Skin Substitutes for Chronic Diabetic Lower Extremity Ulcers (for Louisiana Only)

Policy Number: CS250LA.C
Effective Date: March 1, 2024

Instructions for Use

Content mandated by Louisiana Department of Health

Table of Contents **Page**

Application

This Medical Policy only applies to the state of Louisiana. The coverage rationale contained in this policy represents Louisiana Medicaid coverage policy and is set forth below in accordance with state requirements.

Coverage Rationale

Indications for Coverage

Louisiana Medicaid covers skin substitutes and considers them to be to be medically necessary for the treatment of partial- and full-thickness diabetic lower extremity ulcers when the beneficiary meets all of the following criteria:

- Presence of a lower extremity ulcer that:
  - Is at least 1.0 square centimeter (cm) in size
  - Has persisted at least 4 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
    - 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
    - Triphasic or biphasic Doppler arterial waveforms at the ankle of the affected leg
  - No evidence of untreated wound infection or underlying bone infection
  - 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 individual 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
- Individual is receiving radiation therapy or chemotherapy
- Re-treatment of the same ulcer within one year

Indications for Coverage

The following coverage limitations apply:

- 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 **all** of the following:
  - Offloading of weight
  - Smoking cessation counseling and/or medication, if applicable
  - Edema control
  - Improvement in diabetes control and nutritional status
  - 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
- Hyperbaric oxygen therapy is not covered when used at the same time as skin substitute treatment

Note: If there is no measurable decrease in surface area or depth after five applications further applications are not covered even when prior authorized.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
Q4101	Apligraf, per sq cm
Q4106	Dermagraft, per sq cm
Q4121	TheraSkin, per sq cm
*Q4154	Biovance, per sq cm
Q4160	Nushield, per sq cm
Q4186	Epifix, per sq cm
Q4195	PuraPly, per sq cm
Q4196	PuraPly AM, per sq cm

Codes labeled with an asterisk (*) are not on the State of Louisiana Medicaid Fee Schedule and therefore may not be covered by the State of Louisiana Medicaid Program.

References

Louisiana Department of Health, Professional Services, Provider Manual Chapter Five of the Medicaid Services Manual, Issued September 20, 2021. https://www.lamedicaid.com/provweb1/providermanuals/manuals/PS/PS.pdf. Accessed October 16, 2023.

Policy History/Revision Information

Date	Summary of Changes
03/01/2024	• Routine review; no change to coverage guidelines • Archived previous policy version CS250LA.B

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.