Amniotic Membrane Transplantation

State(s):	LOB(s):
☒ *Idaho* ☒ *Montana* ☒ *Oregon* ☒ *Washington* ☐ *Other:*	☒ *Commercial* ☒ *Medicare* ☒ *Medicaid*

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

Amniotic Membrane Transplantation (AMT) is a procedure that utilizes amniotic membrane tissue to reconstruct damaged ocular surfaces and promote healing of corneal, conjunctival, and eyelid tissues after injury due to trauma, disease, or surgery.

Criteria

Commercial

Preauthorization Required.

PacificSource considers amniotic membrane transplantation (AMT) or limbal stem cell transplantation for ocular surface reconstruction medically necessary when the following criteria are met:
Member has limbal deficiency (hypofunction or total loss of stem cells) refractory to conventional treatment and **one** of the following conditions for:

Reconstruction of Corneal Surface

- Acute thermal/chemical burns
- Band Keratopathy that failed conservative treatment
- Corneal ulceration (central or peripheral)
- Descemetocele or Perforation
- Neurotropic Keratitis
- Painful bullous keratopathy
- Partial or complete limbal stem cell deficiency (with stem cell grafting)
- Persistent epithelial defect that failed conservative treatment
- Reconstruction of the surface of the conjunctiva

Reconstruction of the Surface of the Conjunctiva

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

Medicaid

PacificSource Medicaid follows Oregon Health Plan (OHP) Oregon Administrative Rules (OARs) 410-141-3820 to 3825 & 410-120-1200 for coverage of Amniotic Membrane Transplantation (AMT).

Medicare

PacificSource Medicare follows CMS National Coverage Determination (NCD) coverage guidelines for Amniotic Lens Transplantation

- NCD 80.1 for Hydrophilic Contact Lens for Corneal Bandage

Exclusions

Amniotic membrane used in surgical reconstruction (code V2790)

- no additional payment is provided, this is considered a bundled service

Experimental/Investigational/Unproven

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; not an all-inclusive list) because its effectiveness for indications other than the indications listed above has not been established.

CPT/HCPC Codes

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

Note: V2790 is a bundled service with no additional payment provided.

Definitions

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. Ocular burn injuries are 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). These can lead to complete corneal erosion and blood vessel rupture at the limbus and in the conjunctiva.

Anophthalmia – is when both the globe (human eye) and the ocular tissue are missing from the orbit

Band keratopathy - is a corneal disease derived from the appearance of calcium on the central cornea. This is an example of metastatic calcification, which by definition, occurs in the presence of hypercalcemia. 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 - is a disorder caused by corneal endothelial decompensation due to degeneration (Fuch's endothelial dystrophy), surgical trauma, intractable glaucoma or previous corneal graft failure.

Corneal stromal thinning – is a rare disorder with multiple anterior segment anomalies. The corneal stroma is thinned in the range of 330 to 460 µm with uniform steepening (no cone). The epithelium may be irregular and edematous, the stroma is diffusely hazy, and the endothelium is irregular with many guttae.

Deep corneal ulcer – can be caused by trauma, chemical injury, contact lens and infections. Other eye conditions can cause corneal ulcers, such as entropion, distichiasis (eyelashes constantly rub against cornea), corneal dystrophy, and keratoconjunctivitis sicca (dry eye).

Descemetocele - protrusion of Descemet's membrane through the cornea
Infectious keratitis - is an inflammation of the cornea — the clear, dome-shaped tissue on the front of your eye that covers the pupil and iris. Keratitis may or may not be associated with an infection. Infectious keratitis can be caused by bacteria, viruses, fungi and parasites.

Limbal stem cell deficiency (LSCD) – is when limbal epithelial stem cells are destroyed or become dysfunctional, a pathological state known as LSCD manifests. LSCD is the conjunctivalization of the cornea, and is frequently associated with superficial vascularization and compromised corneal surface. LSCD can be found in of corneal diseases such as chemical burns, Stevens - Johnson syndrome (SJS), aniridia, peripheral keratitis and severe limbitis.

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. Scleral thinning can result after excessive use of cautery in the scleral bed or overuse of antimetabolites. Prolonged irradiation, transscleral diode laser cycloablation, strabismus surgery and deep sclerectomy procedures can also predispose the sclera to thinning. Autoimmune conditions or collagen vascular diseases are known to present with scleral pathologies, which can also lead to scleral thinning.

Scleritis - is a serious inflammatory disease that affects the white outer coating of the eye, known as the sclera. There are three types of scleritis: diffuse scleritis (the most common), nodular scleritis, and necrotizing scleritis (the most severe).

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.

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

Toxic Epidermal Necrolysis (TEN) – is a more severe form of the Stevens - Johnson syndrome disease that results from a necrotic reaction, involving more than 30% of the body surface and has a mortality of 27% to 31%.

References

Barreiro, TP et al (2014). Comparative study of conjunctival limbal transplantation not associated with the use of amniotic membrane transplantation for treatment of total limbal deficiency secondary to chemical injury. Cornea. 2014 Jul; 33(7):716-20. Accessed 11/30/2017, 10/16/2018, 10/2/2019, 7/17/2020
http://www.ncbi.nlm.nih.gov/pubmed/24831198

Center for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) for Hydrophilic Contact Lens for Corneal Bandage (80.1)

Eslani, M et al (2014) The Ocular Surface Chemical Burns. J Ophthalmol. 2014; 2014: 196827. Accessed 11/30/2017, 10/16/2018, 10/2/2019, 7/17/2020
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4106115/

Jingo Lui et al (2010). Update on amniotic membrane transplantation. Expert Rev Ophthalmol. Oct 2010; 5(5): 645–661. Accessed 11/30/2017, 10/16/2018, 10/2/2019, 07/17/2020
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3061461/pdf/nihms263639.pdf

Malhotra, C., et al (2014) Human amniotic membrane transplantation: Different modalities of its use in ophthalmology. World J Transplant. Jun 24, 2014; 4(2): 111–121. Accessed November 30, 2017, October 16, 2018, October 2, 2019, 7/17/2020
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4094946/

Meller D., et al (2011) Amniotic Membrane Transplantation in the Human Eye. Dtsch Arztebl Int. Apr 2011; 108(14): 243–248. Accessed November 30, 2017, October 16, 2018, October 2, 2019, July 17, 2020
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3087122/

Optum 360, LLC (2020) "Billing for Amniotic Membrane" HCPCS code V2790, CMS directives Internet Only Manuals - 100-04, 4,200.4 American Medical Association

Park, JH, et al (2008) Clinical efficacy of amniotic membrane transplantation in the treatment of various ocular surface diseases. Cont Lens Anterior Eye. 2008 Apr;31(2):73-80. Accessed November 30, 2017, October 16, 2018, October 2, 2019, July 17, 2020
http://www.ncbi.nlm.nih.gov/pubmed/18249149

Thatte, Shreya (2011). Amniotic membrane transplantation: An option for ocular surface disorders. Oman J Ophthalmol. 2011 May-Aug; 4(2): 67–72. Accessed November 30, 2017, October 16, 2018, October 2, 2019, July 17, 2020
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3160072/

Washington State Health Technology Reviews, 2020
https://www.hca.wa.gov/about-hca/health-technology-assessment/health-technology-reviews

Appendix

Policy Number: [Policy Number]

Effective: 10/1/2020 **Next review:** 101/2021

Policy type: Enterprise

Depts: Health Services