02-10000-11

Original Effective Date: 01/01/01

Reviewed: 03/28/19

Revised: 10/01/19

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

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
Other	References	Updates			

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.

There are a large number of potential applications for artificial skin and soft tissue products. One large category is nonhealing wounds, which potentially encompasses diabetic neuropathic ulcers, vascular insufficiency ulcers, and pressure ulcers. A substantial minority of such wounds do not heal adequately with standard wound care, leading to prolonged morbidity and increased risk of mortality. For example, nonhealing lower-extremity wounds represent an ongoing risk for infection, sepsis, limb amputation, and

death. Bioengineered skin and soft tissue substitutes have the potential to improve rates of healing and reduce secondary complications.

Other situations in which bioengineered skin products might substitute for living skin grafts include certain postsurgical states (eg, breast reconstruction) in which skin coverage is inadequate for the procedure performed, or for surgical wounds in patients with compromised ability to heal. Second- and third-degree burns are another indication in which artificial skin products may substitute for auto- or allografts. Certain primary dermatologic conditions that involve large areas of skin breakdown (eg, bullous diseases) may also be conditions in which artificial skin products can be considered as substitutes for skin grafts. ADM products are also being evaluated in the repair of other soft tissues including rotator cuff repair, following oral and facial surgery, hernias, and other conditions.

Amniotic Membrane and Amniotic Fluid

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.

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.

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™**.

* 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 are considered **experimental or Investigational**. The evidence is insufficient to determine the effects of the technology on health outcomes.

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:**

- AmnioBand® Membrane
- Biovance®
- Epifix®
- Grafix™.

All other human amniotic membrane products and indications not listed above are considered **experimental or investigational**, including but not limited to treatment of lower extremity ulcers due to venous insufficiency. 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
- Affinity™
- AlloSkin™
- AlloSkin™ AC
- AlloSkin™ RT
- Allowrap™
- Alphaplex™ with MariGen Omega3™
- AmnioBand™ Particulate
- AmnioClear™
- AmnioExCel™
- AmnioFix®
- AmnioFix® Injectable
- AmnioGen™ 45
- AmnioGen™ 200
- AmnioGen™ A
- AmnioGen™ C
- AmnioGraft®
- AmnioMatrix®
- AmnioPro® 45
- AmnioPro® 200
- AmnioPro® Flow
- AmnioVisc™
- Aongen™ Collagen Matrix
- Architect® ECM, PX, FX
- ArthroFlex™ (FlexGraft)
- Atlas Wound Matrix

- Artacent® Wound
- Avagen Wound Dressing
- Avaulta Plus™
- AxoGuard® Nerve Protector (AxoGen)
- Biobrane®/Biobrane-L
- BioDDryFlex®
- BioDfence™
- BioDfence Dryflex™/BioDfactor™
- BioDMatrix™
- BioRenew® 45
- BioRenew® 200
- BioRenew® Flow
- BioSkin® 45
- BioSkin® 200
- BioSkin® Flow
- CellerateRX® (CRXa)
- Clarix®
- Clarix® Flo
- CollaCare®
- CollaCare® Dental
- Collagen Sponge
- Collagen Wound Dressing (Oasis Research)
- CollaGUARD®
- CollaMend™
- CollaSorb™
- CollaWound™
- Collexa®
- Collieva®
- Conexa™
- Coreleader Colla-Pad
- CorMatrix®
- CRXa™
- Cygnus
- Cygnus Max
- Cymetra® (Micronized AlloDerm™)

- Cytal™ (previously MatriStem®)
- Dermadapt™ Wound Dressing
- DermaPure™
- DermaSpan™
- DressSkin
- Dermavest™
- DressSkin
- Durepair Regeneration Matrix®
- Endoform Dermal Template™
- *ENDURA*gen™
- EpiCord™
- Excellagen®
- ExpressGraft™
- E-ZDerm®
- FlexiGraft®
- GammaGraft
- GraftJacket® Xpress, injectable
- HA Absorbent Wound Dressing
- Helicoll™
- Hyalomatrix®
- Hyalomatrix® PA
- hMatrix®
- Hyalomatrix® PA
- HydraTek®
- Integra™ Bilayer Wound Matrix
- Interfyl™
- Jaloskin®
- Kermatrix®
- Kerecis™
- MariGen™/Kerecis™ Omega3™
- MatriDerm®
- Matrix Collagen Wound Dressing
- Matrix HD™
- MediHoney®
- Mediskin®

- MemoDerm™
- Microderm® Biologic Wound Matrix
- NeoForm™
- Neox®100
- Neox®Flo
- Neox® Cord
- Neox® Wound Allograft
- NuCel®
- NuShield™
- Oasis® Burn Matrix
- Oasis® Ultra Tri-Layer Matrix
- OrthoFlo™
- PalinGen® Flow
- PalinGen® Membrane
- PalinGen® SprotFlow
- Pelvicol®/PelviSoft®
- Permacol™
- Plurivest™
- PriMatrix™
- Primatrix™ Dermal Repair Scaffold
- ProMatrX™ ACF
- PuraPly™ Wound Matrix (previously FortaDerm™)
- PuraPly™ AM (Antimicrobial Wound Matrix)
- Puros® Dermis
- RegenePro™
- ReNu™
- Repriza™
- Repliform®
- Repriza™
- Revitalon™
- SIS Wound Dressing ll
- Sport Flow™
- SS Matrix™
- Stimulen™ Collagen
- StrataGraft®

- Strattice™ (xenograft)
- Suprathel®
- SurgiMend®
- Talymed®
- TenoGlide™
- TenSIX™ Acellular Dermal Matrix
- TheraForm™ Standard/Sheet
- TheraSkin®
- TissueMend
- TransCyte™
- TruSkin™
- Unite™ Biomatrix
- Veritas® Collagen Matrix
- WoundEx® 45
- WoundEx® 200
- WoundEx® Flow
- XCM Biologic® Tissue Matrix
- XenMatrix™ AB.

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

BILLING/CODING INFORMATION:

HCPCS Coding:

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 **(Investigational)**
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 **(Investigational)**
Q4115	Alloskin, per square centimeter **(Investigational)**
Q4116	Alloderm, per square centimeter
Q4117	Hyalomatrix, per square centimeter **(Investigational)**
Q4118	Matristem Micromatrix, 1 MG **(Investigational)**
Q4121	Theraskin, per square centimeter **(Investigational)**
Q4122	Dermalcell, dermacell awm or dermacell awm porous, per square centimeter **(Investigational)**
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	FlexHD, AllopatchHD, or Matrix HD, per square centimeter
Q4130	StratticeTM, 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 **(Investigational)**
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 **(Investigational)**
Q4160	Nushield, per square centimeter **(Investigational)**
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, 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 centimeter (**Investigational**)
Q4185	Cellesta flowable amnion (25 mg per cc); per 0.5 cc (**Investigational**)
Q4186	Epifix, per square centimeter
Q4187	Epicord, per square centimeter (**Investigational**)
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**)
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**)
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**)
Q4210	Axolotl graft or axolotl dualgraft, 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**)

ICD-10 Diagnosis Codes That Support Medical Necessity:

C50.011 – C50.019 C50.111 – C50.119 C50.211 – C50.219 C50.311 – C50.319 C50.411 – C50.519 C50.611 – C50.619 C50.811 – C50.819 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 T20.60xA – T20.79xS	Burn and corrosion of head, face and neck
T21.20xA – T21.39xS T21.60xA – T21.79xS	Burn and corrosion of trunk
T22.20xA – T22.399S T22.60xA – T22.799S	Burn and corrosion of shoulder and upper limb except wrist and hand
T23.201A – T23.399S T23.601A – T23.799S	Burn and corrosion of wrist and hand
T24.201A – T24.399S T24.601A – T24.799S	Burn and corrosion of lower limb, except ankle and foot
T25.211A – T25.399S 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

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**.

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 was reviewed on the last guideline reviewed date: Fact Sheet: CMS issues hospital outpatient department and ambulatory surgical center policy and payment changes for 2014, located at cms.gov.

The following Local Coverage Determinations (LCDs) were reviewed on the last guideline reviewed date and are located at fcso.com:

- Application of Skin Substitute Grafts for Treatment of DFU and VLU of Lower Extremities (L36377)

- Amniotic Membrane- Sutureless Placement on the Ocular Surface (L36237).

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.

REFERENCES:

1. Agency for Healthcare Research and Quality (AHRQ), Negative Pressure Wound Therapy Devices, Technology Assessment Report, 2009. Accessed at ahrq.gov 08/02/12.
2. Agency for Healthcare Research and Quality (AHRQ), Skin Substitutes for Treating Chronic Wounds, 12/18/12.
3. American Diabetes Association, Diabetes Care- Graftskin, A Human Skin Equivalent, Is Effective in the Management of Noninfected Neuropathic Diabetic Foot Ulcers, 2001.
4. American Society of Plastic Surgeons. Evidence-Based Clinical Practice Guideline: Breast Reconstruction with Expanders and Implants. 2013; accessed at plasticsurgery.org 01/21/14.
5. American Society of Plastic Surgeons (ASPS). Evidence-based Clinical Practice Guideline: Chronic Wounds of the Lower Extremity. 2007. Accessed at plasticsurgery.org 05/14/13.
6. Athavale SM, Phillips S, Mangus B et al. Complications of alloderm and dermamatrix for parotidectomy reconstruction. Head Neck 2011.
7. Azar FK, Crawford TC, et al. Ventral hernia repair in patients with abdominal loss of domain: an observational study of one institution's experience. Hernia. 2017 Apr;21(2):245-252.
8. Baldursson BT, Kjartansson H, et al, Healing rate and autoimmune safety of full-thickness wounds treated with fish skin acellular dermal matrix versus porcine small-intestine submucosa: a noninferiority study. Int J Low Extrem Wounds. 2015 Mar;14(1):37-43.
9. Ball JF, Sheena Y, et al. A direct comparison of porcine (Strattice™) and bovine (Surgimend™) acellular dermal matrices in implant-based immediate breast reconstruction. J Plast Reconstr Aesthet Surg. 2017 Aug;70(8):1076-1082.
10. Bastidas N, Ashjian PJ, Sharma S, Acellular Dermal Matrix for Temporary Coverage of Exposed Critical Neurovascular Structures in Extremity Wounds, Annals of Plastic Surgery, April 2009, Vol 62, Issue 4, pp 410-413.
11. Bianchi C, Cazzell S, et al. A multicentre randomised controlled trial evaluating the efficacy of dehydrated human amnion/chorion membrane (EpiFix®) allograft for the treatment of venous leg ulcers. Int Wound J. 2018 Feb;15(1):114-122.
12. Blue Cross Blue Shield Association, Medical Policy Reference Manual: 7.01.149 Amniotic Membrane and Amniotic Fluid Injections, 03/19.
13. Blue Cross Blue Shield Association, Medical Policy Reference Manual: 7.01.113 Bio-Engineered Skin and Soft Tissue Substitutes, 02/19.

14. Blue Cross and Blue Shield Technology Evaluation Center. Grafskin for the treatment of skin ulcers. TEC Assessments 2001; Volume 16, Tab 12.
15. Brantley JN, Verla TD, Use of Placental Membranes for the Treatment of Chronic Diabetic Foot Ulcers. Adv Wound Care (New Rochelle). 2015 Sep 1;4(9):545-559.
16. Budny AM, Ley A, Cryopreserved Allograft as an Alternative Option for Closure of Diabetic Foot Ulcers, Podiatry Management, 2013; 131-136.
17. Butterfield JL. 440 Consecutive immediate, implant-based, single-surgeon breast reconstructions in 281 patients: a comparison of early outcomes and costs between SurgiMend fetal bovine and AlloDerm human cadaveric acellular dermal matrices. Plast Reconstr Surg. May 2013;131(5):940-951.
18. Cazzell SM, et al, The Management of Diabetic Foot Ulcers with Porcine Small Intestine Submucosa Tri-Layer Matrix: A Randomized Controlled Trial. Adv Wound Care (New Rochelle). 2015 Dec 1;4(12):711-718.
19. Cazzell S, Vayser D, et al, A randomized clinical trial of a human acellular dermal matrix demonstrated superior healing rates for chronic diabetic foot ulcers over conventional care and an active acellular dermal matrix comparator. Wound Repair Regen. 2017 May;25(3):483-497.
20. Centers for Medicare and Medicaid Services (CMS). Fact Sheet: CMS issues hospital outpatient department and ambulatory surgical center policy and payment changes for 2014; release 11/27/13; accessed at cms.gov.
21. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) for Porcine skin and Gradient Pressure Dressing (270.5), accessed at cms.gov.
22. DiDomenico L, Emch KJ, et al, A Prospective Comparison of Diabetic Foot Ulcers Treated With Either a Cryopreserved Skin Allograft or a Bioengineered Skin Substitute WOUNDS 2011;23(7):184–189.
23. DiDomenico LA, Orgill DP, et al, Aseptically Processed Placental Membrane Improves Healing of Diabetic Foot Ulcerations: Prospective, Randomized Clinical Trial. Plast Reconstr Surg Glob Open. 2016 Oct 12;4(10):e1095.
24. Driver VR, Lavery LA, et al, A clinical trial of Integra Template for diabetic foot ulcer treatment. Wound Repair Regen. 2015 Nov-Dec;23(6):891-900.
25. Duan-Arnold Y, Gyurdieva A, et al; Soluble Factors Released by Endogenous Viable Cells Enhance the Antioxidant and Chemoattractive Activities of Cryopreserved Amniotic Membrane. Advances in Wound Care. May 2015, 4(6): 329-338.
26. Duan-Arnold Y, Uveges TE, et al; Angiogenic Potential of Cryopreserved Amniotic Membrane Is Enhanced Through Retention of All Tissue Components in Their Native State. Advances in Wound Care. August 2015, 4(9): 513-522.
27. Eichler C, Efremova J, et al. A Head to Head Comparison Between SurgiMend® - Fetal Bovine Acellular Dermal Matrix and Tutomesh® - A Bovine Pericardium Collagen Membrane in Breast Reconstruction in 45 Cases. In Vivo. 2017 Jul-Aug;31(4):677-682.
28. Fetterolf D, Savage R, Dehydrated Human Amniotic Tissue Improves Healing Time, Cost of Care. Today's Wound Clinic, Jan/Feb 2013.
29. First Coast Service Options, Inc. (FCSO), LCD for Amniotic Membrane- Sutureless Placement on the Ocular Surface (L36237); accessed at fcso.com.
30. First Coast Service Options, Inc. (FCSO), LCD for Application of Skin Substitute Grafts for Treatment of DFU and VLU of Lower Extremities (L36377); accessed at fcso.com.
31. Fleshman JW, Beck DE, et al. A prospective, multicenter, randomized, controlled study of non-cross-linked porcine acellular dermal matrix fascial sublay for parastomal reinforcement in patients undergoing surgery for permanent abdominal wall ostomies. Dis Colon Rectum. May 2014;57(5):623-631.

32. Frykberg RG, Banks J; Challenges in the Treatment of Chronic Wounds. Advances in Wound Care. August 2015, 4(9): 560-582.

33. Frykberg RG, Gibbons, GW, et al, A prospective, randomized, multicenter, open-label, single-arm clinical trial for treatment of chronic complex diabetic foot wounds with exposed tendon and/or bone: positive clinical outcomes of viable cryopreserved human placental membrane; Int Wound J. 2016 Aug 3. Doi: 10.1111/iwj.12649.

34. Frykberg RG, Zgonis T, Armstrong DG et al. Diabetic foot disorders. A clinical practice guideline (2006 revision). J Foot Ankle Surg 2006; 45 (5 Suppl):S1-66. Accessed at acfas.org 05/14/13.

35. Gaster RS, Berger AJ, Monica SD, et al, Histologic Analysis of Fetal Bovine Derived Acellular Dermal Matrix in Tissue Expander Breast Reconstruction, Annals of Plastic Surgery, Vol.70, Number 4, April 2013.

36. Gibson GW, Grafix®, a Cryopreserved Placental Membrane, for the Treatment of Chronic/Stalled Wounds. Adv Wound Care (New Rochelle). 2015 Sep 1;4(9):534-544.

37. Hankin CS, Knispel J, Lopes M, et al, Clinical and Cost Efficacy of Advanced Wound Care Matrices for Venous Ulcers, J Manag Care Pharm. 2012;18(5):375-84.

38. Hayes Medical Technology Directory. Skin Substitutes for Wound Healing (SKIN0301.19) 02/01/04, update 02/09/07.

39. Hopf HW, Ueno C, Aslam R et al. Guidelines for the treatment of arterial insufficiency ulcers. Wound Repair Regen 2006; 14(6)693-710. 2007/01/04, accessed at plasticsurgery.org 05/14/13.

40. Hsu GS, Utilizing Dehydrated Human Amnion/Chorion Membrane Allograft in Transcanal Tympanoplasty, 4:161. Doi: 10.4172/2161-119X.1000161.

41. Karr JC, Retrospective Comparison of Diabetic Foot Ulcer and Venous Stasis Ulcer Healing Outcome Between a Dermal Repair Scaffold (PriMatrix) and a Bilayered Living Cell Therapy (Apligraf), Adv Skin Wound Care. 2011 Mar;24(3):119-25.

42. Kavros SJ, Dutra T, et al. The use of PriMatrix, a fetal bovine acellular dermal matrix, in healing chronic diabetic foot ulcers: a prospective multicenter study. Adv Skin Wound Care. Aug 2014;27(8):356-362.

43. Keifer OP, Page EK, et al, A Complication Analysis of 2 Acellular Dermal Matrices in Prosthetic-based Breast Reconstruction. Plast Reconstr Surg Glob Open. 2016 Jul; 4(7): e800.

44. Kirsner RS, Warriner R, Michela M et al. Advanced biological therapies for diabetic foot ulcers. Arch Dermatol 2010; 146(8):857-62.

45. Koob TJ, Rennert R, et al, Biological properties of dehydrated human amnion/chorion composite graft: implications for chronic wound healing. Int Wound J. 2013 Oct;10(5):493-500.

46. Koob TJ, Lim JJ, et al, Angiogenic properties of dehydrated human amnion/chorion allografts: therapeutic potential for soft tissue repair and regeneration. Vasc Cell. 2014 May 1;6:10.

47. Landsman A, Living Cell Therapy for Wounds- What's the Big Deal? Podiatry Management;Nov/Dec2013, Vol. 32 Issue 9, p75-80.

48. Landsman A, Cook J, et al, Retrospective Study of 188 consecutive patients treated with a Biologically Active Human Skin Allograft (TheraSkin®) for Diabetic Foot and Venous Leg Ulcers, Foot Ankle Spec. 2011 Feb;4(1):29-41.

49. Landsman A, Rosines E, et al, Characterization of a Cryopreserved Split-Thickness Human Skin Allograft-TheraSkin. Adv Skin Wound Care. 2016 Sep;29(9):399-406.

50. Lavery LA, Fulmer J, et al, The efficacy and safety of Grafix(®) for the treatment of chronic diabetic foot ulcers: results of a multi-centre, controlled, randomized, blinded, clinical trial. Int Wound J. 2014 Oct;11(5):554-60.

51. Lavery LA, Weir D, Advances in Wound Therapy:Understanding Differences Between Cellular and Acellular Therapies in the Treatment of Chronic Wounds. Wounds, 2014; Suppl 8. Accessed at woundsresearch.com 06/02/16.

52. Lipsky BA, Berendt AR, Cornia PB et al. 2012 Infectious Diseases Society of America clinical practice guideline for the diagnosis and treatment of diabetic foot infections. Clin Infect Dis. 2012 Jun;54(12):e132-173. 2012, accessed at idsociety.org 01/22/14.

53. Loo YL, Kamalathevan P, et al. Comparing the Outcome of Different Biologically Derived Acellular Dermal Matrices in Implant-based Immediate Breast Reconstruction: A Meta-analysis of the Literatures. Plast Reconstr Surg Glob Open. 2018 Mar 19;6(3):e1701.

54. Lotan AM, Cohen D, et al. Histopathological Study of Meshed Versus Solid Sheet Acellular Dermal Matrices in a Porcine Model. Ann Plast Surg. 2018 Nov;81(5):609-614.

55. Lullove E, Acellular Fetal Bovine Dermal Matrix in the Treatment of Nonhealing Wounds in Patients with Complex Comorbidities, Journal of the American Podiatric Medical Association, Vol 102, No 3, May/June 2012.

56. Massee M, Chinn K, et al, Dehydrated human amnion/chorion membrane regulates stem cell activity in vitro. J Biomed Mater Res B Appl Biomaster. 2015 Jul 14.

57. Maus EA, Successful Treatment of Two Refractory Venous Stasis Ulcers Treated with a Novel Poly-N-Acetyl Glucosamine-Derived Membrane, BMJ Case Reports 2012; doi:10.1136/bcr.03.2012.6091.

58. Mrugala A, Sui A, et al, Amniotic membrane is a potential regenerative option for chronic non-healing wounds: a report of five cases receiving dehydrated human amnion/chorion membrane allograft. Int Wound J. 2015 May 14. Doi: 10.1111/iwj.12458.

59. National Institute for Health and Clinical Excellence (NICE). Diabetic foot problems: Inpatient management of diabetic foot problems. 2011.

60. National Institute for Health and Clinical Excellence (NICE). Diabetic Foot Problems- Prevention and Management, 2015.

61. Nherera LM, Romanelli M, et al, An Overview of Clinical and Health Economic Evidence Regarding Porcine Small Intestine Submucosa Extracellular Matrix in the Management of Chronic Wounds and Burns. Ostomy Wound Manage. 2017 Dec;63(12):38-47.

62. Ohkuma R, et al Initial experience with the use of foetal/neonatal bovine acellular dermal collagen matrix (SurgiMend™) for tissue-expander breast reconstruction. Journal of Plastic, Reconstructive & Aesthetic Surgery (2013)1-7.

63. Penny H, Rifkah M, et al, Dehydrated human amnion/chorion tissue in difficult-to-heal DFUs: a case series. J Wound Care. 2015 Mar;24(3):104; 106-9; 111. Doi: 10.12968/jowc.2015.24.3.104.

64. Requlski M, Jacobstein DA, et al, A retrospective analysis of a human cellular repair matrix for the treatment of chronic wounds. Ostomy Wound Manage. 2013 Dec;59(12):38-43.

65. Robson MC, Cooper DM, Aslam R et al. Guidelines for the treatment of venous ulcers. Wound Repair Regen 2006; 14(6): 649-62. 2006; 2007/01/04. Accessed at plasticsurgery.org 05/14/13.

66. Sanders L, Landsman AS, Landsman A, et al. A prospective, multicenter, randomized, controlled clinical trial comparing a bioengineered skin substitute to a human skin allograft. Ostomy Wound Manage. Sep 2014;60(9):26-38.

67. Santema TB, Poyck PP, et al. Systematic review and meta-analysis of skin substitutes in the treatment of diabetic foot ulcers: Highlights of a Cochrane systematic review. Wound Repair Regen. 2016 Jul;24(4):737-44.

68. Saudek CD, Kalyani RR, et al, Johns Hopkins Diabetes Guide 2012: Treatment and Management of Diabetes (Johns Hopkins Medicine), accessed at hopkinsmedicine.org 06/02/14.

69. Scheflan M, Grinberg-Rashi H, et al. Bovine Acellular Dermal Matrix in Immediate Breast Reconstruction: A Retrospective, Observational Study with SurgiMend. Plast Reconstr Surg. 2018 Jan;141(1):1e-10e.

70. Scheflan M, Lotan, et al. Trans-Vertical Mastectomy With Immediate Implant-Based Reconstruction: A Retrospective, Observational Study. Aesthet Surg J. 2018 Jul 24.

71. Serena T, Bates-Jensen B, et al, Consensus principles for wound care research obtained using a Delphi process, Wound Repair Regen. 2012 May-Jun;20(3):284-93.

72. Serena TE, et al, Dehydrated human amnion/chorion membrane treatment of venous leg ulcers: correlation between 4-week and 24-week outcomes. J Wound Care. 2015 Nov;24(11):530-4.

73. Serena TE, Carter MJ, et al, A multicenter, randomized, controlled clinical trial evaluating the use of dehydrated human amnion/chorion membrane allografts and multilayer compression therapy vs. multilayer compression therapy alone in the treatment of venous leg ulcers. Wound Repair Regen. 2014 Nov;22(6):688-93.

74. Shah AP, Using amniotic membrane allografts in the treatment of neuropathic foot ulcers. J Am Podiatr Med Assoc. 2014 Mar;104(2):198-202.

75. Sheena Y, Ball J, et al. The Comparison of Strattice and SurgiMend in Acellular Dermal Matrix-Assisted, Implant-Based Immediate Breast Reconstruction. Plast Reconstr Surg. 2018 Nov;142(5):789e-790e.

76. Sheikh ES, Sheikh ES, et al, Use of dehydrated human amniotic membrane allografts to promote healing in patients with refractory non healing wounds. Int Wound J 2013.

77. Solsys™ Medical Dossier: TheraSkin, 03/14/19.

78. Steed DL, Attinger C, Colaizzi T et al. Guidelines for the treatment of diabetic ulcers. Wound Repair Regen 2006; 14(6):680-92. 2006; 2007/01/04. Accessed at plasticsurgery.org 05/14/13.

79. Subach BR, Copay AG. The use of a dehydrated amnion/chorion membrane allograft in patients who subsequently undergo reexploration after posterior lumbar instrumentation. Adv Orthop. 2015;2015:501202.

80. Tettelbach W, Cazzell S, et al. A confirmatory study on the efficacy of dehydrated human amnion/chorion membrane dHACM allograft in the management of diabetic foot ulcers: A prospective, multicentre, randomised, controlled study of 110 patients from 14 wound clinics. Int Wound J. 2019 Feb;16(1):19-29.

81. Towler MA, Rush EW, et al. Randomized, Prospective, Blinded-Enrollment, Head-To-Head Venous Leg Ulcer Healing Trial Comparing Living, Bioengineered Skin Graft Substitute (Apligraf) with Living, Cryopreserved, Human Skin Allograft (TheraSkin). Clin Podiatr Med Surg. 2018 Jul;35(3):357-365.

82. Trinh TT, Dünschede F, et al, Marine Omega3 wound matrix for the treatment of complicated wounds; Phleb-Stuttgart 45(2):93-98, Jan 2016.

83. U.S. Food and Drug Administration (FDA); accessed at fda.gov.

84. Wilson TC, Wilson JA, et al, The Use of Cryopreserved Human Skin Allograft for the Treatment of Wounds With Exposed Muscle, Tendon, and Bone. Wounds. 2016 Apr;28(4):119-25.

85. Yang CK, Polanco TO, Lantis JC, A Prospective, Postmarket, Compassionate Clinical Evaluation of a Novel Acellular Fish-skin Graft Which Contains Omega-3 Fatty Acids for the Closure of Hard-to-heal Lower Extremity Chronic Ulcers. Wounds. 2016 Apr;28(4):112-8.

86. Zelen CM, et al, Dehydrated human amnion/chorion membrane allografts in patients with chronic diabetic foot ulcers: A long-term follow-up study. Wound Medicine 4 (2014) 1–4; available online 11/19/13.

87. Zelen CM, An evaluation of dehydrated human amniotic membrane allografts in patients with DFUs. J Wound Care. 2013 Jul;22(7):347-8, 350-1.

88. Zelen CM, Orgill DP, et al. An aseptically processed, acellular, reticular, allogenic human dermis improves healing in diabetic foot ulcers: A prospective, randomised, controlled, multicentre follow-up trial. Int Wound J. 2018 Oct;15(5):731-739.
89. Zelen CM, Orgill DP, et al, Prospective, randomized, controlled, multicenter clinical trial examining healing rates, safety and cost to closure of an acellular reticular allogenic human dermis versus standard of care in the treatment of chronic diabetic foot ulcers. Int Wound J. 2016 Apr 12. Doi: 10.1111/iwj.12600.
90. Zelen CM, Poka A, et al, Prospective, randomized, blinded, comparative study of injectable micronized dehydrated amniotic/chorionic membrane allograft for plantar fasciitis – a feasibility study. Foot Ankle Int. 2013 Oct;34(10):1332-9.
91. Zelen CM, Serena TE, et al, A prospective, randomized comparative study of weekly versus biweekly application of dehydrated human amnion/chorion membrane allograft in the management of diabetic foot ulcers. Int Wound J. 2014 Apr;11(2):122-8.
92. Zelen CM, Serena TE, Denoziere G et al. A prospective randomized comparative parallel study of amniotic membrane wound graft in the management of diabetic foot ulcers. Int Wound J 2013.
93. Zelen CM, Serena TE, et al, Treatment of chronic diabetic lower extremity ulcers with advanced therapies: a prospective, randomized, controlled, multi-centre comparative study examining clinical efficacy and cost. Int Wound J. 2016 Apr;13(2):272-82.
94. Zelen CM, Snyder RJ, et al, The use of human amnion/chorion membrane in the clinical setting for lower extremity repair: a review. Clin Podiatr Med Surg. 2015 Jan;32(1):135-46.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy & Coverage Committee on 03/28/19.

GUIDELINE UPDATE INFORMATION:

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.
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.
10/01/19	Quarterly CPT/HCPCS coding update. Added codes Q4205-Q4226; revised codes Q4122,

	Q4165, Q4184.