Geisinger

Geisinger Health Plan Policies and Procedure Manual

Policy: MP075

Section: Medical Benefit Policy

Subject: Tissue Engineered Skin Substitutes

Applicable line of business:

Commercial	**x**	**Medicaid**	**x**
Medicare	**x**	**ACA**	**x**
CHIP	**x**		

I. Policy: Tissue Engineered Skin Substitutes

II. Purpose/Objective:

To provide a policy of coverage regarding

III. Responsibility:

A. Medical Directors
B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

Commercial

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicare

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

CHIP

Geisinger Health Plan Kids (GHP Kids) is a Children's Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicaid

Geisinger Health Plan Family (GHP Family) is a Medical Assistance (Medicaid) insurance program offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

DESCRIPTION:

Tissue engineered skin substitutes have been developed to replace autografts, allografts and xenograft in the treatment of extensive burn injuries and hard-to-heal, chronic wounds associated with non-burn etiologies such as venous ulcers and diabetic foot ulcers. The goal of tissue engineered skin substitute therapy is to provide a temporary biologic dressing that encourages skin tissue regeneration and wound healing through its own natural contingent of growth factors and proteins. It delivers new cells to the wound, which are able to adjust to the microenvironment of the wound and stimulate healing.

Treatment of Diabetic Foot Ulcers or Venous Leg Ulcers

For MEDICARE Business Segment, please see: L35041 Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers

For COMMERCIAL and NON-MEDICARE Business Segments:

INDICATIONS:
Tissue engineered skin substitutes, cellular and tissue-based products may be considered **medically necessary** for the treatment of diabetic foot ulcers or venous leg ulcers when the following criteria are met:

1. A chronic, non-infected diabetic foot ulcers that fail to achieve at least 50% ulcer area reduction after four weeks of standard care; OR
2. a chronic, non-infected venous leg ulcers that fail to respond after four weeks of standard care treatment.

Standard of Care treatment includes:

- Comprehensive assessment (history, exam, vascular assessment) and diagnostic tests as indicated
- For members with a diabetic foot ulcer: assessment of Type 1 or Type 2 diabetes and management history with attention to comorbidities, review of current blood glucose levels/hemoglobin A1c (HbA1c), diet and nutritional status, activity level, physical exam that includes assessment of skin, ulcer, and vascular perfusion and assessment of off-loading devices or use of appropriate footwear
- For members with a venous leg ulcer: assessment of clinical history (including prior ulcers, body mass index, history of pulmonary embolism or superficial/deep venous thrombosis), physical exam, evaluation of venous

reflux, perforator incompetence, and venous thrombosis. The use of a firm strength compression garment (>20 mmHg) or multi-layered compressive dressing

Upon request, the following information must be available:

1. An implemented treatment plan to be continued throughout the course of treatment demonstrating all the following:
   - Debridement to a clean granular base.
   - Documented evidence of offloading for diabetic foot ulcer.
   - Documented evidence of sustained compression therapy for venous leg ulcer.
   - Infection control
   - Management of exudate with maintenance of a moist environment.
   - Documentation of smoking history, and counselling on the effect of smoking on wound healing. Treatment for smoking cessation and outcome of counselling (if applicable).

2. Documentation of response to treatment requires measurements of the initial ulcer, pre-treatment ulcer measurements, weekly ulcer measurements, post-completion ulcer measurements following (at least) 4 weeks of standard treatment, ulcer measurements at initial placement of the skin substitute graft/CTP, and before each subsequent placement of the skin substitute graft/CTP.
3. Failure to heal or stalled response despite standard of care measures must have preceded the application for a minimum of 4 weeks and established standard treatment must continue for the course of therapy. Continuous compression therapy for venous leg ulcers must be documented for the episode of care.
4. Documentation must include the interventions having failed during prior ulcer evaluation and management. The record must include an updated medication history, review of pertinent medical problems diagnosed since the previous ulcer evaluation, and explanation of the planned skin replacement with choice of skin substitute graft/CTP.
5. The member is under the care of a qualified provider for the treatment of the underlying systemic disease process(es) (e.g., venous insufficiency, diabetes, neuropathy)

The following products are covered for treatment of diabetic foot ulcers:

Affinity	**Q4159**
AmnioBand, guardian	**Q4151 AmnioBand Requires Program Exception for Medicaid**
Apligraf	**Q4101**
DermACELL, awm, porous	**Q4122**
Derma-Gide	**Q4203**
Dermagraft	**Q4106**
Epicord	**Q4187**
Epifix	**Q4186**
FlexHD or AllopatchHD	**Q4128 FlexHD® Requires Program Exception for Medicaid**
Grafix stravix prime pl	**Q4133**
GraftJacket	**Q4107**
Integra or Omnigraft dermal regeneration template	**Q4105**
Kerecis Omega3/Kerecis omega3, MariGen shield	**A2019, Q4158 Kerecis Omega3 MariGen Shield Requires Program Exception for Medicaid**
NuShield	**Q4160**
Oasis wound matrix	**Q4102**
PriMatrix	**Q4110**
Theraskin	**Q4121**

E08.621* Diabetes mellitus due to underlying condition with foot ulcer
E09.621* Drug or chemical induced diabetes mellitus with foot ulcer
E10.621* Type 1 diabetes mellitus with foot ulcer
E11.621* Type 2 diabetes mellitus with foot ulcer
E13.621* Other specified diabetes mellitus with foot ulcer

The following products are covered for treatment of venous leg ulcers:

AmnioBand, guardian	**Q4151 AmnioBand Requires Program Exception for Medicaid**
Apligraf	**Q4101**
Dermagraft	**Q4106**
Epifix	**Q4186**
Oasis wound matrix	**Q4102**

I83.011*	Varicose veins of right lower extremity with ulcer of thigh
I83.012*	Varicose veins of right lower extremity with ulcer of calf
I83.013*	Varicose veins of right lower extremity with ulcer of ankle
I83.014*	Varicose veins of right lower extremity with ulcer of heel and midfoot
I83.015*	Varicose veins of right lower extremity with ulcer other part of foot
I83.018*	Varicose veins of right lower extremity with ulcer other part of lower leg
I83.021*	Varicose veins of left lower extremity with ulcer of thigh
I83.022*	Varicose veins of left lower extremity with ulcer of calf
I83.023*	Varicose veins of left lower extremity with ulcer of ankle
I83.024*	Varicose veins of left lower extremity with ulcer of heel and midfoot
I83.025*	Varicose veins of left lower extremity with ulcer other part of foot
I83.028*	Varicose veins of left lower extremity with ulcer other part of lower leg
I83.211*	Varicose veins of right lower extremity with both ulcer of thigh and inflammation
I83.212*	Varicose veins of right lower extremity with both ulcer of calf and inflammation
I83.213*	Varicose veins of right lower extremity with both ulcer of ankle and inflammation
I83.214*	Varicose veins of right lower extremity with both ulcer of heel and midfoot and inflammation
I83.215*	Varicose veins of right lower extremity with both ulcer other part of foot and inflammation
I83.218*	Varicose veins of right lower extremity with both ulcer of other part of lower extremity and inflammation
I83.221*	Varicose veins of left lower extremity with both ulcer of thigh and inflammation
I83.222*	Varicose veins of left lower extremity with both ulcer of calf and inflammation
I83.223*	Varicose veins of left lower extremity with both ulcer of ankle and inflammation
I83.224*	Varicose veins of left lower extremity with both ulcer of heel and midfoot and inflammation
I83.225*	Varicose veins of left lower extremity with both ulcer other part of foot and inflammation
I83.228*	Varicose veins of left lower extremity with both ulcer of other part of lower extremity and inflammation
I87.011*	Postthrombotic syndrome with ulcer of right lower extremity
I87.012*	Postthrombotic syndrome with ulcer of left lower extremity
I87.013*	Postthrombotic syndrome with ulcer of bilateral lower extremity
I87.031*	Postthrombotic syndrome with ulcer and inflammation of right lower extremity
I87.032*	Postthrombotic syndrome with ulcer and inflammation of left lower extremity
I87.033*	Postthrombotic syndrome with ulcer and inflammation of bilateral lower extremity
I87.311*	Chronic venous hypertension (idiopathic) with ulcer of right lower extremity
I87.312*	Chronic venous hypertension (idiopathic) with ulcer of left lower extremity
I87.313*	Chronic venous hypertension (idiopathic) with ulcer of bilateral lower extremity
I87.331*	Chronic venous hypertension (idiopathic) with ulcer and inflammation of right lower extremity
I87.332*	Chronic venous hypertension (idiopathic) with ulcer and inflammation of left lower extremity
I87.333*	Chronic venous hypertension (idiopathic) with ulcer and inflammation of bilateral lower extremity

LIMITATIONS:
Liquid or gel preparations are not considered grafts.

EXCLUSIONS:
The use of tissue engineered skin equivalents is considered **unproven** and is **NOT COVERED**

Treatment of Burns and Surgical Wound/Reconstruction:

Tissue engineered skin substitutes, cellular and tissue-based products may be considered **medically necessary** for the treatment of burns and surgical wounds/reconstruction when the following criteria are met:

Biobrane® (Q4100) (biosynthetic dressing) is a knitted nylon fabric bonded to an ultra-thin silicone rubber membrane coated with a protein (gelatin) and is indicated for the treatment of thermal injuries, superficial scald burn or flame injury of the hand when:

- The burn is superficial, partial-thickness with limited involvement of the dermis (less than or equal to 25% total body surface area); **and**
- The burn is clean, non-infected, and free of nonviable tissue and coagulation eschar.

Orcel® (C9200) is an absorbable bilayered cellular matrix, made of bovine collagen, in which human dermal cells have been cultured and is considered medically necessary for the treatment of

- healing donor site wounds in burn victims, and
- for use in persons with dystrophic epidermolysis bullosa undergoing hand reconstruction surgery to close and heal wounds created by the surgery, including those at donor sites when used in accordance with the FDA's Humanitarian Device Exemption.

TransCyte® (Q4182) consists of human dermal fibroblasts grown on nylon mesh, combined with a synthetic epidermal layer and is considered medically necessary for

- the temporary wound covering for surgically excised full-thickness and deep partial-thickness thermal burn wounds in persons who require such a covering before autograft placement.

Integra® Dermal Regeneration Template, Matrix Wound Dressing, Bilayer Matrix Wound Dressing, and Meshed Bilayer Wound Matrix (Q4104 – Q4108) an acellular, biodegradable copolymer matrix coated is considered medically necessary for post-excision treatment of full thickness of deep partial thickness burns when autografting is not feasible due to the lack of suitable healthy tissue or the member's weak physiological state.

Alloderm® (Q4116) (acellular dermal matrix allograft) is considered medically necessary when used

- In association with a covered, medically necessary breast reconstruction procedure.
- Surgical repair of complex abdominal wall wounds (e.g., due to infection, fascial defect, etc.)
- ENT/Head & Neck reconstructive procedures

Neoform® (Q4100) (solvent-dehydrated, gamma-irradiated preserved human allograft) is considered medically necessary when used in association with a covered, medically necessary breast reconstruction procedure.

AlloMax™ (Q4100) is considered medically necessary when used in association with a covered, medically necessary breast reconstruction procedure.

Epicel® (Q4100) is considered medically necessary when used for the treatment of deep dermal or full thickness burns of 30% or more of the total body surface area in accordance with the FDA's Humanitarian Device Exemption

NeuraGen (C9352) and NeuroMatrix (C9355) for the repair and closure of peripheral nerve gaps may be considered medically necessary in all of the following scenarios

- conduit-assisted repair as a technique for tension-relief at the peripheral nerve repair site or major nerve with a gap not exceeding 6 mm
- repair of digital nerve injuries with gaps less than 15 mm
- repair of digital nerve injuries with gaps 15-25 mm, where allograft nerve is not available
- repair of major nerves with small gaps not exceeding 6 mm, where allograft nerve is not available

EXCLUSIONS:

The use of tissue engineered skin equivalents and wound products not specifically listed under Indications is considered **unproven** and is **NOT COVERED.**

Repliform®	Conexa™	Hyalomatrix®	Repriza™
Puros® Dermis	CorMatrix®	IntéguPly™	Restore® Orthobiologic
AlloMend™	CRXa™	Jaloskin®	Seamguard®
Puracol®	CryoSkin®	LiquidGen™	SportMesh™
Alloskin™	Cuffpatch™	MariGen Omega3	SS Matrix™
Alloskin RT™	Cymetra	Matriderm®	Stimulen™ Collagen
AlloWrap®	DeNovo® NT Graft	Matristem®	StrataGraft®
AmnioCare®		Matrix HD™	Strattice™

AmnioExcel™	Dermadapt™ Wound Dressing	MediHoney®	Suprathel®
AmnioFix™	DermaMatrix™	Medeor™	SurgiMend®
Amniomatrix™	DermaSpan™	Mediskin®	Surgisis® (including Surgisis® AFP™ Anal Fistula Plug, Surgisis® Gold™ Hernia Repair Grafts, and Surgisis™)
AmnioMTM™	DressSkin™	Memoderm™	Talymed™
AmnioShield®	Duraform™	Menaflex™	TenoGlide™
Aongen™ Collagen Matrix	Duragen® XS	Meso BioMatrix™	TenSIX™
Architect Extracellular Matrix™	Duragen™ Plus		TheraForm™ Standard/Sheet
ArthroFlex®	DuraMatrix™	NEOX® 100 Quick-Peel	TissueMend®
Atlas Wound Matrix	Durepair® Regeneration Matrix	NEOX® 1k Wound Matrix	TranzGraft®
Avance® Nerve Graft	Endobon® Xenograft Granules	NEOX® FLO NuCel™	Unite™
Avaulta Plus™	Endoform™	Neuragen®	Veritas® Collagen Matrix
AxoGuard® nerve connector	ENDURAgen™	NeuraWrap™	X-Repair
AxoGuard® nerve protector	Inforce®	Neuroflex™	XCM Biologic™
CollaFix™	EpiDex®	NeuroMatrix™	Xelma®
BioDDryFlex®		NeuroMend™	XenMatrix™
Biodesign	Excellagen®	NuCel®	Xwrap™ (Hydro, DRY, and ECM)
BioDExCel™	EZ Derm™	Collamend™	hMatrix®
BioDfactor™	CollaWound™	CollaSorb™	Amniply
BioDfence®	FloGraft™	OrthADAPT™	Reguard
BioDOptix™	FortaDerm™ Wound Dressing	OsseoGuard®	Cortiva
BioFiber™	Gammagraft™	Ovation®	AllopatchHD **Requires Program Exception for Medicaid**
Biovance®		Puraply	
C-QUR™	GORE®Bio –A	Pelvicol®	Guardian **Requires Program Exception for Medicaid**
Celaderm	Grafix® CORE	Pelvisoft®	PTFE felt
CellerateRX®	Grafix® PRIME	Peri-Guard® Repair Patch	Helicoll
CelluTome™	GraftJacket™	Peri-Strips Dry®	CLARIX™ FLO
CLARIX™ 100 Quick-Peel	Graftjacket™ Xpress injectable	Permacol™	Promogran™
CLARIX™ 1k	HA Absorbent Wound Dressing	Via Matrix	

EXCLUSIONS:
The use of tissue engineered skin equivalents not specifically listed in this policy for use in diabetic foot ulcers or venous leg ulcers or in any application outside of the current FDA approvals is considered **unproven** and is **NOT COVERED**.

FOR MEDICAID BUSINESS SEGMENT:

Epifix (Q4186), Grafix Core (Q4132) and Grafix Prime (Q4133) require a program exception to be considered for coverage

Amnioband (Q4151), Guardian (Q4151) FlexHD (Q4128) and Allopatch(Q4128) require a program exception to be considered for coverage

Kerecis Omega3 (A2019) and Kerecis Omega3 MariGen Shield (Q4158) require a program exception to be considered for coverage.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH:
The coding listed in this document may not represent the comprehensive range of codes that may be associated with this service.

HCPCS CODES:

15150 Tissue cultured skin autograft, trunk, arms, legs; first 25 sq. cm or less
15151 Tissue cultured skin autograft, trunk, arms, legs; additional 1 sq. cm to 75 sq. cm
15152 Tissue cultured skin autograft, trunk, arms, legs; each additional 100 sq. cm, or each additional 1% of body area of infants and children, or part thereof
15155 Tissue cultured skin autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 25 sq. cm or less
15156 Tissue cultured skin autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; additional 1 sq. cm to 75 sq. cm
15157 Tissue cultured skin autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 100 sq. cm, or each additional 1% of body area of infants and children, or part thereof
15271 application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq. cm; first 25 cm or less wound surface area
15272 each additional 25 sq. cm wound surface area, or part thereof
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 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
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 each additional 25 sq. cm wound surface area, or part thereof
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 infants and children
15278 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
15777 Implantation of biologic implant (eg, acellular dermal matrix) for soft tissue reinforcement (eg, breast, trunk)
A2001 Innovamatrix ac, per square centimeter
A2002 Mirragen advanced wound matrix, per square centimeter
A2003 bio-connekt wound matrix, per square centimeter
A2004 Xcellistem, 1mg
A2005 Microlyte matrix, per square centimeter
A2006 Novosorb synpath dermal matrix, per square centimeter
A2007 Restrata, per square centimeter
A2008 Theragenesis, per square centimeter
A2009 Symphony, per square centimeter
A2010 Apis, per square centimeter
A2019 Kerecis Omega3
A2022 InnovaBurn or InnovaMatrix XL, per sq cm
A2023 InnovaMatrix PD, 1 mg
A2024 Resolve Matrix, per sq cm

A2025 Miro3D, per cu cm
C5272 Low cost skin substitute app
C5273 Low cost skin substitute app
C5274 Low cost skin substitute app
C5275 Low cost skin substitute app
C5276 Low cost skin substitute app
C5277 Low cost skin substitute app
C5278 Low cost skin substitute app
C9352 Microporous collagen implantable tube (NeuraGen Nerve Guide), per centimeter length
C9353 Microporous collagen implantable slit tube (NeuraWrap Nerve Protector), per centimeter length
C9354 Acellular pericardial tissue matrix of non-human origin (Veritas), per square centimeter
C9355 Collagen nerve cuff (NeuroMatrix), per 0.5 centimeter length
C9356 Tendon, porous matrix of cross-linked collagen and glycosaminoglycan matrix (TenoGlide Tendon Protector Sheet), per square centimeter
C9358 Dermal substitute, native, non-denatured collagen, fetal bovine origin (SurgiMend Collagen Matrix), per 0.5 square centimeters
C9359 Porous purified collagen matrix bone void filler (integra mozaik osteoconductive scaffold putty, integra osteoconductive scaffold putty), per 0.5cc
C9360 Dermal substitute, native, non-denatured collagen, neonatal bovine origin (SurgiMend Collagen Matrix), per 0.5 square centimeters
C9361 Collagen matrix nerve wrap (NeuroMend Collagen Nerve Wrap), per 0.5 centimeter length
C9362 Porous purified collagen matrix bone void filer (integra mozaik osteoconductive scaffold strip), per 0.5 cc
C9363 Skin substitute, Integra Meshed Bilayer Wound Matrix, per square centimeter
C9364 Porcine implant, Permacol, per square centimeter
G0428 Collagen meniscus implant procedure for filling meniscal defects (e.g., CMI, collagen scaffold, Menaflex)
Q4100 Skin substitute, not otherwise classified [when specified as TransCyte]
Q4101 Apligraf, per square cm
Q4102 Skin substitute, Oasis wound matrix, per sq. cm
Q4103 Oasis Burn Matrix, per square centimeter
Q4104 Integra Bilayer Matrix Wound Dressing (BMWD), per square centimeter
Q4105 Integra Dermal Regeneration Template (DRT), per square centimeter
Q4106 Dermagraft, per square centimeter
Q4107 Graftjacket, per square centimeter
Q4108 Integra Matrix, per square centimeter
Q4110 PriMatrix, per square centimeter
Q4111 Gammagraft, per square centimeter
Q4112 Cymetra, injectable, 1 cc
Q4113 Graftjacket Xpress, injectable, 1 cc
Q4114 Integra Flowable Wound Matrix, injectable, 1 cc
Q4115 Alloskin, per square centimeter
Q4116 Skin substitute, AlloDerm, per square centimeter
Q4117 Hyalomatrix, per square centimeter
Q4118 Matristem micromatrix, 1 mg
Q4121 Theraskin, per square centimeter
Q4122 Dermacell, per square centimeter
Q4123 AlloSkin RT, per square centimeter
Q4124 Oasis Ultra Tri-Layer Wound Matrix, per square centimeter
Q4125 ArthroFlex, per square centimeter
Q4126 Memoderm, dermaspan, tranzgraft or integuply, per square centimeter
Q4127 Talymed, per square centimeter
Q4128 FlexHD, AlloPatch HD, or Matrix HD, per square centimeter
Q4130 Strattice, per square centimeter
Q4131 EpiFix, per square centimeter
Q4132 Grafix CORE, per square centimeter
Q4133 Grafix PRIME, per square centimeter
Q4134 hMatrix, per square centimeter
Q4135 Mediskin, per square centimeter
Q4136 EZ-derm, per square centimeter
Q4137 Amnioexcel or biodexcel, per square centimeter
Q4138 Biodfence dryflex, per square centimeter
Q4139 Amniomatrix or biodmatrix, injectable, 1 cc
Q4140 Biodfence, per square centimeter

Q4141 Alloskin ac, per square centimeter
Q4142 Xcm biologic tissue matrix, per square centimeter
Q4143 Repriza, per square centimeter
Q4145 Epifix, injectable, 1 mg
Q4146 Tensix, per square centimeter
Q4147 Architect extracellular matrix, per square centimeter
Q4148 Neox 1k, per square centimeter
Q4149 Excellagen, 0.1 cc
Q4150 Allowrap DS or Dry, per square centimeter
Q4151 AmnioBand or Guardian, per square centimeter
Q4152 DermaPure, per square centimeter
Q4153 Dermavest, per square centimeter
Q4154 Biovance, per square centimeter
Q4155 NeoxFlo or ClarixFlo, 1 mg
Q4156 Neox 100, per square centimeter
Q4157 Revitalon, per square centimeter
Q4158 MariGen, per square centimeter
Q4159 Affinity, per square centimeter
Q4160 NuShield, per square centimeter
Q4161 Bio-connekt wound matrix, per square centimeter
Q4162 Amniopro flow, bioskin flow, biorenew flow, woundex flow, amniogen-a, amniogen-c, 0.5cc
Q4163 Amniopro, bioskin, biorenew, woundex, amniogen-45, amniogen-200, per square centimeter
Q4164 Helicoll, per square centimeter
Q4165 Keramatrix, per square centimeter
Q4166 Cytal, per square centimeter
Q4167 Truskin, per square centimeter
Q4168 Amnioband, 1 mg
Q4169 Artacent wound, per square centimeter
Q4170 Cygnus, per square centimeter
Q4171 Interfyl, 1 mg
Q4172 Puraply or puraply am, per square centimeter
Q4173 Palingen or palingen xplus, per square centimeter
Q4174 Palingen or promatrx, 0.36 mg per 0.25 cc
Q4175 Miroderm, per square centimeter
Q4176 Neopatch, per square centimeter
Q4177 Floweramnioflo, 0.1 cc
Q4178 Floweramniopatch, per square centimeter
Q4179 Flowerderm, per square centimeter
Q4180 Revita, per square centimeter
Q4181 Amnio wound, per square centimeter
Q4182 Transcyte, per square centimeter
Q4186 Epifix 1 sq cm
Q4187 Epicord 1 sq cm
Q4195-Q4197 Puraply
Q4203 Derma-gide, 1 sq cm
Q4249 Amniply, for topical use only, per square centimeter
Q4255 Reguard, for topical use only, per square centimeter
Q4285 NuDYN DL or NuDYN DL MESH, per sq cm
Q4286 NuDYN SL or NuDYN SLW, per sq cm
Q4309 Via matrix, per square centimeter

LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:
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Falanga V, “Tissue Engineering in Wound Repair”, *Advances in Skin and Wound Care*, 13(2 Suppl):15-19, May-June 2000

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Sibbald RG, Torrance GW, Walker V, Attard C, MacNeil P, “Cost-effectiveness of Apligraf in the Treatment of Venous Leg Ulcers”, *Ostomy Wound Management* 47(8):36-46, Aug 2001

Schonfeld WH, Villa KF, Fastenau JM, Mazonson PD, Falanga V, “An Economic Assessment of Apligraf (Graftskin) for the Treatment of Hard to Heal Venous Leg Ulcers”, *Wound Repair and Regeneration* 8(4):251-257, July-Aug 2000

Kaiser Permanente Technology Assessment Program, TEC Review, “Graftskin for the Treatment of Skin Ulcers”, Vol 16(12):1-24, Nov 2001

Medical Device Approvals, Dermagraft®, www.fda.gov/cdrh

Medical Device Approvals, Apligraf® Graftskin, www.fda.gov/cdrh

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This policy will be revised as necessary and reviewed no less than annually.

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