Medicare Medical Policy

Skin and Tissue Substitutes

MEDICARE MEDICAL POLICY NUMBER: 371

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INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PRODUCT AND BENEFIT APPLICATION

☒ Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Service	Medicare Guidelines
Porcine Skin and Gradient Pressure Dressings	National Coverage Determination (NCD): Porcine Skin and Gradient Pressure Dressings (270.5)
Amniotic and Placental-Derived Product Injections and/or Applications for Musculoskeletal ***(Non-Wound)*** *Indications*	Local Coverage Determination (LCD): Amniotic and Placental-Derived Product Injections and/or Applications for Musculoskeletal Indications, Non-Wound (L39118) **NOTE:** For uses of these products **not** addressed by the LCD, see the Company medical policy below.
As of ~~2/12/2025~~ ~~4/13/2025~~ 1/1/2026**: *Skin and Tissue Substitutes for the Treatment of Diabetic Foot Ulcers (DFU) and Venous Leg Ulcers (VLU)* ***The effective date of this LCD has been delayed to 1/1/2026.*	LCD: Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers (L39764) **NOTES:** • This LCD includes information regarding general coverage requirements, definition of standard of care (SOC) wound treatment, utilization limits (e.g., quantity and frequency), and repeat treatments. • The focus of this LCD is skin substitute grafts/cellular and tissue-based products (CTP) for the treatment of DFU and VLU. The use of these products for indications ***other than DFU or VLU*** are **not** addressed by this LCD. However, the LCD states that the use of the products must still meet the reasonable and necessary threshold for coverage. This includes, but is not limited to, the requirement that these products be used in accordance with their United States (U.S.) Food and Drug Administration (FDA) approved intended use. The Company medical policy below is used to determine medical necessity for these products for indications ***other than DFU or VLU***.

Medicare Coverage Criteria: "MA organizations may create publicly accessible internal coverage criteria… when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs." *(§ 422.101(b)(6) – see Policy Guidelines below)*

- **Medicare Coverage Manuals:** Medicare does not have criteria for skin and tissue substitutes in a coverage manual.
- **National Coverage Determination (NCD):** With the exception of the products addressed by the above NCD, Medicare does not otherwise have an NCD for skin and tissue substitutes.
- **Noridian J-F Local Coverage Determination (LCD)/Local Coverage Article (LCA):** While there is a Noridian LCD which addresses the use of amniotic and placental-derived products, this LCD is for ***non-wound*** related indications. In addition, as of ~~April 13, 2025~~ January 1, 2026, there is expected to be an available Noridian LCD to address the use of skin substitute products for DFU and VLU. However, it is not available for use as of the most recent review of this policy. In addition, as of the most recent policy review, no Medicare Administrative Contractors (MACs) have LCDs for skin substitutes in general, or for amniotic and placental-derived products for ***wound*** related indications ***other than DFU or VLU*** (i.e., no LCDs exist for the use of these products in the context of breast reconstructive procedures, nasal reconstructive procedures, burn wounds, surgical or traumatic wounds, etc.).
- Therefore, in the absence of established Medicare coverage criteria in a manual, NCD, LCD, or other regulatory guidance for the health plan's service area, Company criteria below are applied for medical necessity decision-making. In this case, Medicare coverage criteria are considered "not fully established" as defined under CFR § 422.101(6)(i)(B) as the available Medicare coverage policies require coverage decisions beyond the NCD and LCD due to many uses of these products being out of scope.
- ***NOTE:*** *The summary of evidence, as well as the list of citations/references used in the development of the Company's internal coverage criteria, are publicly available and can be found using the Company medical policy link below [CFR § 422.101(6)(ii)(A) and (B)].*

Prior to ~~2/12/2025~~ ~~4/13/2025~~ **1/1/2026: *Skin and Tissue Substitutes for the Treatment of Diabetic Foot Ulcers (DFU) and Venous Leg Ulcers (VLU)* ***The effective date of the LCD has been delayed to 1/1/2026.* ***For all Dates of Service:*** *All Other Skin and/or Tissue Substitute Products or Indications* ***Not Otherwise Addressed****, Including the Use of These Products for Indications Not Otherwise Addressed*	Company medical policy for Skin and Tissue Substitutes I. These services may be considered **medically necessary** for Medicare when the Company medical policy criteria are met. II. These services are considered **not medically necessary** for Medicare Plan members when the Company medical policy criteria are not met. See *Policy Guidelines below.*

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

POLICY CROSS REFERENCES

- Cosmetic and Reconstructive Surgery, MP232
- Breast Reconstructive Surgery, Implant Management, and Reduction Mammoplasty, MP523

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

DOCUMENTATION REQUIREMENTS

Medical records documentation must clearly support the medical necessity of bioengineered skin and tissue substitutes. This would include the following:

- Characteristics of the wound/ulcer
- Wound/ulcer measurement
- Evidence of prior ineffective standard care, including the duration of this treatment
- The presence of qualifying or disqualifying conditions (i.e., HbA1C levels, ankle-brachial index [ABI])
- The name of the product, HCPCS code, size, and the amount of product used (or expected to be used).
- Any amount of wasted skin substitute grafts/CTP must be clearly documented in the procedure note with ALL the following information (at a minimum):
    - Date, time, and location of ulcer(s) treated.
    - Name of skin substitute grafts/CTP, package size and manufacturer's identification.
    - Approximate amount of product unit used.
    - Approximate amount of product unit discarded.
    - Reason for the wastage (including the reason for using a package size larger than was necessary for the size of the ulcer, if applicable).
    - Manufacturer's serial/lot/batch or other unit identification number of grafts/CTP material. When the manufacturer does not supply unit identification, the record must document such. The amount billed as wastage cannot exceed the price of the package.
- The HCPCS code of the applicable skin substitute grafts/CTP and the units billed must be consistent with the medical record regarding wound description and size.

Additional applications

According to LCA A59628, documentation must support medical necessity for the use of **additional** applications or extended episode of treatment time and include:

- Explanation of why extended time or additional applications is medically necessary for the specific patient.
- The current treatment plan resulting in wound healing with the expectation the wound will continue to heal with this plan. Documentation should include estimated time of extended treatment, number of additional applications anticipated, and plan of care if healing is not achieved as planned.
- Modifiable risk factors (e.g., metabolic, vascular, external irritation) are being addressed to improve likelihood of healing.
- Appropriate consultation for the diagnosis and management of venous related ulceration of the lower extremity.

MEDICARE AND MEDICAL NECESSITY

Only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*.

The local Medicare Administrative Contractor (MAC) – Noridian – has a local coverage determination (LCD) for Amniotic and Placental-Derived Product Injections and/or Applications for Musculoskeletal Indications, Non-Wound; however, because this LCD is specific to non-wound related indications, it will not be applicable to many situations where these products are utilized. In addition, the Noridian LCD for *Wound and Ulcer Care* specifically states it does not apply to skin substitutes used in wound care. Therefore, for any service or indication which is **not** addressed by a Medicare policy or guideline, the Company policy criteria will be applied.

MA organizations (MAOs) make medical necessity determinations based on coverage and benefit criteria, current standards of care, the member's unique personal medical history (e.g., diagnoses, conditions, functional status, co-morbidities, etc.), physician recommendations, and clinical notes, as well as involvement of a plan medical director, where appropriate. *(§ 422.101(c)(1))*

In addition:

> "MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question." *(§ 422.101(b)(6) and Medicare Managed Care Manual, Ch. 4, §90.5)*

The Plan's Medicare policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare's definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan's use of evidence-based processes for policy development.

The Noridian LCD for *Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers* (L39764) was intended to be effective in February 2025, then it was postponed to April 2025, then postponed again to January 1, 2026. The Plan will continue to monitor the progress of this LCD for future application.

However, at this time, since there are not fully established coverage criteria for skin or tissue substitute products used for non-DFU or non-VLU purposes available in applicable Medicare statutes, regulations, NCDs or LCDs, then Company medical policy criteria will be applied. See the Medicare Coverage Criteria table above for more information regarding the use of internal coverage criteria when Medicare coverage criteria are not fully established.

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

BILLING GUIDELINES AND CODING

GENERAL

See associated local coverage article (LCA) for additional coding and billing guidance:

- Local coverage article (LCA): Billing and Coding: Skin Substitutes Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers (A59628)

According to the LCA, per the Current Procedural Terminology (CPT) codebook definition, skin substitute grafts include the following:

- non-autologous **human** skin (dermal or epidermal, cellular, and acellular) grafts (e.g., homograft, allograft).
- **non-human** skin substitute grafts (i.e., xenograft), and
- biological products that form a sheet scaffolding for skin growth.

Skin substitute graft application codes are **not** to be reported for application of *non-graft* wound dressings (e.g., gel, powder, ointment, foam, liquid) *or injected* skin substitutes. *(LCA A59628)*

The removal of a current graft and/or simple cleansing of the wound and other surgical preparation services are included in the skin substitute grafts/CTP and HCPCS application codes. Active wound care management procedure codes (e.g., CPT code 97602) should **never** be reported with skin substitute grafts/CTP and HCPCS application codes.

According to the LCA, claims submitted with products using HCPCS code Q4100 or A4100 will be returned to the provider or rejected. The Medicare Advantage plan will not reject these claims, but rather, will review these using the above internal Company coverage criteria to assess medical necessity. Note that many products which may require the use of these "not otherwise specified" codes are not considered medically reasonable or necessary for any indication.

Multiple Wounds

According to the above LCA, skin substitute graft application codes are appropriately coded based upon total surface area of anatomical locations and not by number of ulcers. Therefore, the following is how to determine the surface area for application of skin substitute grafts for multiple wounds:

- Same anatomical area: The size of all wound areas within the same anatomic site described by the skin application code descriptors should be added together for a combined total surface area applied to that site.
- Different anatomic areas: The corresponding application code for each anatomical site should be billed with the composite wound surface area for each site, for each date of service.

Do not use modifier -59 on skin substitute graft application, or skin substitute product codes. *(LCA A59628)*

In addition, since coding for skin substitute graft application is based upon total surface area of the ulcers, the use of modifiers -50, -LT, and -RT would not be appropriate to append to skin substitute codes. *(LCA A59628)*

Associated or Related Services

Codes billed in association with the primary product code may also be denied if the product is not covered per the policy criteria above. Thus, when the skin substitute grafts/CTP HCPCS code is determined to be not medically necessary, the related application code will also be non-covered as not medically necessary. *(LCA A59628)*

Vocal Cord Paralysis Treatment

The following products are considered medically necessary and covered when billed for vocal cord paralysis treatment:

Products

− Q4112 (Cymetra)
− Q4114 (Integra flowable wound matrix)

Diagnosis codes

− J38.02 Paralysis of vocal cords and larynx, bilateral
− J38.00 Paralysis of vocal cords and larynx, unspecified
− J38.01 Paralysis of vocal cords and larynx, unilateral

CODES*		
Note: • Some codes which require prior authorization may have these requirements waived for select diagnosis codes (F64.0, F64.1, F64.8, or F64.9). • Please refer to the Company non-covered and prior authorization lists for additional information.		
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 of harvested skin
	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 multiple 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 multiple 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	Application of skin substitute graft to trunk, arms, legs, 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)
	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	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)
	15275	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
	15276	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)

	15277	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
	15278	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)
	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, 1mg
	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
	C1763	Connective tissue, non-human (includes synthetic)
	C1781	Mesh (implantable)

	C1832	Autograft suspension, including cell processing and application, and all system components
	C5271	Application of low cost 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
	C5272	Application of low cost skin substitute graft to trunk, arms, legs, 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)
	C5273	Application of low cost 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
	C5274	Application of low cost skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)
	C5275	Application of low cost 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
	C5276	Application of low cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure)
	C5277	Application of low cost 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
	C5278	Application of low cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)
	C8002	Preparation of skin cell suspension autograft, automated, including all enzymatic processing and device components (do not report with manual suspension preparation)
	C9354	Acellular pericardial tissue matrix of non-human origin (veritas), per square centimeter
	C9356	Tendon, porous matrix of cross-linked collagen and glycosaminoglycan matrix (tenoglide tendon protector sheet), per square centimeter
	C9358	Dermal substitute, native, non-denatured collagen, fetal bovine origin (surgimend collagen matrix), per 0.5 square centimeters
	C9360	Dermal substitute, native, non-denatured collagen, neonatal bovine origin (surgimend collagen matrix), per 0.5 square centimeters
	C9363	Skin substitute, integra meshed bilayer wound matrix, per square centimeter
	C9364	Porcine implant, permacol, per square centimeter
	C9399	Unclassified drugs or biologicals
	Q4100	Skin substitute, not otherwise specified
	Q4101	Apligraf, per square centimeter
	Q4102	Oasis wound matrix, per square centimeter
	Q4103	Oasis burn matrix, per square centimeter
	Q4104	Integra bilayer matrix wound dressing (bmwd), per square centimeter

	Q4105	Integra dermal regeneration template (drt) or integra omnigraft dermal regeneration matrix, per square centimeter
	Q4106	Dermagraft, per square centimeter
	Q4107	Graftjacket, per square centimeter
	Q4108	Integra matrix, per square centimeter
	Q4110	Primatrix, per square centimeter
	Q4111	Gammagraft, per square centimeter
	Q4112	Cymetra, injectable, 1 cc
	Q4113	Graftjacket xpress, injectable, 1 cc
	Q4114	Integra flowable wound matrix, injectable, 1 cc
	Q4116	Alloderm, per square centimeter
	Q4115	Alloskin, per square centimeter
	Q4117	Hyalomatrix, per square centimeter
	Q4118	Acell Matristem micromatrix, 1 mg
	Q4121	Theraskin, per square centimeter
	Q4122	Dermacell, per square centimeter
	Q4123	Alloskin rt, per square centimeter
	Q4124	Oasis ultra tri-layer wound matrix, per square centimeter
	Q4125	Arthroflex, per square centimeter
	Q4126	Memoderm, dermaspan, tranzgraft or integuply, per square centimeter
	Q4127	Talymed, per square centimeter
	Q4128	Flex hd, or allopatch hd, per square centimeter
	Q4130	Strattice tm, per square centimeter
	Q4132	Grafix core, per square centimeter
	Q4133	Grafix prime , grafixpl prime, stravix and stravixpl, per square centimeter
	Q4134	Hmatrix, per square centimeter
	Q4135	Mediskin, per square centimeter
	Q4136	Ez-derm, per square centimeter
	Q4137	Amnioexcel or biodexcel, per square centimeter
	Q4138	Biodfence dryflex, per square centimeter
	Q4139	Amniomatrix or biodmatrix, injectable, 1 cc
	Q4140	Biodfence, per square centimeter
	Q4141	Alloskin ac, per square centimeter
	Q4142	Xcm biologic tissue matrix, per square centimeter
	Q4143	Repriza, per square centimeter
	Q4145	Epifix, injectable, 1 mg
	Q4146	Tensix, per square centimeter
	Q4147	Architect, architect px, or architect fx, extracellular matrix, per square centimeter
	Q4148	Neox 1k, per square centimeter
	Q4149	Excellagen, 0.1 cc
	Q4150	Allowrap ds or dry, per square centimeter
	Q4151	Amnioband or guardian, per square centimeter
	Q4152	Dermapure, per square centimeter
	Q4153	Dermavest and plurivest, per square centimeter
	Q4154	Biovance, per square centimeter
	Q4155	Neoxflo or clarixflo, 1 mg
	Q4156	Neox 100 or clarix 100, per square centimeter
	Q4157	Revitalon, per square centimeter
	Q4158	Kerecis omega3, per square centimeter

	Q4159	Affinity, per square centimeter
	Q4160	Nushield, per square centimeter
	Q4161	Bio-connekt wound matrix, per square centimeter
	Q4162	Woundex flow, bioskin flow, 0.5 cc
	Q4163	Woundex, bioskin, per square centimeter
	Q4164	Helicoll, per square centimeter
	Q4165	Keramatrix, per square centimeter
	Q4166	Acell Cytal, per square centimeter
	Q4167	Truskin, per square centimeter
	Q4168	Amnioband, 1 mg
	Q4169	Artacent wound, per square centimeter
	Q4170	Cygnus, per square centimeter
	Q4171	Interfyl, 1 mg
	Q4173	Palingen or palingen xplus, per square centimeter
	Q4174	Palingen or promatrx, 0.36 mg per 0.25 cc
	Q4175	Miroderm, per square centimeter
	Q4176	Neopatch, per square centimeter
	Q4177	Floweramnioflo, 0.1 cc
	Q4178	Floweramniopatch, per square centimeter
	Q4179	Flowerderm, per square centimeter
	Q4180	Revita, per square centimeter
	Q4181	Amnio wound, per square centimeter
	Q4182	Transcyte, per square centimeter
	Q4183	Surgigraft, per square centimeter
	Q4184	Cellesta, per square centimeter
	Q4185	Cellesta flowable amnion (25 mg per cc); per 0.5 cc
	Q4186	Epifix, per square centimeter
	Q4187	Epicord, per square centimeter
	Q4188	Amnioarmor, per square centimeter
	Q4189	Artacent ac, 1 mg
	Q4190	Artacent ac, per square centimeter
	Q4191	Restorigin, per square centimeter
	Q4192	Restorigin, 1 cc
	Q4193	Coll-e-derm, per square centimeter
	Q4194	Novachor, per square centimeter
	Q4195	Puraply, per square centimeter
	Q4196	Puraply am, per square centimeter
	Q4197	Puraply xt, per square centimeter
	Q4198	Genesis amniotic membrane, per square centimeter
	Q4199	Cygnus matrix, per square centimeter
	Q4200	Skin te, per square centimeter
	Q4201	Matrion, per square centimeter
	Q4202	Keroxx (2.5g/cc), 1cc
	Q4203	Derma-gide, per square centimeter
	Q4204	Xwrap, per square centimeter
	Q4205	Membrane graft or membrane wrap, per square centimeter
	Q4206	Fluid flow or fluid GF, 1 cc
	Q4208	Novafix, per square cenitmeter
	Q4209	Surgraft, per square centimeter

	~~Q4210~~	**TERMED 6/30/2024** ~~Axolotl graft or axolotl dualgraft, per square centimeter~~
	Q4211	Amnion bio or Axobiomembrane, per square centimeter
	Q4212	Allogen, per cc
	Q4213	Ascent, 0.5 mg
	Q4214	Cellesta cord, per square centimeter
	Q4215	Axolotl ambient or axolotl cryo, 0.1 mg
	Q4216	Artacent cord, per square centimeter
	Q4217	Woundfix, BioWound, Woundfix Plus, BioWound Plus, Woundfix Xplus or BioWound Xplus, per square centimeter
	Q4218	Surgicord, per square centimeter
	Q4219	Surgigraft-dual, per square centimeter
	Q4220	BellaCell HD or Surederm, per square centimeter
	Q4221	Amniowrap2, per square centimeter
	Q4222	Progenamatrix, per square centimeter
	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 square centimeter
	Q4227	Amniocore, per square centimeter
	Q4229	Cogenex amniotic membrane, per square centimeter
	Q4230	Cogenex flowable amnion, per 0.5 cc
	~~Q4231~~	**TERMED 3/31/2025** ~~Corplex p, per cc~~
	Q4232	Corplex, per square centimeter
	Q4233	Surfactor or nudyn, per 0.5 cc
	Q4234	Xcellerate, per square centimeter
	Q4235	Amniorepair or altiply, per square centimeter
	Q4236	Carepatch, per square centimeter
	Q4237	Cryo-cord, per square centimeter
	Q4238	Derm-maxx, per square centimeter
	Q4239	Amnio-maxx or amnio-maxx lite, per square centimeter
	Q4240	Corecyte, for topical use only, per 0.5 cc
	Q4241	Polycyte, for topical use only, per 0.5 cc
	Q4242	Amniocyte plus, per 0.5 cc
	~~Q4244~~	**TERMED 3/31/2024** ~~Procenta, per 200 mg~~
	Q4245	Amniotext, per cc
	Q4246	Coretext or protext, per cc
	Q4247	Amniotext patch, per square centimeter
	Q4248	Dermacyte amniotic membrane allograft, per square centimeter
	Q4249	Amniply, for topical use only, per square centimeter
	Q4250	Amnioamp-mp, per square centimeter
	Q4251	Vim, per square centimeter
	Q4252	Vendaje, per square centimeter
	Q4253	Zenith amniotic membrane, per square centimeter
	Q4254	Novafix dl, per square centimeter
	Q4255	Reguard, for topical use only, per square centimeter
	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
	Q4266	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~~	**TERMED 6/30/2024** ~~Woundplus membrane or e-graft, per square centimeter~~
	Q4278	Epieffect, 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
	Q4279	Vendaje ac, 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	Amniocore 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, 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

***Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

None

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
3/2023	New Medicare Advantage medical policy
4/2023	Q2 2023 code update
7/2023	Q3 2023 code update
10/2023	Q4 2023 code update
1/2024	Q1 2024 code update
2/2024	Annual review, no change to criteria
4/2024	Updated codes to match prior authorization list and Q2 2024 code update

7/2024	Interim update and Q3 2024 code update; add LCD L39118
10/2024	Interim update and Q4 2024 code update; update CMS regulatory language
1/2025	Q1 2025 code update
3/2025	Annual review; add LCD L39764 (Noridian changed the effective date from 2/12/2025 to 4/13/2025)
4/2025	Interim update and Q2 2025 code updates (Noridian changed the effective date from 4/13/2025 to 1/1/2026)
5/2025	Interim update to align with postponed MAC LCD