BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Amniotic Membrane Grafts for Ophthalmic Indications

Policy #: 624
Latest Review Date: March 2024
Category: Vision

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective for dates of service on or after June 26, 2019:

Blue Advantage will treat **human amniotic membrane grafts** (with or without suture, and/or with suture or glue) for the treatment of the following ophthalmic indications as a **covered benefit**:

- Absence of iris;
- Bullous keratopathy;
- Conjunctivochalasis;
- Corneal degeneration;
- Corneal ectasia, corneal staphyloma, descemetocele, or other corneal deformity;
- Corneal ulceration or defect;
- Corneal disorder due to contact lens or recurrent erosion of cornea;
- Corneal perforation when there is active inflammation after corneal transplant requiring adjunctive treatment;
- Following removal of conjunctival lesion(s);
- Hereditary corneal dystrophies;
- Neurotrophic keratoconjunctivitis;
- Ocular burns;
- Stevens-Johnsons Syndrome;
- Partial limbal stem cell deficiency with extensive diseased tissue where selective removal alone is not sufficient;
- Persistent epithelial defects that do not respond to conservative therapy;
- Pterygium;
- Pseudopterygium

Blue Advantage will treat **amniotic membrane transplantation** for the treatment of dry eye syndrome and any other conditions not listed above as a **non-covered benefit.**

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contracts and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Several commercially available forms of human amniotic membrane (HAM) are available. Amniotic membrane is being evaluated for the treatment of a variety of ophthalmic conditions.

Human amniotic membrane consists of two conjoined layers (the amnion and chorion) to form the innermost lining of the amniotic sac or placenta. When prepared for use as an allograft, the membrane is harvested immediately after birth and is cleaned, sterilized, and cryopreserved. Many products available using amnion, chorion, amniotic fluid, and umbilical cord are being studied for use in the treatment of a variety of ophthalmic conditions. The products are formulated either as patches that can be applied as wound covers, or as suspensions, particulates, or connective tissue extractions, which can be injected or applied topically.

Fresh amniotic membrane contains collagen, fibronectin, and hyaluronic acid, a combination of growth factors, cytokines, and anti-inflammatory proteins (such as interleukin-1 receptor antagonist). There is evidence that the tissue has anti-inflammatory, antifibroblastic, and antimicrobial properties. HAM is considered nonimmunogenic 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.

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. The availability of HAM opens the possibility of regenerative medicine for an array of conditions.

KEY POINTS:

The most recent literature update was performed through January 3, 2024.

Summary of Evidence

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 randomized control trials (RCTs). Of the evidence available, relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. The rarity, severity, and variability of the ophthalmic condition was taken into consideration while evaluating the evidence. Clinical input was sought to help determine whether the use of HAM graft either without or with suture fixation for several ophthalmic conditions would provide a clinically meaningful improvement in the net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from two respondents, including one specialty society-level response and one physician-level response identified through specialty societies including physicians with academic medical center affiliations.

Bullous keratopathy as a palliative measure in patients who are not candidates for a curative treatment (e.g., endothelial or penetrating keratoplasty)
For individuals who have bullous keratopathy who are not candidates for curative treatment (e.g., endothelial or penetrating keratoplasty) who receive HAM, the evidence includes an RCT. The RCT found no advantage of sutured HAM over the simpler stromal puncture procedure for the treatment of pain from bullous keratopathy, however, clinical input supported the use of amniotic membrane in individuals with this indication as an alternative to stromal puncture. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Corneal perforation when corneal tissue is not immediately available
For individuals who have corneal perforation when corneal tissue is not immediately available who receive sutured HAM, the evidence is limited. The standard treatment for corneal perforation is corneal transplantation, however, HAM may provide temporary coverage of the severe defect when corneal tissue is not immediately available. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Corneal perforation when there is active inflammation after corneal transplant requiring adjunctive treatment
For individuals with corneal perforation with active inflammation after corneal transplant requiring adjunctive treatment who receive HAM, the evidence is limited. No comparative evidence was identified for this indication. Clinical input supported the use of HAM in individuals with corneal perforation when there is active inflammation after corneal transplant requiring adjunctive treatment. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Corneal ulcers and melts that do not respond to initial medical therapy
For individuals who have corneal ulcers and melts that do not respond to initial medical therapy who receive HAM, the evidence includes a systematic review of primarily case series and a non-randomized comparative study. The systematic review showed healing in 97% of patients with an improvement of vision in 53% of eyes. One retrospective comparative study with 22 patients found more rapid and complete epithelialization and more patients with a clinically significant improvement in visual acuity following early treatment with self-retained HAM when compared to historical controls. Corneal ulcers and melts are uncommon and variable and RCTs are not expected. Clinical input supported the use of HAM in individuals with corneal ulcers and melts that do not respond to initial medical therapy. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Dry eye syndrome
For individuals who have severe dry eye syndrome who receive HAM, the evidence is limited. In the article, 'Treatment outcomes in the Dry Eye Amniotic Membrane (DREAM) study', a retrospective chart review was conducted of patients with dry eye syndrome who received HAM with at least three months of follow-up was discussed. The patients included in this study were affected by at least one of the following indications: severe dry eye, punctate keratitis, filamentary keratitis, exposure keratitis, neurotropic keratitis, and corneal epithelial defect. The

patients in this study continued to use conventional treatment as per their usual routine. It is theorized that the use of HAM can decrease the need for use of prescription medication to alleviate dry eye syndrome, however, evidence for patients who are able to eliminate the standard of care treatment from their treatment plan is insufficient. In the article, 'Sutureless Amniotic Membrane ProKera for Ocular Surface Disorders: Short-Term Results', a retrospective chart review of patients who received HAM for ocular surface disorders was discussed. Some success was seen initially in the treatment of dry eye syndrome, however, recurrence of the primary pathologic condition occurred. Sutured HAM is not typically used for severe dry eye alone, but may be necessary in the face of one or more concomitant diseases discussed in the other sections of this policy. Further, well-designed scientific evidence displaying long-term effects and a meaningful change in treatment protocol with elimination of use of current standard of care is needed. The evidence is insufficient to determine that the technology results in a meaningful improvement in the net health outcome when dry eye disease is not accompanied by another disorder.

Moderate or severe acute ocular chemical burns
For individuals who have moderate or severe acute ocular chemical burns who receive HAM, the evidence includes RCTs and retrospective chart reviews. Evidence includes a total of 197 patients with acute ocular chemical burns who were treated with HAM plus medical therapy or medical therapy alone. Two of the three RCTs did not show a faster rate of epithelial healing, and there was no significant benefit for other outcomes. In the article, Sutureless Amniotic Membrane ProKera for Ocular Surface Disorders: Short-Term Results, a chart review of patients who received HAM reports that treatment is easy to use and reasonably well tolerated, with encouraging results in acute moderate chemical injury. Clinical input supported the use of HAM individuals with moderate or severe acute ocular chemical burn. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Moderate or severe Stevens-Johnson syndrome
For individuals who have moderate or severe Stevens-Johnson syndrome who receive HAM, the evidence includes an RCT that reported 25 patients (50 eyes) found improved symptoms and function with HAM compared to medical therapy alone. Clinical input supported the use of HAM for this indication. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Neurotrophic keratitis with ocular surface damage and inflammation that does not respond to conservative therapy
For individuals who have neurotrophic keratitis with ocular surface damage and inflammation that does not respond to conservative therapy who receive HAM, the evidence includes an RCT of 30 patients that showed no benefit of sutured HAM graft compared to tarsorrhaphy or bandage contact lens. Clinical input supported the use of HAM in individuals with this indication. The evidence is sufficient to determine that the technology results in a clinically meaningful improvement in the net health outcome.

Neuropathic corneal pain
For individuals who suffer neuropathic corneal pain, the evidence includes the article, Efficacy of self-retained cryopreserved amniotic membrane for treatment of neuropathic corneal pain, which is a retrospective single-center medical record review of nine patients that evaluated the efficacy, safety, and tolerability of ProKera for the acute treatment of neuropathic corneal pain. The study concludes that the use of HAM represents a novel and promising therapeutic option for patients with neuropathic corneal pain. Small sample size (ten eyes of nine patients) and reported placebo effect experienced in one patient ("patient #4 reported simultaneous resolution of pain the ProKera® Clear untreated eye") are limitations of this study. Further studies with larger sample sizes and long-term effects are needed to provide efficacy of this treatment. The evidence is insufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Partial limbal stem cell deficiency with extensive diseased tissue where selective removal alone is not sufficient
For individuals who have partial limbal stem cell deficiency with extensive diseased tissue where selective removal alone is not sufficient and receive HAM, the evidence is limited. No RCTs were identified. Improvement in visual acuity has been reported for some patients who have received HAM in conjunction with removal of the diseased limbus. Clinical input supported the use of HAM in individuals with this indication. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Persistent epithelial defects and ulceration that do not respond to conservative therapy
For individuals who have persistent epithelial defects that do not respond to conservative therapy who receive HAM, the evidence is limited. No comparative trials were identified on persistent epithelial defects and ulceration. Clinical input for this indication supported the use of HAM. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Pterygium repair when there is insufficient healthy tissue to create a conjunctival autograft
For individuals who need pterygium repair when there is insufficient healthy tissue to create a conjunctival autograft who receive HAM the evidence includes a systematic review of RCTs that found conjunctival or limbal autograft is more effective than HAM graft in reducing the rate of pterygium recurrence. However, clinical input supported the use of HAM in individuals with pterygium repair when there is insufficient healthy tissue to create a conjunctival autograft. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Superficial punctate keratitis and filamentary keratitis
Superficial punctate keratitis is a nonspecific finding typically caused by an identifiable ocular condition. Filamentary keratitis is an uncommon condition associated with various kinds of ocular surface diseases or conditions. The causative condition of these findings in a patient may be appropriate for treatment with HAM based on scientific evidence or high-quality clinical input that has proven HAM is likely to produce a positive outcome in the net health outcome. These causative conditions/indications are listed in the policy statement of this medical policy.

Due to the paucity of well-designed scientific trials and evidence to demonstrate an improvement in net health outcomes in patients with indications not included in our policy statement, such indications are found to have insufficient evidence to determine that the technology results in a meaningful improvement in the net health outcome.

Practice Guidelines and Position Statements
The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Tear Film and Ocular Surface Society
In 2017, the Tear Film and Ocular Surface Society published the Dry Eye Workshop II (DEWS) management and therapy report. The report evaluated the evidence on treatments for dry eye and provided a treatment algorithm for dry eye disease management that includes four steps.

U.S. Preventive Services Task Force Recommendations
Not applicable.

KEY WORDS:
Absence of iris, Amniotic membrane transplantation, AMT, dry eye syndrome, keratopathy, bullous keratopathy, conjunctivochalasis, corneal degeneration, corneal ectasia, corneal staphyloma, descemetocele, other corneal deformity, corneal ulceration, corneal defect, corneal disorder due to contact lens or recurrent erosion of cornea, conjunctival lesion removal, hereditary corneal dystrophies, neurotrophic keratoconjunctivitis, ocular burns, pterygium, pseudopterygium, Stevens-Johnsons Syndrome, SJS, Prokera, HAM, human amniotic membrane

APPROVED BY GOVERNING BODIES:
The U.S. 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 (CFR) Title 21, parts 1270 and 1271. Human amniotic membrane products and amniotic fluid products are included in these regulations. 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).

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:

1. "The HCT/P is minimally manipulated;
2. The HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent;

3. 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
4. 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:

"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 FDA 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." 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.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group-specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

65778	Placement of amniotic membrane on the ocular surface; without sutures
65779	;single layer, sutured
65780	Ocular surface reconstruction; amniotic membrane transplantation, multiple layers

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POLICY HISTORY:

Adopted for Blue Advantage, February 2016
Available for comment March 4 through May 5, 2016
Medical Policy Group, May 2016
Medical Policy Group, July 2016
Medical Policy Group, March 2018
Medical Policy Group, June 2019
Medical Policy Group, March 2020
Medical Policy Group, February 2021
Medical Policy Group, February 2022
Medical Policy Group, June 2022: Updates to Description, References. No change to policy statement.
Medical Policy Group, February 2023
UM Committee, December 2023: Policy approved by UM Committee for use for Blue Advantage business.
Medical Policy Group, March 2024. Clarification to Policy Statement to remove example, "[e.g. Prokera®, AmbioDisk™]." No change to policy intent.
UM Committee, March 2024: Annual review of policy approved by UM Committee for use for Blue Advantage business.
