



## Amniotic Membrane Transplant for Ocular Surfaces

LOB(s): <input checked="" type="checkbox"/> Commercial  <input checked="" type="checkbox"/> Medicare	State(s): <input checked="" type="checkbox"/> Idaho <input checked="" type="checkbox"/> Montana <input checked="" type="checkbox"/> Oregon <input checked="" type="checkbox"/> Washington <input type="checkbox"/> Other:
<input checked="" type="checkbox"/> Medicaid	<input checked="" type="checkbox"/> Oregon <input type="checkbox"/> Washington

### Enterprise Policy

Clinical Guidelines are written when necessary to provide guidance to providers and members in order to outline and clarify coverage criteria in accordance with the terms of the Member's policy. This Clinical Guideline only applies to PacificSource Health Plans, PacificSource Community Health Plans, and PacificSource Community Solutions in Idaho, Montana, Oregon, and Washington. Because of the changing nature of medicine, this list is subject to revision and update without notice. This document is designed for informational purposes only and is not an authorization or contract. Coverage determination are made on a case-by-case basis and subject to the terms, conditions, limitations, and exclusions of the Member's policy. Member policies differ in benefits and to the extent a conflict exists between the Clinical Guideline and the Member's policy, the Member's policy language shall control. Clinical Guidelines do not constitute medical advice nor guarantee coverage.

### Background

Limbal stem cells are the main source of regeneration for corneal cells that affect the ocular surface. Due to trauma or a variety of diseases, limbal stem cell deficiency (LSCD) can develop which can cause changes to the cornea and or the conjunctiva. Symptoms of LSCD may include photophobia, blurred or decreased vision, tearing, pain, chronic inflammation and redness.

Amniotic Membrane Transplantation (AMT) with or without limbal stem cell transplantation is a surgical treatment option to address LSCD. The purpose is to reconstruct damaged ocular surfaces and promote healing of corneal, conjunctival, and eyelid tissues. The amniotic membrane tissue may be autologous or allogeneic.

Amniotic membrane products have also been used for the management of select ophthalmologic wounds and reconstruction where there is limited access to autologous tissue for transplant, or when allogeneic transplant is not appropriate. These products (e.g., Ambio2, Ambio5, AmnioDisk, AmnioGraft, ProKera, Prokera Slim) come in a wide array of forms and most are obtained directly from tissue banks.

### Criteria

#### Commercial

**Prior authorization is required.**

#### **I. Amniotic Membrane Transplantation (AMT) with or without limbal stem cell transplantation**

PacificSource considers amniotic membrane transplantation (AMT) with or without limbal stem cell transplantation for ocular surface reconstruction medically necessary when at least **ONE** of the criteria are met:

**A.** For reconstruction of Corneal Surface, as indicated for **ONE** of the following conditions:

1. Acute thermal/chemical burns
2. Band Keratopathy
3. Corneal ulceration (central or peripheral)
4. Descemetocele or Perforation
5. Neurotropic Keratitis
6. Painful bullous keratopathy
7. Partial or complete limbal stem cell deficiency (with stem cell grafting)
8. Persistent epithelial defect that failed conservative treatment
9. Reconstruction of the surface of the conjunctiva

**B.** For reconstruction of the Surface of the Conjunctiva, as indicated for **ONE** of the following conditions:

1. Acute Stevens-Johnson syndrome
2. Acute thermal/chemical burns
3. Covering defects after removal of conjunctival lesions (conjunctival intraepithelial neoplasia, tumors, scars, or folds parallel to the edges of the eyelids)
4. Bleb revisions
5. Pterygium if there was insufficient conjunctiva for an autograft
6. Scleral thinning
7. Superior Limbic Keratoconjunctivitis that failed conjunctival resection
8. Symblepharon, fornix reconstruction

## **II. Amniotic Membrane Product**

PacificSource may consider the use of amniotic membrane products with or without suture(s) (e.g., Ambio2, Ambio5, AmnioDisk, AmnioGraft, ProKera, ProKera Slim) to be medically necessary for the treatment of severe ocular surface disease when the **BOTH** of the following criteria are met:

**A.** Documented failure of, intolerance to or contraindication to treatment using conventional medical management; **AND**

**B.** Treatment is for any **ONE** of the following conditions:

1. Bullous keratopathy
2. Chemical or thermal burns to cornea
3. Pterygium
4. Recurrent corneal abrasions, erosions, ulcers, wounds
5. Recurrent severe keratitis (e.g., autoimmune, bacterial, exposure, neurotrophic, viral, etc.)
6. Stevens-Johnson syndrome
7. Trauma

### Medicaid

PacificSource Community Solutions follows Oregon Health Plan (OHP) Oregon Administrative Rules (OARs) 410-141-3820 to 3830 & 410-120-1200 for coverage of Amniotic Membrane Transplantation (AMT).

### Medicare

PacificSource Medicare follows National Coverage Determination 80.1 for Hydrophilic Contact Lens for Corneal Bandage.

### Experimental/Investigational/Unproven

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PacificSource considers amniotic membrane transplantation and limbal stem cell transplantation experimental, investigational or unproven for all other indications (e.g., gelatinous drop-like ulcer, restrictive strabismus, use of trabeculectomy for primary open-angle glaucoma).

### Coding Information

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The following list of codes are for informational purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

65778 Placement of amniotic membrane on the ocular surface for wound healing; self-retaining

65779 Single layer, sutured

65780 Ocular surface reconstruction; amniotic membrane transplantation, multiple layers

V2790 Amniotic membrane for surgical reconstruction, per procedure (bundled payment)

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## Definitions

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**Acute thermal/chemical burns** - consist of burns to the sclera, conjunctiva, cornea, and eyelid and are associated with significant limbal ischemia and lack healthy limbal stem cells for epithelialization; classified by etiologic agents as either chemical injuries (e.g., those caused by acid or alkali) or radiant energy injuries (e.g., those caused by heat or ultraviolet [UV] radiation).

**Band keratopathy** - a corneal disease derived from the appearance of calcium on the central cornea; causes include trauma, eye drops PV Carpine (aka Pilocarpine), and hypercalcemia due to renal failure, sarcoidosis, hyperparathyroidism and certain malignancies.

**Bleb revisions** - excision of avascular bleb tissue, dissection posteriorly between conjunctiva and tenon's capsule, and advancement and suturing of the conjunctiva at the limbus.

**Bullous keratopathy** - a disorder caused by corneal endothelial decompensation due to degeneration (Fuch's endothelial dystrophy), surgical trauma, intractable glaucoma or previous corneal graft failure.

**Deep corneal ulcer** - can be caused by trauma, chemical injury, contact lens and infections or other eye conditions such as entropion, distichiasis, corneal dystrophy, and keratoconjunctivitis sicca.

**Descemetocoele** - protrusion of Descemet's membrane through the cornea.

**Limbal stem cell deficiency (LSCD)** - when limbal epithelial stem cells are destroyed or become dysfunctional, frequently associated with superficial vascularization and compromised corneal surface.

**Persistent epithelial defect (PED)** - is often caused by microtrauma, neurotrophic keratopathy and exposure. Etiologies for PED include dry eye, exposure keratopathy, limbal stem cell deficiency, diabetic keratopathy, neurotrophic keratopathy following corneal transplant surgery (involving the anterior portion of the cornea), and herpetic infections.

**Pterygium** - is a wing-shaped, vascular, fleshy growth that originates on the conjunctiva and that can spread to the corneal limbus and beyond.

**Scleral thinning** - can occur in various conditions, including myopic degeneration, chronic scleritis, local scleral pathologies and scleral injury. Autoimmune conditions or collagen vascular diseases often present with scleral pathologies, which can also lead to scleral thinning.

**Stevens - Johnson syndrome (SJS)** - begins with flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters. Stevens-Johnson syndrome is an immune-complex-mediated hypersensitivity complex that typically involves the skin and the mucous membranes.

**Sympblepharon** - partial or complete adhesion of the palpebral conjunctiva of the eyelid to the bulbar conjunctiva of the eyeball; can be caused by any conjunctival infection (bacterial or viral conjunctivitis) or allergic conjunctivitis (vernal or atopic conjunctivitis) with secondary scarring.

## References

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## Appendix

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**Policy Number:**

**Effective:** 10/1/2020

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**Policy type:** Enterprise

**Author(s):**

**Depts:** Health Services

**Applicable regulation(s):** NCD 80.1; OARs: 410-141-3820 to 3830 3825 & 410-120-1200

**Commercial Ops:** 11/2022

**Government Ops:** 11/2022