Skin Substitutes

State(s):	LOB(s):
☒ Idaho ☒ Montana ☒ Oregon ☒ Washington ☐ Other:	☒ Commercial ☐ Medicare ☐ Medicaid

Commercial Policy

Clinical Guidelines are written when necessary to provide guidance to providers and members in order to outline and clarify coverage criteria in accordance with the terms of the Member's policy. This Clinical Guideline only applies to PacificSource Health Plans, in Idaho, Montana, Oregon, and Washington. Because of the changing nature of medicine, this list is subject to revision and update without notice. This document is designed for informational purposes only and is not an authorization or contract. Coverage determination are made on a case-by-case basis and subject to the terms, conditions, limitations, and exclusions of the Member's policy. Member policies differ in benefits and to the extent a conflict exists between the Clinical Guideline and the Member's policy, the Member's policy language shall control. Clinical Guidelines do not constitute medical advice nor guarantee coverage.

Background

Skin substitutes are bioengineered tissue products that may be acellular or consist of human or animal derived living cells which, when combined with a collagen or synthetic material, function as a scaffold for the cells. Skin substitutes are used to treat burns, chronic ulcers, selected skin conditions, provide temporary coverage of wounds in order to speed healing, reduce incidence of contracture or infection, either eliminate the need for grafting or as a bridge until the wound is ready for grafting. Some skin substitutes are permanent grafts, eventually becoming a "neodermis" replacement for the damaged skin.

Healthy skin consists of two main sections - the dermis and the epidermis. The epidermis is the outer, thinner layer of skin consisting of layers of stratified squamous epithelium. It is devoid of blood vessels and contains a limited distribution of nerve endings. The dermis is a dense connective tissue layer which lies beneath the epidermis. It is comprised of collagenous fibers, blood vessels, lymph channels, nerves, sebaceous glands, sweat glands and hair follicles.

Wounds may be described as superficial, partial-thickness or full-thickness. Full-thickness wounds result from injury which destroys both the dermis and the epidermis. Partial thickness wounds have damage to the epidermis and a portion of the dermis. Full-thickness wounds usually require excision followed by split-thickness grafts of varying thickness. Split-thickness grafts contain only small portions of dermis which is why skin substitutes may be elected for the treatment of larger surface area burns. Partial-thickness wounds may heal spontaneously if kept clean and protected, however contractures formed by scar tissue may result. Negative pressure wound therapy (NWPT) has been reported used in conjunction with some skin substitutes.

Wagner Ulcer Classification System

Grade	Lesion
1	Superficial diabetic ulcer (partial or full thickness)
2	Ulcer extension to ligament, tendon, joint capsule, or deep fascia without abscess or osteomyelitis

3 Deep ulcer with abscess, osteomyelitis, or joint sepsis
4 Gangrene localized to portion of forefoot or heel
5 Extensive gangrenous involvement of the entire foot

Criteria

Preauthorization is required for external applications only.

Alloderm (Q4116) for Breast Reconstruction Surgery:

AlloDerm acellular dermal tissue matrix is considered medically necessary when used in breast reconstruction surgery.

Apligraf (Q4101) and EpiFix (Q4131) for Venous Stasis Ulcers and Diabetic Foot Ulcers:

Apligraf is a two-layer, culture-derived, human skin equivalent (HSE). The upper layer is made of human keratinocytes from neonatal foreskin; the lower layer consists of human fibroblasts combined with bovine collagen. Apligraf is usually applied weekly. **EpiFix**® is a human amniotic membrane allograft which is composed of multiple layers including a single layer of epithelial cells, a basement membrane and an avascular connective tissue matrix. Apligraf or the sheet form of EpiFix (Q4131) may be considered medically necessary for the following applications:

- Treatment of **venous stasis leg ulcers** when all of the following are met:
  - The ulcer is greater than one month old;
  - The ulcer is not infected; and
  - The ulcer has failed to respond to conservative treatment prior to Apligraf application (i.e., compression dressings, Unna boot)
- Treatment of **diabetic foot ulcers** when all of the following are met:
  - The ulcer is full-thickness;
  - The ulcer is greater than 3 weeks duration;
  - The ulcer has failed to respond to standard therapy (i.e., moist-wound therapy with alginates, foams, hydrocolloids or hydrogels); and
  - There is no tendon, muscle, capsule, or bone exposure.

DermACELL (Q4122) for Breast Reconstruction Surgery:

DermACELL human acellular dermal tissue matrix is considered medically necessary when used in breast reconstruction surgery

Dermagraft (Q4106) for Diabetic Plantar Surface Foot Ulcers:

Dermagraft is a single layer skin substitute made of human fibroblast cells. Dermagraft may be used alone or in combination with a split thickness graft is usually applied weekly. The ulcer is full-thickness;

Dermagraft may be considered medically necessary for treatment **diabetic plantar surface foot ulcers** when all of the following are met:

- The ulcer is greater than 3 weeks duration;
- The ulcer has failed to respond to standard therapy (i.e., moist-wound therapy with alginates, foams, hydrocolloids or hydrogels); and
- There is no tendon, muscle, capsule, or bone exposure.

Integra Bilayer Matrix Wound Dressing (Q4104 & Q4108) and Integra Dermal Regeneration Template (Q4105) for Full thickness or Deep Partial Thickness Burns:

Integra Bilayer Matrix Wound Dressing (Q4104) and Integra Dermal Regeneration Template (Q4105) are synthetic acellular skin substitutes composed of an outer silastic sheet (epidermal layer) over a bovine collagen and glycosaminoglycan layer (dermal layer). The matrix covers the burn for 2 to 6 weeks. Once the dermis is adequately vascularized, the silastic epidermal sheet is removed and autografting is performed to complete the reconstruction. Integra Matrix Wound Dressing (Q4108) contains only the bovine collagen and glycosaminoglycan layer.

Integra Bilayer Matrix Wound Dressing (Q4104), Integra Dermal Regeneration Template (Q4105) and Integra Matrix (Q4108) may be considered medically necessary for the postexcisional treatment of full-thickness or deep partial-thickness burns where there is a limited amount of their own skin to use for autografts or the patient is too ill for autografting.

Integra Flowable Wound Matrix (Q4114) Please refer to the experimental/investigational/unproven list below.

Medical Director Review:

Medical Director Review is required for applications of Apligraf, Dermagraft or Integra products which do not meet the criteria above.

Exclusion:

Medical Director Review is required for the following Skin substitutes because they are considered experimental, investigational or unproven:

- AlloDerm (except when used in breast reconstruction surgery)
- AlloMax.
- AmnioExcel
- Amniofix.
- ArthroFlex Decellularized Dermal Allograft
- Biobrane/Biobrane-L
- Biodesign® Surgisis® AFP™ Anal Fistula Plug, GORE BIO-A® Fistula Plug and SIS Fistula Plug is considered experimental investigational for anal fistula plugs.
- BioDexcel
- BioDfactor/BioDfence

- BioDfence Dryflex or BioD DryFlex
- BioDmatrix
- BioDOptix
- Clarix Regenerative Matrix
- DermACELL (except when used in breast reconstruction surgery)
- Epicel
- Epicord
- EpiFix® Injectable (Q4145) (
- FlexHD
- Gammagraft
- Grafix Core
- Grafix Prime
- GraftJacket.
- GraftJacket Express
- Hyalomatrix
- Integra Flowable Wound Matrix
- Integra Meshed Bilayer Wound Matrix
- Integra Omnigraft
- MatriStem
- Mediskin
- Mirragen wound matrix
- NuCel Bioactive Amniotic Suspension
- Oasis Burn Matrix and Oasis Wound Matrix
- OrCel
- Primatrix
- PuraPly or Puraply am.
- Strattice Reconstructive Tissue Matrix.
- Stravix
- Suprathel
- SurgiMend

- TheraSkin
- TissueMend.
- Transcyte
- Viaflow and Viaflow C Flowable Placental Tissue Matrices
- Xelma

Coding Information

Skin Substitute Grafts: The supply of skin substitute graft(s) should be reported separately in conjunction with the application 15271- 15278. Select the appropriate code from 15271-15278 based upon location and size of the defect. For biological implant for soft tissue reinforcement, use 15777 in conjunction with primary procedure.

Codes:

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 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 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 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 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) (List separately in addition to code for primary procedure)

PacificSource Health Plans considers the following **repair of anorectal fistula with plug** to be experimental, investigational or unproven based on the lack of randomized, prospective, long-term studies demonstrating efficacy and safety:

46707 Repair of anorectal fistula with plug (eg: porcine small intestine submucosa [SIS]).

Q4100 Biodesign® Surgisis® AFP™ Anal Fistula Plug, GORE BIO-A® Fistula Plug and SIS Fistula Plug

HCPCS	Product	Manufacturer	Type
C9349	Fortaderm, and fortaderm antimicrobial, any type, per square centimeter	Organogenesis, Inc.	Porcine intestinal collagen coated with 0.1 % Polyhexamethylene Biguanide hydrochloride (PHMB).
J3590	MediSkin	Mölnlycke Health Care US, LLC	porcine xenograft
Q4100	Biodesign® Surgisis® AFP™ Anal Fistula Plug, GORE BIO-A® Fistula Plug and SIS Fistula Plug	Cook Biotech Incorporated and Gore & Associates	biosynthetic devices
Q4100	Biobrane/ Biobrane-L	Bertek Pharmaceuticals	synthetic silicone/collagen membrane derived from pigs
Q4100	Mirragen Wound Matrix	ETS wound Care, LLC	borate-based bioactive glass fiber technology
Q4100	OrCel	Ortec Inter-national, Inc.	allogeneic graft
Q4100	TransCyte/Dermagraft TC	Smith & Nephew, Inc.	allogeneic graft
Q4100	Epicel	Genzyme Tissue Repair	cultured autograft
Q4100	Stravix	Osiris Therapeutics Inc.	cryopreserved placental tissue
Q4101	Apligraf	Organogenesis, Inc.	2-layer culture derived human skin/bovine collagen
Q4102	Oasis Wound Matrix	Cook Biotek Inc.	porcine small intestinal submucosa (SIS)
Q4103	Oasis Burn Matrix	Cook Biotek Inc.	porcine collagen
Q4104	Integra Bilayer Matrix Wound (approved for burns only)	Integra LifeSciences Corp.	2-layer bovine collagen/ poly silicone
Q4105	Integra Dermal Regeneration Template (IDRT) (approved for burns only)	Integra LifeSciences Corp.	bovine collagen
Q4105	Integra Omnigraft Dermal Regeneration Matrix	Integra LifeSciences Corp.	2-layer bovine collagen/ Silicone layer
Q4106	Dermagraft	Advanced Biohealing	allogeneic graft
Q4107	Graftjacket	Wright Medical Technology, Inc.	acellular human derived

Q4108	Integra Matrix Wound (approved for burns only)	Integra LifeSciences Corp.	bovine collagen
Q4110	Primatrix	TEI Biosciences, Inc.	animal derived
Q4111	Gammagraft	Promethean Life Sciences	allogeneic graft
Q4113	GraftJacket Xpress	Wright Medical Technology, Inc.	acellular human derived
Q4114	Integra Flowable Wound Matrix	Integra LifeSciences Corp.	granulated bovine collagen and glyco- saminoglycan
Q4115	Alloskin, per square centimeter	AlloSource	meshed human allograft skin for acute and chronic wound therapy
Q4116	Alloderm	LifeCell, Inc.	acellular allogeneic graft
Q4117	Hyalomatrix, per sq. cm	Anika Therapeutics	derivative of hyaluronic acid (HA) in fibrous form
Q4118	MatriStem micro matrix	ACell Inc.	porcine derived graft
Q4119	MatriStem wound matrix	ACell Inc.	porcine derived graft
Q4120	MatriStem burn matrix	ACell Inc.	porcine derived graft
Q4121	TheraSkin	Solublesystems	human skin allograft
Q4122	DermACELL	Novadaq	decellularized regenerative human tissue matrix allograft
Q4123	Alloskin RT, per sq. cm	AlloSource	meshed human dermal graft
Q4124	Oasis ultra tri layer matrix, per sq cm	OASIS®	extracellular matrix (ECM) derived from porcine small intestinal
Q4125	ArthroFlex, per sq cm	ArthroFlex®	acellular dermal extracellular matrix
Q4126	Memoderm, dermaspan, tranzgraft or integuply, per square centimeter.	MEMOMETAL Inc, Biomet, Aziyo Biologics Inc	acellular dermal matrix - human allograft skin tissue
Q4127	Talymed®, per sq. cm	Marine Polymer Technologies, Inc	poly-N-acetyl glucosamine (pGlcNAc), isolated from microalgae
Q4128	FlexHD Allopatch HD, or Matrix HD, per sq cm	Ethicon Inc. Conmed, RTI Surgical Inc.	allogeneic graft
Q4129	Unite Biomatrix, per square centimeter	Synovis®	Collagen xenograft derived from native equine pericardium
Q4130	Strattice	LifeCell, Inc.	porcine collagen

Q4132	Grafix core, per square centimeter	Osiris Therapeutics, Inc	Extracellular matrix containing growth factors.
Q4133	Grafix prime, per square centimeter	Osiris Therapeutics, Inc	Extracellular matrix containing growth factors.
Q4134	Hmatrix, per square centimeter	Bacterin	acellular dermal matrix
Q4135	MediSkin	Mölnlycke Health Care US, LLC	porcine xenograft
Q4136	Ez-derm, per square centimeter	Mölnlycke Health Care US, LLC	porcine xenograft
Q4137	AmnioExcel or BioDexcel	AmnioGenix™ and BioD, LLC	amniotic extracellular membrane
Q4138	Biodfence dryflex,	Amedica Corp.	amniotic membrane
Q4139	Amniomatrix or biodmatrix, injectable, 1 cc	netcells® and BioD, LLC,	cryo-preserved (frozen) complex of amniotic tissue
Q4140	Biodfence	Amedica Corp.	amniotic membrane
Q4141	Alloskin	AlloSource®	human allograft skin
Q4142	Xcm biologic tissue matrix,	Synthes®	porcine dermis
Q4143	Repriza,	Promethean LifeSciences, Inc	human allograft skin
Q4145	Epifix, injectable, 1 mg	MiMedx® Group, Inc.	human amniotic membrane allografts
Q4146	TenSIX	SolanaSurgical LLC,	acellular dermal matrix
Q4147	Architect extracellular matrix	Harbor Medtech, Inc.	extracellular matrix
Q4148	Neox 1k	Amniox® Medical	cryopreserved human amniotic membrane and umbilical cord
Q4149	Excellagen, 0.1 cc	Cardium Therapeutics.	bovine type I collagen topical gel
Q4150	Allowrap® ds or dry, per square centimeter	AlloSource®	human amniotic membrane
Q4151	Amnioband or guardian, per square centimeter	MTF Wound Care®	human allograft tissue from placental membranes or amnion
Q4152	Dermapure, per square centimeter	Tissue Regenix	decellularized human dermis
Q4153	Dermavest, per square centimeter	AediCell	decellularized human placental tissue extra cellular matrix
Q4154	Biovance, per square centimeter	Alliqua Biomedical	decelluarized dehydrated amniotic membrane
Q4155	Neoxflo or clarixflo, 1 mg	AminoX® Medical Inc	amniotic membrane and umbilical cord tissues

Q4156	Neox 100, per square centimeter	AminoX® Medical Inc	cryopreserved human amniotic membrane
Q4157	Revitalon, per square centimeter	Medline Industries, Inc	amnion and chorion of placental tissue
Q4158	Marigen, per square centimeter	Kerecis Limited	MariGeb Omega3 fish-skin surgical material
Q4159	Affinity, per square centimeter	NuTech Medical	amniotic fluid membrane allograft
Q4160	Nushield, per square centimeter	NuTech Medical	Human placental membrane includes the amniotic epithelial layer, basement membrane and stroma, the chorionic basement membrane, and stroma.
Q4161	Bio-connekt wound matrix, per square centimeter	MLM Biologics Inc	reconstituted collagen derived from equine tendon
Q4162	AmnioPro Flow, BioSkin Flow, BioRenew Flow, WoundEx Flow, Amniogen-A, Amniogen-C, 0.5 cc	Orthopaediclist	Human ECM placental tissue injectable allografts.
Q4163	AmnioPro, BioSkin, BioRenew, WoundEx, Amniogen-45, Amniogen-200, per sq cm	Orthopaediclist	Human ECM placental tissue allografts.
Q4164	Helicoll, per square centimeter	EnColl Corporation	Acellular dermal matrix derived from bovine Type-1 collagen.
Q4165	Keramatrix, per square centimeter	Keraplast Technologies LLC	matrix made from a combination of keratin technology
Q4166	Cytal, per square centimeter	Acell®	Urinary bladder matrix (UBM
Q4167	Truskin, per square centimeter	Osiris Therapeutics, Inc.	Cryopreserved, human cadaver skin allograft with dermis and epidermis.
Q4168	Amnioband, 1 mg	MTF Wound Care®	MTF Wound Care®
Q4169	Artacent wound, per square centimeter	Tides Medical	amniotic patch derived from the submucosa of donated human placenta

Q4170	Cygnus, per square centimeter	Vivex® Biomedical, Inc	amniotic tissue matrixes obtained from umbilical cord
Q4171	Interfyl, 1 mg	Alliqua® Biomedical	Allogenic, decellularized, particulate placenta human tissue
Q4172	PuraPly or PuraPly AM, per sq. cm.	Organogenesis Inc.	Antimicrobial polyhexamethylene Biguanide (PHMB) wound dressing
Q4184	Cellesta, per sq cm	Ventris Medical	Amniotic allograft membrane
Q4185	Cellesta Flowable Amnion (25 mg per cc); per 0.5 cc	Ventris Medical	Amniotic membrane suspended in a saline solution
Q4186	Epifix, per sq cm	MiMedx® Group, Inc.	Human amniotic membrane allografts
Q4187	Epicord, per sq cm	MiMedx® Group, Inc.	Dehydrated, human umbilical cord allograft
Q4188	AmnioArmor, per sq cm	Bone Bank Allografts	Dehydrated human amniotic membrane
Q4189	Artacent AC, 1 mg	Tides Medical	dehydrated, micronized particulate processed from human chorioamniotic membrane
Q4190	Artacent AC, 1 mg	Tides Medical	submucosa of human placenta
Q4191	Restorigin, per sq cm	Parametrics Medical	Amnion and chorion layers
Q4192	Restorigin,1 cc	Parametrics Medical	Frozen allograft derived from amniotic fluid
Q4193	Coll-e-Derm, per sq cm	Parametrics Medical	Human-derived dermal allograft comprised of collagen, elastin and proteoglycans
Q4194	Novachor, per sq cm	Organogenesis, Inc	Chorion membrane allograft
Q4195	PuraPly, per sq cm	Organogenesis, Inc	Antimicrobial polyhexamethylene Biguanide (PHMB) wound dressing
Q4196	PuraPly AM, per sq cm	Organogenesis, Inc	Antimicrobial polyhexamethylene Biguanide (PHMB) wound dressing

Q4197	PuraPly XT, per sq cm	Organogenesis, Inc	Five layer fenestrated and cross-linked sheet of porcine collagen
Q4198	Genesis Amniotic Membrane, per sq cm	Genesis Biologics, Inc	Dehydrated, collagenous human tissue allograft
Q4200	SkinTE, per sq cm	PolarityTE®	autologous, homologous product proposed for skin repair
Q4201	Matrion, per sq cm	LifeNet Health	Regenerative human placental allograft
Q4202	Keroxx (2.5 g/cc), 1 cc	Molecular Biologicals, LLC.	Bovine wound matrix comprised of keratin enriched proteins
Q4203	Derma-Gide, per sq cm	Geistlich Pharma AG	collagen wound dressing
Q4204	XWRAP, per sq cm	Applied Biologics, LLC	chorion-free, amniotic, non-crosslinked soft-tissue wound covering

Q4100 – Skin substitute, not otherwise specific

Related Medical Policies

New and Emerging Technologies – Coverage Status

References

Eisenbud, D. et al. Skin Substitutes and Wound Healing: Current Status and Challenges. Wounds. 2004; 16(1). Accessed September 3, 2009, May 12, 2017, February 26, 2018, June 14, 2018, May 7, 2019
http://www.medscape.com/viewarticle/470251

Fitzgerald RH et al. Essential Insights on Bioengineered Alternative Tissues. Podiatry Today [serial online]. 2009; 22:48-60. Accessed September 3, 2009, May 12, 2017, February 26, 2018, June 14, 2018, may 7, 2019
http://www.podiatrytoday.com/essential-insights-on-bioengineered-alternative-tissues

Frykberg RG et al. Diabetic Foot Ulcers: Pathogenesis and Management, AM Fam Physician. 2002 Nov1; 66(9). https://www.aafp.org/afp/2002/1101/p1655.html

Hayes Clinical Research Response: BioD Products (BioD LLC). Winifred S. Hayes, Inc., July 23, 2015. Archived July 6, 2017,

Hayes Clinical Research Response: Clarix Regenerative Matrix. Winifred S. Hayes, Inc., Jan 15, 2015, Archived July 6, 2017.

Hayes Clinical Research Response: DermACELL Human Acellular Matrix (Novodaq) for nonhealing Wounds, Winifred S. Hayes, Inc. March 2, 2018, Archived April 2, 2019.

Hayes Clinical Research Response: Skin Substitutes for Nonhealing Wounds –Product Comparison Winifred S. Hayes, Inc. August 27, 2018.

Hayes Clinical Research Response: Viaflow and Viaflow C Flowable Placental Tissue Matrices (Wright Medical) for Orthopedic and Podiatric Indications. Winifred S. Hayes, Inc., March 10, 2016. Archived October 11, 2017.

Hayes Health Technology Brief. Oasis Wound Matrix (Cook Biotech, Inc.) For Lower Extremity Ulcers. Winifred S. Hayes, Inc., Dec 21, 2012. Annual review Dec 12, 2014. Archived Jan 31, 2016

Hayes Medical Technology Directory. Biological Tissue-Engineered Skin Substitutes for Wound Healing. Winifred S. Hayes, Inc., Jan 28, 2010, Annual review Feb 11, 2014. Archived Feb 28, 2015.

Hayes Medical Technology Directory. Biosynthetic Tissue-Engineered Skin Substitutes for Wound Healing. Winifred S. Hayes, Inc., Jan 10, 2010, Annual review Feb 14, 2014. Archived Feb 14, 2015.

Hayes Medical Technology Directory: Comparative Effectiveness of Skin Substitutes for Chronic Foot Ulcers in Adults with Diabetes Mellitus. Winifred S. Hayes, Inc., November 9, 2017, Annual Review November 19, 2018

Hayes Medical Technology Directory: Human Acellular Dermal Matrix Grafts for Breast Reconstruction. Winifred S. Hayes, Inc., April 28, 2014. Annual review April 14, 2017.

Hayes Medical Technology Directory: Skin Substitutes for Chronic Venous Leg Ulcers in Adults: A Review of Reviews. Winifred S. Hayes, Inc November 16, 2017, Annual review, November 20, 2018

Hayes Search & Summary. Amniotic Tissue-Derived Allografts for Foot and Leg Ulcers. Winifred S. Hayes, Inc., May 30, 2014. Archived Jul 26, 2015, Archived September 15, 2016.

Hayes Search & Summary. EpiFix (MiMedx Group) for Treatment of Nonhealing Wounds. Winifred S. Hayes, Inc., Apr 16, 2015. Archived Aug 20, 2015.

Hayes Search & Summary. Grafix Cryopreserved Placental Membrane (Osiris Technologies, Inc,) for Treatment of Chronic Nonhealing Wounds. Winifred S. Hayes, Inc., July 31, 2018

Hayes Search & Summary: NuCel Bioactive Amniotic Suspension (NuTech Medical) for Treatment of Nonhealing Wounds. Winifred S. Hayes, Inc. Feb 12, 2015. Archived Mar 12, 2016

Hayes Search & Summary: PriMatrix (TEI Biosciences) for Wound Healing. Winifred S. Hayes, Inc., Dec 30, 2014. Archived Jan 30, 2016.

Hayes Health Technology Brief. FlexHD Acellular Dermis (Musculoskeletal Transplant Foundation) for Breast Reconstruction. Winifred S. Hayes, Inc., March 13, 2012. Annual review Aug 27, 2013. Archived Apr 28, 2014.

Hayes Search & Summary: TheraSkin (Soluble Systems LLC) for Chronic Non-healing Wounds. Winifred S. Hayes, Inc., Dec 30, 2014 Archived Jan 30, 2016.

Hayes Technology Brief. FlexHD Acellular Dermis (Musculoskeletal Transplant Foundation) for Breast Reconstruction. Winifred S. Hayes, Inc., Aug 3, 2012, Annual review Aug 27, 2013. Archived Aug 28, 2014

Hayes Technology Brief. FlexHD Acellular Dermis (Musculoskeletal Transplant Foundation) for Hernia Repair. Winifred S. Hayes, Inc., Aug 8, 2012, Annual review Jun 30, 2014. Archived Sep 08, 2015

Laznger, A and Rogowski, W. Systematic Review of Economic Evaluations of Human Cell-derived Wound Care Products for the Treatment of Venous Leg and Diabetic Foot Ulcers. BMC Health Services Research. 2009; 9:115.

Shores, JT et al. Skin Substitutes and Alternatives: A Review. Advances in Skin & Wound Care. 2007; 20(9):493-507.

Snyder RJ et al. A Prospective, Randomized, Multicenter, Controlled Evaluation of the Use of Dehydrated Amniotic Membrane Allograft Compared to Standard of Care for the Closure of Chronic Diabetic Foot Ulcer Wounds. 2016 Mar;28(3):70-7. Accessed 11/15/2017, 2/26/2018, 6/14/2018, 5/7/2019
https://www.ncbi.nlm.nih.gov/pubmed/26978860

Zelen, CM et al. Treatment of chronic diabetic lower extremity ulcers with advanced therapies: a prospective, randomised, controlled, multi-centre comparative study examining clinical efficacy and cost. Int Wound J. 2016 Apr;13(2):272-82. Accessed 11/15/2017, 2/26/2018, 6/14/2018, 5/7/2019
https://www.ncbi.nlm.nih.gov/pubmed/26695998.

Appendix

Policy Number: [Policy Number]

Effective: 1/1/2020 **Next review:** 1/1/2021

Policy type: Commercial

Depts: Health Services

Applicable regulation(s): N/A

External entities affected: N/A