OHCA Guideline

Medical Procedure Class:	**Ocular Amniotic Membrane without Sutures**
Initial Implementation Date:	**February 2025**
Last Review Date:	**2/18/25**
Effective Date:	**3/17/2025**
Next Review/Revision Date:	**March 2028**

* This document is not a contract, and these guidelines do not reflect or represent every conceived situation. Although all items contained in these guidelines may be met, this does not reflect or imply any responsibility of this agency or department to change the plan provision to include the stated service as an eligible benefit.

■ New Criteria ☐ Revision of Existing Criteria

Summary

Purpose:	To provide guidelines to assure medical necessity and consistency in the prior authorization process.

Definitions

Amniotic Membrane (AM)- an avascular fetal membrane that lies deep to the chorion and is harvested in a sterile environment from placental tissue obtained during elective cesarean sections. Donors are screened for transmissible diseases, and the AM is further treated with broad-spectrum antibiotics immediately after collection.

Bullous Keratopathy- caused by edema of the cornea, most frequently due to Fuchs corneal endothelial dystrophy or corneal endothelial trauma. Subepithelial fluid-filled bullae form, leading to decreased vision acuity, loss of contrast glare, and photophobia.

Dry Eye Syndrome- refers to chronic dryness, inflammation, and irritation of the cornea and conjunctiva.

Keratitis- inflammation or irritation of the cornea, also referred to a corneal ulcer.

Stevens-Johnson Syndrome- serious skin condition that causes skin to develop rashes, blisters, and then peel. Mucous membranes, such as eyes, are also affected.

Description

Human AM graft is placed over the ocular surface without using glue or sutures. AM may be used to promote healing of ocular surface conditions that have the potential to create corneal scarring or are not responding to treatment. These include various types of keratitis, corneal ulcers, neurotrophic keratopathy, and chemical burns. Several characteristics contribute to the efficacy of AM in treating ocular surface problems. First, AM acts as a physical barrier to protect conjunctival and corneal epithelium as it heals, and it reduces pain caused by friction of the eyelids over the surface. In addition, the AM basement membrane promotes epithelial growth through cell migration, adhesion, and differentiation, while also inhibiting cell death. Furthermore, the stroma of AM, which contains fetal hyaluronic acid, inhibits fibroblast growth and reduces inflammation through decreased expression of cytokines.

CPT Code Requiring Prior Authorization (PA)

65778 – placement of amniotic membrane on the ocular surface, without sutures

Approval Criteria

I. GENERAL

A. Medical necessity must be met. All documentation submitted to request services must demonstrate through adequate objective medical records with sufficient evidence to justify the members' needs for the service, in the most cost-effective manner, in accordance with the OAC 317:30-3-1.
B. Documentation must contain information to support the necessity for this treatment, including all conservative treatment tried, with results.

II. INDICATIONS

Human amniotic membrane grafts without suture may be considered medically necessary for the treatment of any of the following ophthalmic indications:

A. Neurotrophic keratitis with ocular surface damage and inflammation that does not respond to conservative therapy. Conservative therapy for neurotrophic keratitis may include 5 days of pressure patching, therapeutic contact lens, topical lubricants, and topical antibiotics; OR
B. Corneal ulcers and melts that do not respond to initial conservative therapy. Conservative therapy or corneal ulcers and melts may include 2 days of patching, therapeutic contact lens, and topical antimicrobial agent; OR
C. Corneal perforation when there is active inflammation after corneal transplant requiring adjunctive treatment; OR
D. Bullous keratopathy as a palliative measure in patients who are not candidates for curative treatment (e.g., endothelial or penetrating keratoplasty); OR
E. Partial limbal stem cell deficiency with extensive diseased tissue where selective removal alone is not sufficient, OR
F. Moderate or severe Stevens-Johnson syndrome; OR
G. Persistent epithelial defects that do not respond within 2 days to conservative therapy; OR
H. Severe dry eye (DEWS 3 or 4) * with ocular surface damage and inflammation that remains symptomatic after Steps 1, 2, & 3 of the dry-eye disease management algorithm; OR
I. Moderate or severe acute ocular chemical burn.

Note: Requests outside of this guideline will require medical director review.

Additional Review Information

I. *Eye Severity Level DEWS 3 to 4

- Discomfort, severity, and frequency - Severe frequent or constant
- Visual Symptoms – chronic and/or constant, limiting to disabling
- Conjunctival Injection -+/-or+/+
- Conjunctive Staining – moderate to marked
- Corneal Staining – marked central or severe punctate erosions
- Corneal/tear signs – Filamentary keratitis, mucus clumping, increase in tear debris
- Lid/meibomian glands – Frequent
- Tear film breakup time - < 5 Schirmer score (mm/5 min) - < 5

II. **Tear Film and Ocular Surface Society Staged Management for Dry Eye Disease

The Tear Film and Ocular Surface Society (2017) published the DEWS [Dry Eye Workshop] II management and therapy report. The report evaluated the evidence on treatments for dry eye and provided the following treatment algorithm for dry-eye disease management:

Step 1:

- Education regarding the condition, its management, treatment and prognosis
- Modification of local environment
- Education regarding protentional dietary modifications (including oral essential fatty acid supplementation)
- Identification and potential modification /elimination of offending systemic and topical medications
- Ocular lubricants of various types (if meibomian gland dysfunction is present, then consider lipid containing supplements)
- Lid hygiene and warm compresses of various types

Step 2: If the Above Options are Inadequate Consider:

- Non-preserved ocular lubricants to minimize preservative-induced toxicity
- Tea tree oil treatment for Demodex (if present)
- Tear conservation
    - Punctal occlusion
    - Moisture chamber spectacles/goggles
- Overnight treatments (such as ointment or moisture chamber devices)
- In-office, physical heating and expression of the meibomian glands
- In-office intense pulsed light therapy for meibomian gland dysfunction
- Prescription drugs to manage dry eye disease
    - Topical antibiotic or antibiotic/steroid combination applied to the lid margins for anterior blepharitis (if present)
    - Topical Corticosteroid (limited duration)
    - Topical secretagogues
    - Topical non-glucocorticoid immunomodulatory drugs (such as cyclosporine)
    - Topical LFA-1 antagonist drugs (such as lifitegrast)
    - Oral macrolide or tetracycline antibiotics

Step 3: If the Above Options Are Inadequate Consider:

- Oral secretagogues
- Autologous/allogeneic serum eye drops
- Therapeutic contact lens options
    - Soft bandage lenses
    - Rigid scleral lenses

Step 4: If the Above Options are Inadequate Consider:

- Topical Corticosteroids for longer duration
- Amniotic membrane grafts
- Surgical punctal occlusion
- Other surgical approaches (e.g. tarsorrhaphy, salivary gland transplantation)

References

- Oklahoma Health Care Authority Policies & Rules, OAC 317:30-3-1 (f)
- Merck Manual Professional Version; Bullous Keratopathy; July 2024 Bullous Keratopathy - Eye Disorders - Merck Manual Professional Edition
- Uma Sridhar; Koushik Tripathy; StatPearls; Amniotic Membrane Graft; August 25, 2023; Amniotic Membrane Graft - StatPearls - NCBI Bookshelf
- BCBS of Oklahoma; Policy SUR704.011; Amniotic Membrane and Amniotic Fluid; 7/1/24

- Tear Film and Ocular Surface Society; TFOS DEWS II Report; TFOS - Tear Film & Ocular Surface Society
- Alex G. McGaughy, BS, and Preeya K. Gupta, MD; Ophthalmic Pearls; In-Office Use of Amniotic Membrane; Feb 1, 2015 In-Office Use of Amniotic Membrane - American Academy of Ophthalmology