Bioengineered Skin and Soft Tissue Substitutes and Amniotic Products

Published: 07/01/2025

Next Review: 02/2026

Last Review: 06/2025 ***Medicare Link(s) Revised:*** *07/01/2025*

IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member, including care that may be both medically reasonable and necessary.

The Medicare Advantage medical policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Some services or items may appear to be medically indicated for an individual, but may be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). In some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.

DESCRIPTION

Bioengineered skin and soft tissue substitutes may be derived from human tissue (autologous or allogeneic), nonhuman tissue, synthetic materials, or a composite of these materials. Amniotic products may be derived from amnion, chorion, amniotic fluid, and umbilical cord. There are many potential applications for these products, including breast reconstruction, chronic full-thickness diabetic lower-extremity ulcers, venous ulcers, severe burns, knee osteoarthritis, plantar fasciitis, and ophthalmic conditions.

MEDICARE ADVANTAGE POLICY CRITERIA

Notes:

- Product-specific HCPCS codes may be provided, where applicable. Skin substitute products without a specific code may use Q4100 (see Appendix I).
- This policy does not apply to dural substitutes used during surgical procedures involving the central nervous system (brain and spinal cord).

CMS Coverage Manuals*	None
National Coverage Determinations (NCDs)*	See "References"[1]
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles*	For amniotic and placental products used for non-wound indications: • Amniotic and Placental-Derived Product Injections and/or Applications for Musculoskeletal Indications, Non-Wound (L39118) *(companion article A58867 can be accessed directly from the LCD).*
Medical Policy Manual	*Medicare coverage guidance for the health plan's service area is not available for other uses of amniotic products or skin and soft tissue substitute products. Therefore, the health plan's medical policy is applicable.* Bioengineered Skin and Soft Tissue Substitutes and Amniotic Products, Medicine, Policy No. 170 *(see "NOTE" below)*

NOTE: If a procedure or device lacks scientific evidence regarding safety and efficacy and is considered investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. (*Medicare IOM Pub. No. 100-04, Ch. 23, §30 A*). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an ***objective, evidence-based process, based on authoritative evidence***. (*Medicare IOM Pub. No. 100-16, Ch. 4, §90.5*). The Medicare Advantage Medical Policy No. M-MED149 provides further details regarding the plan's evidence-assessment process (see Cross References).

POLICY GUIDELINES

REQUIRED DOCUMENTATION

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

- Indication to be treated (e.g., diabetic foot ulcers, venous stasis ulcers, knee osteoarthritis, plantar fasciitis, ophthalmic conditions, etc.);
- Specific product to be used and estimated quantities as appropriate based on wound size;
- Chart notes and medical records pertinent to the request.

BACKGROUND

Human Amniotic and Placental Products

Human amniotic membrane (HAM) consists of two conjoined layers, the amnion, and chorion, and forms the innermost lining of the amniotic sac or placenta. Amniotic fluid surrounds the fetus during pregnancy and provides protection and nourishment. The placenta develops within the uterus during pregnancy, providing oxygen and nutrients to the fetus, as well as removing waste products. It is attached to the uterine wall and the fetus's umbilical cord.

Many products available using placental, amnion, chorion, amniotic fluid, and umbilical cord components 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.

Other Bioengineered Skin and Soft Tissue Substitutes

Bioengineered skin and soft tissue substitutes may be either acellular or cellular.

Acellular dermal matrix (ADM) products (e.g., dermis with cellular material removed) contain a matrix or scaffold composed of materials such as collagen, hyaluronic acid, and fibronectin. These 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 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.

<u>Applications</u>

There are many potential applications for artificial skin and soft tissue products, but one common use is for nonhealing wounds, which can include diabetic neuropathic ulcers, vascular insufficiency ulcers, and pressure ulcers. In some instances, such wounds do not heal adequately with standard wound care, which can lead to prolonged morbidity and increased risk of mortality. Nonhealing lower-extremity wounds can create 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 applications for the use of bioengineered skin products which might be substituted 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

There are many artificial skin and soft-tissue products that are commercially available or in development. Information on specific products is available in a 2020 Technical Brief on skin substitutes for treating chronic wounds that was commissioned by the Agency for Healthcare Research and Quality.

The U.S. Food and Drug Administration (FDA) regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research. ADM and amniotic products are classified as banked human tissue and, therefore, not requiring FDA approval for homologous use. 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.

An HCT/P is regulated solely under section 361 of the PHS Act and 21 CFR Part 1271 if it meets all of the following criteria:

1. "The HCT/P is minimally manipulated;
2. The HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer’s objective intent;
3. The manufacture of the HCT/P does not involve the combination of the cells or tissues with another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of water, crystalloids, or the sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P; and
4. Either:
    i. The HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or
    ii. The HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and:
        a. Is for autologous use;
        b. Is for allogeneic use in a first-degree or second-degree blood relative; or
        c. Is for reproductive use."

The guidance provides the following specific examples of homologous and non-homologous use for amniotic membrane:

a. "Amniotic membrane is used for bone tissue replacement to support bone regeneration following surgery to repair or replace bone defects. This is not a homologous use because bone regeneration is not a basic function of amniotic membrane.

b. An amniotic membrane product is used for wound healing and/or to reduce scarring and inflammation. This is not homologous use because wound healing and reduction of scarring and inflammation are not basic functions of amniotic membrane.

c. An amniotic membrane product is applied to the surface of the eye to cover or offer protection from the surrounding environment in ocular repair and reconstruction procedures. This is homologous use because serving as a covering and offering protection from the surrounding environment are basic functions of amniotic membrane."

The FDA noted the intention to exercise enforcement discretion for the next 36 months after publication of the guidance.

In 2003, Prokera® was cleared for marketing by the FDA through the 510(k) process for the ophthalmic conformer that incorporates amniotic membrane (K032104). The FDA determined that this device was substantially equivalent to the Symblepharon Ring. The Prokera® device is intended “for use in eyes in which the ocular surface cells have been damaged, or underlying stroma is inflamed and scarred.” The development of Prokera®, a commercially available product, was supported in part by the National Institute of Health and the National Eye Institute.

AmnioClip (FORTECH GmbH) is a ring designed to hold the amniotic membrane in the eye without sutures or glue fixation. A mounting device is used to secure the amniotic membrane within the AmnioClip. The AmnioClip currently has CE approval in Europe.

Note that the issuance of a CPT/HCPCS code or FDA approval for a specific indication does not mean that a product or service is medically reasonable and necessary. The FDA determines safety and effectiveness of a device or drug but does not establish medical necessity. While Medicare may adopt FDA determinations regarding safety and effectiveness, Medicare or Medicare contractors determine whether or not the drug or device is reasonable and necessary for the Medicare population under §1862(a)(1)(A).

CROSS REFERENCES

Investigational (Experimental) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services, Medicine, Policy No. M-149

REFERENCES

1. NCD for *Porcine Skin and Gradient Pressure Dressings* (270.5) *(This NCD can be accessed directly from the* Medicare Coverage Database *website)* [Accessed 3/17/2027]
2. U.S. Food and Drug Administration. Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use. December 2017. [Accessed 3/17/2025]; Available from: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/regulatory-considerations-human-cells-tissues-and-cellular-and-tissue-based-products-minimal
3. Food and Drug Administration. 510(k) Summary: ProKera™ Bio-Tissue Inc. (K032104). 2003. [Accessed 3/17/2025]; Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf3/K032104.pdf

CODING

NOTE: While codes for skin substitute application (15271-15278, 15777) do not have pre-authorization requirements, they may be denied when used for the application of a product that does not meet medical necessity criteria.

Codes	Number	Description
CPT	15011	Harvest of skin for skin cell suspension autograft; first 25 sq cm or less
	15012	Harvest of skin for skin cell suspension autograft; each additional 25 sq cm or part thereof (list separately in addition to code for primary procedure)
	15013	Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; first 25 sq cm or less
	15014	Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; each additional 25 sq cm of harvested skin or part thereof (List separately in addition to code for primary procedure)
	15015	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, trunk, arms, legs; first 480 sq cm or less
	15016	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, trunk, arms, legs; each additional 480 sq cm or part thereof (List separately in addition to code for primary procedure)
	15017	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or mukltiple digits; first 480 sq cm or less
	15018	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or mukltiple digits; each additional 480 sq cm or part thereof (List separately in addition to code for primary procedure)
	15271	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
	15272	; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)
	15273	Application of skin substitute graft to trunk, arms, legs, 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
	15274	; 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)
	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	; 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)

	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	; 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)
	15777	Implantation of biologic implant (eg, acellular dermal matrix) for soft tissue reinforcement (ie, breast, trunk) (List separately in addition to code for primary procedure)
HCPCS	A2001	Innovamatrix ac, per square centimeter
	A2002	Mirragen advanced wound matrix, per square centimeter
	A2004	Xcellistem, 1 mg
	A2005	Microlyte matrix, per square centimeter
	A2006	Novosorb synpath dermal matrix, per square centimeter
	A2007	Restrata, per square centimeter
	A2008	Theragenesis, per square centimeter
	A2009	Symphony, per square centimeter
	A2010	Apis, per square centimeter
	A2011	Supra sdrm, per square centimeter
	A2012	Suprathel, per square centimeter
	A2013	Innovamatrix fs, per square centimeter
	A2014	Omeza collagen matrix, per 100 mg
	A2015	Phoenix wound matrix, per square centimeter
	A2016	Permeaderm b, per square centimeter
	A2017	Permeaderm glove, each
	A2018	Permeaderm c, per square centimeter
	A2019	Kerecis omega3 marigen shield, per square centimeter
	A2020	Ac5 advanced wound system (ac5)
	A2021	Neomatrix, per square centimeter
	A2022	Innovaburn or innovamatrix xl, per square centimeter
	A2023	Innovamatrix pd, 1 mg
	A2024	Resolve matrix or xenopatch, per square centimeter
	A2025	Miro3d, per cubic centimeter
	A2026	Restrata minimatrix, 5 mg
	A2027	Matriderm, per square centimeter
	A2028	Micromatrix flex, per mg
	A2029	Mirotract wound matrix sheet, per cubic centimeter
	A2030	Miro3d fibers, per milligram
	A2031	Mirodry wound matrix, per square centimeter
	A2032	Myriad matrix, per square centimeter
	A2033	Myriad morcells, 4 milligrams
	A2034	Foundation drs solo, per square centimeter
	A2035	Corplex p or theracor p or allacor p, per milligram
	A4100	Skin substitute, fda cleared as a device, not otherwise specified

	A6460	Synthetic resorbable wound dressing, sterile, pad size 16 sq in or less, without adhesive border, each dressing
	A6461	Synthetic resorbable wound dressing, sterile, pad size more than 16 sq in but less than or equal to 48 sq in, without adhesive border, each dressing
	C8002	Preparation of skin cell suspension autograft, automated, including all enzymatic processing and device components (do not report with manual suspension preparation)
	C9356	Tendon, porous matrix of cross-linked collagen and glycosaminoglycan matrix (TenoGlide Tendon Protector Sheet), per sq cm
	C9358	Dermal substitute, native, non-denatured collagen, fetal bovine origin (SurgiMend Collagen Matrix), per 0.5 square centimeters
	C9360	Dermal substitute, native, nondenatured collagen, neonatal bovine origin (SurgiMend Collagen Matrix), per 0.5 square centimeters
	C9363	Skin substitute (Integra Meshed Bilayer Wound Matrix), per sq cm
	C9364	Porcine implant, Permacol, per sq cm
	Q4100	Skin substitute, not otherwise specified
	Q4101	Apligraf, per sq cm
	Q4102	Oasis wound matrix, per sq cm
	Q4103	Oasis burn matrix, per sq cm
	Q4104	Integra bilayer matrix wound dressing (BMWD), per sq cm
	Q4105	Integra dermal regeneration template (DRT) or Integra Omnigraft dermal regeneration matrix, per sq cm
	Q4106	Dermagraft, per sq cm
	Q4107	GRAFTJACKET, per sq cm (Graftjacket)
	Q4108	Integra matrix, per sq cm
	Q4110	PriMatrix, per sq cm
	Q4111	GammaGraft, per sq cm
	Q4112	Cymetra, injectable, 1 cc
	Q4113	GRAFTJACKET XPRESS, injectable, 1 cc
	Q4114	Integra flowable wound matrix, injectable, 1 cc
	Q4115	AlloSkin, per sq cm
	Q4116	AlloDerm, per sq cm
	Q4117	HYALOMATRIX, per sq cm (Hyalomatrix)
	Q4118	MatriStem micromatrix, 1 mg
	Q4121	TheraSkin, per sq cm
	Q4122	DermACELL, DermACELL AWM or DermACELL AWM Porous, per sq cm (DermACELL®, DermACELL AWM®, or DermACELL AWM Porous®)
	Q4123	AlloSkin RT, per sq cm
	Q4124	OASIS ultra tri-layer wound matrix, per sq cm (Oasis Ultra Tri-layer Matrix)
	Q4125	ArthroFlex, per sq cm
	Q4126	MemoDerm, DermaSpan, TranZgraft or IntéguPly, per sq cm
	Q4127	Talymed, per sq cm
	Q4128	Flexhd, or allopatchhd, per square centimeter
	Q4130	Strattice TM, per sq cm
	Q4132	Grafix Core and GrafixPL Core, per sq cm (Grafix® Core, GrafixPL® Core, Grafix® Prime, GrafixPL® Prime, Stravix®, and StravixPL®)

Q4133	Grafix PRIME, GrafixPL PRIME, Stravix and StravixPL, per sq cm (Grafix® Core, GrafixPL® Core, Grafix® Prime, GrafixPL® Prime, Stravix®, and StravixPL®)
Q4134	HMatrix, per sq cm (hMatrix)
Q4135	Mediskin, per sq cm
Q4136	E-Z Derm, per sq cm (EZ-Derm)
Q4137	AmnioExcel, AmnioExcel Plus or BioDExcel, per sq cm (AmnioExcel®, AmnioExcel® Plus, and BioDExCel™)
Q4138	BioDFence dryflex, per sq cm (BioDfence™)
Q4139	AmnioMatrix or BioDMatrix, injectable, 1 cc (AmnioMatrix™ and BioDMatrix™)
Q4140	BioDFence, per sq cm (BioDfence™)
Q4141	Alloskin AC, per sq cm (Alloskin™ AC)
Q4142	Xcm biologic tissue matrix, per sq cm (XCM Biologic Tissue Matrix™)
Q4143	Repriza, per sq cm (Repriza®)
Q4145	Epifix, injectable, 1 mg (EpiFix® Injectable)
Q4146	Tensix, per sq cm (TenSIX™)
Q4147	Architect, Architect PX, or Architect FX, extracellular matrix, per sq cm (Architect™)
Q4148	Neox Cord 1K, Neox Cord RT, or Clarix Cord 1K, per sq cm (Clarix™ Cord 1K, NEOX™ Cord 1K, and NEOX™ Cord RT)
Q4149	Excellagen, 0.1 cc (Excellagen®)
Q4150	AlloWrap DS or dry, per sq cm
Q4151	AmnioBand or Guardian, per sq cm
Q4152	DermaPure per sq cm
Q4153	Dermavest and Plurivest, per sq cm
Q4154	Biovance, per sq cm
Q4155	Neox Flo or Clarix Flo, 1 mg
Q4156	Neox 100 or Clarix 100, per sq cm (Clarix™ 100 and Neox™)
Q4157	Revitalon, per sq cm
Q4158	Kerecis Omega3, per sq cm (Kerecis™ Omega3)
Q4159	Affinity, per sq cm
Q4160	NuShield, per sq cm
Q4161	bio-ConneKt wound matrix, per sq cm (Bio-ConneKt®)
Q4162	WoundEx Flow, BioSkin Flow, 0.5 cc (BioSkin® Flow and WoundEx® Flow)
Q4163	WoundEx, BioSkin, per sq cm (BioSkin® and WoundEx®)
Q4164	Helicoll, per sq cm (Helicoll™)
Q4165	Keramatrix or Kerasorb, per sq cm (Keramatrix® or Kerasorb®)
Q4166	Cytal, per sq cm (Cytal®)
Q4167	Truskin, per sq cm (TruSkin)
Q4168	AmnioBand, 1 mg
Q4169	Artacent wound, per sq cm (Artacent® Wound)
Q4170	Cygnus, per sq cm
Q4171	Interfyl, 1 mg
Q4173	PalinGen or PalinGen XPlus, per sq cm (PalinGen XPlus Membrane and PalinGen XPlus Hydromembrane)
Q4174	PalinGen or ProMatrX, 0.36 mg per 0.25 cc (ProMatrX ACF)

Q4175	Miroderm, per sq cm
Q4176	Neopatch, per sq cm (NeoPatch® and Therion)
Q4177	FlowerAmnioFlo, 0.1 cc (FlowerAmnioFlo™)
Q4178	FlowerAmnioPatch, per sq cm (FlowerAmnioPatch™)
Q4179	FlowerDerm, per sq cm (FlowerDerm™)
Q4180	Revita, per sq cm (Revita®)
Q4181	Amnio Wound, per sq cm
Q4182	Transcyte, per sq cm (TransCyte® [formerly Dermagraft-TC™])
Q4183	Surgigraft, per sq cm (SurgiGraft™)
Q4184	Cellesta or Cellesta Duo, per sq cm (Cellesta™, Cellesta™ Duo)
Q4185	Cellesta Flowable Amnion (25 mg per cc); per 0.5 cc (Cellesta™ Flowable)
Q4186	Epifix, per sq cm (EpiFix)
Q4187	Epicord, per sq cm (EpiCord)
Q4188	AmnioArmor, per sq cm (AmnioArmor™)
Q4189	Artacent AC, 1 mg (Artacent® AC)
Q4190	Artacent AC, per sq cm (Artacent® AC)
Q4191	Restorigin, per sq cm (Restorigin™)
Q4192	Restorigin, 1 cc (Restorigin™)
Q4193	Coll-e-derm, per sq cm
Q4194	Novachor, per sq cm
Q4195	PuraPly, per sq cm
Q4196	PuraPly AM, per sq cm
Q4197	PuraPly XT, per sq cm
Q4198	Genesis amniotic membrane, per sq cm
Q4200	SkinTE, per sq cm (SkinTE™)
Q4201	Matrion, per sq cm
Q4202	Keroxx (2.5g/cc), 1cc
Q4203	Derma-Gide, per sq cm
Q4204	XWRAP, per sq cm (XWRAP®)
Q4205	Membrane graft or membrane wrap, per sq cm
Q4206	Fluid Flow or Fluid GF, 1 cc (Fluid Flow™ and Fluid GF)
Q4208	Novafix, per sq cm (Novafix™)
Q4209	SurGraft, per sq cm (SurGraft®)
~~Q4210~~	~~Axolotl Graft or Axolotl DualGraft, per sq cm (Axolotl Graft™ and Axolotl DualGraft™)~~ (Deleted 07/01/2024)
Q4211	Amnion bio or Axobiomembrane, per sq cm (AxoBioMembrane™)
Q4212	AlloGen, per cc (AlloGen®)
Q4213	Ascent, 0.5 mg (Ascent™)
Q4214	Cellesta Cord, per sq cm (Cellesta™)
Q4215	Axolotl Ambient or Axolotl Cryo, 0.1 mg (Axolotl Ambient™ and Axolotl Cryo™)
Q4216	Artacent Cord, per sq cm (Artacent®)
Q4217	WoundFix, BioWound, WoundFix Plus, BioWound Plus, WoundFix Xplus or BioWound Xplus, per sq cm (WoundFix™, BioWound™, WoundFix™ Plus, BioWound™ Plus, WoundFix™ XPlus, BioWound™ XPlus, WoundFix™ XPlus Membrane, and BioWound™ XPlus Membrane)
Q4218	SurgiCORD, per sq cm

Q4219	SurgiGRAFT-DUAL, per sq cm (SurgiGRAFT-DUAL™)
Q4220	BellaCell HD or Surederm, per sq cm
Q4221	Amnio Wrap2, per sq cm (AmnbioWrap2)
Q4222	ProgenaMatrix, per sq cm (ProgenaMatrix™)
Q4224	Human health factor 10 amniotic patch (hhf10-p), per square centimeter
Q4225	Amniobind or dermabind tl, per square centimeter
Q4226	MyOwn Skin, includes harvesting and preparation procedures, per sq cm (MyOwn Skin™)
Q4227	AmnioCore™, per sq cm
Q4229	Cogenex Amniotic Membrane, per sq cm
Q4230	Cogenex Flowable Amnion, per 0.5 cc
Q4231	~~Corplex P, per cc (Corplex™ P)~~ (Deleted 04/01/2025)
Q4232	Corplex, per sq cm (Corplex™)
Q4233	SurFactor or NuDyn, per 0.5 cc (SurFactor® and NuDyn™)
Q4234	XCellerate, per sq cm
Q4235	AMNIOREPAIR or AltiPly, per sq cm (AMNIOREPAIR, AltiPly®)
Q4236	Carepatch, per square centimeter
Q4237	Cryo-Cord, per sq cm (Cryo-Cord™)
Q4238	Derm-Maxx, per sq cm
Q4239	Amnio-Maxx or Amnio-Maxx Lite, per sq cm (Amnio-Maxx™ and Amnio-Maxx™ Lite)
Q4240	CoreCyte, for topical use only, per 0.5 cc (CoreCyte™)
Q4241	Polycyte, for topical use only, per 0.5 cc (PolyCyte™)
Q4242	AmnioCyte Plus, per 0.5 cc (AmnioCyte™)
~~Q4244~~	~~Procenta, per 200 mg (Procenta®)~~
Q4245	AmnioText, per cc
Q4246	CoreText or ProText, per cc (CoreText™ and ProText™)
Q4247	Amniotext patch, per sq cm (AmnioText)
Q4248	Dermacyte Amniotic Membrane Allograft, per sq cm (Dermacyte® Amniotic Membrane Allograft)
Q4249	AMNIPLY, for topical use only, per sq cm
Q4250	AmnioAmp-MP, per sq cm (AmnioAMP-MP)
Q4251	Vim, per square centimeter
Q4252	Vendaje, per square centimeter
Q4253	Zenith amniotic membrane, per square centimeter
Q4254	Novafix DL, per sq cm
Q4255	REGUaRD, for topical use only, per sq cm
Q4256	Mlg-complete, per square centimeter
Q4257	Relese, per square centimeter
Q4258	Enverse, per square centimeter
Q4259	Celera dual layer or celera dual membrane, per square centimeter
Q4260	Signature apatch, per square centimeter
Q4261	Tag, per square centimeter
Q4262	Dual layer impax membrane, per square centimeter
Q4263	Surgraft tl, per square centimeter
Q4264	Cocoon membrane, per square centimeter

Q4265	Neostim tl, per square centimeter
Q2566	Neostim membrane, per square centimeter
Q4267	Neostim dl, per square centimeter
Q4268	Surgraft ft, per square centimeter
Q4269	Surgraft xt, per square centimeter
Q4270	Complete sl, per square centimeter
Q4271	Complete ft, per square centimeter
Q4272	Esano a, per square centimeter
Q4273	Esano aaa, per square centimeter
Q4274	Esano ac, per square centimeter
Q4275	Esano aca, per square centimeter
Q4276	Orion, per square centimeter
~~Q4277~~	~~Woundplus membrane or e-graft, per square centimeter~~ (Deleted 07/01/2024)
Q4278	Epieffect, per square centimeter
Q4279	Vendaje ac, per square centimeter
Q4280	Xcell amnio matrix, per square centimeter
Q4281	Barrera sl or barrera dl, per square centimeter
Q4282	Cygnus dual, per square centimeter
Q4283	Biovance tri-layer or biovance 3l, per square centimeter
Q4284	Dermabind sl, per square centimeter
Q4285	Nudyn dl or nudyn dl mesh, per square centimeter
Q4286	Nudyn sl or nudyn slw, per square centimeter
Q4287	Dermabind dl, per square centimeter
Q4288	Dermabind ch, per square centimeter
Q4289	Revoshield + amniotic barrier, per square centimeter
Q4290	Membrane wrap-hydro, per square centimeter
Q4291	Lamellas xt, per square centimeter
Q4292	Lamellas, per square centimeter
Q4293	Acesso dl, per square centimeter
Q4294	Amnio quad-core, per square centimeter
Q4295	Amnio tri-core amniotic, per square centimeter
Q4296	Rebound matrix, per square centimeter
Q4297	Emerge matrix, per square centimeter
Q4298	Amnicore pro, per square centimeter
Q4299	Amnicore pro+, per square centimeter
Q4300	Acesso tl, per square centimeter
Q4301	Activate matrix, per square centimeter
Q4302	Complete aca, per square centimeter
Q4303	Complete aa, per square centimeter
Q4304	Grafix plus, per square centimeter
Q4305	American amnion ac tri-layer, per square centimeter
Q4306	American amnion ac, per square centimeter
Q4307	American amnion ac, per square centimeter
Q4308	Sanopellis, per square centimeter
Q4309	Via matrix, per square centimeter
Q4310	Procenta, per 100 mg

Q4311	Acesso, per square centimeter
Q4312	Acesso ac, per square centimeter
Q4313	Dermabind fm, per square centimeter
Q4314	Reeva ft, per square cenitmeter
Q4315	Regenelink amniotic membrane allograft, per square centimeter
Q4316	Amchoplast, per square centimeter
Q4317	Vitograft, per square centimeter
Q4318	E-graft, per square centimeter
Q4319	Sanograft, per square centimeter
Q4320	Pellograft, per square centimeter
Q4321	Renograft, per square centimeter
Q4322	Caregraft, per square centimeter
Q4323	Alloply, per square centimeter
Q4324	Amniotx, per square centimeter
Q4325	Acapatch, per square centimeter
Q4326	Woundplus, per square centimeter
Q4327	Duoamnion, per square centimeter
Q4328	Most, per square centimeter
Q4329	Singlay, per square centimeter
Q4330	Total, per square centimeter
Q4331	Axolotl graft, per square centimeter
Q4332	Axolotl dualgraft, per square centimeter
Q4333	Ardeograft, per square centimeter
Q4334	Amnioplast 1, per square centimeter
Q4335	Amnioplast 2, per square centimeter
Q4336	Artacent c, per square centimeter
Q4337	Artacent trident, per square centimeter
Q4338	Artacent velos, per square centimeter
Q4339	Artacent vericlen, per square centimeter
Q4340	Simpligraft, per square centimeter
Q4341	Simplimax, per square centimeter
Q4342	Theramend, per square centimeter
Q4343	Dermacyte ac matrix amniotic membrane allograft, per square centimeter
Q4344	Tri-membrane wrap, per square centimeter
Q4345	Matrix hd allograft dermis, per square centimeter
Q4346	Shelter dm matrix, per square centimeter
Q4347	Rampart dl matrix, per square centimeter
Q4348	Sentry sl matrix, per square centimeter
Q4349	Mantle dl matrix, per square centimeter
Q4350	Palisade dm matrix, per square centimeter
Q4351	Enclose tl matrix, per square centimeter
Q4352	Overlay sl matrix, per square centimeter
Q4353	Xceed tl matrix, per square centimeter
Q4354	Palingen dual-layer membrane, per square centimeter
Q4355	Abiomend xplus membrane and abiomend xplus hydromembrane, per square centimeter

Q4356	Abiomend membrane and abiomend hydromembrane, per square centimeter
Q4357	Xwrap plus, per square centimeter
Q4358	Xwrap dual, per square centimeter
Q4359	Choriply, per square centimeter
Q4360	Amchoplast fd, per square centimeter
Q4361	Epixpress, per square centimeter
Q4362	Cygnus disk, per square centimeter
Q4363	Amnio burgeon membrane and hydromembrane, per square centimeter
Q4364	Amnio burgeon xplus membrane and xplus hydromembrane, per square centimeter
Q4365	Amnio burgeon dual-layer membrane, per square centimeter
Q4366	Dual layer amnio burgeon x-membrane, per square centimeter
Q4367	Amniocore sl, per square centimeter
Q4368	Amchothick, per square centimeter
Q4369	Amnioplast 3, per square centimeter
Q4370	Aeroguard, per square centimeter
Q4371	Neoguard, per square centimeter
Q4372	Amchoplast excel, per square centimeter
Q4373	Membrane wrap lite, per square centimeter
Q4375	Duograft ac, per square centimeter
Q4376	Duograft aa, per square centimeter
Q4377	Trigraft ft, per square centimeter
Q4378	Renew ft matrix, per square centimeter
Q4379	Amniodefend ft matrix, per square centimeter
Q4380	Advograft one, per square centimeter
Q4382	Advograft dual, per square centimeter

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.*

Appendix I. Products with No Specific HCPCS Code

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NOTE: This list was current at the time of publication, but changes may occur over time. This list may not be all-inclusive.

ACell® UBM Hydrated/Lyophilized Wound Dressing	MariGen™/Kerecis™ Omega3™
Aongen™ Collagen Matrix	MatriDerm®
AxoGuard®Nerve Protector (AxoGen)	Matrix HD™
Biobrane®/Biobrane-L	NeoForm™
CollaCare®	NuCel
CollaCare® Dental	Ologen™ Collagen Matrix

Appendix I. Products with No Specific HCPCS Code	Back to Criteria
Collagen Wound Dressing (Oasis Research)	Omega3 Wound
CollaGUARD®	Pelvicol®/PelviSoft®
CollaMend™	Permacol™
CollaWound™	PriMatrix® Dermal Repair Scaffold
Collexa®	Puros® Dermis
Colliea®	RegenePro™
Conexa™	Repliform®
Coreleader Colla-Pad	StrataGraft®
CorMatrix®	Suprathel®
Dermadapt™ Wound Dressing	SurgiMend®
DressSkin	TenoGlide™
Endoform Dermal Template™	TissueMend
ENDURAGen™	TheraForm™ Standard/Sheet
ExpressGraft™	Veritas® Collagen Matrix
Hyalomatrix® PA	XenMatrix™ AB