integra Bilayer Matrix Wound Dressing, 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. 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.

8. Epicel® cultured epidermal autograft for deep dermal or full thickness burns comprising ≥ 30% total body surface area.

9. Oasis® Wound Matrix for chronic, lower extremity, partial or full-thickness, venous or diabetic ulcers, when standard wound therapy has failed.

10. Cymetra when used for treatment of vocal cord paralysis.

11. 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.

12. 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. Grafix core, per square centimeter

11. Grafix prime, per square centimeter

12. GraftJacket Express

13. GraftJacket® Regenerative Tissue Matrix

14. Hyalomatrix
15. Integra Matrix
16. Integra Neurawrap™
17. Integra™ Flowable Wound Matrix
18. MatriStem micromatrix, MatriStem wound matrix and MatriStem burn matrix
19. MemoDerm, per sq cm
20. NeoForm Dermis™
22. NeuroMatrix™ Collagen Nerve Cuff
23. Neumend
24. Oasis Burn Matrix
25. Oasis Ultra Tri-Layer Matrix
26. Surgisis® RVP Recto-Vaginal Fistula Plug
27. Talymed, per sq cm
28. TenoGlide™ Tendon Protector Sheet
29. TissueMend®
30. Unite biomatrix, per sq cm
31. 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
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**  Capsular contracture of breast implant, initial encounter
- **T85.44xD**  Capsular contracture of breast implant, subsequent encounter
- **T85.44xS**  Capsular contracture of breast implant, sequela
- **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
- **Z98.82**  Breast implant status
- **Z90.10**  Acquired absence of unspecified breast and nipple
- **Z90.11**  Acquired absence of right breast and nipple
- **Z90.12**  Acquired absence of left breast and nipple
- **Z90.13**  Acquired absence of bilateral breasts and nipples
- **Z40.01**  Encounter for prophylactic removal of breast
- **Z42.1**  Encounter for breast reconstruction following mastectomy
- **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 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 diabetic neuropathy
E11.40 - E11.69 Type 2 diabetes mellitus with diabetic neuropathy
E13.40 - E13.69 Other specified diabetes mellitus with diabetic neuropathy

CPT/HCPCS Codes:
Q4100 Skin substitute, not otherwise specified
(Explanatory notes must accompany claims billed with unlisted codes.)
- Use for billing: TranCyte™, Orcel®, Biobrane Biosynthetic Dressing®, Epicel®, AlloMax, DermaMatrix™
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 DermACECELL, per sq cm (Not covered for Priority Medicaid)
Q4128 FlexHD or AllopatchHD, per sq cm (Not covered for Priority Medicaid)
Q4130 Strattice TM, per sq cm (Not covered for Priority Medicaid)
Q4131 Epifix, 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
<table>
<thead>
<tr>
<th>Code</th>
<th>Product Description</th>
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<tbody>
<tr>
<td>Q4114</td>
<td>Integra flowable wound matrix, injectable, 1 cc</td>
</tr>
<tr>
<td>Q4115</td>
<td>AlloSkin, per square centimeter</td>
</tr>
<tr>
<td>Q4117</td>
<td>HYALOMATRIX, per sq cm</td>
</tr>
<tr>
<td>Q4118</td>
<td>MatriStem micromatrix, 1 mg</td>
</tr>
<tr>
<td>Q4119</td>
<td>MatriStem wound matrix, per sq cm</td>
</tr>
<tr>
<td>Q4120</td>
<td>MatriStem burn matrix, per sq cm</td>
</tr>
<tr>
<td>Q4123</td>
<td>AlloSkin RT, per sq cm</td>
</tr>
<tr>
<td>Q4124</td>
<td>OASIS ultra tri-layer wound matrix, per sq cm</td>
</tr>
<tr>
<td>Q4125</td>
<td>Arthroflex, per sq cm</td>
</tr>
<tr>
<td>Q4126</td>
<td>MemoDerm, DermaSpan, Tranzgraft or Integuply, per square centimeter</td>
</tr>
<tr>
<td>Q4127</td>
<td>TalyMed, per sq cm</td>
</tr>
<tr>
<td>Q4129</td>
<td>Unite biomatrix, per sq cm</td>
</tr>
<tr>
<td>Q4132</td>
<td>Grafix core, per square centimeter</td>
</tr>
<tr>
<td>Q4133</td>
<td>Grafix prime, per square centimeter</td>
</tr>
<tr>
<td>Q4134</td>
<td>hMatrix, per square centimeter</td>
</tr>
<tr>
<td>Q4135</td>
<td>Mediskin, per square centimeter</td>
</tr>
<tr>
<td>Q4136</td>
<td>Ez-derm, per square centimeter</td>
</tr>
<tr>
<td>Q4137</td>
<td>Amnioexcel or biodexcel, per square centimeter</td>
</tr>
<tr>
<td>Q4138</td>
<td>Biodfence dryflex, per square centimeter</td>
</tr>
<tr>
<td>Q4139</td>
<td>Amniomatrix or biodmatrix, injectable, 1 cc</td>
</tr>
<tr>
<td>Q4140</td>
<td>Biodfence, per square centimeter</td>
</tr>
<tr>
<td>Q4141</td>
<td>Alloskin ac, per square centimeter</td>
</tr>
<tr>
<td>Q4142</td>
<td>XCM biologic tissue matrix, per square centimeter</td>
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<tr>
<td>Q4143</td>
<td>Repriza, per square centimeter</td>
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<tr>
<td>Q4145</td>
<td>EpiFix, injectable, 1 mg</td>
</tr>
<tr>
<td>Q4146</td>
<td>Tensix, per square centimeter</td>
</tr>
<tr>
<td>Q4147</td>
<td>Architect extracellular matrix, per square centimeter</td>
</tr>
<tr>
<td>Q4148</td>
<td>NeoX 1k, per square centimeter</td>
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<tr>
<td>Q4149</td>
<td>Excellagen, 0.1 cc</td>
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<tr>
<td>Q4150</td>
<td>Allowrap ds or dry, per square centimeter</td>
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<tr>
<td>Q4151</td>
<td>Amnioband or guardian, per square centimeter</td>
</tr>
<tr>
<td>Q4152</td>
<td>Dermapure, per square centimeter</td>
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<tr>
<td>Q4153</td>
<td>Dermavest, per square centimeter</td>
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<tr>
<td>Q4154</td>
<td>Biovance, per square centimeter</td>
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<tr>
<td>Q4155</td>
<td>Neoxflo or clarixflo, 1 mg</td>
</tr>
<tr>
<td>Q4156</td>
<td>Neox 100, per square centimeter</td>
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<tr>
<td>Q4157</td>
<td>Revitalon, per square centimeter</td>
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<td>Q4158</td>
<td>Marigen, per square centimeter</td>
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<tr>
<td>Q4159</td>
<td>Affinity, per square centimeter</td>
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<tr>
<td>Q4160</td>
<td>Nushield, per square centimeter</td>
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<tr>
<td>Q4161</td>
<td>Bio-ConneKt wound matrix, per square centimeter</td>
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<tr>
<td>Q4162</td>
<td>AmnioPro Flow, Bioskin Flow, BioRenew Flow, WoundEx Flow, Amniogen-A, Amniogen-C, 0.5 cc</td>
</tr>
<tr>
<td>Q4163</td>
<td>AmnioPro, BioSkin, BioRenew, Woundex, Amniogen-45, Amniogen-200, per square centimeter</td>
</tr>
<tr>
<td>Q4164</td>
<td>Helicoll, per square centimeter</td>
</tr>
<tr>
<td>Q4165</td>
<td>Keramatrix, per square centimeter</td>
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**OP Facility billing only:**

<table>
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<tr>
<th>C</th>
<th>Description</th>
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<tbody>
<tr>
<td>C9358</td>
<td>Dermal substitute, native, non-denatured collagen (SurgiMend Collagen Matrix), per 0.5 square centimeters</td>
</tr>
<tr>
<td>C9363</td>
<td>Skin substitute, Integra Meshed Bilayer Wound Matrix, per square centimeter</td>
</tr>
<tr>
<td>C9364</td>
<td>Porcine implant (Permacol), per square cm</td>
</tr>
<tr>
<td>C9399</td>
<td>Unclassified drugs or biologicals</td>
</tr>
</tbody>
</table>

*These C-codes reportable by outpatient facility only; using rev code 0636*  
If used for billing: TranCyte™, Orcel®, Biobrane Biosynthetic Dressing®, Epicel®, AlloMaz, DermaMatrix

**Not Covered:**

<table>
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<th>C</th>
<th>Description</th>
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<tbody>
<tr>
<td>C9349</td>
<td>PuraPly, and PuraPly Antimicrobial, any type, per square centimeter</td>
</tr>
<tr>
<td>C9352</td>
<td>Microporous collagen implantable tube (NeuraGen Nerve Guide), per cm length</td>
</tr>
<tr>
<td>C9353</td>
<td>Microporous collagen implantable slit tube (NeuraWrap Nerve Protector), per cm length</td>
</tr>
<tr>
<td>C9354</td>
<td>Acellular pericardial tissue matrix of nonhuman origin (Veritas), per square centimeter</td>
</tr>
<tr>
<td>C9355</td>
<td>Collagen nerve cuff (NeuroMatrix), per 0.5 centimeter length</td>
</tr>
<tr>
<td>C9356</td>
<td>Tendon, porous matrix of cross-linked collagen and glycosaminoglycan matrix (TenoGlide Tendon Protector Sheet), per square centimeter</td>
</tr>
<tr>
<td>C9359</td>
<td>Porous purified collagen matrix bone void filler (Integra Mozaik Osteoconductive Scaffold Putty, Integra OS Osteoconductive Scaffold Putty), per 0.5 cc</td>
</tr>
<tr>
<td>C9360</td>
<td>Dermal substitute, native, non-denatured collagen, neonatal bovine origin (SurgiMend Collagen Matrix), per 0.5 square cm</td>
</tr>
<tr>
<td>C9361</td>
<td>Collagen matrix nerve wrap (NeuroMend Collagen Nerve Wrap), per 0.5 cm length</td>
</tr>
<tr>
<td>C9362</td>
<td>Porous purified collagen matrix bone void filler (Integra Mozaik Osteoconductive Scaffold Strip), per 0.5 cc</td>
</tr>
</tbody>
</table>

**VI. REFERENCES**


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


Local Coverage Determination (LCD): Application of Bioengineered SKIN Substitutes (L30135), WPS, @ http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=30135&ContrId=266&ver=61&ContrVer=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=Michigan&Key
Hayes, Inc. EpiFix for Treatment of Nonhealing Wounds, March 26, 2015

Allogeneic, Xenographic, Synthetic and Composite Products for Wound Healing and Soft Tissue Grafting. Anthem blue Cross Medical Policy
@ http://www.anthem.com/ca/medicalpolicies/policies/mp_pw_a053309.htm (Retrieved April 7, 2015)

Allogeneic, Xenographic, Synthetic and Composite Products for Wound Healing and Soft Tissue Grafting, Anthem Blue Cross Medical Policy
@ https://www.anthem.com/ca/medicalpolicies/policies/mp_pw_a053309.htm (Retrieved April 13, 2016)

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