Missouri Care

WellCare (Nebraska)

Skin Substitutes for Chronic Wounds:

Policy Number: CP.MP.185

Last Review Date: 06/20

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

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]

POSITION STATEMENT

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. Skin substitutes are **medically necessary** for diabetic foot ulcers, venous stasis ulcers, or venous leg ulcers when all of the following are met:
- A. Age ≥ 18 years, or type 1 diabetic;
- B. 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;
- C. Wound characteristics and treatment plan are documented;
- D. 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);
- E. Documentation of effort to cease nicotine use, including from sources other than cigarettes but excluding nicotine replacement therapy, for at least 4 weeks during conservative wound care and prior to planned bioengineered skin replacement therapy, or no nicotine use;
- F. 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]);

G. 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;
H. Requested applications comply with FDA guidelines for the specific product, not to exceed 10 applications or treatments;
I. 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;
J. 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. Skin substitutes are **not medically necessary** for the following indications or scenarios:
A. All indications not noted in section I;
B. Decubitus ulcer treatment;
C. 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;
D. Retreatment of healed ulcers (those showing greater than 75% size reduction and smaller than 1 square cm).

CODING

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; 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)

HCPCS®* Codes	Description
Q4100	Skin substitute, nos
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
Q4111	Gammagraft, per sq cm
Q4115	Alloskin, per sq cm
Q4117	Hyalomatrix, per sq cm
Q4118	Matristem micromatrix, 1mg
Q4121	TheraSkin, per sq cm
Q4122	DermACELL, DermACELL AWM or DermACELL AWM Porous, per sq cmr
Q4123	AlloSkin RT, per sq cm
Q4124	Oasis ultra tri-layer wound matrix, per sq cm
Q4126	MemoDerm, DermaSpan, TranZgraft or IntéguPly, per sq cm
Q4127	Talymed, per sq cm
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

Q4134	Hmatrix, per sq cm
Q4135	Mediskin, per sq cm
Q4136	E-Z Derm, per sq cm
Q4137	Amnioexcel, amnioexcel plus or biodexcel, per square centimeter
Q4140	BioDFence, per square centimeter
Q4141	Alloskin AC, 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	AmnioBand or Guardian, per sq cm
Q4152	DermaPure, per sq cm
Q4153	Dermavest and Plurivest, per sq cm
Q4154	Biovance, per sq cm
Q4156	Neox 100 or Clarix 100, per sq cm
Q4157	Revitalon, per sq cm
Q4158	Kerecis Omega3, per sq cm
Q4159	Affinity, per sq cm
Q4160	Nushield, per square centimeter
Q4161	bio-ConneKt wound matrix, per sq cm
Q4163	Woundex, bioskin, per sq cm
Q4164	Helicoll, per square cm
Q4165	Keramatrix or Kerasorb, per sq cm
Q4166	Cytal, per square centimeter
Q4169	Artacent wound, per sq cm
Q4170	Cygnus, per sq cm
Q4173	Palingen or Palingen Xplus, per sq cm
Q4175	Miroderm, per sq cm
Q4178	FlowerAmnioPatch, per sq cm
Q4180	Revita, per sq cm
Q4183	Surgigraft, 1 sq cm
Q4184	Cellesta or Cellesta Duo, per sq cm
Q4186	Epifix, per square centimeter
Q4187	Epicord, per square centimeter
Q4188	AmnioArmor, per sq cm
Q4190	Artacent AC, per sq cm
Q4195	PuraPly, per square cm
Q4196	PuraPly AM , per square cm
Q4197	PuraPly XT, per square cm
Q4203	Derma-Gide, per sq cm
Q4208	Novafix, per sq cm
Q4209	SurGraft, per sq cm
Q4210	Axolotl Graft or Axolotl DualGraft, per sq cm
Q4211	Amnion Bio or AxoBioMembrane, per sq cm
Q4214	Cellesta Cord, per sq cm
Q4216	Artacent Cord, per sq cm
Q4217	WoundFix, BioWound, WoundFix Plus, BioWound Plus, WoundFix Xplus or BioWound Xplus, per sq cm
Q4218	SurgiCORD, per sq cm

Q4219	SurgiGRAFT-DUAL, per sq cm
Q4220	BellaCell HD or Surederm, per sq cm
Q4221	Amnio Wrap2 per sq cm
Q4222	ProgenaMatrix, per sq cm
Q4226	MyOwn Skin, includes harvesting and preparation procedures, per sq cm

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

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.

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
Added criteria of age ≥ 18 years, or type 1 diabetic. Added to the requirement for documentation of effort to cease nicotine use that this does not include nicotine replacement therapy. 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.	05/20	06/20