# Provider Treatment and Documentation Guide

## Criteria for treatment with Skin Sub

- **Diabetic Foot Ulcer**
  - Failed ***Conservative Care*** for 30 days prior to treatment
    - Medical records show that the wound has failed to respond to ***Conservative Care*** and documents what treatments have been tried and failed. ie. Wound is not improving after 30 days of conservative care
    - ***Conservative Care*** includes the following but is not limited to:
      - Control of swelling (edema)
      - Local high blood pressure in the veins (venous hypertension), or type of swelling from blood fluids (lymphedema)
      - Control of infection including infection of the bone (osteomyelitis) and skin (cellulitis)
      - Removal of foreign body or cancer if present
      - Surgery to clean foreign material and dead tissue out of the wound (debridement)
      - Appropriate non-weight bearing or off-loading of pressure
  - Adequate blood flow
  - Controlled diabetes
  - Wound does not involve tendon, muscle, or joint capsule or exposed bone or sinus tracts
  - Wound is at least 1.0 cm2 in size
  - The skin substitute product has been cleared for this use by the FDA (check IFU)
  - No active infection present

- **Venous Leg Ulcer**
  - Presence of a venous stasis ulcer for at least 90 days prior to skin sub treatment
  - Failed ***Conservative Care*** for 30 days prior to treatment
    - Medical records show that the wound has failed to respond to ***Conservative Care*** and documents what treatments have been tried and failed. ie. Wound is not improving after 30 days of conservative care
    - ***Conservative Care*** includes the following but is not limited to:
      - Control of swelling (edema)
      - Local high blood pressure in the veins (venous hypertension), or type of swelling from blood fluids (lymphedema)
      - Control of infection including infection of the bone (osteomyelitis) and skin (cellulitis)
      - Removal of foreign body or cancer if present
      - Surgery to clean foreign material and dead tissue out of the wound (debridement)
      - Compression therapy and limb elevation

    - Adequate blood flow
    - Wound does not involve tendon, muscle, or joint capsule or exposed bone or sinus tracts
    - Wound is at least 1.0 cm2 in size
    - The skin substitute product has been cleared for this use by the FDA (check IFU)
    - No active infection present

- **All Other Wounds**
    - Failed ***Conservative Care*** for 30 days prior to treatment
    - Wound does not involve tendon, muscle, or joint capsule or exposed bone or sinus tracts
    - Wound is at least 1.0 cm2 in size
    - The skin substitute product has been cleared for this use by the FDA (check IFU)
    - No active infection present
    - While there are no other specific criteria guidelines for other wounds, we would recommend applying all relevant qualifying criteria from DFU and VLU guidelines above

## Documentation Requirements for Skin Substitute

- Date, time and location of ulcer treated
- Name of skin substitute
- Amount of product units used
- Amount of product units 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
- Pictures (NOT REQUIRED BUT HIGHLY RECOMMENDED)
    - Pre debridement (with measurements)
    - Post debridement (with measurements)
    - Post graft application (with measurements)

## Skin Substitute Treatment Limitations

- Treatment will not exceed 10 applications and will not last longer than 12 weeks from the start of treatment (exceptions exist)
- Re-treatment of any given course of skin substitute for venous stasis ulcer or diabetic (neuropathic) foot ulcer does not occur within one year, as it is considered treatment failure.
- Use of more than one skin substitute product at a time for the same wound is not permitted.
- Continued use of the same or alternate skin substitute for wounds that have no improvement in size or depth, after four weeks from the start of therapy is not permitted.

Novitas or FCSO policies are referenced as a standard since the criteria in those LCDs are very comprehensive and apply to nearly all scenarios when using skins subs for DFU or for VLU conditions. It's important to read through the ENTIRE LCD including the article link as the criteria points are what need to be documented for all skin subs.

These are the 3 available MAC policies, and all have very similar if not identical criteria for use:

1. **FCSO LCD**: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=36377
2. **NOVITAS LCD**: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=35041&ver=113&articleId=57023&name=331*1&UpdatePeriod=852&bc=AAAAEAAAAAAA&
3. **CGS** LCD - Wound Application of Cellularand/or Tissue Based Products (CTPs), Lower Extremities (L36690) (cms.gov)
4. **Palmetto, Noridian, NGS, WPS do NOT have LCD Guidelines. Reference Novitas or FCSO**