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Medicare Advantage Policy Manual

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Bioengineered Skin and Soft Tissue Substitutes and Amniotic Products

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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:

Medicine

- Product-specific HCPCS codes may be provided, where applicable. Skin substitute products without a specific code may use Q4100 (see <u>Appendix I</u>).
- 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 | For amniotic and placental products used for non- wound indications: | |
| Determinations (LCDs) and Articles* | Amniotic and Placental-Derived Product Injections and/or Applications for Musculoskeletal Indications, Non-Wound (<u>L39118</u>) (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 <u>must</u> 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.

Applications

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;
- 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 nonhomologous 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 <u>Medicare Coverage Database</u> website) [Accessed 3/17/2027]
- 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: <u>https://www.fda.gov/regulatoryinformation/search-fda-guidance-documents/regulatory-considerations-human-cellstissues-and-cellular-and-tissue-based-products-minimal
 </u>
- 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 preauthorization 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 mukItiple 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 mukItiple 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 |
|--|
| less than or equal to 48 sq in, without adhesive border, each dressing |
| |
| 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 InteguPly, 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 |
| 04474 | 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 | AxolotI Graft or AxolotI DualGraft, per sq cm (AxolotI Graft [™] and AxolotI |
| | 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 |
| Q4218 | Membrane, and BioWound [™] XPlus Membrane) 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 3I, 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

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 Specif | ic 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 |