

Medical Coverage Policy

Policy Number – MP21-004E

Revised Effective Date – 04/24/2024

Bioengineered skin substitutes

Definition

Bioengineered skin and soft tissue substitutes 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.

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

The tissue may be used for a variety of conditions and procedures including breast reconstruction, healing of lower extremity ulcers (e.g., diabetic ulcers, venous stasis ulcers), ocular defects, plantar fasciitis, surgical wounds and treatment of severe burns.

Policy statement

Disclaimer: This policy is applicable to TRICARE Prime and Select beneficiaries and may not apply to Active Duty Service Members (ADSM) under Supplemental Health Care Program (SHCP) or TRICARE Prime Remote (TPR) in accordance with TRICARE Operations Manual (TOM) Chapter 17, Section 3. Please review TOM Chapter 17, Section 3, Paragraph 2.0 onwards, regarding SHCP coverage and any TRICARE-specific exclusions included in this coverage policy to accurately determine the benefit for ADSMs.

Bioengineered skin substitutes may be considered medically necessary for the following conditions:

- I. Chronic, non-healing diabetic or venous stasis [ulcers](#) which meet all the following conditions:
 - a. Refractory to at least four weeks of conventional treatment
 - b. No signs of infection at the site
- II. Full thickness or partial thickness [burns](#), both during acute care and repair of scar contractures
- III. Acellular dermal matrices may be considered medically necessary when used during a covered [breast reconstruction](#) in one of the following conditions:
 - a. Insufficient tissue expander or implant coverage by the pectoralis major muscle and additional coverage is required; or
 - b. There is viable, but compromised or thin post-mastectomy skin flaps that are at risk of dehiscence or necrosis; or
 - c. The infra-mammary fold and lateral mammary folds have been undermined during mastectomy and re-establishment of these landmarks are needed.

Limitations of coverage

- I. All other indications not listed above will be subject to medical necessity review and may be considered [uncovered](#) due to insufficient evidence of clinical efficacy.
- II. Amniotic membrane/fluid allografts are not covered for the treatment of pain and inflammation due to insufficient evidence of clinical efficacy.
- III. Amniotic membrane/fluid allografts are not covered for the treatment of osteoarthritis due to insufficient evidence of clinical efficacy.

TRICARE Policy Manual (TPM)**TPM Chapter 4, section 5.1**

4.2 Topical Treatment of Skin Ulcers Caused by Venous Insufficiency. Topical application of Alpigraf by a physician for the treatment of skin ulcers caused by venous insufficiency is a covered benefit.

4.3 Topical Treatment of Diabetic Foot Ulcers.

4.3.1 Application of tissue cultured skin grafts for diabetic foot ulcers is a covered benefit.

TPM Chapter 4, section 5.2

3.8 Acellular allograft is a covered benefit, effective July 8, 2008, when used in a covered breast reconstruction surgery for women who have any of the following indications:

3.8.1 Have insufficient tissue expander or implant coverage by the pectoralis major muscle and additional coverage is required; or

3.8.2 There is viable, but compromised or thin post-mastectomy skin flaps that are at risk of dehiscence or necrosis; or

3.8.3 The infra-mammary fold and lateral mammary folds have been undermined during mastectomy and re-establishment of these landmarks are needed.

TPM, CHAPTER 1, SECTION 2.1, SUBSECTIONS 2.3, 2.4 1.0

1.0 A drug, device, medical treatment, or procedure is unproven:

2.3 Unless reliable evidence shows that any medical treatment or procedure has been the subject of well-controlled studies of clinically meaningful endpoints, which have determined its maximum tolerated dose, its toxicity, its safety, and its efficacy as compared with standard means of treatment or diagnosis.

2.4 If the reliable evidence shows that the consensus among experts regarding the medical treatment or procedure is that further studies or clinical trials are necessary to determine its maximum tolerated dose, its toxicity, its safety, or its effectiveness as compared with the standard means of treatment or diagnosis.

Coding information

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 (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
Q4108	Integra matrix, per sq cm
Q4110	PriMatrix, per sq cm
Q4111	GammaGraft, per sq cm
Q4112	Cymetra, injectable, 1 cc
Q4113	Graftjacket Xpress, injectable, 1 cc
Q4114	Integra flowable wound matrix, injectable, 1 cc
Q4115	AlloSkin, per sq cm
Q4116	AlloDerm, per sq cm
Q4117	Hyalomatrix per sq cm
Q4118	Matristem micromatrix, 1 mg
Q4121	TheraSkin, per sq cm
Q4122	DermACELL, DermACELL AWM or DermACELL AWM Porous, per sq cm
Q4123	AlloSkin RT, per sq cm
Q4124	Oasis ultra tri-layer wound matrix, per sq cm
Q4125	ArthroFlex, per sq cm
Q4126	MemoDerm, DermaSpan, TranZgraft or InteguPly, per sq cm
Q4127	Talymed, per sq cm
Q4128	FlexHD, AllopatchHD, or MatrixHD, per sq cm
Q4130	Strattice TM, per sq cm
Q4132	Grafix Core and GrafixPL Core, per sq cm
Q4133	Grafix Prime, GrafixPL Prime, Stravix and StravixPL, per sq cm
Q4134	HMatrix, per sq cm
Q4135	Mediskin, per sq cm
Q4136	E-Z Derm, per sq cm
Q4137	AmnioExcel, AmnioExcel Plus or BioDExcel, per sq cm
Q4138	BioDFence DryFlex, per sq cm
Q4139	AmnioMatrix or BioDMatrix, injectable, 1 cc
Q4140	BioDFence, per sq cm
Q4141	AlloSkin AC, per sq cm
Q4142	XCM biologic tissue matrix, per sq cm
Q4143	Repriza, per sq cm
Q4145	EpiFix, injectable, 1 mg
Q4146	Tensix, per sq cm
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
Q4149	Excellagen, 0.1 cc
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 1mg
Q4156	Neox 100 or Clarix 100, per sq cm
Q4157	Revitalon, 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
Q4162	WoundEx Flow, BioSkin Flow, 0.5 cc
Q4163	WoundEx, BioSkin, per sq cm
Q4164	Helicoll, per sq cm
Q4165	Keramatrix or Kerasorb, per sq cm
Q4166	Cytal, per sq cm
Q4167	Truskin, per sq cm
Q4168	AmnioBand, 1 mg
Q4169	Artacent wound, per sq cm
Q4170	Cygnus, per sq cm
Q4171	Interfyl, 1 mg
Q4173	PalinGen or PalinGen XPlus, per sq cm
Q4174	PalinGen or ProMatrX, 0.36 mg per 0.25 cc
Q4175	Miroderm, per sq cm
Q4176	Neopatch or Therion, 1 sq cm
Q4177	FlowerAmnioFlo, 0.1 cc
Q4178	FlowerAmnioPatch, per sq cm
Q4179	FlowerDerm, per sq cm
Q4180	Revita, per sq cm
Q4181	Amnio Wound, per sq cm
Q4182	Transcyte, per sq cm
Q4183	Surgigraft, per sq cm
Q4184	Cellesta or Cellesta Duo, per sq cm
Q4185	Epifix, per sq cm
Q4186	Epicord, per sq cm
Q4187	Epicord, per sq cm
Q4188	AmnioArmor, per sq cm
Q4189	Artacent AC, 1 mg
Q4190	Artacent AC, per sq cm
Q4191	Restorigin, per sq cm
Q4192	Restorigin, 1 cc
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
Q4198	Genesis Amniotic Membrane, per sq cm
Q4200	SkinTE, per sq cm
Q4201	Matrion, per sq cm
Q4202	Keroxx (2.5 g/cc), 1 cc
Q4203	Derma-Gide, per sq cm
Q4204	XWrap, per sq cm
Q4205	Membrane Graft or Membrane Wrap, per sq cm
Q4206	Fluid Flow or Fluid GF, 1 cc
Q4208	Novafix, per sq cm
Q4209	SurGraft, per sq cm
Q4210	Axolotl Graft or Axolotl DualGraft, per sq cm
Q4211	Amnion Bio or AxoBioMembrane, per sq cm
Q4212	AlloGen, per cc
Q4213	Ascent, 0.5 mg

Q4214	Cellesta Cord, per sq cm
Q4215	Axolotl Ambient or Axolotl Cryo, 0.1 mg
Q4216	Artacent Cord, per sq cm
Q4217	WoundFix, BioWound, WoundFix Plus, BioWound Plus, WoundFix Xplus or BioWound Xplus, per sq cm
Q4218	SurgiCord, per sq cm
Q4219	SurgiGraft-Dual, per sq cm
Q4220	BellaCell HD or Surederm, per sq cm
Q4221	AmnioWrap2, per sq cm
Q4222	ProgenaMatrix, per sq cm
Q4226	MyOwn Skin, includes harvesting and preparation procedures, per sq cm
Q4227	AmnioCoreTM, per sq cm
Q4228	BioNextPatch, per sq cm
Q4229	Cogenex Amniotic Membrane, per sq cm
Q4230	Cogenex Flowable Amnion, per 0.5 cc
Q4231	Corplex P, per cc
Q4232	Corplex, per sq cm
Q4233	surFactor or NyDyn, per 0.5 cc
Q4234	XCellerate, per sq cm
Q4235	Amniorepair or AltiPly, per sq cm
Q4236	carePatch, per sq cm
Q4237	Cryo-Cord, per sq cm
Q4238	Derm-Maxx, per sq cm
Q4239	Amnio-Maxx or Amnio-Maxx Lite, per sq cm
Q4240	CoreCyte, for topical use only, per 0/5 cc
Q4241	PolyCyte, for topical use only, per 0.5 cc
Q4242	AmnioCyte Plus, per 0.5 cc
Q4244	Procenta, per 200 mg
Q4245	AmnioText, per cc
Q4246	CoreText or ProText, per cc
Q4247	Amniotext patch, per sq cm
Q4248	Dermacyte Amniotic Membrane Allograft, per sq cm
Q4249	Amniplly, for topical use only, per sq cm
Q4250	AmnioAmp-MP, per sq cm
Q4251	Vim, per sq cm
Q4252	Vendaje per sq cm
Q4253	Zenith amniotic membrane, per sq cm
Q4254	NovaFix DL, per sq cm
Q4255	Reguard, for topical use only, per sq cm
Q4256	MLG-Complete, per sq cm
Q4257	Relese, per sq cm
Q4258	Enverse, per sq cm
Q4259	Celera dual layer or celera dual membrane, per sq cm
Q4260	Signature apatch, per sq cm
Q4261	Tag, per sq cm
Q4262	Dual layer impax membrane, per sq cm

Q4263	Surgraft tl, per sq cm
Q4264	Cocoon membrane, per sq cm
Q4265	Neostim tl, per sq cm
Q4266	Neostim membrane, per sq cm
Q4267	Neostim dl, per sq cm
Q4268	Surgraft ft, per sq cm
Q4269	Surgraft xt, per sq cm
Q4270	Complete sl, per sq cm
Q4271	Complete ft, per sq cm
Q4272	Esano a, per square centimeter
Q4273	Esano aaa, per square centimeter
Q4274	Esano ac, per square centimeter
Q4275	Esano aca, per square centimeter
Q4276	Orion, per square centimeter
Q4277	Woundplus membrane or e-graft, 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
Q4284	Dermabind sl, per square centimeter
Q4285	Nudyn dl or nudyn dl mesh, per square centimeter
Q4286	Nudyn sl or nydyn slw, per square centimeter
Q4287	Dermabind dl, per square centimeter
Q4288	Dermabind ch, per square centimeter
Q4289	Revoshield + amniotic barrier, per square centimeter
Q4290	Membrane wrap-hydro, per square centimeter

Q4291	Lamellas xt, per square centimeter
Q4292	Lamellas, 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	Amniocore 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
Q4305	American amnion ac tri-layer, per square centimeter
Q4306	American amnion ac, per square centimeter
Q4307	American amnion, per square centimeter
Q4308	Sanopellis, per square centimeter
Q4309	Via matrix, per square centimeter
Q4310	Procenta, per 100 mg
V2790	Amniotic membrane for surgical reconstruction, per procedure

References

1. TPM Chapter 4 [TRICARE Manuals - Manual Information \(health.mil\)](https://www.health.mil/TPM/Manuals/Manual%20Information)
2. TPM Chapter 1
3. Uptodate Inc. Skin Substitutes. Last updated 08/02/2023
4. Hayes Inc. Amniotic Allografts for the Treatment of Knee Osteoarthritis. Last updated 09/01/2021
5. Hayes Inc. Amniotic Allografts for Tendon and Ligament Injuries. Last updates 09/09/2022

Revision History

April 2024: Updated coding and references

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Approved by:



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