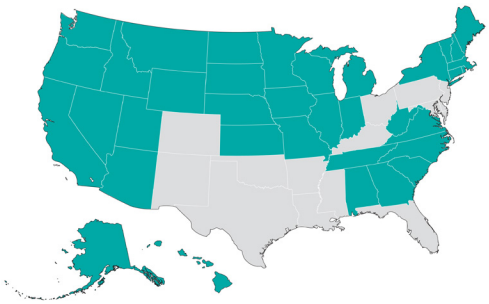
Summary Documentation Criteria for use of Cellular and/or Tissue-Based Products (CTPs) in Chronic Wounds for Medicare Patients*

Jurisdictions:
National Government Services JK: CT, NY, ME, MA, NH, RI, VT
National Government Services J6: IL, MN, WI
Noridian JE: CA, HI, NV, America Samoa, Guam, Northern Mariana Islands
Noridian JF: AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
Palmetto GBA JJ: AL, GA, TN
Palmetto GBA JM: NC, SC, VA, WV
Wisconsin Physician Services J5: IA, KS, MO, NE
Wisconsin Physician Services J8: IN, MI



These Medicare Administrative Contractors (MACs) do not have Local Coverage Decisions (LCDs) specific to the use of Bioengineered Skin Substitutes/Cellular Tissue Products. In the absence of a policy, physicians should use their discretion in treating patients, documenting the treatment rationale, and medical necessity of treatment per the product labeling in the patient medical record. The MACs reserve the right to review claims and request documentation if there are questions related to treatment or product use. The absence of an LCD is not a guarantee of coverage or payment. All coding and billing rules apply.

Definitions of CTPs/skin substitute grafts per CPT/Procedure Code:

- 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; the graft is anchored using the physician's choice of fixation.
- Non-graft CTPs (e.g. gels, ointments, powders, particles, foams, liquids, injectable products) are considered wound dressings and are not to be reported with skin substitute graft procedure codes.
  - Other wound care services, debridement, or Evaluation and Management services may be reported if appropriate and documented in the patient record.

Documentation of conservative wound care measures and of a failed response to conservative care must be detailed in the patient record; this may include but is not limited to the following:

- Comprehensive patient assessment (history, exam, Ankle-Brachial Index (ABI), diagnostic test as indicated) and implemented treatment plan.
- For a patient with a diabetic foot ulcer (DFU), assessment of Type 1 vs. 2 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, check of off-loading prosthetics or shoes for signs of abnormal wear.
- For a patient with a venous stasis ulcer, assessment of history (prior ulcers, thrombosis risks), physical exam (edema, skin changes), ABI, and duplex scan to confirm Clinical-Etiology-Anatomy-Pathophysiology (CEAP) classification. 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.
- Implemented treatment plan as indicated, for example:
  - Debridement;
  - Pressure relief (repositioning schedule, etc.) for DFUs/venous leg ulcers (VLUs); prior and on-going;
  - Compression therapy (e.g. static compression includes compression hosiery (>20 mm HG) and compression bandages) for VLUs;
  - Infection control;
  - Management of exudate, or maintenance of a moist environment (moist saline gauze, other hydrcoloid or film dressings, bioactive dressing, etc.);
  - Patient is a nonsmoker, has refrained from smoking for at least six weeks prior to skin replacement surgery, or has received counseling on the effects of smoking on surgical outcomes and treatment for smoking cessation.

- Use of standard treatment of lower extremity ulcers (e.g. DFUs or VLUs):
  - Mechanical offloading;
  - Infection control;
  - Mechanical compression;
  - Limb elevation;
  - Debridement of necrotic tissue;
  - Management of systemic disease;
  - Counseling on the risk of continued tobacco use.
- Applied to ulcers that have failed to respond to documented conservative wound care measure:
  - "Failed response" is an ulcer that has increased in size or depth, or has 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.
  - Pre-service record specifically addresses 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 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;
    - 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.

Information for patient record documentation and demonstration of medical necessity for application of a CTP for lower extremity (DFU and/or VLU):

- 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 VLU with failure to respond to documented conservative wound care measures (outlined below) for greater than 4-6 weeks with documented compliance.
- Demonstration that only one specific CTP/skin substitute graft product is allowed for an episode of skin replacement wound care, which most payers estimate will not exceed 12 weeks or may be less depending upon the product labeling.
- Evidence of wound improvement must be clearly demonstrated in the medical record as medically necessary to continue a given type of wound care throughout the 12-week period.
- Switching products within a 12-week episode of skin replacement surgery is not anticipated and if necessary, must be documented/authorized based on payer requirements.
- Patient condition is not contraindicated for treatment.
- Units of service and product must be documented and subsequently coded 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; many payers do not pay wastage or only a small/reasonable amount of wastage (discarded amount) is allowed).

ACell's Reimbursement Support Center is dedicated to providing answers to all of your reimbursement questions. Services available for all ACell products include benefit verification, prior authorizations, claim appeals, and general coding and billing questions. Contact ACell's Reimbursement Support Center by phone at **800-826-2926, x 7** (Monday-Friday 8:30am - 6:00pm EST) or by e-mail at **acell@thepinnaclehealthgroup.com**.

***Please note:** Documentation must reflect services performed. This information is shared for educational purposes only. While ACell believes this information to be correct, information is subject to change without notice.

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.

Treatment of other wounds (arterial insufficiency ulcers, pressure sores, traumatic wounds, mixed ulcers, and post-surgical wounds) should follow similar guidelines for documentation as DFUs and VLUs.

Adapted from Medicare Administrative Contractor (MAC) Local Coverage Decisions www.cms.gov Novitas Solutions LCD L35041 (services after 09/13/2018) First Coast Service Options LCD L36377 (services after 10/01/2015)

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