Skin substitutes for chronic diabetic lower extremity ulcers

New policy effective Dec. 16, 2021

The Louisiana Department of Health (LDH) issued a policy for skin substitutes for chronic diabetic lower extremity ulcers in Informational Bulletin 21-26.

The policy is effective Dec. 16, 2021. We'll update the UnitedHealthcare Community Plan of Louisiana Care Provider Manual and our policies.

What's new
Prior authorization will be required for these services. You can read about patient eligibility and coverage limitations here:

Skin Substitutes for Chronic Diabetic Lower Extremity Ulcers

Skin substitutes are covered and considered medically necessary for the treatment of partial and full-thickness diabetic lower extremity ulcers when the enrollee meets all of the below criteria:

Eligibility Criteria

- Presence of a lower extremity ulcer that:
  - Is at least 1.0 square centimeter (cm) in size;
  - Has persisted for at least four weeks;
  - Has not demonstrated measurable signs of healing, defined as a decrease in surface area and depth or a decreased amount of exudate and necrotic tissue, with comprehensive therapy including all of the following:
    - Application of dressings to maintain a moist wound environment;
    - Debridement of necrotic tissue, if present; and
    - Offloading of weight.
- A diagnosis of type 1 or type 2 diabetes mellitus;
- A glycated hemoglobin (HbA1c) level of ≤9% within the last 90 days or a documented plan to improve HbA1c to 9% or below as soon as possible;
- Evidence of adequate circulation to the affected extremity, as indicated by one or more of the following:
  - Ankle-brachial index (ABI) of at least 0.7;
  - Toe-brachial index (TBI) of at least 0.5;
  - Dorsum transcutaneous oxygen test (TcPO2) >=30 mm Hg; and/or
  - Triphasic or biphasic Doppler arterial waveforms at the ankle of the affected leg.
- No evidence of untreated wound infection or underlying bone infection; and
- Ulcer does not extend to tendon, muscle, joint capsule, or bone or exhibit exposed sinus tracts unless the product indication for use allows application to such ulcers.

The enrollee must not have any of the following:

- Active Charcot deformity or major structural abnormalities of the foot, when the ulcer is on the foot;
- Active and untreated autoimmune connective tissue disease;
- Known or suspected malignancy of the ulcer;
- Enrollee is receiving radiation therapy or chemotherapy; and
- Re-treatment of the same ulcer within one year

Coverage Limitations

- ❖ Coverage is limited to a maximum of 10 treatments within a 12-week period;
- ❖ If there is no measurable decrease in surface area or depth after five applications, then further applications are not covered;
- ❖ For all ulcers, a comprehensive treatment plan must be documented, including at least all of the following:
  - Offloading of weight;
  - Smoking cessation counseling and/or medications, if applicable;
  - Edema control; o Improvement in diabetes control and nutritional status; and
  - Identification and treatment of other comorbidities that may affect wound healing such as ongoing monitoring for infection.
- ❖ While providers may change products used for the diabetic lower extremity ulcers, simultaneous use of more than one product for the diabetic lower extremity ulcers is not covered; and
- ❖ Hyperbaric oxygen therapy is not covered when used at the same time as skin substitute treatment

Prior Authorization

Prior authorization is required, and medical documentation submitted must demonstrate that the enrollee meets all of the aforementioned requirements.

- If there is no measurable decrease in surface area, or depth, after five applications, then the MCO shall not cover further applications, even when prior authorized.

Questions? Call customer service at 866-875-1607, 7 a.m. —7 p.m., Monday—Friday.

United Healthcare