LA.CLI.083 Skin and Tissue Substitutes

Humana

Louisiana Medicaid Medical Coverage Policy

Original Effective Date: 02/04/2025
Effective Date: 02/04/2025
Review Date: 02/04/2025
Policy Number: LA.CLI.083
Line of Business: Medicaid
State: Louisiana

Table of Contents

Description

Bioengineered skin and soft tissue substitutes, often referred to as cellular and/or tissue-based products (CTPs), are acellular (no biological component) or cellular (contain living cells) matrices. Acellular dermal matrices (ADM) or extracellular matrices (ECM) have had all cellular material removed during the manufacturing process and contain a matrix or scaffold composed of materials such as collagen, elastin, fibronectin and hyaluronic acid. These products vary in several ways including source (biological tissue, synthetic materials or a combination), additives (antibiotics, surfactants), hydration (freeze dried, wet) and required preparation (multiple rinses, rehydration).

Cellular matrices contain living cells such as fibroblasts and keratinocytes within a matrix which are derived from either autologous or allogeneic (human tissue) or xenographic (animal tissue), synthetic materials or a composite of these materials.

Manufacturing processes of bioengineered skin and tissue substitutes vary by company, but generally involve seeding selected cells onto a matrix, where they receive proteins and growth factors necessary for them to multiply and develop into the desired tissue. The tissue may be used for a variety of conditions and procedures including breast reconstruction, healing of lower extremity ulcers (eg, diabetic and/or venous ulcers), ocular defects, plantar fasciitis, surgical wounds and treatment of severe burns.

Coverage Determination

Humana members enrolled in Healthy Horizons Louisiana may be eligible under the Plan for skin and tissue substitutes when the following criteria are met:

Skin / Tissue Substitute	Indication(s) / Criteria	Associated HCPCS Code(s)
Apligraf Much like human skin as it has two primary layers; the epidermal (outer) layer consists of live human keratinocytes, while the dermal (inner) layer contains living fibroblasts. Also referred to as human skin equivalent.	• Treatment of diabetic foot ulcers, venous leg ulcers, or full thickness skin-loss ulcers, of greater than 4 weeks duration that have not responded to standard wound therapy, where there is no bone, capsule, muscle or tendon exposure; AND • Used in conjunction with standard wound therapy	Q4101
Biobrane, Biobrane-L Constructed using collagen (porcine type 1) that is incorporated with both silicone and nylon and mechanically bonded to a flexible knitted nylon fabric.	• Full-thickness (third-degree) burns; OR • Partial-thickness (second-degree) burns	Q4100
Dermagraft Manufactured from human fibroblast cells derived from newborn foreskin tissue. The fibroblasts are cultured on a bioarbsorbable polyglactin mesh. Proteins and growth factors are secreted during the culture period and generate a three dimensional (3D) human dermis.	• Treatment of diabetic foot ulcers, venous leg ulcers, or full thickness skin-loss ulcers, of greater than 4 weeks duration that have not responded to standard wound therapy, where there is no bone, capsule, muscle or tendon exposure; AND • Used in conjunction with standard wound therapy	Q4106
Dual Layer Impax Membrane Dehydrated dual layered human amniotic membrane allograft. Designed to function as a barrier or cover for acute and chronic wounds and for use as a barrier to protect wounds from the surrounding environment.	• Treatment of diabetic foot ulcers, venous leg ulcers, or full thickness skin-loss ulcers, of greater than 4 weeks duration that have not responded to standard wound therapy, where there is no bone, capsule, muscle or tendon exposure; AND • Used in conjunction with standard wound therapy	Q4262
Epifix Biologic human amniotic membrane.	• Treatment of diabetic foot ulcers, venous leg ulcers, or full thickness skin-loss ulcers, of greater than 4 weeks duration that have	Q4186

Skin / Tissue Substitute	Indication(s) / Criteria	Associated HCPCS Code(s)
	not responded to standard wound therapy, where there is no bone, capsule, muscle or tendon exposure; AND • Used in conjunction with standard wound therapy	
Integra Bilayer Matrix Wound Dressing Comprised of a porous matrix of cross-linked bovine tendon collagen and glycosaminoglycan and a semipermeable polysiloxane (silicone layer). The collagen-glycosaminoglycan biodegradable matrix provides a scaffold for cellular invasion and capillary growth.	• Partial-thickness (second-degree) burns; OR • Treatment of diabetic foot ulcers, venous leg ulcers, or full thickness skin-loss ulcers, of greater than 4 weeks duration that have not responded to standard wound therapy, where there is no bone, capsule, muscle or tendon exposure; AND • Used in conjunction with standard wound therapy	Q4104
Integra Dermal Regeneration Template, Omnigraft Bilayer membrane system for skin replacement. The dermal replacement layer is made of a porous matrix of fibers of cross-linked bovine tendon collagen and glycosaminoglycan (chondroitin-6-sulfate). The epidermal substitute layer is made of thin polysiloxane (silicone) layer.	• Post excisional treatment of life-threatening, full-thickness or deep partial-thickness thermal injuries where sufficient autograft is not available at the time of excision or not desirable due to the physiological condition of the individual; OR • Repair of scar contractures when other therapies have failed or when donor sites for repair are not sufficient or desirable due to the physiological condition of the individual; OR • Treatment of diabetic foot ulcers, venous leg ulcers, or full thickness skin-loss ulcers, of greater than 4 weeks duration that have not responded to standard wound therapy, where there is no bone, capsule, muscle or tendon exposure; AND • Used in conjunction with standard wound therapy	Q4105
Integra Meshed Bilayer Wound Matrix	• Partial-thickness (second-degree) burns; OR	Q4104,

Skin / Tissue Substitute	Indication(s) / Criteria	Associated HCPCS Code(s)
Porous matrix of cross-linked bovine tendon collagen and glycosaminoglycan. The collagen-glycosaminoglycan biodegradable matrix provides a scaffold for cellular invasion and capillary growth. The meshed bilayer matrix allows drainage of wound exudate and provides a flexible adherent covering for the wound surface.	• Treatment of diabetic foot ulcers, venous leg ulcers, or full thickness skin-loss ulcers, of greater than 4 weeks duration that have not responded to standard wound therapy, where there is no bone, capsule, muscle or tendon exposure; AND • Used in conjunction with standard wound therapy	C9363
NuShield Allograft derived from amniotic and chorionic membranes.	• Treatment of diabetic foot ulcers, venous leg ulcers, or full thickness skin-loss ulcers, of greater than 4 weeks duration that have not responded to standard wound therapy, where there is no bone, capsule, muscle or tendon exposure; AND • Used in conjunction with standard wound therapy	Q4160
PuraPly, PuraPly AM Purified Type 1 native collagen matrix creates a durable biocompatible scaffold.	• Treatment of diabetic foot ulcers, venous leg ulcers, or full thickness skin-loss ulcers, of greater than 4 weeks duration that have not responded to standard wound therapy, where there is no bone, capsule, muscle or tendon exposure; AND • Used in conjunction with standard wound therapy	Q4195, Q4196
TheraSkin Biologically active cryopreserved human skin allograft with both epidermis and dermis layers; the cellular and extracellular composition provides a supply of collagen, cytokines and growth factors.	• Treatment of diabetic foot ulcers, venous leg ulcers, or full thickness skin-loss ulcers, of greater than 4 weeks duration that have not responded to standard wound therapy, where there is no bone, capsule, muscle or tendon exposure; AND • Used in conjunction with standard wound therapy	Q4121

Skin / Tissue Substitute	Indication(s) / Criteria	Associated HCPCS Code(s)
Transcyte Combines a synthetic epidermis with a bioengineered human dermal layer that contains fibronectin growth factors and collagen	• For use as a temporary wound covering for surgically excised full-thickness and deep partial-thickness thermal burn wounds in an individual who requires such a covering prior to autograft placement; OR • Treatment of mid-dermal to indeterminate depth burn wounds that typically require debridement and that may be expected to heal without autografting	Q4182

Coverage Limitations

Humana Healthy Horizons in Louisiana members may NOT be eligible under the Plan for any of the following skin and tissue substitutes for ANY other indication or when the above criteria are not met including, but may not be limited to:

- Apligraf; OR
- Biobrane, Biobrane-L; OR
- Dermagraft; OR
- Dual Layer Impax Membrane; OR
- Epifix; OR
- Integra Bilayer Matrix Wound Dressing; OR
- Integra Dermal Regeneration Template, Omnigraft (Integra DRT); OR
- Integra Meshed Bilayer Wound Matrix; OR
- NuShield; OR
- PuraPly, PuraPly AM; OR
- TheraSkin; OR
- Transcyte

These are considered experimental/investigational as they are not identified as widely used and generally accepted for any other proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Humana Healthy Horizons in Louisiana members may NOT be eligible under the Plan for any other skin or tissue substitutes not addressed in the Coverage Determination section. These are considered experimental/investigational as they are not identified as widely used and generally accepted for the proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Coding Information

Any codes listed on this policy are for informational purposes only. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure. Coverage is subject to each requested codes inclusion on the corresponding LDH fee schedule. Non-covered codes are reviewed for medical necessity for members under 21 years of age on a per case basis.

CPT® Code(s)	Description	Comments
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)	
HCPCS Code(s)	**Description**	**Comments**
A2001	InnovaMatrix AC, per sq cm	Not Covered
A2002	Mirragen Advanced Wound Matrix, per sq cm	Not Covered
A2004	XCelliStem, per sq cm	Not Covered
A2005	Microlyte Matrix, per sq cm	Not Covered
A2007	Restrata, per sq cm	Not Covered
A2008	TheraGenesis, per sq cm	Not Covered
A2009	Symphony, per sq cm	Not Covered
A2010	Apis, per sq cm	Not Covered
A2011	Supra sdrm, per square centimeter	Not Covered
A2012	Suprathel, per square centimeter	Not Covered
A2013	Innovamatrix fs, per square centimeter	Not Covered
A2014	Omeza collagen matrix, per 100 mg	Not Covered
A2015	Phoenix wound matrix, per square centimeter	Not Covered
A2016	Permeaderm b, per square centimeter	Not Covered
A2017	Permeaderm glove, each	Not Covered
A2018	Permeaderm c, per square centimeter	Not Covered
A2019	Kerecis omega3 marigen shield, per square centimeter	Not Covered
A2020	Ac5 advanced wound system (ac5)	Not Covered
A2021	Neomatrix, per square centimeter	Not Covered
A2022	Innovaburn or innovamatrix xl, per square centimeter	Not Covered
A2023	Innovamatrix pd, 1 mg	Not Covered
A2024	Resolve matrix, per square centimeter	Not Covered
A2025	Miro3d, per cubic centimeter	Not Covered
A2026	Restrata minimatrix, 5 mg	Not Covered
A2027	Matriderm, per square centimeter	Not Covered
A2028	Micromatrix flex, per mg	Not Covered
A2029	Mirotract wound matrix sheet, per cubic centimeter	Not Covered
A4100	Skin substitute, fda cleared as a device, not otherwise specified	Not Covered
C1832	Autograft suspension, including cell processing and application, and all system components	Not Covered
C9354	Acellular pericardial tissue matrix of nonhuman origin (Veritas), per sq cm	Not Covered
C9358	Dermal substitute, native, nondenatured collagen, fetal bovine origin (SurgiMend Collagen Matrix), per 0.5 sq cm	Not Covered
C9360	Dermal substitute, native, nondenatured collagen, neonatal bovine origin (SurgiMend Collagen Matrix), per 0.5 sq cm	Not Covered
C9361	Collagen matrix nerve wrap (NeuroMend Collagen Nerve Wrap), per 0.5 cm length	Not Covered
C9363	Skin substitute (Integra Meshed Bilayer Wound Matrix), per sq cm	Not Covered

C9364	Porcine implant, Permacol, per sq cm	Not Covered
Q4100	Skin substitute, not otherwise specified	
Q4101	Apligraf, per sq cm	Not Covered
Q4102	Oasis wound matrix, per sq cm	
Q4103	Oasis burn matrix, per sq cm	Not Covered
Q4104	Integra bilayer matrix wound dressing (BMWD), per sq cm	
Q4105	Integra dermal regeneration template (DRT) or Integra Omnigraft dermal regeneration matrix, per sq cm	
Q4106	Dermagraft, per sq cm	
Q4107	GRAFTJACKET, per sq cm	Not Covered
Q4108	Integra matrix, per sq cm	Not Covered
Q4110	PriMatrix, per sq cm	Not Covered
Q4111	GammaGraft, per sq cm	Not Covered
Q4112	Cymetra, injectable, 1 cc	Not Covered
Q4113	GRAFTJACKET XPRESS, injectable, 1 cc	Not Covered
Q4114	Integra flowable wound matrix, injectable, 1 cc	Not Covered
Q4115	AlloSkin, per sq cm	Not Covered
Q4116	AlloDerm, per sq cm	
Q4117	HYALOMATRIX, per sq cm	Not Covered
Q4118	MatriStem micromatrix, 1 mg	Not Covered
Q4121	TheraSkin, per sq cm	
Q4122	DermACELL, DermACELL AWM or DermACELL AWM Porous, per sq cm	Not Covered
Q4123	AlloSkin RT, per sq cm	Not Covered
Q4124	OASIS ultra tri-layer wound matrix, per sq cm	Not Covered
Q4125	ArthroFlex, per sq cm	Not Covered
Q4126	MemoDerm, DermaSpan, TranZgraft or IntéguPly, per sq cm	Not Covered
Q4127	Talymed, per sq cm	Not Covered
Q4128	FlexHD, AllopatchHD, or Matrix HD, per sq cm	Not Covered
Q4130	Strattice TM, per sq cm	Not Covered
Q4132	Grafix Core and GrafixPL Core, per sq cm	Not Covered
Q4133	Grafix PRIME, GrafixPL PRIME, Stravix and StravixPL, per sq cm	Not Covered
Q4134	HMatrix, per sq cm	Not Covered
Q4135	Mediskin, per sq cm	Not Covered
Q4136	E-Z Derm, per sq cm	Not Covered
Q4137	AmnioExcel, AmnioExcel Plus or BioDExcel, per sq cm	Not Covered
Q4138	BioDFence DryFlex, per sq cm	Not Covered
Q4139	AmnioMatrix or BioDMatrix, injectable, 1 cc	Not Covered
Q4140	BioDFence, per sq cm	Not Covered
Q4141	AlloSkin AC, per sq cm	Not Covered
Q4142	XCM biologic tissue matrix, per sq cm	Not Covered
Q4143	Repriza, per sq cm	Not Covered
Q4145	EpiFix, injectable, 1 mg	Not Covered

Q4146	Tensix, per sq cm	Not Covered
Q4147	Architect, Architect PX, or Architect FX, extracellular matrix, per sq cm	Not Covered
Q4148	Neox Cord 1K, Neox Cord RT, or Clarix Cord 1K, per sq cm	Not Covered
Q4149	Excellagen, 0.1 cc	Not Covered
Q4150	AlloWrap DS or dry, per sq cm	Not Covered
Q4151	AmnioBand or Guardian, per sq cm	Not Covered
Q4152	DermaPure, per sq cm	Not Covered
Q4153	Dermavest and Plurivest, per sq cm	Not Covered
Q4154	Biovance, per sq cm	Not Covered
Q4155	Neox Flo or Clarix Flo 1 mg	Not Covered
Q4156	Neox 100 or Clarix 100, per sq cm	Not Covered
Q4157	Revitalon, per sq cm	Not Covered
Q4158	Kerecis Omega3, per sq cm	Not Covered
Q4159	Affinity, per sq cm	Not Covered
Q4160	Nushield, per sq cm	
Q4161	bio-ConneKt wound matrix, per sq cm	Not Covered
Q4162	WoundEx Flow, BioSkin Flow, 0.5 cc	Not Covered
Q4163	WoundEx, BioSkin, per sq cm	Not Covered
Q4164	Helicoll, per sq cm	Not Covered
Q4165	Keramatrix or Kerasorb, per sq cm	Not Covered
Q4166	Cytal, per sq cm	Not Covered
Q4167	Truskin, per sq cm	Not Covered
Q4168	AmnioBand, 1 mg	Not Covered
Q4169	Artacent wound, per sq cm	Not Covered
Q4170	Cygnus, per sq cm	Not Covered
Q4171	Interfyl, 1 mg	Not Covered
Q4173	PalinGen or PalinGen XPlus, per sq cm	Not Covered
Q4174	PalinGen or ProMatrX, 0.36 mg per 0.25 cc	Not Covered
Q4175	Miroderm, per sq cm	Not Covered
Q4176	Neopatch or therion, per square centimeter	Not Covered
Q4177	FlowerAmnioFlo, 0.1 cc	Not Covered
Q4178	FlowerAmnioPatch, per sq cm	Not Covered
Q4179	FlowerDerm, per sq cm	Not Covered
Q4180	Revita, per sq cm	Not Covered
Q4181	Amnio Wound, per sq cm	Not Covered
Q4182	Transcyte, per sq cm	
Q4183	Surgigraft, per sq cm	Not Covered
Q4184	Cellesta or Cellesta Duo, per sq cm	Not Covered
Q4185	Cellesta Flowable Amnion (25 mg per cc); per 0.5 cc	Not Covered
Q4186	Epifix, per sq cm	
Q4187	Epicord, per sq cm	Not Covered
Q4188	AmnioArmor, per sq cm	Not Covered

Q4189	Artacent AC, 1 mg	Not Covered
Q4190	Artacent AC, per sq cm	Not Covered
Q4191	Restorigin, per sq cm	Not Covered
Q4192	Restorigin, 1 cc	Not Covered
Q4193	Coll-e-Derm, per sq cm	Not Covered
Q4194	Novachor, per sq cm	Not Covered
Q4195	PuraPly, per sq cm	
Q4196	PuraPly AM, per sq cm	
Q4197	PuraPly XT, per sq cm	Not Covered
Q4198	Genesis Amniotic Membrane, per sq cm	Not Covered
Q4199	Cygnus matrix, per sq cm	Not Covered
Q4200	SkinTE, per sq cm	Not Covered
Q4201	Matrion, per sq cm	Not Covered
Q4202	Keroxx (2.5 g/cc), 1 cc	Not Covered
Q4203	Derma-Gide, per sq cm	Not Covered
Q4204	XWRAP, per sq cm	Not Covered
Q4205	Membrane Graft or Membrane Wrap, per sq cm	Not Covered
Q4206	Fluid Flow or Fluid GF, 1 cc	Not Covered
Q4208	Novafix, per sq cm	Not Covered
Q4209	SurGraft, per sq cm	Not Covered
Q4211	Amnion Bio or AxoBioMembrane, per sq cm	Not Covered
Q4212	AlloGen, per cc	Not Covered
Q4213	Ascent, 0.5 mg	Not Covered
Q4214	Cellesta Cord, per sq cm	Not Covered
Q4215	Axolotl Ambient or Axolotl Cryo, 0.1 mg	Not Covered
Q4216	Artacent Cord, per sq cm	Not Covered
Q4217	WoundFix, BioWound, WoundFix Plus, BioWound Plus, WoundFix Xplus or BioWound Xplus, per sq cm	Not Covered
Q4218	SurgiCORD, per sq cm	Not Covered
Q4219	SurgiGRAFT-DUAL, per sq cm	Not Covered
Q4220	BellaCell HD or Surederm, per sq cm	Not Covered
Q4221	Amnio Wrap2, per sq cm	Not Covered
Q4222	ProgenaMatrix, per sq cm	Not Covered
Q4224	Human health factor 10 amniotic patch (hhf10-p), per square centimeter	Not Covered
Q4225	Amniobind, per square centimeter	
Q4226	MyOwn Skin, includes harvesting and preparation procedures, per sq cm	Not Covered
Q4227	AmnioCoreTM, per sq cm	Not Covered
Q4229	Cogenex Amniotic Membrane, per sq cm	Not Covered
Q4230	Cogenex Flowable Amnion, per 0.5 cc	Not Covered
Q4231	Corplex P, per cc	Not Covered
Q4232	Corplex, per sq cm	Not Covered

Q4233	SurFactor or NuDyn, per 0.5 cc	Not Covered
Q4234	XCellerate, per sq cm	Not Covered
Q4235	AMNIOREPAIR or AltiPly, per sq cm	Not Covered
Q4236	Carepatch, per square centimeter	Not Covered
Q4237	Cryo-Cord, per sq cm	Not Covered
Q4238	Derm-Maxx, per sq cm	Not Covered
Q4239	Amnio-Maxx or Amnio-Maxx Lite, per sq cm	Not Covered
Q4240	CoreCyte, for topical use only, per 0.5 cc	Not Covered
Q4241	PolyCyte, for topical use only, per 0.5 cc	Not Covered
Q4242	AmnioCyte Plus, per 0.5 cc	Not Covered
Q4245	AmnioText, per cc	Not Covered
Q4246	CoreText or ProText, per cc	Not Covered
Q4247	Amniotext patch, per sq cm	Not Covered
Q4248	Dermacyte Amniotic Membrane Allograft, per sq cm	Not Covered
Q4249	AMNIPLY, for topical use only, per sq cm	Not Covered
Q4250	AmnioAmp-MP, per sq cm	Not Covered
Q4251	Vim, per sq cm	Not Covered
Q4252	Vendaje, per sq cm	Not Covered
Q4253	Zenith Amniotic Membrane, per sq cm	Not Covered
Q4254	Novafix DL, per sq cm	Not Covered
Q4255	REGUaRD, for topical use only, per sq cm	Not Covered
Q4256	Mlg-complete, per square centimeter	Not Covered
Q4257	Relese, per square centimeter	Not Covered
Q4258	Enverse, per square centimeter	Not Covered
Q4259	Celera dual layer or celera dual membrane, per square centimeter	Not Covered
Q4260	Signature apatch, per square centimeter	Not Covered
Q4261	Tag, per square centimeter	Not Covered
Q4262	Dual layer impax membrane, per square centimeter	
Q4263	Surgraft tl, per square centimeter	Not Covered
Q4264	Cocoon membrane, per square centimeter	Not Covered
Q4265	Neostim tl, per square centimeter	Not Covered
Q4266	Neostim membrane, per square centimeter	Not Covered
Q4267	Neostim dl, per square centimeter	Not Covered
Q4268	Surgraft ft, per square centimeter	Not Covered
Q4269	Surgraft xt, per square centimeter	Not Covered
Q4270	Complete sl, per square centimeter	Not Covered
Q4271	Complete ft, per square centimeter	Not Covered
Q4272	Esano a, per square centimeter	Not Covered
Q4273	Esano aaa, per square centimeter	Not Covered
Q4274	Esano ac, per square centimeter	Not Covered
Q4275	Esano aca, per square centimeter	Not Covered
Q4276	Orion, per square centimeter	Not Covered
Q4277	Woundplus membrane or e-graft, per square centimeter	Not Covered

Q4278	Epieffect, per square centimeter	Not Covered
Q4279	Vendaje ac, per square centimeter	Not Covered
Q4280	Xcell amnio matrix, per square centimeter	Not Covered
Q4281	Barrera sl or barrera dl, per square centimeter	Not Covered
Q4282	Cygnus dual, per square centimeter	Not Covered
Q4283	Biovance tri-layer or biovance 3l, per square centimeter	Not Covered
Q4284	Dermabind sl, per square centimeter	Not Covered
Q4285	Nudyn dl or nudyn dl mesh, per square centimeter	Not Covered
Q4286	Nudyn sl or nudyn slw, per square centimeter	Not Covered
Q4287	Dermabind dl, per square centimeter	Not Covered
Q4288	Dermabind ch, per square centimeter	Not Covered
Q4289	Revoshield + amniotic barrier, per square centimeter	Not Covered
Q4290	Membrane wrap-hydro, per square centimeter	Not Covered
Q4291	Lamellas xt, per square centimeter	Not Covered
Q4292	Lamellas, per square centimeter	Not Covered
Q4293	Acesso dl, per square centimeter	Not Covered
Q4294	Amnio quad-core, per square centimeter	Not Covered
Q4295	Amnio tri-core amniotic, per square centimeter	Not Covered
Q4296	Rebound matrix, per square centimeter	Not Covered
Q4297	Emerge matrix, per square centimeter	Not Covered
Q4298	Amniocore pro, per square centimeter	Not Covered
Q4299	Amnicore pro+, per square centimeter	Not Covered
Q4300	Acesso tl, per square centimeter	Not Covered
Q4301	Activate matrix, per square centimeter	Not Covered
Q4302	Complete aca, per square centimeter	Not Covered
Q4303	Complete aa, per square centimeter	Not Covered
Q4304	Grafix plus, per square centimeter	Not Covered
Q4305	American amnion ac tri-layer, per square centimeter	Not Covered
Q4306	American amnion ac, per square centimeter	Not Covered
Q4307	American amnion, per square centimeter	Not Covered
Q4308	Sanopellis, per square centimeter	Not Covered
Q4309	Via matrix, per square centimeter	Not Covered
Q4310	Procenta, per 100 mg	Not Covered
Q4311	Acesso, per square centimeter	Not Covered
Q4312	Acesso ac, per square centimeter	Not Covered
Q4313	Dermabind fm, per square centimeter	Not Covered
Q4314	Reeva ft, per square cenitmeter	Not Covered
Q4315	Regenelink amniotic membrane allograft, per square centimeter	Not Covered
Q4316	Amchoplast, per square centimeter	Not Covered
Q4317	Vitograft, per square centimeter	Not Covered
Q4318	E-graft, per square centimeter	Not Covered
Q4319	Sanograft, per square centimeter	Not Covered
Q4320	Pellograft, per square centimeter	Not Covered

Q4321	Renograft, per square centimeter	Not Covered
Q4322	Caregraft, per square centimeter	Not Covered
Q4323	Alloply, per square centimeter	Not Covered
Q4324	Amniotx, per square centimeter	Not Covered
Q4325	Acapatch, per square centimeter	Not Covered
Q4326	Woundplus, per square centimeter	Not Covered
Q4327	Duoamnion, per square centimeter	Not Covered
Q4328	Most, per square centimeter	Not Covered
Q4329	Singlay, per square centimeter	Not Covered
Q4330	Total, per square centimeter	Not Covered
Q4331	Axolotl graft, per square centimeter	Not Covered
Q4332	Axolotl dualgraft, per square centimeter	Not Covered
Q4333	Ardeograft, per square centimeter	Not Covered
Q4334	Amnioplast 1, per square centimeter	Not Covered
Q4335	Amnioplast 2, per square centimeter	Not Covered
Q4336	Artacent c, per square centimeter	Not Covered
Q4337	Artacent trident, per square centimeter	Not Covered
Q4338	Artacent velos, per square centimeter	Not Covered
Q4339	Artacent vericlen, per square centimeter	Not Covered
Q4340	Simpligraft, per square centimeter	Not Covered
Q4341	Simplimax, per square centimeter	Not Covered
Q4342	Theramend, per square centimeter	Not Covered
Q4343	Dermacyte ac matrix amniotic membrane allograft, per square centimeter	Not Covered
Q4344	Tri-membrane wrap, per square centimeter	Not Covered
Q4345	Matrix hd allograft dermis, per square centimeter	Not Covered

References

1. Agency for Healthcare Research and Quality (AHRQ). Technical Brief. Skin substitutes for treating chronic wounds. https://ahrq.gov. Published February 2, 2020.

2. ECRI Institute. Clinical Evidence Assessment. Affinity amniotic allograft (Organogenesis, Inc.) for treating diabetic foot ulcers. https://ecri.org. Published September 15, 2015. Updated June 20, 2024.

3. ECRI Institute. Clinical Evidence Assessment. AlloDerm regenerative tissue matrix (AbbVie, Inc.) for reconstructing breast tissue. https://ecri.org. Published December 18, 2018. Updated November 30, 2023.

4. ECRI Institute. Clinical Evidence Assessment. Amnioband allograft placental matrix (MTF Biologics) for treating chronic wounds. https://ecri.org. Published June 20, 2016. Updated September 23, 2020.

5. ECRI Institute. Clinical Evidence Assessment. Apligraf (Organogenesis, Inc.) for treating venous leg ulcers. https://ecri.org. Published December 2, 2022. Updated April 11, 2023.

6. ECRI Institute. Clinical Evidence Assessment. Arthroflex acellular dermal matrix (LifeNet Health and Arthrex, Inc.) for repairing large to massive rotator cuff tears. https://ecri.org. Published October 23, 2017. Updated June 16, 2022.

7. ECRI Institute. Clinical Evidence Assessment. AxoGuard nerve protector (AxoGen, Inc.) for treating peripheral nerve injuries. https://ecri.org. Published August 9, 2023.

8. ECRI Institute. Clinical Evidence Assessment. Biodesign sinonasal repair graft (Cook Medical, Inc.) for repairing sinus and nasal cavity defects. https://ecri.org. Published December 9, 2021.

9. ECRI Institute. Clinical Evidence Assessment. Biovance amniotic membrane allograft (Celularity, Inc.) for treating chronic wounds. https://ecri.org. Published January 3, 2017. Updated July 24, 2020.

10. ECRI Institute. Clinical Evidence Assessment. Cortiva and Cortiva 1 mm allograft dermis (RTI Surgical, Inc.) for breast reconstruction. https://ecri.org. Published November 13, 2018. Updated November 30, 2020.

11. ECRI Institute. Clinical Evidence Assessment. Cygnus amniotic allografts (Vivex Medical, Inc.) for treating chronic wounds. https://ecri.org. Published April 29, 2022.

12. ECRI Institute. Clinical Evidence Assessment. Dermacell advanced decellularized dermis (LifeNet Health Bio-Implants Division) for breast reconstruction. https://ecri.org. Published August 15, 2016. Updated December 2, 2020.

13. ECRI Institute. Clinical Evidence Assessment. Dermacell AWM (LifeNet Health Bio-Implants Division) for chronic wounds. https://ecri.org. Published March 8, 2018. Updated December 18, 2020.

14. ECRI Institute. Clinical Evidence Assessment. DermaPure decellularized dermal allograft (ARMS Medical) for treating acute or chronic wounds. https://ecri.org. Published November 6, 2024.

15. ECRI Institute. Clinical Evidence Assessment. FlexHD pliable acellular hydrated dermis (Musculoskeletal Transplant Foundation) for breast reconstruction. https://ecri.org. Published October 30, 2015. Updated November 8, 2023.

16. ECRI Institute. Clinical Evidence Assessment. Fortify Flowable extracellular matrix (Sanara Medtech, Inc.) for treating wounds. https://ecri.org. Published October 3, 2022.

17. ECRI Institute. Clinical Evidence Assessment. GalaFlex surgical scaffold (Galatea Surgical, Inc.) for soft-tissue reinforcement in breast reconstruction surgery. https://ecri.org. Published October 7, 2022.

18. ECRI Institute. Clinical Evidence Assessment. Gentrix surgical matrix (ACell, Inc.) for hiatal hernia repair. https://ecri.org. Published July 22, 2020.

19. ECRI Institute. Clinical Evidence Assessment. Grafix cellular repair matrix (Osiris Therapeutics, Inc.) for treating chronic wounds. https://ecri.org. Published November 9, 2012. Updated July 14, 2021.

20. ECRI Institute. Clinical Evidence Assessment. Hyalomatrix tissue reconstruction matrix (Anika Therapeutics, Inc.) for treating chronic wounds. https://ecri.org. Published June 7, 2018. Updated April 13, 2021.

21. ECRI Institute. Clinical Evidence Assessment. Integra bilayer matrix (Integra LifeSciences Corp.) for treating diabetic foot ulcers. https://ecri.org. Published April 8, 2021.

22. ECRI Institute. Clinical Evidence Assessment. Leneva allograft adipose matrix (MTF Biologics) for treating wounds. https://ecri.org. Published October 3, 2022.

23. ECRI Institute. Clinical Evidence Assessment. Matriderm acellular dermal matrix (MedSkin Solutions) for treating burns. https://ecri.org. Published April 19, 2023.

24. ECRI Institute. Clinical Evidence Assessment. Matriderm (MedSkin Solutions) for managing wounds following otorhinolaryngology surgery. https://ecri.org. Published April 11, 2022.

25. ECRI Institute. Clinical Evidence Assessment. Mirragen advanced wound matrix (ETS Wound Care LLC) for treating diabetic foot ulcers. https://ecri.org. Published October 4, 2023.

26. ECRI Institute. Clinical Evidence Assessment. Myriad soft-tissue matrix (Aroa Biosurgery Ltd.) for treating chronic wounds. https://ecri.org. Published September 21, 2020.

27. ECRI Institute. Clinical Evidence Assessment. NEOX Flo wound matrix (Amniox Medical, Inc.) for treating chronic wounds. https://ecri.org. Published December 4, 2015. Updated August 27, 2021.

28. ECRI Institute. Clinical Evidence Assessment. NeuraGen 3D nerve guide (Integra LifeSciences) for repairing nerve gap injuries. https://ecri.org. Published April 28, 2022.

29. ECRI Institute. Clinical Evidence Assessment. NovoSorb biodegradable temporizing matrix (PolyNovo Ltd.) for managing wounds. https://ecri.org. Published September 1, 2019. Updated November 2, 2021.

30. ECRI Institute. Clinical Evidence Assessment. NovoSorb biodegradable temporizing matrix (PolyNovo Ltd.) for treating full-thickness wounds. https://ecri.org. Published May 4, 2023.

31. ECRI Institute. Clinical Evidence Assessment. NuShield placental allograft (Organogenesis, Inc.) for treating burns. https://ecri.org. Published November 29, 2021.

32. ECRI Institute. Clinical Evidence Assessment. Oasis Wound Matrix (Smith & Nephew, Inc.) for treating burns. https://ecri.org. Published July 1, 2023.

33. ECRI Institute. Clinical Evidence Assessment. Omega3 wound matrix (Kerecis) for treating burns. https://ecri.org. Published February 23, 2024.

34. ECRI Institute. Clinical Evidence Assessment. Omega3 wound matrix (Kerecis) for treating chronic wounds. https://ecri.org. Published May 1, 2019. Updated April 1, 2023.

35. ECRI Institute. Clinical Evidence Assessment. Overview of flowable matrices for treating chronic and acute wounds. https://ecri.org. Published September 1, 2022.

36. ECRI Institute. Clinical Evidence Assessment. Overview of selected human amniotic membranes for treating chronic wounds. https://ecri.org. Published May 1, 2022.

37. ECRI Institute. Clinical Evidence Assessment. OviTex PRS reinforced tissue matrix (TELA Bio) for breast reconstruction. https://ecri.org. Published December 13, 2021.

38. ECRI Institute. Clinical Evidence Assessment. OviTex reinforced bioscaffolds (Tela Bio, Inc.) for hernia repair. https://ecri.org. Published December 16, 2021.

39. ECRI Institute. Clinical Evidence Assessment. ProLayer acellular dermal matrix (Stryker Corp.) for breast reconstruction. https://ecri.org. Published March 4, 2021.

40. ECRI Institute. Clinical Evidence Assessment. PuraPly AM antimicrobial wound matrix (Organogenesis, Inc.) for treating chronic wounds. https://ecri.org. Published November 7, 2018. Updated April 29, 2022.

41. ECRI Institute. Clinical Evidence Assessment. Restrata resorbable wound matrix (Acera Surgical) for treating acute and surgical wounds. https://ecri.org. Published March 22, 2024.

42. ECRI Institute. Clinical Evidence Assessment. Restrata resorbable wound matrix (Acera Surgical) for treating complex and chronic wounds. https://ecri.org. Published March 22, 2024.

43. ECRI Institute. Clinical Evidence Assessment. Revita placental allograft (StimLabs, LLC) for treating diabetic foot ulcers. https://ecri.org. Published February 1, 2022.

44. ECRI Institute. Clinical Evidence Assessment. SimpliDerm (Aziyo Biologics, Inc.) for breast reconstruction. https://ecri.org. Published June 14, 2022.

45. ECRI Institute. Clinical Evidence Assessment. Skin substitutes for treating diabetic foot ulcers in patients aged 65 years or older. https://ecri.org. Published January 25, 2021.

46. ECRI Institute. Clinical Evidence Assessment. Skin substitutes for treating pressure injuries in patients aged 65 years or older. https://ecri.org. Published October 29, 2024.

47. ECRI Institute. Clinical Evidence Assessment. Standard-of-care practices for managing diabetic foot ulcers. https://ecri.org. Published January 28, 2020. Updated December 31, 2021.

48. ECRI Institute. Clinical Evidence Assessment. StrataGraft allogeneic cellularized scaffold (Mallinckrodt Pharmaceuticals) for treating thermal burns. https://ecri.org. Published February 6, 2022.

49. ECRI Institute. Clinical Evidence Assessment. Strattice reconstructive tissue matrix (Abbvie, Inc.) for hernia repair. https://ecri.org. Published October 29, 2024.

50. ECRI Institute. Clinical Evidence Assessment. Stravix cryopreserved placental tissue (Osiris Therapeutics, Inc.) for treating surgical wounds. https://ecri.org. Published July 8, 2021.

51. ECRI Institute. Clinical Evidence Assessment. Suprathel skin substitute (PolyMedics Innovations GmbH) for treating burns. https://ecri.org. Published April 25, 2023.

52. ECRI Institute. Clinical Evidence Assessment. Suprathel skin substitute (PolyMedics Innovations GmbH) for treating donor site wounds. https://ecri.org. Published February 22, 2021.

53. ECRI Institute. Clinical Evidence Assessment. SurgiMend collagen matrix (Integra LifeSciences Corp.) for breast reconstruction. https://ecri.org. Published November 14, 2019. Updated May 4, 2021.

54. ECRI Institute. Clinical Evidence Assessment. Synthetic versus biologic mesh for breast reconstructive surgery. https://ecri.org. Published October 30, 2015. Updated November 11, 2024.

55. ECRI Institute. Clinical Evidence Assessment. TheraGenesis bilayer wound matrix (Gunze International USA, Inc.) for treating partial- and full-thickness wounds. https://ecri.org. Published February 22, 2023.

56. ECRI Institute. Hotline Response. Skin substitutes for managing pilonidal disease excision wounds. https://ecri.org. Published March 31, 2020.

57. ECRI Institute. Hotline Response. Synthetic versus biologic mesh for abdominal wall reconstructive surgery. https://ecri.org. Published October 15, 2015. Updated November 13, 2019.

58. ECRI Institute. Product Brief. AlloMax surgical graft (C.R. Bard, Inc./Davol, Inc.) for reconstructive surgery. https://ecri.org. Published October 9, 2015. Updated July 25, 2016.

59. ECRI Institute. Product Brief. AlloPatch HD acellular dermal matrix (Musculoskeletal Transplant Foundation) for repairing rotator cuff tears. https://ecri.org. Published October 23, 2017.

60. ECRI Institute. Product Brief. AmnioFix amnion/chorion membrane allograft (MiMedx) for treating surgical wounds. https://ecri.org. Published April 14, 2015. Updated May 10, 2019.

61. ECRI Institute. Product Brief. Avance nerve graft (AxoGen, Inc.) for repairing nerve gap injuries. https://ecri.org. Published March 14, 2012. Updated January 27, 2020.

62. ECRI Institute. Product Brief. Biodesign dural graft (Cook Medical) for repairing dural tears. https://ecri.org. Published August 26, 2015.

63. ECRI Institute. Product Brief. Biodesign hernia graft (Cook Biotech, Inc.) for reconstructive surgery. https://ecri.org. Published July 20, 2016.

64. ECRI Institute. Product Brief. Biodesign nipple reconstruction cylinder (Cook Medical) for plastic surgery. https://ecri.org. Published April 5, 2018.

65. ECRI Institute. Product Brief. Biodesign otologic repair graft (Cook Medical) for tympanic reconstruction. https://ecri.org. Published January 22, 2018.

66. ECRI Institute. Product Brief. BioDFactor viable tissue matrix (Integra LifeSciences) for treating surgical and chronic wounds. https://ecri.org. Published September 24, 2018.

67. ECRI Institute. Product Brief. CopiOs pericardium membrane (Zimmer Dental, Inc.) for use during oral surgery. https://ecri.org. Published February 6, 2017.

68. ECRI Institute. Product Brief. Cytal wound matrix (ACell, Inc.) for treating acute and chronic wounds. https://ecri.org. Published October 23, 2017. Updated March 15, 2019.

69. ECRI Institute. Product Brief. Epicord umbilical cord allograft (MiMedx) for treating diabetic foot ulcers. https://ecri.org. Published February 6, 2020.

70. ECRI Institute. Product Brief. EpiFix amnion/chorion membrane allograft (MiMedx) for treating chronic wounds. https://ecri.org. Published September 10, 2018. Updated December 2, 2019.

71. ECRI Institute. Product Brief. Gentrix surgical matrix (ACell, Inc.) for reinforcing soft tissue. https://ecri.org. Published June 30, 2018.

72. ECRI Institute. Product Brief. GraftJacket Regenerative Tissue Matrix (Wright Medical Technology) to augment tendon and ligament repair. https://ecri.org. Published April 7, 2004. Updated February 12, 2018.

73. ECRI Institute. Product Brief. Helicoll (EnColl, Corp.) type-1 collagen-based sterile dressing for treating burns and wounds. https://ecri.org. Published August 1, 2014.

74. ECRI Institute. Product Brief. Integra flowable wound matrix (Integra LifeSciences Corp.) for treating deep soft-tissue or tunneling wounds. https://ecri.org. Published February 20, 2017.

75. ECRI Institute. Product Brief. Integra template and matrix wound skin substitutes (Integra LifeSciences Corp.) for treating chronic wounds. https://ecri.org. Published April 1, 2018.

76. ECRI Institute. Product Brief. MatriStem MicroMatrix (ACell, Inc.) for treating surgical and chronic wounds. https://ecri.org. Published August 28, 2018.

77. ECRI Institute. Product Brief. NuShield placental allograft (Nutech Medical) for use in chronic and surgical wounds. https://ecri.org. Published September 15, 2015.

78. ECRI Institute. Product Brief. Oasis wound matrix (Smith & Nephew, Inc.) for treating surgical and chronic wounds. https://ecri.org. Published April 7, 2004. Updated July 25, 2016.

79. ECRI Institute. Product Brief. Permacol surgical implant (Medtronic plc) for repairing hernias and abdominal wall defects. https://ecri.org. Published July 25, 2016.

80. ECRI Institute. Product Brief. PriMatrix dermal repair scaffold (Integra LifeSciences Corp.) for treating chronic wounds. https://ecri.org. Published July 25, 2016. Updated October 31, 2019.

81. ECRI Institute. Product Brief. Promogran Prisma Matrix (Acelity L.P., Inc.) for promoting surgical wound healing. https://ecri.org. Published August 22, 2018.

82. ECRI Institute. Product Brief. Strattice reconstructive tissue matrix (Allergan plc) for breast reconstruction. https://ecri.org. Published February 3, 2012. Updated November 25, 2019.

83. ECRI Institute. Product Brief. Surgimend collagen matrix (Integra LifeSciences Corp.) for reconstructive surgery. https://ecri.org. Published July 5, 2016.

84. ECRI Institute. Product Brief. TheraSkin human skin allograft (Solsys Medical, LLC) for treating surgical and chronic wounds. https://ecri.org. Published October 5, 2018. Updated March 1, 2019.

85. ECRI Institute. Product Brief. XCM biologic tissue matrix (Ethicon US, LLC/DePuy Synthes) for reconstructive surgery. https://ecri.org. Published November 4, 2015. Updated July 25, 2016.

86. ECRI Institute. Product Brief. XenMatrix surgical grafts (C.R. Bard, Inc.) for hernia repair. https://ecri.org. Published December 5, 2019.

87. ECRI Institute. Product Brief. XenMatrix surgical grafts (C.R. Bard, Inc./Davol, Inc.) for reconstructive surgery. https://ecri.org. Published October 30, 2015. Updated July 25, 2016.

88. Hayes, Inc. Clinical Research Response. SimpliDerm acellular dermal matrix (Elutia). https://evidence.hayesinc.com. Published December 8, 2023.

89. Hayes, Inc. Evidence Analysis Research Brief. AlloDerm Regenerative Tissue Matrix (AbbVie Inc.) for head and neck procedures. https://evidence.hayesinc.com. Published July 13, 2023.

90. Hayes, Inc. Evidence Analysis Research Brief. AmnioBind placental membrane allograft (Pipeline Healthcare Solutions) for wound management. https://evidence.hayesinc.com. Published December 29, 2023.

91. Hayes, Inc. Evidence Analysis Research Brief. Apis wound dressing (SweetBio Inc.) for treatment of wounds. https://evidence.hayesinc.com. Published February 3, 2023.

92. Hayes, Inc. Evidence Analysis Research Brief. Artacent Flex (Tides Medical) for treatment of wounds. https://evidence.hayesinc.com. Published December 29, 2023.

93. Hayes, Inc. Evidence Analysis Research Brief. ArthroFLEX decellularized dermal allograft (Arthrex, Inc.) for anterior cruciate ligament repair or reconstruction. https://evidence.hayesinc.com. Published August 3, 2023.

94. Hayes, Inc. Evidence Analysis Research Brief. bio-ConneKt wound matrix (MLM Biologics Inc.) for treatment of wounds. https://evidence.hayesinc.com. Published January 20, 2023.

95. Hayes, Inc. Evidence Analysis Research Brief. carePatch (Extremity Care) for treatment of wounds. https://evidence.hayesinc.com. Published March 12, 2024.

96. Hayes, Inc. Evidence Analysis Research Brief. Celera patch (Nvision Biomedical Technologies Inc.) for treatment of wounds or burns. https://evidence.hayesinc.com. Published December 5, 2023.

97. Hayes, Inc. Evidence Analysis Research Brief. Cygnus Matrix (Vivex Biologics) for wound management. https://evidence.hayesinc.com. Published March 6, 2023.

98. Hayes, Inc. Evidence Analysis Research Brief. Dermaspan (Biomet Orthopedics) for management of musculoskeletal indications. https://evidence.hayesinc.com. Published September 12, 2023.

99. Hayes, Inc. Evidence Analysis Research Brief. Enverse (StimLabs LLC) for treatment of wounds. https://evidence.hayesinc.com. Published July 25, 2023.

100. Hayes, Inc. Evidence Analysis Research Brief. FlowerPatch (Conventus Flower Orthopedics) for treatment of wounds. https://evidence.hayesinc.com. Published January 18, 2024.

101. Hayes, Inc. Evidence Analysis Research Brief. Human Health Factor 10 amniotic patch (Wolver & Poole Distribution LLC) for wound management. https://evidence.hayesinc.com. Published January 29, 2024.

102. Hayes, Inc. Evidence Analysis Research Brief. Impax Dual Layer amniotic graft (Legacy Medical Consultants) for treatment of wounds. https://evidence.hayesinc.com. Published February 8, 2024.

103. Hayes, Inc. Evidence Analysis Research Brief. InnovaMatrix AC (Triad Life Sciences Inc.) for treatment of wounds. https://evidence.hayesinc.com. Published January 20, 2023.

104. Hayes, Inc. Evidence Analysis Research Brief. InnovaMatrix FS (Triad Life Sciences Inc.) for treatment of wounds. https://evidence.hayesinc.com. Published July 25, 2023.

105. Hayes, Inc. Evidence Analysis Research Brief. IntéguPly (PuraGraft) for management of musculoskeletal indications. https://evidence.hayesinc.com. Published September 29, 2023.

106. Hayes, Inc. Evidence Analysis Research Brief. MemoDerm (Stryker) for management of musculoskeletal indications. https://evidence.hayesinc.com. Published September 19, 2023.

107. Hayes, Inc. Evidence Analysis Research Brief. Microlyte Matrix (Imbed Biosciences) for treatment of wounds. https://evidence.hayesinc.com. Published March 20, 2023.

108. Hayes, Inc. Evidence Analysis Research Brief. MicroMatrix (ACell Inc.) for treatment of wounds. https://evidence.hayesinc.com. Published March 25, 2022.

109. Hayes, Inc. Evidence Analysis Research Brief. Mirragen Advanced Wound Matrix (ETS Wound Care) for management of diabetic foot ulcers. https://evidence.hayesinc.com. Published May 2, 2022.

110. Hayes, Inc. Evidence Analysis Research Brief. MLG-Complete (Samaritan Biologics) for treatment of wounds. https://evidence.hayesinc.com. Published July 27, 2023.

111. Hayes, Inc. Evidence Analysis Research Brief. NuShield placental allograft for the management of diabetic foot ulcers. https://evidence.hayesinc.com. Published March 17, 2022.

112. Hayes, Inc. Evidence Analysis Research Brief. Omeza Collagen Matrix (Omeza) for treatment of wounds. https://evidence.hayesinc.com. Published December 1, 2023.

113. Hayes, Inc. Evidence Analysis Research Brief. PermeaDerm products (Stedical Scientific) for treatment of wounds. https://evidence.hayesinc.com. Published February 1, 2024.

114. Hayes, Inc. Evidence Analysis Research Brief. Phoenix Wound Matrix (RenovoDerm) for treatment of wounds. https://evidence.hayesinc.com. Published February 1, 2024.

115. Hayes, Inc. Evidence Analysis Research Brief. ProMatrX ACF (Amino Technology LLC) for treatment of diabetic foot ulcers. https://evidence.hayesinc.com. Published January 4, 2024.

116. Hayes, Inc. Evidence Analysis Research Brief. Relese (StimLabs LLC) for treatment of wounds. https://evidence.hayesinc.com. Published April 28, 2023.

117. Hayes, Inc. Evidence Analysis Research Brief. Restrata (Acera Surgical Inc.) for wound management. https://evidence.hayesinc.com. Published February 3, 2023.

118. Hayes, Inc. Evidence Analysis Research Brief. Signature APatch (Signature Biologics) for treatment of wounds. https://evidence.hayesinc.com. Published February 26, 2024.

119. Hayes, Inc. Evidence Analysis Research Brief. Skin substitutes for treatment of acute wounds. https://evidence.hayesinc.com. Published January 31, 2024.

120. Hayes, Inc. Evidence Analysis Research Brief. Supra SDRM (PolyMedics Innovations Inc.). https://evidence.hayesinc.com. Published July 25, 2023.

121. Hayes, Inc. Evidence Analysis Research Brief. Suprathel (PolyMedics Innovations Inc.) for wound management. https://evidence.hayesinc.com. Published August 22, 2023.

122. Hayes, Inc. Evidence Analysis Research Brief. SurgiMend (Integra Life Sciences) for postmastectomy breast reconstruction. https://evidence.hayesinc.com. Published March 24, 2023.

123. Hayes, Inc. Evidence Analysis Research Brief. SurGraft TL (Surgenex LLC) for treatment of wounds. https://evidence.hayesinc.com. Published February 21, 2024.

124. Hayes, Inc. Evidence Analysis Research Brief. Symphony (Aroa Biosurgery Ltd.) for treatment of wounds. https://evidence.hayesinc.com. Published March 21, 2023.

125. Hayes, Inc. Evidence Analysis Research Brief. TheraGenesis (Bioventus LLC) for treatment of wounds. https://evidence.hayesinc.com. Published March 21, 2023.

126. Hayes, Inc. Evidence Analysis Research Brief. Vendaje (BioStem Technologies) for wound management. https://evidence.hayesinc.com. Published March 14, 2023.

127. Hayes, Inc. Evidence Analysis Research Brief. Vim amniotic membrane (Cook Biotech) for treatment of surgical and nonsurgical wounds. https://evidence.hayesinc.com. Published February 13, 2023.

128. Hayes, Inc. Evidence Analysis Research Brief. XCelliStem wound powder (Stemsys) for treatment of wounds. https://evidence.hayesinc.com. Published January 19, 2023.

129. Hayes, Inc. Evidence Analysis Research Brief. Zenith amniotic membrane (Legacy Medical Consultants) for wound management. https://evidence.hayesinc.com. Published March 6, 2023.

130. Hayes, Inc. Evolving Evidence Review. Kerecis Omega3 wound (Kerecis) fish skin grafts for management of burns. https://evidence.hayesinc.com. Published February 22, 2024.

131. Hayes, Inc. Evolving Evidence Review. Kerecis Omega3 wound (Kerecis) fish skin grafts for the management of diabetic foot ulcers. https://evidence.hayesinc.com. Published February 22, 2024.

132. Hayes, Inc. Evolving Evidence Review. NovoSorb biodegradable temporizing matrix (BTM) (PolyNovo Pty Ltd.) for treatment of diabetic foot ulcers. https://evidence.hayesinc.com. Published January 25, 2024. Updated October 18, 2024.

133. Hayes, Inc. Evolving Evidence Review. PuraPly AM antimicrobial wound matrix (Organogenesis) for treatment of wounds. https://evidence.hayesinc.com. Published December 12, 2022. Updated December 18, 2024.

134. Hayes, Inc. Health Technology Assessment. Acellular skin substitutes for chronic foot ulcers in adults with diabetes mellitus. https://evidence.hayesinc.com. Published May 6, 2020. Updated May 10, 2023.

135. Hayes, Inc. Health Technology Assessment. Amniotic allografts for tendon and ligament injuries. https://evidence.hayesinc.com. Published September 16, 2020. Updated August 29, 2023.

136. Hayes, Inc. Health Technology Assessment. Cellular skin substitutes for chronic foot ulcers in adults with diabetes mellitus. https://evidence.hayesinc.com. Published March 26, 2020. Updated April 24, 2023.

137. Hayes, Inc. Health Technology Assessment. Grafix cryopreserved placental membrane (Osiris Technologies Inc.) for treatment of chronic foot ulcers in patients with diabetes mellitus. https://evidence.hayesinc.com. Published September 3, 2019. Updated October 25, 2022.

138. Hayes, Inc. Health Technology Assessment. Processed nerve allografts with the Avance Nerve Graft (Axogen Corporation) for peripheral nerve discontinuities. https://evidence.hayesinc.com. Published March 2, 2020. Updated May 10, 2023.

139. Hayes, Inc. Health Technology Assessment. Skin substitutes for venous leg ulcers in adults. https://evidence.hayesinc.com. Published July 23, 2020. Updated July 11, 2023.

140. Hayes, Inc. Health Technology Brief. FlexHD acellular dermis (Musculoskeletal Transplant Foundation) for hernia repair. https://evidence.hayesinc.com. Published August 8, 2012. Updated June 30, 2014.

141. Hayes, Inc. Health Technology Brief. Oasis wound matrix (Cook Biotech Inc.) for lower extremity ulcers. https://evidence.hayesinc.com. Published December 31, 2012. Updated December 12, 2014.

142. Hayes, Inc. Health Technology Brief. Surgisis AFP anal fistula plug (a.k.a. SIS Fistula Plug) (Cook Biotech Inc.) for repair of anal fistulas. https://evidence.hayesinc.com. Published April 7, 2008. Updated April 9, 2010.

143. Hayes, Inc. Medical Technology Directory. Comparative effectiveness review of biologic mesh for hernia repair: a review of reviews. https://evidence.hayesinc.com. Published March 16, 2018. Updated March 1, 2022.

144. Hayes, Inc. Medical Technology Directory. Comparative effectiveness review of human acellular dermal matrix for breast reconstruction. https://evidence.hayesinc.com. Published January 28, 2019. Updated February 28, 2022.

145. Hayes, Inc. Medical Technology Directory. Synthetic tissue for dural repair. https://evidence.hayesinc.com. Published May 14, 2015. Updated June 11, 2019.

146. National Pressure Injury Advisory Panel (NPIAP). Clinical Practice Guideline. Prevention and treatment of pressure ulcers/injuries: quick reference guide. https://npiap.com. Published 2009. Updated 2019.

147. Society for Vascular Surgery (SVS). Clinical Practice Guidelines (ARCHIVED) of the Society for Vascular Surgery and the American Venous Forum. Management of venous leg ulcers. https://jvascsurg.org. Published August 2014.

148. UpToDate, Inc. Basic principles of wound healing. https://uptodate.com. Updated December 2024.

149. UpToDate, Inc. Implant-based breast reconstruction and augmentation. https://uptodate.com. Updated December 2024.

150. UpToDate, Inc. Management of diabetic foot ulcers. https://uptodate.com. Updated December 2024.

151. UpToDate, Inc. Management of ventral hernias. https://uptodate.com. Updated December 2024.

152. UpToDate, Inc. Operative management of anorectal fistulas. https://uptodate.com. Updated December 2024.

153. UpToDate, Inc. Overview of surgical procedures used in the management of burn injuries. https://uptodate.com. Updated December 2024.

154. UpToDate, Inc. Overview of treatment of chronic wounds. https://uptodate.com. Updated December 2024.

155. UpToDate, Inc. Principles of acute wound management. https://uptodate.com. Updated December 2024.

156. UpToDate, Inc. Skin substitutes. https://uptodate.com. Updated December 2024.

157. UpToDate, Inc. Topical agents and dressings for local burn wound care. https://uptodate.com. Updated December 2024.

158. UpToDate, Inc. Treatment of superficial burns requiring hospital admission. https://uptodate.com. Updated December 2024.

159. US Government Publishing Office. Electronic code of federal regulations: part 1271 – human cells, tissues, and cellular and tissue-based products. https://ecfr.gov. Published January 19, 2001. Updated November 24, 2004.

Appendix

Standard wound therapy based on the specific type of wound includes:

- **Appropriate offloading[47,150]; AND**
- **Assessment of an individual's vascular status and correction of any amenable vascular problems for arterial and/or venous ulcers[150,154]; AND**
- **Comprehensive patient assessment (history, exam, Ankle-Brachial Index [ABI]) and diagnostic tests as indicated) and implemented treatment plan[154]; AND**
- **Compression garments/dressings have been consistently applied for venous ulcers[150,154]; AND**
- **Frequent repositioning of an individual with pressure injuries (usually every 2 hours)[154]; AND**
- **Improvement of glucose control[150,154]; AND**
- **Individual with venous leg ulcer (VLU) - assessment of clinical history (prior ulcers, thrombosis risks), physical exam (edema, skin changes), ABI, diagnostic testing to verify superficial or deep venous reflux, perforator incompetence, and chronic (or acute) venous thrombosis[154]; AND**
- **Maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings (eg, alginate, films, foams, hydrocolloid, hydrogels that provide a moist wound environment)[47,154,155]; AND**
- **Necessary treatment to resolve any infection that may be present (eg, antibiotics, debridement of devitalized tissue, surgical management of osteomyelitis)[47,150,154,155]**

Change Summary

02/04/2025 New Policy.