First Coast Service Options (FCSO) Medicare Policy Primer

Medicare Jurisdiction (JN)
Florida, Puerto Rico and U.S. Virgin Islands
Application of Skin Substitute Grafts for the treatment of DFU and VLU of Lower Extremities—#L36377

Indications

- 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:
  1. Comprehensive patient assessment (history, exam, ABI (Ankle-Brachial Index) & diagnostic test as indicated) and implemented treatment plan.
  2. **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.
  3. **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.
  4. Implemented treatment plan as indicated.

- 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.

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).
- 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.
- 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.
- 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.

- 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 pre-payment medical review (records requested) or post-payment audit.

Documentation

- **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 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.

Coding

HCPCS Codes:

- **Q4101:** Apligraf, per square centimeter
- **Q4106:** Dermagraft, per square centimeter
- **Q4172:** PuraPly, PuraPly Antimicrobial per square centimeter
- **Q4159:** Affinity, per square centimeter
- **Q4160:** NuShield, per square centimeter

JW Modifier:

Effective January 1, 2017 in Physician Office Setting, Place of service 11: Claims for discarded drug or biological amount not administered to any patient, shall be submitted using the JW modifier. This modifier, billed on a separate line, will provide payment for the amount of discarded drug or biological. Providers must document the discarded drugs or biologicals in patient's medical record.

CPT Codes:

Application Codes for Leg, Arm or Trunk:

- **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
- **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 (List separately in addition to code for primary procedure)

Application Codes for Foot, face, scalp, etc.:

- **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

- **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 (List separately in addition to code for primary procedure)

FCSO Medicare Sample Model Documentation

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Pre-Treatment

1. Duration of ulcer: _____ weeks
2. Exact location of ulcer
3. Describe adequate treatment of the underlying disease process contributing to the ulcer
4. Diagnosis of patient
5. Implement 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.

Treatment

6. Document measurement of ulcer (width and length or circumference and depth) immediately prior to application of the skin substitute _____ sq cm
7. Document whether this is an initial application of skin substitute or a reapplication.
8. For skin substitute reapplications, document that applications have been successful (e.g. decrease in size or depth, increase in granulation tissue).
9. Document the wound dressing changes and the standard conservative measures accompanying the wound treatment with the skin substitute.
10. Document how the wound site was prepared, and how the skin substitute was fixated on the wound.

11. Document 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.

12. 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).

13. Product Wastage Documentation Requirements:

- Date and time
- Location of ulcer
- Approximate amount of product unit used
- Approximate amount of product unit discarded
- Reason for the wastage
- Manufacture's serial/lot/batch number

Modifiers

JW: Skin substitute not applied to wound, wastage