MEDICAL POLICY STATEMENT
Marketplace

Policy Name & Number	Date Effective
Skin Substitutes-MP-MM-1414	05/01/2024
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 Marketplace(s):				
☒ **Georgia**	☒ **Indiana**	☒ **Kentucky**	☒ **Ohio**	☒ **West Virginia**

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

A. Treatment of diabetic foot ulcer when adequate circulation to the affected extremity is present as indicated by at least **ONE** of the following:
1. palpable pedal
2. ankle-brachial index (ABI) between 0.7 and 1.2
3. dorsum transcutaneous oxygen test (TcPO2) ≥ 30 mm Hg within the last 60 days
4. triphasic or biphasic Doppler arterial waveforms at the ankle of affected leg

B. Treatment of venous insufficiency ulcers when **ALL** of the following criteria are met:
1. adequate perfusion of involved limb
2. concurrent conventional wound care
3. concurrent glycemic management, if patient is also diabetic
4. duration greater than 1 month
5. partial-thickness or full-thickness ulcer due to venous insufficiency
6. no allergy to bovine products
7. no response to conventional therapy, including all of the following:
   a. compression therapy
   b. dressings to maintain moist wound environment (eg, saline-moistened dressings)
   c. sharp debridement
8. 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.

II. Exclusions
Skin substitute products that are not on the applicable fee schedule may not be reimbursable and may be considered experimental and investigational.

E. State-Specific Information
NA

F. Conditions of Coverage
NA

G. Related Policies/Rules
Breast Reconstruction Surgery

H. Review/Revision History

	DATE	ACTION
Date Issued	02/15/2023	New Policy.
Date Revised	02/14/2024	Updated references. Approved at Committee.
Date Effective	05/01/2024	
Date Archived		

I. References

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