Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Skin Substitute Grafts	MP-SSG-FP-03-23	☒ MMM MA ☐ MMM Multihealth

Service Category

- ☐ Anesthesia
- ☐ Surgery
- ☐ Radiology Procedures
- ☐ Pathology and Laboratory Procedures
- ☐ Medicine Services and Procedures
- ☐ Evaluation and Management Services
- ☐ DME/Prosthetics or Supplies
- ☒ Other Wound Skin Substitute Grafts

Service Description

First Coast L36377
Application of Skin Substitute Grafts for Treatment of DFU and VLU of Lower Extremities

This LCD addresses the reasonable and necessary (R&N) threshold for coverage of skin replacement surgery with particular emphasis on the indications for application of skin substitute grafts for diabetic foot ulcers DFU and venous leg ulcers VLU. Evaluation of the clinical literature indicates that studies comparing the efficacy of skin substitute grafts as an adjunct to chronic wound care are limited in number, apply mainly to generally healthy patients, and examine only a small portion of the skin substitute products available in the United States. Therefore, no individual product can be considered for payment unless the applicable skin replacement surgery code meets the requirements of this LCD.

Application of skin substitute graft for indications other than for DFU or VLU are not addressed by this LCD. Such application must meet the reasonable and necessary threshold for coverage and the supply must be used per its FDA requirements.

Chronic wounds of the lower extremities, including venous stasis ulcers, diabetic foot ulcers 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. Standard treatment of lower extremity ulcers (e.g., diabetic foot ulcers (DFU) and/or venous leg ulcers (VLU)) may include mechanical offloading, infection control, mechanical compression, limb elevation, debridement of necrotic tissue, management of systemic disease and counseling on the risk of continued tobacco use. In addition, maintenance of a moist wound environment through appropriate dressings facilitates development of healthy granulation tissue and epithelialization and thus may potentiate complete healing at a wound site. Dressings are an integral part of wound management by not only maintaining a moist environment but by stopping contamination and absorbing exudate. Despite advancements in various synthetic occlusive dressings some ulcers fail to heal so other adjuncts to wound care such as the development of skin substitutes have been employed to increase success rates of healing.

Generally depending on the purpose of the product and how it functions, skin substitutes are regulated by the FDA premarket approval (PMA) process, FDA 510(k) premarket notification process, or the FDA regulations for human cells, tissues, and cellular and tissue-based products, and the FDA humanitarian device exemption process. Although skin substitutes have attributes of both biologicals and devices, the current Medicare position is that these products are best characterized as surgical supplies or devices as a result of their required surgical application and their similarity to other surgical supplies. It has been noted that there are instances in which certain products might have a wound healing indication, but may not necessarily meet the definition of skin substitutes and similar products that aid wound healing. Therefore, FDA classification and indication alone does not determine if a product meets the definition of skin substitute and/or meets the reasonable and necessary threshold for coverage.

Per the American Medical Association (AMA) and the Current Procedural Terminology (CPT), skin replacement surgery consists of surgical preparation and topical placement of an autograft (including tissue cultured autograft) or skin substitute graft (i.e., homograft, allograft, xenograft). The graft is anchored using the individual's choice of fixation. When services are performed in the office, routine dressing supplies are not

reported separately. Skin substitute graft procedures include the application of non-autologous human skin (dermal or epidermal, cellular and acellular) grafts (e.g., homograft, allograft), non-human skin substitute grafts (i.e., xenograft), and biological products that form a sheet scaffolding for skin growth. These procedures are not to be reported for application of non-graft wound dressings (e.g., gel, ointment, foam, liquid) or injected skin substitutes. Removal of current graft and/or simple cleansing of the wound is included, when performed. Non-graft wound dressings are generally included in standard wound care management though such products may provide value and, in fact, may preclude the need for skin substitute grafts. The application of skin substitute grafts is distinguished according to the anatomic location and surface area rather than by product description. The ideal skin substitute for the treatment of DFU and VLU of the lower extremity has yet to be developed, and current products are sometimes utilized inappropriately as dressings.

Chronic wounds and frequently recurring wounds related to DFUs and VLUs are a challenge to treat effectively. Chronic wounds are unresponsive to appropriate initial therapy or persistent in the face of appropriate additional care. A wound that has not healed within one to three months may be considered chronic and the application of a skin substitute graft, an advance treatment modality, may be considered for certain patients.

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 discernable in the medical record and available upon request.

It is the expectation that a specific skin substitute graft product will be used 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 Food and Drug Administration (FDA) assessments (e.g., indications, contraindications, how supplied and directions for use, etc.) and/or the American Association of Tissue Banks (AATB) approved use and assuming there is one related wound (definitions in CPT). Repeat application of a skin substitute graft within the 12 week episode of skin replacement surgery wound care may be considered upon re-assessment and must be supported in the medical record documentation for that encounter. Continuation of a skin substitute product within the 12- week episode of skin replacement wound care is not expected if the wound has responded to the skin replacement surgery with epithelialization and other progression. This LCD does not endorse particular products for separate payment so the physician's documentation must support the need for skin replacement surgery and the product used. Specific products may be listed as noncovered in the future (LCD for Noncovered Services) based on clinical literature that establishes inferiority.

Definitions per CPT:

Autografts/tissue cultured autografts: Include the harvest and/or application of an autologous skin graft.

Skin substitute grafts: Include non-autologous human skin (e.g., dermal or epidermal, cellular and acellular) grafts (e.g., homograft, allograft), non-human skin substitute grafts (i.e., xenograft), and biological products that form a sheet scaffolding for skin growth.

Please note that all services described in this policy require prior authorization.

- Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.
- Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.
- Providers must submit all required and requested documentation for case evaluation and determination.
- The plan may request additional documentation and information not received and or provided initially related to condition and diagnosis for case evaluation and determination.
- Any additional documentation submitted specifying medical necessity criteria and considered important for case evaluation and determination will be reviewed by Clinical Team utilizing guidelines and regulation criteria.

Medical Necessity Guidelines

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Application of Skin Substitute Grafts for Treatment of DFU and VLU of Lower Extremities

Application of a skin substitute graft for lower extremity DFU and VLU will be covered when the following conditions are met and documented as appropriate for the individual patient:

•Presence of neuropathic diabetic foot ulcer(s) having failed to respond to documented conservative wound-care measures of greater than four weeks.

•Presence of a chronic, non-infected venous stasis ulcer with failure to respond to documented conservative wound-care measures (outlined below) for greater than 4-6 weeks with documented compliance.

•For purposes of this LCD, conservative wound care measures include, but are not limited to:

o Comprehensive patient assessment (history, exam, ABI (Ankle-Brachial Index) & diagnostic test as indicated) and implemented treatment plan.

o For patient with DFU-assessment of type I vs. II Diabetes Mellitus and management history with attention to certain comorbidities (vascular disease, neuropathy, osteomyelitis); review of the current blood sugars/ HgbA1c, diet and nutritional status, activity level, physical exam that includes assessment of skin and wound, ABI (Ankle-Brachial Index), check of off-loading prosthetics or shoes for signs of abnormal wear.

o For patient with VLU- 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.

o Implemented treatment plan as indicated.

a. debridement

b. pressure relief [repositioning schedule, etc. for DFUs/VLUs; prior and on-going compression therapy (e.g., static compression includes compression hosiery (>20 mm HG) and compression bandages) for VLUs

c. infection control

d. management of exudate- maintenance of a moist environment (moist saline gauze, other classic dressings, bioactive dressing, etc.). (For indications of negative pressure wound therapy (NPWT) see DME MAC LCD Negative Pressure Wound Therapy Pumps (L5008))

e. Patient is a nonsmoker, or has refrained from smoking for at least 6 weeks prior to planned skin replacement surgery, or has received counseling on the effects of smoking on surgical outcomes and treatment for smoking cessation.

•Applied to ulcers that have failed to respond to documented conservative wound-care measures. “Failed response” is defined as an ulcer that has increased in size or depth, or 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). Documentation of response requires measurements of the initial ulcer, measurements at the completion of at least four weeks DFU (4-6 weeks for VLU) of conservative wound-care measures and measurements immediately prior to placement of the skin substitute graft. For VLUs, completion of conservative wound-care measures must include 4-6 weeks and on-going compression therapy.

•A skin replacement surgery is considered an advanced treatment modality (not a conservative wound care measure). Pre-service record specifically addresses circumstances as to why the wound has failed to respond to standard wound care treatment of greater than 4 weeks and must reference specific interventions that have failed based on the prior wound evaluation. Such record should include updated medication history, review of pertinent medical problems that may have arisen since the previous wound evaluation, and explanation of the planned skin replacement surgery with choice of skin substitute graft product. The procedure risks and complications should also be reviewed and documented.

Limits or Restrictions

Limitations:

- 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.
- Switching products in a 12-week episode of skin replacement surgery wound care or application of a product beyond 12-weeks is not expected.
- Repeat applications of skin substitute grafts are not considered medically reasonable and necessary when a previous application was unsuccessful. Unsuccessful treatment is defined as increase in size or depth of an ulcer or no change in baseline size or depth and no sign of improvement or indication that improvement is likely (such as granulation, epithelialization, or progress towards closing).
- Application of skin substitute grafts are contraindicated and noncovered in patients with inadequate control of underlying conditions or exacerbating factors, or other contraindication (e.g., uncontrolled diabetes, active infection, active Charcot arthropathy of the ulcer extremity, active vasculitis).
- Application of skin substitute grafts are contraindicated in patients with known hypersensitivity to any component of the specific skin substitute graft (e.g., allergy to bovine).
- Use of surgical preparation services in conjunction with routine, simple and/or repeat application of skin substitute grafts is not reasonable and necessary and will be denied accordingly.
- Most repeat applications of skin replacement materials will not require separate debridement procedures. Such procedures may be subject to pre or post payment medical review. If documentation does not support cross contamination requiring extended cleansing and removal of appreciable amounts of devitalized tissue was performed, the service will be denied.
- Only a reasonable amount of wastage (discarded amount) is covered.
- Though arterial insufficiency ulcers, pressure sores, traumatic wounds, mixed ulcers, and post-surgical wounds are not directly addressed by this LCD, the comprehensive patient assessment and treatment plan requirement would apply to any patient with lower extremity ulcers/chronic wounds.
- The patient must be under the care of a qualified Physician/ NPP for their underlying chronic condition. Skin replacement surgery services must be performed by a qualified physician/NPP within their scope of practice.
- The rare clinical circumstance necessitating switching to a different product must be clearly supported in the medical record and may be subject to pre or post payment medical review. Repeat application of a skin substitute graft within the 12-week episode of skin replacement surgery wound care may be considered upon re-assessment and must be supported in the medical record documentation for that encounter. Repeated application of a skin substitute graft after 12 weeks could result in claim denial(s) and/or initiate a request for records and complex medical review addressing DFU and VLU wound care services.
- It is noted the FDA labeling for most skin substitute grafts include language suggesting frequency of applications. Some products highlight one application needed in an episode of care so no anticipated repeat applications and some products note the need for repeat application at varying intervals in the 12 week episode of skin replacement surgery wound care. Medicare does not expect that every ulcer in every patient will require the maximum number of applications listed on the product label. The expectation is the fewest repeat applications and amount of product to heal the wound.

- Utilization of more than one application of a skin substitute product in the 12-week episode of skin replacement surgery wound care, for all indications, may be subject to pre or post payment medical review (record requested).
- Physician and allied providers demonstrating higher application utilization than peers for similar episodes of care may be subject to prepayment medical review (records requested) or post payment audit.
- The risk versus benefit of the procedure and alternative options for care should be documented as discussed with the patient.
- Documentation of smoking history and that the patient has received counseling on the effects of smoking on surgical outcomes and treatment for smoking cessation (if applicable).
- One would not expect E/M with each procedure (application of skin substitute graft) in an episode of care unless a separately identified service.
- Medicare coverage for wound care on a continuing basis, for a given wound, in a given patient, is contingent upon evidence documented in the patient's medical record that the wound is improving in response to the specific wound care being provided. It is neither reasonable nor medically necessary to continue a given type of wound care if evidence of wound improvement cannot be clearly demonstrated as documented in the medical record.

As published in the CMS IOM Publication 100-08, *Medicare Program Integrity Manual*, Chapter 13, Section 13.5.4, an item or service may be covered by a contractor LCD if it is reasonable and necessary under the Social Security Act Section 1862 (a)(1)(A). Contractors shall determine and describe the circumstances under which the item or service is considered reasonable and necessary.

Reference Information

CMS
First Coast A57680
Billing and Coding: Application of Skin Substitute Grafts for Treatment of DFU and VLU of Lower Extremities
Link: https://www.cms.gov/medicare-coverage-database/view/ncd.aspx
https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=57680&ver=7&bc=0

CMS
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Medicare Coverage Database (MCD)
Link: https://www.cms.gov/medicare-coverage-database/view/ncd.aspx
https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=36377&ver=7&bc=0

Policy History

Date	Version	Comments
12/07/2023	Draft	New Medical Policy
12/15/2023	Final	Approved by Medical Policy Committee