MEDICAL POLICY

POLICY TITLE	**BIO-ENGINEERED SKIN AND SOFT TISSUE SUBSTITUTES**
POLICY NUMBER	**MP 1.158**

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**4/1/2026**

POLICY

Breast reconstructive surgery using allogeneic acellular dermal matrix products (including each of the following: AlloDerm®, Cortiva® [AlloMax™], DermACELL™, DermaMatrix™, FlexHD®, FlexHD® Pliable™) may be considered **medically necessary**:

- When there is insufficient tissue expander or implant coverage by the pectoralis major muscle and additional coverage is required,
- When there is viable but compromised or thin postmastectomy skin flaps that are at risk of dehiscence or necrosis; **or**
- The inframammary fold and lateral mammary folds have been undermined during mastectomy and reestablishment of these landmarks is needed.

Treatment of chronic, noninfected, full-thickness diabetic lower-extremity ulcers using the following tissue-engineered skin substitutes may be considered **medically necessary**:

- AlloPatch®[a]
- Apligraf®[b]
- Dermagraft®[b]
- Integra® Omnigraft™ Dermal Regeneration Matrix (also known as Omnigraft™) and Integra Flowable Wound Matrix
- mVASC®
- TheraSkin®.

Treatment of chronic, noninfected, partial- or full-thickness lower-extremity skin ulcers due to venous insufficiency, which have not adequately responded following a 1-month period of conventional ulcer therapy, using the following tissue-engineered skin substitutes may be considered **medically necessary**:

- Apligraf®[b]
- Oasis™ Wound Matrix[c].

Treatment of dystrophic epidermolysis bullosa using the following tissue-engineered skin substitutes may be considered **medically necessary**:

- OrCel™ (for the treatment of mitten-hand deformity when standard wound therapy has failed and when provided in accordance with the humanitarian device exemption [HDE] specifications of the U.S. Food and Drug Administration [FDA])[d].

Treatment of second- and third-degree burns using the following tissue-engineered skin substitutes may be considered **medically necessary**:

- Epicel® (for the treatment of deep dermal or full-thickness burns comprising a total body surface area ≥30% when provided in accordance with the HDE specifications of the FDA)[d]
- Integra® Dermal Regeneration Template[b].

[a] Banked human tissue.
[b] FDA premarket approval.
[c] FDA 510(k) clearance.
[d] FDA-approved under an HDE.

All other uses reviewed herein of the bioengineered skin and soft tissue substitutes listed above are considered **investigational** as there is insufficient evidence to support a conclusion concerning the general health outcomes or benefits associated with this procedure.

Cross-References:

MP 1.103 Reconstructive Breast Surgery/Management of Breast Implants
MP 1.159 Amniotic Membrane and Amniotic Fluid
MP 2.033 Recombinant and Autologous Platelet-Derived Growth Factors as a Treatment of Wound Healing and Other Conditions
MP 4.028 Wound and Burn Care and Specialized Treatment Centers

PRODUCT VARIATIONS

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies

DESCRIPTION/BACKGROUND

Skin and Soft Tissue 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 (ADM) products can differ in a number of ways, including as 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 dermal and epidermal cells, and may provide growth factors to stimulate healing. Bioengineered skin substitutes can be used as either temporary or permanent wound coverings.

Applications

There are a large number of potential applications for artificial skin and soft tissue products. One large category is nonhealing wounds, which potentially encompasses 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.

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 patients 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. ADM products are also being evaluated in the repair of other soft tissues including rotator cuff repair, following oral and facial surgery, hernias, and other conditions.

Regulatory Status

The FDA does not refer to any product or class of products as “; skin substitutes.” However, products commonly described as “; skin substitutes” are regulated by FDA under one of the four categories described below depending on the origin and composition of the product.

Human Cells, Tissues, and Cellular and Tissue-Based Products - Cells and tissues taken from human donors and transplanted to a recipient are regulated under PHS 361 [21 CFR 1270 & 1271]. This regulation describes the rules concerning the use of HCT/Ps for human medical purposes. The final rule, 21 CFR Part 1271, became effective on April 4, 2001, for human tissues intended for transplantation that are regulated under section 361 of the PHS Act and 21 CFR Part 1270. HCT/Ps are regulated by the Center for Biologics Evaluation and Research (CBER). The Center for Biologics Evaluation and Research is responsible for regulating biological and related products including blood, vaccines, allergenics, tissues, and cellular and gene therapies. Establishments producing HCT/Ps must register with FDA and list their HCT/Ps.

HCT/Ps establishments are not required to demonstrate the safety or effectiveness of their products and FDA does not evaluate the safety or effectiveness of these products.

Premarket Approval - Premarket approval (PMA) by FDA is the required process of scientific review to ensure the safety and effectiveness of Class III devices. Before Class III devices can be marketed, they must have an approved PMA application. Therefore, wound care products regulated under the PMA process will require evidence that they promote wound healing before they are approved for marketing.

510(k) Submissions - According to FDA documents a “510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent (SE), to a legally marketed device (21 CFR 807.92(a)(3)) that is not subject to PMA." Submitters must compare their device to one or more similar legally marketed devices and make and support their substantial equivalency claims. Unlike PMA, 510(k) confers reasonable assurance of safety and effectiveness via demonstration of substantial equivalence to a legally marketed device that does not require premarket approval. Therefore, wound care products regulated under the 510(k) process will not typically require clinical evidence to establish effectiveness in wound healing, as compared with products regulated under the PMA process in which substantial clinical evidence is always required.

Humanitarian Device Exemption (HDE) - An HDE is similar in both form and content to a premarket approval (PMA) application but is exempt from the effectiveness requirements of a PMA. An HDE application is not required to contain the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose. The applicant must demonstrate that no comparable devices are available to treat or diagnose the disease or condition, and that they could not otherwise bring the device to market. Humanitarian Device Exemption approval is based on evidence of probable benefit in a disease population occurring at a frequency of less than 4,000 patients per year in the United States.

Human Amniotic Membrane (HAM)

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 available using amnion, chorion, amniotic fluid, and umbilical cord are being studied for the treatment of a variety of conditions, including chronic full-thickness diabetic lower-extremity ulcers, venous ulcers, knee osteoarthritis, plantar fasciitis, and ophthalmic conditions. The products are formulated either as patches, which can be applied as wound covers, or as suspensions or 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 the tissue has anti-inflammatory, anti-fibroblastic, and antimicrobial properties. HAM is considered nonimmunogenic and has not been observed to cause a substantial immune response. It is believed these properties are retained in

cryopreserved HAM and HAM products, resulting in a readily available tissue with regenerative potential. In support, one 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.

Use of a HAM graft, which is fixated by sutures, is an established treatment for disorders of the corneal surface, including neurotrophic keratitis, corneal ulcers, and melts, following pterygium repair, Stevens-Johnson syndrome, and persistent epithelial defects. Amniotic membrane products that are inserted like a contact lens have more recently been investigated for the treatment of corneal and ocular surface disorders. Amniotic membrane patches are also being evaluated for the treatment of various other conditions, including skin wounds, burns, leg ulcers, and 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 an array of conditions.

Amniotic Fluid

Amniotic fluid surrounds the fetus during pregnancy and provides protection and nourishment. In the second half of gestation, most of the fluid is a result of micturition and secretion from the respiratory tract and gastrointestinal tract of the fetus, along with urea. The fluid contains proteins, carbohydrates, peptides, fats, amino acids, enzymes, hormones, pigments, and fetal cells. Use of human and bovine amniotic fluid for orthopedic conditions was first reported in 1927. Amniotic fluid has been compared with synovial fluid, containing hyaluronan, lubricant, cholesterol, and cytokines. Injection of amniotic fluid or amniotic fluid–derived cells is currently being evaluated for the treatment of osteoarthritis and plantar fasciitis.

Amniotic membrane and amniotic fluid are also being investigated as sources of pluripotent stem cells. Pluripotent stem cells can be cultured and are capable of differentiation toward any cell type. The use of stem cells in orthopedic applications is addressed in evidence review MP 2.080.

Regulatory Status

The U.S. Food and Drug Administration regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation, Title 21, parts 1270 and 1271. In 2017, the FDA published clarification of what is considered minimal manipulation and homologous use for human cells, tissues, and cellular and tissue-based products (HCT/Ps).

HCT/Ps are defined as human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. If an HCT/P does not meet the criteria below and does not qualify for any of the stated exceptions, the HCT/P will be regulated as a drug, device, and/or biological product, and applicable regulations and premarket review will be required.

RATIONALE

Breast Reconstruction

For individuals who are undergoing breast reconstruction who receive allogeneic acellular dermal matrix (ADM) products, the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, morbid events, functional outcomes, quality of life (QOL), and treatment-related morbidity. A systematic review found no difference in overall complication rates with ADM allograft compared with standard procedures for breast reconstruction. Reconstructions with ADM have been reported to have higher seroma, infection, and necrosis rates than reconstructions without ADM. However, capsular contracture and malposition of implants may be reduced. Thus, in cases where there is limited tissue coverage, the available evidence may inform patient decision making about reconstruction options. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Tendon Repair

For individuals who are undergoing tendon repair who receive GraftJacket, the evidence includes an RCT. Relevant outcomes are symptoms, morbid events, functional outcomes, QOL, and treatment-related morbidity. The RCT identified found improved outcomes with the GraftJacket ADM allograft for rotator cuff repair. Although these results were positive, additional studies with a larger number of patients is needed to evaluate the consistency of the effect. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Surgical Repair of Hernias or Parastomal Reinforcement

For individuals who are undergoing surgical repair of hernias or parastomal reinforcement who receive acellular collagen-based scaffolds, the evidence includes RCTs. Relevant outcomes are symptoms, morbid events, functional outcomes, QOL, and treatment-related morbidity. Several comparative studies including RCTs have shown no difference in outcomes between tissue-engineered skin substitutes and either standard synthetic mesh or no reinforcement. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Diabetic Lower-Extremity Ulcers

For individuals who have diabetic lower-extremity ulcers who receive AlloPatch, Apligraf, Dermagraft, Integra, mVASC, or TheraSkin, the evidence includes RCTs. Relevant outcomes are symptoms, change in disease status, morbid events, and QOL. Randomized controlled trials reporting complete wound healing outcomes with at least 12 weeks of follow-up have demonstrated the efficacy of AlloPatch (reticular ADM), Apligraf and Dermagraft (living cell therapy), Integra (biosynthetic), mVASC, and TheraSkin over the standard of care (SOC). The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have diabetic lower-extremity ulcers who receive ADM products other than AlloPatch, Apligraf, Dermagraft, Integra, mVASC, or TheraSkin, the evidence includes RCTs. Relevant outcomes are symptoms, change in disease status, morbid events, and QOL. Results

from a multicenter RCT showed some benefit of DermACELL that was primarily for the subgroup of patients who only required a single application of the ADM. Studies are needed to further define the population who might benefit from this treatment. Additional study with a larger number of subjects is needed to evaluate the effect of GraftJacket, DermACELL, Cytal, PriMatrix, and Oasis Wound Matrix, compared with current SOC or other advanced wound therapies. An RCT of Omega3 Wound (Kerecis) has been published and 2 larger RCTs are registered and reported as completed but have not been published. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Lower-Extremity Ulcers due to Venous Insufficiency

For individuals who have lower-extremity ulcers due to venous insufficiency who receive Apligraf or Oasis Wound Matrix, the evidence includes RCTs. Relevant outcomes are symptoms, change in disease status, morbid events, and QOL. Randomized controlled trials have demonstrated the efficacy of Apligraf living cell therapy and xenogeneic Oasis Wound Matrix over the SOC. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have lower-extremity ulcers due to venous insufficiency who receive bioengineered skin substitutes other than Apligraf or Oasis Wound Matrix, the evidence includes RCTs. Relevant outcomes are disease-specific survival, symptoms, change in disease status, morbid events, and QOL. In a moderately large RCT, Dermagraft was not shown to be more effective than controls for the primary or secondary endpoints in the entire population and was only slightly more effective than controls (an 8% to 15% increase in healing) in subgroups of patients with ulcer durations of 12 months or less or size of 10 cm or less. Additional studies with a larger number of subjects is needed to evaluate the effect of the xenogeneic PriMatrix skin substitute versus the current SOC. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Deep Dermal Burns

For individuals who have deep dermal burns who receive bioengineered skin substitutes (ie, Epicel, Integra Dermal Regeneration Template), the evidence includes RCTs. Relevant outcomes are symptoms, change in disease status, morbid events, functional outcomes, QOL, and treatment-related morbidity. Overall, few skin substitutes have been approved, and the evidence is limited for each product. Epicel (living cell therapy) has received U.S. Food and Drug Administration approval under a humanitarian device exemption for the treatment of deep dermal or full-thickness burns comprising a total body surface area of 30% or more. Comparative studies have demonstrated improved outcomes for biosynthetic skin substitute Integra Dermal Regeneration Template for the treatment of burns. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have deep dermal burns who are treated with the ReCell autologous cell harvesting device, the evidence includes RCTs. One RCT evaluated ReCell as an adjunct to meshed autologous skin grafting and the other compared ReCell head-to-head with skin grafting. Although the ReCell device was comparable to standard care on outcomes such as complete wound closure, confidence in the strength of the overall body of evidence is limited by individual study limitations and heterogeneity of populations, interventions, and outcome

measures across studies. Additional RCT evidence in the intended use population is needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Dystrophic Epidermolysis Bullosa

For individuals who have dystrophic epidermolysis bullosa who receive OrCel, the evidence includes a case series. Relevant outcomes are symptoms, change in disease status, morbid events, and QOL. OrCel was approved under a humanitarian drug exemption for use in patients with dystrophic epidermolysis bullosa undergoing hand reconstruction surgery, to close and heal wounds created by the surgery, including those at donor sites. Outcomes have been reported in a small series (e.g., 5 patients). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

DEFINITIONS/BACKGROUND

AUTOLOGOUS SKIN GRAFTS, also referred to as autografts, are permanent covers that use skin from different parts of the individual's body. These grafts consist of the epidermis and a dermal component of variable thickness. A split-thickness skin graft (STSG) includes the entire epidermis and a portion of the dermis. A full thickness skin graft (FTSG) includes all layers of the skin. Although autografts are the optimal choice for full thickness wound coverage, areas for skin harvesting may be limited, particularly in cases of large burns or venous stasis ulceration. Harvesting procedures are painful, disfiguring and require additional wound care.

ALLOGRAFTS which use skin from another human (e.g., cadaver) and **XENOGRAFTS** which use skin from another species (e.g., porcine or bovine) may also be employed as temporary skin replacements, but they must later be replaced by an autograft or the ingrowth of the patient's own skin.

BIOENGINEERED SKIN / CULTURED EPIDERMAL AUTOGRAFTS (CEA) are autografts derived from the patient's own skin cells grown or cultured from very small amounts of skin or hair follicle. Production time is prolonged. One such product is grown on a layer of irradiated mouse cells, bestowing some elements of a xenograft. Widespread usage has not been available due to limited availability or access to the technology.

BIOENGINEERED SKIN SUBSTITUTES OR CELLULAR AND TISSUE BASED PRODUCTS (CTPS), REFERRED TO AS SKIN SUBSTITUTES BY CMS, THE CURRENT PROCEDURAL TERMINOLOGY (CPT) AND THE HEALTHCARE COMMON PROCEDURE CODING MANUALS, have been developed in an attempt to circumvent problems inherent with autografts, allografts and xenografts. These constitute biologic covers for refractory wounds with full thickness skin loss secondary to 3rd degree burns or other disease processes such as diabetic neuropathic ulcers and the skin loss of chronic venous stasis or venous hypertension. The production of these biologic skin substitutes or CTPs varies by company and product but generally involves the creation of immunologically inert biological products containing protein, hormones or enzymes seeded into a matrix which may provide protein or growth factors proposed to stimulate or

facilitate healing or promote epithelization. A variety of biosynthetic and tissue-engineered skin substitution products marketed as **HUMAN SKIN EQUIVALENTS (HSE) OR CELLULAR OR TISSUE-BASED PRODUCTS (CTP)** are manufactured under an array of trade names and marketed for a variety of indications. All are procured, produced, manufactured, processed and promoted in sufficiently different manners to preclude direct product comparison for equivalency or superiority in randomized controlled trials. Sufficient data is available to establish distinct inferiority to human skin autografts and preclude their designation as skin equivalence.

BIOENGINEERED SKIN SUBSTITUTES or **CTPS** are classified into the following types:

- **Human skin allografts** derived from donated human skin (cadavers)
- **Allogeneic matrices** derived from human tissue (fibroblasts or membrane)
- **Composite matrices** derived from human keratinocytes, fibroblasts and xenogeneic collagen
- **Acellular matrices** derived from xenogeneic collagen or tissue

HUMAN SKIN ALLOGRAFTS are bioengineered from human skin components and human tissue which have had intact cells removed or treated to avoid immunologic rejection. They are available in different forms promoted to allow scaffolding, soft tissue filling, growth factors and other bioavailable hormonal or enzymatic activity.

ALLOGENEIC MATRICES are usually derived from human neonatal fibroblasts of the foreskin that may contain metabolically active or regenerative components primarily used for soft tissue support, though some have been approved for the treatment of full-thickness skin and soft tissue loss. Most are biodegradable and disappear after 3-4 weeks implantation.

COMPOSITE MATRICES are derived from human keratinocytes and fibroblasts supported by a scaffold of synthetic mesh or xenogeneic collagen. These are also referred to as human skin equivalent but are unable to be used as autografts due to immunologic rejection or degradation of the living components by the host. Active cellular components continue to generate bioactive compounds and protein that may accelerate wound healing and epithelial regrowth.

ACELLULAR MATRICES are derived from other than human skin and include the majority of bioengineered skin substitutes. All are composed of allogeneic or xenogeneic derived collagen, membrane, or cellular remnants proposed to simulate or exaggerate the characteristics of human skin. All propose to promote healing by the creation of localized intensification of an array of hormonal and enzymatic activity to accelerate closure by migration of native dermal and epithelial components, rather than function as distinctly incorporated tissue closing the skin defect.

DISCLAIMER

Capital Blue Cross' medical policies are used to determine coverage for specific medical technologies, procedures, equipment, and services. These medical policies do not constitute

medical advice and are subject to change as permitted by law or applicable clinical evidence from independent treatment guidelines. Treating providers are solely responsible for medical advice and treatment of members. These policies are not a guarantee of coverage or payment. Payment of claims is subject to a determination regarding the member's benefit program and eligibility on the date of service, and a determination that the services are medically necessary and appropriate. Final processing of a claim is based upon the terms of contract that applies to the members' benefit program, including benefit limitations and exclusions. If a provider or a member has a question concerning this medical policy, please contact Capital Blue Cross' Provider Services or Member Services.

CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary, associated procedures:

Procedure Codes				
15271	15272	15273	15274	15275
15276	15277	15278	15777	15011
15012	15013	15014	15015	15016
15017	15018	G0681	G0682	G0683
G0684				

Covered when medically necessary for breast reconstructive surgery using allogeneic acellular dermal matrix products:

Procedure Codes				
Q4116	Q4122	Q4128	Q4431	Q4432
Q4433				

Covered when medically necessary for treatment of chronic, noninfected, full-thickness diabetic lower-extremity ulcers:

Procedure Codes				
Q4101	Q4105	Q4106	Q4114	Q4121

Q4128	Q4431	Q4432	Q4433	

Covered when medically necessary for treatment of chronic, noninfected, partial- or full-thickness lower-extremity skin ulcers due to venous insufficiency:

Procedure Codes				
Q4101	Q4102			

Covered when medically necessary for treatment of dystrophic epidermolysis bullosa:

Procedure Codes				
Q4431	Q4432	Q4433		

Covered when medically necessary for treatment of treatment of second- and third-degree burns:

Procedure Codes				
Q4431	Q4432	Q4433		

Investigational:

Procedure Codes				
A2001	A2002	A2005	A2006	A2007
A2009	A2010	A2011	A2012	A2013
A2014	A2015	A2016	A2017	A2018
A2022	A2023	A2024	A2025	A2026
A2027	A2028	A2029	A2030	A2031
A2032	A2033	A2034	A2035	A2040
A2041	A2043	A2044	A2045	A4100
C9356	C9358	C9360	C9363	C9364
Q4103	Q4104	Q4107	Q4108	Q4110
Q4111	Q4112	Q4113	Q4115	Q4117
Q4118	Q4123	Q4125	Q4126	Q4127
Q4130	Q4134	Q4135	Q4136	Q4138
Q4140	Q4141	Q4142	Q4143	Q4146
Q4147	Q4149	Q4152	Q4158	Q4161
Q4164	Q4165	Q4166	Q4167	Q4168

Q4171	Q4175	Q4179	Q4182	Q4193
Q4194	Q4195	Q4196	Q4197	Q4198
Q4199	Q4200	Q4202	Q4203	Q4205
Q4206	Q4209	Q4216	Q4219	Q4220
Q4222	Q4224	Q4225	Q4226	Q4251
Q4252	Q4253	Q4256	Q4257	Q4258
Q4259	Q4260	Q4261	Q4262	Q4263
Q4264	Q4265	Q4266	Q4267	Q4268
Q4269	Q4270	Q4271	Q4272	Q4273
Q4274	Q4275	Q4276	Q4277	Q4278
Q4279	Q4280	Q4281	Q4282	Q4283
Q4284	Q4285	Q4286	Q4287	Q4288
Q4289	Q4290	Q4291	Q4292	Q4293
Q4294	Q4295	Q4296	Q4297	Q4298
Q4299	Q4300	Q4301	Q4302	Q4303
Q4304	Q4305	Q4306	Q4307	Q4308
Q4309	Q4310	Q4322	Q4331	Q4334
Q4335	Q4336	Q4337	Q4338	Q4339
Q4340	Q4341	Q4342	Q4343	Q4344
Q4345	Q4346	Q4347	Q4348	Q4349
Q4350	Q4351	Q4352	Q4353	Q4354
Q4355	Q4356	Q4357	Q4358	Q4359
Q4360	Q4361	Q4362	Q4363	Q4364
Q4365	Q4366	Q4367	Q4368	Q4369
Q4370	Q4371	Q4372	Q4373	Q4375
Q4376	Q4377	Q4378	Q4379	Q4380
Q4382	Q4418	Q4419	Q4421	Q4422
Q4423	Q4424	Q4425	Q4426	Q4435
Q4436	Q4440	V2790		

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POLICY HISTORY

MP 1.158	**10/24/2023 New Policy**
	03/15/2024 Administrative Update. Codes A2026, Q4305, Q4306, Q4307, Q4308, Q4309, Q4310 added for 04/01/2024.
	06/10/2024 Administrative Update. Deleted code Q4210. Added Q43111-Q4333. Effective 07/01/2024.
	07/11/2024 Consensus Review. No changes to the policy statement. References and coding reviewed and updated.
	09/18/2024 Administrative Update. New codes A2027-A2029; Q4334-Q4345 added effective 10/01/2024**.**
	12/11/2024 Administrative Update. Added Q4346-Q4353. Effective 01/01/2025.

POLICY TITLE	BIO-ENGINEERED SKIN AND SOFT TISSUE SUBSTITUTES
POLICY NUMBER	MP 1.158

	02/17/2025 Consensus Review. No changes to policy statement. References and coding reviewed and updated.
	03/12/2025 Administrative Update. Removed Q4231. Added A2030-A2035, Q4354-Q4367. Effective 04/01/2025
	6/12/2025 Major review. Updated statements to add medical criteria, other products moving to investigational stance. Reviewed and updated coding and references.
	12/12/2025 Administrative update. Added Q4431-Q4433
	03/12/2026 Administrative update. Added G0681-4, A2040-A2045, Q4418, Q4419, Q4421-Q4426, Q4435, Q4436, Q4440. Effective 04/01/2026.