



- 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).



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](mailto: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:** 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](http://www.cms.gov) Novitas Solutions LCD L35041 (services after 09/13/2018) First Coast Service Options LCD L36377 (services after 10/01/2015)