

# Medicare Medical Policy

## Skin and Tissue Substitutes

MEDICARE MEDICAL POLICY NUMBER: 371

**Effective Date:** 4/1/2025

**Last Review Date:** 1/2025

**Next Annual Review:** 1/2026

|                                     |    |
|-------------------------------------|----|
| MEDICARE COVERAGE CRITERIA.....     | 2  |
| POLICY CROSS REFERENCES.....        | 4  |
| POLICY GUIDELINES.....              | 4  |
| REGULATORY STATUS.....              | 6  |
| BILLING GUIDELINES AND CODING ..... | 6  |
| REFERENCES.....                     | 16 |
| POLICY REVISION HISTORY.....        | 16 |

**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  |
|--|--|
| <i>Porcine Skin and Gradient Pressure Dressings</i>  | National Coverage Determination (NCD): Porcine Skin and Gradient Pressure Dressings ( <a href="#">270.5</a> )  |
| <i>Amniotic and Placental-Derived Product Injections and/or Applications for Musculoskeletal (Non-Wound) Indications</i>   | Local Coverage Determination (LCD): Amniotic and Placental-Derived Product Injections and/or Applications for Musculoskeletal Indications, Non-Wound ( <a href="#">L39118</a> )<br><br><b>NOTE:</b> For uses of these products <b>not</b> addressed by the LCD, see the Company medical policy below.  |
| <b>As of 2/12/2025 4/13/2025 1/1/2026**:</b> <i>Skin and Tissue Substitutes for the Treatment of Diabetic Foot Ulcers (DFU) and Venous Leg Ulcers (VLU)</i><br><br><i>**The effective date of this LCD has been delayed to 1/1/2026.</i> | LCD: Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers ( <a href="#">L39764</a> )<br><br><b>NOTES:</b> <ul style="list-style-type: none"><li>• 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.</li><li>• 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 <b>other than DFU or VLU</b> are <b>not</b> 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 <b>other than DFU or VLU</b>.</li></ul> |

**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 also a Noridian LCD which addresses the use of skin substitute products for DFU and VLU. 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.

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.



|            |              |  |
|------------|--------------|--|
| <b>CPT</b> | <b>15011</b> | Harvest of skin for skin cell suspension autograft; first 25 sq cm or less   |
|            | <b>15012</b> | 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)   |
|            | <b>15013</b> | 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  |
|            | <b>15014</b> | 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)  |
|            | <b>15015</b> | 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  |
|            | <b>15016</b> | 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)  |
|            | <b>15017</b> | 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  |
|            | <b>15018</b> | 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)  |
|            | <b>15271</b> | 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   |
|            | <b>15272</b> | 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)  |
|            | <b>15273</b> | 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   |
|            | <b>15274</b> | 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)   |
|            | <b>15275</b> | 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   |
|            | <b>15276</b> | 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)  |
|            | <b>15277</b> | 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   |
|            | <b>15278</b> | 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)   |
| <b>HCPCS</b> | A2001 | Innovamatrix ac, per square centimeter   |
|              | A2002 | Mirrugen advanced wound matrix, per square centimeter  |
|              | A2004 | Xcellitem, 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            | Restorign, per square centimeter  |
|  | Q4192            | Restorign, 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 centimeter  |
|  | Q4209            | Surgraft, per square centimeter   |
|  | <del>Q4210</del> | <b>TERMED 6/30/2024</b><br><del>Axolotl graft or axolotl dualgraft, per square centimeter</del> |
|  | 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   |
| <del>Q4231</del> | <b>TERMED 3/31/2025</b><br><del>Corplex p, per cc</del>   |
| 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  |
| <del>Q4244</del> | <b>TERMED 3/31/2024</b><br><del>Procenta, per 200 mg</del>  |
| 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            | Amniplly, 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   |
|  | <del>Q4277</del> | <b>TERMED 6/30/2024</b><br><del>Woundplus membrane or e-graft, per square centimeter</del> |
|  | 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 centimeter   |
| 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 | Choriplay, per square centimeter  |
| Q4360 | Amchoplast fd, per square centimeter  |



|  |       |   |
|--|-------|---|
|  | Q4361 | Epipress, 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) |