Subject: Application and Use of Tissue-Engineered/Bioengineered Skin Substitutes

Medical Policy #: 35.0

Original Effective Date: 11/29/2017

Status: Reviewed

Last Annual Review Date: 08/21/2024

Disclaimer

Refer to the member's specific benefit plan and Schedule of Benefits to determine coverage. This may not be a benefit on all plans or the plan may have broader or more limited benefits than those listed in this Medical Policy.

Description

There are currently a wide variety of bioengineered products available for soft tissue coverage to affect closure. These products may be derived from allogeneic, xenogeneic, synthetic sources or a combination of any or all of these types of materials. However, without the component of the recipient's own distinct epithelium and cellular skin elements, permanent skin replacement or coverage by the graft cannot be accomplished.

Coverage Determination

Prior Authorization is required. Logon to Pres Online to submit a request: https://ds.phs.org/preslogin/index.jsp

Application of Bioengineered Skin Substitutes to Lower Extremity for Chronic Non-Healing Wounds of Venous Stasis Ulcer, Diabetic Foot Ulcers and Burn Wounds:

For Commercial, Medicaid, and Medicare.

Presbyterian Health Plan follows the Local Coverage Determination (L35041) for the application of bioengineered skin substitute material to diabetic foot ulcers and venous leg ulcers of the lower extremities when standard or conservative measures have failed. Additional criteria noted in the Table below for coverage.

Medicaid Non-Covered or Experimental or investigational service:
NMAC, Health Care Professional Services General Benefit Description- GENERAL NONCOVERED SERVICES, Experimental or investigational services see section 8.310.2.12(P) and Services not covered by Medicare, see section 8.310.2.13(K).

Other wound treatment:

- For more information on negative pressure wound therapy please see L35125-Wound Care.
- Autologous Platelet Rich Plasma (PRP) used in the treatment of Chronic Non-Healing Wounds, see Platelet-Rich Plasma, Blood Derived Products, and Platelet-Derived Growth Factor Products for the Treatment of Wounds and Other Injuries, MPM 16.16.
- For Porcine skin and Gradient Pressure Dressings see section (Elastic stockings) of the Durable Medical Equipment, Miscellaneous, MPM 4.5.
- For bioengineered skin and soft tissue substitutes of the breast, see Breast Surgical Procedures, MPM 27.0.

Covered Indication for Venous Stasis Ulcers of the lower extremity		
Skin Substitute Product	**Product HCPCS Codes**	**Criteria**
AmnioBand®	Q4151, Q4168	Considered medically necessary when BOTH of the following are met: • partial- or full-thickness venous stasis ulcer of greater than four weeks duration for which standard wound therapy has failed • treated lower extremity has adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.60 When the above medical necessity criteria are met, the following conditions of coverage apply: • treatment is limited to one initial application • additional applications at a minimum of one week intervals, for up to a maximum of twelve in 12 weeks when evidence of wound healing is present (e.g., signs of epithelialization and reduction in ulcer size) Additional applications beyond 12 weeks are considered not

Covered Indication for Venous Stasis Ulcers of the lower extremity		
Skin Substitute Product	**Product HCPCS Codes**	**Criteria**
		medically necessary regardless of wound status for ALL skin substitute products listed in this table
Apligraf®	Q4101	Considered medically necessary when BOTH of the following are met: • partial- or full-thickness venous stasis ulcer of greater than four weeks duration for which standard wound therapy has failed • treated lower extremity has adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.60 When the above medical necessity criteria are met, the following conditions of coverage apply: • treatment is limited to one initial application • additional applications at a minimum of one week intervals, for up to a maximum of four in 12 weeks when evidence of wound healing is present (e.g., signs of epithelialization and reduction in ulcer size) Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status for ALL skin substitute products listed in this table
EpiFix® Amniotic Membrane	Q4186	
Grafix® Core and GrafixPL Core	Q4132	Considered medically necessary when BOTH of the following are met: • partial- or full-thickness venous stasis ulcer of greater than four weeks duration for which standard wound therapy has failed • treated lower extremity has adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.60 When the above medical necessity criteria are met, the following conditions of coverage apply: • treatment is limited to one initial application • additional applications at a minimum of one week intervals, for up to a maximum of six in 12 weeks when evidence of wound healing is present (t (e.g., signs of epithelialization and reduction in ulcer size) Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status for ALL skin substitute products listed in this table
Grafix PRIME, GrafixPL PRIME	Q4133	
Oasis wound matrix	Q4102	Considered medically necessary when BOTH of the following are met: • partial or full-thickness, lower extremity venous stasis ulcer of four weeks duration for which standard wound therapy has failed • treated lower extremity has adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.60 When the above medical necessity criteria are met, the following conditions of coverage apply: • treatment is limited to one initial application • additional applications at a minimum of one week intervals, for up to a maximum of four in 12 weeks are considered medically necessary when evidence of wound healing is present **(**t (e.g., signs of epithelialization and reduction in ulcer size) Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status for ALL skin substitute products listed in this table
Oasis® Ultra Tri-Layer Matrix	Q4124	Considered medically necessary when BOTH of the following are met: • partial or full-thickness, lower extremity venous stasis ulcer of four weeks duration for which standard wound therapy has failed • treated lower extremity has adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.60 When the above medical necessity criteria are met, the following conditions of coverage apply: • treatment is limited to one initial application • additional applications at a minimum of one week intervals, for up to a maximum of four in 12 weeks are considered medically necessary when evidence of wound healing is present **(**t (e.g., signs of epithelialization and reduction in ulcer size) Additional applications beyond 12 weeks are considered not

Covered Indication for Venous Stasis Ulcers of the lower extremity		
Skin Substitute Product	**Product HCPCS Codes**	**Criteria**
		medically necessary regardless of wound status for ALL skin substitute products listed in this table
PriMatrix™	Q4110	Considered medically necessary when BOTH of the following are met: • partial or full-thickness, lower extremity venous stasis ulcer of four weeks duration for which standard wound therapy has failed • treated lower extremity has adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.60 When the above medical necessity criteria are met, the following conditions of coverage apply: • treatment is limited to one initial application • additional applications at a minimum of one week intervals, for up to a maximum of three in 12 weeks are considered medically necessary when evidence of wound healing is present **(**t (e.g., signs of epithelialization and reduction in ulcer size) Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status for ALL skin substitute products listed in this table
TheraSkin®	Q4121	Considered medically necessary when BOTH of the following are met: • partial or full-thickness, venous stasis ulcer of greater than four weeks duration for which standard wound therapy has failed • treated lower extremity has adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.60 When the above medical necessity criteria are met, the following conditions of coverage apply: • treatment is limited to one initial application • additional applications at a minimum of one week intervals, for up to a maximum of four in 12 weeks when evidence of wound healing is present **(**t (e.g., signs of epithelialization and reduction in ulcer size) Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status for ALL skin substitute products listed in this table

Covered Indication for Diabetic Foot Ulcers		
Skin Substitute Product	**Product HCPCS Codes**	**Criteria**
AlloPatch Pliable®	Q4128	Considered medically necessary when ALL of the following are met: • full-thickness diabetic foot ulcer of greater than six weeks duration for which standard therapy has failed • type I or type II diabetes mellitus with a hemoglobin A1c (HbA1C) less than 12% • treated foot has adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.60. When the above medical necessity criteria are met, the following conditions of coverage apply: • treatment is limited to up to (5) applications • additional applications for up to **a maximum of eight** in 12 weeks when there is evidence of wound healing (e.g., signs of epithelialization and reduction in ulcer size) Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status for ALL skin substitute products listed in this table
AmnioBand	Q4151, Q4168	
Dermagraft®	Q4106	
Apligraf®	Q4101	Considered medically necessary when ALL of the following are met: • full-thickness diabetic foot ulcer of greater than three weeks duration for which standard therapy has failed • type I or type II diabetes mellitus with a hemoglobin A1c (HbA1C) less than 12% • treated foot has adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.60

Covered Indication for Diabetic Foot Ulcers		
Skin Substitute Product	**Product HCPCS Codes**	**Criteria**
		When the above medical necessity criteria are met, the following conditions of coverage apply: • initial treatment is limited to up to (4) applications • additional applications at a minimum of one week intervals, for up to a **maximum of four** in 12 weeks are considered medically necessary when evidence of wound healing is present (e.g., signs of epithelialization and reduction in ulcer size) Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status for ALL skin substitute products listed in this table
DermACELL™ AWM	Q4122	Considered medically necessary when ALL of the following are met: • partial or full-thickness diabetic foot ulcer of greater than (4) weeks duration for which standard therapy has failed • type I or type II diabetes mellitus with a hemoglobin A1c (HbA1C) less than 12% • treated foot has adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.60 When the above medical necessity criteria are met, treatment is limited to a total of (2) applications. Additional applications beyond (12) weeks are considered not medically necessary regardless of wound status for ALL skin substitute products listed in this table
EpiFix® Amniotic Membrane	Q4186	Considered medically necessary when ALL of the following are met: • partial or full-thickness diabetic foot ulcer of greater than (4) weeks duration for which standard therapy has failed • type I or type II diabetes mellitus with a hemoglobin A1c (HbA1C) less than 12% • treated foot has adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.60 When the above medical necessity criteria are met the following conditions of coverage apply: • initial treatment is limited to up to (4) applications • additional applications may be applied at a minimum of one week intervals, for up to a maximum of four in 12 weeks are considered medically necessary when evidence of wound healing is present (e.g., signs of epithelialization and reduction in ulcer size) Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status for ALL skin substitute products listed in this table
Geistlich Derma-Gide® Advanced Wound Matrix	Q4203	Considered medically necessary when ALL of the following are met: • full-thickness diabetic foot ulcer of greater than four weeks duration for which standard therapy has failed • type I or type II diabetes mellitus with a hemoglobin A1c (HbA1C) less than 12% • treated foot has adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.60 When the above medical necessity criteria are met, the following conditions of coverage apply: • treatment is limited to (5) initial applications • additional applications at a minimum of one week intervals, for up to a maximum of 8 in 12 weeks are considered medically necessary when evidence of wound healing is present (e.g., signs of epithelialization and reduction in ulcer size) Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status for ALL skin substitute products listed in this table

Covered Indication for Diabetic Foot Ulcers		
Skin Substitute Product	**Product HCPCS Codes**	**Criteria**
Grafix® Core and GrafixPL Core	Q4132	Considered medically necessary when ALL of the following are met: • partial or full-thickness diabetic foot ulcer of greater than four weeks duration for which standard therapy has failed • type I or type II diabetes mellitus with a hemoglobin A1c (HbA1C) less than 12% • treated foot has adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.60 When the above medical necessity criteria are met, the following conditions of coverage apply: • treatment is limited to up to (5) initial applications • additional applications at a minimum of one week intervals, for up to a maximum of six in 12 weeks are considered medically necessary when evidence of wound healing is present (e.g., signs of epithelialization and reduction in ulcer size Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status for ALL skin substitute products listed in this table
Grafix® PRIME, GrafixPL PRIME	Q4133	
GraftJacket NOW™, formerly GraftJacket® regenerative tissue matrix	Q4107	Considered medically necessary when ALL of the following are met: • partial or full-thickness, diabetic foot ulcer of greater than four weeks duration for which standard wound therapy has failed • type 1 or type 2 diabetes mellitus with a hemoglobin A1c (HbA1C) less than 12% • treated foot has adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.60 When the above medical necessity criteria are met, one application is considered medically necessary.
Integra® dermal regeneration template or Integra Omnigraft dermal regeneration matrix	Q4105	Considered medically necessary when ALL of the following are met: • partial or full-thickness diabetic foot ulcer of greater than six weeks duration for which standard wound therapy has failed • type 1 or type 2 diabetes mellitus with a hemoglobin A1c (HbA1C) less than 12% • treated foot has adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.60 When the above medical necessity criteria are met, the following conditions of coverage apply: • treatment is limited to up to (4) initial applications • additional applications at a minimum of one week intervals, for up to a maximum of four in 12 weeks are considered medically necessary when evidence of wound healing is present (e.g., signs of epithelialization and reduction in ulcer size) Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status for ALL skin substitute products listed in this table
Oasis® wound matrix	Q4102	Considered medically necessary when ALL of the following are met: • partial or full-thickness diabetic foot ulcer of greater than four weeks duration for which standard wound therapy has failed • type 1 or type 2 diabetes mellitus with a hemoglobin A1c (HbA1C) less than 12% • treated foot has adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.60 When the above medical necessity criteria are met, the following conditions of coverage apply: • treatment is limited to up to (4) initial applications • additional applications at a minimum of one week intervals, for up to a maximum of four in 12 weeks are considered medically necessary when evidence of wound healing is present (e.g., signs of epithelialization and reduction in ulcer size Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status for ALL skin substitute products listed in this table
Oasis® ultra tri-layer matrix	Q4124	

Covered Indication for Diabetic Foot Ulcers		
Skin Substitute Product	**Product HCPCS Codes**	**Criteria**
PriMatrix™	Q4110	Considered medically necessary when ALL of the following are met: • partial or full-thickness diabetic foot ulcer of greater than six weeks duration for which standard wound therapy has failed • type 1 or type 2 diabetes mellitus with a hemoglobin A1c (HbA1C) less than 12% • treated foot has adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.60 When the above medical necessity criteria are met, the following conditions of coverage apply: • treatment is limited to up to (3) initial applications • additional applications at a minimum of one week intervals, for up to a maximum of three in 12 weeks are considered medically necessary when evidence of wound healing is present (e.g., signs of epithelialization and reduction in ulcer size Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status for ALL skin substitute products listed in this table
TheraSkin®	Q4121	Considered medically necessary when ALL of the following are met: • partial or full-thickness, diabetic foot ulcer of greater than four weeks duration for which standard wound therapy has failed • type 1 or type 2 diabetes mellitus with a hemoglobin A1c (HbA1C) less than 12% • treated foot has adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.60 When the above medical necessity criteria are met, the following conditions of coverage apply: • treatment is limited to up to (4) initial applications • additional applications may be applied at a minimum of one week intervals, for up to a maximum of four in 12 weeks are considered medically necessary when evidence of wound healing is present (e.g., signs of epithelialization and reduction in ulcer size Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status for ALL skin substitute products listed in this table

Covered Indication for Burn Wounds		
Skin Substitute Product	**Product HCPCS Codes**	**Criteria**
Biobrane	Q4100, C9399	When used for temporary covering of a partial-thickness freshly debrided or excised burn wound is considered medically necessary
Biobrane-L	Q4100, C9399	Considered medically necessary when BOTH of the following are met: • used for temporary covering of a partial-thickness freshly debrided or excised burn wound • when adjunct to meshed autograft
Epicel	Q4100, C9399	Considered medically necessary when used as indicated by the U.S. Food and Drug Administration (FDA)-approved Humanitarian Device Exemption (HDE) for: • an individual with deep dermal or full-thickness burns comprising a total body surface area of greater than or equal to 30%
Integra™ Meshed Bilayer Wound Matrix	C9363	Considered medically necessary when BOTH of the following are met: • post excisional treatment of a full-
Integra™ bilayer matrix wound dressing (BMWD)	Q4104,	

Covered Indication for Burn Wounds		
Skin Substitute Product	**Product HCPCS Codes**	**Criteria**
Integra® dermal regeneration (DRT) template or Integra Omnigraft dermal regeneration matrix	Q4105	thickness or deep partial-thickness burn • sufficient autograft is unavailable at time of the excision or is contraindicated
Integra™ matrix Wound Dressing	Q4108	
Suprathel®	A2012	Considered medically necessary when used for the purpose of treating first and second-degree burns
Transcyte®	Q4182	Considered medically necessary when used for the purpose of temporary covering of: • a surgically excised deep partial- or full-thickness burn wound as a covering prior to autografting.

Each of the following products listed below are considered experimental, investigational, or unproven for ANY indication:		
Not Covered Products	**Request for Product Reason(s) (not an all-inclusive list)**	**Product HCPCS Codes**
AC5® Advanced Wound System	Wound healing	A2020
Actigraft®	Wound healing	Q4100, C9399
Actishield™ Amniotic Barrier Membrane	Soft and/or hard tissue repair	Q4100, C9399
Actishield™CF Amniotic Barrier Membrane	Soft and/or hard tissue repair	Q4100, C9399
ActiveBarrier®	Wound care	Q4100, C9399
ActiveMatrix® flowable	Connective tissue repair	Q4100, C9399
Acuseal Cardiovascular Patch	Cardiovascular reconstruction	C1768
Adherus Dural Sealant®	Dural repair	Q4100 C9399
Affinity	Wound care	Q4159
AlloGen™	Soft tissue repair	Q4212
AlloMend® Acellular Dermal Matrix	Soft tissue repair	Q4100 C1762
Allopatch HD™	Tendon augmentation	Q4128
AlloSkin™	Wound care	Q4115
AlloSkin™ AC	Wound care	Q4141
AlloSkin™ RT	Wound care	Q4123
Allowrap™ DS and Dry	Wound care	Q4150
AmnioAMP-MP™	Wound care	Q4250
AmnioArmor	Wound care	Q4188
AmnioBand® Particulate	Wound care	Q4168
Amniobind™	Wound care	Q4225
AmnioCare®	Tendon/nerve repair	Q4100 C9399
AmnioClear®	Wound care Surgical barrier	Q4100 C9399
AmnioClear LTC flowable	Knee pain and inflammation	J3590
AmnioCore™	Wound care	Q4227
Amniocyte™ Flowable Matrix	Connective tissue repair	J3590
Amniocyte Plus Injectable	Connective tissue repair	Q4242
AmnioEffect™	Wound care Surgical barrier	Q4100 C9399
AmnioExCel/AmnioExcel	Wound care	Q4137

Each of the following products listed below are considered experimental, investigational, or unproven for ANY indication:		
Not Covered Products	**Request for Product Reason(s) (not an all-inclusive list)**	**Product HCPCS Codes**
Plus/BioDExCel™	Soft tissue repair	
Amniofix® Amniotic Membrane	Tendon/nerve repair	Q4100 C9399
Amniofix® Injectable	Tendon repair Soft tissue repair	J3590
AmnioHeal® Plus	Wound care	Q4100 C9399
Amnio-Maxx	Wound care	Q4239
AmnioMatrix®	Wound care Soft tissue repair	Q4139
AmnioMTM Injectable	Wound care Soft tissue repair	Q4100 C9399
AmnioPro Membrane	Wound care	Q4100 C9399
AmnioPro Flow	Wound care	Q4100 C9399
Amniorepair/Altiply	Wound care	Q4235
Amniotext Injectable	Tissue defect	Q4245
Amniotext Patch	Wound care	Q4247
Amnio Wound	Wound care	Q4181
Amnios®/Amnios® RT	Wound care	Q4100 C9399
Amniovo™	Soft tissue repair Tendon repair	Q4100 C9399
Amniowrap2™	Wound care	Q4221
Amniply	Wound care	Q4249
Anu RHEO™	Connective tissue repair	Q4100 C9399
Apis®	Wound care	A2010
Architect™ Biomatrix	Wound care	Q4147
Artacent™ Cord	Wound Care	Q4216
Artacent™ Wound	Surgical barrier	Q4169
Artacent® ac, membrane	Wound care	Q4190
Artacent® ac, powder	Wound care	Q4189
Arthrex Amnion™ Matrix	Orthopedic barrier or wrap	Q4100 C1762
Arthrex Amnion™ Viscous	Orthopedic barrier or wrap	J3590
ArthroFlex™ (FlexGraft®)	Shoulder reconstruction Achilles tendon repair	Q4125
ARTIA™ Reconstructive Tissue Matrix	Soft tissue repair	C1763
Ascent™	Wound care Joint and tendon repair	Q4213
Avance Nerve Graft	Peripheral nerve repair	Q4100 C9399
Avive® Soft Tissue Membrane	Soft tissue repair	Q4100 C9399
AxoBioMembrane	Soft tissue repair	Q4211
AxoGuard® Nerve Connector	Peripheral nerve repair	Q4100 C1763
AxoGuard® Nerve Protector	Peripheral nerve repair	Q4100 C1763
Axolotl Ambient™	Soft tissue repair	Q4215
Axolotl Cryo™	Soft tissue repair	Q4215
Axolotl DualGraft™	Soft tissue repair	Q4332
Axolotl Graft™	Soft tissue repair	Q4331
Barrera™ SL and Barrera™ DL	Wound covering	Q4281
BellaCell HD	Soft tissue repair	Q4220

Each of the following products listed below are considered experimental, investigational, or unproven for ANY indication:		
Not Covered Products	**Request for Product Reason(s) (not an all-inclusive list)**	**Product HCPCS Codes**
BellaDerm® Acellular Hydrated Dermis	Integumental tissue repair Soft tissue repair	Q4100 C9399
Bio-ConneKt®	Wound care	Q4161
BioDfactor™	Wound care Soft tissue repair	Q4100 C9399
BioDfence™	Surgical wrap/barrier Tendon repair	Q4140
BioDfence™ DryFlex	Surgical wrap/barrier Tendon repair	Q4138
BioDRestore flowable	Soft tissue repair	Q4100 C9399
Biodesign® Dural Graft	Dural repair	Q4100 C1763
Biodesign® (Surgisis®) AFP™ Anal Fistula Plug	Anal and rectal fistula repair	Q4100 C1763
Biodesign® (Surgisis®) Hiatal Hernia Graft	Hernia repair	Q4100 C1781
Biodesign® (Surgisis®) Inguinal Hernia Graft	Hernia repair	Q4100 C1781
Biodesign® Otologic Repair Graft	Otologic repair	Q4100 C1763
Biodesign® Fistula Plug Set, previously Biodesign® (Surgisis®) RVP™ Recto-Vaginal Fistula Plug	Recto-vaginal fístula repair	Q4100 C1763
Biodesign® Peyronie's Repair Graft	Urological deficits	Q4100 C1763
Biodesign Rectopexy Graft	Rectal prolapse/rectal intussusception	Q4100 C1763
Biodesign® Sinonasal Repair Graft	Wound care	Q4100 C1763
BioFix®	Wound care	Q4100 C9399
BioNextPatch	Burn care Wound care	Q4100 C9399
BioVance®	Wound care	Q4154
Biovance® 3L or Biovance® Tri-Layer	Wound covering	Q4283
BioWound™	Wound care	Q4217
BioWound™ Plus	Wound care	Q4217
BioWound™ XPlus	Wound care	Q4217
CardioCel®	Pericardial closure Cardiac and vascular defect repairs	Q4100 C9399
CardioGRAFT MC® Decellularized Pulmonary Patch Graft	Repair of right ventricular outflow tract	Q4100 C9399
carePATCH	Burn care Wound care	Q4236
Celera dual layer or celera dual membrane	Wound care	Q4259
CellerateRX®	Wound care	A6010
Cellesta™ Amniotic Membrane	Wound care	Q4184
Cellesta™ Cord	Wound care	Q4214
Cellesta™ Duo	Wound care	Q4184
Cellesta™ Flowable Amnion	Surgical covering/barrier	Q4185
Clarix 100	Surgical covering/wrap/barrier	Q4156
Clarix Cord 1K	Surgical covering/wrap/barrier	Q4148
Clarix® Regenerative Matrix	Surgical covering/wrap/barrier	Q4100 C9399
Clarix® Flo	Integumental tissue repair	Q4155
Cocoon membrane	Wound care	Q4264

Each of the following products listed below are considered experimental, investigational, or unproven for ANY indication:		
Not Covered Products	**Request for Product Reason(s) (not an all-inclusive list)**	**Product HCPCS Codes**
Coll-e-Derm	Soft tissue repair	Q4193
Cogenex Amniotic Membrane	Burn care Wound care	Q4229
Cogenex Flow Amnion	Wound care	Q4230
Complete™ FT	Wound care	Q4271
Complete™ SL	Wound care	Q4270
Conexa™	Tendon repair	Q4100 C1781
Corecyte™	Tissue repair	Q4240
Coretext and Protext	Tissue repair	Q4246
Cormatrix CanGaroo™ Protect ECM Envelope	Implantable electronic device pocket	Q4100 C9399
CorMatrix® ECM® for Cardiac Tissue Repair	Intracardiac patch	Q4100 C9399
CorMatrix® ECM® for Carotid Repair	Carotid artery repair	Q4100 C9399
CorMatrix® ECM® for Pericardial Closure	Pericardial repair	Q4100 C9399
Corplex	Wound care	Q4232
Corplex P	Connective tissue repair	Q4231
Creos™ Xenoprotect	Bone and tissue regeneration	Q4100 C9399
Cryo-Cord	Wound care	Q4237
CryoMatrix®	Connective tissue repair	Q4100 C9399
CryoSkin®	Wound care	Q4100 C9399
Cygnus®	Wound care Nerve wrap	Q4170
Cygnus dual	Soft tissue covering Wound covering	Q4282
CYGNUS® Matrix	Burn care Wound care	Q4199
Cytal®	Wound care	Q4166
Cymetra™	Integumental tissue repair	Q4112
Derm-maxx	Wound covering	Q4238
DermaBind SL	Wound care	Q4284
Dermacyte	Wound care	Q4248
DermaMatrix Acellular Dermis	Facial soft tissue defects Breast reconstruction	Q4100 C9399
DermaPure™	Wound care	Q4152
DermaSpan™	Wound covering Tendon repair	Q4126
Dermavest	Wound care	Q4153
Dual layer impax membrane	Wound care	Q4262
Duraform™	Dural repair	Q4100 C9399
DuraGen®	Dural repair	Q4100 C9399
Dura-Guard	Dural repair	Q4100 C1763
DuraMatrix™	Dural repair	Q4100 C9399
DuraSeal® Dural Sealant System	Dural repair	Q4100 C9399
DuraSeal® Exact Spine Sealant System	Dural repair	Q4100 C9399
DuraSorb® Monofilament Mesh/ Polydioxanone Surgical Scaffold™	Soft tissue reinforcement	C1718
Durepair Regeneration Matrix®	Dural repair	Q4100 C9399

Each of the following products listed below are considered experimental, investigational, or unproven for ANY indication:		
Not Covered Products	**Request for Product Reason(s) (not an all-inclusive list)**	**Product HCPCS Codes**
Endoform Dermal Template™	Wound care	Q4100 C9399
Enverse®	Wound care	Q4258
EpiBurn®	Wound care	Q4100 C9399
EpiCord™	Wound care	Q4187
EPIEFFECT™	Wound covering	Q4278
Epifix® Injectable	Wound care	Q4145
Esano™ A	Wound care	Q4272
Esano™ AAA	Wound care	Q4273
Esano™ AC	Wound care	Q4274
Esano™ ACA	Wound care	Q4275
Excellagen®	Wound care	Q4149
EZ Derm™	Wound care	Q4136
FloGraft™ flowable	Tendonitis Soft tissue trauma	Q4100 C9399
FlowerDerm™	Wound care	Q4179
FlowerFlo™	Wound care	Q4177
FlowerPatch™	Wound care	Q4178
Fluid Flow™	Soft tissue repair	Q4206
Fluid GF™	Soft tissue repair	Q4206
Fortaderm™/Puraply™	Wound care	Q4195
Fortiva® Porcine Dermis	Soft tissue reinforcement	Q4100 C1763
GalaFLEX® Scaffold	Soft tissue repair	Q4100 C9399
GalaFLEX 3DR Scaffold	Soft tissue repair	Q4100 C9399
GalaFLEX 3D Scaffold	Solft tissue repair	Q4100 C9399
GammaGraft	Wound care	Q4111
Genesis Amniotic Membrane	Wound care	Q4198
Gentrix®	Soft tissue reinforcement	C1763 C1781
GORE® BIO-A® Fistula Plug	Anorectal fistulas	Q4100 C1781
GORE® BIO-A® Tissue Reinforcement	Soft tissue reinforcement	Q4100 C1781
GraftJacket® Xpress	Wound care	Q4113
Helicoll™	Wound care	Q4164
hMatrix®	Integumental tissue repair	Q4134
Human Health Factor 10 Amniotic Patch™ (HHF10P™)	Wound care	Q4224
Hyalomatrix® PA	Wound care	Q4117
HydroFix® Vaso Shield	Vessel guard	Q4100 C9399
InnovaMatrix® AC	Wound care	A2001
InnovaMatrix® FS	Wound care	A2013
Integra™ Flowable Wound Matrix	Wound care	Q4114
Integra® Reinforcement Matrix	Soft tissue reinforcement	Q4100 C1763
InteguPly (TranZgraft))	Tendon repair	Q4126
Interfyl™	Integumental tissue repair	Q4171
Keramatrix®	Wound care	Q4165
Kerasorb®	Wound care	Q4165

Each of the following products listed below are considered experimental, investigational, or unproven for ANY indication:		
Not Covered Products	**Request for Product Reason(s) (not an all-inclusive list)**	**Product HCPCS Codes**
Kerecis Omega3 Marigen Shield	Wound care	A2019
Kerecis® Omega3 Wound	Wound care	Q4158
Keroxx Flowable Matrix	Wound care	Q4202
Lyoplant®	Dural repair	Q4100 C1763
Matrion	Wound Care	Q4201
MatriStem®	Wound care	Q4118
Matrix HD™	Wound care Tendon repair	Q4100 C9399
Mediskin™	Wound care	Q4135
Membrane Graft™	Wound care	Q4205
Membrane Wrap™	Wound care	Q4205
MemoDerm™	Wound care Tendon repair	Q4126
Miamnion®	Wound care	Q4100 C9399
Microlyte® Matrix	Wound care	A2005
Miroderm®	Wound care	Q4175
MiroFlex® (formerly Miromesh®)	Soft tissue reinforcement	Q4100 C9399
Miro3D® Wound Matrix	Wound care	Q4100 C9399
Mirragen® Advanced Wound Matrix	Wound care	A2002
Multi-Layer Graft (MLG Complete™)	Wound care	Q4256
MyOwn Skin	Wound care	Q4226
Myriad Matrix™	Wound care	Q4100 C9399
NeoMatriX®	Wound care	A2021
NeoPatch™/Therion	Wound care	Q4176
NeoStim DL	Wound care	Q4267
NeoStim Membrane	Wound care	Q4266
NeoStim TL	Wound care	Q4265
Neox® 100	Wound care	Q4156
Neox® Cord 1K	Wound care	Q4148
Neox® Flo	Wound care	Q4155
Neox® Wound Matrix	Wound care	Q4100 C9399
NeuraGen® Nerve Guide	Peripheral nerve repair	C9352
NeuraWrap™ Nerve Protector	Peripheral nerve repair	C9353
NeuroFlex™	Peripheral nerve repair	Q4100 C9399
NeuroMatrix™	Peripheral nerve repair	C9355
NeuroMend™	Peripheral nerve repair	C9361
Novachor	Wound care	Q4194
NovaFix™	Wound care	Q4208
Novafix® DL	Wound care	Q4254
NovoSorb SynPath	Wound care	A2006
NuCel™	Tendon repair	Q4100 C9399
Nucel Bioactive Amniotic Suspension	Tissue repair	Q4100 C9399
NuShield™ Orthopaedics	Tendon repair	Q4160
NuShield™ Spine	Dura repair	Q4160
Oasis® Burn Matrix	Burn wounds	Q4103

Each of the following products listed below are considered experimental, investigational, or unproven for ANY indication:		
Not Covered Products	**Request for Product Reason(s) (not an all-inclusive list)**	**Product HCPCS Codes**
Omeza® collagen matrix	Wound care	A2014
Orcel®	Burn wounds	Q4100 C9399
Orion Amniotic Membrane	Wound covering	Q4276
OrthADAPT™ Bioimplant	Soft tissue reinforcement	Q4100 C1781
OrthoNovis Guard Allograft Membrane	Wound care	Q4100 C9399
OsseoGuard®	Oral defects	Q4100 C9399
Ovation®	Wound healing	Q4100 C9399
OviTex®	Soft tissue reinforcement Breast reconstruction	C1781
PalinGen® Flow	Soft tissue repair	Q4174
PalinGen® Xplus	Soft tissue repair	Q4173
Paraderm™ Dermal Matrix	Integumental tissue repair	Q4100 C9399
Permeaderm b	Burn wounds	A2016
Permeaderm c	Wound healing	A2018
Permeaderm glove	Burn wounds	A2017
Peri-Guard® Repair Patch	Soft tissue repair Pericardial and intracardiac repair	Q4100 C1763
Peri-Strips® Dry	Staple line reinforcement	Q4100 C9399
Permacol™	Soft tissue reinforcement/repair	C9364
Phasix Mesh	Soft tissue reinforcement/repair	C1781
Phasix™ Plug and Patch	Soft tissue reinforcement/repair	C1781
Phoenix™ wound matrix	Wound care	A2015
PhotoFix® Decellularized Bovine Pericardium	Vascular repair	Q4100 C1763
Polycyte™	Tissue repair	Q4241
Preclude® Dura Substitute	Dural repair	Q4100 C9399
Preclude® Pericardial Membrane	Pericardial repair	Q4100 C9399
Preclude® Vessel Guard	Vessel covering	Q4100 C9399
Pro3™ Amniotic Fluid	Wound care	J3590
Pro3™ Membrane	Wound care	Q4100 C9399
Proceed® Surgical Mesh	Hernia repair	Q4100 C9399
Procenta	Wound care	Q4244
ProgenaMatrix™	Wound care	Q4222
ProLayer Acellular Matrix	Wound care	Q4100 C9399
ProLayer Xenograft	Soft tissue repair	Q4100 C9399
ProMatriX™	Wound care	Q4174
Promote™ Amnio-Frt™	Wound care	Q4100 C9399
Promote™ Amnio F™	Wound care	Q4100 C9399
Promote AmnioStrip®	Wound care	Q4100 C9399
Puracol®	Wound care	Q4100 C9399

Each of the following products listed below are considered experimental, investigational, or unproven for ANY indication:		
Not Covered Products	**Request for Product Reason(s) (not an all-inclusive list)**	**Product HCPCS Codes**
PuraPly® Wound Matrix	Wound care	Q4195
PuraPly® Antimicrobial/PuraPly® AM	Wound care	Q4196
Puraply Antimicrobial XT/Puraply® AM XT	Wound care	Q4197
PX50®/PX50® Plus	Damaged or inadequate tissue repair	Q4100 C9399
RECELL® Autologous Cell Harvesting Device	Burn Care	C1832
REGUaRD	Wound care	Q4255
Relese™	Wound care	Q4257
Renuva® Allograft Adipose Matrix	Reconstructive surgery Breast reconstruction	J3590
Repliform™	Integumental tissue repair	C1762
Repriza®	Reconstructive surgery Breast reconstruction Abdominal wall repair	Q4143
Restore® Orthobiologic Soft Tissue Implant	Soft tissue reinforcement	Q4100 C1763
Restorgin™ Amnion Patch	Wound care	Q4191
Restorgin™ Amniotic Fluid	Wound care	Q4192
Restrata® Wound Matrix	Wound care	A2007
Revita	Wound care	Q4180
Revitalon™	Wound care	Q4157
RX Flow	Connective tissue repair	Q4100 C9399
Rx Membrane	Soft tissue repair	Q4100 C1781
Seamguard® Staple Line Reinforcement	Staple line reinforcement	Q4100 C9399
SERI™ Surgical Scaffold	Soft tissue reinforcement/repair	Q4100 C1781
Signature APatch	Wound care	Q4260
Simpliderm™	Soft tissue reinforcement/repair Breast reconstruction	Q4100 C9399
SJM™ Pericardial Patch with EnCap™ AC Technology	Pericardial repair	Q4100 C9399
SkinTE™	Wound care	Q4200
SomaGen® Meshed Tissue	Wound care	Q4100 C9399
SportMesh™	Soft tissue reinforcement	Q4100 C1781
SteriShield™	Soft tissue reinforcement/repair	Q4100, C9399
Strattice™ Reconstructive Tissue Matrix	Soft tissue reinforcement/repair	Q4130
Stravix ™	Integumental tissue repair	Q4133
SUPRA SDRM®	Wound care Burn Care	A2011
SureDerm®	Soft tissue repair	Q4220
Surfactor/Nudyn Injectable	Soft tissue repair Wound healing	Q4233
SurGraft®	Wound care	Q4209
SurGraft® FT	Wound care	Q4268
SurGraft TL®	Wound care	Q4263
SurGraft® XT	Wound care	Q4269
SurgiCORD®	Wound care	Q4218
surgiGRAFT™	Wound care	Q4183
SurgiGRAFT-DUAL	Wound care	Q4219
SurgiMend®	Breast reconstruction	C9358

Each of the following products listed below are considered experimental, investigational, or unproven for ANY indication:		
Not Covered Products	**Request for Product Reason(s) (not an all-inclusive list)**	**Product HCPCS Codes**
		C9360
Symbotex™ Composite Mesh	Soft tissue reinforcement	Q4100 C9399
Symphony™	Wound care	A2009
SYNTHECEL™ Dura Repair	Dural repair	Q4100 C1781
TAG	Wound care	Q4261
Talymed™	Wound care	Q4127
tarSys™	Eyelid reconstruction	Q4100 C9399
TenoGlide® Tendon Protector Sheet	Tendon repair	C9356
TenSIX™	Wound care Tendon repair	Q4146
TEXAGEN Amniotic Membrane Allograft	Wound care	Q4100 C9399
TheraGenesis®	Wound care	A2008
TissueMend	Soft tissue repair Tendon repair	C1781 Q4100
Tornier® BioFiber Absorbable Biological Scaffold	Soft tissue reinforcement/repair	Q4100 C1781
Tornier® Collagen Coated BioFiber Scaffold	Soft tissue reinforcement/repair	Q4100 C1781
TruSkin™	Wound care	Q4167
Tutopatch® Bovine Pericardium	Soft tissue reinforcement/repair	Q4100 C1781
Unite® Biomatrix	Wound care	Q4100 C9399
VascuCel®	Vascular patch	Q4100 C9399
Vascu-Guard®	Peripheral vascular reconstruction	Q4100 C9399
Vendaje	Burn care Wound care	Q4252
VersaShield™	Wound care Soft tissue covering	Q4100 C9399
Veritas Collagen Matrix	Soft tissue reinforcement/repair	Q4100 C9354
Veritas Collagen Matrix Peri-Strips Dry	Staple line reinforcement	Q4100 C9399
Viaflow™/Viaflow C	Connective tissue repair	Q4100 C1781
VIAGENEX™ Matrix Amnion Allograft	Soft tissue covering Wound covering	Q4100 C9399
VIAGENEX™ Max Umbilical Cord Membrane	Soft tissue covering Wound covering	Q4100 C9399
VIM	Wound care	Q4251
WoundEx® Membrane	Wound care	Q4163
WoundEx® Flow	Integumental tissue repair	Q4162
Woundfix™	Wound care	Q4217
Woundfix™ Plus	Wound care	Q4217
Woundfix™ XPlus	Wound care	Q4217
WoundPlus™ Membrane	Wound covering	Q4277
XCM Biologic Vascular Patch	Soft tissue reinforcement/repair	Q4142
Xceed™	Wound care	Q4100 C9399
Xcell Amnio Matrix®	Wound covering	Q4280
Xcellerate	Burn care Wound care	Q4234
XCelliStem® Wound Powder	Wound care	A2004

Each of the following products listed below are considered experimental, investigational, or unproven for ANY indication:		
Not Covered Products	**Request for Product Reason(s) (not an all-inclusive list)**	**Product HCPCS Codes**
Xenform®	Soft tissue reinforcement/repair	C1763
XenMatrix™ Surgical Graft	Soft tissue reinforcement/repair	C1781
XenoSure® Biologic Patch	Cardiac reconstruction/repair Vascular reconstruction/repair	Q4100 C1781
XWrap®	Wound care	Q4204
Zenith™ Amniotic Membrane	Burn care Wound care	Q4253

Newly released codes: Codes contained in this section are for informational purposes only. PHP makes no representation as to the validity on the use of these skin substitute products. There is insufficient evidence to support incorporation of these products.		
Product Names	Used for:	Codes
Acesso, per sq cm	For acute and chronic wounds	Q4311
Acesso ac, per sq cm	For acute and chronic wounds	Q4312
Dermabind fm, per sq cm	For use as a wound covering to protect wounds from the environment	Q4313
Reeva, per sq cm	For acute and chronic wounds	Q4314
Regenelink amniotic mem allo	For acute and chronic wounds	Q4315
Amchoplast, per sq cm	For acute and chronic wounds	Q4316
Vitograft, per sq cm	For acute and chronic wounds	Q4317
E-graft, per sq cm	For acute and chronic wounds	Q4318
Sanograft, per sq cm	For acute and chronic wounds	Q4319
Pellograft, per sq cm	For acute and chronic wounds	Q4320
Renograft, per sq cm	For acute and chronic wounds	Q4321
Caregraft, per sq cm	For acute and chronic wounds	Q4322
Alloply, per sq cm	For acute and chronic wounds	Q4323
Amniotx, per sq cm	For acute and chronic wounds	Q4324
Acapatch, per sq cm	For acute and chronic wounds	Q4325
Woundplus, per sq cm	For acute and chronic wounds	Q4326
Duoamnion, per sq cm	For acute and chronic wounds	Q4327
Most, per sq cm	For acute and chronic wounds	Q4328
Singlay, per sq cm	For acute and chronic wounds	Q4329
Total, per sq cm	For acute and chronic wounds	Q4330
Ardeograft, per sq cm	For acute and chronic wounds	Q4333
Skin substitute, FDA-cleared as a device, not otherwise specified	Unknown	A4100
AlloDerm, per sq cm	AlloDerm is a regenerative tissue matrix used to repair hernias and in postmastectomy reconstruction	Q4116
InnovaBurn or InnovaMatrix XL, per sq cm	Unknown	A2022
Resolve Matrix, per sq cm	Unknown	A2024
Vendaje AC, per sq cm	Unknown	Q4279
NuDYN DL or NuDYN DL MESH, per sq cm	Unknown	Q4285
NuDYN SL or NuDYN SLW, per sq cm	Unknown	Q4286
DermaBind DL, per sq cm	Unknown	Q4287
DermaBind CH, per sq cm	Unknown	Q4288
RevoShield+ Amniotic Barrier, per sq cm	Unknown	Q4289
Membrane Wrap-Hydro, per sq cm	Unknown	Q4290
Lamellas xt, per sq cm	intended for use as a wound covering for the treatment of various acute and chronic wounds.	Q4291
Lamellas, per sq cm	Unknown	Q4292

Acesso DL, per sq cm	Unknown	Q4293
Amnio Quad-Core, per sq cm	Unknown	Q4294
Amnio Tri-Core Amniotic, per sq cm	Unknown	Q4295
Rebound Matrix, per sq cm	Unknown	Q4296
Emerge Matrix, per sq cm	Unknown	Q4297
AmniCore Pro, per sq cm	Unknown	Q4298
AmniCore Pro+, per sq cm	Unknown	Q4299
Acesso TL, per sq cm	Unknown	Q4300
Activate Matrix, per sq cm	Unknown	Q4301
Complete ACA, per sq cm	Unknown	Q4302
Complete AA, per sq cm	Unknown	Q4303
GRAFIX PLUS, per sq cm	Unknown	Q4304

Coding

The coding listed in this medical policy is for reference only. Covered and non-covered codes are within this list.

CPT Codes	Description
15002	Wound prep trk/arm/leg
15003	Wound prep addl 100 cm
15004	Wound prep f/n/hf/g
15005	Wound prep f/n/hf/g addl cm
15040	Harvest cultured skin graft
15050	Skin pinch graft
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)

CPT Codes	Description
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)

Reviewed by / Approval Signatures

Population Health & Clinical Quality Committee: Clinton White MD
Senior Medical Director: Jim Romero MD
Date Approved: 08/21/2024

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Publication History

11-29-17 Approved by CQUMC on 11/29/2017
03/27/19 Update policy

07/22/20 Annual review. Reviewed by PHP Medical Policy Committee on 07/03 & 07/16/2020. Agreed to continue following LCD L35041 for all LOBs. New HCPCS codes added: C9363, Q4116, Q4138, Q4143, Q4150, Q4167, Q4170, Q4176, Q4177, Q4179, Q4181, Q4182, Q4183, Q4184, Q4186, Q4187, Q4188, Q4190, Q4191, Q4193, Q4194, Q4195, Q4196, Q4197, Q4198, Q4200, Q4201, Q4203, Q4204, Q4205, Q4206, Q4208, Q4209, Q4210, Q4211, Q4214, Q4216, Q4217, Q4218, Q4219, Q4220, Q4221, Q4222, Q4226, Q4227, Q4228, Q4229, Q4232, Q4234, Q4235, Q4236, Q4237, Q4238, Q4239, Q4247, & Q4248. No prior authorization will be required for ALL the listed Q-Codes, except Q4145. Prior authorization will continue to remain but will also be applied to this policy for codes Q4145, 15271, 15272, 15273, and 15274. *The reporting of skin substitutes represented by a Q code must contain the presence of an appropriate application CPT code. HCPCS codes Q4177 and Q4206 are exceptions and do not require an application code. The skin substitute products are divided into two groups for packaging purposes: 1) high cost skin substitute products and 2) low cost skin substitute products. High cost skin substitute products should only be utilized in combination with the performance of one of the skin application procedures described by CPT codes 15271-15278. Low cost skin substitute products should only be utilized in combination with the performance of one of the skin application procedures described by HCPCS code C5271-C5278.

07/28/21 Annual review. Reviewed by PHP Medical Policy committee on 06/09/2021. No change, continue to follow: L35041 for all LOB and continue PA for applications CPT codes 15271, 15272, 15273, 15274, 15275, 15276, 15277, 15278, C5271, C5272, C5273, C5274, C5275, C5276, C5277, C5278, Q4145. Codes review: pass-through payment expired for Q4195, Q4196 as of Sept 2020 and are now Status Indicator -N-. New codes added: C1849, Q4249, Q4250, Q4254, Q4255. These codes are recognized as either high-cost skin substitute products or low-cost skin substitute products for packaging purposes per CMS, Transmittal # R10557CP as of January 08, 2021. Also, CMS has moved the following codes to "high-cost" category: Q4167, Q4182, Q4188, Q4190, Q4193, Q4200, Q4209, Q4211, Q4219, Q4222, Q4227, Q4232, Q4237, Q4238, and Q4239. All of these codes are OPPS status Indicator -N- and will be set to not pay per Addendum B, April 2021.

12-27-2021: Update only for Skin Substitute Product Low Cost Group/High Cost Group Assignment Effective January 1, 2022 per CR 12552, date Dec 10, 2021. Code **Q4199 is a new code for CY 2022** with Status Indicator -N- assigned as "Low" cost skin substitute. The overall change from CY 2021 to Final CY 2022 the following changed from "Low" to "High" cost skin substitute: Q4167, Q4182, Q4188, Q4190, Q4193, Q4198, Q4200, Q4201, Q4209, Q4211, Q4219, Q4222, Q4227, Q4232, Q4237, Q4238, Q4239 and Q4249. These Q-codes were deleted as of 10-01-2021: Q4228 and Q4236. These Q-codes were deleted as of 10-01-2021: Q4228 and Q4236. New codes for 01/01/2022 (A2001, A2002, A2003, A2004, A2005, A2006, A2007, A2008 and A2009) were mentioned in the policy under column three to say these A-codes are not yet classified by CMS. Codes Q4145, Q4177 and Q4206 are not listed by CMS as low/high group, but are listed as status indicator -N- per OPPS.

04-08-2022-Update to add codes effective April 1, 2022 (A2011, A2012, A2013, A4100, Q4224, Q4225, Q4256, Q4257 and Q4258) per CMS, Pub 1 00-04 Medicare Claims Processing, TN 11303, CR 12679, Date: March 24, 2022.

07/27/22 Annual review. Reviewed by PHP Medical Policy committee on 07/08/2022. Continue to follow the LCD (L35041) that is still current as of 07/08/2022. Continue PA for 15271, 15272, 15273, 15274, 15275, 15276, 15277, 15278, C5271, C5272, C5273, C5274, C5275, C5276, C5277, C5278, Q4145. According to Change Request 12666, TN# 11305 (date: 03-24-22) the following has changed: Code A2003 was created in error; code Q4199, has been reassigned from the low cost to high cost group as of April 1, 2022. Code A2004 no longer a skin substitute product effective from 01/01/22 thru 06/30/2022, per TN#11457-CR#12761. Codes A2005, A2006, A2008, A2009, A2010 reassigned to SI-N and classified as Low-Cost effect April 01, 2022. Code A2007 reassigned to SI-N and classified as to High Cost effective 04/01/2022. According to Change Request 12761, TN#11457 (06-15-22) the following has been updated: Codes A2001 changed from Low Cost to High Cost and to be retro to 04/01/2022. Codes (A2001, A2002, Q4229, Q4258) changed from Low Cost to High Cost, effective 07/01/2022. New codes (Q4259, Q4260, Q4261) added to Low Cost effective 07/01/2022. Policy updated with language about non-facility guidelines provided by Novitas that providers who bill for CPT 15271-15278 can bill separately for skin substitute codes A2001, A2002, A2005, A2006, A2007, A2008, A2009 and A2010. These same codes A2001 thru A2010 can also be used in the OPPS setting and are classified as SI-N for OPPS. These A-codes and other "A & Q-codes" listed within the policy will not require PA.

Update on 09-28-22: HCPCS code *Q4246* will require prior authorization for all LOB. Currently, there is insufficient evidence in the published peer reviewed scientific literature to support the efficacy of the extracellular matrix (ECM) allografts derived from human umbilical cord tissue, including the epithelial layer and the Wharton's Jelly (the product called CoreText or ProText) for all indications. Also, Q4246 is injectable and is not part of CMS high/low designated code. Update on 11-16-22: Add codes Q4251, Q4252, and Q4253 (TN#10997/CR#12436-effective 10/01/2021); and codes A2015, A2016, A2017, and A2018 (TN#11594/CR#12885-effective 10-01-2022). Payment methodology will apply based on CMS fee schedules for both facility and non-facility and/or physician for these codes and all other skin substitute codes listed in this policy. Removed codes Q4177 and Q4206 which are not part of CMS High/Low square centimeter but are injectable. All previously configured Skin Substitute codes for ALOB were corrected and moved into production on 12/18/2022. Commercial will follow Medicare (OPPs & MPFS) fee schedule. Codes found on the DME fee schedule include: Q4101, Q4102, Q4106, Q4110, Q4111, Q4121, Q4133, Q4137, Q4151, Q4159, Q4160, Q4163 Q4186, Q4187, Q4195, Q4196; and codes denoted as SI-C- on the MPFS include: A2001, A2002, A2005, A2006, A2007, A2008, A2009, and A2010,

A2011, A2012, A2013 and A4100. For Medicaid both OPPS Fee Schedule and Fee for Service (HCPCS) were reviewed to allow for facility and professional. Update of references for other wound treatment option. The coverage determination guideline language removed from policy and reformatted to only include LCD weblink(s). **Updated on May 24, 2023:** Skin substitute HCPCS codes effective as of April 1, 2023: Q4265, Q4266, Q4267, Q4268, Q4269, Q4270, and Q4271 were added to policy. These newly released codes will be config according to fee schedules to determine if payment is allowable for the different locations. Per TN (11927), CR (13143), Date: March 24, 2023, are assigned as "low" cost skin substitute product. The policy will no longer manage the information regarding appropriate billing of skin substitute in terms of payment packaging purposes, when the skin substitute products are divided by 1) high-cost skin substitute products and 2) low cost skin substitute products.

07-26-23 Annual review. Reviewed by PHP Medical Policy committee on 05-1-2023 and 07-21-2023. Continue to follow L35041 for all LOB. Pending pricing review for A2001, A2002, A2005, A2006, A2007, A2009, and A2010 for physician services in the office setting. The newly released skin substitute codes, effective July 01, 2023: Q4272, Q4273, Q4274, Q4275, Q4276, Q4277, Q4278, Q4280, Q4281, Q4282, Q4283, and Q4284 were added to policy which will be config according to the applicable fee schedules. Code Q4101 will be allowed in POS-11 for ALOB. **Updated on 11-03-2023:** Added the new codes (A2022, A2024, Q4285 and Q4286) effective 10/01/2023 to policy which will be configured the same manner as other skin substitute products that were previously configured based on status indicators (SI) from all applicable fee schedules.
Updated on 02-07-2024: PHP Medical Policy Committee on 02/07/2024. Added 19 new codes (Q4279, Q4287, Q4288, Q4289, Q4290, Q4291, Q4292, Q4293, Q4294, Q4295, Q4296, Q4297, Q4298, Q4299, Q4300, Q4301, Q4302, Q4303, and Q4304), these codes are effective Jan 01, 2024. These codes will be configured the same manner as other skin substitute products that were previously configured based on status indicators (SI) from all applicable fee schedules.

08/21/24 Annual review. The final annual review by PHP Medical Policy committee was on 07/31/2024. Continue to follow Novitas LCD (L35041) for the application of bioengineered skin substitute material to diabetic foot ulcers and venous leg ulcers of the lower extremities when standard or conservative measures have failed. Criteria were added to supplement and/or expand coverage for burn wounds, diabetic foot ulcers, and venous leg ulcers. The policy update provides guidance for medically necessary skin substitute products and the products that are Investigational and Experimental for any indication. The following named product and HCPCS codes are considered medically necessary for the condition in which it is listed:

- **For Venous stasis Ulcers:** AmnioBand® (Q4151/Q4168), Apligraf® (Q4101), EpiFix® Amniotic Membrane (Q4186), Grafix® Core and GrafixPL Core (Q4132), Grafix PRIME, GrafixPL PRIME (Q4133), Oasis wound matrix (Q4102), Oasis® Ultra Tri-Layer Matrix (Q4124), PriMatrix™ (Q4110), TheraSkin® (Q4121)
- **For Diabetic Foot Ulcers:** AlloPatch Pliable® (Q4128), AmnioBand (Q4151/Q4168), Dermagraft® (Q4106), Apligraf® (Q4101), DermACELL™ AWM (Q4122), EpiFix® Amniotic Membrane (Q4186), Geistlich Derma-Gide® Advanced Wound Matrix (Q4203), Grafix® Core and GrafixPL Core (Q4132), Grafix® PRIME, GrafixPL PRIME (Q4133), GraftJacket NOW™, formerly GraftJacket® regenerative tissue matrix (Q4107), Integra® dermal regeneration template or Integra Omnigraft dermal regeneration matrix (Q4105), Oasis® wound matrix (Q4102), Oasis® ultra tri-layer matrix (Q4124), PriMatrix™ (Q4110), TheraSkin® (Q4121)
- **For Burn Wounds:** Biobrane, Biobrane-L or Epicel (Q4100/C9399), Integra™ Meshed Bilayer Wound Matrix (C9363), Integra™ bilayer matrix wound dressing (BMWD) (Q4104), Integra® dermal regeneration (DRT) template or Integra Omnigraft dermal regeneration matrix (Q4105), Integra™ matrix Wound Dressing (Q4108), Suprathel® (A2012), Transcyte® (Q4182)

Additionally, the revision added language including coverage for Venous Stasis Ulcer, Diabetic Foot Ulcers and Burn Wounds. The coding advisement was removed for: "*The skin substitute graft codes are not to be reported for application of non-graft wound dressings. Non-graft wound dressings (e.g., gel, ointment, foam, liquid, powder) or injected skin substitutes (e.g. Q4246 & Q4145) are generally included in standard wound care management; such products may provide value and, in fact, may preclude the need for skin substitute application*."

The Table for Non-facility (i.e. provider's office setting) has been removed and these codes moved to the section for Investigational and experimental now requires PA for ALOB: A2001, A2002, A2005, A2006, A2007, A2008, A2009, A2010. Code Q4101 was removed from Table for Non-facility and the code moved to the covered section will require PA.

Continue PA requirement for codes: C5271, C5272, C5273, C5274, C5275, C5276, C5277, C5278, Q4145, Q4246, Q4265, Q4266, Q4267, Q4268, Q4269, Q4270, Q4271, Q4272, Q4274, Q4275, Q4276, Q4277, Q4278, Q4280, Q4281, Q4282, Q4283, Q4284, A2022, A2024, Q4279, Q4285, Q4286, Q4287, Q4288, Q4289, Q4290, Q4291, Q4292, Q4293, Q4294, Q4295, Q4296, Q4297, Q4298, Q4299, Q4300, Q4301, Q4302, Q4303, Q4304.

Removed code Q0491 from PA grid. This is not a skin substitute code but Emergency power source for use with electric/pneumatic ventricular assist device, replacement only.

Removed deleted codes: Q4210 and Q4277

PA now required for the newly released codes for July 2024 for ALOB: Q4311, Q4312, Q4313, Q4314, Q4315, Q4316, Q4317, Q4318, Q4319, Q4320, Q4321, Q4322, Q4323, Q4324, Q4325, Q4326, Q4327, Q4328, Q4329, Q4330, *Q4331*, *Q4332*, Q4333. Codes Q4331 and Q4332 are listed under products that are considered investigational and experimental and all the other codes are listed under the Table for newly released codes. The

codes contained in the newly released Table are for informational purposes only. PHP has not made a representation as to the validity on the use of these skin substitute products, because at this time there is insufficient evidence to support these products.

PA now required for the medically necessary codes: Q4151, A2012, C9363, C9399, Q4100, Q4101, Q4102, Q4104, Q4105, Q4106, Q4107, Q4108, Q4110, Q4121, Q4122, Q4124, Q4128, Q4132, Q4133, Q4151, Q4168, Q4182, Q4186 and Q4203. Codes C9399 and Q4168 are added to this review.

PA to be required for the added codes on this review for ALOB. These code are listed under Investigation and experimental section: A2004, A2014, A2019, A2021, A6010, C1718, C1762, C1763, C1768, C1781, C1832, C9352, C9353, C9354, C9355, C9356, C9358, C9360, C9361, C9364, J3590, Q4112, Q4113, Q4114, Q4118, Q4125, Q4130, Q4139, Q4142, Q4149, Q4155, Q4162, Q4171, Q4174, Q4177, Q4185, Q4189, Q4192, Q4202, Q4206, Q4212, Q4213, Q4215, Q4230, Q4231, Q4233, Q4236, Q4240, Q4241, Q4242, Q4244, Q4245, Q4262, Q4263, Q4264.

PA to be required for ALOB for codes that were already in the MPM that are considered experimental: A2011, A2013, A2015, A2016, A2017, A2018, A2020, Q4103, Q4111, Q4115, Q4117, Q4123, Q4127, Q4134, Q4135, Q4136, Q4137, Q4138, Q4140, Q4141, Q4143, Q4146, Q4147, Q4148, Q4150, Q4152, Q4153, Q4154, Q4156, Q4157, Q4158, Q4159, Q4160, Q4161, Q4163, Q4164, Q4165, Q4166, Q4167, Q4169, Q4170, Q4173, Q4175, Q4176, Q4178, Q4179, Q4180, Q4181, Q4183, Q4184, Q4187, Q4188, Q4190, Q4191, Q4193, Q4194, Q4195, Q4196, Q4197, Q4198, Q4199, Q4200, Q4201, Q4204, Q4205, Q4208, Q4209, Q4211, Q4214, Q4216, Q4217, Q4218, Q4219, Q4220, Q4221, Q4222, Q4224, Q4225, Q4226, Q4227, Q4229, Q4232, Q4234, Q4235, Q4237, Q4238, Q4239, Q4247, Q4248, Q4249, Q4250, Q4251, Q4252, Q4253, Q4254, Q4255, Q4256, Q4257, Q4258, Q4259, Q4260, Q4261, Q4273.

PA to be required for ALOB for codes that were already in the MPM that are not listed under covered or I&E or under covered indication: A4100 and Q4116.

This Medical Policy is intended to represent clinical guidelines describing medical appropriateness and is developed to assist Presbyterian Health Plan and Presbyterian Insurance Company, Inc. (Presbyterian) Health Services staff and Presbyterian medical directors in determination of coverage. The Medical Policy is not a treatment guide and should not be used as such.

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When PHP follows a particular guideline such as LCDs, NCDs, MCG, NCCN etc., for the purposes of determining coverage; it is expected providers maintain or have access to appropriate documentation when requested to support coverage. See the References section to view the source materials used to develop this resource document.