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Department: Utilization Management
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Health Plans

X Medicare Advantage **X Commercial**

Skin Substitutes- Human Skin Equivalents Policy

I. Purpose

Indiana University Health Plans (IU Health Plans) considers clinical indications when making a medical necessity determination for Skin Substitutes- Human Skin Equivalents.

II. Scope

This policy applies to all Utilization Management staff having decision-making responsibilities where authorization is required for Fully Insured commercial plan.

III. Exceptions/Variations

1. Any product must have FDA clearance for specified use (i.e., must be approved for treatment of diabetic ulcer, venous insufficiency, breast reconstruction, burns, or surgical wounds
2. 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.
3. The application of Human Skin Equivalents/Skin Substitutes (HSE) is limited to:
   a. Clinicians and physicians who are highly skilled in wound care management and have experience in the use of HSE for the treatment of wounds.
   b. HSE should be applied to a clean ulcer that has undergone one detailed debridement prior to each application.
   c. The member should be under the care of a physician for the treatment and monitoring of their systemic disease processes.
4. Prior to HSE application:
   a. 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.
   b. 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.
   c. 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.

Medicare Exceptions

All skin substitutes used must have been specifically FDA labelled or cleared for use in the type of wound being treated, or they will be considered biologic dressings and not reimbursed.

IV. Definitions

Skin Substitutes- Per Centers for Medicare and Medicaid Services (CMS), Skin Substitutes or Cellular or Tissue Based Products (CTP's) are a wide variety of bio-engineered products available for soft tissue coverage to affect closure. They may be derived from allogenic, xenogeneic, or synthetic sources or a combination of materials. However, without the component of the recipient's own epithelium, permanent skin replacement cannot be accomplished.

V. Policy Statements

IU Health Plans considers **Skin Substitutes- Human Skin Equivalents (HSE)** medically necessary when **ONE of the following** indications are met:

1. **Breast Reconstruction:-** Use of **AlloDerm, Cortiva (AlloMax), DermACELL or Flex HD** are covered when medically necessary
2. **Venous Insufficiency Ulcers-** Must meet **ALL** of the following:
    a. Use of AmnioBand, sheet or membrane form, or Apligraf, or Epifix
    b. Unresponsive to treatment measures care for at least 30 days with documented compliance. (Failed to decrease in size, no indication of growth and progression towards closure)
    c. Evidence on no smoking or tobacco use for at least 4 weeks during conservative care and prior to skin replacement or evidence of smoking cessation counseling and cessation measures.
    d. The treatment area is at least 1.0 cm^2 in size,
    e. Area is free of infection and/or necrotic debris
    f. Adequate circulation/oxygenation to support tissue growth/wound healing as evidenced by physical examination (Ankle Brachial Index -ABI- of no less than 0.60, toe pressure greater than 30 mm Hg.

3. **Diabetic foot ulcers** in conjunction with the recommended post-application compression therapy when **ALL of the following** are met:
    a. Use of AmnioBand, sheet or membrane form, or Apligraf, or DermACELL, or Dermagraft, or Epicord, or Epifix, or Grafix PRIME, or Kerecis Omega 3, or mVASC, or TheraSkin
    b. 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)
    c. The ulcer is of at least three (4) weeks in duration and has failed conservative therapy by no decrease in size- type of conservative therapy must be in documentation provided.
    d. The ulcer is located on the surface of the foot and is free of infection, Charcot arthropathy, 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.
    e. The ulcer extends through the dermis, but it does not involve the tendon, muscle, capsule or have bone exposure
    f. There is adequate arterial blood supply to support tissue growth

g. 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 ofthree weeks and has failed to decrease in size
h. The ulcer(s) has not shown any indication (e.g., epithelial in-growth and progression towards closure) that improvement is likely
i. The member is competent and/or has the support system required to participate in follow-up care associated with treatment of the wound with human skin Equivalent

4. Hand and wrist wounds-**Graftjacket ® Regenerative Tissue Matrix**(non-injectable) is covered for **ONE of the following**:
a. Open wound of the wrist
b. Open wound of the hand
c. Open wound of the fingers with tendon involvement

5. Burn care/Contracture Surgical Care/Significant Open Wounds-HSE with Integra or Theraskin is indicated for the treatment of **ONE of the following:**
a. Severe (2^{nd} or 3^{rd} degree) burns
1. Burn scars/contracture reconstructive surgery
2. Significant open wounds, such as severe necrotizing fasciitis
b. When there is a limited amount of member's skin for autografts
c. The member is too ill to have more wound graft sites created.

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):	
A2002	Mirragen Adv wound Material per sq cm
A2007	Restrata, per sq cm
A2009	Symphony, per sq cm
A2010	Apis, per sq cm
A2011	Supra subdermal per sq cm
A2012	Suprathel, per sq cm
C5271	Application of low-cost 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
C5272	Application of low-cost skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; each additional 25 sq cm or less wound surface area
C5273	Application of low-cost 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
C5274	Application of low-cost 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 1% of body area of infants and children
C5275	Application of low-cost 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
C5276	Application of low-cost 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 or less wound surface area
C5277	Application of low-cost 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
C5278	Application of low-cost 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 1% of body area of infants and children
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
Q4106	Dernagraft per sq cm
Q4017	Graftjacket, per sq cm
Q4108	Integra Matrix, per sq cm
Q4110	Primatrix, per sq cm
Q4111	Gammagraft, per sq cm

Q4114	Integra™ Flowable Wound Matrix
Q4115	Alloskin, per sq cm
Q4117	Hyalomatrix, per sq cm
Q4121	TheraSkin, per square centimeter
Q4122	Dermacell, awm, porous, per sq cm
Q4123	Alloskin
Q4124	Oasis tri-layer wound matrix
Q4127	Talymed
Q4131	Epifix
Q4132	Grafix core, grafixl core
Q4133	Grafix stravix prime pl, per sq cm
Q4136	Ezderm
Q4141	Alloskin ac, per sq cm
Q4152	Dermapure, per sq cm
Q4158	Kerecis Omega 3, per sq cm
Q4186	Epifix, per sq cm
Alloderm code covered when billed with any of the following breast reconstruction diagnoses:	
Q4116	Alloderm, per sq cm
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
D07.39	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 code covered when billed with any of the following diagnoses:	
Q4107	Graftjacket skin substitute (*non injectable*), per sq cm
ICD-10 codes	
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
S61.409A	Unspecified open wound of unspecified hand, initial encounter
S61.509A	Unspecified open wound of unspecified wrist, initial encounter
S66.021A	Laceration of long flexor muscle, fascia, and tendon of right thumb at wrist and hand level, initial encounter
S66.022A	Laceration of long flexor muscle, fascia, and tendon of left thumb at wrist and hand level, initial encounter
S66.029A	Laceration of long flexor muscle, fascia, and tendon of unspecified thumb at wrist and hand level, initial encounter
S66.120A	Laceration of flexor muscle, fascia, and tendon of right index finger at wrist and hand level, initial encounter
S66.121A	Laceration of flexor muscle, fascia, and tendon of right index finger at wrist and hand level, initial encounter
S66.122A	Laceration of flexor muscle, fascia, and tendon of right middle finger at wrist and hand level, initial encounter
S66.123A	Laceration of flexor muscle, fascia, and tendon of left middle finger at wrist and hand level, initial encounter
S66.124A	Laceration of flexor muscle, fascia, and tendon of right ring finger at wrist and hand level, initial encounter
S66.125A	Laceration of flexor muscle, fascia, and tendon of left ring finger at wrist and hand level, initial encounter
S66.126A	Laceration of flexor muscle, fascia, and tendon of right little finger at wrist and hand level, initial encounter
S66.127A	Laceration of flexor muscle, fascia, and tendon of left little finger at wrist and hand level, initial encounter
S66.128A	Laceration of flexor muscle, fascia, and tendon of other finger at wrist and hand level, initial encounter
S66.129A	Laceration of flexor muscle, fascia, and tendon of unspecified finger at wrist and hand level, initial encounter
S66.221A	Laceration of extensor muscle, fascia, and tendon of right thumb at wrist and hand level, initial encounter
S66.229A	Laceration of extensor muscle, fascia, and tendon of unspecified thumb at wrist and hand level, initial encounter
S66.320A	Laceration of extensor muscle, fascia, and tendon of right index finger at wrist and hand level, initial encounter
S66.321A	Laceration of extensor muscle, fascia, and tendon of left index finger at wrist and hand level, initial encounter
S66.322A	Laceration of extensor muscle, fascia, and tendon of right middle finger at wrist and hand level, initial encounter

S66.323A	Laceration of extensor muscle, fascia, and tendon of left middle finger at wrist and hand level, initial encounter
S66.324A	Laceration of extensor muscle, fascia, and tendon of right ring finger at wrist and hand level, initial encounter
S66.325A	Laceration of extensor muscle, fascia, and tendon of left ring finger at wrist and hand level, initial encounter
S66.326A	Laceration of extensor muscle, fascia, and tendon of right little finger at wrist and hand level, initial encounter
S66.327A	Laceration of extensor muscle, fascia, and tendon of left little finger at wrist and hand level, initial encounter
S66.328A	Laceration of extensor muscle, fascia, and tendon of other finger at wrist and hand level, initial encounter
S66.329A	Laceration of extensor muscle, fascia, and tendon of unspecified finger at wrist and hand level, initial encounter
S66.421A	Laceration of intrinsic muscle, fascia, and tendon of right thumb at wrist and hand level, initial encounter
S66.422A	Laceration of intrinsic muscle, fascia, and tendon of left thumb at wrist and hand level, initial encounter
S66.429A	Laceration of intrinsic muscle, fascia, and tendon of unspecified thumb at wrist and hand level, initial encounter
S66.520A	Laceration of intrinsic muscle, fascia, and tendon of right index finger at wrist and hand level, initial encounter
S66.521A	Laceration of intrinsic muscle, fascia, and tendon of left index finger at wrist and hand level, initial encounter
S66.522A	Laceration of intrinsic muscle, fascia, and tendon of right middle finger at wrist and hand level, initial encounter
S66.523A	Laceration of intrinsic muscle, fascia, and tendon of left middle finger at wrist and hand level, initial encounter
S66.524A	Laceration of intrinsic muscle, fascia, and tendon of right ring finger at wrist and hand level, initial encounter
S66.525A	Laceration of intrinsic muscle, fascia, and tendon of left ring finger at wrist and hand level, initial encounter
S66.526A	Laceration of intrinsic muscle, fascia, and tendon of right little finger at wrist and hand level, initial encounter
S66.527A	Laceration of intrinsic muscle, fascia, and tendon of left little finger at wrist and hand level, initial encounter
S66.528A	Laceration of intrinsic muscle, fascia, and tendon of other finger at wrist and hand level, initial encounter
S66.529A	Laceration of intrinsic muscle, fascia, and tendon of unspecified finger at wrist and hand level, initial encounter
S66.821A	Laceration of other specified muscles, fascia and tendons at wrist and hand level, right hand, initial encounter
S66.822A	Laceration of other specified muscles, fascia and tendons at wrist and hand level, left hand, initial encounter
S66.829A	Laceration of other specified muscles, fascia and tendons at wrist and hand level, unspecified hand, initial encounter

S66.921A	Laceration of unspecified muscle, fascia and tendon at wrist and hand level, right hand, initial encounter
S66.922A	Laceration of unspecified muscle, fascia and tendon at wrist and hand level, left hand, initial encounter
S66.929A	Laceration of unspecified muscle, fascia and tendon at wrist and hand level, unspecified hand, initial encounter

VI. Procedures

None

VII. References/Citations

1. Boyce, S.T., Lalley, A.L. Tissue engineering of skin and regenerative medicine forwound care. *Burn Trauma* **6,** 4 (2018). https://doi.org/10.1186/s41038-017-0103-y
2. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) Wound Application of Cellular and/or Tissue Based Products (CTP's), Lower extremities. Contractor: CGS Administrators.Revision Effective Date: 09/01/2022 LCD - Wound Application of Cellular and/or Tissue Based Products (CTPs), Lower Extremities (L36690) (cms.gov)
3. Centers for Medicare and Medicaid Services (CMS). LCD Reference Article. Billing and Coding Article. Biling and Coding: Wound Application of Cellular and/or Tissue Based Products (CTPs), Lower Extremities. A56696. Contractor CGS Administrators, LLC. Revision effective Date 11/16/2023. Article - Billing and Coding: Wound Application of Cellular and/or Tissue Based Products (CTPs), Lower Extremities (A56696) (cms.gov)
4. Jorgensen, A. M., Mahajan, N., Atala, A., & Murphy, S. V. (2023). Advances in Skin Tissue Engineering and Regenerative Medicine. *Journal of burn care & research : official publication of the American Burn Association*, *44*(Suppl_1), S33–S41. Advances in Skin Tissue Engineering and Regenerative Medicine | Journal of Burn Care & Research | Oxford Academic (oup.com)
5. NIH: National Institute of General Medical Sciences. Last updated 4/25/2023. *Burns.* Burns (nih.gov)

VIII. Forms/Appendices

None

IX. Responsibility

Medical Director