Medicare covers application of skin substitutes to Ulcers or Wounds with **Failed Response** 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;
- Skin deficit at least 1.0 square centimeter (cm) 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 greater than 30 millimeters of mercury [mmHg]);
- 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.

Wound healing is impaired by the systemic use of tobacco. Therefore, ideally patients who have smoked will have ceased smoking or have refrained from systemic tobacco intake for at least 4 weeks during conservative wound care and prior to planned bioengineered skin replacement therapy.

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 4 weeks and must reference specific interventions that have failed. Such record should include updated medication history, review of pertinent medical problems that may have occurred since the previous wound evaluation, and 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. Documentation of smoking cessation counseling and cessation measures prescribed, if applicable, must also be documented in the patient's record.

Application of a skin substitute graft for lower extremity chronic wound (DFU and VLU) will be covered when the following conditions are met for the individual patient:

- Presence of neuropathic 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 3 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 4 weeks or longer.

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. For purposes of this LCD, appropriate therapy includes, but is not limited to:

- Control of edema, venous hypertension or lymphedema
- Control of any nidus of infection or colonization with bacterial or fungal elements
- Elimination of underlying cellulitis, osteomyelitis, foreign body, or malignant process
- Appropriate debridement of necrotic tissue or foreign body (exposed bone or tendon)
- For diabetic foot ulcers, appropriate non-weight bearing or off-loading pressure
- For venous stasis ulcers, compression therapy provided with documented diligent use of multilayer dressings, compression stockings of greater than 20 mmHg pressure, or pneumatic compression
- Provision of wound environment to promote healing (protection from trauma and contaminants, elimination of inciting or aggravating processes)

Limitations

The following are considered not reasonable and necessary and therefore will be denied:

Due to the propensity for misuse of skin substitute and biological dressing products, reimbursement may be made only when the medical record clearly documents that these products have been used in a comprehensive, organized wound management program. **All listed products, unless they are specifically FDA-labeled or cleared for use in the types of wounds being treated, will be considered to be biologic dressings and part of the relevant Evaluation and Management (E/M) service provided and not separately reimbursed.**

- 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.
- Skin substitute grafts will be allowed for the episode of wound care in compliance with FDA guidelines for the specific product (see utilization guidelines) not to exceed 10 applications or treatments. In situations where more than one specific product is used, it is expected that the number of applications or treatments will still not exceed 10.
- Simultaneous use of more than one product for the episode of wound is not covered. Product change within the episode of wound is allowed, not to exceed the 10 application limit per wound per 12 week period of care.
- Treatment of any chronic skin wound will typically last no more than twelve (12) 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 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 4 weeks past start of therapy.

- Retreatment of healed ulcers, those showing greater than 75% size reduction and smaller than 0.5 square cm, is not considered medically reasonable and necessary.
- Skin substitute grafts are contraindicated and are not considered reasonable and necessary in patients with inadequate control of underlying conditions or exacerbating factors (e.g., uncontrolled diabetes, active infection, and active Charcot arthropathy of the ulcer extremity, vasculitis or continued tobacco smoking without physician attempt to affect smoking cessation).
- 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).
- Repeat use of surgical preparation services in conjunction with skin substitute application codes will be considered not reasonable and necessary. It is expected that each wound will require the use of appropriate wound preparation code at least once at initiation of care prior to placement of the skin substitute graft.
- Re-treatment within one (1) 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.

Documentation Requirements

1. All documentation must be maintained in the patient's medical record and made available to the contractor upon request.
2. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service[s]). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.
3. Medical record documentation must support the medical necessity of the services as stated in this policy.
4. The documentation must support that the service was performed and must be included in the patient's medical record. This information is normally found in the history and physical, office/progress notes, hospital notes, and/or procedure report.
5. The medical record must clearly show that the criteria listed under the Covered Indications and Limitations sections have been met, as well as, the appropriate diagnosis and response to treatment.
6. The documentation must support the need for skin substitute application and the product used.
7. A description of the wound(s) must be documented at baseline (prior to beginning conservative treatment) relative to size, location, stage, duration, and presence of infection, in addition to type of treatment given and response.
    - This information must be updated in the medical record throughout treatment.

- Wound description must also be documented pre and post treatment with the skin substitute graft being used.
- If obvious signs of worsening or lack of treatment response is noted, continuing treatment with the skin substitute would not be considered medically reasonable and necessary without documentation of a reasonable rationale for doing so.

8. Documentation of smoking history, and that the patient has received counseling on the effects of smoking on surgical outcomes and treatment for smoking cessation (if applicable) as well as outcome of counselling must be in the medical record.
9. The amount of utilized and wasted skin substitute must be clearly documented in the procedure note with the following minimum information:

    - Date, time and location of ulcer treated;
    - Name of skin substitute and how product supplied;
    - Amount of product unit used;
    - 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.

Note: Novitas expects that where multiple sizes of a specific product are available, the size that best fits the wound with the least amount of wastage will be utilized. Please refer to article A54117 for coding/billing instructions regarding drug wastage.