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# Subject: Bio-Engineered Skin and Soft Tissue Substitutes; Amniotic Membrane and Amniotic Fluid

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## DESCRIPTION:

Bio-engineered skin and soft tissue substitutes may be derived from human tissue (autologous or allogeneic), non-human tissue (xenographic), synthetic materials, or a composite of these materials. Bioengineered skin and soft tissue substitutes are being evaluated for a variety of conditions, including breast reconstruction and healing lower-extremity ulcers and severe burns. Acellular dermal matrix (ADM) products are also being evaluated for soft tissue repair. Bioengineered skin and soft tissue substitutes may be either acellular or cellular. Acellular products (eg, dermis with cellular material removed) contain a matrix or scaffold composed of materials such as collagen, hyaluronic acid, and fibronectin. Acellular dermal matrix (ADM) products can differ in a number of ways, including as species source (human, bovine, porcine), tissue source (eg dermis, pericardium, intestinal mucosa), additives (eg antibiotics, surfactants), hydration (wet, freeze-dried), and required preparation (multiple rinses, rehydration). Cellular products contain living cells such as fibroblasts and keratinocytes within a matrix. The cells contained within the matrix may be autologous, allogeneic, or derived from other species (eg, bovine, porcine). Skin substitutes may also be composed of dermal cells, epidermal cells, or a combination of dermal and epidermal cells, and may provide growth factors to stimulate healing. Bioengineered skin substitutes can be used as either temporary or permanent wound coverings.

Several commercially available forms of human amniotic membrane (HAM) and amniotic fluid can be administered by patches, topical application, or injection. Amniotic membrane and amniotic fluid are being evaluated for the treatment of various conditions, including chronic full thickness diabetic lower extremity ulcers, venous ulcers, knee osteoarthritis, plantar fasciitis, and ophthalmic conditions. Human amniotic membrane (HAM) consists of 2 conjoined layers, the amnion, and chorion, and forms the innermost lining of the amniotic sac or placenta. When prepared for use as an allograft, the membrane

is harvested immediately after birth, cleaned, sterilized, and either cryopreserved or dehydrated. Many products available using amnion, chorion, amniotic fluid, and umbilical cord are being studied for the treatment of a variety of conditions, including chronic full-thickness diabetic lower-extremity ulcers, venous ulcers, knee osteoarthritis, plantar fasciitis, and ophthalmic conditions. The products are formulated either as patches, which can be applied as wound covers, or as suspensions or particulates, or connective tissue extractions, which can be injected or applied topically. Injection of amniotic fluid or amniotic fluid-derived cells is currently being evaluated for the treatment of osteoarthritis and plantar fasciitis.

**Summary and Analysis of Evidence**: Skin and Soft Tissue Substitutes- Patients who are undergoing breast reconstruction who receive allogeneic acellular dermal matrix (ADM) products, the evidence includes randomized controlled trials (RCTs) and systematic reviews. A systematic review found no difference in overall complication rates with ADM allograft compared with standard procedures for breast reconstruction. Reconstructions with ADM have been reported to have higher seroma, infection, and necrosis rates than reconstructions without ADM. However, capsular contracture and malposition of implants may be reduced. In cases where there is limited tissue coverage, the available evidence may inform patient decision making about reconstruction options. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome. Patients undergoing tendon repair who receive GraftJacket, the evidence includes an RCT. The RCT identified found improved outcomes with the GraftJacket ADM allograft for rotator cuff repair. Although these results were positive, additional studies with a larger number of patients is needed to evaluate the consistency of the effect. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. Diabetic lower-extremity ulcers for patients who receive AlloPatch, Apligraf, Dermagraft, Integra, mVASC, or TheraSkin, the evidence includes RCTs. RCTs reportingcomplete wound healing outcomes with at least 12 weeks of follow-up have demonstrated the efficacy of AlloPatch (reticular ADM), Apligraf and Dermagraft (living cell therapy), Integra (biosynthetic), mVASC, and TheraSkin over the standard of care (SOC). The evidence is sufficient to determine that the technology results in an improvement in the net health outcome. Patients with diabetic lower-extremity ulcers who receive ADM products other than AlloPatch, Apligraf, Dermagraft, orIntegra, mVASC, or TheraSkin, the evidence includes RCTs. Results from a multicenter RCT showed some benefit of DermACELL that was primarily for the subgroup of patients who only required a single application of the ADM. Studies are needed to further define the population who might benefit from this treatment. Additional study with a larger number of subjects is needed to evaluate the effect of GraftJacket, DermACELL, Cytal, PriMatrix, and Oasis Wound Matrix, compared with current SOC or other advanced wound therapies. An RCT of Omega3 Wound (Kerecis) has been published and 2 larger RCTs are registered and reported as completed but have not been published. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. Patients who have lower-extremity ulcers due to venous insufficiency who receive Apligraf or Oasis Wound Matrix, the evidence includes RCTs. RCTs have demonstrated the efficacy of Apligraf living cell therapy and xenogeneic Oasis Wound Matrix over the SOC. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome. Lower-extremity ulcers due to venous insufficiency treated with bioengineered skin substitutes other than Apligraf or Oasis Wound Matrix, the evidence includes RCTs. In a moderately large RCT, Dermagraft was not shown to be more effective than controls for the primary or secondary endpoints in the entire population and was only slightly more effective than controls (an 8% to 15% increase in healing) in subgroups of patients with ulcer durations of 12 months or less or size of 10 cm or

less. Additional studies with a larger number of subjects is needed to evaluate the effect of the xenogeneic PriMatrix skin substitute versus the current SOC. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. Patients who have dystrophic epidermolysis bullosa who receive OrCel, the evidence includes a case series. OrCel was approved under a humanitarian drug exemption for use in patients with dystrophic epidermolysis bullosa undergoing hand reconstruction surgery, to close and heal wounds created by the surgery, including those at donor sites. Outcomes have been reported in a small series (eg, 5 patients). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. Deep dermal burns treated with bioengineered skin substitutes (ie, Epicel, Integra Dermal Regeneration Template), the evidence includes RCTs. Overall, few skin substitutes have been approved, and the evidence is limited for each product. Epicel (living cell therapy) has received FDA approval under a humanitarian device exemption for the treatment of deep dermal or full-thickness burns comprising a total body surface area of 30% or more. Comparative studies have demonstrated improved outcomes for biosynthetic skin substitute Integra Dermal Regeneration Template for the treatment of burns. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome. Amniotic Membrane and Amniotic Fluid- Patients with non-healing diabetic lower-extremity ulcers who receive a patch formulation of HAM or placental membrane (ie, Affinity, AmnioBand Membrane, AmnioExcel, Biovance, EpiCord, EpiFix, Grafix), the evidence includes randomized controlled trials (RCTs). The RCTs evaluating amniotic and placental membrane products for the treatment of non-healing (<20% healing with ≥2 weeks of standard care) diabetic lower-extremity ulcers have compared HAM with standard care or with an established advanced wound care product. These trials used wound closure as the primary outcome measure, and some used power analysis, blinded assessment of wound healing, and intention-to-treat analysis. For the HAM products that have been sufficiently evaluated (ie, Affinity, AmnioBand Membrane, Biovance, EpiCord, EpiFix, Grafix), results have shown improved outcomes compared with standard care, and outcomes that are at least as good as an established advanced wound care product. Improved health outcomes in the RCTs are supported by multicenter registries. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome. Lower-extremity ulcers due to venous insufficiency treated with a patch formulation of HAM, the evidence includes 3 RCTs. The published evidence on HAM for the treatment of venous leg ulcers includes 2 multicenter RCTs with EpiFix and 1 multicenter RCT with Amnioband. One RCT reported a larger percent wound closure at 4 weeks, but the percentage of patients with complete wound closure at 4 weeks did not differ between EpiFix and the standard of care. A second RCT evaluated complete wound closure at 12 weeks after weekly application of EpiFix or standard dressings with compression, but interpretation is limited by methodologic concerns. A third RCT demonstrated significantly greater blinded assessor-confirmed rates of complete wound closure at 12 weeks after weekly or twice-weekly application of AmnioBand Membrane with compression bandaging compared with compression bandaging alone. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. Patientw with knee osteoarthritis who receive an injection of suspension or particulate formulation of HAM or amniotic fluid, the evidence includes a feasibility study. The pilot study assessed the feasibility of a larger RCT evaluating HAM injection. Additional trials, which will have a larger sample size and longer follow-up, are needed to permit conclusions on the effect of this treatment. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. Patients with plantar fasciitis who receive an injection of amniotic membrane, the includes preliminary studies and a larger (N=145) patient-blinded comparison of

micronized injectable-HAM and placebo control. Injection of micronized amniotic membrane resulted in greater improvements in the visual analog score for pain and the Foot Functional Index compared to placebo controls. The primary limitation of the study is that this is an interim report with 12-month results pending. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

## POSITION STATEMENT:

**Note**: This guideline does not address the use of meshes or patches of non-biologic origin used for standard repair procedures such as hernia repairs.

**Bio-Engineered Skin and Soft Tissue Substitutes**

Breast reconstructive surgery using allogeneic acellular dermal matrix products* (i.e. AlloDerm®, AlloMend®, Cortiva® (AlloMax™), DermACELL™, DermaMatrix™, FlexHD®, FlexHD® Pliable™, GraftJacket®) **meets the definition of medical necessity** for **ONE** of the following indications:

- when there is insufficient tissue expander or implant coverage by the pectoralis major muscle and additional coverage is required, **OR**
- when there is viable but compromised or thin post-mastectomy skin flaps that are at risk of dehiscence or necrosis, **OR**
- the inframammary fold and lateral mammary folds have been undermined during mastectomy and re-establishment of these landmarks is needed.

Treatment of chronic, non-infected, full-thickness diabetic lower extremity ulcers using the following tissue-engineered skin substitutes **meets the definition of medical necessity**:

- AlloPatch®*
- Apligraf®**
- Dermagraft®**
- Integra® Omnigraft Dermal Regeneration Matrix (also known as Omnigraft)
- Integra™ Flowable Wound Matrix
- Primatrix®
- Primatrix® Dermal Repair Scaffold
- mVASC®
- TheraSkin®.

Treatment of chronic, noninfected, partial- or full-thickness lower extremity skin ulcers due to venous insufficiency, which have not adequately responded following a one-month period of conventional ulcer therapy, using the following tissue-engineered skin substitutes **meets the definition of medical necessity**:

- Apligraf®**
- Oasis™ Wound Matrix***.

Treatment of dystrophic epidermolysis bullosa using the following tissue-engineered skin substitutes **meets the definition of medical necessity**:

- OrCel™ (for the treatment of mitten-hand deformity when standard wound therapy has failed and when provided in accordance with the Humanitarian Device Exemption (HDE) specifications of the FDA)****.

Treatment of second- and third-degree burns using the following tissue-engineered skin substitutes **meets the definition of medical necessity**:

- Epicel® (for the treatment of deep dermal or full-thickness burns comprising a total body surface area of greater than or equal to 30% when provided in accordance with the HDE specifications of the FDA)****
- Integra® Dermal Regeneration Template™**
- Primatrix® Dermal Repair Scaffold.

* Banked Human Tissue.

** FDA premarket approval.

*** FDA 510(k) clearance.

**** FDA-approved under an HDE.

All other uses of the bio-engineered skin and soft tissue substitutes listed above **do not meet the definition of medical necessity.**

**Amniotic Membrane and Amniotic Fluid**

Treatment of nonhealing diabetic lower-extremity ulcers using the following human amniotic membrane products **meets the definition of medical necessity:**

- Affinity®
- AmnioBand® Membrane
- AmnioExcel®
- Biovance®
- Epicord®
- Epifix®
- Grafix™.

All other indications not listed above are considered **experimental or investigational**, including but not limited to treatment of lower extremity ulcers due to venous insufficiency and repair following Mohs micrographic surgery. The evidence is insufficient to determine the effects of the technology on health outcomes.

The following is considered **experimental or investigational** for all indications, including but not limited to treatment of osteoarthritis and plantar fasciitis:

- Injection of micronized or particulated human amniotic membrane
- Injection of human amniotic fluid.

The evidence is insufficient to determine the effects of the technology on health outcomes.

All other bio-engineered skin substitutes, soft tissue substitutes, amniotic membranes and amniotic fluids are considered **experimental or Investigational**, including, but not limited to:

- Acell® UBM Hydrated/Lyophilized Wound Dressing
- ActiveBarrier® 45, 200, 2000
- Allogen
- AlloSkin™
- AlloSkin™ AC
- AlloSkin™ RT
- Allowrap™
- Alphaplex™ with MariGen Omega3™
- Altrazeal™ Transforming Powder Dressing
- AmnioAMP-MP
- Amnioarmor™
- Amnion bio or Axomembrane
- AmnioClear™
- Amniocore™
- Amniocyte
- Amnio-maxx or Manio-maxx lite
- AmnioFix®
- AmnioFix® Injectable
- AmnioGen™ 45
- AmnioGen™ 200
- AmnioGen™ A
- AmnioGen™ C
- AmnioGraft®
- AmnioMatrix®
- AmnioPro® 45
- AmnioPro® 200
- AmnioPro® Flow
- Amniorepair or AltiPly
- Amniotext and Amniotext Patch
- AmnioVisc™

- Amniowound
- AmnioWrap2™
- Amniply
- Aongen™ Collagen Matrix
- Apis®
- Architect® ECM, PX, FX
- Artacent® Cord, Wound
- ArthroFlex™ (FlexGraft)
- Articent ac flowable, patch
- Artacent® Wound
- Ascent
- Atlas Wound Matrix
- Avagen Wound Dressing
- Avaulta Plus™
- Axolotl ambien or Axolotl Cryo
- Biobrane®/Biobrane-L
- Bio-ConneKt® Wound Matrix
- BioDDryFlex®
- BioDfence™
- BioDfence Dryflex™/BioDfactor™
- BioDMatrix™
- BioNextPATCH
- BioRenew® 45
- BioRenew® 200
- BioRenew® Flow
- BioSkin® 45
- BioSkin® 200
- BioSkin® Flow
- BioWound, BioWound Plus™, BioWound Xplus™
- carePATCH
- CellerateRX® (CRXa)
- Cellesta/Cellesta duo, Cord, flowable
- Clarix®
- Clarix® Flo
- Cogenex amniotic membrane

- CollaCare®
- CollaCare® Dental
- Collagen Sponge
- Collagen Wound Dressing (Oasis Research)
- CollaGUARD®
- CollaMend™
- CollaSorb™
- CollaWound™
- Coll-e-derm
- Collexa®
- Collieva®
- Conexa™
- Corecyte
- Coreleader Colla-Pad
- Coretext or Protext
- CorMatrix®
- Corplex, Corplex P
- CRXa™
- Cryo-cord
- Cygnus
- Cygnus Max
- Cymetra® (Micronized AlloDerm™)
- Cytal™ (previously MatriStem®)
- DeNovoSkin™
- Dermacyte
- Dermadapt™ Wound Dressing
- Derma-gide
- DermaPure™
- DermaSpan™
- Derm-maxx
- DressSkin
- Dermavest™
- DUPRA SDRM
- Durepair Regeneration Matrix®
- Endoform Dermal Template™
- Epifix injectable

- *ENDURA*gen™
- Excellagen®
- ExpressGraft™
- E-Zderm®
- FlexiGraft®
- Floweramnioflo, Floweramniopatch
- FlowerDerm™
- Fluid flow or Fluid GF
- GammaGraft
- Geistlich Derma-Gide™
- Genesis
- GraftJacket® Xpress, injectable
- Guardian/AmniBand®
- HA Absorbent Wound Dressing
- Helicoll™
- Hyalomatrix®
- Hyalomatrix® PA
- hMatrix®
- HydraTek®
- InnovaMatrix®
- Integra™ Bilayer Wound Matrix
- Integra® Matrix Wound Dressing (previously Avagen)
- IntéguPly®
- Interfyl™
- Jaloskin®
- Kermatrix®
- Kerecis™ Omega3
- Keroxx™
- MatriDerm®
- Matrion
- MatriStem
- Matrix Collagen Wound Dressing
- Matrix HD™
- MediHoney®
- Mediskin®

- MemoDerm™
- Microderm® Biologic Wound Matrix
- Microlyte matrix®
- MicroMatrix®
- MyOwn skin
- NeoForm™
- Neopatch or Therion
- Neox®100
- Neox®Flo
- Neox® Cord
- Neox® Wound
- Novachor
- Novafix® , Novafix DL
- NovoSorb® Biodegradable Temporizing Matrix (BMT)
- NuCel®
- NuShield™
- Oasis® Burn Matrix
- Oasis® Ultra Tri-Layer Matrix
- Ologen™ Collagen Matrix
- Omega3 Wound (originally Merigen wound dressing)
- Omeza®Collagen Matrix
- OrthoFlo™
- OviTex®
- PalinGen® Flow
- PalinGen® Membrane
- PalinGen® SprotFlow
- Pelvicol®/PelviSoft®
- Permacol™
- PermeaDerm® B
- PermeaDerm® C
- PermeaDerm® Glove
- Phoenix™ Wound Matrix
- Plurivest™
- Polycyte
- Procenta

- Progenamatrix
- ProMatrX™ ACF
- Puracol® and Puracol® Plus Collagen Wound Dressings
- PuraPly™ Wound Matrix (previously FortaDerm™)
- PuraPly™ AM (Antimicrobial Wound Matrix)
- Puros® Dermis
- RECELL® Autologous Cell Harvesting Device
- RegenePro™
- ReNu™
- Repliform®
- Repriza™
- Restorigin Injectible
- Restrata®
- Revita
- Revitalon™
- SIS Wound Dressing ll
- SkinTE™
- Sport Flow™
- SS Matrix™
- Stimulen™ Collagen
- StrataGraft®
- Strattice™ (xenograft)
- Suprathel®
- Surgenex, Surfactor, and Nudyn
- Surgicord
- SurgiGRAFT™
- SurgiMend®
- Symphony™
- Talymed®
- TenoGlide™
- TenSIX™ Acellular Dermal Matrix
- TheraForm™ Standard/Sheet
- TheraGenesis®
- TissueMend
- TransCyte™

- TruSkin™
- Unite™ Biomatrix
- Veritas® Collagen Matrix
- WoundEx®, 45, 200
- WoundEx® Flow
- Woundfix, Woundfix Plus, Woundfix Xplus
- Xcellerate
- Xcellistem®
- XCM Biologic® Tissue Matrix
- XenMatrix™ AB
- Xwrap.

The evidence is insufficient to determine the effects of the technology on health outcomes.

**Collagen-Based Dressing Or Wound Filler (A6010, A6011, A6021-A6024)**

Collagen-based dressing or wound filler **meets the definition of medical necessity** for full thickness wounds (e.g., stage 3 or 4 ulcers), wounds with light to moderate exudate, or wounds that have stalled or have not progressed toward a healing goal.

Collagen-based dressing or wound filler **does not meet the definition of medical necessity** for wounds with heavy exudate, third-degree burns, or when an active vasculitis is present.

## BILLING/CODING INFORMATION:

### HCPCS Coding:

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|---|---|
| A2001 | Innovamatrix ac, per square centimeter (**Investigational**) |
| A2002 | Mirragen advanced wound matrix, per square centimeter (**Investigational**) |
| A2004 | Xcellistem, 1 mg (**Investigational**) |
| A2005 | Microlyte matrix, per square centimeter (**Investigational**) |
| A2006 | Novosorb synpath dermal matrix, per square centimeter (**Investigational**) |
| A2007 | Restrata, per square centimeter (**Investigational**) |
| A2008 | Theragenesis, per square centimeter (**Investigational**) |
| A2009 | Symphony, per square centimeter (**Investigational**) |
| A2010 | Apis, per square centimeter (**Investigational**) |
| A2011 | Supra sdrm, per square centimeter (**Investigational**) |
| A2012 | Suprathel, per square centimeter (**Investigational**) |
| A2013 | Innovamatrix fs, per square centimeter (**Investigational**) |
| A2014 | Omeza collagen matrix, per 100 mg (**Investigational**) |
| A2015 | Phoenix wound matrix, per square centimeter (**Investigational**) |
| A2016 | Permeaderm b, per square centimeter (**Investigational**) |

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| A2017 | Permeaderm glove, each (**Investigational**) |
| A2018 | Permeaderm c, per square centimeter (**Investigational**) |
| A2019 | Kerecis omega3 marigen shield, per square centimeter (**Investigational**) |
| A2020 | Ac5 advanced wound system (ac5) (**Investigational**) |
| A2021 | Neomatrix, per square centimeter (**Investigational**) |
| A2022 | Innovaburn or innovamatrix xl, per square centimeter (**Investigational**) |
| A2023 | Innovamatrix pd, 1 mg (**Investigational**) |
| A2024 | Resolve matrix or xenopatch, per square centimeter (**Investigational**) |
| A2025 | Miro3d, per cubic centimeter (**Investigational**) |
| A2026 | Restrata MiniMatrix, 5 mg (**Investigational**) |
| A2027 | Matriderm, per square centimeter (**Investigational**) |
| A2028 | Micromatrix flex, per mg (**Investigational**) |
| A2029 | Mirotract wound matrix sheet, per cubic centimeter (**Investigational**) |
| A4100 | Skin substitute, fda cleared as a device, not otherwise specified |
| C1832 | Autograft suspension, including cell processing and application, and all system components (**Investigational**) |
| C9354 | Acellular pericardial tissue matrix of nonhuman origin (Veritas), per sq cm **(Investigational)** |
| C9356 | Tendon, porous matrix of cross-linked collagen and glycosaminoglycan matrix (TenoGlide Tendon Protector Sheet), per sq cm **(Investigational)** |
| C9358 | Dermal substitute, native, nondenatured collagen, fetal bovine origin (SurgiMend Collagen Matrix), per 0.5 sq cm **(Investigational)** |
| C9360 | Dermal substitute, native, nondenatured collagen, neonatal bovine origin (SurgiMend Collagen Matrix), per 0.5 sq cm **(Investigational)** |
| C9363 | Skin substitute (Integra Meshed Bilayer Wound Matrix), per square cm **(Investigational)** |
| C9364 | Porcine implant, Permacol, per sq cm **(Investigational)** |
| Q4100 | Skin substitute, not otherwise classified |
| Q4101 | Apligraf, per square centimeter |
| Q4102 | Oasis Wound Matrix, per square centimeter |
| Q4103 | Oasis Burn Matrix, per square centimeter **(Investigational)** |
| Q4104 | Integra Bilayer Matrix Wound Dressing (BMWD), per square centimeter **(Investigational)** |
| 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 **(Investigational)** |
| Q4110 | PriMatrix, per square centimeter |
| Q4111 | Gammagraft, per square centimeter **(Investigational)** |
| Q4112 | Cymetra, injectable, 1 cc **(Investigational)** |
| Q4113 | Allograft, Graftjacket Xpress, injectable, 1 cc **(Investigational)** |
| Q4114 | Integra Flowable Wound Matrix, injectable, 1 cc |
| Q4115 | Alloskin, per square centimeter **(Investigational)** |

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| Q4116 | Alloderm, per square centimeter |
| Q4117 | Hyalomatrix, per square centimeter **(Investigational)** |
| Q4118 | Matristem Micromatrix, 1 MG **(Investigational)** |
| Q4121 | Theraskin, per square centimeter |
| Q4122 | DermACELL, DermACELL AWM or DermACELL AWM Porous, per sq cm |
| Q4123 | AlloskinRT, per square centimeter **(Investigational)** |
| Q4124 | Oasis Ultra Tri-layer wound matrix, per square centimeter **(Investigational)** |
| Q4125 | Arthroflex, per square centimeter **(Investigational)** |
| Q4126 | Memoderm, Dermospan, Tranzgraft or Integuply, per square centimeter **(Investigational)** |
| Q4127 | Talymed, per square centimeter **(Investigational)** |
| Q4128 | Flex hd, or allopatch hd, per square centimeter |
| Q4130 | Strattice™, per square centimeter **(Investigational)** |
| Q4132 | Grafix core and grafixpl core, per square centimeter |
| Q4133 | Grafix prime, grafixpl prime, stravix and stravixpl, per square centimeter |
| Q4134 | hMmatrix, per square centimeter **(Investigational)** |
| Q4135 | Mediskin, per square centimeter **(Investigational)** |
| Q4136 | EZ-Derm, per square centimeter **(Investigational)** |
| Q4137 | Amnioexcel, amnioexcel plus or biodexcel, per square centimeter |
| Q4138 | BioDfence Dryflex per square centimeter **(Investigational)** |
| Q4139 | AmnioMatrix or BioDMatrix, injectable, 1 cc **(Investigational)** |
| Q4140 | BioDfense, per square centimeter **(Investigational)** |
| Q4141 | Alloskin AC, per square centimeter **(Investigational)** |
| Q4142 | XCM Biologic Tissue Matrix, per square centimeter **(Investigational)** |
| Q4143 | Repriza, per square centimeter **(Investigational)** |
| Q4145 | Epifix, injectable, 1 mg **(Investigational)** |
| Q4146 | TenSIX, per square centimeter **(Investigational)** |
| Q4147 | Architect, Architect PX, or Architect FX, extracellular matrix, per square centimeter **(Investigational)** |
| Q4148 | Neox cord 1k, neox cord rt, or clarix cord 1k, per square centimeter **(Investigational)** |
| Q4149 | Excellagen, 0.1 cc **(Investigational)** |
| Q4150 | Allowrap DS or dry, per square centimeter **(Investigational)** |
| Q4151 | Amnioband or guardian, per square centimeter |
| Q4152 | Dermapure, per square centimeter **(Investigational)** |
| Q4153 | Dermavest and plurivest, per square centimeter **(Investigational)** |
| Q4154 | Biovance, per square centimeter |
| Q4155 | Neoxflo or clarixflo, 1 mg **(Investigational)** |
| Q4156 | Neox 100 or clarix 100, per square centimeter **(Investigational)** |
| Q4157 | Revitalon, per square centimeter **(Investigational)** |
| Q4158 | Kerecis omega3, per square centimeter **(Investigational)** |
| Q4159 | Affinity, per square centimeter |
| Q4160 | Nushield, per square centimeter **(Investigational)** |

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

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|---|---|
| Q4205 | Membrane graft or membrane wrap, per square centimeter (**Investigational**) |
| Q4206 | Fluid flow or fluid GF, 1 cc (**Investigational**) |
| Q4208 | Novafix, per square centimeter (**Investigational**) |
| Q4209 | Surgraft, per square centimeter (**Investigational**) |
| Q4211 | Amnion bio or Axobiomembrane, per square centimeter (**Investigational**) |
| Q4212 | Allogen, per cc (**Investigational**) |
| Q4213 | Ascent, 0.5 mg (**Investigational**) |
| Q4214 | Cellesta cord, per square centimeter (**Investigational**) |
| Q4215 | Axolotl ambient or axolotl cryo, 0.1 mg (**Investigational**) |
| Q4216 | Artacent cord, per square centimeter (**Investigational**) |
| Q4217 | Woundfix, BioWound, Woundfix Plus, BioWound Plus, Woundfix Xplus or BioWound Xplus, per square centimeter (**Investigational**) |
| Q4218 | Surgicord, per square centimeter (**Investigational**) |
| Q4219 | Surgigraft-dual, per square centimeter (**Investigational**) |
| Q4220 | BellaCell HD or Surederm, per square centimeter (**Investigational**) |
| Q4221 | Amniowrap2, per square centimeter (**Investigational**) |
| Q4222 | Progenamatrix, per square centimeter (**Investigational**) |
| Q4226 | MyOwn skin, includes harvesting and preparation procedures, per square centimeter (**Investigational**) |
| Q4224 | Human health factor 10 amniotic patch (hhf10-p), per square centimeter (**Investigational**) |
| Q4225 | Amniobind or dermabind tl, per square centimeter (**Investigational**) |
| Q4227 | Amniocore, per square centimeter (**Investigational**) |
| Q4229 | Cogenex amniotic membrane, per square centimeter (**Investigational**) |
| Q4230 | Cogenex flowable amnion, per 0.5 cc (**Investigational**) |
| Q4231 | Corplex p, per cc (**Investigational**) |
| Q4232 | Corplex, per square centimeter (**Investigational**) |
| Q4233 | Surfactor or nudyn, per 0.5 cc (**Investigational**) |
| Q4234 | Xcellerate, per square centimeter (**Investigational**) |
| Q4235 | Amniorepair or altiply, per square centimeter (**Investigational**) |
| Q4236 | Carepatch, per square centimeter (**Investigational**) |
| Q4237 | Cryo-cord, per square centimeter (**Investigational**) |
| Q4238 | Derm-maxx, per square centimeter (**Investigational**) |
| Q4239 | Amnio-maxx or amnio-maxx lite, per square centimeter (**Investigational**) |
| Q4240 | Corecyte, for topical use only, per 0.5 cc (**Investigational**) |
| Q4241 | Polycyte, for topical use only, per 0.5 cc (**Investigational**) |
| Q4242 | Amniocyte plus, per 0.5 cc (**Investigational**) |
| Q4245 | Amniotext, per cc (**Investigational**) |
| Q4246 | Coretext or protext, per cc (**Investigational**) |
| Q4247 | Amniotext patch, per square centimeter (**Investigational**) |
| Q4248 | Dermacyte amniotic membrane allograft, per square centimeter **(Investigational)** |
| Q4249 | Amniply, for topical use only, per square centimeter (**Investigational**) |

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|---|---|
| Q4250 | Amnioamp-mp, per square centimeter (**Investigational**) |
| Q4251 | Vim, per square centimeter (**Investigational**) |
| Q4252 | Vendaje, per square centimeter (**Investigational**) |
| Q4253 | Zenith amniotic membrane, per square centimeter (**Investigational**) |
| Q4254 | Novafix dl, per square centimeter (**Investigational**) |
| Q4255 | Reguard, for topical use only, per square centimeter (**Investigational**) |
| Q4256 | Mlg-complete, per square centimeter (**Investigational**) |
| Q4257 | Relese, per square centimeter (**Investigational**) |
| Q4258 | Enverse, per square centimeter (**Investigational**) |
| Q4259 | Celera dual layer or celera dual membrane, per square centimeter (**Investigational**) |
| Q4260 | Signature apatch, per square centimeter (**Investigational**) |
| Q4261 | Tag, per square centimeter (**Investigational**) |
| Q4262 | Dual layer impax membrane, per square centimeter (**Investigational**) |
| Q4263 | Surgraft tl, per square centimeter (**Investigational**) |
| Q4264 | Cocoon membrane, per square centimeter (**Investigational**) |
| Q4265 | Neostim tl, per square centimeter (**Investigational**) |
| Q4266 | Neostim membrane, per square centimeter (**Investigational**) |
| Q4267 | Neostim dl, per square centimeter (**Investigational**) |
| Q4268 | Surgraft ft, per square centimeter (**Investigational**) |
| Q4269 | Surgraft xt, per square centimeter (**Investigational**) |
| Q4270 | Complete sl, per square centimeter (**Investigational**) |
| Q4271 | Complete ft, per square centimeter (**Investigational**) |
| Q4272 | Esano a, per square centimeter (**Investigational**) |
| Q4273 | Esano aaa, per square centimeter (**Investigational**) |
| Q4274 | Esano ac, per square centimeter (**Investigational**) |
| Q4275 | Esano aca, per square centimeter (**Investigational**) |
| Q4276 | Orion, per square centimeter (**Investigational**) |
| Q4278 | Epieffect, per square centimeter (**Investigational**) |
| Q4279 | Vendaje ac, per square centimeter (**Investigational**) |
| Q4280 | Xcell amnio matrix, per square centimeter (**Investigational**) |
| Q4281 | Barrera sl or barrera dl, per square centimeter (**Investigational**) |
| Q4282 | Cygnus dual, per square centimeter (**Investigational**) |
| Q4283 | Biovance tri-layer or biovance 3l, per square centimeter |
| Q4284 | Dermabind sl, per square centimeter (**Investigational**) |
| Q4285 | Nudyn dl or nudyn dl mesh, per square centimeter (**Investigational**) |
| Q4286 | Nudyn sl or nudyn slw, per square centimeter (**Investigational**) |
| Q4287 | Dermabind dl, per square centimeter (**Investigational**) |
| Q4288 | Dermabind ch, per square centimeter (**Investigational**) |
| Q4289 | Revoshield + amniotic barrier, per square centimeter (**Investigational**) |
| Q4290 | Membrane wrap-hydro, per square centimeter (**Investigational**) |
| Q4291 | Lamellas xt, per square centimeter (**Investigational**) |
| Q4292 | Lamellas, per square centimeter (**Investigational**) |

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|---|---|
| Q4293 | Acesso dl, per square centimeter (**Investigational**) |
| Q4294 | Amnio quad-core, per square centimeter (**Investigational**) |
| Q4295 | Amnio tri-core amniotic, per square centimeter (**Investigational**) |
| Q4296 | Rebound matrix, per square centimeter (**Investigational**) |
| Q4297 | Emerge matrix, per square centimeter (**Investigational**) |
| Q4298 | Amnicore pro, per square centimeter (**Investigational**) |
| Q4299 | Amnicore pro+, per square centimeter (**Investigational**) |
| Q4300 | Acesso tl, per square centimeter (**Investigational**) |
| Q4301 | Activate matrix, per square centimeter (**Investigational**) |
| Q4302 | Complete aca, per square centimeter (**Investigational**) |
| Q4303 | Complete aa, per square centimeter (**Investigational**) |
| Q4304 | Grafix plus, per square centimeter |
| Q4305 | American amnion ac tri-layer, per square centimeter (**Investigational**) |
| Q4306 | American amnion ac, per square centimeter (**Investigational**) |
| Q4307 | American amnion, per square centimeter (**Investigational**) |
| Q4308 | Sanopellis, per square centimeter (**Investigational**) |
| Q4309 | Via matrix, per square centimeter (**Investigational**) |
| Q4310 | Procenta, per 100 mg (**Investigational**) |
| Q4311 | Acesso, per square centimeter (**Investigational**) |
| Q4312 | Acesso ac, per square centimeter (**Investigational**) |
| Q4313 | Dermabind fm, per square centimeter (**Investigational**) |
| Q4314 | Reeva ft, per square cenitmeter (**Investigational**) |
| Q4315 | Regenelink amniotic membrane allograft, per square centimeter (**Investigational**) |
| Q4316 | Amchoplast, per square centimeter (**Investigational**) |
| Q4317 | Vitograft, per square centimeter (**Investigational**) |
| Q4318 | E-graft, per square centimeter (**Investigational**) |
| Q4319 | Sanograft, per square centimeter (**Investigational**) |
| Q4320 | Pellograft, per square centimeter (**Investigational**) |
| Q4321 | Renograft, per square centimeter (**Investigational**) |
| Q4322 | Caregraft, per square centimeter (**Investigational**) |
| Q4323 | Alloply, per square centimeter (**Investigational**) |
| Q4324 | Amniotx, per square centimeter (**Investigational**) |
| Q4325 | Acapatch, per square centimeter (**Investigational**) |
| Q4326 | Woundplus, per square centimeter (**Investigational**) |
| Q4327 | Duoamnion, per square centimeter (**Investigational**) |
| Q4328 | Most, per square centimeter (**Investigational**) |
| Q4329 | Singlay, per square centimeter (**Investigational**) |
| Q4330 | Total, per square centimeter (**Investigational**) |
| Q4331 | Axolotl graft, per square centimeter (**Investigational**) |
| Q4332 | Axolotl dualgraft, per square centimeter (**Investigational**) |
| Q4333 | Ardeograft, per square centimeter (**Investigational**) |
| Q4336 | Artacent c, per square centimeter (**Investigational**) |

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|---|---|
| Q4337 | Artacent trident, per square centimeter (**Investigational**) |
| Q4338 | Artacent velos, per square centimeter (**Investigational**) |
| Q4339 | Artacent vericlen, per square centimeter (**Investigational**) |
| Q4340 | Simpligraft, per square centimeter (**Investigational**) |
| Q4341 | Simplimax, per square centimeter (**Investigational**) |
| Q4342 | Theramend, per square centimeter (**Investigational**) |
| Q4343 | Dermacyte ac matrix amniotic membrane allograft, per square centimeter (**Investigational**) |
| Q4344 | Tri-membrane wrap, per square centimeter (**Investigational**) |
| Q4345 | Matrix hd allograft dermis, per square centimeter (**Investigational**) |

## ICD-10 Diagnosis Codes That Support Medical Necessity:

| | |
|---|---|
| C50.011 – C50.019<br>C50.111 – C50.119<br>C50.211 – C50.219<br>C50.311 – C50.319<br>C50.411 – C50.519<br>C50.611 – C50.619<br>C50.811 – C50.819<br>C50.911 – C50.919 | Malignant neoplasm of breast |
| D05.00 – D05.92 | Carcinoma in situ of breast |
| E08.621 | Diabetes mellitus due to underlying condition with foot ulcer |
| E08.622 | Diabetes mellitus due to underlying condition with other skin ulcer |
| E09.621 | Drug or chemical induced diabetes mellitus with foot ulcer |
| E09.622 | Drug or chemical induced diabetes mellitus with other skin ulcer |
| E10.621 | Type 1 diabetes mellitus with foot ulcer |
| E10.622 | Type 1 diabetes mellitus with other skin ulcer |
| E11.621 | Type 2 diabetes mellitus with foot ulcer |
| E11.622 | Type 2 diabetes mellitus with other skin ulcer |
| E13.621 | Other specified diabetes mellitus with foot ulcer |
| E13.622 | Other specified diabetes mellitus with other skin ulcer |
| I83.001 – I83.029 | Varicose veins of lower extremities with ulcer |
| I83.201 – I83.229 | Varicose veins of lower extremities with both ulcer and inflammation |
| Q81.2 | Epidermolysis bullosa dystrophica |
| T20.20xA – T20.39xS<br>T20.60xA – T20.79xS | Burn and corrosion of head, face and neck |
| T21.20xA – T21.39xS<br>T21.60xA – T21.79xS | Burn and corrosion of trunk |
| T22.20xA – T22.399S<br>T22.60xA – T22.799S | Burn and corrosion of shoulder and upper limb except wrist and hand |
| T23.201A – T23.399S<br>T23.601A – T23.799S | Burn and corrosion of wrist and hand |
| T24.201A – T24.399S<br>T24.601A – T24.799S | Burn and corrosion of lower limb, except ankle and foot |

| | |
|---|---|
| T25.211A – T25.399S<br>T25.611A – T25.799S | Burn and corrosion of ankle and foot |
| T30.0 – T32.99 | Burns classified according to extent of body surface involvement |
| T34.011A – T34.99XS | Frostbite with tissue necrosis |

## Application Codes: (See reimbursement section below)

| | |
|---|---|
| 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) |

### Collagen Dressing or Wound Filler: (See reimbursement section below)

| | |
|---|---|
| A6010 | Collagen based wound filler, dry form, sterile, per g of collagen |
| A6011 | Collagen based wound filler, gel/paste, per g of collagen |
| A6021 | Collagen dressing, sterile, size 16 sq in or less, each |
| A6022 | Collagen dressing, sterile, size more than 16 sq in but less than or equal to 48 sq in, each |
| A6023 | Collagen dressing, sterile, size more than 48 sq in, each |
| A6024 | Collagen dressing wound filler, sterile, per 6 in |

## REIMBURSEMENT INFORMATION:

Apligraf® is limited to five (5) applications per ulcer. The safety and the effectiveness of Apligraf have not been established for patients receiving greater than 5 applications.

Dermagraft® is limited to eight (8) applications per treatment site over a twelve (12) week period. Dermagraft has not been studied in patients receiving greater than 8 device applications.

OrCel™ is limited to a single, one-time application per donor site. No more than eight (8) pieces should be used per donor site. The safety and effectiveness of OrCel has not been evaluated in burn patients with split thickness donor sites larger than 288cm (8 pieces of Orcel).

Safety and effectiveness of **re-treatment** of a single wound using Apligraf®, Dermagraft® or OrCel™ has not been established and is considered **experimental or Investigational**.

Application codes (15271-15278, C5271-C5278) must be submitted with product codes.

Collagen-based dressings or wound fillers (A6010, A6011, A6021-A6024) can stay in place up to 7 days. Dressings are limited to 26 units per treatment site per 6-month period.

## PROGRAM EXCEPTIONS:

**Federal Employee Program (FEP):** Follow FEP guidelines.

**State Account Organization (SAO):** Follow SAO guidelines.

**Medicare Advantage products:**

The following National Coverage Determination (NCD) was reviewed on the last guideline reviewed date: Porcine skin and Gradient Pressure Dressing (270.5) located at cms.gov.

The following were reviewed on the last guideline reviewed date: Local Coverage Determination (LCD) Application of Skin Substitute Grafts for Treatment of DFU and VLU of Lower Extremities (L36377); LCD Surgical Dressings (L33831); and Local Coverage Article Billing and Coding: Application of Skin Substitute Grafts for Treatment of DFU and VLU of Lower Extremities A57680 located at fcso.com.

## DEFINITIONS:

**Nonhealing**- less than a 20% decrease in wound area with standard wound care for at least 2 weeks.

## RELATED GUIDELINES:

**Amniotic Membrane and Limbal Stem Cell Transplantation for the Treatment of Ocular Conditions, 02-65000-19**

## OTHER:

None.

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## COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 04/25/24.

## GUIDELINE UPDATE INFORMATION:

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|---|---|
| 01/01/01 | New Medical Coverage Guideline. |
| 01/01/02 | Annual HCPCS coding update. |
| 01/01/03 | Annual HCPCS coding update. |
| 02/15/03 | Annual Review. |
| 06/15/04 | Unscheduled review and revision to guideline; consisting of updated references, deleted J7350 and changed name of MCG from Apligraf (Graftskin) to Human Skin Equivalent Grafts. |
| 01/01/05 | Annual HCPCS coding update: consisting of addition of J7343 and J7344 and deletion of Q0182 and Q0183. |
| 01/01/06 | Annual HCPCS coding update: added 15000, 15340, 15341, 15360, 15361, 15365, and 15366. Deleted: 15342, 15343, J7343. Revised: J7340, J7342, and J7344. |
| 08/15/06 | Biennial review; new information added for Integra, TransCyte, allograft, OrCel, xenograft, AlloDerm; revision to code information; code J7343 added. |
| 01/01/07 | Annual HCPCS coding update: added J7345, J7346; deleted 15000 – 15400 & changed to 15002 – 15005 to describe codes used for graft site preparation & graft application. |
| 03/15/07 | Revision to guideline; consisting of addition of OASIS Wound Matrix (J7341), revision to criteria for Apligraf (J7340), revision to code information for J7344 and J7343, updated references. |
| 06/15/07 | Reformatted guideline. |
| 08/15/07 | Review, coverage statements maintained, references updated. |
| 01/01/08 | Annual HCPCS coding update: deleted J7345; added J7347, J7348, J7349. |
| 01/01/09 | Annual HCPCS coding update: added HCPCS codes Q4100 – Q4114; updated ICD-9 codes 707.10 – 707.19 & 707.8; and deleted HCPCS codes J7340-J7349. |
| 07/01/09 | Biennial review: description section, Alloderm position statement, coding and references updated. HCPCS 3rd quarter coding update: added new codes Q4115 and Q4116. |
| 10/15/10 | Revision; related ICD-10 codes added. |

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| 01/01/11 | Annual HCPCS coding update. Added Q4117 – Q4121; revised Q4101 – Q4116; deleted Q4109. |
| 07/15/11 | Scheduled review; position statements maintained, coding section and references updated. |
| 01/01/12 | Annual HCPCS coding update; added HCPCS codes Q4122-Q4130; CPT coding section updated. |
| 07/15/12 | Annual review; position statements, billing/coding information, description section, Medicare program exception, and references updated; formatting changes. |
| 01/01/13 | Annual HCPCS update; added Q4131-Q4136; revised Q4119, Q4126, & Q4128. Experimental list updated; formatting changes. |
| 07/15/13 | Annual review; description section, position statement, and references updated; formatting changes. |
| 01/01/14 | Annual HCPCS update. Added codes Q4137-Q4149. Position statement updated; formatting changes. |
| 03/15/14 | Annual review; position statements, Coding, Description, and references updated; formatting changes. |
| 06/15/14 | Revision; references updated. |
| 01/01/15 | Annual HCPCS/CPT update. Added codes Q4150-Q4160; revised codes Q4119 & Q4147. |
| 03/15/15 | Annual review; description and position statement section updated; coding and references updated; formatting changes. |
| 10/01/15 | Revision; ICD9 and ICD10 coding sections updated. |
| 11/01/15 | Revision: ICD-9 Codes deleted. |
| 01/01/16 | Annual HCPCS/CPT update; codes Q4161-Q4165 added; code Q4153 revised. |
| 08/15/16 | Revision; policy title, description section, position statement section, coding, and references updated; formatting changes. |
| 10/01/16 | Revision; formatting changes. Investigational product list updated. |
| 11/15/16 | Revision; coding section updated. |
| 01/01/17 | Annual CPT/HCPCS update. Added Q4166-Q4175; revised Q4105 & Q4131; deleted Q4119, Q4120, Q4129. |
| 03/15/17 | Revision; Position statements including treatment of diabetic ulcers, amniotic membrane, and investigational product list updated; Code Q4151, program exception, and references updated. |
| 04/15/17 | Revision; code C9349 deleted. |
| 08/15/17 | Revision; Integra Omnigraft deleted from investigational product list and added to bullet for Integra® Dermal Regeneration Template. |
| 01/01/18 | Annual CPT/HCPCS update. Added codes Q4176-Q4182; revised codes Q4132, Q4133, Q4148, Q4156, Q4158, Q4162, Q4163. |
| 04/15/18 | Revision; description, position statements, coding, and references updated. |
| 01/01/19 | Annual CPT/HCPCS coding update. Added codes Q4183-Q4204; revised codes Q4133 & Q4137; deleted codes Q4131 & Q4172. |
| 04/15/19 | Review;Investigational product list and references updated. |
| 07/01/19 | Revision; Investigational product list updated. |

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| 10/01/19 | Quarterly CPT/HCPCS coding update. Added codes Q4205-Q4226; revised codes Q4122, Q4165, Q4184. |
| 04/15/20 | Review; position statements and references updated. |
| 07/01/20 | Quarterly CPT/HCPCS coding update. Added codes Q4227-Q4248; revised code Q4176. |
| 08/15/20 | Revision; coding section updated. |
| 10/01/20 | Quarterly CPT/HCPCS coding update. Added codes Q4249, Q4250, Q4254, Q4255. |
| 04/15/21 | Review; Position statements, investigational product list, coding and references updated. |
| 05/21/21 | Revision; investigational product list updated. |
| 10/01/21 | Quarterly CPT/HCPCS coding update. Codes Q4251-Q4253 added; codes Q4228 & Q4236 deleted. |
| 01/01/22 | Annual CPT/HCPCS coding update. Codes A2001-A2010, Q4199 added. |
| 01/05/22 | Revision; code A2003 deleted. |
| 04/01/22 | Review: Amniotic membrane position statement updated and references updated.<br>Quarterly CPT/HCPCS coding update. Codes A2011-A2013, A4100, Q4224, Q4225, Q4256-Q4258 added. |
| 07/01/22 | Quarterly CPT/HCPCS coding update. Codes Q4259-Q4261 added; code A2004 revised. |
| 10/01/22 | Quarterly CPT/HCPCS coding update. Codes A2014-A2018 added; code Q4128 revised. |
| 01/01/23 | Annual CPT/HCPCS coding update. Codes Q4236, Q4262-Q4264 added. |
| 04/01/23 | Quarterly CPT/HCPCS coding update. Codes A2019-A2021, Q4265-Q4271 added. |
| 07/01/23 | Quarterly CPT/HCPCS coding update. Codes Q4272-Q4284 added. |
| 10/01/23 | Review: Investigational product list, coding, and references updated.<br>Quarterly CPT/HCPCS coding update. Codes A2022-A2025, Q4285, Q4286 added. |
| 01/01/24 | Annual CPT/HCPCS coding update. Codes Q4279, Q4287-Q4304 added; code Q4225 revised. |
| 04/01/24 | Quarterly CPT/HCPCS coding update. Codes A2026, Q4305-Q4310 added; deleted Q4244. |
| 05/15/24 | Review: Position statements, decscription, coding, reimbursement, and references updated. |
| 07/01/24 | Quarterly CPT/HCPCS coding update. Codes Q4311-Q4333 added; codes Q4210, Q4277 deleted. |
| 09/15/24 | Revision: Collagen dressing positon statements added; coding, reimbursement, and references updated. |
| 10/01/24 | Quarterly CPT/HCPCS coding update. Codes A2027-A2029, Q4336-Q4345 added; code A2024 revised. |