Policy	MM-098
Effective Date	**09/01/2024**
Reviewed/Revised Date	05/11/2026
Next Review Date	05/11/2027
Origination Date	01/18/2025
Originated Department	Clinical Operations

Bio-Engineered Skin and Soft Skin Substitutes Policy

Audience
Medical Management

Purpose

Medical policies provide general support for applying Mountain Health Co-Op member policy document coverage decisions and must reference the member-specific benefit plan document. The terms of the member-specific Policy document may differ from the standard benefit plan on which this medical policy is based. If there is a conflict between a member-specific policy document and the Mountain Health Co-Op medical policy, the member-specific policy document supersedes this medical policy. Any person(s) applying this medical policy must identify member eligibility, the member-specific policy document, and related policies or guidelines before applying this medical policy, including the existence of any state or federal guidance. Mountain Health Co-Op medical policies are designed for informational purposes only and are not an authorization, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of the member-specific policy document coverage. Mountain Health Co-Op reserves the sole discretionary right to modify all policies and guidelines at any time.

Definition

Per the Current Procedural Terminology (CPT) definition, skin substitute grafts include non-autologous skin (dermal or epidermal, cellular and acellular) grafts (e.g., homograft, allograft), non-human skin substitute grafts (i.e., xenograft), and biological products that form a sheet scaffolding for skin growth. Skin substitute graft codes are not to be reported for application of non-graft wound dressings (e.g., gel, powder, ointment, foam, liquid) or injected skin substitutes. Bioengineered skin and soft tissue substitutes may be either acellular or cellular. Acellular products (e.g., dermis with cellular material removed) contain a matrix or scaffold composed of materials such as collagen, hyaluronic acid, and fibronectin. Acellular dermal matrix products can differ in

several ways, including species source (human, bovine, porcine), tissue source (e.g., dermis, pericardium, intestinal mucosa), additives(e.g., antibiotics, surfactants), hydration (wet, freeze-dried), and required preparation (multiple rinses, rehydration).

Cellular products contain living cells such as fibroblasts and keratinocytes within a matrix. The cells contained within the matrix may be autologous, allogeneic, or derived from other species (e.g., bovine, porcine). Skin substitutes may also be composed of dermal cells, epidermal cells, or a combination of both, and may provide growth factors to stimulate healing. Tissue-engineered skin substitutes can be used as either temporary or permanent wound coverings.

There are numerous potential applications for artificial skin and soft tissue products. One large category is nonhealing wounds, which potentially encompass diabetic neuropathic ulcers, vascular insufficiency ulcers, and pressure ulcers. A substantial minority of such wounds do not heal adequately with standard wound care, leading to prolonged morbidity and increased risk of mortality. For example, nonhealing lower-extremity wounds represent an ongoing risk for infection, sepsis, limb amputation, and death. Bioengineered skin and soft tissue substitutes have the potential to improve rates of healing and reduce secondary complications.

The preferred outcomes for the healing of lower-extremity ulcers and burn wounds are the percentage of individuals with complete wound healing and the time to complete wound healing. The percentage of individuals with 50% wound healing and time to 50% wound healing have also been considered appropriate outcomes for these conditions. The percent change in wound area at 4 weeks is predictive of complete healing at 12 weeks in individuals with diabetic foot ulcers. Thus, minimal improvement at 30 days can be considered as an indicator that a wound is unlikely to heal in individuals with comorbidities known to affect wound healing.

Peripheral nerve injuries may occur because of trauma or acute compression. The nerve injury may result in demyelination and/or axonal degeneration, which can disrupt sensory function, motor function, or both in the injured nerve. Several methods of nerve grafting have been investigated when a significant gap exists between the proximal and distal ends of the injured nerve. The use of autologous nerve grafts for bridging nerve gaps is the gold standard for nerve repair; however, it requires the sacrifice of healthy nerves. Nerve allograft transplantation from cadavers offers an alternative without the morbidities associated with nerve autografts, but these grafts require appropriate immunosuppression. The limitations of nerve autografting and allografting have led to the engineering of processed, acellular nerve allografts and nerve guidance conduits. Acellular nerve grafts are processed to remove antigenic factors such as Schwann cells and myelin to reduce immunogenicity, while retaining the natural basement membrane and three-dimensional extracellular matrix to guide axonal regeneration. Nerve conduits, also known as nerve tubulization, involve the use of nonabsorbable or absorbable single-lumen tubes, designed to bridge the gap of a sectioned nerve. The tube serves to protect the nerve during nerve regeneration and guides the regenerating axons to the distal nerve stump. A closed tube system may also facilitate the accumulation of neurotrophic factors.

Other situations in which bioengineered skin products might substitute for living skin grafts include certain postsurgical states (e.g., breast reconstruction) in which skin coverage is inadequate for the procedure performed, or for surgical wounds in individuals with compromised ability to heal.

Second- and third-degree burns are another indication in which artificial skin products may substitute for auto- or allografts. Certain primary dermatologic conditions that involve large areas of skin breakdown (e.g., bullous diseases) may also be conditions in which artificial skin products can be considered as substitutes for skin grafts. Acellular dermal matrix products are also being evaluated for the repair of other soft tissues, including rotator cuff repairs, following oral and facial surgeries, hernias, and other conditions.

Human amniotic membrane (HAM) consists of two conjoined layers, the amnion and chorion, and forms the innermost lining of the amniotic sac or placenta. When prepared for use as an allograft, the membrane is harvested immediately after birth, cleaned, sterilized, and either cryopreserved or dehydrated. Many products derived from amniotic, chorionic, and amniotic fluid, as well as the umbilical cord, are being studied for the treatment of various conditions, including chronic full-thickness diabetic lower-extremity ulcers, venous ulcers, knee osteoarthritis, plantar fasciitis, and ophthalmic conditions. The products are formulated as either patches, which can be applied as wound covers, or as suspensions, particulates, or connective tissue extractions, which can be injected or applied topically.

Fresh amniotic membrane contains collagen, fibronectin, and hyaluronic acid, along with a combination of growth factors, cytokines, and anti-inflammatory proteins such as interleukin-1 receptor antagonist. There is evidence that the tissue has anti-inflammatory, antifibroblastic, and antimicrobial properties. HAM is considered nonimmunogenic and has not been observed to cause a substantial immune response. It is believed that these properties are retained in cryopreserved HAM and dehydrated HAM products, resulting in a readily available tissue with regenerative potential. In support, one d-HAM product has been shown to elute growth factors into saline and stimulate the migration of mesenchymal stem cells both in vitro and in vivo.

HAM is an established treatment for corneal reconstruction and is being evaluated for the treatment of various conditions, including skin wounds, burns, leg ulcers, and the prevention of tissue adhesion in surgical procedures. Additional indications studied in preclinical models include tendonitis, tendon repair, and nerve repair. The availability of HAM opens the possibility of regenerative medicine for a wide variety of conditions.

Policy/Procedure

Mountain Health Co-Op may provide coverage for skin and soft tissue substitutes when it is determined to be medically necessary, provided the medical criteria and guidelines outlined below are met.

Mountain Health Co-Op considers the following products medically necessary for breast reconstruction.

- AlloDerm®
- AlloMend®
- Cortiva® [AlloMax™]
- DermACELL™
- DermaMatrix™ FlexHD®
- FlexHD® Pliable™

- Graftjacket®
-

Mountain Health Co-Op may consider the following as medically necessary for the treatment of chronic, non-infected, full-thickness diabetic ulcers in the lower extremities.

- AlloPatch®
- AmnioBand® Membrane
- Apligraf® (limited to no more than 4 applications per wound, applied weekly)
- Biovance®
- Dermagraft® (limited to no more than 8 applications per wound, applied weekly) EpiCord®
- Epifix® (limited to no more than 5 applications per wound, applied weekly)
- GrafixCore™ or GrafixPrime™
- Integra® Omnigraft Dermal Regeneration Matrix [Omnigraft]
- Integra Flowable Wound Matrix
- PuraPly
- TheraSkin®

Mountain Health Co-Op may consider the following as medically necessary for the treatment of chronic, noninfected, partial- or full-thickness lower-extremity skin ulcers due to venous insufficiency that have ot adequately responded to 1 month of conventional ulcer therapy:

- Oasis™ Wound Matrix
- Apligraf®

Mountain Health Co-Op may consider the following as medically necessary for the treatment of mitten-hand deformity in dystrophic epidermolysis bullosa, provided in accordance with the humanitarian device exemption (HDE) specifications (Humanitarian Device Exemption | FDA) of the U.S. Food and Drug Administration (FDA), when standard wound therapy has failed:

- OrCel™

Mountain Health Co-Op may consider Autologous **cell harvesting** as medically necessary for the treatment of any of the following:

- acute partial-thickness thermal burn wounds in individuals 18 years of age and older, or
- application in combination with meshed autografting for acute full-thickness thermal burn wounds in pediatric as well as adult individuals, or
- full-thickness skin defects after traumatic avulsion (e.g., degloving) or surgical excision (e.g., necrotizing soft tissue infection) or resection (e.g., skin cancer) in individuals 15 years of age and older.

Mountain Health Co-Op may consider the following as medically necessary for the treatment of **second degree burns** if it is provided in accordance with the specifications of the HDE (Humanitarian Device Exemption | FDA), premarket approval by the FDA (FDA Premarket Approval (PMA) or FDA Tissue & Tissue Products, or American Association of Tissue Banks

American Association of Tissue Banks:

Products with an * are only approved for burn indications.

- ActaShield™*
- Affinity™*
- AlloDerm®

- AlloPatch®
- AmnioBand®
- AmnioFix®*
- AmnioMatrix®*
- Amnioshield®*
- Aongen™ Collagen Matrix*
- Architect®*
- Aquacel®*
- Atlas Wound Matrix*
- Avagen Wound Dressing*
- Biobrane®*
- Bio-connekt®*
- Biovance®
- Clarix™*
- Collaguard®*
- CollaSorb™*
- CollaWound™ *
- Collieva™*
- Collexa® *
- Coreleader Colla-Pad *
- Cytal®*
- DermaCell®
- Dermadapt™*
- DermaMatrix™
- DermaPure™*
- Dermavest™*
- DressSkin *
- EndoForm™*
- Epicel®*
- EpiFix®
- Excellagen *
- EZ Derm®*
- FlexHD®
- FortaDerm™*
- GammaGraft™*
- GraftJacket™
- Grafix®*
- Helicoll™*
- Hyalomatrix®*
- Integra® Bilayer Wound Matrix*
- Integra Dermal Regeneration Template™
- LTM Wound Dressing*
- Kerecis* (formerly known as MariGen™*) MatriStem® UBM*
- Matrix Collagen Wound Dressing*
- Maxxeus™*
- Medline Collagen Wound Dressing*

- MicroMatrix*
- Neox®*
- NuShield™*
- Oasis™ Burn Matrix *
- OrCel™
- Primatrix™*
- PuraPly™*
- ReadiGraft®*
- Revitalon™*
- SIS Wound Dressing*
- SS Matrix™ *
- Stimulen™*
- StrataGraft®
- Suprathel®*
- Talymed®*
- TheraForm™*
- TheraSkin®*
- TransCyte™*
- Unite® Biomatrix*

Mountain Health Co-Op may consider the following products as medically necessary for the treatment of **third degree burns** if provided in accordance with the specifications of the HDE (Humanitarian Device Exemption | FDA), premarket approval by the FDA (FDA Premarket Approval (PMA) or FDA Tissue & Tissue Products, or American Association of Tissue Banks American Association of Tissue Banks:

Products with an * are only approved for burn indications.

- Epicel® (for the treatment of deep dermal or full-thickness burns comprising a total body surface area ≥30%)*
- Integra Dermal Regeneration Template™ (for the treatment of life threatening burn injuries)*
- TransCyte™ (for the treatment of full-thickness burn wounds in patients prior to autograft placement)*

Skin and soft tissue substitutes may be considered medically necessary for dural reconstruction and/or repair in spinal and/or cranial surgery (i.e., tumor resection, Chiari malformation decompression or trauma) when it is determined that a graft is needed for dural closure for FDA approved products.

Cadaver-derived skin grafts may be considered medically necessary for the management of traumatic skin wounds and burn wounds if the wound is too large for autograft.

Non-Covered Bio-engineered Skin Substitutes and Soft Skin Substitutes

Skin and soft tissue substitutes are not covered when the application site is infected, or the member has an allergy to the product.

All other skin and soft tissue substitutes, as well as applications, are considered investigational and non-covered unless specified in **the policy section.**

Mountain Health Co-Op may compare the cost-effectiveness of alternatives when determining which products to include in coverage.

Mountain Health Co-Op requires providers to use the most cost-effective skin substitute application and procedure available to contain costs. High-cost skin substitute applications may be denied as not medically necessary when a more cost-effective alternative is available that produces the same quality outcomes for the patient.

Claims and Billing Guidelines

When a portion of a drug/biological is discarded, the medical record must clearly document the amount administered and the amount wasted. The documentation must include the date, time, amount of medication wasted, and the reason for the wastage.

In situations where a portion of a single-use package must be discarded, payment will be made for the portion discarded, along with the amount applied up to the amount of the product on the package label. Medical record documentation must clearly indicate the information noted above.

Non-graft wound dressings or injected skin substitute codes are not used with skin replacement surgery application codes and are considered incorrect coding. Such products are bundled into other standard management procedures if medically necessary and not separately payable.

Claims reporting skin substitute grafts must contain the presence of an appropriate application CPT code.

Non-graft wound dressings or injected skin substitute codes are not used with skin replacement surgery application codes and are considered incorrect coding. Such products are bundled into other standard management procedures if medically necessary and not separately payable.

If the service for the application code is denied, the service for the skin substitute will also be denied.

The use of the JW modifier is required to identify unused drugs or biologicals from singleuse vials or packages that are appropriately discarded. The discarded amount shall be billed on a separate claim line using the JW modifier. Providers are required to document the discarded drug or biological in the patient's medical record.

Mountain Health Co-Op expects that where multiple sizes of a specific product are available, the size that best fits the wound with the least amount of wastage will be utilized.
The following list of products is considered investigational and non-covered for all indications (may not be all-inclusive):

AlloSkin™
Amnio-maxx™

Amniocore™
Amniocyte plus™
AmnioExcel®
Amniorepair™
Amniotext™
ArthroFlex™ (FlexGraft)
Avance™ Nerve Graft
AxoGuard® Nerve Connector (Axogen/AxioGuard®)
BioDexCel®
BioDfence™
Bionextpatch®
Carepatch®
Cogenex
CollaCare®
CollaCare® Dental
Collamend™
Conexa™
Corecyte™
Coretext™
CorMatrix®
Corplex™
Cryo-cord™
Cymetra®
Dermacyte®
Derm-maxx™
DermaSpan™
ENDURAgen™
ExpressGraft™
FlexiGraft®
HMatrix®
MatriDerm®
Mediskin®
MemoDerm™
Miroderm® biologic wound matrix
NeoForm Dermis™
NeuraGen™ Nerve Guide
NeuroMatrix™
NeuroMend™
NeuraWrap™ Nerve Protector
Pelvicol®/Pelvisoft®
Permacol™
Phasix™
Polycyte™
Procenta®
Puros® Dermis
RegenePro™

Repliform®
Repriza™
Strattice™
Surfactor®
SurgiMend®
TenoGlide™
TenSIX™ Acellular Dermal Matrix
TissueMend
TruSkin™
Veritas® Collagen Matrix
Xcellerate®
XCM Biologic/Medeor Matrix XenMatrix™ AB

Applicable CPT and HCPCS
15002
15003
15004
15005
15011
15012
15013
15014
15015
15017
15018
15040-15279
15777

HCPCS modifiers:

Q4100 – Q4108, Q4110 – Q4118, Q4121 – Q4128, Q4130, Q4132, Q4133 – Q4143, Q4145, Q4148, Q4150, Q4151, Q4153 – Q4157, Q4159, Q4160, Q4162, Q4163, Q4168 – Q4171, Q4173, Q4174, Q4177, Q4178, Q4181, Q4183 – Q4192, Q4194, Q4198, Q4199, Q4201, Q4202, Q4205, Q4206, Q4208 – Q4222, Q4224 – Q4242, Q4244 – Q4250, Q4254-Q4271, Q4279, Q4285 -Q4299, Q4300-Q4333, Q4346-Q4397, C1763, C1832, C5271- C5278, C9349, C9352 – C9356, C9358, C9360, C9361, C9363, C9364, A2001 – A2026, A2030 – A2039, A4100

JC: skin substitute used as a graft
JD: skin substitute not used as a graft
KX: more than four applications within a 12–16-week period

Vendors
• **MedCom** • **Health Plan Services (HPS)**

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Review/Revision/Approval History	
Date	Description
01/01/2025	**New Policy**
09/01/2024	**Effective Date**
05/11/2026	**Reviewed and Approved by Policy Committee**

Disclaimer

This document is for informational purposes only and should not be relied on in the diagnosis and care of individual patients. Medical and Coding/Reimbursement policies do not constitute medical advice, plan preauthorization, certification, an explanation of benefits, or a contract. Members should consult appropriate healthcare providers for medical advice, care, and treatment. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the member's benefit plan, effective when services are rendered.

The codes for treatments and procedures applicable to this policy are included for informational purposes. Including or excluding a procedure, diagnosis, or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as they apply to an individual member.

Mountain Health Co-Op makes no representations and accepts no liability regarding the content of any external information cited or relied upon in this policy. Mountain Health Co-Op updates its Coverage Policies regularly and reserves the right to amend these policies and give notice per State and Federal requirements.