MEDICAL POLICY STATEMENT
Nevada Medicaid

Policy Name & Number	Date Effective
Skin Substitutes-NV MCD-MM-1736	01/01/2026
Policy Type	
MEDICAL	

Medical Policy Statement prepared by CareSource and its affiliates are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CareSource and its affiliates do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination. According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

Table of Contents

A. Subject
Skin Substitutes

B. Background
Wounds are disruptions of the skin's structural and functional integrity and normally transition through distinct phases until the skin's structure and function are restored, including hemostasis, inflammation, cellular migration and proliferation, and remodeling. Chronic wounds can result in loss of function, wound recurrence, and significant morbidity. Pressure ulcers, diabetic foot ulcers, and venous leg ulcers are the three categories that comprise the majority of chronic wounds.

Skin substitutes are a heterogeneous group of biologics, nonautologous human skin such as acellular, allograft, cellular, dermal, epidermal, or homograft, synthetics, or biosynthetic materials. When determining if the use of a skin substitute is appropriate, the clinician evaluates the material being used and its properties. Individual wounds have a specific microenvironment. Various manufacturers may utilize differing processes in the development of skin substitutes but generally seed selected cells onto a matrix. The matrices subsequently receive proteins and growth factors necessary to divide and develop into the desired tissue.

Skin substitutes provide coverage for open wounds, both deep thermal and full-thickness wounds. Skin substitutes have the function and composition of skin or have the potential for autologous regenerative healing when applied to a wound. Uses span acute or chronic wounds, burns, or reconstruction, such as release of contractures secondary to severe burns. The most common classification system utilized to determine the type of skin substitute that would be appropriate for a particular wound is the Kumar Classification system, in which Class I includes temporary impervious dressing material, Class II includes single-layer durable skin substitutes, and Class III includes composite skin substitutes that replace both dermal and epidermal layers.

C. Definitions
- **Ankle-Brachial Index** – A comparison of the blood pressure measured at the ankle with blood pressure measured at the arm with lower numbers indicating narrowing or blockage of the arteries in the legs.
- **Autologous** – Derived from the same individual, such as an individual serving as both donor and recipient.
- **Cellular and Tissue-Based Products (CTPs)** – Wound dressings or coverings that contain or consist of cells and/or tissue to promote wound healing. They are often used as alternatives to skin grafts for chronic wounds, burns, and ulcers.
- **Chronic Wounds** – Wounds that have not progressed along the normal healing process, generally after a 4-week duration.
- **Chronic Venous Ulcers** – A wound that takes longer than usual to heal and often occurs on the legs or ankles when oxygen-poor blood flow is impaired and pools, creating pressure in the veins.

- **Diabetic Foot Ulcers** – An open sore or wound located on the foot occurring in approximately 15% of patients with diabetes.
- **Pressure Ulcers** – Injuries to skin and underlying tissue resulting from prolonged pressure on the skin, including bedsores that most often develop on skin covering bony areas of the body, such as heels, ankles, hips, and tailbone.
- **Tissue Engineering** – The practice of combining scaffolds, cells, and biologically active molecules into functional tissues to assemble functional constructs that restore, maintain, or improve damaged tissues or whole organs.

D. Policy

I. Prior authorization is required for all wound substitutes

A. The treating provider must submit a signed and dated wound care treatment plan or submit a letter of medical necessity that includes the following documentation:

1. the planned interventions for the problem identified
2. treatment goals
3. the expected outcomes

B. A signed and dated treatment plan or a letter of medical necessity is considered current when signed and dated within 30 calendar days prior to or on the date the procedure is performed. If the signed and dated treatment plan or letter of medical necessity is older than 30 days, PA may be denied.

II. Skin substitute products not used within the scope of the FDA's intended use and indications are considered experimental and/or investigational.

III. Skin Substitutes may be used for the treatment of chronic Stage 3 or 4 wounds that have failed to respond to standard wound care treatment after 30 days. A failed response is defined as a wound that has increased in size or depth or has not changed in baseline size of depth and shows not measurable signs of healing improvements after 30 days of appropriate wound care measures.

IV. CareSource considers the use of skin substitute products medically necessary under **ANY** of the following circumstances:

A. The presence of a chronic, non-infected diabetic foot ulcer (DFU) having failed to achieve at least 50% ulcer area reduction with documented standard of care (SOC) treatment) for a minimum of 4 weeks with documented compliance. Treatment of diabetic foot ulcer as indicated by all of the following:

1. when adequate circulation to the affected extremity is present as indicated by **ONE** of the following:
   a. palpable pedal
   b. ankle-brachial index (ABI) between 0.7 and 1.2
   c. dorsum transcutaneous oxygen test (TcPO2) ≥ 30 mm Hg within the last 60 days
   d. triphasic or biphasic Doppler arterial waveforms at the ankle of affected leg
2. appropriate glycemic control

3. no wound infection.
4. no response to conventional therapy, including all of the following:
   a. offloading (pressure relief)
   b. appropriate dressings to facilitate healing
   c. debridement as needed

B. The presence of a chronic, non-infected venous insufficiency ulcers having failed to respond to documented SOC treatment for a minimum of 4 weeks with documented compliance. Treatment of venous insufficiency ulcers when **ALL** of the following criteria are met:
   1. noninvasive duplex ultrasound documenting chronic venous disease
   2. adequate perfusion of involved limb
   3. appropriate surgical venous interventions
   4. concurrent conventional wound care
   5. concurrent glycemic management if patient is also diabetic
   6. duration greater than 6 weeks
   7. partial-thickness or full-thickness ulcer due to venous insufficiency
   8. no allergy to bovine products
   9. no response to conventional therapy, including all of the following:
      a. compression therapy
      b. surgical intervention for UVD (if applicable)
      c. dressings to maintain moist wound environment (eg, saline-moistened dressings, negative pressure wound therapy)
      d. sharp debridement
   10. no wound infection

C. Treatment of burn wounds when **ONE** of the following criteria are met:
   1. a temporary wound covering for excised full-thickness and deep partial-thickness burn wounds in individuals who require such a covering prior to autograft placement
   2. treatment of mid-dermal to indeterminate depth burn wounds that typically require debridement and that may be expected to heal without autografting

D. Repair of scar contractures when more conservative therapeutic options have failed when used in conjunction with a breast reconstruction procedure.

E. Complications of surgically created or traumatic wounds, where accelerated granulation therapy is necessary but cannot be achieved by other available topical wound treatment.

F. Pressure redistribution support surfaces for pressure ulcers

V. Documentation Requirements

A. Standard of Care treatment documentation includes:
   1. Comprehensive patient assessment (history, exam, vascular assessment) and diagnostic tests as indicated as part of the implemented treatment plan
   2. Assessment of Type 1 or 2 diabetes for DFU patients including management history and any comorbidities (eg. vascular disease, neuropathy, osteomyelitis), current blood glucose levels (A1c) and assessment of off-loading devices and footwear.

3. Assessment of clinical history for venous insufficiency ulcer patients including
   a. prior ulcers
   b. body mass index
   c. history of pulmonary embolism or superficial/deep venous thrombosis
   d. number of pregnancies and physical inactivity
   e. physical exam
   f. evaluation of venous reflux, perforator incompetence, and venous thrombosis
   g. the use of any compression garments

B. Treatment Plan documentation Includes **ALL** of the following:
   1. debridement as appropriate to a clean granular base
   2. documented evidence of offloading for DFUs
   3. documented evidence of sustained compression dressings for venous insufficiency ulcers
   4. infection control with removal of foreign body or focus of infection
   5. management of exudate with maintenance of a moist environment
   6. documentation of smoking history, counseling on the effects of smoking on wound healing
   7. treatment for smoking cessation and current status

VI. Non-Covered or Medically Necessary
   A. New Quarterly skin substitutes or Q-codes that have not been used outside clinical trials
   B. Greater than 3 applications of a skin substitute graft/CTP over 12 weeks if volume has not decreased by at least 50%
   C. Repeat applications of skin substitute graft/CTP when a previous application was unsuccessful. Unsuccessful treatment is defined as increase in size or depth of an ulcer, no measurable change from baseline, and no sign of significant improvement or indication that significant improvement is likely (such as granulation, epithelialization, or progress towards closure).
   D. Application of skin substitute graft/CTP in patients with inadequate control of underlying conditions or exacerbating factors, or other contraindications (eg, active infection, progressive necrosis, active Charcot arthropathy of the ulcer extremity, active vasculitis, ischemia
   E. Use of surgical preparation services (eg, debridement), in conjunction with routine, simple or repeat skin replacement therapy with a skin substitute graft/CTP
   F. All liquid or gel skin substitute products or CTPs for ulcer care
   G. Placement of skin substitute graft/CTP on infected, ischemic, or necrotic wound bed
   H. Skin substitute products that are not on the applicable fee schedule may not be reimbursable and may be considered experimental and investigational.
   I. Life expectancy would not allow long-term healing or clinical benefit or decrease of substantive morbidity.

E. Conditions of Coverage
NA

F. Related Policies/Rules
Breast Reconstruction Surgery
Experimental or Investigational Item or Service

G. Review/Revision History

	DATE	ACTION
Date Issued	08/27/2025	New Policy. Approved at Committee.
Date Revised		
Date Effective	01/01/2026	
Date Archived		

H. References

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