



Skin Substitute Grafts, Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers Policy

Effective May 1, 2025, the *Skin Substitute Grafts, Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers* policy will replace the following existing policies:

- *Tissue-Engineered Skin Substitutes for Medicare Plan Members*
- *Tissue-Engineered Skin Substitutes for Members other than Medicare Plan Members*

The new policy is attached. You can also find it when you log in at **hap.org** and select *Benefit Admin Manual* under *More*.



Skin Substitute Grafts, Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers

DESCRIPTION

FUTURE EFFECTIVE 05/01/2025

This policy addresses the use of dermal or epidermal substitute tissue of human or non-human origin, with or without bioengineered or processed elements, with or without metabolically active elements, with a designated use as coverage for a superficial skin deficit that has persisted, despite optimal wound care for a period of 4 weeks or greater.

These products are FDA regulated under PHS 361 [21 CFR 1270 & 1271]: Human cells, tissues, and cellular and tissue-based products (HCT/Ps). Creates a unified registration and listing system for establishments that manufacture HCT/Ps and establishes donor eligibility, current good tissue practice, and other procedures to prevent the introduction, transmission, and spread of communicable diseases by HCT/Ps. Among other criteria, HCT/Ps are required to be minimally manipulated and intended for homologous use. Homologous use means the repair, reconstruction, replacement, or supplementation of a recipient's cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor. In the case of amniotic membranes, homologous use includes serving as a selective barrier, protection and covering of a wound.

Liquid or gel preparations are not considered grafts. Their fluidity does not allow graft placement and stabilization of the product on the wound.

Note: The application of skin substitute graft/Cellular tissue-based products (CTP) for indications other than Diabetic Foot Ulcers and Venous Leg Ulcers is not addressed by this policy.

Please Note:

Any specific products/tests referenced in this policy are just examples and are intended for illustrative purposes only. It is not intended to be a recommendation of one product over another and is not intended to represent a complete listing of all products available. These examples are contained in a "such as" or "e.g." statement in parentheses. The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

RELEVANT CODES - Application Procedure Codes for Skin Substitute Products.

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)
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)

RELEVANT CODES - Skin Substitute Grafts/CTP codes for Diabetic Foot Ulcers (DFU) or Venous Leg Ulcers (VLU)

Q4101	Apligraf, per sq cm
Q4102	Oasis wound matrix, per sq cm
Q4106	Dermagraft, per sq cm
Q4151	AmnioBand or Guardian, per sq cm
Q4186	Epifix, per sq cm

RELEVANT CODES - Skin Substitute Grafts/CTP codes for Diabetic Foot Ulcers (DFU) ONLY

A2019	Kerecis omega3 marigen shield, per square centimeter
Q4105	Integra dermal regeneration template (drt) or integra omnigraft dermal regeneration matrix, per square centimeter
Q4107	Graftjacket, per sq cm
Q4110	PriMatrix, per sq cm
Q4121	TheraSkin, per sq cm
Q4122	DermACELL, DermACELL AWM or DermACELL AWM Porous, per sq cm
Q4128	FlexHD, or AllopatchHD, per sq cm
Q4133	Grafix PRIME, GrafixPL PRIME, Stravix and StravixPL, per sq cm
Q4158	Kerecis Omega3, per sq cm
Q4159	Affinity, per sq cm
Q4160	NuShield, per sq cm
Q4187	Epicord, per sq cm
Q4203	Derma-Gide, per sq cm

COVERAGE CRITERIA

Skin substitute grafts or cellular tissue-based products for the treatment of Diabetic Foot ulcers and Venous leg ulcers are covered when ALL the following are met:

1. Skin substitute grafts or cellular tissue-based products:

- a. Products must be used in accordance with their intended use as approved/regulated by the United States (U.S.) Food and Drug Administration (FDA). Skin substitute graft/CTP are regulated by one of the following:
 - i. FDA premarket approval (PMA) process,
 - ii. FDA 510(k) premarket notification process,
 - iii. FDA regulations for human cells, tissues, and cellular and tissue-based products (HCT/Ps).
- b. To qualify as skin substitute graft/CTP the product must meet BOTH the following:
 - i. ONE of the following:
 - A. A non-autologous human cellular or tissue product (e.g., dermal or epidermal, cellular and acellular, homograft OR allograft),
 - B. Non-human cellular and tissue product (i.e., xenograft),
 - C. Biological product (synthetic or xenogeneic) applied as a sheet, allowing scaffold for skin growth, intended to remain on the recipient and grow in place or allow recipient's cells to grow into the implanted graft material
 - c. Supported by high-certainty supporting evidence to demonstrate the product's safety, effectiveness, and positive clinical outcomes in the function as a graft for DFU and/or VLU.
 - i. NOTE: Substantial equivalence to predicate products does not allow sufficient evidence to support similar cleared products.

2. Eligible wounds: HAP covers application of the FDA approved Skin Substitute or Cellular or Tissue Based Product (CTP) when the following criteria are met:

- a. Member has ONE of the following:
 - i. A chronic, non-infected diabetic foot ulcer (DFU) that failed to achieve at least 50% ulcer area reduction with documented standard of care (SOC) treatment (outlined below) for a minimum of 4 weeks with documented compliance.
 - ii. A chronic, non-infected venous leg ulcer (VLU) that failed to respond to documented SOC treatment (outlined below) for a minimum of 4 weeks with documented compliance.
- b. Member's medical record reflects that the Member is under the care of a qualified provider for the treatment of the systemic disease process(es) etiologic for the condition (e.g., venous insufficiency, diabetes, neuropathy)

3. Documentation of Failed Response: The Member's medical record must include ALL the following:

- a. Comprehensive patient assessment (history, exam, vascular assessment) and diagnostic tests indicated as part of the implemented treatment plan, including:
 - i. **Diabetic foot ulcer (DFU):** assessment of Type 1 or Type 2 diabetes and management history with attention to certain comorbidities (e.g., vascular disease, neuropathy, osteomyelitis), review of current blood glucose levels/hemoglobin A1c (HbA1c), diet and nutritional status, activity level, physical exam that includes assessment of skin, ulcer, and vascular perfusion), and assessment of off-loading device or use of appropriate footwear.
 - ii. **Venous leg ulcer (VLU):** assessment of clinical history (that includes prior ulcers, higher body mass index, history of pulmonary embolism or superficial/deep venous thrombosis, higher number of pregnancies, and physical inactivity), physical exam (edema, skin changes and vascular competence*), evaluation of superficial or deep venous reflux, perforator incompetence, and chronic (or acute) venous thrombosis. The use of a firm strength compression garment (>20 mmHg) or multi-layered compressive dressings is an essential component of SOC for venous stasis ulcers.
- b. Treatment plan should include ALL the following:
 - i. Debridement as appropriate to a clean granular base.
 - ii. Infection control with removal of foreign body or nidus of infection.
 - iii. Management of exudate with maintenance of a moist environment (moist saline gauze, other classic dressings, bioactive dressing, etc.
 - iv. Diabetic foot ulcer: Documented evidence of offloading
 - v. Venous leg ulcer: some form of sustained compression dressings
 - vi. Documentation of smoking history, and counselling on the effect of smoking on wound healing. Treatment for smoking cessation and outcome of counselling, if applicable.
- c. Documentation of wound care and response including:
 - i. Initial measurements of the ulcer and weekly measurements during standard of care therapies for at least 4 weeks.
 - ii. Measurements of the ulcer when initial skin substitute graft or cell-tissue based product is applied and at time of each subsequent application.
 - iii. Standard of care interventions should continue during treatment with skin substitute grafts or cell-tissue based products.

- iv. Venous leg ulcers should continue compression therapy for the episode of care.
- 4. An episode of skin replacement therapy is defined as 12 to 16 weeks from the first application of a skin substitute graft or cell-tissue based product.
- 5. Applications:
 - a. Average number of applications for wound healing is 4.
 - i. Use exceeding four applications requires added documentation/attestation in the medical record that the above criteria continue to be met.
 - ii. Maximum number of applications is 8 applications
 - b. The graft must be applied in a single layer without overlay of product or adjacent skin in compliance with the correct label application techniques for the skin substitute graft/CTP.
 - c. Only skin substitute grafts/CTP with labeled indications for use over exposed muscle, tendon or bone can be used in these cases and only in the absence of contraindications (e.g., infected, ischemic, or necrotic wound bed).

For all the above:

- 1. Coverage of services is based on the Member's subscriber documents. Please refer to those resources for information regarding eligibility for coverage, network or provider requirements. If the Member has coverage for the services discussed in this policy, then the medical criteria applies.
- 2. Some services require pre-authorization by a HAP Medical Director or designee, please refer to the Procedure reference list for specific code information.

DEFINITIONS:

- 1. An episode of skin replacement therapy is defined as 12 to 16 weeks from the first application of a skin substitute graft/CTP).
- 2. Standard of Care (SOC) treatment includes the following:
 - a. **Autografts/tissue cultured autografts:** Includes the harvest and application of an autologous skin graft. These products are designed to circumvent the challenges with autologous skin grafts in the treatment of chronic wounds, ulcers or burns.
 - b. **Chronic Wound:** A chronic wound may be defined as a wound physiologically impaired due to a disruption of the wound healing cycle resulting from impaired angiogenesis, innervation, cellular migration, or other defects for 4 weeks or longer.
 - c. **Cellular and Tissue-Based Products (CTP) grafts** (also called skin substitute graft): Includes homologous human cellular and tissue products (e.g., dermal or epidermal, cellular and acellular, homograft or allograft), non-human cellular and tissue products (i.e., xenograft), and biological products (synthetic or xenogeneic) that form a sheet scaffolding for skin growth when applied in a sheet over an open wound or ulcer to augment closure or skin growth.
 - i. NOTE: There is a lack of clarity in the definition of skin substitute. For the purpose of this policy, skin substitute grafts will align with the AMA CPT codebook description "non-human skin substitute grafts and biological products that form a sheet scaffolding for skin growth". This surface is not intended to be removed but grows into place or serves as base for new skin to grow.
 - d. **Cellular, acellular, and matrix-like products (CAMPs):** also referred to as acellular/tissue product (CTP)
 - e. **Failed response:** Increased size or depth, no change in baseline size or depth, or no sign of improvement or indication that improvement is likely (such as granulation, epithelialization, or progress towards closing).
 - f. **Healed ulcer (completed healing):** 100 percent re-epithelialization without drainage or dressing noted on 2 occasions at least 2 weeks apart.
 - g. **Scaffolding:** a support, delivery vehicle, or matrix for facilitating the migration, binding, or transport of cells or bioactive molecules used to replace, repair, or regenerate tissues.
 - h. **Stalled Wound:** An ulcer that has entered a nonhealing or intransigent phase.
 - i. **Standard of Care (SOC):** SOC treatment of lower extremity ulcers (e.g., DFU and VLU) should include mechanical offloading, infection control, mechanical compression, limb elevation, debridement of necrotic tissue, management of systemic disease and medications, nutrition assessment, tissue perfusion and oxygenation, education regarding care of the foot, callus, and nail and fitting of shoes, as well as counseling on the risk of continued tobacco use. In addition, maintenance of a moist ulcer environment through appropriate dressings facilitates development of healthy granulation tissue and epithelialization and potentiates complete healing at an ulcer site. Dressings are an integral part of ulcer management by maintaining a moist environment, limiting contamination, and absorbing exudate
 - j. **Wound dressing or coverings:** Applications applied to wounds as a selective barrier to clean, cover and protect wounds from the surrounding environment to promote optimal environment for wound healing.
 - k. **Non-graft wound dressings** (e.g., gel, powder, ointment, foam, liquid) or injected skin substitutes. Skin substitute graft application codes [15271-15278 or C5271-C5278] do not apply to these types of services.

US Food and Drug Administration (FDA) Regulation

The FDA does not refer to any product or class of products as “skin substitutes.” However, products commonly described as “skin substitutes” are regulated by FDA under one of the four categories described below depending on the origin and composition of the product. “Skin Substitutes” are billed with a HCPCS code Q41XX.

Updated designation and approved usage criteria may be found under Medical Devices/Products and Medical Procedures at: <http://www.fda.gov/>

- **Human Cells, Tissues, and Cellular and Tissue-Based Products** - Cells and tissues taken from human donors and transplanted to a recipient are regulated under PHS 361 [21 CFR 1270 & 1271]. This regulation describes the rules concerning the use of HCT/Ps for human medical purposes. The Center for Biologics Evaluation and Research (CBER) is responsible for regulating biological and related products including blood, vaccines, allergenics, tissues, and cellular and gene therapies. HCT/Ps establishments are not required to demonstrate the safety or effectiveness of their products and FDA does not evaluate the safety or effectiveness of these products.
 - <https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products>
- **Premarket Approval** - Premarket approval (PMA) by FDA is the required process of scientific review to ensure the safety and effectiveness of Class III devices. Wound care products regulated under the PMA process will require evidence that they promote wound healing before they are approved for marketing.
 - <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm>
- **510(k) Submissions** - According to FDA documents a “510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent (SE), to a legally marketed device (21 CFR 807.92(a)(3)) that is not subject to PMA.” Wound care products regulated under the 510(k) process will not typically require clinical evidence to establish effectiveness in wound healing, as compared with products regulated under the PMA process in which substantial clinical evidence is always required.
 - <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmnm.cfm>
- **Humanitarian Device Exemption (HDE)** - An HDE is similar in both form and content to a premarket approval (PMA) application, but is exempt from the effectiveness requirements of a PMA. The applicant must demonstrate that no comparable devices are available to treat or diagnose the disease or condition, and that they could not otherwise bring the device to market. Humanitarian Device Exemption approval is based on evidence of probable benefit in a disease population occurring at a frequency of less than 4,000 patients per year in the United States.
 - <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfhde/hde.cfm>

LIMITATIONS

1. A maximum of 8 skin substitute graft/CTP applications per ulcer will be allowed for the episode of skin replacement surgery (defined as 12 to 16 weeks from the first application of a skin substitute graft/CTP). Product change within the episode of skin replacement surgery may be appropriate. When more than 1 specific product is used during the 12–16-week period, it is expected that the total number of applications or treatments will still not exceed 8.
2. HAP follows Medicare billing rules and guidelines.

EXCLUSIONS

- I. The following uses are considered not reasonable and necessary and therefore are not covered for HAPAH Members, including Medicare Plan Members:
 1. Greater than 8 applications of a skin substitute graft/CTP within an episode of care (up to 16 weeks).
 2. Repeat applications of skin substitute graft/CTP when a previous application was unsuccessful. Unsuccessful treatment is defined as an increase in size or depth of an ulcer, no measurable change from baseline, and no sign of significant improvement or indication that significant improvement is likely (such as granulation, epithelialization, or progress towards closure).
 3. Application of skin substitute graft/CTP in Members with inadequate control of underlying conditions or exacerbating factors, or other contraindications (e.g., active infection, progressive necrosis, active Charcot arthropathy of the ulcer extremity, active vasculitis, ischemia).
 4. Use of surgical preparation services (e.g., debridement), in conjunction with routine, simple or repeat skin replacement therapy with a skin substitute graft/CTP because all granulation tissue should be excised before placing the graft as it can have a significant bacterial burden and prevent adherence to the graft.
 5. All liquid or gel skin substitute products or CTPs for ulcer care as their fluidity does not allow graft placement and stabilization of the product on the wound.
 6. Placement of skin substitute graft/CTP on infected, ischemic, or necrotic wound bed.
- II. The following HCPCS codes are non-covered for the treatment of Diabetic Foot Ulcers or Venous Leg Ulcers:

1. A2001 INNOVAMATRIX AC, PER SQUARE CENTIMETER
2. A2002 MIRRAGEN ADVANCED WOUND MATRIX, PER SQUARE CENTIMETER
3. A2004 XCELLISTEM, 1 MG
4. A2005 MICROLYTE MATRIX, PER SQUARE CENTIMETER
5. A2006 NOVOSORB SYNPATH DERMAL MATRIX, PER SQUARE CENTIMETER
6. A2007 RESTRATA, PER SQUARE CENTIMETER
7. A2008 THERAGENESIS, PER SQUARE CENTIMETER
8. A2009 SYMPHONY, PER SQUARE CENTIMETER
9. A2010 APIS, PER SQUARE CENTIMETER
10. A2011 SUPRA SDRM, PER SQUARE CENTIMETER
11. A2012 SUPRATHEL, PER SQUARE CENTIMETER
12. A2013 INNOVAMATRIX FS, PER SQUARE CENTIMETER
13. A2014 OMEZA COLLAGEN MATRIX, PER 100 MG
14. A2015 PHOENIX WOUND MATRIX, PER SQUARE CENTIMETER
15. A2016 PERMEADERM B, PER SQUARE CENTIMETER
16. A2018 PERMEADERM C, PER SQUARE CENTIMETER
17. A2020 AC5 ADVANCED WOUND SYSTEM (AC5)
18. A2021 NEOMATRIX, PER SQUARE CENTIMETER
19. A2022 INNOVABURN OR INNOVAMATRIX XL, PER SQUARE CENTIMETER
20. A2023 INNOVAMATRIX PD, 1 MG
21. A2024 RESOLVE MATRIX OR XENOPATCH, PER SQUARE CENTIMETER
22. A2025 MIRO3D, PER CUBIC CENTIMETER
23. C9358 DERMAL SUBSTITUTE, NATIVE, NON-DENATURED COLLAGEN, FETAL BOVINEORIGIN (SURGIMEND COLLAGEN MATRIX), PER 0.5 SQUARE CENTIMETERS
24. C9360 DERMAL SUBSTITUTE, NATIVE, NON-DENATURED COLLAGEN, NEONATALBOVINE ORIGIN (SURGIMEND COLLAGEN MATRIX), PER 0.5 SQUARECENTIMETERS
25. C9363 SKIN SUBSTITUTE, INTEGRA MESHED BILAYER WOUND MATRIX, PERSQUARE CENTIMETER
26. C9364 PORCINE IMPLANT, PERMACOL, PER SQUARE CENTIMETER
27. Q4103 OASIS BURN MATRIX, PER SQUARE CENTIMETER
28. Q4104 INTEGRA BILAYER MATRIX WOUND DRESSING (BMWD), PER SQUARECENTIMETER
29. Q4108 INTEGRA MATRIX, PER SQUARE CENTIMETER
30. Q4111 GAMMAGRAFT, PER SQUARE CENTIMETER
31. Q4112 CYMETRA, INJECTABLE, 1 CC
32. Q4113 GRAFTJACKET XPRESS, INJECTABLE, 1 CC
33. Q4114 INTEGRA FLOWABLE WOUND MATRIX, INJECTABLE, 1 CC
34. Q4115 ALLOSKIN, PER SQUARE CENTIMETER
35. Q4116 ALLODERM, PER SQUARE CENTIMETER
36. Q4117 HYALOMATRIX, PER SQUARE CENTIMETER
37. Q4118 MATRISTEM MICROMATRIX, 1 MG
38. Q4123 ALLOSKIN RT, PER SQUARE CENTIMETER
39. Q4124 OASIS ULTRA TRI-LAYER WOUND MATRIX, PER SQUARE CENTIMETER
40. Q4125 ARTHROFLEX, PER SQUARE CENTIMETER
41. Q4126 MEMODERM, DERMSPAN, TRANZGRAFT OR INTEGUPLY, PER SQUARECENTIMETER
42. Q4127 TALYMED, PER SQUARE CENTIMETER
43. Q4130 STRATTICE TM, PER SQUARE CENTIMETER
44. Q4132 GRAFIX CORE AND GRAFIXPL CORE, PER SQUARE CENTIMETER
45. Q4134 HMATRIX, PER SQUARE CENTIMETER
46. Q4135 MEDISKIN, PER SQUARE CENTIMETER
47. Q4136 EZ-DERM, PER SQUARE CENTIMETER
48. Q4137 AMNIOEXCEL, AMNIOEXCEL PLUS OR BIODEXCEL, PER SQUARE CENTIMETER
49. Q4138 BIODFENCE DRYFLEX, PER SQUARE CENTIMETER
50. Q4139 AMNIOMATRIX OR BIODMATRIX, INJECTABLE, 1 CC
51. Q4140 BIODFENCE, PER SQUARE CENTIMETER
52. Q4141 ALLOSKIN AC, PER SQUARE CENTIMETER
53. Q4142 XCM BIOLOGIC TISSUE MATRIX, PER SQUARE CENTIMETER
54. Q4143 REPRIZA, PER SQUARE CENTIMETER
55. Q4145 EPIFIX, INJECTABLE, 1 MG
56. Q4146 TENSIX, PER SQUARE CENTIMETER
57. Q4147 ARCHITECT, ARCHITECT PX, OR ARCHITECT FX, EXTRACELLULAR MATRIX,PER SQUARE CENTIMETER
58. Q4148 NEOX CORD 1K, NEOX CORD RT, OR CLARIX CORD 1K, PER SQUARECENTIMETER

59. Q4149 EXCELLAGEN, 0.1 CC
60. Q4150 ALLOWRAP DS OR DRY, PER SQUARE CENTIMETER
61. Q4152 DERMAPURE, PER SQUARE CENTIMETER
62. Q4153 DERMAVEST AND PLURIVEST, PER SQUARE CENTIMETER
63. Q4154 BIOVANCE, PER SQUARE CENTIMETER
64. Q4155 NEOXFLO OR CLARIXFLO, 1 MG
65. Q4156 NEOX 100 OR CLARIX 100, PER SQUARE CENTIMETER
66. Q4157 REVITALON, PER SQUARE CENTIMETER
67. Q4161 BIO-CONNKT WOUND MATRIX, PER SQUARE CENTIMETER
68. Q4162 WOUNDEX FLOW, BIOSKIN FLOW, 0.5 CC
69. Q4163 WOUNDEX, BIOSKIN, PER SQUARE CENTIMETER
70. Q4164 HELICOLL, PER SQUARE CENTIMETER
71. Q4165 KERAMATRIX OR KERASORB, PER SQUARE CENTIMETER
72. Q4166 CYTAL, PER SQUARE CENTIMETER
73. Q4167 TRUSKIN, PER SQUARE CENTIMETER
74. Q4168 AMNIOBAND, 1 MG
75. Q4169 ARTACENT WOUND, PER SQUARE CENTIMETER
76. Q4170 CYGNUS, PER SQUARE CENTIMETER
77. Q4171 INTERFYL, 1 MG
78. Q4173 PALINGEN OR PALINGEN XPLUS, PER SQUARE CENTIMETER
79. Q4174 PALINGEN OR PROMATRX, 0.36 MG PER 0.25 CC
80. Q4175 MIRODERM, PER SQUARE CENTIMETER
81. Q4176 NEOPATCH OR THERION, PER SQUARE CENTIMETER
82. Q4177 FLOWERAMNIOFLO, 0.1 CC
83. Q4178 FLOWERAMNIOPATCH, PER SQUARE CENTIMETER
84. Q4179 FLOWERDERM, PER SQUARE CENTIMETER
85. Q4180 REVITA, PER SQUARE CENTIMETER
86. Q4181 AMNIO WOUND, PER SQUARE CENTIMETER
87. Q4182 TRANSCYTE, PER SQUARE CENTIMETER
88. Q4183 SURGIGRAFT, PER SQUARE CENTIMETER
89. Q4184 CELLESTA OR CELLESTA DUO, PER SQUARE CENTIMETER
90. Q4185 CELLESTA FLOWABLE AMNION (25 MG PER CC); PER 0.5 CC
91. Q4188 AMNIOARMOR, PER SQUARE CENTIMETER
92. Q4189 ARTACENT AC, 1 MG
93. Q4190 ARTACENT AC, PER SQUARE CENTIMETER
94. Q4191 RESTORIGIN, PER SQUARE CENTIMETER
95. Q4192 RESTORIGIN, 1 CC
96. Q4193 COLL-E-DERM, PER SQUARE CENTIMETER
97. Q4194 NOVACHOR, PER SQUARE CENTIMETER
98. Q4195 PURAPLY, PER SQUARE CENTIMETER
99. Q4196 PURAPLY AM, PER SQUARE CENTIMETER
100. Q4197 PURAPLY XT, PER SQUARE CENTIMETER
101. Q4198 GENESIS AMNIOTIC MEMBRANE, PER SQUARE CENTIMETER
102. Q4199 CYGNUS MATRIX, PER SQUARE CENTIMETER
103. Q4200 SKIN TE, PER SQUARE CENTIMETER
104. Q4201 MATRION, PER SQUARE CENTIMETER
105. Q4202 KEROXX (2.5G/CC), 1CC
106. Q4204 XWRAP, PER SQUARE CENTIMETER
107. Q4205 MEMBRANE GRAFT OR MEMBRANE WRAP, PER SQUARE CENTIMETER
108. Q4206 FLUID FLOW OR FLUID GF, 1 CC
109. Q4208 NOVAFIX, PER SQUARE CENTIMETER
110. Q4209 SURGRAFT, PER SQUARE CENTIMETER
111. Q4211 AMNION BIO OR AXOBIOMEMBRANE, PER SQUARE CENTIMETER
112. Q4212 ALLOGEN, PER CC
113. Q4213 ASCENT, 0.5 MG
114. Q4214 CELLESTA CORD, PER SQUARE CENTIMETER
115. Q4215 AXOLOTL AMBIENT OR AXOLOTL CRYO, 0.1 MG
116. Q4216 ARTACENT CORD, PER SQUARE CENTIMETER
117. Q4217 WOUNDFIX, BIOWOUND, WOUNDFIX PLUS, BIOWOUND PLUS, WOUNDFIXPLUS OR BIOWOUND XPLUS, PER SQUARE CENTIMETER
118. Q4218 SURGICORD, PER SQUARE CENTIMETER

119. Q4219 SURGIGRAFT-DUAL, PER SQUARE CENTIMETER
120. Q4220 BELLACELL HD OR SUREDERM, PER SQUARE CENTIMETER
121. Q4221 AMNIOWRAP2, PER SQUARE CENTIMETER
122. Q4222 PROGENAMATRIX, PER SQUARE CENTIMETER
123. Q4225 AMNIOBIND OR DERMABIND TL, PER SQUARE CENTIMETER
124. Q4226 MYOWN SKIN, INCLUDES HARVESTING AND PREPARATION PROCEDURES, PER SQUARE CENTIMETER
125. Q4227 AMNIOCORE, PER SQUARE CENTIMETER
126. Q4229 COGENEX AMNIOTIC MEMBRANE, PER SQUARE CENTIMETER
127. Q4230 COGENEX FLOWABLE AMNION, PER 0.5 CC
128. Q4231 CORPLEX P, PER CC
129. Q4232 CORPLEX, PER SQUARE CENTIMETER
130. Q4233 SURFACTANT OR NUDYN, PER 0.5 CC
131. Q4234 XCELLERATE, PER SQUARE CENTIMETER
132. Q4235 AMNIOREPAIR OR ALTIPLY, PER SQUARE CENTIMETER
133. Q4236 CAREPATCH, PER SQUARE CENTIMETER
134. Q4237 CRYO-CORD, PER SQUARE CENTIMETER
135. Q4238 DERM-MAXX, PER SQUARE CENTIMETER
136. Q4239 AMNIO-MAXX OR AMNIO-MAXX LITE, PER SQUARE CENTIMETER
137. Q4240 CORECYTE, FOR TOPICAL USE ONLY, PER 0.5 CC
138. Q4241 POLYCYTE, FOR TOPICAL USE ONLY, PER 0.5 CC
139. Q4242 AMNIOCYTE PLUS, PER 0.5 CC
140. Q4245 AMNIOTEXT, PER CC
141. Q4246 CORETEXT OR PROTEXT, PER CC
142. Q4247 AMNIOTEXT PATCH, PER SQUARE CENTIMETER
143. Q4248 DERMACYTE AMNIOTIC MEMBRANE ALLOGRAFT, PER SQUARE CENTIMETER
144. Q4249 AMNIPLY, FOR TOPICAL USE ONLY, PER SQUARE CENTIMETER
145. Q4250 AMNIOAMP-MP, PER SQUARE CENTIMETER
146. Q4251 VIM, PER SQUARE CENTIMETER
147. Q4252 VENDAJE, PER SQUARE CENTIMETER
148. Q4253 ZENITH AMNIOTIC MEMBRANE, PER SQUARE CENTIMETER
149. Q4254 NOVAFIX DL, PER SQUARE CENTIMETER
150. Q4255 REGUARD, FOR TOPICAL USE ONLY, PER SQUARE CENTIMETER
151. Q4256 MLG-COMPLETE, PER SQUARE CENTIMETER
152. Q4257 RELESE, PER SQUARE CENTIMETER
153. Q4258 ENVERSE, PER SQUARE CENTIMETER
154. Q4259 CELERA DUAL LAYER OR CELERA DUAL MEMBRANE, PER SQUARECENTIMETER
155. Q4260 SIGNATURE APATCH, PER SQUARE CENTIMETER
156. Q4261 TAG, PER SQUARE CENTIMETER
157. Q4262 DUAL LAYER IMPAX MEMBRANE, PER SQUARE CENTIMETER
158. Q4263 SURGRAFT TL, PER SQUARE CENTIMETER
159. Q4264 COCOON MEMBRANE, PER SQUARE CENTIMETER
160. Q4265 NEOSTIM TL, PER SQUARE CENTIMETER
161. Q4266 NEOSTIM MEMBRANE, PER SQUARE CENTIMETER
162. Q4267 NEOSTIM DL, PER SQUARE CENTIMETER
163. Q4268 SURGRAFT FT, PER SQUARE CENTIMETER
164. Q4269 SURGRAFT XT, PER SQUARE CENTIMETER
165. Q4270 COMPLETE SL, PER SQUARE CENTIMETER
166. Q4271 COMPLETE FT, PER SQUARE CENTIMETER
167. Q4272 ESANO A, PER SQUARE CENTIMETER
168. Q4273 ESANO AAA, PER SQUARE CENTIMETER
169. Q4274 ESANO AC, PER SQUARE CENTIMETER
170. Q4275 ESANO ACA, PER SQUARE CENTIMETER
171. Q4276 ORION, PER SQUARE CENTIMETER
172. Q4278 EPIEFFECT, PER SQUARE CENTIMETER
173. Q4279 VENDAJE AC, PER SQUARE CENTIMETER
174. Q4280 XCELL AMNIO MATRIX, PER SQUARE CENTIMETER
175. Q4281 BARRERA SL OR BARRERA DL, PER SQUARE CENTIMETER
176. Q4282 CYGNUS DUAL, PER SQUARE CENTIMETER
177. Q4283 BIOVANCE TRI-LAYER OR BIOVANCE 3L, PER SQUARE CENTIMETER
178. Q4284 DERMABIND SL, PER SQUARE CENTIMETER

179. Q4285 NUDYN DL OR NUDYN DL MESH, PER SQUARE CENTIMETER
180. Q4286 NUDYN SL OR NUDYN SLW, PER SQUARE CENTIMETER
181. Q4287 DERMABIND DL, PER SQUARE CENTIMETER
182. Q4288 DERMABIND CH, PER SQUARE CENTIMETER
183. Q4289 REVOSHIELD + AMNIOTIC BARRIER, PER SQUARE CENTIMETER
184. Q4290 MEMBRANE WRAP-HYDRO, PER SQUARE CENTIMETER
185. Q4291 LAMELLAS XT, PER SQUARE CENTIMETER
186. Q4292 LAMELLAS, PER SQUARE CENTIMETER
187. Q4293 ACESSO DL, PER SQUARE CENTIMETER
188. Q4294 AMNIO QUAD-CORE, PER SQUARE CENTIMETER
189. Q4295 AMNIO TRI-CORE AMNIOTIC, PER SQUARE CENTIMETER
190. Q4296 REBOUND MATRIX, PER SQUARE CENTIMETER
191. Q4297 EMERGE MATRIX, PER SQUARE CENTIMETER
192. Q4298 AMNICORE PRO, PER SQUARE CENTIMETER
193. Q4299 AMNICORE PRO+, PER SQUARE CENTIMETER
194. Q4300 ACESSO TL, PER SQUARE CENTIMETER
195. Q4301 ACTIVATE MATRIX, PER SQUARE CENTIMETER
196. Q4302 COMPLETE ACA, PER SQUARE CENTIMETER
197. Q4303 COMPLETE AA, PER SQUARE CENTIMETER
198. Q4304 GRAFIX PLUS, PER SQUARE CENTIMETER
199. Q4305 AMERICAN AMNION AC TRI-LAYER, PER SQUARE CENTIMETER
200. Q4306 AMERICAN AMNION AC, PER SQUARE CENTIMETER
201. Q4307 AMERICAN AMNION, PER SQUARE CENTIMETER
202. Q4308 SANOPELLIS, PER SQUARE CENTIMETER
203. Q4309 VIA MATRIX, PER SQUARE CENTIMETER
204. Q4310 PROCENTA, PER 100 MG

RATIONALE:

This policy provides coverage of skin substitute grafts and cellular tissue products when used for Diabetic Foot Ulcers or Venous Leg Ulcers consistent with the Local Coverage Determination (LCD): Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers, L39865 ¹ coverage documents. Any subsequent changes to coverage based on Medicare & Medicaid services (CMS) will be applied in place of the content displayed on this policy. This policy applies to all product lines as consistent with the individual's subscriber documents.

REFERENCES:

1. Local Coverage Determination (LCD): Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers, L39865 <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=39865>
 - a. LCD Reference Article Billing and Coding Article: Billing and Coding: Skin Substitutes Grafts/Cellular Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers, A59740 <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=59740>
2. MLN Matters. January 2019 Update of the Ambulatory surgical Center (ASC) Payment System. MLN Matters Number: MM11108 Revised. Related CR Release Date: December 31, 2018. Related CR Transmittal Number: R4191CP. Related Change Request (CR) Number: 11108. Effective Date: January 1, 2019. Implementation Date: January 7, 2019. <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM11108.pdf>
3. CMS IOM Publication 100-03, Medicare National Coverage Determinations (NCD) Manual, Chapter 1, Part 4, Section 270.3 Blood-Derived Products for Chronic Non-Healing Wounds. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/ncd103c1_part4.pdf
4. CMS IOM Publication 100-04, Medicare Claims Processing Manual, Chapter 17, Section 40 Discarded Drugs and Biologicals. <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c17.pdf>
5. CMS IOM Publication 100-08, Medicare Program Integrity Manual, Chapter 13, Section 13.5.4 Reasonable and Necessary Provisions in LCDs. Medicare Program Integrity Manual (cms.gov)
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7. Food & Drug Administration. Tissue & Tissue Products. <https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products>
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Benefit Administration Manual Policies are developed to provide guidance to Members and Providers. This Policy relates only to the services or supplies described in it. The existence of a Benefit Administration Manual Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Policy. Coverage of services for Members is based on the Member's subscriber documents and is subject to all terms and conditions including specific exclusions and limitations. This type of document includes the following: Subscriber contract and associated riders; Member Benefit Guide; or an Evidence of Coverage document (for Medicare Plan Members).

HAP HMO/POS and AHL EPO/PPO Members:

If there is a discrepancy between this policy and coverage described in the subscriber documents, the Member's subscriber documents will apply.

ASO Members:

Coverage as discussed in this policy may not apply to employer groups that are self-funded (referred to as an ASO group [Administrative Services Only]). Each ASO group determines the coverage available to their members which is found in the ASO Benefit Guide and associated riders. If a member has coverage for the type of service covered by this policy, then the medical criteria as discussed in this policy applies to those services.

Medicare Plan Members:

Coverage is based on Medicare (CMS) regulations and guidelines which include the NCDs (National Coverage Decision) and LCDs (Local Coverage Decision) for our area. When no coverage determination has been made by CMS, then this policy will apply.

EFFECTIVE DATE

05/01/2025

REVISED DATE

02/27/2025

REVIEWED DATE

02/27/2025

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