Skin and Tissue Substitutes – Engineered

Date of Origin: 10/2017 **Last Review Date: 02/26/2020** **Effective Date: 03/01/2020**

Dates Reviewed: 12/06/2017, 11/28/2018, 02/27/2019, 03/27/2019, 05/2019, 11/2019, 02/2020

Developed By: Medical Necessity Criteria Committee

I. Description

Apligraf and Dermagraft:

For diabetic ulcers, evidence demonstrates at least moderate certainty of at least moderate net benefit. Systematic reviews and a health technology assessment concluded that add-on therapy with skin substitutes, including Apligraf (Graftskin) and Dermagraft, may be an alternative to standard wound care for treatment of diabetic ulcers of the lower extremity, leading to a higher proportion of patients with complete wound closure and shorter time to complete wound healing. A meta-analysis and systematic review concluded, from 2 studies using Apligraf and 3 studies using Dermagraft, that skin substitutes improve the rate of healing of diabetic foot ulcers and result in slightly fewer amputations; however, the data were insufficient to draw conclusions about the effectiveness of specific products or long-term results. A randomized controlled trial of patients with diabetic foot ulcers found that the 35 patients who received standard wound care healed in a mean time of 57.4 days, while the 33 patients who received Apligraf healed in a mean time of 47.9 days.

For venous insufficiency ulcers, evidence demonstrates at least moderate certainty of at least moderate net benefit. Systematic reviews found randomized controlled trials that indicate greater effectiveness of bilayer artificial skin, including Apligraf (Graftskin), in treating such lesions as compared with standard compression and a simple dressing. In a randomized controlled trial using standard care with or without addition of Dermagraft for treatment of venous insufficiency ulcers, healing rate after 12 weeks was statistically similar in both groups. A comparative effectiveness review found limited evidence of the effectiveness of cryopreserved, living, single-layer skin substitutes derived from human allogeneic fibroblasts due to few studies and small sample sizes.

AlloDerm:

AlloDerm (Life Cell Corp., The Woodlands, TX), an acellular dermal matrix processed from human allograft skin. AlloDerm is processed from human cadaver skin with the cells responsible for immune response and graft rejection removed. The remainder is a matrix or framework of natural biological components, ready to enable the body to mount its own tissue regeneration process. AlloDerm is indicated for use in association with breast reconstruction procedures.

Epifix:

EpiFix amniotic membrane allograft (MiMedx Group, Inc., Kennesaw, GA) is a biologic human amniotic membrane processed through Surgical Biologic's proprietary Purion® process, which combines cleaning, dehydration and sterilization to produce a safe, technically sterilized tissue allowing for storage at room temperature. It is used for the treatment of dermal wounds.

EpiFix is a multi-layer biologic dehydrated human amniotic membrane allograft comprised of an epithelial layer and two fibrous connective tissue layers specifically processed to be used for the repair or replacement of lost or damaged dermal tissue. It is prepared from human placenta. The processed allograft contains collagen types IV, V, and VII that promote cellular differentiation and adhesion. Usage includes on lay applications for, but not limited to, neuropathic ulcers, venous stasis ulcers, post-traumatic wounds and post-surgical wounds and pressure ulcers. According to the manufacturer, EpiFix provides a matrix for cellular migration/proliferation, provides a natural biological barrier, and is non-immunogenic. The manufacturer states that it also delivers well-known essential wound healing growth factors; delivers minimally manipulated extracellular matrix (ECM) proteins; provides unique anti-inflammatory cytokines, and contains tissue inhibitors of metallo-proteinases. Each allograft is packed in a hermetically sealed double peel pouch packaging in an outer box carton. According to the manufacturer, EpiFix differs from other products produced from human tissue based upon the derived source of the tissue allograft and allograft contents. Only EpiFix is composed of normal dehydrated human amniotic membrane (dHAM) and has no synthetic components. EpiFix has been used in burns, plastic surgery and wound care.

Grafix:
Grafix Core and Grafix Prime are extracellular matrix containing growth factors for acute and chronic wounds, including diabetic foot ulcers and burns.

Grafix Core is an allograft containing endogenous mesenchymal stem cells indicated for the treatment of deep chronic wounds, limb salvage procedures, tendon repair and burns. Grafix Prime is an allograft containing endogenous mesenchymal stem cells indicated for upper epithelial layer chronic wounds and burns.

Grafix CORE is an allograft derived from human chorionic placental tissue “intended” for patients with acute and chronic wounds including, but not limited to, diabetic foot ulcers, venous stasis ulcers and pressure ulcers that have not responded to standard of care therapy. Grafix CORE has one layer (a thick stromal layer), a collagen rich membrane, mesenchymal stem cells (MSCs), and anti-inflammatory cytokines and regenerative growth factors. The thick stromal layer of Grafix CORE has been used in wounds with exposed bone and tendon to help promote granulation of deep tissue. The collagen matrix provides a physiological microenvironment for cells and proteins to promote cellular adhesion and migration in addition to supporting growth factor function. Cytokines and growth factors, epidermal growth factor and transforming growth factor-beta3 in Grafix CORE mediate integral events such as angiogenesis, cell recruitment and proliferation. Once thawed and rinsed, Grafix CORE is applied to the wound and covered with a standard, non-adherent dressing. Additional applications are used as needed with frequency ranging from every 7-14 days until the wound is closed. Grafix CORE is supplied as a cryopreserved membrane mounted on nitrocellulose paper and is available in 5 sizes: 16mm disc, 1.5cm x 2cm, 2cm x 3cm, 3cm x 4cm, and 5cm x 5cm. According to the manufacturer, the presence of MSCs in Grafix distinguishes it from all other skin substitutes.

Grafix PRIME is an allograft derived from the amniotic membrane of human placental tissue used for the management of acute and chronic wounds including, but not limited to, diabetic foot ulcers, venous stasis ulcers and pressure ulcers that have not responded to standard of care therapy. Additional uses include burns, adhesion barriers, and Mohs procedures. Grafix PRIME has two layers (epithelial layer

and stromal layer) and is comprised of a collagen rich membrane, mesenchymal stem cells, and anti-inflammatory cytokines and regenerative growth factors. The collagen matrix provides a physiological microenvironment for cells and proteins to promote cellular adhesion and migration in addition to supporting growth factor function. Cytokines and growth factors, epidermal growth factor and transforming growth factor-beta3 in Grafix PRIME mediate integral events such as angiogenesis, cell recruitment and proliferation. Once thawed and rinsed, Grafix PRIME is applied to the wound and covered with a standard, non-adherent dressing. Additional applications are used as needed with frequency ranging from every 7-14 days for up to 12 weeks or until the wound is closed. Grafix PRIME is supplied as a cryopreserved membrane mounted on nitrocellulose paper and is available in 6 sizes: 16mm disc, 1.5cm x 2cm, 2cm x 3cm, 3cm x 3cm, 3cm x 4cm, and 5cm x 5cm. According to the manufacturer, the presence of mesenchymal stem cells in Grafix distinguishes it from all other skin substitutes. Mesenchymal stem cells coordinate the tissue repair process through down regulation of inflammation, by stimulating blood vessel formation (angiogenesis), and by supporting fibroblast and epithelial cells resulting in rapid wound closure. Grafix PL PRIME, when fully rehydrated is equivalent to thawed Grafix PRIME. Grafix PL Prime does not require ultra-low temperature storage. Grafix PL PRIME is available in 6 sizes: 16mm disc, 1.5cm x 2cm, 2cm x 3cm, 3cm x 3cm, 3cm x 4cm, and 5cm x 5cm).

As part of an agreement with the FDA, Grafix is indicated as a “wound cover” for the treatment of acute and chronic wounds. The manufacturer has announced its intent to submit a Biologics License Application to support clinical indications for Grafix.

II. Criteria: CWQI HCS-0219

A. Tissue-engineered skin substitute may be indicated for **1 or more** of the following:

a. **Apligraf or Oasis wound matrix skin substitute** is medically necessary for **ALL** of the following:

i. The patient has **1 or more** of the following indications:

1. Full thickness neuropathic diabetic foot ulcer of greater than 3 weeks duration and does not include muscle, tendon, capsule, or bone exposure
2. Chronic, non-infected, partial and full-thickness venous stasis ulcers of greater than 1 month duration

ii. The patient has not responded to conventional ulcer therapy such as:

1. Moist dressings
2. Non-weight bearing
3. Optimal glycemic management if diabetic
4. Sharp debridement

iii. No wound infection

iv. The skin substitute is being used along with standard therapy.

v. Adequate perfusion of involved limb

vi. Apligraf is experimental and investigational for all other indications

b. **Dermagraft dermal substitute** is medically necessary for **ALL** of the following:

i. The patient has **1 or more** of the following indications:

1. Full-thickness diabetic foot ulcer for greater than 6 weeks duration and does not include muscle, tendon, capsule, or bone exposure.
2. Wound is related to dystrophic epidermolysis bullosa

ii. The patient has not responded to conventional ulcer therapy such as:
    1. Moist dressings
    2. Non-weight bearing
    3. Optimal glycemic control if diabetic
    4. Sharp debridement
iii. No wound infection
iv. Adequate perfusion of the involved limb
v. The skin substitute is being used along with standard therapy.

c. **EpiFix or Grafix (Grafix Core, Grafix Prime, GrafixPL Prime) skin substitute** is medically necessary for **ALL** of the following:
    i. The patient has a partial of full thickness neuropathic diabetic foot ulcers for greater than 6 weeks duration
    ii. No capsule, tendon, or bone are exposed
    iii. The patient has not responded to conventional ulcer therapy such as:
        1. Moist dressings
        2. Non-weight bearing
        3. Optimal glycemic management if diabetic
        4. Sharp debridement
    iv. Adequate perfusion of the involved limb
    v. The requested EpiFix skin substitute is being used along with standard ulcer therapy
    vi. EpiFix and Grafix are experimental and investigational for all other indications

d. **Alloderm acellular dermal tissue matrix and Dermacell** are medically necessary for breast reconstruction only.

B. The following skin substitutes are considered investigational products (not an all-inclusive list):

HCPC code	Description
A4649	DermaClose RC; MediHoney
A6010, A6011	CellerateRX
A6021, A6022	Promogran Matrix; Puracol
C1155	Repliform
C1763	Biodesign fistula plug
C1781	XenMatrix
C9355	Collagen nerve cuff (neuromatrix), per 0.5 centimeter length
C9356	TenoGlide Tendon Protector
C9361	Collagen matrix nerve wrap (neuromend collagen wrap), per 0.5 centimeter length
C9364	Permacol Biologic Implant
C9367	Endoform dermal template
G0281, G0282	Radiofrequency stimulation devices (Provant or MicroVas)
L8658	Artelon
Q4100-Q4176	Adherus Dural Sealant; AlloMax; AmnioCare; AmnioFix; AmnioGenix; AmnioHeal amniotic membrane; AmnioMTM; AmnioShield; AmnioStrip; Amniotic Fluid Injection (AmniFix); Amniox; Arthrex GraftRope; Autologous Fat, Autologous platelet-rich plasma, autologous platelet-gel, and autologous platelet derived growth factors (e.g. Autogel, Procuren, and

	Safeblood) Avotermin; Axogen Nerve Wrap; BioDRestore elemental tissue matrix; BioFiber; Bionect; Biostat Biologix fibrin sealant; Biotape; CellECT; CollaFix; Conexa; CorMatrix ECM; Cortiva Allograft Dermis; C-QUR biosynthetic mesh; CRXa; DermaMatrix; DuraGen Plus; DuraMatrix; DuraSeal; Durepair regeneration matrix; ENDURAGen; Epidex; EPIFLO; Evical Fibrin sealant; FloGraft; Fortiva; HydroFix Vaso Shield; Inforce; LiquidGen; MatriDerm; Medeor; Meso BioMatrix; NeoForm Dermis; Neuroflex; NuCel liquid wound covering; OrthoFlo; OsseoGuard; Ovation; Parietex Composite (PCO) Mesh; Peri-Guard; Peri-Strips Dry; placental tissue matrix allograft; porcine-derived decellularized collagen products; porcine-derived polypropylene composite wound dressing; PTFE felt; Puros Dermis; Seamguard; silver-coated wound dressings; Sonafine wound dressing; SportMatrix; SportMesh; SteriShield II; Suprathel; Surgisis; TenFUSE allograft; TissueMend; Viaflow; Viaflow C; Vitagel; X-Repair; Xelma; XWrap
Q4103	Oasis burn matrix
Q4104	Integra bilayer matrix wound dressing
Q4105	Integra dermal regeneration template or Integra omnigraft dermal regeneration matrix
Q4107	Graftjacket
Q4108	Integra matrix
Q4110	PriMatrix
Q4111	GammaGraft
Q4112	Cymetra, injectable
Q4113	GraftJacket Xpress
Q4114	Integra flowable wound matrix
Q4115	AlloSkin
Q4117	Hyalomatrix
Q4118	Matristem; micromatrix
Q4119	Matrix wound matrix
Q4120	Matrix burn matrix
Q4121	Theraskin
Q4123	Alloskin Rt
Q4124	Oasis Ultra Tri-layer Matrix
Q4125	Arthroflex
Q4126	Memoderm; DermaSpan
Q4127	Talymed
Q4128	FlexHD; Alloderm HD; AlloPatch HD; Matrix HD
Q4129	Unite Biomatrix
Q4130	Strattice TM
Q4134	hMatrix
Q4135	Mediskin
Q4136	Ezderm
Q4137	Amnioexcel or BioDExCel
Q4138	BioDFence DryFlex
Q4139	Amniomatrix or Biodmatrix
Q4140	BioDFence
Q4141	AlloSkin AC
Q4142	XCM Biologic Tissue Matrix
Q4143	Repriza

Q4146	Tensix
Q4147	Architect, Architect PX, or Architect FX, extracellular matrix
Q4148	Neox
Q4149	Excellagen
Q4150	AlloWrap DS or dry
Q4151	AmnioBand or Guardian
Q4152	Dermapure
Q4153	Dermavest
Q4154	Biovance
Q4155	Neoxflo
Q4156	Neox 100
Q4157	Revitalon
Q4158	Marigen
Q4159	Affinity
Q4160	Nushield
Q4161	Bio-connekt wound matrix
Q4162	AmnioPro flow; BioSkin Flow; BioRenew Flow; WoundEx Flow; AmnioGen-A; AmnioGen-C
Q4163	AmnioPro; BioSkin; BioRenew; WoundEx; AmnioGen 45; AmnioGen 200
Q4164	Helicoll
Q4165	Keramatrix
Q4166	Cytal (Acell)
Q4167	TruSkin
Q4168	AmnioBand
Q4169	Artacent wound
Q4170	Cygnus
Q4171	Intefyl
Q4173	PalinGen or PalinGen Xplus
Q4174	PalinGen or ProMatrX
Q4175	Miroderm
Q4176	Neopatch
Q4183	Surgigraft
Q4184	Cellesta or Cellesta duo
Q4185	Cellesta flowable amnion
Q4188	Amnioarmor
Q4189	Artacent AC, 1mg
Q4190	Artacent AC, per sq cm
Q4191, Q4192	Restorigin
Q4193	Coll-e-derm
Q4194	Novachor
Q4195	PuraPly, per sq cm
Q4196	PuraPly AM, per sq cm
Q4197	PuraPly XT, per sq cm
Q4198	Genesis amniotic membrane
Q4200	Skin TE
Q4201	Matrion
Q4202	Keroxx

Q4203	Derma-gide
Q4204	Xwrap
Q4205	Membrane Graft or Membrane Wrap, per sq cm
Q4206	Fluid Flow or Fluid GF, 1cc
Q4208	Novafix, per sq cm
Q4209	SurGraft, per sq cm
Q4210	Axolotl Graft or Axolotl DualGraft, per sq cm
Q4211	Amnion Bio or AxoBioMembrane, per sq cm
Q4212	Allogen, per cc
Q4213	Ascent, 0.5 mg
Q4214	Cellesta Cord, per sq cm
Q4215	Axolotl Ambient or Axolotl Cryo, 0.1 mg
Q4216	Artacent Cord, per sq cm
Q4217	Woundfix, Biowound, WoundFix Plus, WoundFix Xplus or BioWound Plus, per sq cm
Q4218	SurgiCORD, per sq cm
Q4219	SurgiGRAFT-DUAL, per sq cm
Q4220	BellaCell HD or SureDerm, per sq cm
Q4221	Amnio Wrap 2, per sq cm
Q4222	ProgenaMatrix, per sq cm
Q4226	MyOwn Skin, includes harvesting and preparation procedures, per sq cm
Q4227	Amniocore, per square centimeter
Q4228	Bionextpatch, per square centimeter
Q4229	Cogenex amniotic membrane, per square centimeter
Q4230	Cogenex flowable amnion, per 0.5 cc
Q4231	Corplex p, per cc
Q4232	Corplex, per square centimeter
Q4233	Surfactor or nudyn, per 0.5 cc
Q4234	Xcellerate, per square centimeter
Q4235	Amniorepair or altiply, per square centimeter
Q4236	Carepatch, per square centimeter
Q4237	Cryo-cord, per square centimeter
Q4238	Derm-maxx, per square centimeter
Q4239	Amnio-maxx or amnio-maxx lite, per square centimeter
Q4240	Corecyte, for topical use only, per 0.5 cc
Q4241	Polycyte, for topical use only, per 0.5 cc
Q4242	Amniocyte plus, per 0.5 cc
Q4244	Procenta, per 200 mg
Q4245	Amniotext, per cc
Q4246	Coretext or protext, per cc
Q4247	Amniotext patch, per square centimeter
Q4248	Dermacyte amniotic membrane allograft, per square centimeter

III. Information Submitted with the Prior Authorization Request:

1. Chart notes documenting the condition and type of skin substitute requested.

IV. CPT or HCPC codes covered:

Codes	Description
C5271	Application of low cost skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
C5272	Application of low cost skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure)
C5273	Application of low cost skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
C5274	Application of low cost skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)
C5275	Application of low cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
C5276	Application of low cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure)
C5277	Application of low cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
C5278	Application of low cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)
Q4101	Apligraf, per sq cm
Q4102	Oasis wound matrix, per sq cm
Q4106	Dermagraft, per sq cm
Q4116	AlloDerm, per sq cm
Q4122	Dermacell
Q4132	Grafix Core, per sq cm
Q4133	Grafix Prime, per sq cm; GrafixPL Prime, per sq cm
Q4145	EpiFix, injectable, 1 mg
Q4186	EpiFix
Q4187	EpiCord
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)

V. CPT or HCPC codes NOT covered:
See above investigational code table section II.B

VI. Annual Review History

Review Date	Revisions	Effective Date
09/29/2017	New criteria adopted from MCG guidelines A-0326 Skin Substitutes with the additional products added.	1/1/2018
11/28/2018	Annual Review: Addition of non-covered substitutes	11/28/2018
02/27/2019	Update HCPC codes and product sizes for Grafix	03/01/2019
03/27/2019	Clarify codes covered related to breast reconstruction and Oasis wound matrix	04/01/2019
05/2019	Specified Grafix skin substitutes to be covered, updated the skin substitutes on covered and noncovered lists	05/2019

11/2019	Reworded title 'Skin Substitutes – Tissue Engineered' to 'Skin and Tissue Substitutes - Engineered	11/20/2019
02/26/2020	Annual Review: added 2020 New skin substitutes codes	03/01/2020
08/07/2020	Update: Added 2020 new Q codes	

VII. References

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Appendix 1 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): 5, 8	NCD/LCD Document (s):

NCD/LCD Document (s):

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC