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

Patients receiving skin replacement surgery with a skin substitute graft should be under the care of a physician for the treatment of their systemic disease process (e.g., diabetes mellitus, chronic venous insufficiency, and/or peripheral vascular disease). It is imperative that their systemic disease be monitored/treated in order to insure adequate healing of the wound site. This concurrent medical management and the identity of the managing medical physician should be clearly discernible in the medical record and available upon request.¹

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**

**Applicable To:**

- Medicaid – Kentucky

**Exclusions**

This guideline is not for skin substitute or wound care request related to burns. For all requests related to burns please use the burn care CCG, Burn Surgery HS-321.

Skin substitutes are not considered medically necessary and not a covered benefit for any of the following conditions:

1. Partial thickness loss with the retention of epithelial appendages is not a candidate for grafting or replacement, as epithelium will repopulate the deficit from the appendages, negating the benefit of over grafting.
2. Skin substitute grafts will be allowed for the episode of wound care in compliance with FDA guidelines for the specific product not to exceed 10 applications or treatments. In situations where more than one specific product is used, it is expected that the number of applications or treatments will still not exceed 10.
3. Simultaneous use of more than one product for the episode of wound is not covered. Product change within the episode of wound is allowed, not to exceed the 10 application limit per wound per 12 week period of care.
4. Treatment of any chronic skin wound will typically last no more than twelve (12) weeks.
5. Repeat or alternative applications of skin substitute grafts are not considered medically reasonable and necessary.
6. Retreatment of healed ulcers, those showing greater than 75% size reduction and smaller than 1 square cm, is not considered medically reasonable and necessary.
7. Skin substitute grafts are contraindicated and are not considered reasonable and necessary in patients with inadequate control of underlying conditions or exacerbating factors (e.g., uncontrolled diabetes with Hgb A1c > 7%, active infection, and active Charcot arthropathy of the ulcer extremity, vasculitis or continued...
tobacco smoking without physician attempt to affect smoking cessation).

8. Skin substitute grafts are contraindicated in patients with known hypersensitivity to any component of the specific skin substitute graft (e.g., allergy to avian, bovine, porcine, equine products).

9. Repeat use of surgical preparation services in conjunction with skin substitute application codes will be considered not reasonable and necessary. It is expected that each wound will require the use of appropriate wound preparation code at least once at initiation of care prior to placement of the skin substitute graft.

10. Re-treatment within one (1) year of any given course of skin substitute treatment for a venous stasis ulcer or (diabetic) neuropathic foot ulcer is considered treatment failure and does not meet reasonable and necessary criteria for re-treatment of that ulcer with a skin substitute procedure.

11. One specific skin substitute graft product will be allowed for the episode of skin replacement surgery wound care (defined as 12 weeks from the first application of a skin substitute graft) assuming its use is not in conflict with FDA assessments and assuming there is one related wound.

12. Switching products in a 12-week episode of skin replacement surgery wound care or application of a product beyond 12-weeks is not expected.

13. Skin substitutes with concurrent hyperbaric oxygen therapy (HBOT) treatment is not covered.

14. Skin substitute use for decubitus ulcer treatment is not covered.

Coverage

Skin substitutes are considered medically necessary and a covered benefit for Diabetic foot ulcers (DFU) or Venous Stasis Ulcers (VSU) or Venous leg ulcers (VLU) when the member meets ALL of the following criteria. Please note that all requests for skin substitutes must go for mandatory secondary medical director review:

1. Member has a chronic wound which is defined as a wound that does not respond to standard wound treatment for at least 4 weeks during organized comprehensive conservative therapy.

2. For all wounds, documentation and a comprehensive treatment plan, before initiation of a specialized wound therapy product is required.

3. Member has had a failed response to standard wound care which is defined as an ulcer or skin deficit that has failed to respond to documented appropriate wound-care measures, including debridement, standard dressings (including silver dressings), compression, off-loading, and has increased in size or depth, or has not changed in baseline size or depth and has no indication that improvement is likely (such as granulation, epithelialization or progress towards closing).

4. Nicotine use adversely affects healing. If member is a smoker, they will cease smoking or have refrained from nicotine use for at least 4 weeks during conservative wound care and prior to planned bioengineered skin replacement therapy.

5. All of the following apply to the member’s wound:
   A. Partial- or full-thickness ulcers, must not involve tendon, muscle, joint capsule or exhibit exposed bone or sinus tracts, and must have a clean granular base;
   B. No wound infection, wound must be clean and free of necrotic debris or exudate;
   C. Member must have 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 toe pressure greater than 30 millimeters of mercury [mmHg]);

6. One of the following must apply to member’s lower extremity chronic wound:
   A. Diabetic foot ulcers (DFU) with all of the following:
      I. Presence of a neuropathic diabetic foot ulcer(s) having failed to respond to documented conservative wound-care measures of greater than four weeks; AND,  
      II. During conservative treatment the member is compliant with recommendations: AND, 
      III. Member’s wound is without evidence of underlying osteomyelitis or nidus of infection; AND, 
      IV. Members must have an assessment of type I or type 2 Diabetes Mellitus and management history with attention to certain comorbidities (vascular disease, neuropathy, osteomyelitis); review of the current blood sugars/ HgbA1c (requires Hgb Alc of 7% or lower), diet and
SKIN SUBSTITUTES

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V. Member must have had a physical exam that includes assessment of skin and wound, ABI (Ankle-Brachial Index), and check of off-loading prosthetics or shoes for signs of abnormal wear.

B. Venous stasis ulcer or venous leg ulcers (VSU or VLU) with all of the following:
   I. Presence of a chronic, non-infected venous stasis ulcer with failure to respond to documented conservative wound-care measures for greater than 4-6 weeks with documented compliance; AND,
   II. Member must have an assessment of history (prior ulcers, thrombosis risks), physical exam (edema, skin changes), ABI (Ankle-Brachial Index), and duplex scan to confirm CEAP classification (Clinical-Etiology-Anatomy-Pathophysiology (*CEAP) classification categorizes chronic venous disorders to facilitate communication between physicians, to serve as a basis for standardized reporting during scientific analysis of management alternatives, and to identify segments of venous incompetence amenable to vein ablation therapies.
   III. All VLU should have a venous duplex ultrasound to evaluate for saphenous vein incompetency/venous reflux and contributory superficial ulcer bed perforators.

C. Full thickness skin loss ulcer that is the result of abscess, injury or trauma that has failed to respond to appropriate control of infection, foreign body, tumor resection, or other disease process for a period of 4 weeks or longer.

7. All requests for skin substitutes must go for mandatory secondary medical director review.

CODING

Covered CPT Codes – None.

Covered HCPCS Codes – None.

Covered HCPCS Codes (Products)

Q4101 Apligraf, per square centimeter
Q4102 Oasis Wound Matrix, per square centimeter
Q4106 Dermagraft, per square centimeter
Q4107 Graftjacket, per square centimeter
Q4110 Primatrix, per square centimeter
Q4121 Theraskin, per square centimeter
Q4124 Oasis Ultra Tri-Layer Wound Matrix, per square centimeter
Q4131 Epifix, per square centimeter
Q4116 Alloderm, per square centimeter
Q4151 Amnioband or Guardian, per sq cm

Covered ICD-10 Codes

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


4. Local Coverage Determination Application of Skin Substitute Grafts for Treatment of DFU and VLU of Lower Extremities (L36377). Centers Clinical Coverage Guideline

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MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

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