CareSource

MEDICAL POLICY STATEMENT
Ohio MyCare FIDE

Policy Name & Number	Date Effective
Skin Substitutes-MyCare OH FIDE-MM-1823	09/01/2026
Policy Type	
MEDICAL	

Medical Policy Statements are developed from a review of the available evidence-based, clinical information based on and supported by clinical guidelines from medical specialties, peer-reviewed medical and scientific studies, nationally recognized utilization and technology assessment guidelines, and other medical management industry standards to aid in determining the medical necessity of a service. Medically necessary services are defined in the plan-specific Evidence of Coverage, Member Handbooks, Provider Manuals, Medical Policy Statements, and/or other plan policies and procedures.

Medical Policy Statements do not guarantee an authorization or payment of services. Please refer to the plan contract (e.g., Evidence of Coverage, Member Handbook) for the service(s) referenced in the Medical Policy Statement. Except as otherwise required by law, if there is a conflict between the Medical Policy Statement and the plan contract and/or provider agreement, then the plan contract and/or provider agreement will be the controlling document. Reasonable discretion may be used in interpreting and applying this Policy Statement to services provided in a particular case, and the policy may be modified at any time. Medical Policy Statements may be superseded by federal and state laws and regulations, as applicable. In the case of a discrepancy between the Policy Statement's effective date and any applicable legal or regulatory requirement, the law or regulation will govern.

Coverage for mental health and substance use disorder (MH/SUD) benefits are provided at the same level as coverage for medical and surgical (M/S) benefits, as required by the Mental Health Parity and Addiction Equity Act (MHPAEA). MH/SUD benefits are not subject to limits or requirements that are more restrictive than those that apply to M/S benefits.

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, 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 (for example, Apligraf or Dermagraft) 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:
7. noninvasive duplex ultrasound documenting chronic venous disease
8. adequate perfusion of involved limb
9. appropriate surgical venous interventions
10. concurrent conventional wound care
11. concurrent glycemic management if patient is also diabetic
12. duration greater than 6 weeks
13. partial-thickness or full-thickness ulcer due to venous insufficiency
14. no allergy to bovine products
15. 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
16. 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. Pressure redistribution support surfaces for pressure ulcers

II. 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

III. 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 (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. 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	06/18/2025	New policy. Approved at Committee
Date Revised	06/17/2026	Added MCG criteria to Sec. I to replace LCD that CMS removed and examples of skin graft products. Updated references. Approved at Committee
Date Effective	09/01/2026	
Date Archived		

H. References

1. Ankle- brachial index. Mayo Clinic. Accessed May 18, 2026. www.mayoclinic.org
2. Bay C, Chizmar Z, Reece EM, et al. Comparison of Skin Substitutes for Acute and Chronic Wound Management. *Semin Plast Surg*. 2021;35(3):171-180. doi:10.1055/s-0041-1731463
3. Bedsores (pressure ulcers). Mayo Clinic. Accessed May 18, 2026. www.mayoclinic.org
4. Hart CE, Loewen-Rodriguez A, Lessem J. Dermagraft: use in the treatment of chronic wounds. *Adv Wound Care*. 2012;1(3):138-141. doi:10.1089/wound.2011.0282
5. Marquez JL, French M, Ormiston L, et al. Outcomes after tissue expander exchange to implant in two-stage prepectoral breast reconstruction with and without acellular dermal matrix: a retrospective cohort study. *J Plast Reconstr Aesthet Surg*. 2024;89:97-104. doi:10.1016/j.bjps.2023.12.008
6. Porcine skin and gradient pressure dressings. Centers for Medicare & Medicaid Services. Accessed May 18, 2026. www.cms.gov
7. *Research Protocol: Skin Substitutes for Treating Chronic Wounds*. Effective Health Care Program, Agency for Healthcare Research and Quality; 2018. Reviewed January 2020. Accessed May 18, 2026. www.effectivehealthcare.ahrq.gov

8. Roshangar L, Soleimani Rad J, Kheirjou R, et al. Skin burns: review of molecular mechanisms and therapeutic approaches. *Wounds*. 2020; 31(12):308-315.
9. Shahrokhi S. Skin substitutes. UpToDate. Updated July 31, 2025. Accessed May 18, 2026. www.uptodate.com
10. Skin substitute, tissue-engineered (human cellular), for diabetic foot ulcer and venous ulcer: A-0326. MCG Health. 30th ed. Accessed May 20, 2026. www.careweb.careguidelines.com
11. Tissue engineering and regenerative medicine. National Institute of Biomedical Imaging and Bioengineering. Accessed June 3, 2026. www.nibib.nih.gov
12. Venous ulcers. Cleveland Clinic. Reviewed May 26, 2022. Accessed May 18, 2026. www.myclevelandclinic.org
13. What is a diabetic foot ulcer? American Podiatric Medical Association. Accessed May 18, 2026. www.apma.org

ODM Approved 06/24/2026