Subject: Epifix and Other Skin Substitutes for Chronic Wound Healing in the Out-Patient Setting-IL		Original Effective Date: 8/21/20
Policy Number: IL 357	Revision Date(s):	
MCPC Approval Date: Corp policy 357 approved 4/23/20	Review Date:	

DISCLAIMER

This Molina clinical policy is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina clinical policy document and provide the directive for all Medicare members.[1]

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL [4]

Normal healthy skin provides a protective barrier against microbes, water loss, and ultraviolet light damage; helps with thermoregulation; and provides tactile sensations. 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. Chronic wounds have failed to pass through the normal healing process. A wound may be considered chronic if it has not entered the cellular migration and proliferation phase after 4 weeks (30 days) of standard treatment. The usual treatment or standard of care for established chronic wounds incorporates common principles that apply to managing all wound types:

- Remove necrotic tissue through debridement (typically sharp debridement).
- Maintain moisture balance by selecting the proper wound dressing to control exudate.
- Take measures to prevent or treat wound infections.
- Correct ischemia in the wound area.
- For venous leg ulcers, apply some form of compression.
- For diabetic foot ulcers, apply some form of offloading.

However, the methods for achieving each of these wound management principles varies among clinical practice guidelines and clinical studies. Using saline wet-to-dry gauze on any chronic wound is no longer considered part of standard wound care. Patients with chronic wounds, such as diabetic foot ulcers and venous leg ulcers, experience loss of function, pain, wound recurrence, and significant morbidity. Usual care for chronic wounds involves removing necrotic tissue, applying dressings that maintain a moist wound environment, treating wound infections, and restoring blood flow to the wound site. If these procedures fail to restore the healing process, additional therapies such as the application of skin substitutes to promote wound healing may be considered. The three most common uses for skin substitutes are for the treatment of venous leg ulcers, diabetic foot ulcers and burns.

Skin substitutes are proposed as a treatment to cover open chronic ulcers and promote wound healing, with the goals of preventing infection and amputation. They are thought to function by physically covering the wound and providing extracellular matrices to induce regeneration and immune function. Skin substitutes, also known as bioengineered, tissue-engineered, or artificial skin, are a heterogeneous group of products and can generally be classified into 3 main types: cellular (comprised of living cells), acellular (composed of synthetic materials or tissue from which living cells have been removed), or a combination of cellular and acellular components. Skin Substitutes are also categorized as tissue-engineered products that that may be biological (i.e., using human cells, animal cells, or both, in a scaffold of natural or synthetic extracellular matrices) or biosynthetic (i.e., with both biological and synthetic elements comprising the scaffold or matrix). There is no universally accepted classification system that allows for simple categorization of all the products that are commercially available. Each skin substitute has unique advantages and disadvantages. The type of skin substitute chosen depends upon the type of wound (i.e., acute, chronic), its etiology (e.g., trauma, chronic inflammation), the skin component that requires replacement (i.e., epidermis, dermis, or both), and need for permanence. Regardless of the source or classification, the skin substitute provides a matrix into which cells can migrate. Cells are placed in single or bilayer matrixes. Skin substitutes are developed from different materials and therefore are evaluated by different regulatory pathways as outlined below:

Food and Drug Administration (FDA): The term "skin substitutes" describes a heterogeneous collection of products, materials, and applications intended to heal open wounds; the various types are regulated differently.

- Premarket Approval (PMA): Devices that support or sustain human life or have the potential to cause risk of illness or injury are approved through the PMA process. Examples of products approved through the PMA process include (Apligraf [P950032A] and, Dermagraft [P000036A]) under product code MGR (dressing, wound and burn, interactive). For information on additional products, search by product code or applicant name in the Premarket Approval Database.[2]
- Premarket Clearance (510(k)): Devices that are deemed substantively equivalent to legally marketed predicate devices that do not require a PMA can be marketed under this designation. Examples of products reviewed in this evidence base had 510(k) clearance under product code KGN (dressing, wound, collagen) include (Oasis [K061711]), and clearance under product code FRO (dressing, wound, drug) (Talymed [K102002]). For information on additional products, search by product code or applicant name in the 510(k) Premarket Notification Database.[2]
- Public Health Service (PHS) 361 [21 Code of Federal Regulations (CFR) 1270 & 1271]: Human cells, tissues, and cellular and tissue-based products (HCT/Ps) can only be commercially prepared by licensed establishments (FDA). Examples of products include (TheraSkin; LifeNet Health). Search by establishment name or other information in the Human Cell and Tissue Establishment Registration database. [2]

At the time this MCP was developed and according to various databases there is an exhaustive list of skin substitute products and some are regulated by FDA and sold in the United States through the premarket approval (PMA) process, the 510(k) premarket submission process, or are regulated as human cells, tissues, and cellular and tissue-based products (HCT/Ps) derived from human cadaver skin and human placental membranes.[3] Any list of commercially available skin substitutes should not be considered comprehensive because the industry is expanding with ongoing FDA approvals, including skin substitute products currently in development or in the clinical trial phase. A technology assessment report from the Agency for Healthcare Research and Quality (AHRQ) from January 2019 listed 74 products classified as skin substitutes.[4]

Of the available skin substitutes, three systematic reviews and 22 RCTs (23 publications) examined the use of 16 distinct skin substitutes, including acellular dermal substitutes, cellular dermal substitutes, and cellular epidermal and dermal substitutes in diabetic foot ulcers, pressure ulcers, and venous leg ulcers. Most studies enrolled fewer than 25 patients per arm and measured outcomes up to 16 weeks. Of the 16 distinct skin substitutes, EpiFix was examined the most often (5

studies). Diabetic foot ulcers were examined in the majority of reviews and RCTs. Based upon this limited evidence, the following criteria have been developed.

Definitions

Acellular Products:

Dermal substitutes made from natural biological materials includes decellularized human cadaver dermis, human amniotic membranes, and animal tissue. These are the most common commercially available skin substitute products for the treatment or management of chronic wounds.

Cellular Products:

Autograft: A sample of the patient's own healthy skin is harvested and placed in the ulcer in split- or full-thickness from pinch or mesh grafts or patients' cells may be grown in a laboratory to form a thin film (cultured keratinocyte autograft, or cultured epidermal autograft), which can take 3 to 4 weeks; their downside is the potential for donor site morbidity.

Allografts: Skin or tissue is harvested from another human such as a cadaver or from cultured keratinocytes or cultured epidermal fibroblasts.

Xenograft: Skin or tissue is harvested from an animal with similar skin structure (usually pigs or cows).

Bioengineered are skin substitutes that may be completely synthetic (e.g., polymer matrix) or may be composite products (biosynthetic, i.e., contain 2 or more components, which may be biological or synthetic)

Human Cells, Tissues, or Cellular or Tissue-based Products (HCT/Ps): Products containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient.

RECOMMENDATION CLINICAL CRITERIA [2 4 44 45]

Please note that there may be state mandates and health plan regulations regarding coverage of skin substitutes therefore please check mandates and individual state health plan regulations before applying this MCP. Mandates and/or regulations supersede this MCP. Breast Reconstruction is NOT addressed in this MCP as there are Federal/State mandates that are applicable.

The purpose of this policy is to outline what specific products may be considered medically necessary.

RECOMMENDATION

Skin Substitutes other than EpiFix are considered experimental, investigational and unproven based on insufficient published evidence to assess their efficacy and/or impact on health outcomes.

Clinical Criteria:

EpiFix is medically necessary for the treatment of chronic foot ulcers when ALL of the following are met:

- ❑ Age equal to or greater than 18 years;
- ❑ Type I or II diabetes;
- ❑ Foot ulcer surface area* > 1 cm2 and< 25 cm2;
- ❑ Ulcer duration greater than 4 weeks, unresponsive to standard wound care;
- ❑ No clinical signs of infection;
- ❑ Ulcer does not probe to tendon, muscle, capsule or bone;

- ❑ HbA1c <12;
- ❑ Serum creatinine less than 3.0 mg/dl;
- ❑ Adequate circulation to affected extremity as demonstrated by dorsum transcutaneous oxygen test (TcPO2) greater than or equal 30 mmHg, or ankle-brachial index (ABI) between 0.7 and 1.2 or triphasic or biphasic Doppler arterial waveforms at the ankle of affected leg.

  **Surface area can be calculated by multiplying width in cm by length in cm.*

Continuation of therapy

- ❑ Continued treatment with EpiFix is **not medically necessary** when the ulcer fails to heal by ≥ 50% within the first 6 weeks of treatment. Treatment beyond 12 weeks is considered **not medically necessary** regardless of wound status.

- ❑ Treatment with EpiFix for any other types of nonhealing wounds is considered **investigational.**

SUMMARY OF MEDICAL EVIDENCE [12-41]

Diabetic foot ulcers are particularly burdensome and associated with markedly increased morbidity and mortality. They are associated with a high risk of limb amputation, with about 20% of moderate to severe diabetic foot ulcer infections leading to amputation. Mortality after amputation exceeds 70% at 5 years.

The overall quality of evidence evaluating EpiFix is low, however, among diabetic patients with chronic foot ulcers, although studies are limited, reported a greater reduction in mean wound size and higher proportion of wound healing among patients treated with EpiFix compared with those treated with standard of care.

The Agency for Healthcare Research and Quality (AHRQ) Technology Assessment (2020)[4]: This document describes skin substitute products commercially available in the United States used to treat chronic wounds, examine systems used to classify skin substitutes, identify and assess randomized controlled trials (RCTs), and suggest best practices for future studies. 74 commercially available skin substitutes were identified and categorized based on the Davison-Kolter classification system. Sixty-eight (89%) were categorized as acellular dermal substitutes, mostly replacements from human amniotic membranes and animal tissue sources. Three systematic reviews and 22 RCTs examined use of 16 distinct skin substitutes, including acellular dermal substitutes, cellular dermal substitutes, and cellular epidermal and dermal substitutes in diabetic foot ulcers and venous leg ulcers. Twenty-one ongoing clinical trials (all RCTs) examined an additional nine skin substitutes with similar classifications. Studies rarely reported clinical outcomes such as amputation, wound recurrence at least 2 weeks after treatment ended, and patient-related outcomes such as return to function, pain, exudate, and odor. The lack of studies examining the efficacy of most skin substitute products and the need for better-designed and -reported studies providing more clinically relevant data in this field are this Technical Brief's clearest implication.

CODING INFORMATION: THE CODES LISTED IN THIS CLINICAL POLICY ARE FOR INFORMATIONAL PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS A COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE AND INCLUSION OR EXCLUSION OF ANY CODES DOES NOT GUARANTEE COVERAGE. PROVIDERS SHOULD REFERENCE THE MOST UP-TO-DATE SOURCES OF PROFESSIONAL CODING GUIDANCE PRIOR TO THE SUBMISSION OF CLAIMS FOR REIMBURSEMENT OF COVERED SERVICES.

CPT® Codes	Description

15275	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq. cm; first 25 sq. cm or less wound surface area
15276	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq. cm; each additional 25 sq. cm wound surface area, or part thereof (List separately in addition to code for primary procedure)
HCPCS	**Description:**
Q4186	EpiFix, per sq. cm
CPT® Codes	**Description**
15277	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq. cm; first 100 sq. cm wound surface area, or 1% of body area of infants and children
15278	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq. cm; each additional 100 sq. cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)

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Revision/Review History:

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