

Skin and Tissue Substitutes



Medicaid Medical Coverage Policy

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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 may be eligible under the Plan for **skin and tissue substitutes** when **1 or more** the following criteria are met:

- Treatment of partial- and full-thickness diabetic foot ulcers (DFU), of greater than 4 weeks in duration, with no bone, capsule or tendon exposed, when used in conjunction with standard wound therapy, including **ALL** the following:
 - Appropriate offloading^{50,150}; **AND**
 - Comprehensive assessment (history, exam, ABI, adequate perfusion of involved limb and diagnostic tests as indicated) and implemented treatment plan¹⁵³; **AND**
 - Diabetes mellitus (type 1 or type 2)¹⁵⁰; **AND**
 - Frequent repositioning of an individual with pressure injuries (usually every 2 hours)¹⁵³; **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)^{50,153,154}; **AND**
 - Necessary treatment to resolve any infection that may be present (eg, antibiotics, debridement of devitalized tissue, surgical management of osteomyelitis)^{50,150,153,154}; **AND**
 - Optimal glycemic management or improvement of glucose control^{150,153}
- Treatment of chronic venous leg ulcers (VLU), of greater than 4 weeks in duration, with no bone, capsule or tendon exposed, when used in conjunction with standard wound therapy, including **ALL** the following:
 - Clinical history (prior ulcers, thrombosis risks), physical exam (edema, skin changes), ABI, adequate perfusion of involved limb, diagnostic testing to verify superficial or deep venous reflux, perforator incompetence, and chronic (or acute) venous thrombosis¹⁵³; **AND**
 - Comprehensive assessment of an individual's vascular status and correction of any amenable vascular problems for arterial and/or venous ulcers^{150,153}; **AND**
 - Compression garments/dressings have been consistently applied for venous ulcers (edema control)^{150,153}; **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)^{50,153,154}; **AND**

- Necessary treatment to resolve any infection that may be present (eg, antibiotics, debridement of devitalized tissue, surgical management of osteomyelitis)^{50,150,153,154}; **AND**
- Optimal glycemic management or improvement of glucose control, if individual is diabetic^{150,153}

Coverage Limitations

For members under age 21, requests are reviewed for medical necessity in accordance with Early and Periodic Screening, Diagnostic and Treatment (EPSDT) requirements.

Humana members may **NOT** be eligible under the Plan for **skin and tissue substitutes** for any indications other than those listed above. All other indications are considered not medically necessary.

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
No code(s) identified		
CPT® Category III Code(s)	Description	Comments
No code(s) identified		
HCPCS Code(s)	Description	Comments
Q4101	Apligraf, per sq cm	
Q4102	Oasis wound matrix, per sq cm	
Q4103	Oasis burn matrix, per sq cm	
Q4104	Integra bilayer matrix wound dressing (BMWWD), per sq cm	
Q4105	Integra dermal regeneration template (DRT) or Integra Omnigraft dermal regeneration matrix, per sq cm	
Q4108	Integra matrix, per sq cm	
Q4110	PriMatrix, per sq cm	
Q4111	GammaGraft, per sq cm	
Q4114	Integra flowable wound matrix, injectable, 1 cc	
Q4115	AlloSkin, per sq cm	
Q4118	MatriStem micromatrix, 1 mg	

Q4121	TheraSkin, per sq cm	
Q4123	AlloSkin RT, per sq cm	
Q4124	OASIS ultra tri-layer wound matrix, per sq cm	
Q4126	MemoDerm, DermaSpan, TranZgraft or InteguPly, per sq cm	
Q4127	Talymed, per sq cm	
Q4128	FlexHD, AllopatchHD, or Matrix HD, per sq cm	
Q4132	Grafix Core and GrafixPL Core, per sq cm	
Q4133	Grafix PRIME, GrafixPL PRIME, Stravix and StravixPL, per sq cm	
Q4137	AmnioExcel, AmnioExcel Plus or BioDExcel, per sq cm	
Q4138	BioDFence DryFlex, per sq cm	
Q4140	BioDFence, per sq cm	
Q4141	AlloSkin AC, per sq cm	
Q4143	Repriza, per sq cm	
Q4145	EpiFix, injectable, 1 mg	
Q4147	Architect, Architect PX, or Architect FX, extracellular matrix, per sq cm	
Q4148	Neox Cord 1K, Neox Cord RT, or Clarix Cord 1K, per sq cm	
Q4150	AlloWrap DS or dry, per sq cm	
Q4151	AmnioBand or Guardian, per sq cm	
Q4152	DermaPure, per sq cm	
Q4153	Dermavest and Plurivest, per sq cm	
Q4154	Biovance, per sq cm	
Q4155	Neox Flo or Clarix Flo 1 mg	
Q4156	Neox 100 or Clarix 100, per sq cm	
Q4158	Kerecis Omega3, per sq cm	
Q4159	Affinity, per sq cm	
Q4160	Nushield, per sq cm	
Q4161	bio-ConneKt wound matrix, per sq cm	
Q4163	WoundEx, BioSkin, per sq cm	
Q4164	Helicoll, per sq cm	
Q4166	Cytal, per sq cm	
Q4169	Artacent wound, per sq cm	
Q4170	Cygnus, per sq cm	
Q4171	Interfyl, 1 mg	
Q4173	PalinGen or PalinGen XPlus, per sq cm	
Q4175	Miroderm, per sq cm	
Q4178	FlowerAmnioPatch, per sq cm	
Q4180	Revita, per sq cm	
Q4184	Cellesta or Cellesta Duo, per sq cm	
Q4186	Epifix, per sq cm	
Q4187	Epicord, per sq cm	

Q4188	AmnioArmor, per sq cm	
Q4190	Artacent AC, per sq cm	
Q4191	Restorigin, per sq cm	
Q4193	Coll-e-Derm, per sq cm	
Q4194	Novachor, per sq cm	
Q4195	PuraPly, per sq cm	
Q4196	PuraPly AM, per sq cm	
Q4197	PuraPly XT, per sq cm	
Q4199	Cygnus matrix, per sq cm	
Q4201	Matrion, per sq cm	
Q4203	Derma-Gide, per sq cm	
Q4204	XWRAP, per sq cm	
Q4205	Membrane Graft or Membrane Wrap, per sq cm	
Q4217	WoundFix, BioWound, WoundFix Plus, BioWound Plus, WoundFix Xplus or BioWound Xplus, per sq cm	
Q4221	Amnio Wrap2, per sq cm	
Q4222	ProgenaMatrix, per sq cm	
Q4225	Amniobind, per square centimeter	
Q4227	AmnioCore™, per sq cm	
Q4229	Cogenex Amniotic Membrane, per sq cm	
Q4232	Corplex, per sq cm	
Q4234	XCellerate, per sq cm	
Q4235	AMNIOREPAIR or AltiPly, per sq cm	
Q4236	Carepatch, per square centimeter	
Q4238	Derm-Maxx, per sq cm	
Q4239	Amnio-Maxx or Amnio-Maxx Lite, per sq cm	
Q4248	Dermacyte Amniotic Membrane Allograft, per sq cm	
Q4249	AMNIPLY, for topical use only, per sq cm	
Q4250	AmnioAmp-MP, per sq cm	
Q4252	Vendaje, per sq cm	
Q4253	Zenith Amniotic Membrane, per sq cm	
Q4256	Mlg-complete, per square centimeter	
Q4257	Relese, per square centimeter	
Q4258	Enverse, per square centimeter	
Q4259	Celera dual layer or celera dual membrane, per square centimeter	
Q4262	Dual layer impax membrane, per square centimeter	
Q4263	Surgraft tl, per square centimeter	
Q4264	Cocoon membrane, per square centimeter	
Q4265	Neostim tl, per square centimeter	
Q4266	Neostim membrane, per square centimeter	

Q4267	Neostim dl, per square centimeter	
Q4268	Surgraft ft, per square centimeter	
Q4269	Surgraft xt, per square centimeter	
Q4270	Complete sl, per square centimeter	
Q4271	Complete ft, per square centimeter	
Q4274	Esano ac, per square centimeter	
Q4275	Esano aca, per square centimeter	
Q4276	Orion, per square centimeter	
Q4278	Epieffect, per square centimeter	
Q4279	Vendaje ac, per square centimeter	
Q4280	Xcell amnio matrix, per square centimeter	
Q4281	Barrera sl or barrera dl, per square centimeter	
Q4282	Cygnus dual, per square centimeter	
Q4283	Biovance tri-layer or biovance 3l, per square centimeter	
Q4289	Revoshield + amniotic barrier, per square centimeter	
Q4290	Membrane wrap-hydro, per square centimeter	
Q4293	Acesso dl, per square centimeter	
Q4294	Amnio quad-core, per square centimeter	
Q4295	Amnio tri-core amniotic, per square centimeter	
Q4296	Rebound matrix, per square centimeter	
Q4297	Emerge matrix, per square centimeter	
Q4298	Amniocore pro, per square centimeter	
Q4299	Amnicore pro+, per square centimeter	
Q4300	Acesso tl, per square centimeter	
Q4301	Activate matrix, per square centimeter	
Q4302	Complete aca, per square centimeter	
Q4303	Complete aa, per square centimeter	
Q4304	Grafix plus, per square centimeter	
Q4309	Via matrix, per square centimeter	
Q4310	Procenta, per 100 mg	
Q4312	Acesso ac, per square centimeter	
Q4313	Dermabind fm, per square centimeter	
Q4314	Reeva ft, per square centimeter	
Q4316	Amchoplast, per square centimeter	
Q4317	Vitograft, per square centimeter	
Q4319	Sanograft, per square centimeter	
Q4320	Pellograft, per square centimeter	
Q4321	Renograft, per square centimeter	
Q4322	Caregraft, per square centimeter	
Q4323	Alloply, per square centimeter	
Q4325	Acapatch, per square centimeter	

Q4326	Woundplus, per square centimeter	
Q4328	Most, per square centimeter	
Q4331	Axolotl graft, per square centimeter	
Q4332	Axolotl dualgraft, per square centimeter	
Q4339	Artacent vericlen, per square centimeter	
Q4340	Simpligraft, per square centimeter	
Q4341	Simplimax, per square centimeter	
Q4342	Theramend, per square centimeter	
Q4343	Dermacyte ac matrix amniotic membrane allograft, per square centimeter	
Q4344	Tri-membrane wrap, per square centimeter	
Q4345	Matrix hd allograft dermis, per square centimeter	
Q4346	Shelter DM Matrix, per sq cm (add-on, list separately in addition to primary procedure)	
Q4347	Rampart DL Matrix, per sq cm (add-on, list separately in addition to primary procedure)	
Q4348	Sentry SL Matrix, per sq cm (add-on, list separately in addition to primary procedure)	
Q4350	Palisade DM Matrix, per sq cm (add-on, list separately in addition to primary procedure)	
Q4353	Xceed TL Matrix, per sq cm (add-on, list separately in addition to primary procedure)	
Q4355	Abiomend Xplus Membrane and Abiomend Xplus Hydromembrane, per sq cm (add-on, list separately in addition to primary procedure)	
Q4357	XWRAP Plus, per sq cm (add-on, list separately in addition to primary procedure)	
Q4358	XWRAP Dual, per sq cm (add-on, list separately in addition to primary procedure)	
Q4359	ChoriPly, per sq cm (add-on, list separately in addition to primary procedure)	
Q4361	EPIXPRESS, per sq cm (add-on, list separately in addition to primary procedure)	
Q4367	AmnioCore SL, per sq cm (add-on, list separately in addition to primary procedure)	

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://home.ecri.org>. Published September 15, 2015. Updated June 20, 2024.
3. ECRI Institute. Clinical Evidence Assessment. AlloDerm regenerative tissue matrix (AbbVie, Inc.) for breast reconstruction. <https://home.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://home.ecri.org>. Published June 20, 2016. Updated September 23, 2020.
5. ECRI Institute. Clinical Evidence Assessment. AmnioExcel and AmnioExcel Plus (Integra LifeSciences Corp.) for treating diabetic foot ulcers. <https://home.ecri.org>. Published October 22, 2025.
6. ECRI Institute. Clinical Evidence Assessment. Apligraf (Organogenesis, Inc.) for treating venous leg ulcers. <https://home.ecri.org>. Published December 2, 2022. Updated April 11, 2023.
7. ECRI Institute. Clinical Evidence Assessment. Arthroflex acellular dermal matrix (LifeNet Health and Arthrex, Inc.) for repairing large to massive rotator cuff tears. <https://home.ecri.org>. Published October 23, 2017. Updated June 16, 2022.
8. ECRI Institute. Clinical Evidence Assessment. AxoGuard nerve protector (AxoGen, Inc.) for treating peripheral nerve injuries. <https://home.ecri.org>. Published August 9, 2023.
9. ECRI Institute. Clinical Evidence Assessment. Biobrane dressing (Smith & Nephew, Inc.) for treating burns. <https://home.ecri.org>. Published June 4, 2025.
10. ECRI Institute. Clinical Evidence Assessment. Biodesign sinonasal repair graft (Cook Medical, Inc.) for repairing sinus and nasal cavity defects. <https://home.ecri.org>. Published December 9, 2021.
11. ECRI Institute. Clinical Evidence Assessment. Biovance amniotic membrane allograft (Celularity, Inc.) for treating chronic wounds. <https://home.ecri.org>. Published January 3, 2017. Updated July 24, 2020.
12. ECRI Institute. Clinical Evidence Assessment. Cortiva and Cortiva 1 mm allograft dermis (Evergen) for breast reconstruction. <https://home.ecri.org>. Published November 13, 2018. Updated November 24, 2025.
13. ECRI Institute. Clinical Evidence Assessment. Cygnus amniotic allografts (Vivex Medical, Inc.) for treating chronic wounds. <https://home.ecri.org>. Published April 29, 2022.
14. ECRI Institute. Clinical Evidence Assessment. Dermacell advanced decellularized dermis (LifeNet Health Bio-Implants Division) for breast reconstruction. <https://home.ecri.org>. Published August 15, 2016. Updated December 2, 2020.

15. ECRI Institute. Clinical Evidence Assessment. Dermacell AWM (LifeNet Health Bio-Implants Division) for chronic wounds. <https://home.ecri.org>. Published March 8, 2018. Updated December 18, 2020.
16. ECRI Institute. Clinical Evidence Assessment. DermaPure decellularized dermal allograft (ARMS Medical) for treating acute or chronic wounds. <https://home.ecri.org>. Published November 6, 2024.
17. ECRI Institute. Clinical Evidence Assessment. FlexHD pliable acellular hydrated dermis (Musculoskeletal Transplant Foundation) for breast reconstruction. <https://home.ecri.org>. Published October 30, 2015. Updated November 8, 2023.
18. ECRI Institute. Clinical Evidence Assessment. Fortify Flowable extracellular matrix (Sanara Medtech, Inc.) for treating wounds. <https://home.ecri.org>. Published October 3, 2022.
19. ECRI Institute. Clinical Evidence Assessment. GalaFlex surgical scaffold (Galatea Surgical, Inc.) for soft-tissue reinforcement in breast reconstruction surgery. <https://home.ecri.org>. Published October 7, 2022. Updated January 16, 2025.
20. ECRI Institute. Clinical Evidence Assessment. Gentrix surgical matrix (ACell, Inc.) for hiatal hernia repair. <https://home.ecri.org>. Published July 22, 2020.
21. ECRI Institute. Clinical Evidence Assessment. Grafix cellular repair matrix (Osiris Therapeutics, Inc.) for treating chronic wounds. <https://home.ecri.org>. Published November 9, 2012. Updated July 14, 2021.
22. ECRI Institute. Clinical Evidence Assessment. Hyalomatrix tissue reconstruction matrix (Anika Therapeutics, Inc.) for treating chronic wounds. <https://home.ecri.org>. Published June 7, 2018. Updated April 13, 2021.
23. ECRI Institute. Clinical Evidence Assessment. Integra bilayer matrix (Integra LifeSciences Corp.) for treating diabetic foot ulcers. <https://home.ecri.org>. Published April 8, 2021.
24. ECRI Institute. Clinical Evidence Assessment. Kerecis Omega3 (Kerecis LLC) for treating chronic wounds. <https://home.ecri.org>. Published June 1, 2019. Updated January 16, 2025.
25. ECRI Institute. Clinical Evidence Assessment. Leneva allograft adipose matrix (MTF Biologics) for treating wounds. <https://home.ecri.org>. Published October 3, 2022.
26. ECRI Institute. Clinical Evidence Assessment. Matriderm acellular dermal matrix (MedSkin Solutions) for treating burns. <https://home.ecri.org>. Published April 19, 2023.
27. ECRI Institute. Clinical Evidence Assessment. Matriderm (MedSkin Solutions) for managing wounds following otorhinolaryngology surgery. <https://home.ecri.org>. Published April 11, 2022.
28. ECRI Institute. Clinical Evidence Assessment. Mirragen advanced wound matrix (ETS Wound Care LLC) for treating diabetic foot ulcers. <https://home.ecri.org>. Published October 4, 2023.

29. ECRI Institute. Clinical Evidence Assessment. Myriad soft-tissue matrix (Aroa Biosurgery Ltd.) for treating chronic wounds. <https://home.ecri.org>. Published September 21, 2020.
30. ECRI Institute. Clinical Evidence Assessment. Neox Flo wound matrix (AmnioX Medical, Inc.) for treating chronic wounds. <https://home.ecri.org>. Published December 4, 2015. Updated August 27, 2021.
31. ECRI Institute. Clinical Evidence Assessment. NeuraGen 3D nerve guide (Integra LifeSciences) for repairing nerve gap injuries. <https://home.ecri.org>. Published April 28, 2022.
32. ECRI Institute. Clinical Evidence Assessment. NovoSorb biodegradable temporizing matrix (PolyNovo Ltd.) for treating full-thickness wounds. <https://home.ecri.org>. Published May 4, 2023.
33. ECRI Institute. Clinical Evidence Assessment. NuShield placental allograft (Organogenesis, Inc.) for treating burns. <https://home.ecri.org>. Published November 29, 2021.
34. ECRI Institute. Clinical Evidence Assessment. Oasis Wound Matrix (Smith & Nephew, Inc.) for treating burns. <https://home.ecri.org>. Published August 1, 2023.
35. ECRI Institute. Clinical Evidence Assessment. Omega3 wound matrix (Kerecis) for treating burns. <https://home.ecri.org>. Published February 23, 2024.
36. ECRI Institute. Clinical Evidence Assessment. Overview of flowable matrices for treating chronic and acute wounds. <https://home.ecri.org>. Published September 1, 2022.
37. ECRI Institute. Clinical Evidence Assessment. OviTex PRS reinforced tissue matrix (TELA Bio) for breast reconstruction. <https://home.ecri.org>. Published December 13, 2021. Updated September 22, 2025.
38. ECRI Institute. Clinical Evidence Assessment. OviTex reinforced tissue matrix (Tela Bio, Inc.) for hernia repair. <https://home.ecri.org>. Published December 16, 2021. Updated July 24, 2025.
39. ECRI Institute. Clinical Evidence Assessment. PermeaDerm dressing (Avita Medical) for treating burns. <https://home.ecri.org>. Published June 27, 2025.
40. ECRI Institute. Clinical Evidence Assessment. Processed nerve allografts for repairing peripheral nerve gap injuries. <https://home.ecri.org>. Published July 15, 2025.
41. ECRI Institute. Clinical Evidence Assessment. ProLayer acellular dermal matrix (Stryker Corp.) for breast reconstruction. <https://home.ecri.org>. Published March 4, 2021.
42. ECRI Institute. Clinical Evidence Assessment. PuraPly AM antimicrobial wound matrix (Organogenesis, Inc.) for treating chronic wounds. <https://home.ecri.org>. Published November 7, 2018. Updated April 29, 2022.

43. ECRI Institute. Clinical Evidence Assessment. Restrata resorbable wound matrix (Acera Surgical) for treating acute and surgical wounds. <https://home.ecri.org>. Published March 22, 2024.
44. ECRI Institute. Clinical Evidence Assessment. Restrata resorbable wound matrix (Acera Surgical) for treating complex and chronic wounds. <https://home.ecri.org>. Published March 22, 2024.
45. ECRI Institute. Clinical Evidence Assessment. Revita placental allograft (StimLabs, LLC) for treating diabetic foot ulcers. <https://home.ecri.org>. Published March 1, 2022.
46. ECRI Institute. Clinical Evidence Assessment. Skin substitutes for treating acute wounds in patients aged 65 years or older. <https://home.ecri.org>. Published January 15, 2025.
47. ECRI Institute. Clinical Evidence Assessment. Skin substitutes for treating burns in patients aged 65 years or older. <https://home.ecri.org>. Published January 23, 2025.
48. ECRI Institute. Clinical Evidence Assessment. Skin substitutes for treating diabetic foot ulcers in patients aged 65 years or older. <https://home.ecri.org>. Published January 25, 2021.
49. ECRI Institute. Clinical Evidence Assessment. Skin substitutes for treating pressure injuries in patients aged 65 years or older. <https://home.ecri.org>. Published October 29, 2024.
50. ECRI Institute. Clinical Evidence Assessment. Standard-of-care practices for managing diabetic foot ulcers. <https://home.ecri.org>. Published January 28, 2020. Updated December 31, 2021.
51. ECRI Institute. Clinical Evidence Assessment. StrataGraft allogeneic cellularized scaffold (Mallinckrodt Pharmaceuticals) for treating thermal burns. <https://home.ecri.org>. Published February 6, 2022.
52. ECRI Institute. Clinical Evidence Assessment. Stravix cryopreserved placental tissue (Osiris Therapeutics, Inc.) for treating surgical wounds. <https://home.ecri.org>. Published July 8, 2021.
53. ECRI Institute. Clinical Evidence Assessment. Suprathel skin substitute (PolyMedics Innovations GmbH) for treating burns. <https://home.ecri.org>. Published April 25, 2023.
54. ECRI Institute. Clinical Evidence Assessment. Suprathel skin substitute (PolyMedics Innovations GmbH) for treating donor site wounds. <https://home.ecri.org>. Published February 22, 2021.
55. ECRI Institute. Clinical Evidence Assessment. SurgiMend collagen matrix (Integra LifeSciences Corp.) for breast reconstruction. <https://home.ecri.org>. Published November 14, 2019. Updated May 4, 2021.
56. ECRI Institute. Clinical Evidence Assessment. TheraGenesis bilayer wound matrix (Gunze International USA, Inc.) for treating partial- and full-thickness wounds. <https://home.ecri.org>. Published February 22, 2023.

57. ECRI Institute. Hotline Response. Skin substitutes for managing pilonidal disease excision wounds. <https://home.ecri.org>. Published March 31, 2020.
58. ECRI Institute. Hotline Response. Synthetic versus biologic mesh for abdominal wall reconstructive surgery. <https://home.ecri.org>. Published October 15, 2015. Updated November 13, 2019.
59. ECRI Institute. Product Brief. AlloMax surgical graft (C.R. Bard, Inc./Davol, Inc.) for reconstructive surgery. <https://home.ecri.org>. Published October 9, 2015. Updated July 25, 2016.
60. ECRI Institute. Product Brief. AlloPatch HD acellular dermal matrix (Musculoskeletal Transplant Foundation) for repairing rotator cuff tears. <https://home.ecri.org>. Published October 23, 2017.
61. ECRI Institute. Product Brief. AmnioFix amnion/chorion membrane allograft (MiMedx) for treating surgical wounds. <https://home.ecri.org>. Published April 14, 2015. Updated May 10, 2019.
62. ECRI Institute. Product Brief. Biodesign dural graft (Cook Medical) for repairing dural tears. <https://home.ecri.org>. Published August 26, 2015.
63. ECRI Institute. Product Brief. Biodesign hernia graft (Cook Biotech, Inc.) for reconstructive surgery. <https://home.ecri.org>. Published July 20, 2016.
64. ECRI Institute. Product Brief. Biodesign nipple reconstruction cylinder (Cook Medical) for plastic surgery. <https://home.ecri.org>. Published April 5, 2018.
65. ECRI Institute. Product Brief. Biodesign otologic repair graft (Cook Medical) for tympanic reconstruction. <https://home.ecri.org>. Published January 22, 2018.
66. ECRI Institute. Product Brief. BioDFactor viable tissue matrix (Integra LifeSciences) for treating surgical and chronic wounds. <https://home.ecri.org>. Published September 24, 2018.
67. ECRI Institute. Product Brief. CopiOs pericardium membrane (Zimmer Dental, Inc.) for use during oral surgery. <https://home.ecri.org>. Published February 6, 2017.
68. ECRI Institute. Product Brief. Cytal wound matrix (ACell, Inc.) for treating acute and chronic wounds. <https://home.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://home.ecri.org>. Published February 6, 2020.
70. ECRI Institute. Product Brief. EpiFix amnion/chorion membrane allograft (MiMedx) for treating chronic wounds. <https://home.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://home.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://home.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://home.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://home.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://home.ecri.org>. Published May 1, 2018.
76. ECRI Institute. Product Brief. MatriStem MicroMatrix (ACell, Inc.) for treating surgical and chronic wounds. <https://home.ecri.org>. Published August 28, 2018.
77. ECRI Institute. Product Brief. NuShield placental allograft (Nutech Medical) for use in chronic and surgical wounds. <https://home.ecri.org>. Published September 15, 2015.
78. ECRI Institute. Product Brief. Oasis wound matrix (Smith & Nephew, Inc.) for treating surgical and chronic wounds. <https://home.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://home.ecri.org>. Published July 25, 2016.
80. ECRI Institute. Product Brief. PriMatrix dermal repair scaffold (Integra LifeSciences Corp.) for treating chronic wounds. <https://home.ecri.org>. Published July 25, 2016. Updated October 31, 2019.
81. ECRI Institute. Product Brief. Promogran Prisma Matrix (Acelyty L.P., Inc.) for promoting surgical wound healing. <https://home.ecri.org>. Published August 22, 2018.
82. ECRI Institute. Product Brief. Strattice reconstructive tissue matrix (Allergan plc) for breast reconstruction. <https://home.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://home.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://home.ecri.org>. Published October 5, 2018. Updated April 1, 2019.
85. ECRI Institute. Product Brief. XCM biologic tissue matrix (Ethicon US, LLC/DePuy Synthes) for reconstructive surgery. <https://home.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://home.ecri.org>. Published December 5, 2019.

87. ECRI Institute. Product Brief. XenMatrix Surgical Grafts (C.R. Bard, Inc./Davol, Inc.) for reconstructive surgery. <https://home.ecri.org>. Published October 30, 2015. Updated July 25, 2016.
88. Hayes, Inc. Clinical Research Response. Leneva allograft adipose matrix (MTF Biologics) for treatment of wounds. <https://evidence.hayesinc.com>. Published January 16, 2025.
89. Hayes, Inc. Clinical Research Response. SimpliDerm acellular dermal matrix (Elutia). <https://evidence.hayesinc.com>. Published December 8, 2023.
90. Hayes, Inc. Emerging Technology Report. SkinTE (PolarityBio) for diabetic foot ulcers. <https://evidence.hayesinc.com>. Published October 21, 2025.
91. 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.
92. Hayes, Inc. Evidence Analysis Research Brief. AmnioBind placental membrane allograft (Pipeline Healthcare Solutions) for wound management. <https://evidence.hayesinc.com>. Published December 29, 2023.
93. Hayes, Inc. Evidence Analysis Research Brief. Apis wound dressing (SweetBio Inc.) for treatment of wounds. <https://evidence.hayesinc.com>. Published February 3, 2023.
94. Hayes, Inc. Evidence Analysis Research Brief. Artacent Flex (Tides Medical) for treatment of wounds. <https://evidence.hayesinc.com>. Published December 29, 2023.
95. 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.
96. 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.
97. Hayes, Inc. Evidence Analysis Research Brief. carePatch (Extremity Care) for treatment of wounds. <https://evidence.hayesinc.com>. Published March 12, 2024.
98. 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.
99. Hayes, Inc. Evidence Analysis Research Brief. Cygnus Matrix (Vivex Biologics) for wound management. <https://evidence.hayesinc.com>. Published March 6, 2023.
100. Hayes, Inc. Evidence Analysis Research Brief. Dermaspan (Biomet Orthopedics) for management of musculoskeletal indications. <https://evidence.hayesinc.com>. Published September 12, 2023.

101. Hayes, Inc. Evidence Analysis Research Brief. Enverse (StimLabs LLC) for treatment of wounds. <https://evidence.hayesinc.com>. Published July 25, 2023.
102. Hayes, Inc. Evidence Analysis Research Brief. FlowerPatch (Conventus Flower Orthopedics) for treatment of wounds. <https://evidence.hayesinc.com>. Published January 18, 2024.
103. 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.
104. 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.
105. Hayes, Inc. Evidence Analysis Research Brief. InnovaMatrix AC (Triad Life Sciences Inc.) for treatment of wounds. <https://evidence.hayesinc.com>. Published January 20, 2023.
106. Hayes, Inc. Evidence Analysis Research Brief. InnovaMatrix FS (Triad Life Sciences Inc.) for treatment of wounds. <https://evidence.hayesinc.com>. Published July 25, 2023.
107. Hayes, Inc. Evidence Analysis Research Brief. InteguPly (PuraGraft) for management of musculoskeletal indications. <https://evidence.hayesinc.com>. Published September 29, 2023.
108. Hayes, Inc. Evidence Analysis Research Brief. MemoDerm (Stryker) for management of musculoskeletal indications. <https://evidence.hayesinc.com>. Published September 19, 2023.
109. Hayes, Inc. Evidence Analysis Research Brief. Microlyte Matrix (Imbed Biosciences) for treatment of wounds. <https://evidence.hayesinc.com>. Published March 20, 2023.
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. Omeza Collagen Matrix (Omeza) for treatment of wounds. <https://evidence.hayesinc.com>. Published December 1, 2023.
112. Hayes, Inc. Evidence Analysis Research Brief. PermeaDerm products (Stedical Scientific) for treatment of wounds. <https://evidence.hayesinc.com>. Published February 1, 2024.
113. Hayes, Inc. Evidence Analysis Research Brief. Phoenix Wound Matrix (RenovoDerm) for treatment of wounds. <https://evidence.hayesinc.com>. Published February 1, 2024.
114. 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.
115. Hayes, Inc. Evidence Analysis Research Brief. Release (StimLabs LLC) for treatment of wounds. <https://evidence.hayesinc.com>. Published April 28, 2023.

116. Hayes, Inc. Evidence Analysis Research Brief. Restrata (Acera Surgical Inc.) for wound management. <https://evidence.hayesinc.com>. Published February 3, 2023.
117. Hayes, Inc. Evidence Analysis Research Brief. Signature APatch (Signature Biologics) for treatment of wounds. <https://evidence.hayesinc.com>. Published February 26, 2024.
118. Hayes, Inc. Evidence Analysis Research Brief. Skin substitutes for treatment of acute wounds. <https://evidence.hayesinc.com>. Published January 31, 2024.
119. Hayes, Inc. Evidence Analysis Research Brief. Supra SDRM (PolyMedics Innovations Inc.). <https://evidence.hayesinc.com>. Published July 25, 2023.
120. Hayes, Inc. Evidence Analysis Research Brief. Suprathel (PolyMedics Innovations Inc.) for wound management. <https://evidence.hayesinc.com>. Published August 22, 2023.
121. Hayes, Inc. Evidence Analysis Research Brief. SurgiMend (Integra Life Sciences) for postmastectomy breast reconstruction. <https://evidence.hayesinc.com>. Published March 24, 2023.
122. Hayes, Inc. Evidence Analysis Research Brief. SurGraft TL (Surgenex LLC) for treatment of wounds. <https://evidence.hayesinc.com>. Published February 21, 2024.
123. Hayes, Inc. Evidence Analysis Research Brief. Symphony (Aroa Biosurgery Ltd.) for treatment of wounds. <https://evidence.hayesinc.com>. Published March 21, 2023.
124. Hayes, Inc. Evidence Analysis Research Brief. TheraGenesis (Bioventus LLC) for treatment of wounds. <https://evidence.hayesinc.com>. Published March 21, 2023.
125. Hayes, Inc. Evidence Analysis Research Brief. Vendaje (BioStem Technologies) for wound management. <https://evidence.hayesinc.com>. Published March 14, 2023.
126. 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.
127. Hayes, Inc. Evidence Analysis Research Brief. XCelliStem wound powder (Stemsys) for treatment of wounds. <https://evidence.hayesinc.com>. Published January 19, 2023.
128. Hayes, Inc. Evidence Analysis Research Brief. Zenith amniotic membrane (Legacy Medical Consultants) for wound management. <https://evidence.hayesinc.com>. Published March 6, 2023.
129. Hayes, Inc. Evolving Evidence Review. Kerecis Omega3 wound (Kerecis) fish skin grafts for management of burns. <https://evidence.hayesinc.com>. Published February 22, 2024. Updated February 26, 2025.

130. 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. Updated February 21, 2025.
131. 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 February 5, 2025.
132. 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.
133. 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.
134. Hayes, Inc. Health Technology Assessment. Amniotic allografts for tendon and ligament injuries. <https://evidence.hayesinc.com>. Published September 16, 2020. Updated August 29, 2023.
135. 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.
136. 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.
137. 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.
138. 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.
139. 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.
140. 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.
141. 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.

142. 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.
143. 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.
144. Hayes, Inc. Medical Technology Directory. Synthetic tissue for dural repair. <https://evidence.hayesinc.com>. Published May 14, 2015. Updated June 11, 2019.
145. National Pressure Injury Advisory Panel (NPIAP). The International Guideline. Prevention and treatment of pressure ulcers/injuries: quick reference guide prevention recommendations. <https://npiap.com>. Published 2009. Updated February 25, 2025.
146. Society for Vascular Surgery (SVS). Clinical Practice Guidelines of the Society for Vascular Surgery and the American Venous Forum (ARCHIVED). Management of venous leg ulcers. <https://ivascsurg.org>. Published August 2014.
147. UpToDate, Inc. Basic principles of wound healing. <https://uptodate.com>. Updated October 2025.
148. UpToDate, Inc. Evaluation and management of chronic venous insufficiency including venous leg ulcer. <https://uptodate.com>. Updated October 2025.
149. UpToDate, Inc. Implant-based breast reconstruction and augmentation. <https://uptodate.com>. Updated October 2025.
150. UpToDate, Inc. Local care of diabetic foot ulcers. <https://uptodate.com>. Updated October 2025.
151. UpToDate, Inc. Operative management of anorectal fistulas. <https://uptodate.com>. Updated October 2025.
152. UpToDate, Inc. Overview of surgical procedures used in the management of burn injuries. <https://uptodate.com>. Updated October 7, 2025.
153. UpToDate, Inc. Overview of treatment of chronic wounds. <https://uptodate.com>. Updated October 13, 2025.
154. UpToDate, Inc. Principles of acute wound management. <https://uptodate.com>. Updated October 2025.
155. UpToDate, Inc. Skin substitutes. <https://uptodate.com>. Updated October 2025.
156. UpToDate, Inc. Topical agents and dressings for local burn wound care. <https://uptodate.com>. Updated October 2025.

157. 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.

Change Summary

02/03/2026 Annual Review, Coverage Change. Updated Coding Information Policy ID change from [HUM-2208]