PREMERA HMO

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MEDICAL POLICY – 7.01.583

Amniotic Membrane and Amniotic Fluid

BCBSA Ref. Policy:	7.01.149
Effective Date:	May 1, 2023
Last Revised:	April 1, 2024
Replaces:	N/A

RELATED MEDICAL POLICIES:

2.01.16	Recombinant and Autologous Platelet-Derived Growth Factors for Wound Healing and Other Non-Orthopedic Conditions
7.01.113	Bioengineered Skin and Soft Tissue Substitutes
8.01.52	Orthopedic Applications of Stem Cell Therapy (Including Allografts and Bone Substitutes Used with Autologous Bone Marrow)

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

The amniotic membrane and amniotic fluid are structures that surround the fetus in the uterus (womb). The fluid protects the fetus from injury. The membrane is a thin mesh of protein and contains growth factors, stem cells, and other items crucial to a developing fetus. Processing and then using the amniotic membrane and/or fluid (after delivery), has been proposed to treat a number of conditions in adults. High quality medical studies show that using specific amniotic membrane products may be useful for treating diabetic ulcers in some cases, for specific eye conditions, and for a disorder known as Stevens-Johnson syndrome. This policy describes when these products may be considered medically necessary. Using amniotic membrane for other conditions or using amniotic fluid products is considered unproven (investigational).

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Service	Medical Necessity
Treatment of nonhealing diabetic lower-extremity ulcers	**Treatment of nonhealing* diabetic lower-extremity ulcers using the following human amniotic membrane products may be considered medically necessary:** • Affinity • AmnioBand Membrane • Biovance • EpiCord • Epifix • Grafix ***Note:** Nonhealing is defined as less than a 20% decrease in wound area with standard wound care for at least 2 weeks based on the entry criteria for clinical trials (e.g., Zelen et al, 2015). **When the above medical necessity criteria are met, the following conditions of coverage will apply:** • Treatment is limited to a maximum of 6 applications in 12 weeks when evidence of wound healing is present **Graft applications that exceed what is reasonable and necessary as size-appropriate based on the size of the wound are considered not medically necessary (see Related Information).** **Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status.**
Human amniotic membrane grafts for ophthalmic indications	**Human amniotic membrane grafts with or without suture (Prokera, AmbioDisk) or glue may be considered medically necessary for the treatment of ophthalmic conditions.**

Service	Investigational
Injection of micronized or particulated human amniotic membrane	**Injection of micronized or particulated human amniotic membrane is considered investigational for all indications, including but not limited to treatment of:**

Service	Investigational
	• Osteoarthritis • Plantar fasciitis
Injection of human amniotic fluid	**Injection of human amniotic fluid is considered investigational for all indications.**
All other human amniotic products	**All other human amniotic products (e.g., derived from amnion, chorion, amniotic fluid, umbilical cord, or Wharton's jelly) not listed above are considered investigational**
Other indications	**All other indications not listed above are considered investigational, including but not limited to, treatment of lower extremity ulcers due to venous insufficiency and repair following Mohs micrographic surgery.**
All other human amnionic membrane products	**All other human amniotic membrane products not listed above are considered investigational, including but not limited to, those listed in the Coding section of this policy in the Investigational (Not Eligible for Coverage) subsection.**

Note: HRT: Human Regenerative Technologies; MTF Musculoskeletal Transplant Foundation

[a] Processed by HRT and marketed under different tradename

Documentation Requirements
The individual's medical records submitted for review should document that medical necessity criteria are met. The record should include clinical documentation of: • Diagnosis/condition • History and physical examination documenting the severity of the condition • Name of product to be used • Previous therapy attempted and for how long • The size (measurements) of the affected area to be treated

Coding

Code	Description
HCPCS	
Reviewed for Medical Necessity	

Code	Description
Q4132	Grafix Core and GrafixPL Core, per sq cm
Q4133	Grafix PRIME, GrafixPL PRIME, Stravix and StravixPL, per square centimeter
Q4151	AmnioBand or Guardian, per sq cm
Q4154	Biovance, per sq cm
Q4159	Affinity, per sq cm
Q4186	Epifix, per square centimeter
Q4187	EpiCord, per square centimeter
Investigational (Not Eligible for Coverage)	
Q4100	Skin substitute, not otherwise specified (e.g., AmnioFix)
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
Q4145	EpiFix, injectable, 1 mg
Q4148	Neox Cord 1k, Neox Cord-RT, or Clarix Cord 1K, per sq cm
Q4150	AlloWrap DS or dry, per square centimeter
Q4153	Dermavest and Plurivest, per sq cm
Q4155	NeoxFlo or Clarix Flo, 1 mg
Q4156	Neox 100 or Clarix 100, per sq cm (e.g., NeoxWound)
Q4157	Revitalon, per sq cm
Q4160	Nushield, per sq cm
Q4162	WoundEx Flow, BioSkin Flow, 0.5 cc (e.g., BioSkin)
Q4163	WoundEx,, BioSkin,, per sq cm
Q4168	AmnioBand, 1 mg (Particulate)
Q4169	Artacent Wound, per sq cm

Code	Description
Q4170	Cygnus per sq cm
Q4171	Interfyl, 1 mg
Q4173	PalinGen or PalinGen XPlus, per sq cm (e.g., PalinGen Membrane)
Q4174	PalinGen or ProMatrX, 0.36 mg per 0.25 cc (e.g., PalinGen SportFlow, ProMatrX liquid)
Q4176	Neopatch or Therion, per square centimeter
Q4177	FlowerAmnioFlo, 0.1 cc
Q4178	FlowerAmnioPatch, per sq cm
Q4180	Revita, per sq cm
Q4181	Amnio Wound, per sq cm
Q4183	SurgiGRAFT, per square centimeter
Q4184	Cellesta or Cellesta Duo, per square centimeter
Q4185	Cellesta flowable amnion (25 mg per cc); per 0.5 cc
Q4188	AmnioArmor, per square centimeter
Q4189	Artacent AC, 1 mg (flowable)
Q4190	Artacent AC, per square centimeter (patch)
Q4191	Restorigin, per square centimeter
Q4192	Restorigin, 1 cc (injectable)
Q4194	Novachor, per square centimeter
Q4198	Genesis Amniotic Membrane, per square centimeter
Q4199	Cygnus Matrix, per sq cm
Q4201	Matrion, per sq cm
Q4202	Keroxx (2.5 g/cc), 1 cc
Q4204	XWRAP, per square centimeter
Q4205	Membrane Graft or Membrane Wrap, per sq cm
Q4206	Fluid Flow or Fluid GF, 1 cc

Code	Description
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
Q4221	Amnio Wrap2, per sq cm
Q4224	Human Health Factor 10 amniotic patch (hhf10-p), per square centimeter
Q4225	AmnioBind, per square centimeter
Q4227	AmnioCore 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 NuDyn, 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

Code	Description
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 (e.g., AmnioCyte)
Q4244	Procenta, per 200 mg (code termed effective 4/1/2024)
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	Amniply, for topical use only, per square centimeter
Q4250	AmnioAmp-MPMP, per square centimeter
Q4251	Vim, per sq cm
Q4252	Vendaje, per sq cm
Q4253	Zenith Amniotic Membrane, per sq cm
Q4254	Novafix DL, per square centimeter
Q4255	REGUaRD, for topical use only, per square centimeter
Q4256	MLG-CompleteTM, per square centimeter
Q4257	Release, per square centimeter
Q4258	Enverse, per square centimeter
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 square centimeter

Code	Description
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
Q4272	Esano a, per square centimeter (new code effective 7/1/2023)
Q4273	Esano aaa, per square centimeter (new code effective 7/1/2023)
Q4274	Esano ac, per square centimeter (new code effective 7/1/2023)
Q4275	Esano aca, per square centimeter (new code effective 7/1/2023)
Q4276	Orion, per square centimeter (new code effective 7/1/2023)
Q4277	Woundplus membrane or e-graft, per square centimeter (new code effective 7/1/2023)
Q4278	Epieffect, per square centimeter (new code effective 7/1/2023)
Q4279	Vendaje AC, per sq cm (new code effective 1/1/2024)
Q4280	Xcell amnio matrix, per square centimeter (new code effective 7/1/2023)
Q4281	Barrera sl or barrera dl, per square centimeter (new code effective 7/1/2023)
Q4282	Cygnus dual, per square centimeter (new code effective 7/1/2023)
Q4283	Biovance tri-layer or biovance 3l, per square centimeter (new code effective 7/1/2023)
Q4284	Dermabind sl, per square centimeter (new code effective 7/1/2023)
Q4285	Nudyn dl or nudyn dl mesh, per square centimeter (new code effective 10/1/2023)
Q4286	Nudyn sl or nudyn slw, per square centimeter (new code effective 10/1/2023)
Q4287	DermaBind DL, per sq cm (new code effective 1/1/2024)
Q4288	DermaBind CH, per sq cm (new code effective 1/1/2024)
Q4289	RevoShield+ Amniotic Barrier, per sq cm (new code effective 1/1/2024)
Q4290	Membrane Wrap-Hydro™, per sq cm (new code effective 1/1/2024)
Q4291	Lamellas XT, per sq cm (new code effective 1/1/2024)

Code	Description
Q4292	Lamellas, per sq cm (new code effective 1/1/2024)
Q4293	Acesso DL, per sq cm (new code effective 1/1/2024)
Q4294	Amnio Quad-Core, per sq cm (new code effective 1/1/2024)
Q4295	Amnio Tri-Core Amniotic, per sq cm (new code effective 1/1/2024)
Q4296	Rebound Matrix, per sq cm (new code effective 1/1/2024)
Q4297	Emerge Matrix, per sq cm (new code effective 1/1/2024)
Q4298	AmniCore Pro, per sq cm (new code effective 1/1/2024)
Q4299	AmniCore Pro+, per sq cm (new code effective 1/1/2024)
Q4300	Acesso TL, per sq cm (new code effective 1/1/2024)
Q4301	Activate Matrix, per sq cm (new code effective 1/1/2024)
Q4302	Complete ACA, per sq cm (new code effective 1/1/2024)
Q4303	Complete AA, per sq cm (new code effective 1/1/2024)
Q4304	GRAFIX PLUS, per sq cm (new code effective 1/1/2024)
Q4305	American amnion ac tri-layer, per square centimeter (new code effective 4/1/2024)
Q4306	American amnion ac, per square centimeter (new code effective 4/1/2024)
Q4307	American amnion, per square centimeter (new code effective 4/1/2024)
Q4308	Sanopellis, per square centimeter (new code effective 4/1/2024)
Q4309	Via matrix, per square centimeter (new code effective 4/1/2024)
Q4310	Procenta, per 100 mg (new code effective 4/1/2024)

Related Information

Epifix Sizing Guidelines

The allograft is intended for single-patient use only. All unused material should be discarded. Multiple sizes are available in a wide range of sheet and mesh configurations covering wounds To determine the measure of a wound in square centimeters multiply the length of the wound by the width of the wound in centimeters. (e.g., 10 cm in length x 5 cm in width =50 cm^2)

Here is a sample of the package standard sizes for Epifix:

Table 1. Epifix Sample of Package Standard Sizes

Item Number	Size & Description
GS-5024	24 mm disk
GS-5330	3 cm x 3 cm sheet (9 sq cm)
GS-5350	3 cm x 5 cm sheet (15 sq cm)
GS-5460	4 cm x 6 cm sheet (24 sq cm)
GS-5560	5 cm x 6 cm sheet (30 sq cm)
GS-5770	7 cm x 7 cm sheet (49 sq cm)
ES-3500	3 cm x 5 cm mesh sheet (15 sq cm)
ES-4400	4 cm x 4.5 cm mesh sheet (18 sq cm)
ES-5500	5 cm x 5.5 cm mesh sheet (27.5 sq cm)

Source: **https://mimedx.com/epifix/** (Accessed March 15, 2023).

Table 2. AmnioBand Sizing Guidelines

Tissue Code	Product Specifications
WC3010	AmnioBand Membrane, 10mm Disk
WC3014	AmnioBand Membrane, 14mm Disk
WC3016	AmnioBand Membrane, 16mm Disk
WC3018	AmnioBand Membrane, 18mm Disk
WC3022	AmnioBand Membrane, 2cm x 2cm
WC3023	AmnioBand Membrane, 2cm x 3cm
WC3024	AmnioBand Membrane, 2cm x 4cm

Tissue Code	Product Specifications
WC3034	AmnioBand Membrane, 3cm x 4cm
WC3044	AmnioBand Membrane, 4cm x 4cm
WC3038	AmnioBand Membrane, 3cm x 8cm
WC3046	AmnioBand Membrane, 4cm x 6cm
WC3056	AmnioBand Membrane, 5cm x 6cm
WC3077	AmnioBand Membrane, 7cm x 7cm

Source: **https://www.mtfbiologics.org/our-products/detail/amnioband-membrane** (Accessed March 15, 2023).

Table 3. Other Product Size Specifications

Name	Available Sizes	Link
Affinity	1.5 x 1.5 cm (2.25 square cm) 2.5 x 2.5 cm (6.25 square cm)	**https://affinityfresh.com/why-choose-affinity/product-details-and-resources.html**
Biovance	1 cm x 2 cm 2 cm x 2 cm 2 cm x 3 cm 2 cm x 4 cm 3 cm x 3.5 cm 4 cm x 4 cm 5 cm x 5 cm 6 cm x 6 cm	**https://cdn.arthrex.io/image/upload/dec74ab9-9ca5-4c07-9052-fe1bbf6e4a2c.pdf**
Epicord	1 cm x 2 cm (2 sq cm) 2 cm x 3 cm (6 sq cm) 3 cm x 5 cm (15 sq cm) 2 cm x 3 cm (6 sq cm) Epicord Expandle	**https://mimedx.com/epicord/** (see product details, other information)
Grafix	16 mm Disc (2 sq cm) 1.5 cm x 2 cm (3 sq cm) 2 cm x 3 cm (6 sq cm) 3 cm x 3 cm (9 sq cm) 3 cm x 4 cm (12 sq cm) 5 cm x 5 cm (25 sq cm)	**https://www.grafixpl.com/products**

Evidence Review

Description

Several commercially available forms of human amniotic membrane (HAM) and amniotic fluid can be administered by patches, topical application, or injection. Amniotic membrane and amniotic fluid are being evaluated for the treatment of a variety of conditions, including chronic full-thickness diabetic lower extremity ulcers, venous ulcers, knee osteoarthritis, plantar fasciitis, and ophthalmic conditions.

Background

Human Amniotic Membrane

HAM consists of two conjoined layers, the amnion and chorion, and forms the innermost lining of the amniotic sac or placenta. When prepared for use as an allograft, the membrane is harvested immediately after birth, cleaned, sterilized, and either cryopreserved or dehydrated. Many products available using amnion, chorion, amniotic fluid, and umbilical cord are being studied for the treatment of a variety of conditions, including chronic full-thickness diabetic lower-extremity ulcers, venous ulcers, knee osteoarthritis, plantar fasciitis, and ophthalmic conditions. The products are formulated either as patches, which can be applied as wound covers, or as suspensions or particulates, or connective tissue extractions, which can be injected or applied topically.

Fresh amniotic membrane contains collagen, fibronectin, and hyaluronic acid, along with a combination of growth factors, cytokines, and anti-inflammatory proteins such as interleukin-1 receptor antagonist.[1] There is evidence that the tissue has anti-inflammatory, antifibroblastic, and antimicrobial properties. HAM is considered to be non-immunogenic and has not been observed to cause a substantial immune response. It is believed that these properties are retained in cryopreserved HAM and HAM products, resulting in a readily available tissue with regenerative potential. In support, one HAM product has been shown to elute growth factors into saline and stimulate the migration of mesenchymal stem cells both in vitro and in vivo.[2]

Use of a HAM graft, which is fixated by sutures, is an established treatment for disorders of the corneal surface, including neurotrophic keratitis, corneal ulcers and melts, following pterygium repair, Stevens-Johnson syndrome, and persistent epithelial defects. Amniotic membrane

products that are inserted like a contact lens have more recently been investigated for the treatment of corneal and ocular surface disorders. Amniotic membrane patches are also being evaluated for the treatment of various other conditions, including skin wounds, burns, leg ulcers, and prevention of tissue adhesion in surgical procedures.[1] Additional indications studied in pre-clinical models include tendonitis, tendon repair, and nerve repair. The availability of HAM opens the possibility of regenerative medicine for an array of conditions.

Amniotic Fluid

Amniotic fluid surrounds the fetus during pregnancy and provides protection and nourishment. In the second half of gestation, most of the fluid is a result of micturition and secretion from the respiratory tract and gastrointestinal tract of the fetus, along with urea.[1] The fluid contains proteins, carbohydrates, peptides, fats, amino acids, enzymes, hormones, pigments, and fetal cells. Use of human and bovine amniotic fluid for orthopedic conditions was first reported in 1927.[3] Amniotic fluid has been compared with synovial fluid, containing hyaluronan, lubricant, cholesterol, and cytokines. Injection of amniotic fluid or amniotic fluid–derived cells is currently being evaluated for the treatment of osteoarthritis and plantar fasciitis.

Amniotic membrane and amniotic fluid are also being investigated as sources of pluripotent stem cells.[1] Pluripotent stem cells can be cultured and are capable of differentiation toward any cell type. The use of stem cells in orthopedic applications is addressed in a separate policy (see **Related Medical Policies**).

Summary of Evidence

Diabetic Lower-Extremity Ulcers

For individuals who have nonhealing diabetic lower-extremity ulcers who receive a patch or flowable formulation of HAM or placental membrane (i.e., Affinity, AmnioBand Membrane, AmnioExcel, Biovance, EpiCord, EpiFix, Grafix), the evidence includes randomized controlled trials (RCTs). The relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. The RCTs evaluating amniotic and placental membrane products for the treatment of nonhealing (<20% healing with ≥2 weeks of standard care) diabetic lower-extremity ulcers have compared HAM with standard care or with an established advanced wound care product. These trials used wound closure as the primary outcome measure, and some used power analysis, blinded assessment of wound healing, and intention-to-treat (ITT) analysis. For the HAM

products that have been sufficiently evaluated (i.e., Affinity, AmnioBand Membrane, Biovance, EpiCord, EpiFix, Grafix), results have shown improved outcomes compared with standard care, and outcomes that are at least as good as an established advanced wound care product. Improved health outcomes in the RCTs are supported by multicenter registries. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Lower-Extremity Ulcers Due to Venous Insufficiency

For individuals who have lower-extremity ulcers due to venous insufficiency who receive a patch or flowable formulation of HAM, the evidence includes two RCTs. The relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. The published evidence on HAM for the treatment of venous leg ulcers includes two multicenter RCTs with EpiFix. One RCT reported a larger percent wound closure at 4 weeks, but the percentage of individuals with complete wound closure at four weeks did not differ between EpiFix and the standard of care. A second RCT evaluated complete wound closure at 12 weeks after weekly application of EpiFix or standard dressings with compression, but the interpretation is limited by methodologic concerns. Two additional studies with other HAM products have been completed but not published, raising further questions about the efficacy of HAM for venous insufficiency ulcers. Therefore, corroboration with well-designed and well-conducted RCTs evaluating wound healing is needed to demonstrate efficacy for this indication. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Osteoarthritis

For individuals who have knee osteoarthritis who receive an injection of suspension or particulate formulation of HAM or amniotic fluid, the evidence includes a feasibility study. The relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The pilot study assessed the feasibility of a larger RCT evaluating HAM injection. Additional trials, which will have a larger sample size and longer follow-up, are needed to permit conclusions on the effect of this treatment. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Plantar Fasciitis

The evidence on injection of amniotic membrane for the treatment of plantar fasciitis includes preliminary studies and a larger (n=145) patient-blinded comparison of micronized injectable-HAM and placebo control. Injection of micronized amniotic membrane resulted in greater improvements in the visual analog score for pain and the Foot Functional Index compared to placebo controls. The primary limitation of the study is that this is an interim report with 12-month results pending. The evidence is insufficient to determine that the technology results in an improvement the net health outcome.

Ophthalmic Conditions

Sutured and self-retained HAM has been evaluated for a variety of ophthalmologic conditions. Traditionally, the amniotic membrane has been fixed onto the eye with sutures or glue or placed under a bandage contact lens for a variety of ocular surface disorders. Several devices have been reported that use a ring around a HAM allograft that allows it to be inserted under topical anesthesia similar to insertion of a contact lens. Sutured HAM transplant has been used for many years for the treatment of ophthalmic conditions. Many of these conditions are rare, leading to difficulty in conducting RCTs. The rarity, severity, and variability of the ophthalmic condition was taken into consideration in evaluating the evidence. Based on clinical input received in 2019, it was determined that there is a clinically meaningful improvement in the net health outcome and the use of HAM is consistent with generally accepted medical practice for the treatment of ophthalmic conditions.

Repair Following Mohs Micrographic Surgery

For individuals who have undergone Mohs micrographic surgery for skin cancer on the face, head, neck, or dorsal hand who receive human amniotic/chorionic membrane, the evidence includes a nonrandomized, comparative study and no RCTs. Relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. A retrospective analysis using data from medical records compared a dehydrated human amnionic/chorionic membrane product (dHACM, Epifix) to repair using autologous surgery in 143 propensity-score matched pairs of individuals requiring same-day reconstruction after Mohs microsurgery for skin cancer on the head, face, or neck. A greater proportion of individuals who received dHACM repair experienced zero complications (97.9% vs. 71.3%; p<.0001; relative risk 13.97; 95% CI 4.33 to 43.12). Placental allograft reconstructions developed less infection (p=.004) and were less likely to experience

poor scar cosmesis (p<.0001). This study is limited by its retrospective observational design. Well-designed and conducted prospective studies are lacking. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in **Table 4**.

Table 4. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04457752[a]	A Randomised Controlled Multicentre Clinical Trial, Evaluating the Efficacy of Dual Layer Amniotic Membrane (Artacent) and Standard of Care Versus Standard of Care Alone in the Healing of Chronic Diabetic Foot Ulcers	124	Mar 2023
NCT03390920[a]	Evaluation of Outcomes With Amniotic Fluid for Musculoskeletal Conditions	200	Jan 2030
NCT04612023	A Prospective, Double-Blinded, Randomized Controlled Trial of an Amniotic Membrane Allograft Injection Comparing Two Doses (1 mL and 2mL Injection) and a Placebo (Sterile Saline) in the Treatment of Osteoarthritis of the Knee	90	Jul 2022
NCT04553432[a]	Dry Eye OmniLenz Application of Omnigen Research Study	130	Jul 2024
NCT04599673	Prospective Analysis of Intraoperative AMNIOGEN Injection in Patients With Rotator Cuff Tear	100	Sep 2022
NCT04636229[a]	A Phase 3 Prospective, Multicenter, Double-blind, Randomized, Placebo-controlled Study to Evaluate the Efficacy of Amniotic Suspension Allograft (ASA) in Patients With Osteoarthritis of the Knee	474	Dec 2023
Unpublished			
NCT03855514[a]	A Prospective, Multicenter, Randomized, Controlled Clinical Study Of NuShield and Standard of Care (SOC) Compared to SOC Alone For The Management Of Diabetic Foot Ulcers	200	Dec 2021 (Recruiting)

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

Clinical Input from Physician Specialty Societies and Academic Medical Centers

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

Society for Vascular Surgery et al

In 2016, the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine made the following recommendation: "For DFUs [diabetic foot ulcers] that fail to demonstrate improvement (>50% wound area reduction) after a minimum of 4 weeks of standard wound therapy, we recommend adjunctive wound therapy options. These include negative pressure therapy, biologics (platelet-derived growth factor [PDGF], living cellular therapy, extracellular matrix products, amniotic membrane products), and hyperbaric oxygen therapy. Choice of adjuvant therapy is based on clinical findings, availability of therapy, and cost-effectiveness; there is no recommendation on ordering of therapy choice."[40]

Wound Healing Society

In 2016, the Wound Healing Society updated their guidelines on diabetic foot ulcer treatment.[41] The Society concluded that there was level 1 evidence that cellular and acellular skin equivalents improve diabetic foot ulcer healing, noting that, "healthy living skin cells assist in healing DFUs [diabetic foot ulcers] by releasing therapeutic amounts of growth factors, cytokines, and other proteins that stimulate the wound bed." References from two randomized controlled trials on amniotic membrane were included with references on living and acellular bioengineered skin substitutes.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

The US Food and Drug Administration (FDA) regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation title 21, parts 1270 and 1271. In 2017, the FDA published clarification of what is considered minimal manipulation and homologous use for human cells, tissues, and cellular and tissue-based products (HCT/Ps).[4]

HCT/Ps are defined as human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. If an HCT/P does not meet the criteria below and does not qualify for any of the stated exceptions, the HCT/P will be regulated as a drug, device, and/or biological product and applicable regulations and premarket review will be required.

An HCT/P is regulated solely under section 361 of the PHS Act and 21 CFR Part 1271 if it meets all of the following criteria:

- "The HCT/P is minimally manipulated;
- The HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent;
- The manufacture of the HCT/P does not involve the combination of the cells or tissues with another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent,

provided that the addition of water, crystalloids, or the sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P; and

- Either:
    - The HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or
    - The HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and:
        - Is for autologous use;
        - Is for allogeneic use in a first-degree or second-degree blood relative; or
        - Is for reproductive use."

The guidance provides the following specific examples of homologous and non-homologous use for amniotic membrane:

- "Amniotic membrane is used for bone tissue replacement to support bone regeneration following surgery to repair or replace bone defects. This is not a homologous use because bone regeneration is not a basic function of amniotic membrane.
- An amniotic membrane product is used for wound healing and/or to reduce scarring and inflammation. This is not homologous use because wound healing and reduction of scarring and inflammation are not basic functions of amniotic membrane.
- An amniotic membrane product is applied to the surface of the eye to cover or offer protection from the surrounding environment in ocular repair and reconstruction procedures. This is homologous use because serving as a covering and offering protection from the surrounding environment are basic functions of amniotic membrane."

The FDA noted the intention to exercise enforcement discretion for the next 36 months after publication of the guidance.

In 2003, Prokera was cleared for marketing by the Food and Drug Administration through the 510(k) process for the ophthalmic conformer that incorporates amniotic membrane (K032104). The FDA determined that this device was substantially equivalent to the Symblepharon Ring. The Prokera device is intended "for use in eyes in which the ocular surface cells have been damaged, or underlying stroma is inflamed and scarred."[5] The development of Prokera, a commercially available product, was supported in part by the National Institute of Health and the National Eye Institute.

AmnioClip (FORTECH GmbH) is a ring designed to hold the amniotic membrane in the eye without sutures or glue fixation. A mounting device is used to secure the amniotic membrane within the AmnioClip. The AmnioClip currently has CE approval in Europe.

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History

Date	Comments
08/01/20	New policy, approved July 14, 2020. Policy replaces 7.01.149. AmnioFix added as investigational. All other policy statements remain unchanged.
10/01/20	Coding update. Added HCPCS codes Q4249, Q4250, Q4254, Q4255.
05/01/21	Annual Review, approved April 13, 2021. Policy updated with literature review through December 28, 2020; references added. Affinity added to medically necessary statement for the treatment of diabetic foot ulcers; edits made to investigational statement on human amniotic products.
10/01/21	Coding update, Added HCPCS codes Q4251, Q4252 and Q4253.
1/1/2022	Coding update, Added HCPCS codes A2001 and Q4199.
05/01/22	Annual Review, approved April 12, 2022. Policy updated with literature review through January 3, 2022; references added. Added investigational statement for treatment following Mohs microsurgery and all other human amniotic products not listed. Modified medically necessary statement for ophthalmic conditions to a general statement rather than listing specific indications. Removed code A2001 InnovaMatrix AC (new code effective 1/1/22) as it was moved to policy 7.01.113 since it is a skin substitute. Added new CPT codes Q4224, Q4225, Q4256,

Date	Comments
	Q4257, and Q4258. Added new product names AmnioBind, Relese, MLG-CompleteTM, and Enverse.
07/01/22	Coding update. Added HCPC codes Q4259, Q4260 and Q4261.
12/01/22	Coding update. Added AmnioFix as it was inadvertently deleted in error.
01/01/23	Coding update. Added new HCPC codes Q4236, Q4262, Q4263, & Q4264.
04/01/23	Coding update. Removed Derm-maxx name from product table. Added new HCPC codes Q4265, Q4266, Q4267, Q4268, Q4269, Q4270, Q4271. Added product names NeoStim DL, NeoStim TL, NeoStim membrane, SurGraft FT, SurGraft XT, Complete FT, and Complete SL.
05/01/23	Annual Review, approved April 10, 2023. Policy updated with literature review through January 20, 2023; no references added. Policy statements unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization. Removed Surgenex from product table.
07/01/23	Coding update. Added new HCPCS codes Q4272, Q4273, Q4274, Q4275, Q4276, Q4277, Q4278, Q4280, Q4281, Q4282, Q4283, Q4284.
10/01/23	Coding update. Added new HCPCS codes Q4285 and Q4286.
01/01/24	Coding update. Added new HCPCS codes Q4279 and Q4287-Q4304.
04/01/24	Coding Update. Added new HCPCS codes Q4305-Q4310 and termed HCPCS code Q4244.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

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Language Assistance

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 844-722-4661 (TTY: 711).

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주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 844-722-4661 (TTY: 711) 번으로 전화해 주십시오.

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注意事項：日本語を話される場合、無料の言語支援をご利用いただけます。844-722-4661（TTY:711）まで、お電話にてご連絡ください。

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ਧਿਆਨ ਦਿਓ: ਜੇ ਤੁਸੀਂ ਪੰਜਾਬੀ ਬੋਲਦੇ ਹੋ, ਤਾਂ ਭਾਸ਼ਾ ਵਿੱਚ ਸਹਾਇਤਾ ਸੇਵਾ ਤੁਹਾਡੇ ਲਈ ਮੁਫਤ ਉਪਲਬਧ ਹੈ। 844-722-4661 (TTY: 711) 'ਤੇ ਕਾਲ ਕਰੋ।

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 844-722-4661 (TTY: 711).

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UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 844-722-4661 (TTY: 711).

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