

FEP 7.01.149 Amniotic Membrane and Amniotic Fluid

Effective Date: April 15, 2018

Related Policies:

2.01.16 Recombinant and Autologous Platelet-Derived Growth Factors for Healing and Other Non-Orthopedic Conditions
7.01.113 Bioengineered Skin and Soft Tissue Substitutes
8.01.52 Orthopedic Applications of Stem Cell Therapy

Amniotic Membrane and Amniotic Fluid

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.

FDA REGULATORY STATUS

The U.S. Food and Drug Administration 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. HAM products and amniotic fluid products are included in these regulations.

In 2003, Prokera™ was cleared for marketing by FDA through the 510(k) process for the ophthalmic conformer that incorporates amniotic membrane (K032104). 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.”⁴

POLICY STATEMENT

Treatment of nonhealing diabetic lower-extremity ulcers using the following human amniotic membrane products (AmnioBand® Membrane, Biovance®, Epifix®, Grafix™) may be considered **medically necessary**.

Sutured human amniotic membrane grafts may be considered **medically necessary** for the treatment of the following ophthalmic indications:

- Neurotrophic keratitis
- Corneal ulcers and melts
- Pterygium repair
- Stevens-Johnson syndrome
- Persistent epithelial defects.

Sutured human amniotic membrane grafts are considered **investigational** for the treatment of all other ophthalmic conditions including but not limited to dry eye syndrome, burns, corneal perforation, bullous keratopathy, limbus stem cell deficiency, and after photorefractive keratectomy.

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Human amniotic membrane without suture (eg, Prokera®, AmbioDisk™) for ophthalmic indications is **investigational**.

Injection of micronized or particulated human amniotic membrane is considered **investigational** for all indications, including but not limited to treatment of osteoarthritis and plantar fasciitis.

Injection of human amniotic fluid is considered **investigational** for all indications.

All other human amniotic membrane products and indications not listed above are considered **investigational**, including but not limited to treatment of lower-extremity ulcers due to venous insufficiency.

POLICY GUIDELINES

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 (eg, Zelen et al, 2015).

A persistent epithelial defect is one that failed to close completely after 5 days of conservative treatment or has failed to demonstrate a decrease in size after 2 days of conservative treatment. Conservative treatment is defined as use of topical lubricants and/or topical antibiotics and/or therapeutic contact lens and/or patching. Failure of multiple modalities should not be required prior to moving to human amniotic membrane grafts. An amniotic membrane graft requires less effort on the part of the patient to adhere to a treatment regimen and has a significant advantage in regarding treatments requiring multiple drops per day.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

RATIONALE

Summary of Evidence

Overwrite with Summary.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

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POLICY HISTORY

Date	Action	Description
January 2017	New Policy	
March 2017	Update Policy	Policy updated with literature review through November 7, 2016; material on patch formulations of amniotic membrane moved from policy 7.01.113 (Bioengineered Skin and Soft Tissue Substitutes); references 7-8, 15, 18, 20, and 22-23 added. AmnioBand® Membrane, Biovance®, Epifix®, Grafix™ considered medically necessary for diabetic foot ulcers; all other products and indications are investigational.
June 2017	Revise Policy	Policy updated with literature review through April 27, 2017; references 21-28 added. Clinical input reviewed. Fixated amniotic membrane grafts considered medically necessary for neurotrophic keratitis, corneal ulcers and melts, following pterygium repair, Stevens Johnson, and persistent epithelial defects.
March 2018	Update Policy	Policy updated with literature review through December 11, 2017; references 15, 22, and 27 added. Specific indications added to the investigational policy statements.

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