Clinical Policy: Skin Substitutes for Chronic Wounds

Reference Number: PA.CP.MP.185 Coding Implications
Last Review Date: 04/20 Revision Log
Plan Effective Date: 07/01/2020

See Important Reminder **at the end of this policy for important regulatory and legal information.**

Description

Patients receiving skin replacement surgery with a skin substitute graft should be under the care of a wound care physician or surgeon. It is imperative that systemic disease be monitored/treated in order to insure adequate healing of the wound site. This policy addresses the medical necessity criteria for skin substitutes in the treatment of chronic wounds.

Note: *For skin substitutes for burns, refer to PA.CP.MP.186 Burn Surgery.*

Policy/Criteria

I. It is the policy of health plans affiliated with PA Health & Wellness® that skin substitutes are **medically necessary** for diabetic foot ulcers, venous stasis ulcers, or venous leg ulcers when all of the following are met:

A. Wound is chronic, defined as a wound that does not respond to at least 4 weeks of standard wound treatment as a component of organized, comprehensive conservative therapy;
B. Wound characteristics and treatment plan are documented;
C. Standard wound care has failed, evidenced by all of the following:
   1. The ulcer or skin deficit has been treated with appropriate wound-care measures, including debridement, standard dressings (including silver dressings), compression, off-loading;
   2. Wound has increased in size or depth; or has not changed in baseline size or depth and there is no indication that improvement is likely (such as granulation, epithelialization or progress towards closing);
D. Documentation of effort to cease nicotine use, including from sources other than cigarettes, for at least 4 weeks during conservative wound care and prior to planned bioengineered skin replacement therapy, or no nicotine use;
E. Wound characteristics, all of the following:
   1. Partial- or full-thickness ulcer with a clean, granular base;
   2. No involvement of tendon, muscle, joint capsule, or exposed bone or sinus tracts;
   3. No wound infection; wound must be clean and free of necrotic debris or exudate;
   4. Member has adequate circulation/oxygenation to support tissue growth/wound healing, as evidenced by physical examination (e.g., Ankle-Brachial Index [ABI] of no less than 0.7 or TCOM pressure greater than 30 millimeters of mercury [mmHg]);
F. For lower extremity chronic wounds (diabetic foot ulcer or venous leg ulcer), one of the following:
   1. Diabetic foot ulcer (DFU), and all of the following:

a. Hgb AIc of ≤ 8 or documentation of improving control;
b. Documented conservative wound care for ≥ than 4 weeks;
c. Wound is without evidence of osteomyelitis or nidus of infection;

2. Venous stasis ulcer or venous leg ulcers (VSU or VLU), all of the following:
   a. A chronic, non-infected ulcer VSU or VLU has failed to respond to documented conservative wound-care measures for ≥ 4 weeks with documented compliance;
   b. Completed assessment includes:
      i. History (prior ulcers, thrombosis risks);
      ii. Physical exam (edema, skin changes);
      iii. ABI (Ankle-Brachial Index) and duplex scan to confirm Clinical-Etiology-Anatomy-Pathophysiology (*CEAP);
   c. If VLU is present, a venous duplex ultrasound has evaluated for saphenous vein incompetency/venous reflux and contributory superficial ulcer bed perforators;
3. Full thickness skin-loss ulcer is the result of abscess, injury or trauma and has failed to respond to appropriate control of infection, foreign body, tumor resection, or other disease process for ≥ 4 weeks;

G. Requested applications comply with FDA guidelines for the specific product, not to exceed 10 applications or treatments;
H. Only one skin substitute will be simultaneously in place per wound episode. Product change within the wound episode is allowed, not to exceed the 10 application limit per wound per 12 week period of care;
I. None of the following contraindications:
   1. Inadequate control of underlying conditions or exacerbating factors (e.g., uncontrolled diabetes with Hgb A1c > 8%, or no documented improvement of glucose levels in the last 4 weeks, active infection, and active Charcot arthropathy of the ulcer surface, vasculitis or continued tobacco smoking without physician attempt to affect smoking cessation);
   2. Known hypersensitivity to any component of the specific skin substitute graft (e.g., allergy to avian, bovine, porcine, equine products);
   3. Concurrent treatment with hyperbaric oxygen therapy;
   4. Partial thickness loss with the retention of epithelial appendages (epithelium will repopulate the deficit).

Note: Treatment of any chronic skin wound will typically last no more than 12 weeks.

II. It is the policy of health plans affiliated with PA Health & Wellness® that skin substitutes are **not medically necessary** for the following indications or scenarios:
A. Decubitus ulcer treatment;
B. Continued skin substitute use after treatment failure, which is defined as the repeat or alternative application course (of up to 12 weeks) of skin substitute grafts within one year of any given course of skin substitute treatment for a venous stasis ulcer or diabetic foot ulcer;
C. Retreatment of healed ulcers (those showing greater than 75% size reduction and smaller than 1 square cm).

Background

According to the Centers for Medicare & Medicaid Services (CMS), chronic wounds of the lower extremities, including venous stasis ulcers (VSU), venous leg ulcers (VLU), Diabetic foot ulcers (DFU) and pressure sores, are a major public health problem. While lower extremity ulcers have numerous causes such as burns, trauma, mixed venous-arterial disease, immobility and vasculitis, nutritional or other neuropathy, over 90% of the lesions in the United States are related to venous stasis disease and diabetic neuropathy.[1]

Standard care for lower extremity wounds and ulcers includes infection control and management of edema, mechanical offloading of the affected limb, mechanical compression, limb elevation, debridement of necrotic tissue, management of systemic disease and counseling on the risk of continued tobacco use. Additionally, maintenance of a therapeutic wound environment with appropriate dressings can facilitate development healthy granulation tissue and re-epithelialization. Dressings are an important part of wound management by not only maintaining a moist environment but by stopping contamination, absorbing exudate and helping to prevent further trauma.[1,2]

A wound that has not healed within one to three months may be considered a chronic wound and can be a challenge to treat effectively. Even with advancements in standard wound care and synthetic occlusive dressings, some ulcers fail to heal and may benefit from a skin substitute.[1,2]

For venous leg ulcers (VLU), it is essential to evaluate for presence of saphenous vein reflux prior to consideration of skin substitute. If there is significant saphenous vein incompetency and reflux (valve closure time defined as > 500 milliseconds), or if ulcer bed veins are identified as contributory on ultrasound, a referral to a vascular surgeon or interventional radiologist is required. For significant saphenous vein reflux, endovascular laser or radiofrequency ablation can have enhanced rates of healing compared to other treatments. Without significant reflux, sclerotherapy may also be more beneficial.[3]

There are currently a wide variety of bioengineered products available for soft tissue coverage to affect closure.

Autologous skin grafts, also referred to as autografts, are permanent covers that use skin from different parts of the individual's body. These grafts consist of the epidermis and a dermal component of variable thickness. A split-thickness skin graft (STSG) includes the entire epidermis and a portion of the dermis. A full thickness skin graft (FTSG) includes all layers of the skin. Although autografts are the optimal choice for full thickness wound coverage, areas for skin harvesting may be limited, particularly in cases of large burns or venous stasis ulceration. Harvesting procedures are painful, disfiguring and require additional wound care.[2,4]

Allografts which use skin from another human (e.g., cadaver) and Xenografts which use skin from another species (e.g., porcine or bovine) may also be employed as temporary skin replacements, but they must later be replaced by an autograft or the ingrowth of the patient's own skin. [2,4]

Bioengineered Skin / Cultured Epidermal Autografts (CEA) are autografts derived from the patient's own skin cells grown or cultured from very small amounts of skin or hair follicle. Production time is prolonged. One such product is grown on a layer of irradiated mouse cells, bestowing some elements of a xenograft. Wide spread usage has not been available due to limited availability or access to the technology. [2,4]

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2020, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS®* Codes	Description
Q4101	Apligraf, per sq cm
Q4102	Oasis wound matrix, per sq cm
Q4103	Oasis burn matrix, per sq cm
Q4104	Integra bilayer matrix wound dressing (BMWD), per sq cm
Q4105	Integra dermal regeneration template (DRT) or Integra Omnigraft dermal regeneration matrix, per sq cm
Q4106	Dermagraft, per sq cm
Q4107	Graftjacket, per square centimeter
Q4108	Integra matrix, per sq cm
Q4110	Primatrix, per square centimeter
Q4116	AlloDerm, per sq cm
Q4121	TheraSkin, per sq cm
Q4122	Dermacell, per square centimeter
Q4128	FlexHD, AllopatchHD, or Matrix HD, per sq cm
Q4132	Grafix Core and GrafixPL Core, per sq cm
Q4133	Grafix PRIME, GrafixPL PRIME, Stravix and StravixPL, per sq cm
Q4137	Amnioexcel, amnioexcel plus or biodexcel, per square centimeter
Q4138	Biodfence dryflex, per square centimeter
Q4140	Biodfence, per square centimeter
Q4141	Alloskin ac, per square centimeter
Q4143	Repriza, per square centimeter
Q4146	Tensix, per square centimeter
Q4147	Architect, architect px, or architect fx, extracellular matrix, per square centimeter
Q4148	Neox cord 1k, neox cord rt, or clarix cord 1k, per square centimeter
Q4150	Allowrap ds or dry, per square centimeter
Q4151	Allowrap ds or dry, per square centimeter
Q4152	Amnioband or guardian, per square centimeter
Q4153	Dermapure, per square centimeter

HCPCS®* Codes	Description
Q4154	Dermavest and plurivest, per square centimeter
Q4155	Biovance, per square centimeter
Q4156	Neoxflo or clarixflo, 1 mg
Q4157	Neox 100 or clarix 100, per square centimeter
Q4158	Revitalon, per square centimeter
Q4159	Kerecis omega3, per square centimeter
Q4160	Nushield, per square centimeter
Q4161	bio-ConneKt wound matrix, per sq cm
Q4186	Epifix, per square centimeter
Q4187	Epicord, per square centimeter
Q4195	Puraply, per square cntimeter
Q4196	puraply am, per square centimeter
Q4197	puraply xt, per square centimeter

Reviews, Revisions, and Approvals	Date	Approval Date
Policy adapted from WellCare's HS433 Skin Substitutes policy. Removed description information about identification of MD managing chronic conditions. Removed requirement for MD review of all requests. Rearranged some not medically necessary indications into the contraindications section. In I.D, changed requirement for no nicotine use for at least 4 weeks to documentation of effort to cease nicotine use, or no nicotine use for at least 4 weeks. In the diabetic foot ulcer criteria, removed requirement of neuropathy. In I.I.1, changed contraindication of "active Charcot arthropathy of the ulcer extremity" to "active Charcot arthropathy of the ulcer surface." In DFU section, removed documentation of assessment of physical activity, nutrition, physical exam, check of prosthetics, and history of diabetes management, including comorbidities. Changed requirement of HbA1c ≤7% to ≤8%, or with documented improvement of blood glucose in last 4 weeks. Changed HbA1c contraindication to >8% or with no document improvement of blood glucose in last 4 weeks. Reworded some extraneous language with no clinical significance. Removed criteria stating that switching products during an episode of wound care is not allowed. Removed not medically necessary language about repeated billing of surgical preparation services. Revised name of the policy to Skin Substitutes for Chronic Wounds.	04/20	04/20
New PHW Policy	06/2020	08/2020

References

1. Local Coverage Determination Wound Application Of Cellular And/Or Tissue Based Products (Ctps), Lower Extremities (L36690). Centers for Medicare and Medicaid Services Web site. https://www.cms.gov/medicare-coverage-database/overview-and-quick-

search.aspx. Published October 10, 2016 (revised September 23, 2019). Accessed April 9, 2020.
2. Local Coverage Determination Application of Bioengineered SKIN Substitutes to Lower Extremity Chronic Non-Healing Wounds (L35041). Centers for Medicare and Medicaid Services Web site. https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Published October 1, 2015 (revised September 26, 2019). Accessed April 9, 2020.
3. Mangit S. Gohell, MD, Fancine Heatly, B Sc, Xinxue Liu , PhD, Andrew Bradbury, MD et al. for the EVRA Trial Investigators. N Engl J Med 2018; 378:2105-2114
4. Local Coverage Determination Application of Skin Substitute Grafts for Treatment of DFU and VLU of Lower Extremities (L36377). Centers for Medicare and Medicaid Services Web site. https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Published October 1, 2015 (revised January 8, 2019. Accessed April 9, 2020.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by PA Health & Wellness Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise

professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.