WOUND CARE GUIDELINES

1

Patients with wounds need to be under the care of a licensed physician, with full scope of practice to address the underlying systemic disease process(es) of the condition (e.g., venous insufficiency, diabetes, neuropathy).

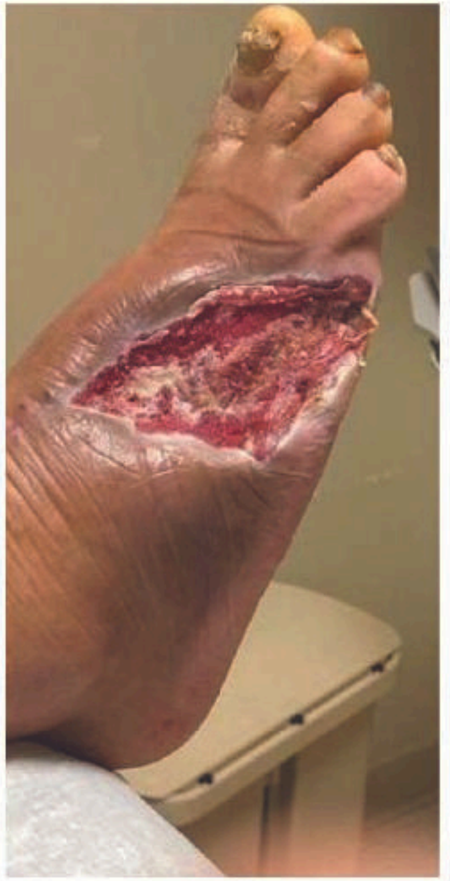
In the medical record, it's important that it be easy to distinguish between concurrently administered medical treatments and the responsible physician for each. Additionally, this information should be available upon request.

2 The following conditions must be met:

a. Diabetic neuropathic ulcers that have not responded for more than 4 weeks to documented conservative wound care, with patient compliance during that time and no evidence of underlying osteomyelitis or infection nidus.

b. For venous stasis ulcers, they should be present for 3 months but not respond to appropriate wound care for at least 30 days, with documented compliance.

c. Presence of a full-thickness skin loss ulcer resulting from an abscess, injury, or trauma that has not responded to proper control of infection, foreign body removal, tumor resection, or other pathological process for a period of 4 weeks or more.



Pre-application

3 Possible causes for delayed wound healing and treatment modifications should be noted when indicated.

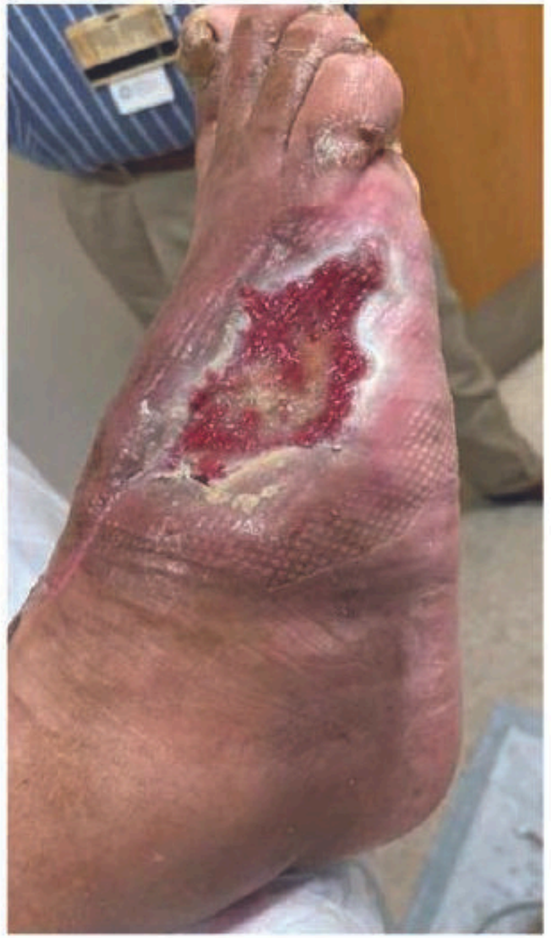
a. Wound assessments may require comprehensive medical evaluation, medication list, vascular assessment, orthopedic evaluations, functional assessment, metabolic/nutritional evaluation, and care plan.

b. Pressure reduction and/or infection control have been shown to facilitate healing and may reduce the need for repeated debridement services.

c. An additional example might be noting for a diabetic patient the recommendation to receive comprehensive diabetes care, including nutritional counseling and education, as well as seeking other care to help maintain their A1C and a healthy lifestyle.

d. Explain to the patient the risks and complications.

e. Provide an explanation and medical necessity for the graft to be used.



21 Day Reveal

4 **Has the wound not improved after 30 days?**

a. Has it increased in size or depth? or

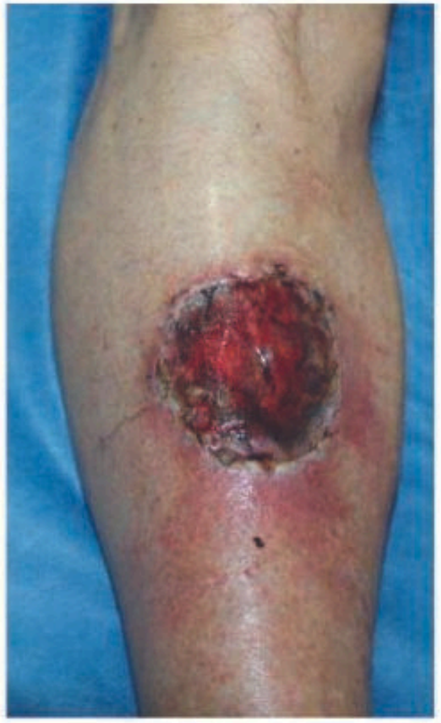
b. Is there any change from the initial size or depth? or

Is there any sign of improvement or indication that it is likely to improve?

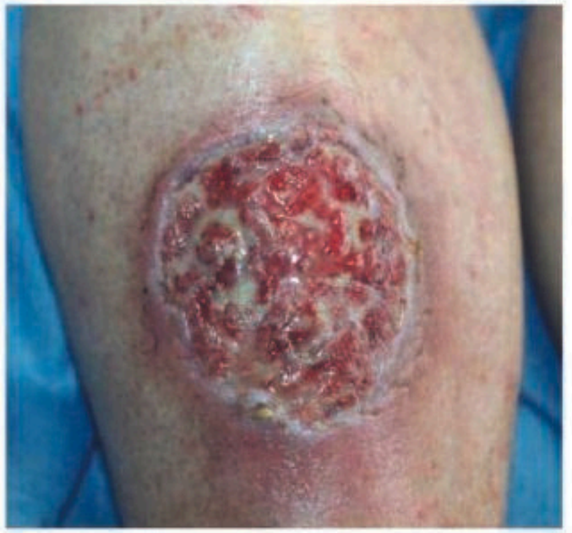
i. Such as granulation, epithelialization, or progress toward closure.

5 **Note any complicating circumstances supporting additional wound care.**

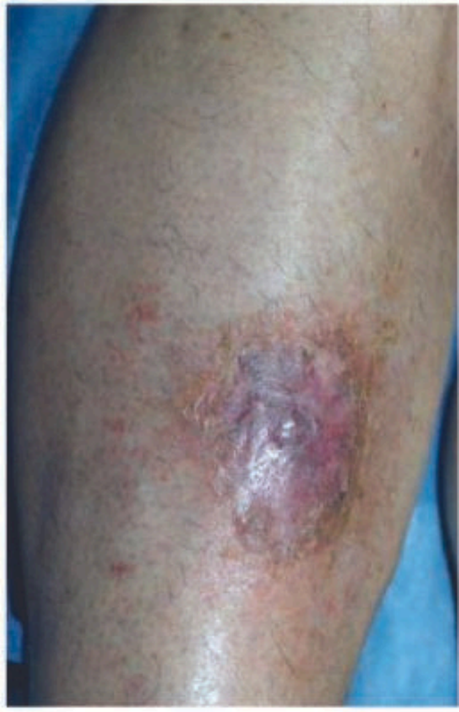
6 **If infection is present, identify, treat, and confirm that the patient is infection-free before starting or continuing treatment.**



Pre-application



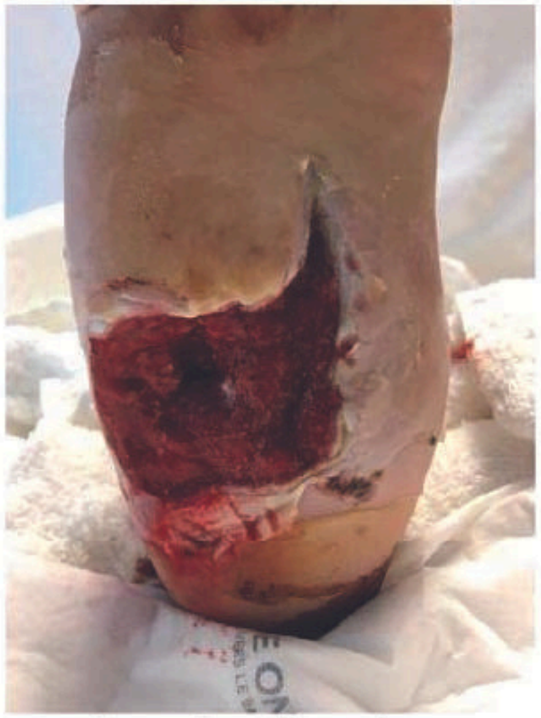
21 Day Reveal



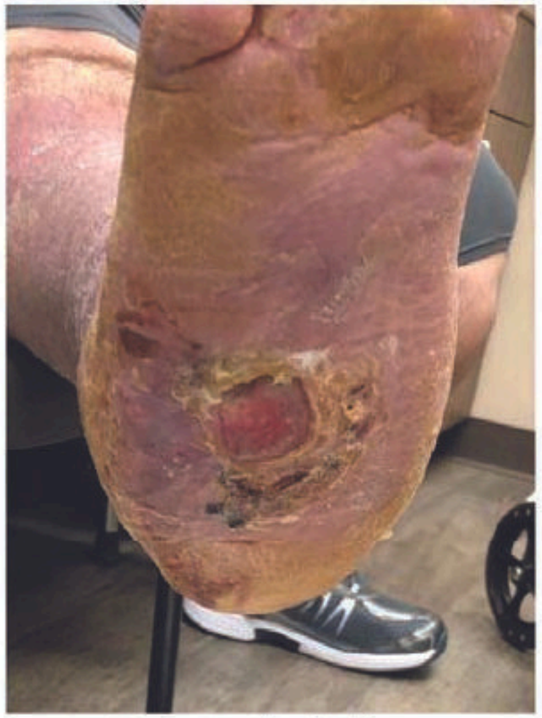
6 Week follow up

7 **Tobacco use?** Ideally, refrain from smoking or tobacco use for at least **4 weeks** during conservative wound care and before planned biologic wound treatment.

a Documentation of smoking cessation attempt and ongoing monitoring of tobacco use.



Pre-Application



6 month follow up

8 Examples of appropriate treatment:

a. Edema control, venous hypertension, or lymphedema management.

b. Control of any focus of infection or colonization with bacterial or fungal elements.

c. Removal of underlying cellulitis, osteomyelitis, foreign body, or malignant process.

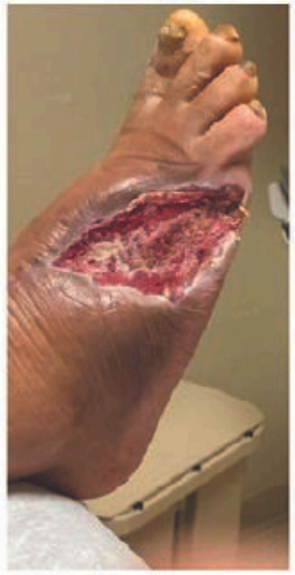
d. Proper debridement of necrotic tissue or foreign body (exposed bone or tendon).

e. For diabetic foot ulcers, appropriate non-weight-bearing or pressure offloading.

f. For venous stasis ulcers, compression therapy provided with diligently documented use of multi-layer dressings, compression stockings with over 20 mmHg pressure, or pneumatic compression.

g. Provision of a wound environment to promote healing (protection against trauma and contaminants, removal of inciting or aggravating factors).

50 Yr Old Male * Uncontrolled Diabetic * Non-Compliant w/Off Loading



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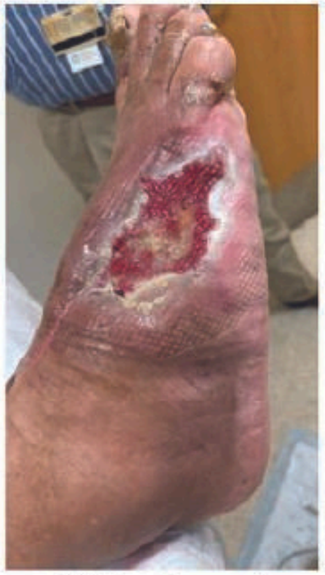
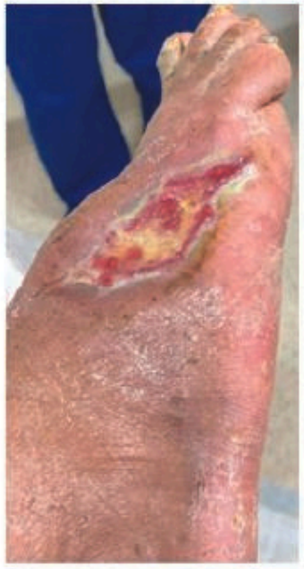
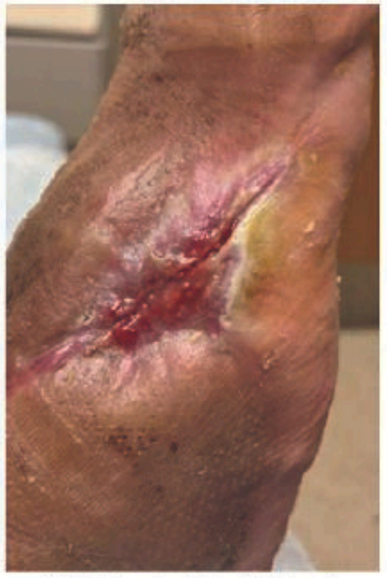


21 Day Reveal



8 Weeks Post Appl



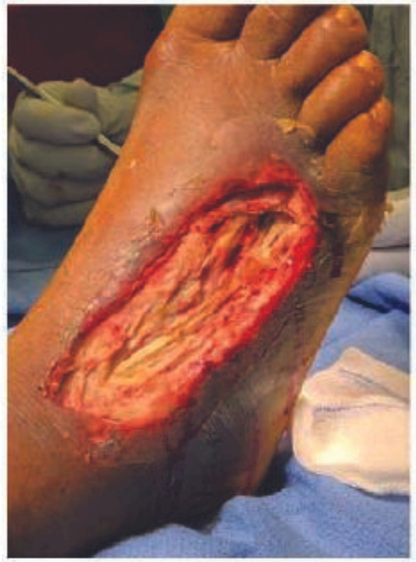
12 Weeks Post Appl

9 To continue with care, as well as to initiate biologic wound care, include documentation:

a. Ongoing measurements: should be at least 1.0 cm^2 in size.

b. Medical necessity for each application.

c. Partial or full-thickness ulcers that do not involve tendons, muscles, joint capsule, or exhibit exposed bone or sinus tracts, with a clean granular base.



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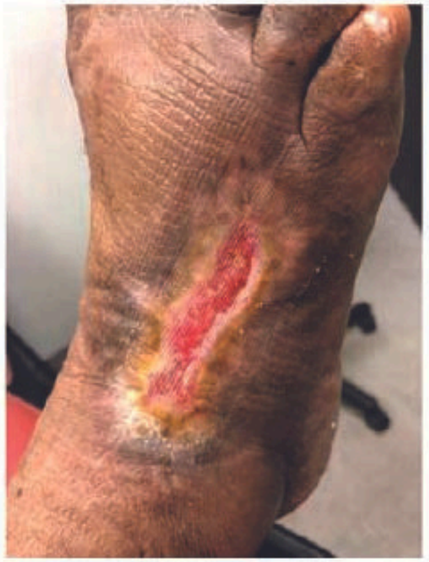
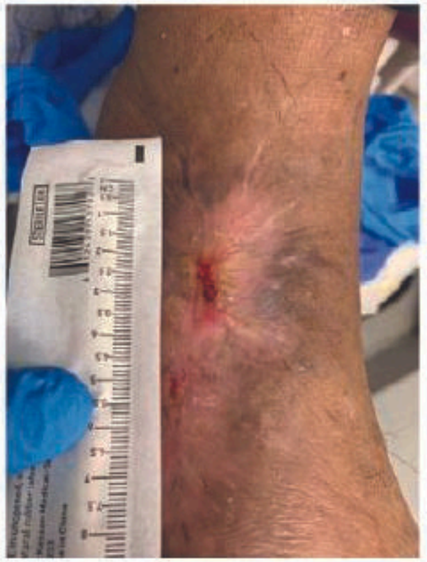


6 Week Follow Up



12 Weeks Follow Up

d. Free from necrotic debris or exudate.

e. Having adequate circulation/oxygenation to support tissue growth/wound healing as evidenced by physical examination (e.g., Ankle-brachial index [ABI] not less than 0.60, toe pressure greater than 30 millimeters of mercury [mmHg]).

f. Improvement, such as measurable changes in:

   i. Drainage, inflammation, swelling, pain and/or tenderness, wound dimensions, granulation tissue, necrotic/eschar tissue, and/or tunnels or undermining.

g. For diabetic foot ulcers, patient medical records reflect a diagnosis of Type 1 or Type 2 Diabetes and also reflect medical management of this condition.

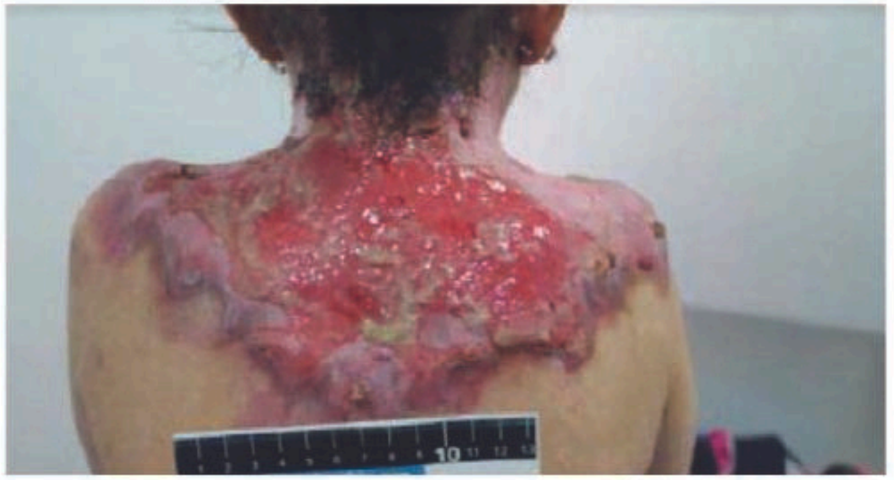
10 **No more than 10 applications of biologics within a 12-week period.**

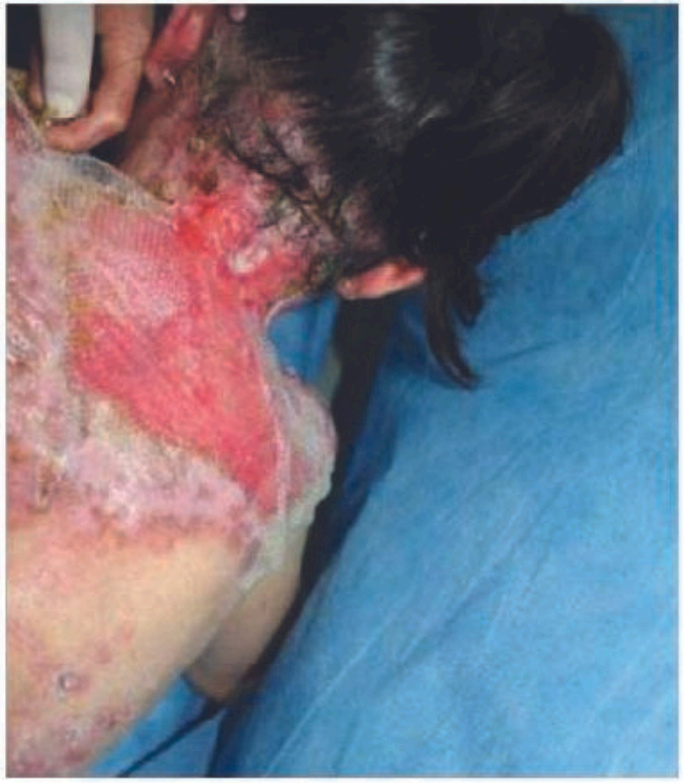
a Simultaneous use of multiple products is not covered.

11 If you need to extend care beyond the 12 weeks, ensure medical necessity is documented in your notes. Complex record review may be requested by the insurer.

12 Retreatment of healed ulcers showing more than 75% reduction and a size reduction of less than 0.5 cm^2 is not considered medically necessary.

13 Retreatment within 1 year of any given course of treatment with a skin substitute for lower extremity venous ulcers (VLU) or diabetic foot ulcers (DFU) is considered treatment failure and does not meet reasonable and necessary criteria for retreatment of that ulcer with a skin substitute procedure.





14 **The amount of skin substitute used and wasted must be clearly documented in the procedure note with the following minimum information:**

a. Date, time, and location of the treated ulcer;
b. Name of the skin substitute and how the product is supplied;
c. Quantity of product units used;
d. Quantity of product units discarded;
e. Reason for waste;
f. Serial/lot/batch number or other manufacturer unit identification of the graft material.

g. **Note:** Novitas expects that, when multiple sizes of a specific product are available, the size best suited to the wound should be used with the least amount of waste.

15 **FDA** labeling for most skin substitute grafts includes language suggesting the frequency of applications. It is expected that these guidelines be followed. Documentation of medical necessity is required for patients requiring additional treatments.

The above information serves as a guide. It is the provider's responsibility to ensure that all National/Local Coverage Determinations (LCDs), Articles, and Commercial Medical Policies for wound care are reviewed and followed.