

LCD - Application of Skin Substitute Grafts for Treatment of DFU and VLU of Lower Extremities (L36377)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

Superseded

To see the currently-in-effect version of this document, go to the [Public Versions](#) section.

Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
First Coast Service Options, Inc.	A and B MAC	09101 - MAC A	J - N	Florida
First Coast Service Options, Inc.	A and B MAC	09102 - MAC B	J - N	Florida
First Coast Service Options, Inc.	A and B MAC	09201 - MAC A	J - N	Puerto Rico Virgin Islands
First Coast Service Options, Inc.	A and B MAC	09202 - MAC B	J - N	Puerto Rico
First Coast Service Options, Inc.	A and B MAC	09302 - MAC B	J - N	Virgin Islands

LCD Information

Document Information

LCD ID

L36377

LCD Title

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

Proposed LCD in Comment Period

N/A

Source Proposed LCD

N/A

Original Effective Date

For services performed on or after 10/01/2015

Revision Effective Date

N/A

Revision Ending Date

N/A

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

CPT codes, descriptions and other data only are copyright 2020 American Medical Association. All Rights Reserved. Applicable FARS/HHSARS apply.

Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

Current Dental Terminology © 2020 American Dental Association. All rights reserved.

Copyright © 2013 - 2021, the American Hospital Association, Chicago, Illinois. Reproduced by CMS with permission. No portion of the American Hospital Association (AHA) copyrighted materials contained within this publication may be copied without the express written consent of the AHA. AHA copyrighted materials including the UB-04 codes and descriptions may not be removed, copied, or utilized within any software, product, service, solution or derivative work without the written consent of the AHA. If an entity wishes to utilize any AHA materials, please contact the AHA at 312-893-6816. Making copies or utilizing the content of the UB-04 Manual, including the codes and/or descriptions, for internal purposes, resale and/or to be used in any product or publication; creating any modified or derivative work of the UB-04 Manual and/or codes and descriptions; and/or making any commercial use of UB-04 Manual or any portion thereof, including the codes and/or descriptions, is only authorized with an express license from the American Hospital Association. To license the electronic

Retirement Date

N/A

Notice Period Start Date

N/A

Notice Period End Date

N/A

CMS National Coverage Policy

Language quoted from CMS National Coverage Determination (NCDs) and coverage provisions in interpretive manuals are italicized throughout the Local Coverage Determination (LCD). NCDs and coverage provisions in interpretive manuals are not subject to the LCD Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See §1869(f)(1)(A)(i) of the Social Security Act.

Unless otherwise specified, *italicized* text represents quotation from one or more of the following CMS sources:

CMS Internet-Only Manual (IOM), Pub. 100-04, Medicare Claims Processing Manual, Chapter 17, Section 40.

CMS Internet-Only Manual (IOM), Pub. 100-08, Medicare Program Integrity Manual, Chapter 13, Section 13.1.3

Title XVIII of the Social Security Act, 1862(a)(1)(A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.

Title XVIII of the Social Security Act, Section 1833(e) states that no payment shall be made to any provider for any claim that lacks the necessary information to process the claim.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

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 (ie, 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 (eg, homograft, allograft), non-human skin substitute grafts (ie, 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 (eg, 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 (CPT codes 15271-15278) 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.

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.

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 (ie, xenograft), and biological products that form a sheet scaffolding for skin growth.

Indications:

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.

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. (see utilization guidelines)
- Switching products in a 12-week episode of skin replacement surgery wound care or application of a product beyond 12-weeks is not expected. (see utilization guidelines)
- 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).
- Per CPT definition, injected skin substitutes are not used with skin replacement surgery application codes and will be denied. Such products are bundled into other standard management procedures if medically necessary and not separately payable.
- Use of surgical preparation services (CPT codes 15002, 15003, 15004, and 15005) 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.
- Removal of current graft and/or simple cleansing of wound is included in the skin replacement surgery application codes. Active wound care management (CPT code 97602) procedures should never be reported.
- Application procedure and associated supply must be coded correctly. The units of service must be reported correctly. The units of service billed for the supply must be accounted for in the medical record (i.e., amount

used, amount discarded and reason for the discarded amount). 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. Diagnosis coding to avoid the applications of this policy is abuse.

- 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.

Summary of Evidence

Analysis of Evidence (Rationale for Determination)

Coding Information

Bill Type Codes

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the article does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the article should be assumed to apply equally to all claims.

CODE	DESCRIPTION
013x	Hospital Outpatient
018x	Hospital - Swing Beds
022x	Skilled Nursing - Inpatient (Medicare Part B only)
083x	Ambulatory Surgery Center
085x	Critical Access Hospital

Revenue Codes

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the article, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the article should be assumed to apply equally to all Revenue Codes.

N/A

CPT/HCPCS Codes

Group 1 Paragraph:

Note: An Advance Beneficiary Notice of Noncoverage (ABN) is required for items and services not covered by Medicare due to being considered not medically reasonable and necessary. The beneficiary should be thoroughly educated about the benefits and risks of this item or service. *If such notice is not given providers may not shift*

financial liability for such items or services to beneficiaries should a claim for such items or services be denied by Medicare.

Group 1 Codes:

CODE	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)
C5271	APPLICATION OF LOW COST 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

CODE	DESCRIPTION
C5272	APPLICATION OF LOW COST 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)
C5273	APPLICATION OF LOW COST 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
C5274	APPLICATION OF LOW COST 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)
C5275	APPLICATION OF LOW COST 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
C5276	APPLICATION OF LOW COST 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)
C5277	APPLICATION OF LOW COST 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
C5278	APPLICATION OF LOW COST 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)

ICD-10-CM Codes that Support Medical Necessity

Group 1 Paragraph:

N/A

Group 1 Codes:

CODE	DESCRIPTION
XX000	Not Applicable

ICD-10-CM Codes that DO NOT Support Medical Necessity

N/A

Additional ICD-10 Information

N/A

General Information

Associated Information

Documentation Requirements

Medical record documentation maintained by the treating provider must substantiate the medical necessity of the services being billed. In addition, documentation that the service was performed must be included in the patient's medical record. This information is normally found in the history and physical, office/progress notes, hospital notes, and/or procedure report.

The medical record must clearly show that the criteria listed under the "Indications and Limitations of Coverage and/or Medical Necessity" sections have been met, as well as, the appropriate diagnosis and response to treatment. Description of the wound(s) must be documented at baseline (prior to beginning conservative wound care measures) relative to size, location, stage, duration, and presence of infection, in addition to the type of treatment given and response. This information must be updated in the medical record throughout the episode of skin replacement surgery wound care. Wound description must also be documented pre- and post- treatment with the skin substitute graft being used. If obvious signs of worsening or lack of treatment response is noted, continuing treatment with the skin substitute graft would not be considered medically reasonable and necessary. The reason(s) for any continued application should be specifically addressed in the medical record, though it may not be a covered service.

Documentation should include an assessment (generally in an E/M service) outlining the plan for skin replacement surgery and the choice of skin substitute product for the 12 week period as well as any anticipated repeat applications in the 12 week period. Some products highlight one application needed in an episode of care, so no anticipated repeat applications and some products note the need for repeat applications at varying intervals in the 12 week episode of care. The risk versus benefit of the procedure and alternative options for care should be documented as discussed with the patient. An operative note must support the procedure (e.g. application of skin substitute graft to legs) for the relevant date of service (first application starts the 12 week episode of care). At a minimum the operative note(s) should include pre and post op diagnosis, name of surgeon, anesthesia, reason for the procedure, complete description of the procedure including product used (with identifying package label in the chart), and relevant findings.

The rare exceptions to indications/limitations outlined in this policy should be addressed and supported in the medical record for the given patient. The clinical judgement of the treating physician is always a consideration if

clearly addressed in the pre procedure record and if consistent with the episode of care for the patient as documented in patient record(s) and claim history.

One would not expect E/M with each procedure (application of skin substitute graft) in an episode of care unless a separately identified service.

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).

Any amount of wasted skin substitute must be clearly documented in the procedure note with the following minimum information: Date, time and location of ulcer(s) treated; Name of skin substitute and how product supplied; Approximate amount of product unit used; Approximate amount of product unit discarded; Reason for the wastage; Manufacturer's serial/lot/batch or other unit identification number of graft material. When manufacturer does not supply unit identification, record must document such.

Utilization Guidelines

It is the expectation that only one 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 FDA assessments and assuming there is one related wound. 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.

Documentation requirements include addressing how product supplied, any wastage, etc. The HCPCS code of the applicable skin substitute and the units billed must be consistent with medical record in regard to wound description and size.

Sources of Information and Basis for Decision

Agency for Healthcare Research and Quality. (2012). Technology assessment: Skin substitutes for treating chronic wounds. Final report December 18, 2012.

Alguire, PC, Mathes, BM. Clinical manifestations of lower extremity chronic venous disease. In: UpToDate, Collins, KA (Ed), UpToDate, Waltham, MA. (Accessed on June 2015.)

Alguire, PC, Mathes, BM. Medical management of lower extremity chronic venous disease. In: UpToDate, Collins, KA (Ed), UpToDate, Waltham, MA. (Accessed on June 2015.)

American Medical Association. (2014). *Current Procedural Terminology (CPT®) Fourth Edition*

Armstrong, DG, Meyr, AJ. Basic principles of wound management. In: UpToDate, Collins, KA (Ed), UpToDate, Waltham, MA. (Accessed on June 2015.)

De Asla, RJ, McCullouch, DK. Management of diabetic foot lesions. In: UpToDate, Collins, KA (Ed), UpToDate, Waltham, MA. (Accessed on June 2015.)

Greer, N., Foman, N., MacDonald, R., Dorrian, J., Fitzgerald, P., Rutks, I., and Wilt, T. (2013). Advanced wound care therapies for nonhealing diabetic, venous, and arterial ulcers. *Annals of Internal Medicine*, 159(8), 532-542.

LCDs and policies from other Medicare contractors and private insurers

Nathoo, R., Howe, N., Cohen, G., (2014). Skin substitutes An overview of the key players in wound management. *J Clin Aesthet Dermatol*, 7(10), 44-48

National Guideline Clearinghouse. (2010). Association for the Advancement of Wound Care (AAWC) venous ulcer guideline. *Agency for Healthcare Research and Quality*. Retrieved from <http://www.guideline.gov/content.aspx?id=36081&search=wound+care>

National Guideline Clearinghouse. (2010). Management of chronic venous leg ulcers: A national clinical guideline. *Agency for Healthcare Research and Quality*. Retrieved from <http://www.guideline.gov/content.aspx?id=24126&search=wound+care>

O'Donnell, T.F., Passman, M.A., Marston, W.A., Ennis, W.J., Dalsing, M., Kistner, R.L., et al. (2014). Management of venous leg ulcers: Clinical practice guidelines of the Society for Vascular Surgery® and the American Venous Forum. *Society for Vascular Surgery*, doi:10.1016/j.jvs.2014.04.049

Revision History Information

N/A

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Articles

[A55813 - Response to Comments: Application of Skin Substitute Grafts for Treatment of DFU and VLU of Lower](#)

Related National Coverage Documents

N/A

Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS
11/21/2019	01/08/2019 - N/A	Currently in Effect
08/12/2015	10/01/2015 - N/A	Superseded (This Version)

Keywords

N/A