New Policy -
Skin Substitute Grafts, Amniotic Membrane, Cellular and Tissue-Based Products

Effective immediately, the new *Skin Substitute Grafts, Amniotic Membrane, Cellular and Tissue-Based Products* policy will replace:

- Tissue-Engineered Skin Substitutes for Medicare Plan Members
- Tissue-Engineered Skin Substitutes for Members Other Than Medicare Plan Members

The new policy provides guidance for specific criteria to use for specific HAP plans. The policy is attached for your convenience.

Skin Substitute Grafts, Amniotic Membrane, Cellular and Tissue-Based Products

DESCRIPTION

This policy addresses the use of dermal or epidermal substitute tissue of human or non-human origin, with or without bioengineered or processed elements, with or without metabolically active elements, with a designated use as coverage for a superficial skin deficit that has persisted, despite optimal wound care for a period of 4 weeks or greater.

These products are FDA regulated under PHS 361 [21 CFR 1270 & 1271]: Human cells, tissues, and cellular and tissue-based products (HCT/Ps). Creates a unified registration and listing system for establishments that manufacture HCT/Ps and establishes donor eligibility, current good tissue practice, and other procedures to prevent the introduction, transmission, and spread of communicable diseases by HCT/Ps. Among other criteria, HCT/Ps are required to be minimally manipulated and intended for homologous use. Homologous use means the repair, reconstruction, replacement, or supplementation of a recipient's cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor. In the case of amniotic membranes, homologous use includes serving as a selective barrier, protection and covering of a wound.

Please Note:
Any specific products/tests referenced in this policy are just examples and are intended for illustrative purposes only. It is not intended to be a recommendation of one product over another and is not intended to represent a complete listing of all products available. These examples are contained in a "such as" or "e.g." statement in parentheses.
The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

RELEVANT CODES - Procedure Code for Application of Skin Substitute Products

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 (List separately in addition to code for primary procedure)
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 (List separately in addition to code for primary procedure)
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
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 (List separately in addition to code for primary procedure)
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 (List separately in addition to code for primary procedure)
15777	Implantation of biologic implant (eg, acellular dermal matrix) for soft tissue reinforcement (ie, breast, trunk) (List separately in addition to code for primary procedure)
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 wound surface area, or part thereof (list separately in addition to code for primary procedure)

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 part thereof, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)
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 wound surface area, or part thereof (list separately in addition to code for primary procedure)
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

RELEVANT CODES - Skin Substitute Grafts, Cellular and Tissue-Based Products

A2019	Kerecis Omega3 MariGen Shield, per sq cm
Q4100	Skin substitute, not otherwise specified
Q4101	Apligraf skin sub, per sq cm
Q4102	Oasis wound matrix skin sub, per sq cm
Q4104	Integra BMWD skin sub, per sq cm
Q4105	Integra dermal regeneration template (drt) or integra omnigraft dermal regeneration matrix, per square centimeter
Q4106	Dermagraft skin sub, per sq cm
Q4107	Graftjacket skin sub, per sq cm
Q4110	Primatrix skin sub, per sq cm
Q4116	Alloderm skin sub, per sq cm
Q4121	Theraskin, per sq cm
Q4122	Dermacell, dermacell awm or dermacell awm porous, per square centimeter
Q4128	FlexHD, or AllopatchHD, per sq cm
Q4132	Grafix Core and GrafixPL Core, per sq cm
Q4133	Grafix PRIME, GrafixPL PRIME, Stravix and StravixPL, per sq cm
Q4151	AmnioBand or Guardian, per square centimeter
Q4154	Biovance, per square centimeter
Q4158	Marigen, per square centimeter
Q4159	Affinity, per square centimeter
Q4160	NuShield, per square centimeter
Q4182	Transcyte, per square centimeter
Q4186	Epifix, per square centimeter
Q4187	Epicord, per square centimeter
Q4251	Vim, per sq cm
Q4252	Vendaje, per sq cm
Q4253	Zenith Amniotic Membrane, per sq cm

COVERAGE CRITERIA

Note: This policy applies to all HAP/AHL Members including Medicare Plan Members.

Product eligibility:

1. Products must be used in accordance with their intended use as approved/regulated by the United States (U.S.) Food and Drug Administration (FDA) or American Association of Tissue Banks (AATB):
    a. Non-human skin substitutes graft/CTP are regulated by one of the following:

i. FDA premarket approval (PMA) process,
ii. FDA 510(k) premarket notification process,
iii. FDA regulations for human cells, tissues, and cellular and tissue-based products (HCT/Ps).

b. Human derived skin substitutes/CTP are regulated by the American Association of Tissue Banks (AATB) and do not receive FDA approval.

2. **Skin substitute grafts or cellular tissue-based products**: To qualify as skin substitute graft/CTP the product must meet BOTH the following
   a. ONE of the following:
      i. A non-autologous human cellular or tissue product (e.g., dermal or epidermal, cellular and acellular, homograft OR allograft),
      ii. Non-human cellular and tissue product (i.e., xenograft),
      iii. Biological product (synthetic or xenogeneic) applied as a sheet, allowing scaffold for skin growth, intended to remain on the recipient and grow in place or allow recipient's cells to grow into the implanted graft material
   b. Supported by high-certainty supporting evidence to demonstrate the product's safety, effectiveness, and positive clinical outcomes in the function as a graft for the Member's condition.
      i. NOTE: Substantial equivalence to predicate products does not allow sufficient evidence to support similar cleared products.
3. **Amniotic Membrane products**: Products must be used in accordance with their intended use as approved/regulated by the United States (U.S.) Food and Drug Administration (FDA).
   a. The Code of Federal Regulation, title 21, parts 1270 and 1271 provides the following specific examples of homologous and non-homologous use for amniotic membrane:
      i. Amniotic membrane is used for bone tissue replacement to support bone regeneration following surgery to repair or replace bone defects. This is not a homologous use because bone regeneration is not a basic function of amniotic membrane.
      ii. An amniotic membrane product is used for wound healing and/or to reduce scarring and inflammation. This is not homologous use because wound healing and reduction of scarring and inflammation are not basic functions of amniotic membrane.
      iii. An amniotic membrane product is applied to the surface of the eye to cover or offer protection from the surrounding environment in ocular repair and reconstruction procedures. This is homologous use because serving as a covering and offering protection from the surrounding environment are basic functions of amniotic membrane.

Treatment of Diabetic Foot Ulcers (DFU) or Venous Leg Ulcers (VLU)

1. Eligible wounds: HAP covers application of the FDA approved Skin Substitute or Cellular or Tissue Based Product (CTP) when the following criteria are met:
   a. Member has ONE of the following:
      i. **A chronic, non-infected diabetic foot ulcer (DFU**) that failed to achieve at least 50% ulcer area reduction with documented standard of care (SOC) treatment (outlined below) for a minimum of 4 weeks with documented compliance.
         A. Skin substitute grafts or cellular tissue-based products:
            I. AlloPatchHD® [Q4128]
            II. Apligraft® [Q4101]
            III. Dermagraft® [Q4106]
            IV. DermACELL® [Q4122]
            V. Flex HD®]Q4128]
            VI. Grafix Prime, Grafix PL Prime, Stravix and StravixPL [Q4133]
            VII. GraftJacket® [Q4107]
            VIII. Integra®, OmnigraftTM Dermal Regeneration Matrix (also known as Omnigraft™) [Q4105]
            IX. Oasis® Tri-layer Wound [Q4124]
            X. Oasis® Wound Matrix [Q4102]
            XI. PriMatrix® [Q4110]
            XII. Theraskin® [Q4121]
         B. Amniotic Membrane Products:
            I. Affinity® [Q4159]
            II. AmnioBand® Membrane [Q4151]
            III. Biovance® [Q4154]
            IV. Epicord® [Q4187]
            V. Epifix® [Q4186]
            VI. Grafix™ [Q4132, Q4133]

ii. **A chronic, non-infected venous leg ulcer (VLU)** that failed to respond to documented SOC treatment (outlined below) for a minimum of 4 weeks with documented compliance.
A. Skin substitute grafts or cellular tissue-based products:
I. AmnioBand® [Q4151]
II. Aplifraf® [Q4101]
III. DermACELL™ AWM [Q4122]
IV. EpiCord® [Q4187]
V. Grafix® [Q4133]
VI. Oasis™ Wound Matrix [Q4102]
VII. PriMatrix™ [Q4110]
VIII. Theraskin® [Q4121]

b. Member's medical record reflects that the Member is under the care of a qualified provider for the treatment of the systemic disease process(es) etiologic for the condition (e.g., venous insufficiency, diabetes, neuropathy)

2. Documentation of Failed Response: The Member's medical record must include ALL the following:
a. Comprehensive patient assessment (history, exam, vascular assessment) and diagnostic tests indicated as part of the implemented treatment plan, including:
i. **Diabetic foot ulcer (DFU)**: assessment of Type 1 or Type 2 diabetes and management history with attention to certain comorbidities (e.g., vascular disease, neuropathy, osteomyelitis), review of current blood glucose levels/hemoglobin A1c (HbA1c), diet and nutritional status, activity level, physical exam that includes assessment of skin, ulcer, and vascular perfusion), and assessment of off-loading device or use of appropriate footwear.
ii. **Venous leg ulcer (VLU)**: assessment of clinical history (that includes prior ulcers, higher body mass index, history of pulmonary embolism or superficial/deep venous thrombosis, higher number of pregnancies, and physical inactivity), physical exam (edema, skin changes and vascular competence*), evaluation of superficial or deep venous reflux, perforator incompetence, and chronic (or acute) venous thrombosis. The use of a firm strength compression garment (>20 mmHg) or multi-layered compressive dressings is an essential component of SOC for venous stasis ulcers.

Use for Breast Reconstructive Surgery:

1. Applications of skin substitute grafts or cellular tissue-based products used for Breast reconstructive surgery are covered when one of the following clinical situations is met:
a. Additional coverage is required due to insufficient tissue expander or implant coverage by the pectoralis major muscle,
b. Member has viable but compromised or thin postmastectomy skin flaps that are at risk of dehiscence or necrosis,
c. Member's inframammary fold and lateral mammary folds have been undermined during mastectomy and reestablishment of these landmarks is needed
2. Skin substitute grafts or cellular tissue-based products (allogeneic acellular dermal matrix products approved as banked human tissue by the AATB):
a. AlloDerm® [Q4116]
b. AlloMend® [Q4100]
c. Cortiva® [aka AlloMax™] [Q4100]
d. DermACELL™ [Q4122]
e. DermaMatrix™ [Q4100]
f. FlexHD® [Q4128]
g. FlexHD® Pliable™[Q4128]
h. Graftjacket® [Q4107]

Use for Treatment of Burns:

1. Skin substitute grafts or cellular tissue-based products for the treatment of second or third degree skin wounds and burn wounds if the wound is too large for autograft.
a. Products:
i. Epicel® (for the treatment of deep dermal or full-thickness burns comprising a total body surface area ≥30% when provided in accordance with the HDE specifications of the FDA) [Q4100]
ii. Integra® for partial thickness burns [Q4104]
iii. TRANSCYTE - Full thickness (third degree) and deep partial thickness (second degree) burns prior to autograft [Q4182]
2. Human amniotic membrane grafts are covered when the following criteria are met:
a. Products:
i. Vendaje when used as a protective covering during repair and reconstruction of partial to full thickness burns [Q4252]

ii. Zenith amniotic membrane when used as a barrier or cover forburns that have not responded to conventional therapy [Q4253]

Treatment of Dystrophic epidermolysis bullosa:

1. Skin substitute grafts or cellular tissue-based products for the treatment of dystrophic epidermolysis bullosa mitten-hand deformity is covered when standard wound therapy has failed.
    a. Products:
        i. OrCel™ when provided consistent with the humanitarian device exemption [HDE] specifications of the U.S. Food and Drug Administration [Q4100]

Treatment of Trauma or Surgical wounds:

1. Skin substitute grafts or cellular tissue-based products for wounds are covered when the wound is too large for an autograft or other conservative measures and use is consistent with FDA approved indications such as but not limited to:
    a. Surgical repair of complex abdominal wall wounds (e.g., due to infection, fascial defect, etc.) and other surgical wounds including donor sites
    b. Reconstructive surgery
2. Human amniotic membrane grafts are covered when the following criteria are met:
    a. Vendaje [Q4252] when used as a protective covering during repair and reconstruction of one of the following:
        i. Chronic or acute pressure sores/ulcers related to disease processes
        ii. Draining wounds
        iii. Post-surgical wounds
        iv. Trauma wounds
    b. VIM™ Human Amniotic Membrane [Q4251] when used as a wound covering or barrier in one of the following wounds:
        i. Surgical
        ii. Orthopedic
        iii. Ophthalmic
    c. Zenith amniotic membrane [Q4253] when used as a barrier or cover for one of the following that have not responded to conventional therapy:
        i. Acute or chronic non-healing wounds, including but not limited to:
            A. Noninfected partial or full-thickness diabetic foot ulcers
            B. Venous leg ulcers
            C. Pressure ulcers
            D. Surgical wounds

Use for Ocular Conditions:

1. Use of amniotic membrane to treat ocular conditions is not addressed by this policy. Please refer to the Benefit Administration Manual policy: Amniotic Membrane or Limbal Stem Cell Transplantation for Ocular Indications.

FOR ALL THE ABOVE INDICATIONS:

1. Documentation in the medical records must include:
    a. A treatment plan including ALL the following:
        i. Debridement as appropriate to a clean granular base.
        ii. Infection control with removal of foreign body or nidus of infection.
        iii. Management of exudate with maintenance of a moist environment (moist saline gauze, other classic dressings, bioactive dressing, etc.
        iv. Specific wound types:
            A. Diabetic foot ulcer: Documented evidence of offloading
            B. Venous leg ulcer: some form of sustained compression dressings
        v. Documentation of both smoking/vaping history including current status and counselling on the effect of smoking on wound healing to improve the outcomes of treatment with Skin Substitute Grafts, Amniotic Membrane, Cellular, or Tissue-Based Products. Documentation in the medical record, that Member has completed or is currently in smoking cessation therapy if history reflects a positive smoking/vaping status.
    b. Documentation of wound care and response including:
        i. Initial measurements of the wound/ulcer and weekly measurements during standard of care therapies for at least 4 weeks.
        ii. Measurements of the wound/ulcer when initial skin substitute graft or cell-tissue based product is applied and at time of each subsequent application.

iii. Standard of care interventions should continue during treatment with Skin Substitute Grafts, Amniotic Membrane, Cellular and Tissue-Based Products.
iv. Venous leg ulcers should continue compression therapy for the episode of care.

2. Coverage of services is based on the Member's subscriber documents. Please refer to those resources for information regarding eligibility for coverage, network or provider requirements. If the Member has coverage for the services discussed in this policy, then the medical criteria applies. Medicare Plan Members are covered as directed by the applicable National Coverage Determination (NCD) or by the Local Coverage Determination (LCD).
    a. HAP reserves the right to redirect to HAP preferred alternatives.
3. Some services require pre-authorization by a HAP Medical Director or designee, please refer to the Procedure reference list for specific code information.

DEFINITIONS

- **An episode of skin replacement therapy** is defined as 12 to 16 weeks from the first application of a skin substitute graft/CTP).
- **Standard of Care (SOC) treatment** includes the following:
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        - SOC treatment of lower extremity ulcers (e.g., DFU and VLU) should include mechanical offloading, infection control, mechanical compression, limb elevation, debridement of necrotic tissue, management of systemic disease and medications, nutrition assessment, tissue perfusion and oxygenation, education regarding care of the foot, callus, and nail and fitting of shoes, as well as counseling on the risk of continued tobacco use. In addition, maintenance of a moist ulcer environment through appropriate dressings facilitates development of healthy granulation tissue and epithelialization and potentiates complete healing at an ulcer site. Dressings are an integral part of ulcer management by maintaining a moist environment, limiting contamination, and absorbing exudate
- **Autografts/tissue cultured autografts**: Includes the harvest and application of an autologous skin graft. These products are designed to circumvent the challenges with autologous skin grafts in the treatment of chronic wounds, ulcers or burns.
- **Chronic Wound**: A chronic wound may be defined as a wound physiologically impaired due to a disruption of the wound healing cycle resulting from impaired angiogenesis, innervation, cellular migration, or other defects for 4 weeks or longer.
- **Cellular and Tissue-Based Products** (CTP) grafts (also called skin substitute graft): Includes homologous human cellular and tissue products (e.g., dermal or epidermal, cellular and acellular, homograft or allograft), non-human cellular and tissue products (i.e., xenograft), and biological products (synthetic or xenogeneic) that form a sheet scaffolding for skin growth when applied in a sheet over an open wound or ulcer to augment closure or skin growth.
    - NOTE: There is a lack of clarity in the definition of skin substitute. For the purpose of this policy, skin substitute grafts will align with the AMA CPT codebook description "non-human skin substitute grafts and biological products that form a sheet scaffolding for skin growth". This surface is not intended to be removed but grows into place or serves as base for new skin to grow.
- **Cellular, acellular, and matrix-like products (CAMPs**): also referred to as acellular/tissue product (CTP)
- **Failed response:** Increased size or depth, no change in baseline size or depth, or no sign of improvement or indication that improvement is likely (such as granulation, epithelialization, or progress towards closing).
- **Healed ulcer** (completed healing): 100 percent re-epithelialization without drainage or dressing noted on 2 occasions at least 2 weeks apart.
- **Scaffolding**: a support, delivery vehicle, or matrix for facilitating the migration, binding, or transport of cells or bioactive molecules used to replace, repair, or regenerate tissues.
- **Stalled Wound**: An ulcer that has entered a nonhealing or intransigent phase.
- **Wound dressing or coverings**: Applications applied to wounds as a selective barrier to clean, cover and protect wounds from the surrounding environment to promote optimal environment for wound healing.
- **Non-graft wound dressings** (e.g., gel, powder, ointment, foam, liquid) or injected skin substitutes. Skin substitute graft application codes [15271-15278 or C5271-C5278] do not apply to these types of services.

US Food and Drug Administration (FDA) Regulation Resources:

The FDA does not refer to any product or class of products as "skin substitutes." However, products commonly described as "skin substitutes" are regulated by FDA under one of the four categories described below depending on the origin and composition of the product. "Skin Substitutes" are billed with a HCPCS code Q41XX. Updated designation and approved usage criteria may be found under Medical Devices/Products and Medical Procedures at: **http://www.fda.gov/**

- **Human Cells, Tissues, and Cellular and Tissue-Based Products**
    - Cells and tissues taken from human donors and transplanted to a recipient are regulated under PHS 361 [21 CFR 1270 & 1271]. This regulation describes the rules concerning the use of HCT/Ps for human medical purposes. The Center for Biologics Evaluation and Research (CBER) is responsible for regulating biological and related products

including blood, vaccines, allergenics, tissues, and cellular and gene therapies. HCT/Ps establishments are not required to demonstrate the safety or effectiveness of their products and FDA does not evaluate the safety or effectiveness of these products.
    - **https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products**
- **Premarket Approval** - Premarket approval (PMA) by FDA is the required process of scientific review to ensure the safety and effectiveness of Class III devices. Wound care products regulated under the PMA process will require evidence that they promote wound healing before they are approved for marketing.
    - **https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm**
- **510(k) Submissions** - According to FDA documents a “510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent (SE), to a legally marketed device (21 CFR 807.92(a)(3)) that is not subject to PMA." Wound care products regulated under the 510(k) process will not typically require clinical evidence to establish effectiveness in wound healing, as compared with products regulated under the PMA process in which substantial clinical evidence is always required.
    - **https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm**
- **Humanitarian Device Exemption (HDE)** - An HDE is similar in both form and content to a premarket approval (PMA) application, but is exempt from the effectiveness requirements of a PMA. The applicant must demonstrate that no comparable devices are available to treat or diagnose the disease or condition, and that they could not otherwise bring the device to market. Humanitarian Device Exemption approval is based on evidence of probable benefit in a disease population occurring at a frequency of less than 4,000 patients per year in the United States.
    - **https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfhde/hde.cfm**

LIMITATIONS

Skin substitute grafts or cellular tissue-based products

1. **An episode of skin replacement therapy** is defined as 12 to 16 weeks from the first application of a skin substitute graft or cell-tissue based product.
2. **Applications:**
    a. Average number of applications for wound healing is 4.
        i. Use exceeding four applications requires added documentation/attestation in the medical record that the above criteria continue to be met.
        ii. Maximum of 8 skin substitute graft/CTP applications per ulcer will be allowed for the episode of skin replacement surgery (defined as 12 to 16 weeks from the first application of a skin substitute graft/CTP). Product change within the episode of skin replacement surgery may be appropriate. When more than 1 specific product is used during the 12–16-week period, it is expected that the total number of applications or treatments will still not exceed 8.
    b. The graft must be applied in a single layer without overlay of product or adjacent skin in compliance with the correct label application techniques for the skin substitute graft/CTP.
    c. Only skin substitute grafts/CTP with labeled indications for use over exposed muscle, tendon or bone can be used in these cases and only in the absence of contraindications (e.g., infected, ischemic, or necrotic wound bed).

EXCLUSIONS

1. **Skin substitute grafts or cellular tissue-based products**: The following uses are considered not reasonable and necessary and therefore are not covered for HAP/AHL Members:
    a. Greater than 8 applications of a skin substitute graft/CTP within an episode of care (up to 16 weeks).
    b. Repeat applications of skin substitute graft/CTP when a previous application was unsuccessful. Unsuccessful treatment is defined as an increase in size or depth of an ulcer, no measurable change from baseline, and no sign of significant improvement or indication that significant improvement is likely (such as granulation, epithelialization, or progress towards closure).
    c. Application of skin substitute graft/CTP in Members with inadequate control of underlying conditions or exacerbating factors, or other contraindications (e.g., active infection, progressive necrosis, active Charcot arthropathy of the ulcer extremity, active vasculitis, ischemia).
    d. Use of surgical preparation services (e.g., debridement), in conjunction with routine, simple or repeat skin replacement therapy with a skin substitute graft/CTP because all granulation tissue should be excised before placing the graft as it can have a significant bacterial burden and prevent adherence to the graft.
    e. All liquid or gel skin substitute products or CTPs used for ulcer care as their fluidity does not allow graft placement and stabilization of the product on the wound.
    f. Placement of skin substitute graft/CTP on infected, ischemic, or necrotic wound bed.

2. **Amniotic membrane, amniotic fluid or other placental derived product injections** and/or applications as a means of managing musculoskeletal injuries, joint conditions, and all other conditions excluding uses with approval for burns, wounds, or ophthalmic conditions are not covered for HAP/AHL Members as these uses are considered investigational or unproven. Such as but not limited to:
    a. Osteoarthritis of the knee, hip, and other joints
    b. Plantar Fasciitis/Achilles tendinopathies/tendinitis
    c. Rotator Cuff tears, patellar tendinopathies/tendinitis, lateral epicondylitis, carpal tunnel syndrome, and trigger finger
    d. Low back pain (including intradiscal and facet joint-related back pain) and cervical facet joint pain.
    e. Injection of human amniotic fluid for all indications
    f. Treatment of lower-extremity ulcers due to venous insufficiency
    g. The use of amniotic membrane products following Mohs micrographic surgery
3. **All other uses** of bioengineered skin and soft tissue substitutes or amniotic membrane products are not covered for HAP/AHL Members unless they meet ONE of the following criteria:
    a. FDA approval and provided in accordance with the FDA guidelines
    b. Covered by Centers for Medicare & Medicaid Services
4. The following HCPCS codes/products are non-covered due to a lack of evidence in the peer-reviewed, published literature to support to support the clinical value and/or safety and effectiveness of these products [list may not be all-inclusive]:

A2001 INNOVAMATRIX AC, PER SQUARE CENTIMETER
A2002 MIRRAGEN ADVANCED WOUND MATRIX, PER SQUARE CENTIMETER
A2004 XCELLISTEM, 1 MG
A2005 MICROLYTE MATRIX, PER SQUARE CENTIMETER
A2006 NOVOSORB SYNPATH DERMAL MATRIX, PER SQUARE CENTIMETER
A2007 RESTRATA, PER SQUARE CENTIMETER
A2008 THERAGENESIS, PER SQUARE CENTIMETER
A2009 SYMPHONY, PER SQUARE CENTIMETER
A2010 APIS, PER SQUARE CENTIMETER
A2011 SUPRA SDRM, PER SQUARE CENTIMETER
A2012 SUPRATHEL, PER SQUARE CENTIMETER
A2013 INNOVAMATRIX FS, PER SQUARE CENTIMETER
A2014 OMEZA COLLAGEN MATRIX, PER 100 MG
A2015 PHOENIX WOUND MATRIX, PER SQUARE CENTIMETER
A2016 PERMEADERM B, PER SQUARE CENTIMETER
A2018 PERMEADERM C, PER SQUARE CENTIMETER
A2020 AC5 ADVANCED WOUND SYSTEM (AC5)
A2021 NEOMATRIX, PER SQUARE CENTIMETER
A2022 INNOVABURN OR INNOVAMATRIX XL, PER SQUARE CENTIMETER
A2023 INNOVAMATRIX PD, 1 MG
A2024 RESOLVE MATRIX OR XENOPATCH, PER SQUARE CENTIMETER
A2025 MIRO3D, PER CUBIC CENTIMETER
C9358 DERMAL SUBSTITUTE, NATIVE, NON-DENATURED COLLAGEN, FETAL BOVINEORIGIN (SURGIMEND COLLAGEN MATRIX), PER 0.5 SQUARE CENTIMETERS
C9360 DERMAL SUBSTITUTE, NATIVE, NON-DENATURED COLLAGEN, NEONATALBOVINE ORIGIN (SURGIMEND COLLAGEN MATRIX), PER 0.5 SQUARECENTIMETERS
C9363 SKIN SUBSTITUTE, INTEGRA MESHED BILAYER WOUND MATRIX, PERSQUARE CENTIMETER
C9364 PORCINE IMPLANT, PERMACOL, PER SQUARE CENTIMETER
Q4108 INTEGRA MATRIX, PER SQUARE CENTIMETER
Q4111 GAMMAGRAFT, PER SQUARE CENTIMETER
Q4112 CYMETRA, INJECTABLE, 1 CC
Q4113 GRAFTJACKET XPRESS, INJECTABLE, 1 CC
Q4114 INTEGRA FLOWABLE WOUND MATRIX, INJECTABLE, 1 CC
Q4115 ALLOSKIN, PER SQUARE CENTIMETER
Q4117 HYALOMATRIX, PER SQUARE CENTIMETER
Q4118 MATRISTEM MICROMATRIX, 1 MG
Q4123 ALLOSKIN RT, PER SQUARE CENTIMETER
Q4125 ARTHROFLEX, PER SQUARE CENTIMETER
Q4126 MEMODERM, DERMASPAN, TRANZGRAFT OR INTEGUPLY, PER SQUARECENTIMETER
Q4127 TALYMED, PER SQUARE CENTIMETER
Q4130 STRATTICE TM, PER SQUARE CENTIMETER
Q4132 GRAFIX CORE AND GRAFIXPL CORE, PER SQUARE CENTIMETER
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
Q4148 NEOX CORD 1K, NEOX CORD RT, OR CLARIX CORD 1K, PER SQUARECENTIMETER
Q4149 EXCELLAGEN, 0.1 CC
Q4150 ALLOWRAP DS OR DRY, PER SQUARE CENTIMETER
Q4152 DERMAPURE, PER SQUARE CENTIMETER
Q4153 DERMAVEST AND PLURIVEST, PER SQUARE CENTIMETER
Q4155 NEOXFLO OR CLARIXFLO, 1 MG
Q4156 NEOX 100 OR CLARIX 100, PER SQUARE CENTIMETER
Q4157 REVITALON, PER SQUARE CENTIMETER
Q4162 WOUNDEX FLOW, BIOSKIN FLOW, 0.5 CC
Q4163 WOUNDEX, BIOSKIN, PER SQUARE CENTIMETER
Q4164 HELICOLL, PER SQUARE CENTIMETER
Q4165 KERAMATRIX OR KERASORB, 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 OR THERION, PER SQUARE CENTIMETER
Q4177 FLOWERAMNIOFLO, 0.1 CC
Q4178 FLOWERAMNIOPATCH, PER SQUARE CENTIMETER
Q4179 FLOWERDERM, PER SQUARE CENTIMETER
Q4180 REVITA, PER SQUARE CENTIMETER
Q4181 AMNIO WOUND, PER SQUARE CENTIMETER
Q4183 SURGIGRAFT, PER SQUARE CENTIMETER
Q4184 CELLESTA OR CELLESTA DUO, PER SQUARE CENTIMETER
Q4185 CELLESTA FLOWABLE AMNION (25 MG PER CC); PER 0.5 CC
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-DERM, 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
Q4199 CYGNUS MATRIX, PER SQUARE CENTIMETER
Q4200 SKIN TE, PER SQUARE CENTIMETER
Q4201 MATRION, PER SQUARE CENTIMETER
Q4202 KEROXX (2.5G/CC), 1CC
Q4204 XWRAP, PER SQUARE CENTIMETER
Q4205 MEMBRANE GRAFT OR MEMBRANE WRAP, PER SQUARE CENTIMETER
Q4206 FLUID FLOW OR FLUID GF, 1 CC
Q4208 NOVAFIX, PER SQUARE CENITMETER
Q4209 SURGRAFT, PER SQUARE CENTIMETER

Q4211 AMNION BIO OR AXOBIOMEMBRANE, PER SQUARE CENTIMETER
Q4212 ALLOGEN, PER CC
Q4213 ASCENT, 0.5 MG
Q4214 CELLESTA CORD, PER SQUARE CENTIMETER
Q4215 AXOLOTL AMBIENT OR AXOLOTL CRYO, 0.1 MG
Q4216 ARTACENT CORD, PER SQUARE CENTIMETER
Q4217 WOUNDFIX, BIOWOUND, WOUNDFIX PLUS, BIOWOUND PLUS, WOUNDFIXXPLUS OR BIOWOUND XPLUS, PER SQUARE CENTIMETER
Q4218 SURGICORD, PER SQUARE CENTIMETER
Q4219 SURGIGRAFT-DUAL, PER SQUARE CENTIMETER
Q4220 BELLACELL HD OR SUREDERM, PER SQUARE CENTIMETER
Q4221 AMNIOWRAP2, PER SQUARE CENTIMETER
Q4222 PROGENAMATRIX, PER SQUARE CENTIMETER
Q4225 AMNIOBIND OR DERMABIND TL, PER SQUARE CENTIMETER
Q4226 MYOWN SKIN, INCLUDES HARVESTING AND PREPARATION PROCEDURES,PER SQUARE CENTIMETER
Q4227 AMNIOCORE, PER SQUARE CENTIMETER
Q4229 COGENEX AMNIOTIC MEMBRANE, PER SQUARE CENTIMETER
Q4230 COGENEX FLOWABLE AMNION, PER 0.5 CC
Q4231 CORPLEX P, PER CC
Q4232 CORPLEX, PER SQUARE CENTIMETER
Q4233 SURFACTOR OR NUDYN, PER 0.5 CC
Q4234 XCELLERATE, PER SQUARE CENTIMETER
Q4235 AMNIOREPAIR OR ALTIPLY, PER SQUARE CENTIMETER
Q4236 CAREPATCH, PER SQUARE CENTIMETER
Q4237 CRYO-CORD, PER SQUARE CENTIMETER
Q4238 DERM-MAXX, PER SQUARE CENTIMETER
Q4239 AMNIO-MAXX OR AMNIO-MAXX LITE, PER SQUARE CENTIMETER
Q4240 CORECYTE, FOR TOPICAL USE ONLY, PER 0.5 CC
Q4241 POLYCYTE, FOR TOPICAL USE ONLY, PER 0.5 CC
Q4242 AMNIOCYTE PLUS, PER 0.5 CC
Q4245 AMNIOTEXT, PER CC
Q4246 CORETEXT OR PROTEXT, PER CC
Q4247 AMNIOTEXT PATCH, PER SQUARE CENTIMETER
Q4248 DERMACYTE AMNIOTIC MEMBRANE ALLOGRAFT, PER SQUARE CENTIMETER
Q4249 AMNIPLY, FOR TOPICAL USE ONLY, PER SQUARE CENTIMETER
Q4250 AMNIOAMP-MP, PER SQUARE CENTIMETER
Q4254 NOVAFIX DL, PER SQUARE CENTIMETER
Q4255 REGUARD, FOR TOPICAL USE ONLY, PER SQUARE CENTIMETER
Q4256 MLG-COMPLETE, PER SQUARE CENTIMETER
Q4257 RELESE, PER SQUARE CENTIMETER
Q4258 ENVERSE, PER SQUARE CENTIMETER
Q4259 CELERA DUAL LAYER OR CELERA DUAL MEMBRANE, PER SQUARECENTIMETER
Q4260 SIGNATURE APATCH, PER SQUARE CENTIMETER
Q4261 TAG, PER SQUARE CENTIMETER
Q4262 DUAL LAYER IMPAX MEMBRANE, PER SQUARE CENTIMETER
Q4263 SURGRAFT TL, PER SQUARE CENTIMETER
Q4264 COCOON MEMBRANE, PER SQUARE CENTIMETER
Q4265 NEOSTIM TL, PER SQUARE CENTIMETER
Q4266 NEOSTIM MEMBRANE, PER SQUARE CENTIMETER
Q4267 NEOSTIM DL, PER SQUARE CENTIMETER
Q4268 SURGRAFT FT, PER SQUARE CENTIMETER
Q4269 SURGRAFT XT, PER SQUARE CENTIMETER
Q4270 COMPLETE SL, PER SQUARE CENTIMETER
Q4271 COMPLETE FT, PER SQUARE CENTIMETER
Q4272 ESANO A, PER SQUARE CENTIMETER
Q4273 ESANO AAA, PER SQUARE CENTIMETER
Q4274 ESANO AC, PER SQUARE CENTIMETER
Q4275 ESANO ACA, PER SQUARE CENTIMETER
Q4276 ORION, PER SQUARE CENTIMETER
Q4278 EPIEFFECT, PER SQUARE CENTIMETER

Q4279 VENDAJE AC, PER SQUARE CENTIMETER
Q4280 XCELL AMNIO MATRIX, PER SQUARE CENTIMETER
Q4281 BARRERA SL OR BARRERA DL, PER SQUARE CENTIMETER
Q4282 CYGNUS DUAL, PER SQUARE CENTIMETER
Q4283 BIOVANCE TRI-LAYER OR BIOVANCE 3L, PER SQUARE CENTIMETER
Q4284 DERMABIND SL, PER SQUARE CENTIMETER
Q4285 NUDYN DL OR NUDYN DL MESH, PER SQUARE CENTIMETER
Q4286 NUDYN SL OR NUDYN SLW, PER SQUARE CENTIMETER
Q4287 DERMABIND DL, PER SQUARE CENTIMETER
Q4288 DERMABIND CH, PER SQUARE CENTIMETER
Q4289 REVOSHIELD + AMNIOTIC BARRIER, PER SQUARE CENTIMETER
Q4290 MEMBRANE WRAP-HYDRO, PER SQUARE CENTIMETER
Q4291 LAMELLAS XT, PER SQUARE CENTIMETER
Q4292 LAMELLAS, PER SQUARE CENTIMETER
Q4293 ACESSO DL, PER SQUARE CENTIMETER
Q4294 AMNIO QUAD-CORE, PER SQUARE CENTIMETER
Q4295 AMNIO TRI-CORE AMNIOTIC, PER SQUARE CENTIMETER
Q4296 REBOUND MATRIX, PER SQUARE CENTIMETER
Q4297 EMERGE MATRIX, PER SQUARE CENTIMETER
Q4298 AMNICORE PRO, PER SQUARE CENTIMETER
Q4299 AMNICORE PRO+, PER SQUARE CENTIMETER
Q4300 ACESSO TL, PER SQUARE CENTIMETER
Q4301 ACTIVATE MATRIX, PER SQUARE CENTIMETER
Q4302 COMPLETE ACA, PER SQUARE CENTIMETER
Q4303 COMPLETE AA, PER SQUARE CENTIMETER
Q4304 GRAFIX PLUS, PER SQUARE CENTIMETER
Q4305 AMERICAN AMNION AC TRI-LAYER, PER SQUARE CENTIMETER
Q4306 AMERICAN AMNION AC, PER SQUARE CENTIMETER
Q4307 AMERICAN AMNION, PER SQUARE CENTIMETER
Q4308 SANOPELLIS, PER SQUARE CENTIMETER
Q4309 VIA MATRIX, PER SQUARE CENTIMETER
Q4310 PROCENTA, PER 100 MG
Q4311 Acesso, per sq cm
Q4312 Acesso AC, per sq cm
Q4313 DermaBind FM, per sq cm
Q4314 Reeva FT, per sq cm
Q4315 RegeneLink Amniotic Membrane Allograft, per sq cm
Q4316 AmchoPlast, per sq cm
Q4317 VitoGraft, per sq cm
Q4318 E-Graft, per sq cm
Q4319 SanoGraft, per sq cm
Q4320 PelloGraft, per sq cm
Q4321 RenoGraft, per sq cm
Q4322 CaregraFT, per sq cm
Q4323 alloPLY, per sq cm
Q4324 AmnioTX, per sq cm
Q4325 ACApatch, per sq cm
Q4326 WoundPlus, per sq cm
Q4327 DuoAmnion, per sq cm
Q4328 MOST, per sq cm
Q4329 Singlay, per sq cm
Q4330 TOTAL, per sq cm
Q4331 Axolotl Graft, per sq cm
Q4332 Axolotl DualGraft, per sq cm
Q4333 ArdeoGraft, per sq cm
Q4334 AmnioPlast 1, per sq cm
Q4335 AmnioPlast 2, per sq cm
Q4336 Artacent C, per sq cm
Q4337 Artacent Trident, per sq cm
Q4338 Artacent Velos, per sq cm
Q4339 Artacent Vericlen, per sq cm

Q4340 SimpliGraft, per sq cm
Q4341 SimpliMax, per sq cm
Q4342 TheraMend, per sq cm
Q4343 Dermacyte AC Matrix Amniotic Membrane Allograft, per sq cm
Q4344 Tri-Membrane Wrap, per sq cm
Q4345 Matrix HD Allograft Dermis, per sq cm
Q4346 Shelter DM Matrix, per sq cm
Q4347 Rampart DL Matrix, per sq cm
Q4348 Sentry SL Matrix, per sq cm
Q4349 Mantle DL Matrix, per sq cm
Q4350 Palisade DM Matrix, per sq cm
Q4351 Enclose TL Matrix, per sq cm
Q4352 Overlay SL Matrix, per sq cm
Q4353 Xceed TL Matrix, per sq cm
Q4354 PalinGen Dual-Layer Membrane, per sq cm
Q4355 Abiomend Xplus Membrane and Abiomend Xplus Hydromembrane, per sq cm
Q4356 Abiomend Membrane and Abiomend Hydromembrane, per sq cm
Q4357 XWRAP Plus, per sq cm
Q4358 XWRAP Dual, per sq cm
Q4359 ChoriPly, per sq cm
Q4360 AmchoPlast FD, per sq cm
Q4361 EPIXPRESS, per sq cm
Q4362 CYGNUS Disk, per sq cm
Q4363 Amnio Burgeon Membrane and Hydromembrane, per sq cm
Q4364 Amnio Burgeon Xplus Membrane and Xplus Hydromembrane, per sq cm
Q4365 Amnio Burgeon Dual-Layer Membrane, per sq cm
Q4366 Dual Layer Amnio Burgeon X-Membrane, per sq cm
Q4367 AmnioCore SL, per sq cm
Q4368 AmchoThick, per sq cm
Q4369 AmnioPlast 3, per sq cm
Q4370 AeroGuard, per sq cm
Q4371 NeoGuard, per sq cm
Q4372 AmchoPlast EXCEL, per sq cm
Q4373 Membrane Wrap-Lite, per sq cm
Q4375 duoGRAFT AC, per sq cm
Q4376 Duograft AA, per sq cm
Q4377 triGRAFT FT, per sq cm
Q4378 Renew FT Matrix, per sq cm
Q4379 AmnioDefend FT Matrix, per sq cm
Q4380 AdvoGraft One, per sq cm
Q4382 AdvoGraft Dual, per sq cm
Q4383 Axolotl Graft Ultra, per sq cm
Q4384 Axolotl DualGraft Ultra, per sq cm
Q4385 Apollo FT, per sq cm
Q4386 Acesso TrifACA, per sq cm
Q4387 NeoThelium FT, per sq cm
Q4388 NeoThelium 4L, per sq cm
Q4389 NeoThelium 4L Plus, per sq cm
Q4390 Ascendion, per sq cm
Q4391 AmnioPlast Double, per sq cm
Q4392 GRAFIX Duo, per sq cm
Q4393 SurGraft AC, per sq cm
Q4394 SurGraft ACA, per sq cm
Q4395 Acelagraft, per sq cm
Q4396 Natalin, per sq cm
Q4397 Summit AAA, per sq cm

SUMMARY OF EVIDENCE:

Peer-reviewed studies and CMS guidance evaluating skin substitute grafts and cellular/tissue-based products (CTPs) for diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs) reveal mixed evidence regarding efficacy and long-term outcomes. While some trials report improved wound closure rates compared to standard care (e.g., debridement, compression therapy, offloading), the

overall evidence base is considered low quality due to manufacturer sponsorship bias and limited generalizability to Medicare populations [1,9,11,13,16]. CMS has acknowledged that many studies lack definitive proof of improved health outcomes and has delayed final coverage determinations to allow for submission of higher-quality data [1,9,11,13,16]. Adherence metrics such as treatment persistence and real-world utilization are poorly reported, further complicating medical decision-making. Coverage is currently limited to cases where ulcers have failed conventional therapy and where peer-reviewed evidence supports adjunctive use [1,13,16].

Peer-reviewed randomized controlled trials (RCTs), systematic reviews, and government sources including CMS and AHRQ have evaluated skin substitute grafts and cellular and tissue-based products (CTPs) for chronic wounds beyond diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs), such as pressure injuries, surgical wounds, and traumatic wounds. Evidence shows that certain acellular dermal matrices and amniotic-derived products may improve wound closure rates when used adjunctively with standard of care (SOC), which includes debridement, infection control, moisture management, and offloading or compression depending on wound type [9,10,11]. Compared to SOC alone, studies report relative risk ratios for complete healing ranging from 1.5 to 2.3, with time to closure reduced by 2–3 weeks in some trials [9,12]. Adherence data from real-world retrospective cohorts suggest mean application numbers of 4–6 over 12–16 weeks, with diminishing returns after 7 applications [5]. However, limitations include high heterogeneity across studies, lack of long-term safety data, and frequent industry sponsorship, raising concerns about bias and generalizability. Products used as dressings rather than grafts (e.g., gels or liquids) or those applied to infected or ischemic wounds are not considered medically necessary due to lack of efficacy and potential harm [1,9].

Coverage for skin substitute grafts/CTPs for all indications should be limited to products supported by high-certainty evidence demonstrating improved healing outcomes when used adjunctively with SOC, with restrictions on application frequency, wound type, and documentation of medical necessity.

RATIONALE:

This policy provides coverage of skin substitute grafts and cellular tissue products when used for Diabetic Foot Ulcers or Venous Leg Ulcers consistent with the Local Coverage Determination (LCD): Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers, L39865 1 coverage documents. Any subsequent changes to coverage based on Medicare & Medicaid services (CMS) will be applied in place of the content displayed on this policy. This policy applies to all product lines as consistent with the individual's subscriber documents.

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    a. LCD Reference Article Billing and Coding Article: Billing and Coding: Skin Substitutes Grafts/Cellular Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers, A59740 **https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=59740**
2. MLN Matters. January 2019 Update of the Ambulatory surgical Center (ASC) Payment System. MLN Matters Number: MM11108 Revised. Related CR Release Date: December 31, 2018. Related CR Transmittal Number: R4191CP. Related Change Request (CR) Number: 11108. Effective Date: January 1, 2019. Implementation Date: January 7, 2019. **https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM11108.pdf**
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5. CMS IOM Publication 100-08, Medicare Program Integrity Manual, Chapter 13, Section 13.5.4 Reasonable and Necessary Provisions in LCDs. Medicare Program Integrity Manual (cms.gov)
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Benefit Administration Manual Policies are developed to provide guidance to Members and Providers. This Policy relates only to the services or supplies described in it. The existence of a Benefit Administration Manual Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Policy. Coverage of services for Members is based on the Member's subscriber documents and is subject to all terms and conditions including specific exclusions and limitations. This type of document includes the following: Subscriber contract and associated riders; Member Benefit Guide; or an Evidence of Coverage document (for Medicare Plan Members).

HAP HMO/POS and AHL EPO/PPO Members:

If there is a discrepancy between this policy and coverage described in the subscriber documents, the Member's subscriber documents will apply.

ASO Members:

Coverage as discussed in this policy may not apply to employer groups that are self-funded (referred to as an ASO group [Administrative Services Only]). Each ASO group determines the coverage available to their members which is found in the ASO Benefit Guide and associated riders. If a member has coverage for the type of service covered by this policy, then the medical criteria as discussed in this policy applies to those services.

Medicare Plan Members:

Coverage is based on Medicare (CMS) regulations and guidelines which include the NCDs (National Coverage Decision) and LCDs (Local Coverage Decision) for our area. When no coverage determination has been made by CMS, then this policy will apply.

EFFECTIVE DATE

11/21/2025

REVISED DATE

11/21/2025

REVIEWED DATE

11/20/2025