POLICY & PROCEDURE

Policy Title:	Bioengineered Skin	Number & Version:	UM BioEng. Skin v6
Functional Unit:	Utilization Management	Effective Date:	04/18/2025
Policy Owner (Title):	Senior Director, Utilization Management	Page Number:	1 of 7

I. POLICY STATEMENT and PURPOSE

In its administration of Medicare Advantage plans (Health Plans), the Company shall determine benefits in accordance with the requirements of the Centers for Medicare & Medicaid Services (CMS). Where CMS has established a national coverage policy on an item or service or a local Medicare contractor has done so as authorized by CMS, the Company follows the Medicare coverage policy. In the absence of fully established Medicare coverage criteria, the Company may develop and implement internal criteria based on current evidence in widely used treatment guidelines or clinical literature. Internal criteria are reviewed and approved by the Medical Management Committee and are made publicly accessible.

CMS has not established coverage criteria for Bioengineered Skin, therefore the Company has developed and implemented this coverage policy to ensure that patients receive clinically appropriate, medically necessary care at the appropriate level, which allows for the best clinical outcome and prevents harm. The purpose of this policy is to describe the circumstances under which Bioengineered Skin would be medically necessary.

II. BACKGROUND

Bioengineered Skin is designed to temporarily assume the functions of the epidermis and/or dermis until the patient's skin barrier repairs naturally or until definitive skin replacement can be achieved with a skin graft or cultured equivalent. It is thought that Bioengineered Skin accelerates wound healing by introducing living cells to re-establish the conditions needed for repair including a moist wound environment, structural support, and cytokines and other growth factors to promote an immune response and tissue regeneration (Ranweera, 2011).

III. SCOPE

This Policy applies to the procedures required to prepare and apply Bioengineered Skin as well as the material used (Bioengineered Skin / Skin Substitute).

IV. DEFINITIONS

Acute Wound: is defined as a recent wound that has yet to progress through the sequential stages of wound healing. An acute wound is acquired as a result of an incision or trauma and heals in a timely and systematic fashion. Surgically created wounds include all incisions, excisions, and wounds that are surgically debrided. Surgical wounds include all skin lesions that occur as a result of trauma (e.g. falls, burns, punctures), as a result of an underlying condition (e.g. leg ulcers), or as a combination of both (Ather, 2009).

Bioengineered Skin: is defined as an outer epidermal layer (the outermost layer of skin) and/or a dermal layer (the layer of skin between the epidermis and the subcutaneous tissue) embedded into an acellular matrix (a support structure) forming a biological skin substitute. This 'artificial' tissue can be grown from the patient's own cells or from another 'allogeneic' (non-self) source (Ranweera, 2011).

Chronic Wound: is one that has failed to progress through the phases of healing in a period of 8-12 weeks (Ather, 2009). Chronic wounds include, but are not limited, to diabetic foot ulcers, venous leg ulcers, and pressure ulcers. Common features include prolonged or excessive inflammation, persistent infections, formation of drug-resistant microbial biofilms, and the inability of dermal and/or epidermal cells to respond to reparative stimuli. Chronic lower extremity ulcers are those that do not progress through the healing process in a timely manner. Chronic leg and foot ulcers occur in many adults with vascular disease or diabetes and are attributed to chronic venous insufficiency, arterial disease, prolonged pressure, or neuropathy. These ulcers last on average 12 to 13 months, recur in up to 60% to 70% of patients and can lead to loss of function and decreased quality of life. They are also a significant cause of morbidity (Frykberg, 2015).

Medically Necessary – Covered Services rendered by a Health Care Provider that the Plan determines are:

1) Safe and effective
2) Not experimental or investigational
3) Appropriate for patients,
   a) including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is—
      i) furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member,
      ii) furnished in a setting appropriate to the patient's medical needs and condition,
      iii) ordered and furnished by qualified personnel,
      iv) one that meets, but does not exceed, the patient's medical need; and
      v) are at least as beneficial as existing and available medically appropriate alternatives.

V. OWNERSHIP & TRAINING

The Senior Director, Utilization Management, is responsible for administration, oversight, and training regarding performance under this Policy.

VI. PROTOCOLS / COVERAGE POLICY

The protocols / coverage policy that follow pertain only to the following states: IN, MO, IL, MI

Before considering if the Bioengineered Skin and associated procedure(s) to apply the material is considered covered / medically necessary, it must first be determined that the skin product is approved* by the Food and Drug Administration (FDA) for the indication requested. To determine if the Bioengineered Skin product is approved by the FDA:

- For premarket approvals, visit
  - https://www.fda.gov/ OR https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm
- For humanitarian exemptions (HDE), visit:
  - https://www.fda.gov/vaccines-blood-biologics/approved-blood-products/premarket-approvals-and-humanitarian-device-exemptions-supporting-documents
    - enter the product name in the search box
    - download current approval documents
      - search for the product name and status.

*** Includes: FDA premarket approval, FDA 510(k) clearance, or FDA-approved under an HDE***

Documentation in the medical record must support the conditions for approval and none of the conditions for non-coverage:

1) Documentation (in the pre-service record)
   a) Treatments and circumstances as to why the wound has failed to respond to standard wound care treatment of greater than 4 weeks
   b) Specific interventions that have failed
   c) Updated medication history
   d) History and presence of complications (e.g., infection, trauma)
   e) The procedure risks and complications should also be reviewed and documented
2) Documentation in the Medical Record
   a) Details of the wound including size and depth, location, clinical status, and changes in clinical status over time
   b) Review of pertinent medical problems that may have occurred since the previous wound evaluation
   c) Explanation of the planned skin replacement surgery with choice of skin substitute graft product and rationale
   d) Identity of the treating physician.
3) Documentation in the procedure note
   a) Date and time of procedure
   b) Name of skin substitute, how supplied, and manufacturer's unit identification (e.g., lot number)

c) Amount of skin substitute used
d) Amount of skin substitute discarded and reason for the wastage.

Bioengineered Skin **IS** considered covered / medically necessary only when ordered by a physician AFTER the following has been attempted and the listed conditions are met:

- Removal of any necrotic tissue through debridement (typically sharp debridement),
- Maintenance of moisture balance by selecting the proper wound dressing to control exudate,
- Measures taken to prevent or treat wound infections,
- Measures taken to correct ischemia in the wound area,
- For venous leg ulcers, application of some form of compression,
- For diabetic foot ulcers, application of some form of offloading,
- The patient is compliant with recommendations*,
- There is no evidence of underlying osteomyelitis or nidus of infection, and
- The patient has NOT responded to this standard wound treatment for at least a 30-day period.

*Note: Wound healing is impaired by the systemic use of tobacco. Therefore, **ideally**, patients who have smoked will have ceased smoking or have refrained from systemic tobacco intake for at least 4 weeks during conservative wound care and prior to planned Bioengineered Skin replacement therapy.

Additional criteria that must be met:
The following patient conditions must be documented:

- Partial- or full-thickness ulcers, not involving tendon, muscle, joint capsule or exhibiting exposed bone or sinus tracts, with a clean granular base,
- Skin deficit at least 1.0 square centimeter (cm) in size,
- Clean and free of necrotic debris or exudate,
- Have adequate circulation/oxygenation to support tissue growth/wound healing as evidenced by physical examination (e.g., Ankle-Brachial Index [ABI] of no less than 0.60, toe pressure greater than 30 millimeters of mercury [mmHg]),
- For diabetic foot ulcers, the patient's medical record reflects a diagnosis of Type 1 or Type 2 Diabetes and reflects medical management for this condition.

Bioengineered Skin is **NOT** considered covered / medically necessary in the following circumstances:

- Partial thickness loss with the retention of epithelial appendages is not a candidate for grafting or replacement, as epithelium will repopulate the deficit from the appendages, negating the benefit of over-grafting.

- Skin substitute grafts will be allowed for the episode of wound care in compliance with FDA guidelines for the specific product (see utilization guidelines) not to exceed 10 applications or treatments. In situations where more than one specific product is used, it is expected that the number of applications or treatments will still not exceed 10.
- Simultaneous use of more than one product for the episode of wound is not covered. Product change within the episode of wound is allowed, not to exceed the 10-application limit per wound per 12-week period of care.
- Treatment of any chronic skin wound will typically last no more than twelve (12) weeks.
- Repeat or alternative applications of skin substitute grafts are not considered medically reasonable and necessary when a previous full course of applications was unsuccessful. Unsuccessful treatment is defined as increase in size or depth of an ulcer or no change in baseline size or depth and no sign of improvement or indication that improvement is likely (such as granulation, epithelialization, or progress towards closing) for a period of 4 weeks past start of therapy.
- Retreatment of healed ulcers, those showing greater than 75% size reduction and smaller than 0.5 square cm, is not considered medically reasonable and necessary.
- Skin substitute grafts are contraindicated and are not considered reasonable and necessary in patients with inadequate control of underlying conditions or exacerbating factors (e.g., uncontrolled diabetes, active infection, and active Charcot arthropathy of the ulcer extremity, vasculitis, or continued tobacco smoking without physician attempt to affect smoking cessation).
- Skin substitute grafts are contraindicated in patients with known hypersensitivity to any component of the specific skin substitute graft (e.g., allergy to avian, bovine, porcine, equine products).
- Repeat use of surgical preparation services in conjunction with skin substitute application codes will be considered not reasonable and necessary. It is expected that each wound will require the use of appropriate wound preparation code at least once at initiation of care prior to placement of the skin substitute graft.
- Re-treatment within one (1) year of any given course of skin substitute treatment for a venous stasis ulcer or (diabetic) neuropathic foot ulcer is considered treatment failure and does not meet reasonable and necessary criteria for re-treatment of that ulcer with a skin substitute procedure.

VII. SUMMARY of EVIDENCE

There is strong evidence to support Bioengineered Skin substitutes are at least as safe as standard therapies for wound care as they are designed to temporarily take over the functions of the epidermis and/or dermis until the patient's skin barrier repairs spontaneously, or until definitive skin replacement is possible with skin graft (Ranaweera, 2011).

VIII. REGULATORY REFERENCES / CITATIONS

CMS National Coverage Determinations (NCDs): None
CMS Local Coverage Determinations (LCDs): L36377, L35041, L36690

ID	Title	Type	Service Area	Contractor
L36377	Application of Skin Substitute Grafts for Treatment of DFU and VLU of Lower Extremities	LCD	FL, PR, VI	First Coast Service Options, Inc.
L35041	Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds	LCD	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX	Novitas Solutions, Inc.
L36690	Wound Application of Cellular and/or Tissue Based Products (CTPs), Lower Extremities	LCD	KY, OH	CGS Administrators, LLC

IX. PROFESSIONAL REFERENCES / CITATIONS

1. Ather, S. and Harding, K.G. Science Direct: Advanced Textiles for Wound Care. Issued 2009. Accessed April 2025. https://www.sciencedirect.com/topics/engineering/acute-wound

2. Frykberg, R. G. and Banks, J. National Library of Medicine – National Center for Biotechnology Information: Challenges in the Treatment of Chronic Wounds. Issued 2015. Accessed April 2025. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4528992/#:~:text=Chronic%20wounds%20are%20defined%20as,the%20inflammation%20phase%20of%20healing

3. Ranaweera, Anoma. DermNet – All About the Skin: Bioengineered Skin. Issued 2011. Accessed April 2025. https://dermnetnz.org/topics/bioengineered-skin

APPROVALS:

Chief Medical Officer
(MMC Chair): Saria Saccocio, MD ___

VERSION HISTORY:

Version	Date	Author	Purpose/Summary of Major Changes
01	01/2019		Original Issue
02	01/2020	Bob Brault	Annual review. Removed: Essence logo and EHI references & smoking cessation requirement. Added Failed Response criteria to Coverage Criteria, CPT and HCPCS codes to list of FDA approved products & "Reapplication and continued use" in Limitations
03	03/26/2021	Julie Braundmeier	Annual review; no substantive changes.
04	08/12/2022	Gina Vehige	Annual review, reformatted; no substantive changes; approved at Lumeris QMMC 08122022
05	08/2/2021	Gina Vehige	Annual review; no substantive changes. Updated references and links, Updated MAC list, Updated CMS Articles List.
06	04/10/2024	Gina Vehige	Annual review; no substantive changes. Updated references and links & updated Policy Statement and Purpose. Added Summary of Evidence. Approved by MMC 6/7/2024.
07	04/11/2025	Sheila Gray / Kerrie Stehl	Annual review; no substantive changes. Approved by MMC 04/16/2025.