MEDICAL POLICY STATEMENT
D-SNP

Policy Name & Number	Date Effective
Skin Substitutes-DSNP-MM-1427	12/01/2025 Ohio inactive as of 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.

This policy applies to the following Market(s):	
☒ **Georgia**	☒ **Ohio**

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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, 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.
- **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. For the treatment of diabetic foot ulcers (DFUs)and venous leg ulcers (VLUs) CareSource uses the medical necessity criteria found in Local Coverage Determination (LCD) L39865, Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers.

II. CareSource considers the use of skin substitute products medically necessary under ANY of the following circumstances:
   A. 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
   B. Repair of scar contractures when more conservative therapeutic options have failed when used in conjunction with a breast reconstruction procedure.
   C. Pressure redistribution support surfaces for pressure ulcers.

III. 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

IV. 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 (e.g., active infection, progressive necrosis, active Charcot arthropathy of the ulcer extremity, active vasculitis, ischemia
- E. use of surgical preparation services (e.g., 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. Summary of Evidence

A systematic review identified 20 trials of skin substitutes (Roshangar, et al, 2020). For the management of partial-thickness burns, bioengineered skin substitutes and allogeneic cultured skin were at least as effective as topical agents/wound dressings or allograft. In two trials, a bi-layered living cell construct (BLCC) had a significantly faster time to healing (11 versus 14 days) compared with autografts, allografts, or xenografts; however, the proportion of patients with ≥75 percent of wound closure was significantly lower. In a separate review, a skin substitute (Biobrane) significantly reduced pain during the treatment of superficial and partial thickness burn wounds compared with topical agents.

One drawback of skin substitutes in the treatment of burns may be the potential for infection. In a multicenter trial that included 216 burn patients, the rate of invasive

infection at sites treated with BLCC was 3 percent (consistent with 1 to 3 percent rate for autografting) and the superficial wound infection rate was 13 percent. In a later systematic review of studies that compared dermal substitutes and split-thickness skin grafts for the treatment of burn wounds, three trials reported either low rates of infection or no significant difference in infection rates between dermal substitutes and skin grafts, and four of the seven trials reported no significant differences in scar quality. Statistical pooling of data was not performed due to heterogeneity of the studies.

Human-derived acellular dermal matrices (ADM) are sterilized and decellularized to remove immunogenic cellular material such as major histocompatibility complex (MHC) proteins, thereby diminishing host immune response and improving incorporation into the wound. With increasing frequency, surgeons are electing to use acellular dermis to assist with tissue expander– or implant-based primary breast reconstruction. In 2022, of 151,641 breast reconstructions performed, as projected by the American Society of Plastic Surgeons, 82,597 (54.5%) used a tissue expander and implant, and 76,257 (50.3%) employed an acellular dermal matrix (ADM). Several authors have reported favorable results for procedures involving acellular dermis, and rapid early expansion has led to improved cosmetic outcomes.

In the literature, comparisons of ADM-assisted reconstruction with traditional expander reconstruction generally do not show statistically relevant differences in overall complication rates. The overall complication rates for reconstructions using ADM range from 3.2% to 48.7%. In patients who underwent expander-to-implant procedures, a study by Marquez et al reported that at 1-year follow-up after the second stage, differences between the ADM-assisted and non-ADM–assisted procedures with regard to incidence of implant rippling (24.6% vs 12.1%, respectively), capsular contracture (4.5% vs 3.3%, respectively), and explantation (6.6% vs 1.7%, respectively) were not statistically significant.

F. Related Policies/Rules

Breast Reconstruction Surgery
Experimental or Investigational Item or Service

G. Review/Revision History

	DATE	ACTION
Date Issued	02/15/2023	New policy.
Date Revised	02/14/2024 02/12/2025 08/27/2025	Updated references. Approved at Committee. Added I. A. 1-4. Added II. B. “Life expectancy would not allow long-term healing, clinical benefit or decrease of substantive morbidity.” Added new requirements for D. I .A, B, and D.II; added Sec. E Documentation Requirements. Added more non-covered items to D.III, and Related Policies/Rules. Updated references. Approved at Committee
Date Effective	12/01/2025	
Date Archived		

The MEDICAL Policy Statement detailed above has received due consideration as defined in the MEDICAL Policy Statement Policy and is approved.

H. References

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Independent medical review – 01/19/2023