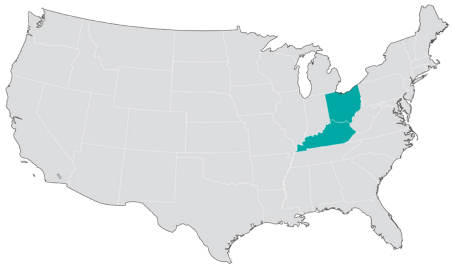
Medicare Coverage Guidelines for the Wound Application of Cellular and/or Tissue-Based Products (CTPs), Lower Extremities:

CGS Local Coverage Determination[1]

Jurisdiction: J15: KY, OH | **LCD Number:** L36690 | **Effective Date:** 10/01/2018

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.
- Patients receiving skin replacement surgery with a skin substitute graft must be under the care of a physician or non-physician practitioner licensed by the state with full scope of practice for the treatment of the systemic disease process(es) etiologic for the condition (e.g. venous insufficiency, diabetes, neuropathy).
- Reimbursement may be made only when the medical record clearly documents that these products have been used in a comprehensive, organized wound management program.
- It is expected that the wounds response to treatment will be documented in the medical record at least once every 30 days for each episode of wound treatment. Documentation of a non-healing wound and a comprehensive treatment plan, before application of a skin substitute product, is also required.
    - A wound that fails to show evidence of healing by reduction in overall size and advancement of epithelial margins following four weeks of optimization, including all aspects of standard therapy, is considered a chronic, non-healing wound.
    - Documentation of response requires measurements of the initial ulcer, measurements at the completion of at least four weeks of appropriate wound care, and measurements immediately prior to placement, and with each subsequent placement, of the bioengineered skin substitute or CTP.
    - Examples of "failed response" to standard wound treatment appear in the LCD.

Indications:

Application of a skin substitute graft for lower extremity chronic wounds (diabetic foot ulcer and venous leg ulcer) will be covered when the following conditions are met for the individual patient:

- Presence of a chronic, non-healing wound (i.e. has not responded to standard wound treatment) for at least a 30-day period.
- Presence of neuropathic ulcers and diabetic foot ulcer(s) having failed to respond to documented conservative wound care measures of greater than four weeks, during which the patient is compliant with recommendations, and without evidence of underlying osteomyelitis or nidus of infection.
- Presence of a venous stasis ulcer for at least three months, but unresponsive to appropriate wound care for at least 30 days with documented compliance.
- Presence of a 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 four weeks or longer.
- Ulcers or wounds with a failed response to standard wound care that are:
    - Partial- or full-thickness ulcers, not involving tendon, muscle, joint capsule, or exhibiting exposed bone or sinus tracts, with a clean granular base unless the CTP package label indicates the CTP is approved for use involving tendon, muscle, joint capsule, or exhibiting exposed bone or sinus tracts, with a clean granular base;
    - Skin deficit at least 1.0 cm^2 in size;
    - Clean and free of necrotic debris or exudate;
    - 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 0.60, toe pressure > 30 mm Hg);
    - For diabetic foot ulcers, the patient's medical record reflects a diagnosis of Type 1 or Type 2 Diabetes and also reflects medical management for this condition.

Limitations/Restrictions on Coverage:

- Ideally, patients who have smoked will have ceased smoking or have refrained from systemic tobacco intake for at least four weeks during conservative wound care and prior to planned bioengineered skin replacement therapy.
- In all wound management, the ulcer must be free of infection and underlying osteomyelitis with documentation of the conditions that have been treated and resolved prior to the institution of skin substitute therapy. Appropriate wound management therapy is described in the LCD.
- 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 overgrafting.

Coding Guidance:

HCPCS listed in the LCD are FDA approved and meet necessary regulatory requirements for CTPs for chronic ulcer treatment as of publication and include:

- **Q4118** - MicroMatrix®, 1 mg
- **Q4166** - Cytal® Wound Matrix, per cm^2

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

- One specific skin substitute graft per wound, per treatment will be allowed for wound care in compliance with FDA guidelines for that specific product, not to exceed ten applications or treatments.
- Treatment of any chronic skin wound will typically last no more than twelve weeks.
- Repeat or alternative applications of skin substitute grafts are not considered medically reasonable and necessary when a previous full course of applications was unsuccessful.
    - Unsuccessful treatment is defined as an 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) for a period of four weeks past start of therapy.
- Re-treatment of healed ulcers, those showing greater than 75% size reduction and smaller than 0.5 cm^2.
- Skin substitute grafts are contraindicated and not considered reasonable and necessary in patients with inadequate control of underlying conditions or exacerbating factors (e.g. uncontrolled diabetes, active infection, or active Charcot arthropathy of the ulcer extremity, vasculitis or continued tobacco use where no documented counseling on the effects of smoking on surgical outcomes and the success of the application of skin grafts is available.)
- 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).
- Re-treatment within one 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.
- If the provider performing the CTP graft/application is not the one providing treatment for the patient's systemic condition, then a statement in the documentation that (s)he is aware of the systemic condition and that the patient is under the care of the treating provider is required. This concurrent medical management and the identity of the managing medical physician shall be clearly discernable in the medical record and available upon request.
- Medicare coverage for wound care on a continuing basis, for a single wound in an individual patient, is contingent upon evidence documented in the patient's medical record that the wound is improving in response to the wound care being provided. Since it is neither reasonable nor medically necessary to continue a given type of wound care in the absence of wound improvement, it is expected that the wounds response to treatment will be documented in the medical record at least once every 30 days for each episode of wound treatment and made available to the contractor upon request.

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 - 5:00 pm 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): Wound Application of Cellular and/or Tissue Based Products (CTPs), Lower Extremities (L36690). https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36690&ver=16&CntrctrSelected=228*2&Cntrctr=228&DocType=Active&DocStatus=Active&s=22&bc=AggAAAQBAAAA&. Revised October 1, 2018.

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