Premier Health Insuring Corporation
POLICY AND PROCEDURE MANUAL

Policy Number: MP.083.PC
Last Review Date: 11/12/2015
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MP.083.PC - Skin Substitutes- Human Skin Equivalents

This policy applies to the following line(s) of business:
- ✓ Premier Health Insuring Corporation MA – DSNP

Premier Health Insuring Corporation considers Skin Substitutes- Human Skin Equivalents (HSE) medically necessary for the following indications:

APLIGRAF® (formerly marketed as Graftskin) is indicated for the treatment of venous insufficiency ulcers in conjunction with the recommended post-application compression therapy when all of the following are met:

1. The treatment is specific to non-infected partial or full-thickness skin ulcers, at least 1.0 cm^2 in size, due to clinically documented venous insufficiency (venous insufficiency should be objectively documented either by history of previous deep venous thrombosis in the index leg, or objective documentation of valvular reflux by duplex ultrasound, venography, or air/photo plethysmography); And
2. The ulcer(s) is of at least four weeks in duration; And
3. The medical record supports that the ulcer(s) has been treated by the provider applying the human skill equivalents (HSE) with conventional non-surgical therapy for a minimum of four weeks and has failed to decrease in size, and the ulcer(s) has not shown any indication (e.g., epithelial in growth and progression towards closure) that improvement is likely;

   Or

   The medical record supports that the ulcer is so clinically severe that it requires immediate, aggressive therapy; And
4. Adequate circulation/oxygenation supported by documented physical examination and an Ankle-Brachial Index (ABI) of no less than 0.65; And
5. The member is competent and/or has the support services required to participate in follow-up care associated with the treatment of the wound following the application of Apligraf®;

OR

APLIGRAF® (Graftskin) is indicated for the treatment of diabetic foot ulcers in conjunction with the recommended post-application compression therapy when all of the following are met:

1. The treatment is specific to non-infected full thickness foot ulcers, at least 1.0 cm^2 in size, due to clinically documented diabetic neuropathy (type 1 or type 2 diabetes should be objectively documented as well as the current medical management for the diabetes, including medical management of neuropathy); And
2. The ulcer is of at least three (3) weeks in duration; And
3. The ulcer is located on the surface of the foot and is free of infection, tunnels, and tracts. The ulcer must be free of cellulitis, eschar, or obvious necrotic material as this will interfere with the device adherence and wound healing; And
4. The ulcer extends through the dermis but it does not involve the tendon, muscle, capsule or have bone exposure; And
5. The medical record supports that the ulcer(s) has been treated by the provider applying the HSE with conventional non-surgical therapy for a minimum of three (3) weeks and has failed to decrease in size; And
6. The ulcer(s) has not shown any indication (e.g., epithelial in-growth and progression towards closure) that improvement is likely;

   Or

   The medical record supports that the ulcer is so clinically severe that it requires immediate, aggressive therapy; And
7. The extremity is free of active Charcot's arthropathy; And
8. The member must have adequate arterial blood supply to support tissue growth; And
9. The member is competent and/or has the support system required to participate in the follow-up care associated with treatment of the wound with Apligraf®.

DERMAGRAFT® is indicated for the treatment of diabetic foot ulcers when all of the following are met and documented:

1. The treatment is specific to non-infected full thickness diabetic foot ulcers, is at least 1.0 cm^2 in size, (type 1 or type 2 diabetes should be objectively documented as well as the current medical management for the diabetes); And
2. The ulcer is of at least three weeks in duration; And
3. The ulcer is located on the surface of the foot and is free of infection, tunnels, and tracts, cellulitis, eschar, or obvious necrotic material as this will interfere with the device adherence and wound healing; And
4. The ulcer extends through the dermis but it does not involve the tendon, muscle, joint capsule or have bone exposure; And
5. The medical record supports that the ulcer(s) has been treated by the provider applying the HSE with conventional non-surgical therapy for a minimum of three weeks and has failed to decrease in size; And

6. The ulcer(s) has not shown any indication (e.g., epithelial in-growth and progression towards closure) that improvement is likely;
   OR
   The medical record supports that the ulcer is so clinically severe that it requires immediate, aggressive therapy; And
7. The extremity must be free of active Charcot's arthropathy; And
8. The member must have adequate arterial blood supply to support tissue growth; And
9. The member is competent and/or has the support system required to participate in follow-up care associated with treatment of the wound with Dermagraft®.

INTEGRA products are indicated for the treatment of:

1. Severe (2nd or 3rd degree) burns
   Or
   Burn scars/contracture reconstructive surgery
   Or
   Significant open wounds, such as severe necrotizing fasciitis
   And
2. When there is a limited amount of member's skin for autografts
   Or
   The member is too ill to have more wound graft sites created.

OASIS WOUND MATRIX®:

1. The product is being used for the management of wounds including:
   - Treatment of neuropathic diabetic foot ulcers that have failed conservative measures of at least four weeks duration.
     Or
   - Treatment of partial and full-thickness skin venous insufficiency ulcers present for a minimum of four weeks duration and have failed conventional treatment for at least two weeks.
     Or
   - Skin substitute used in conjunction with standard wound care regiment.
     And
2. The medical record clearly documents that the product is being used in an office or clinic based comprehensive, organized wound management program

TheraSkin is indicated when used for any of the following:

1. In conjunction with standard therapeutic compression for the treatment of chronic, non-infected, partial or full-thickness skin ulcers due to venous insufficiency of greater than one month in duration and which have not adequately responded to a

four week period of conventional ulcer therapy (such as standard dressing changes, and standard therapeutic compression)
Or

2. In conjunction with standard diabetic foot ulcer care for the treatment of full-thickness neuropathic diabetic foot ulcers of greater than one month duration which have not adequately responded following at least a four week period of conventional ulcer therapy (such as surgical debridement, complete off-loading and standard dressing changes) and which can extend through the dermis, including tendon, muscle, joint capsule or bone exposure
   Or
3. Large surgical wounds
   Or
4. Pressure ulcers

Limitations

Apligraf®

1. A single application of Apligraf® may be all that is required to affect the wound healing in those wounds that are likely to improve by this therapy.
   - The use of additional applications if less than 50% “take” is observed, is limited to a total of four additional applications for the same ulcer.
   - Additional applications beyond this for one year are considered not medically necessary.
   - Apligraf® is not covered for use with acute surgical wounds, pressure sores and burns.
2. Retreatment:
   - Within one year following the last successful Apligraf® application is considered not medically necessary.
   - Of an ulcer following the unsuccessful treatment where it consisted of two failed Apligraf® applications is considered not medically necessary.

   NOTE: Debridement of the ulcer is not payable during active treatment with Apligraf®, except for debridement prior to re-applications, or prior to retreatment.
3. Contraindications:
   - Clinically infected wounds (i.e. increased exudate, odor, redness, swelling, heat, pain, tenderness to the touch, purulent drainage);
   - Known allergies to bovine collagen; and
   - A known hypersensitivity to the components of the agarose shipping medium

Dermagraft®

1. A single application of Dermagraft® may be all that is required to affect the wound healing in those wounds that are likely to improve by this therapy.
   - The use of additional applications if less than 50% "take" is observed, is limited to a total of seven additional applications for the same ulcer.
   - Additional applications beyond this for one year are considered not medically necessary.
   - Dermagraft® is not covered for use with acute surgical wounds, pressure sores and burns.
2. Retreatment:
   - Within one year following the last successful Dermagraft® application is considered not medically necessary.
   - Of an ulcer following the unsuccessful treatment where it consisted of two failed Dermagraft® applications is considered not medically necessary.

   NOTE: Debridement of the ulcer is not payable during active treatment with Dermagraft®, except for debridement prior to re-applications, or prior to retreatment.
3. Contraindications:
   - Clinically infected ulcers (i.e. increased exudate, odor, redness, swelling, heat, pain, tenderness to the touch, purulent discharge) or ulcers with sinus tracts;
   - Known hypersensitivity to bovine products, as it may contain trace amounts of bovine proteins from the manufacturing medium and storage solution.

Integra

1. Use of Integra for any other indications than those listed in this policy will result in a claims denial.
2. Contraindications:
   - Clinically infected ulcers (i.e. increased exudate, odor, redness, swelling, heat, pain, tenderness to the touch, purulent discharge) or ulcers with sinus tracts;
   - Known hypersensitivity or allergy to bovine products

Oasis® Wound Matrix

A non-adherent, secondary dressing should be used over the Oasis® Wound Matrix to maintain a moist wound environment.

TheraSkin

The use of TheraSkin on an ulcer with any of the following conditions is not considered medically necessary and will result in a claims denial:

- Cellulitis;
- Osteomyelitis;
- Necrotic ulcer;

- Draining wound;
- Clinically significant wound healing impairment due to uncontrolled diabetes.

Human Skin Equivalents/Skin Substitutes

The application of HSE is limited to clinicians and physicians who are highly skilled in wound care management and have experience in the use of HSE for the treatment of wounds.

1. HSE should be applied to a clean ulcer that has undergone one detailed debridement prior to each application.
2. The member should be under the care of a physician for the treatment and monitoring of their systemic disease processes.
3. Prior to HSE application:
   - The medical record documentation should contain evidence that the conservative measures have failed, or support that the ulcer is so clinically severe that it requires immediate, aggressive therapy.
   - The medical record should indicate failure of the ulcer to decrease in size and depth, or that there has been no change in baseline size or depth with no signs of improvement, or no indication that improvement is likely.
4. Medical record documentation should contain the frequency of the HSE application for both venous insufficiency ulcers and neuropathic diabetic foot ulcers and be consistent with each member's specific history and response to the device application.
5. Contraindications:
   - Clinically infected wounds (i.e., increased exudate, odor, redness, swelling, heat, pain, tenderness to the touch, purulent discharge)
   - Known allergies to bovine collagen - for bovine derived products
   - Known hypersensitivity to the components of the agarose (gel-like substance derived from seaweed) shipping medium.
6. Not medically necessary applications of Apligraf® and Dermagraft ®
   - Surgical wounds,
   - Pressure sores, and
   - Burns
7. Experimental and Investigational:
   - AlloDerm skin substitute *****
   - AlloPatch (FlexHD)
   - AlloSkin skin substitute
   - Amnioexcel or Biodexcel
   - AmnioFix
   - Amniomatrix or Biodmatrix

- Arthroflex
- Artiss (Human plasma fibrin sealant, vapor-heated, solvent-detergent)
- Biodfence
- Dermacell
- Endoform Dermal Template
- Epicel
- EpiFix
- Excellagen
- FlexHD (AKA: AlloPatch)
- Graftjacket® Regenerative Tissue Matrix- (*non injectable*) *****
- Graftjacket X-Press® Flowable Soft Tissue Scaffold (*injectable*)
- Integra Meshed Bilayer Wound Matrix skin substitute
- Memoderm
- NeoX
- NeuroMend Collagen Nerve Wrap (Collagen matrix nerve wrap)
- Permacol Porcine implant
- Primatrix
- Repriza
- Strattice
- Tensix
- Oasis Burn Matrix
- Oasis Ultra Tri-Layer Matrix
- SurgiMend Collagen Matrix (Dermal substitute, native, non-denatured collagen, neonatal bovine origin)
- Talymed
- Unite Biomatrix
- XCM Biologic Tissue Matrix

Background

In the United States, the total prevalence of chronic wounds related to venous ulcers, diabetic foot ulcers, and pressure sores, has been estimated to range from 3 to 6 million. These wounds are categorized as chronic as they have occurred in duration for a minimum of four weeks. Skin substitutes, also referred to as human skin equivalents (HSE), are tissue-engineered products using human cells, animal cells, or both, in a scaffold of natural or synthetic extracellular matrices. The extracellular matrices provide mechanical stability and a 3-dimensional framework for eventual tissue infiltration and development, and can also promote wound healing by stimulating the host to produce a variety of cytokines.

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Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes	
Code	Description
CPT Codes	
15271	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
15272	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof
15273	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
15274	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof
15275	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
15276	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof
15277	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
15278	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof

15777	Implantation of biologic implant (eg, acellular dermal matrix) for soft tissue reinforcement (eg, breast, trunk)
HCPCS codes covered if selection criteria are met (If Appropriate):	
Q4101	Apligraf, per square centimeter
Q4102	Oasis Wound Matrix, per square centimeter
Q4104	Skin Substitute, Integra Bilayer Matrix Wound Dressing (BMWD), per sq cm
Q4105	Skin Substitute, Integra Dermal Regeneration Template (DRT), per sq cm
Q4108	Integra Matrix, per sq cm
Q4114	Integra™ Flowable Wound Matrix
Q4106	Dermagraft, per square centimeter
Q4121	TheraSkin, per square centimeter
Alloderm code covered when billed with any of the following breast reconstruction diagnoses:	
Q4116	Alloderm, per sq cm
ICD-9 codes	
173.5	Unspecified malignant neoplasm of skin of trunk, except scrotum
198.2	Secondary Malignant Neoplasm of skin
198.81	Secondary Malignant Neoplasm of Breast
174.0 - 174.9	Malignant Neoplasm of Female Breast
175.0, 175.9	Malignant Neoplasm of Male Breast
233.0	Carcinoma in situ of breast
233.3	Carcinoma in situ, unspecified female genital organ
238.3	Neoplasm of uncertain behavior of breast
239.3	Neoplasm of unspecified nature of Breast
V10.3	Personal History of Malignant Neoplasm of Breast
V45.71	Acquired Absence of Breast and nipple
Graftjacket code covered when billed with any of the following diagnoses:	
Q4107	Graftjacket skin substitute (*non injectable*), per sq cm

ICD-9 codes	
881.22	Open wound of wrist with tendon involvement
882.2	Open wound of hand, except fingers alone, with tendon involvement
883.2	Open wound of fingers with tendon involvement
ICD-10 codes	
C44.500	Unspecified malignant neoplasm of anal skin
C44.501	Unspecified malignant neoplasm of skin of breast
C44.509	Unspecified malignant neoplasm of skin of other part of trunk
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C79.2	Secondary malignant neoplasm of skin
C79.81	Secondary malignant neoplasm of breast
D05.90	Unspecified type of carcinoma in situ of unspecified breast
D07.30	Carcinoma of situ of unspecified female genital organs
D07.2	Carcinoma in situ of vagina
D07.1	Carcinoma in situ of vulva
D07.39	Carcinoma in situ of other female genital organs

D48.60	Neoplasm of uncertain behavior of unspecified breast
D49.3	Neoplasm of unspecified behavior of breast
Z85.3	Personal history of malignant neoplasm of breast
Z90.10	Acquired absence of unspecified breast and nipple
Graftjacket	
S66.929A	Laceration of unspecified muscle, fascia and tendon at wrist and hand level, unspecified hand, initial encounter
S61.509A	Unspecified open wound of unspecified wrist, initial encounter
S66.929A	Laceration of unspecified muscle, fascia and tendon at wrist and hand level, unspecified hand, initial encounter
S61.409A	Unspecified open wound of unspecified hand, initial encounter
S66.529A	Laceration of intrinsic muscle, fascia and tendon of unspecified finger at wrist and hand level, initial encounter
S61.109A	Unspecified open wound of unspecified thumb with damage to nail, initial encounter
S61.209A	Unspecified open wound of unspecified finger without damage to nail, initial encounter

Variations

1. Alloderm is covered for medically necessary breast reconstruction.
2. Graftjacket ® Regenerative Tissue Matrix (*non injectable*) is covered for open wound of wrist, hand or fingers with tendon involvement.

References

1. American Burn Association White Paper: Surgical Management of the Burn Wound and the Use of Skin Substitutes, 2009 http://www.ucdenver.edu/academics/colleges/medicalschool/departments/surgery/divisions/GITES/burn/Documents/American%20Burn%20Association%20White%20Paper.pdf
2. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) No L34938. .Human Skin Equivalents (HSE) - Use in the Treatment of Chronic Cutaneous Ulcer Wounds. (Contractor: Novitas Solutions, Inc). Revision Effective Date: 10/01/2015. https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34938&ContrId=321&ver=3&ContrVer=1&Date=&DocID=L34938&bc=iAAAAAgAAAAAAA%3d%3d&
3. Cuadra A, Correa G, Roa R, et al. Functional results of burned hands treated with Integra®. J Plast Reconstr Aesthet Surg. 2012 Feb; 65(2):228-234. http://ac.els-cdn.com/S1748681511005171/1-s2.0-S1748681511005171-main.pdf?_tid=3b52983e-f0ed-11e3-bf45-00000aacb361&acdnat=1402438924_d5c8f21a5f3192db8017115c1c15b2af
4. DiDomenico L, Emch KJ, Landsman A, et al. A prospective comparison of diabetic foot ulcers treated with either a cryopreserved skin allograft or a bioengineered skin substitute. Wounds. 2011;23(7):184–189 http://www.medscape.com/viewarticle/747481
5. Felder III JM, Goyal SS, Attinger CE. A systematic review of skin substitutes for foot ulcers. Plast Reconstr Surg 2012 Jul;130(1):145-164. doi: 10.1097/PRS.0b013e318254b1ea. http://www.ncbi.nlm.nih.gov/pubmed/22743881
6. Greaves NS, Iqbal SA, Baguneid M, et al. The role of skin substitutes in the management of chronic cutaneous wounds. Wound Repair Regen. 2013 Mar-Apr;21(2):194-210. doi: 10.1111/wrr.12029. Epub 2013 Feb 25. http://www.ncbi.nlm.nih.gov/pubmed/23437811
7. Greer N, Foman N, Dorrian J, et al. Advanced Wound Care Therapies for Non-Healing Diabetic, Venous, and Arterial Ulcers: A Systematic Review [Internet]. VA Evidence-based Synthesis Program Reports. 2012 Nov. Available at: http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0054957/pdf/TOC.pdf
8. Halim A, Khoo T, Yusoof S. Biologic and synthetic skin substitutes: An overview. Indian J Plast Surg. September 2010. 43(Suppl): S23-S28). http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3038402/?report=printable

9. Han G. State-of-the-art wound healing: skin substitutes for chronic wounds. Cutis. 2014 Jan;93(1):E13-6. http://www.cutis.com/uploads/media/CT093010E13.pdf
10. Hayes Medical Technology Directory. Biological Tissue-Engineered Skin Substitutes for Wound Healing. Annual Review February 11, 2014.
11. Hayes Medical Technology Directory. Biosynthetic Tissue-Engineered Skin Substitutes for Wound Healing. Annual Review February 14, 2014.
12. Landsman A, Cook J, Cook E, et al: A retrospective clinical study of 188 consecutive patients to examine the effectiveness of a biologically active cryopreserved human skin allograft (TheraSkin®) on the treatment of diabetic foot ulcers and venous leg ulcers. Foot Ankle Spec. 2011 Feb;4(1):29-41 http://www.ncbi.nlm.nih.gov/pubmed/21135263
13. Langer A, Rogowski W. Systematic review of economic evaluations of human cell-derived wound care products for the treatment of venous leg and diabetic foot ulcers. BMC Health Serv Res. 2009 Jul 10;9:115. doi: 10.1186/1472-6963-9-115. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2716319/pdf/1472-6963-9-115.pdf
14. Mazzone L, Schiesti C. Management of septic skin necroses. Eur J Pediatr Surg. 2013 Oct;23(5):349-358. doi: 10.1055/s-0033-1352530. Epub 2013 Sep 5. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1493442/
15. NIH/ National Institute of General Medical Sciences: Burns Fact Sheet. Last reviewed: Nov. 22, 2013. http://www.nigms.nih.gov/Education/Factsheet_Burns.htm
16. Orgill DP, Ogawa R. Current methods of burn reconstruction. Plast Reconstr Surg. 2013 May;131(5):827e-836e. doi: 10.1097/PRS.0b013e31828e2138. http://www.ncbi.nlm.nih.gov/pubmed/23629122
17. U.S. Food and Drug Administration (FDA): 510(k) Summary approval for INTEGRA™ Flowable Wound Matrix, 10/10/2007 http://www.accessdata.fda.gov/cdrh_docs/pdf7/K072113.pdf
18. U.S. Food and Drug Administration (FDA): 510(k) Summary approval for INTEGRA™ Bilateral Matrix Wound Dressing, 8/14/2002 http://www.accessdata.fda.gov/cdrh_docs/pdf2/k021792.pdf
19. U.S. Food and Drug Administration (FDA): 510(k) Summary approval for INTEGRA® Dermal Regeneration Template. Last updated: 09/15/2013. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm083520.htm

Disclaimer:

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