Policy Title:	Bioengineered Skin	Number & Version:	UM_BIOENG_ SKIN V.4
Functional Unit:	Utilization Management	Effective Date:	09/01/2022
Policy Owner (Title):	Director, Utilization Management	Page Number:	1 of 8

I. POLICY STATEMENT and PURPOSE

The purpose of this policy is to describe the circumstances under which bioengineered skin or skin substitutes would or would not be considered medically necessary for members under the guidelines used for clinical review of organizational determinations.

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: An *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: Bioengineered skin is defined as an outer epidermal layer 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) sources (Ranweera, 2011).

Chronic Wounds: A chronic wound is one that has failed to progress through the phases of healing in an orderly and timely fashion and has shown no significant progress toward healing in 30 days (Couch, 2019). Chronic wounds include, but are not limited, to diabetic foot ulcers, venous leg ulcers, and pressure ulcers. Common features shared by each of these wounds 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) is at least as beneficial as existing and available medically appropriate alternatives.

V. OWNERSHIP & TRAINING

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

VI. PROTOCOLS / COVERAGE POLICY

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

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

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

Documentation must include:

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 also 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. REGULATORY REFERENCES / CITATIONS

CMS National Coverage Determinations (NCDs): None
CMS Local Coverage Determinations (LCDs): See table next
CMS Articles: See table next

ID	Title	Type	Contractor
L35041	Application of Bioengineered Skin Substitutes to Lower	LCD	Novitas Solutions, Inc.
A54117	Billing and Coding: Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds	Article	Novitas Solutions, Inc.
A56696	Billing and Coding: Wound Application of Cellular and/or Tissue Based Products (CTPs), Lower Extremities	Article	CGS Administrators, LLC
A55813	Response to Comments: Application of Skin Substitute Grafts for Treatment of DFU and VLU of Lower Extremities	Article	First Coast Service Options, Inc.
A55276	Response to Comments: Wound Application of Cellular and/or Tissue Based products (CTPs), Lower Extremities	Article	CGS Administrators, LLC
L36690	Wound Application of Cellular and/or Tissue Based Products	LCD	CGS Administrators, LLC

NOTE: A table on the last page of the policy lists the states covered by the contractor.

VIII. PROFESSIONAL REFERENCES / CITATIONS

1. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination: *L35041*. Accessed at: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=35041&ver=113&keyword=bioengineered%20skin&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1 on May 4, 2022.

2. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination: *L36690*. Accessed at: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=36690&ver=30&keyword=bioengineered%20skin&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1 on May 4, 2022.

3. Ather, S., Harding, K.G. Harding (2009). Advanced Textiles for Wound Care. Accessed at: https://www.sciencedirect.com/topics/engineering/acute-wound on May 4, 2022.

4. Couch, Kara (2019). Chronic Wounds. *Wound Source*. Accessed at: https://www.woundsource.com/print/patientcondition/chronic-wounds on May 4, 2022.

5. Frykberg, R. G., & Banks, J. (2015). Challenges in the Treatment of Chronic Wounds. *Advances in wound care*, *4*(9), 560–582. https://doi.org/10.1089/wound.2015.0635 . Accessed at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4528992/#:~:text=Chronic%20wounds%20are%20defined%20as,the%20inflammation%20phase%20of%20healing on May 4, 2022.

6. Ranaweera, Anoma (2011). Bioengineered Skin. DermNet NZ. Accessed at: https://dermnetnz.org/topics/bioengineered-skin on May 4, 2022.

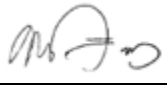
IX. RELATED POLICIES / PROCEDURES

None

X. ATTACHMENTS

LCDs as cited above

APPROVALS:

	Printed Name	Signature
Senior Medical Director, UM:	Michael Fusco, MD	
Corporate Chief Medical Officer (QMMC Chair):	Debbie Zimmerman, MD	

VERSION HISTORY:

Version #	Date	Author	Purpose/Summary of Major Changes
1	01/2019		Original Issue
2	01/2020	Bob Brault	Removed Essence logo and EHI references
			Removed the smoking cessation requirement
			Added Failed Response criteria to Coverage Criteria
			Added pre-service record in Documentation
			Included “Reapplication and continued use” in Limitations
			Added CPT and HCPCS codes to list of FDA approved products.
3	03/26/2021	Julie Braundmeier	General review, no substantive changes.
4	08/12/2022	Gina Vehige	Reformatting, general review, no substantive changes; approved at Lumeris QMMC 08122022

Medicare Administrative Contractors (MACs)
As of June 2021

MAC Jurisdiction	Processes Part A & Part B Claims for the following states/territories:	MAC
DME A	Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont	Noridian Healthcare Solutions, LLC
DME B	Illinois, Indiana, Kentucky, Michigan, Minnesota, Ohio, Wisconsin	CGS Administrators, LLC
DME C	Alabama, Arkansas, Colorado, Florida, Georgia, Louisiana, Mississippi, New Mexico, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, West Virginia, Puerto Rico, U.S. Virgin Islands	CGS Administrators, LLC
DME D	Alaska, Arizona, California, Hawaii, Idaho, Iowa, Kansas, Missouri, Montana, Nebraska, Nevada, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming, American Samoa, Guam, Northern Mariana Islands	Noridian Healthcare Solutions, LLC
5	Iowa, Kansas, Missouri, Nebraska	Wisconsin Physicians Service Government Health Administrators
6	Illinois, Minnesota, Wisconsin ****HH + H for the following states:** Alaska, American Samoa, Arizona, California, Guam, Hawaii, Idaho, Michigan, Minnesota, Nevada, New Jersey, New York, Northern Mariana Islands, Oregon, Puerto Rico, US Virgin Islands, Wisconsin and Washington	National Government Services, Inc.
8	Indiana, Michigan	Wisconsin Physicians Service Government Health Administrators
15	Kentucky, Ohio ****HH + H for the following states:** Delaware, District of Columbia, Colorado, Iowa, Kansas, Maryland, Missouri, Montana, Nebraska, North Dakota, Pennsylvania, South Dakota, Utah, Virginia, West Virginia, and Wyoming	CGS Administrators, LLC
E	California, Hawaii, Nevada, American Samoa, Guam, Northern Mariana Islands	Noridian Healthcare Solutions, LLC
F	Alaska, Arizona, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming	Noridian Healthcare Solutions, LLC
H	Arkansas, Colorado, New Mexico, Oklahoma, Texas, Louisiana, Mississippi	Novitas Solutions, Inc.
J	Alabama, Georgia, Tennessee	Palmetto GBA, LLC
K	Connecticut, New York, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont ****HH + H for the following states:** Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont	National Government Services, Inc.
L	Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania (includes Part B for counties of Arlington and Fairfax in Virginia and the city of Alexandria in Virginia)	Novitas Solutions, Inc.
M	North Carolina, South Carolina, Virginia, West Virginia (excludes Part B for the counties of Arlington and Fairfax in Virginia and the city of Alexandria in Virginia) ****HH + H for the following states:** Alabama, Arkansas, Florida, Georgia, Illinois, Indiana, Kentucky, Louisiana, Mississippi, New Mexico, North Carolina, Ohio, Oklahoma, South Carolina, Tennessee, and Texas	Palmetto GBA, LLC
N	Florida, Puerto Rico, U.S. Virgin Islands	First Coast Service Options, Inc.

**Also Processes Home Health and Hospice claims