

Medicare Coverage Guidelines for the Application of Skin Substitute Grafts for Treatment of DFU and VLU of Lower Extremities:

First Coast Service Options Local Coverage Determination¹

Jurisdiction: JN: FL, Puerto Rico, Virgin Islands | **LCD Number:** L36377 | **Effective Date:** 10/01/2015

LCD Guidelines:

- All products with FDA clearance/approval, or designated 361 HCT/P exemption, used in accordance with that product's individualized application guidelines, will be equally considered for coverage and may be considered reasonable and necessary.
 - ▶ This LCD does not endorse particular products for separate payment. As a result, 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.
- Application of skin substitute grafts for indications, other than for diabetic foot ulcers (DFUs) or venous leg ulcers (VLUs), are not addressed in this LCD.
 - ▶ 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.
- Skin substitutes may be appropriate for chronic wounds (i.e. wounds that have not responded to standard wound care treatments for a period of 30 days).
- Patients receiving a skin substitute graft must be under the care of a qualified Physician or non-physician practitioner (NPP) licensed by the state with full scope of practice for the treatment of the underlying chronic condition. This concurrent medical management and the identity of the managing medical physician shall be clearly discernable in the medical record and available upon request.



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 DFUs 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 for greater than 4-6 weeks with documented compliance. Conservative wound care measures are described in the LCD.
- Documentation in the pre-service record, specifically addressing circumstances as to why the wound has failed to respond to standard wound care treatment of greater than four weeks, and must reference specific interventions that have failed.
- "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 for 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.
- 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.

Limitations/Restrictions on Coverage:

- 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 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 by documentation in the medical record 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.
 - ▶ 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).
- 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).
- 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.
- 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.
- 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.
- Skin replacement surgery services must be performed by a qualified physician/NPP within their scope of practice.

Coding Guidance:

- 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.
- 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.



For other coding questions related to ACell products please contact ACell's Reimbursement Support Center at **800-826-2926, x 7, Monday-Friday 9:00 am - 5:00pm Eastern or by e-mail at reimbursement@acell.com**. ACell's Reimbursement Support Center is dedicated to providing answers to all of your reimbursement questions. It also serves as a resource for obtaining accurate billing information and reimbursement support for ACell's wound and burn products.

***Please Note:** The decision of how to complete a reimbursement claim form, including codes and amounts to bill, is exclusively the responsibility of the QHPs and other providers. Coding requirements are subject to change at any time; please check with your local payer regularly for updates. The information contained in this flashcard is a summary of the information in the LCD. Please review the complete LCD for additional information and to ensure proper documentation requirements for claim submission are met.

1. Centers for Medicare and Medicaid Services. Local Coverage Determination (LCD): Application of Skin Substitute Grafts for Treatment of DFU and VLU of Lower Extremities (L36377). <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36377&ver=2>. Effective October 1, 2015.

