Clinical Policy: Skin and Soft Tissue Substitutes for Chronic Wounds

Reference Number: WA.CP.MP.185
Date of Last Revision: 04/24
Effective Date: 09/01/24

Coding Implications
Revision Log

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 CP.MP.186 Burn Surgery.*

Policy/Criteria

I. It is the policy of Coordinated Care of Washington, Inc., in accordance with the Health Care Authority's Billing Guidelines, that skin substitutes are **medically necessary** for wound treatment under the following conditions:

A. For treatment of *diabetic foot ulcers*, when *all* of the following are met:
   a. Partial or full-thickness diabetic foot ulcer of > 4 weeks duration;
   b. Ulcer has extended through the dermis but without tendon, muscle, or bone exposure;
   c. Unresponsive to standard wound therapy, including all of the following:
      i. Assessment of vascular status with treatment as indicated
      ii. Nutritional optimization
      iii. Optimal glucose control
      iv. Adequate debridement
      v. Moist dressing
      vi. Off-loading
      vii. Treatment of infection
      viii. Tobacco/nicotine cessation intervention when applicable.

B. For the treatment of chronic venous stasis ulcers, when all of the following are met:
   a. Partial or full-thickness venous stasis ulcer;
   b. Failure of > 4 weeks standard ulcer therapy using regular dressing changes and therapeutic compression;
   c. No active infection

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

II. It is the policy of Coordinated Care of Washington, Inc., in accordance with the Health Care Authority's Billing Guidelines, that skin substitutes are **medically necessary** for the treatment of wounds related to dystrophic *epidermolysis bullosa* when standard wound therapy has failed.

III. It is the policy of Coordinated Care of Washington, Inc., in accordance with the Health Care Authority's Billing Guidelines, that skin substitutes are **medically necessary** for *breast reconstruction surgery* as a part of breast cancer treatment.

IV. It is the policy of Coordinated Care of Washington, Inc., in accordance with the Health Care Authority's Billing Guidelines, that reapplication of a skin substitute when the initial treatment episode is not successful is **not covered**.

V. It is the policy of Coordinated Care of Washington, Inc., in accordance with the Health Care Authority's Billing Guidelines, that coverage is limited to a maximum of 10 applications per year for all indications in sections I-III.

VI. It is the policy of Coordinated Care of Washington, Inc., that skin substitutes are **not medically necessary** for the following indications or scenarios:

A. Decubitus (pressure) ulcer treatment;
B. Retreatment of healed ulcers (those showing greater than 75% size reduction and smaller than 1 square cm);
C. Continued skin or soft tissue 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.

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] These wounds frequently require detailed interventions to start the healing process again; furthermore, patients experience significant functional loss, wound recurrence, and increased morbidity.[6]

Standard care for lower extremity wounds and ulcers includes infection control, 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 of healthy granulation tissue and re-epithelialization. Dressings are essential to wound management because the appropriate dressing not only maintains the moisture balance within the wound, but the dressing also controls exudate, which protects the wound from additional 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 The National Institute for Health and Care Excellence (NICE) recommends consideration of

dermal or skin substitutes as an adjunct to standard care when treating diabetic wounds that are not healing.18 Skin substitutes promote wound healing by replacing extracellular matrix.7 Skin substitutes are categorized based on the composition of epidermal, dermal, and composite skin present.7 They are heterogeneous and can be largely separated into two primary categories: cellular (comprised of living cells); or acellular (composed of synthetic materials or tissue from which living cells have been removed).8,9 The categories are further split based on composition and source of material, including xenograft, acellular allograft, cellular allograft, autograft and synthetic skin substitute choices.7

For VLU, an evaluation for the presence of saphenous vein reflux is essential prior to consideration of skin substitutes. 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. Endovascular laser or radiofrequency ablation can enhance rates of healing compared to other treatments for significant saphenous vein reflux. Without significant reflux, sclerotherapy may also be more beneficial.[3]

According to a 2016 Cochrane review, the overall therapeutic outcome of skin grafts and tissue replacements used with standard wound care demonstrated an increase in the healing rate of foot ulcers and slightly fewer amputations in patients with diabetes compared with standard wound care alone.10 The Wound Healing Society updated their guidelines in 2016, indicating that cellular and acellular skin equivalents positively affect healing in diabetic ulcers by "releasing therapeutic amounts of growth factors, cytokines, and other proteins that stimulate the wound bed."11 A health technology assessment of skin substitutes conducted for adults with neuropathic diabetic foot ulcers and venous leg ulcers found that adults with difficult to heal neuropathic diabetic ulcers and difficult to heal venous leg ulcers who used skin substitutes were more likely to experience complete wound healing than those who used standard care alone.15 A systematic review of 17 trials using several skin substitutes to treat diabetic foot ulcers noted that completed closure of diabetic ulcers was significantly improved when compared to standard care alone.14

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.1,2,4

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. However, they must later be replaced by an autograft or the ingrowth of the patient's own skin.1,2,4

Bioengineered Skin and 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, displaying some components of a xenograft. Widespread usage has not been available due to limited availability or access to the technology.1,2,4

Cellular and/or Tissue Based Products (CTPs) were developed to address problems with autografts, allografts, and xenografts. These consist of biologic covers for refractory wounds with full thickness skin loss secondary to third degree burns, diabetic neuropathic ulcers and the skin loss of chronic venous stasis or venous hypertension. The production of these biologic CTPs varies by company and product, but generally involves the creation of immunologically inert biological products containing protein, hormones or enzymes seeded into a matrix which may provide protein or growth factors intended to stimulate or facilitate healing or promote epithelization.1,2 There are currently a broad range of bioengineered products available for soft tissue coverage to affect closure.1,2,6 Sufficient data is available to establish distinct inferiority to human skin autografts and preclude their designation as skin equivalence.1,2 Although there is no universally accepted classification system for the various bioengineered products, it is advised that the clinician understands the materials used and their fundamental purpose.14

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.

CPT® Codes	Description
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 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;

CPT® Codes	Description
	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)

Note to Providers: Please contact Coordinated Care of Washington, Inc., for current HCPCS coding implications and coverage determinations for specific skin substitutes.

Reviews, Revisions, and Approvals	Revision Date	Approval Date
New policy adapted from WellCare's HS433 Skin Substitutes policy.	05/20	06/20
Reworded section regarding nicotine use. Added to section II that all indications not noted in section I are not medically necessary. Added CPT codes: 15271-15278; updated list of HCPCS codes of current products available, although not inclusive or guarantee of coverage.	07/20	08/20
References reviewed and updated. All instances of "member" changed to "member/enrollee." HCPCS code listing updated. Non-covered codes reported separately.	05/21	06/21
Annual review. References reviewed and updated. Changed "Review Date" in the header to "Date of Last Revision" and "Date" in the revision log header to "Revision Date." Reworded some extraneous language with no clinical significance. Added to I.F.2. "unless Integra® is used per FDA guidelines". Removed I.J.3. "Concurrent treatment with hyperbaric oxygen therapy". Background section updated with no additional impact to criteria. Update code listing of covered and non-covered codes to mirror HCA Billing Guidelines. Added reference CMS A56696. Specialist reviewed.	04/22	05/22
Updated description for code Q4128. Added new HCPCS codes that are covered and not covered per the HCA.	11/22	11/22
Annual review. References reviewed and updated. Policy name changed to align with corporate policy. Section I. medical necessity criteria updated to mirror billing guidelines. Moved HCA limit of 10 applications per year to new section V. Section VI. updated to include continued use after treatment failure per corporate policy update. Background section updated with no additional impact to criteria.	05/23	05/23

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Annual review. References reviewed and updated. Reviewed by external specialist. Policy description updated with no impact on criteria. Section V corrected to reflect "all indications in section I-III." HCPCS covered and non-covered coding tables removed and added note for providers to contact Coordinated Care for current coding implications and coverage determinations.	04/24	04/24

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/search.aspx. Published October 10, 2016 (revised September 1, 2022). Accessed January 22, 2024.
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/search.aspx. Published October 1, 2015 (revised September 26, 2019). Accessed January 22, 2024.
3. Gohel MS, Heatley F, Liu X, et al. A randomized trial of early endovenous ablation in venous ulceration. N Engl J Med. 2018;378(22):2105 to 2114. doi:10.1056/NEJMoa1801214
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/search.aspx. Published October 1, 2015 (revised January 8, 2019). Accessed January 22, 2024.
5. Armstrong DG, deAsla RJ. Management of diabetic foot ulcers. UpToDate. www.uptodate.com. Updated April 25, 2022. Accessed January 22, 2024.
6. Snyder D, Sullivan N, Margolis D, Schoelles K. Skin substitutes for treating chronic wounds. Technology Assessment Program Project ID No.WNDT0818. (Prepared by the ECRI Institute-Penn Medicine Evidence-based Practice Center under Contract No. HHSA 290-2015-0005-I) Rockville, MD: Agency for Healthcare Research and Quality. February 2020. https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id109TA.pdf Accessed January 22, 2024.
7. Dai C, Shih S, Khachemoune A. Skin substitutes for acute and chronic wound healing: an updated review. J Dermatolog Treat. 2020;31(6):639 to 648. doi:10.1080/09546634.2018.1530443
8. Health Technology Assessment. Cellular skin substitutes for chronic foot ulcers in adults with diabetes mellitus. Hayes. www.hayesinc.com. Published March 26, 2020 (annual review April 24, 2023). Accessed January 22, 2024.
9. Health Technology Assessment. Skin substitutes for venous leg ulcers in adults. Hayes. www.hayesinc.com. Published July 23, 2020 (annual review July 11, 2023). Accessed January 22, 2024.
10. Santema TB, Poyck PP, Ubbink DT. Skin grafting and tissue replacement for treating foot ulcers in people with diabetes. Cochrane Database Syst Rev. 2016;2(2):CD011255. Published 2016 Feb 11. doi:10.1002/14651858.CD011255.pub2
11. Lavery LA, Davis KE, Berriman SJ, et al. WHS guidelines update: Diabetic foot ulcer treatment guidelines. Wound Repair Regen. 2016;24(1):112 to 126. doi:10.1111/wrr.12391

12. Local coverage article. billing and coding: wound application of cellular and/or tissue based products (CTPs), lower extremities (A56696). Centers for Medicare and Medicaid Services Web site: https://www.cms.gov/medicare-coverage-database/search.aspx. Published July 11, 2019 (revised December 28, 2023). Accessed January 22, 2024.
13. Urciuolo F, Casale C, Imparato G, Netti PA. Bioengineered Skin Substitutes: the Role of Extracellular Matrix and Vascularization in the Healing of Deep Wounds. J Clin Med. 2019;8(12):2083. Published 2019 Dec 1. doi:10.3390/jcm8122083
14. Shahrokhi S. Skin substitutes. UpToDate. www.uptodate.com. Updated August 02, 2023. Accessed January 22, 2024.
15. Ontario Health. Skin substitutes for adults with diabetic foot ulcers and venous leg ulcers: a health technology assessment. Ont Health Technol Assess Ser [Internet]. 2021 June 21(7):1 to 165. Available from: https://www.hqontario.ca/evidence-to-improve-care/health-technology-assessment/reviews-and-recommendations/skin-substitutes-for-adults-with-diabetic-foot-ulcers-and-venous-leg-ulcers Accessed January 22, 2024.
16. Local coverage article. billing and coding: application of bioengineered skin substitutes to lower extremity chronic non-healing wounds (A54117). Centers for Medicare and Medicaid Services Web site: https://www.cms.gov/medicare-coverage-database/search.aspx. Published October 1, 2015 (revised August 13, 2020). Accessed January 22, 2024.
17. Xiang J, Wang S, He Y, Xu L, Zhang S, Tang Z. Reasonable glycemic control would help wound healing during the treatment of diabetic foot ulcers. Diabetes Ther. 2019;10(1):95 to 105. doi:10.1007/s13300-018-0536-8
18. Diabetic foot problems: prevention and management. NICE guideline[NG19] on diabetes and other endocrinal, nutritional and metabolic conditions. https://www.nice.org.uk/guidance/ng19/chapter/Recommendations#diabetic-foot-ulcer Published August 26, 2015 (updated October 11, 2019). Accessed January 22, 2024.
19. Health Technology Assessment. Acellular skin substitutes for chronic foot ulcers in adults with diabetes mellitus. Hayes. www.hayesinc.com. Published May 6, 2020 (annual review May 10, 2023). Accessed January 22, 2024.
20. Hingorani A, LaMuraglia GM, Henke P, et al. The management of diabetic foot: A clinical practice guideline by the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine. J Vasc Surg. 2016;63(2 Suppl):3S-21S. doi:10.1016/j.jvs.2015.10.003
21. Washington State Health Care Authority. *Physician-Related Services/Health Care Billing Guide*. https://www.hca.wa.gov/assets/billers-and-providers/Physician-related-services-bg-20240401.pdf Revision effective April 1, 2024.
22. Washington State Health Care Authority. Outpatient Hospital *OPPS Fee Schedule.* https://www.hca.wa.gov/billers-providers-partners/prior-authorization-claims-and-billing/provider-billing-guides-and-fee-schedulesRevision effective April 1, 2024.

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

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Note: For Medicaid members/enrollees, 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.