



<b>POLICY TITLE</b>	<b>Amniotic Membrane Ocular Surface Treatment</b>		
<b>CATEGORY</b>	Medical Surgical	<b>POLICY ID NUMBER</b>	425_IMED_BASE_v1
<b>AUTHOR DATE</b>	05/06/2024	<b>LAST REVIEW DATE</b>	08/12/2024

**EXCLUSIONS**

**DISCLAIMER**

CPT® Codes, Descriptors, and other data are copyright 2024 American Medical Association (or such other date of publication of CPT®). All Rights Reserved to AMA. Additional resources include CMS Medicare Provider Guidelines @ CMS.gov. This information may not be sold, licensed, or unlawfully used and is intellectual property of EyeMed and the aforementioned entities.

**Applicable Codes:**

- 65778** Placement of amniotic membrane on the ocular surface; without sutures
- 65779** Placement of amniotic membrane on the ocular surface; single layer, sutured
- 65780** Ocular surface reconstruction; amniotic membrane transplantation, multiple layers
- 65781** Ocular surface reconstruction; limbal stem cell allograft
- 65782** Ocular surface reconstruction; limbal conjunctival autograft (includes obtaining graft)
- V2790** Amniotic membrane for surgical reconstruction, per procedure (not billable with 65778 or 65779)

**1 Indication and Limitations<sup>1</sup>**

**1.1 General Information and Definition**

- 1.1.1** Human amniotic membrane is a unique collagenous membrane derived from the innermost submucosa of the placenta
- 1.1.2** It consists of the collagen-rich thick basement membrane and avascular stroma.
- 1.1.3** Promotes healing and is favorable due to its attributes: anti-inflammatory, anti-fibrotic, anti-vascularization, and anti-scarring effects.
- 1.1.4** Promotes re-epithelialization
- 1.1.5** Often used as a sutureless “biological corneal bandage”

<sup>1</sup> Physician attests at time of request submission that physician signed documentation across the full timeframe of treatment rendered (chart, procedures, order, testing interpretation) supports all indications and limitations for service based on this policy and industry billing guidance.

## 1.2 Medical Necessity

- 1.2.1 Used in variety of surgical procedures to cover a defect on the ocular surface to facilitate wound healing and decrease inflammation.
- 1.2.2 Used to facilitate healing of lesions, surgical excisions, necrotic tissue from surgery, injury, infection, or degeneration.
- 1.2.3 Pterygium repair when there is insufficient healthy tissue to create a conjunctival autograft.
- 1.2.4 Severe ophthalmological conditions with ocular surface cell damage, failure and/or underlying scarring or ulceration of underlying stroma
- 1.2.5 Severe condition requiring acute treatment with amniotic membrane including chemical, thermal, and radiation injuries, Stevens Johnson Syndrome, limbal stem cell failure
- 1.2.6 Band keratopathy after treatment with other surgery, topical medications, bandage CL or patching
- 1.2.7 Bullous keratopathy with persistent epithelial defect after treatment with topical medications AND bandage contact lens or patching.
- 1.2.8 Scleral melting
- 1.2.9 Corneal ulcer following anti-infective therapy and demonstration of clinical response for the purpose of healing the persistent epithelial defect
  - 1.2.9.1 Persistent defect is defined as non-closure after 5 days of conservative therapy
- 1.2.10 Chemical burns to ocular surface
- 1.2.11 Corneal melting
- 1.2.12 Limbal stem cell deficiency
- 1.2.13 Recurrent corneal erosions after treatment failure with a minimum of 2 of the 3 modalities:
  - 1. Bandage contact lens or patching
  - 2. Topical ophthalmic medications
  - 3. Anterior stromal puncture, surface debridement or PTK
- 1.2.14 Significant keratitis (including exposure, neurotrophic, filamentary) after treatment failure with bandage contact lens AND topical lubrication or prescription medications.

## 1.3 Utilization Guidelines

- 1.3.1 One placement per eye is expected in an episode of care. More than one will be subject to prepayment review and possible denial
- 1.3.2 Treatment is typically considered to be acute short-term care (65778)

## 1.4 Limitations

- 1.4.1 Severe dry eye syndrome treatment is considered under special circumstances and subject to prior authorization
  - 1.4.1.1 **All** prior authorization criteria must be satisfied prior to treatment (65778, 65779)
    - 1.4.1.1.1 Must have documented failure, nonresponse, or contraindication of conservative therapy to **ALL** of the following:

- 1. Topical lubrication AND

2. Punctal occlusion AND
3. Prescription ophthalmic medication (Cyclosporin A, steroids, NSAIDs, antibiotics, and/or autologous serum eye drops)

- 1.4.1.1.2** Dry Eye Workshop Score (DEWS) of 4, indicating severe dry eye with ocular surface disease
- 1.4.1.1.3** Surface staining (Rose Bengal or fluorescein) to indicated damaged cell membranes and/or gaps in the epithelial cell surface
- 1.4.1.1.4** Must have clinical findings of active ocular surface disease including but not limited to keratitis, staining defects, or epithelial defect.
- 1.4.1.2** Prior authorization good for one episodic treatment of one amniotic bandage per eye within 6 months
  - 1.4.1.2.1** Repeat treatment is rare and will be considered on a case-by-case basis
- 1.4.1.3** Maximum usage is 2 amniotic bandages per year per eye
- 1.4.2** Amniotic membrane must be cleared by or registered with the US Food and Drug Administration (FDA) for sutureless application of the eye, (for appropriate code)
- 1.4.3** During the global period following surgery, unplanned usage not requiring a return to the operating room is subject to the principles for global surgery defined in the Medicare Claims Processing manual (Chap 12 SS. 40) and will not be reimbursed separately
- 1.4.4** The supply code V2790 is considered bundled into the CPT and is not reimbursed separately.

## 2 Supporting Diagnoses

H11.001-11.003	Unspecified pterygium of (right, left, bilateral) eye
H11.009	Unspecified pterygium of unspecified eye
H11.011-11.013	Amyloid pterygium of (right, left, bilateral) eye
H11.019	Amyloid pterygium of unspecified eye
H11.021-11.023	Central pterygium of (right, left, bilateral) eye
H11.029	Central pterygium of unspecified eye
H11.031-H11.033	Double pterygium of (right, left, bilateral) eye
H11.039	Double pterygium of unspecified eye
H11.041-H11.043	Peripheral pterygium of (right, left, bilateral) eye, stationary
H11.049	Peripheral pterygium of unspecified eye, stationary
H11.051-H11.053	Peripheral pterygium of (right, left, bilateral) eye, progressive
H11.059	Peripheral pterygium of unspecified eye, progressive
H11.061-H11.063	Recurrent pterygium of (right, left, bilateral) eye
H11.069	recurrent pterygium of unspecified eye

H11.811-813	Pseudopterygium of conjunctiva, (right, left, bilateral) eye
H11.819	Pseudopterygium of conjunctiva,unspecified eye
H11.821-823	Conjunctivochalasis, (right, left, bilateral) eye
H11.829	Conjunctivochalasis, unspecified eye
H15.89	Other disorders of sclera
H15.9	Unspecified disorder of sclera
H16.001-H16.003	Unspecified corneal ulcer, (right, left, bilateral) eye
H16.009	Unspecified corneal ulcer, unspecified eye
H16.011-H16.013	Central corneal ulcer, (right, left, bilateral) eye
H16.019	Central corneal ulcer, unspecified eye
H16.021-H16.023	Ring corneal ulcer, (right, left, bilateral) eye
H16.029	Ring corneal ulcer, unspecified eye
H16.031-H16.033	Corneal ulcer w hypopyon, (right, left, bilateral) eye
H16.039	Corneal ulcer w hypopyon, unspecified eye
H16.041-H16.043	Marginal corneal ulcer, (right, left, bilateral) eye
H16.049	Marginal corneal ulcer, unspecified eye
H16.051-H16.053	Mooren’s corneal ulcer, (right, left, bilateral) eye
H16.059	Mooren’s corneal ulcer, unspecified eye
H16.061-H16.063	Mycotic corneal ulcer, (right, left, bilateral) eye
H16.069	Mycotic corneal ulcer, unspecified) eye
H16.071-H16.073	Perforated corneal ulcer, (right, left, bilateral) eye
H16.079	Perforated corneal ulcer, (unspecified eye
H16.121-H16.123	Filamentary keratitis, (right, left, bilateral) eye
H16.129	Filamentary keratitis, unspecified eye
H16.231-H16.233	Neurotrophic keratoconjunctivitis, (right, left, bilateral) eye
H16.239	Neurotrophic keratoconjunctivitis, unspecified eye
H18.10-18.13	Bullous keratopathy, (right, left, bilateral) eye
H18.40	Unspecified corneal degeneration
H18.421-H18.423	Band keratopathy, (right, left, bilateral) eye
H18.429	Band keratopathy, unspecified eye
H18.821-H18.823	Corneal disorder due to contact lens, (right, left, bilateral) eye
H18.829	Corneal disorder due to contact lens, unspecified eye
H18.831-H18.833	Recurrent erosion of cornea, (right, left, bilateral) eye
H18.839	Recurrent erosion of cornea, unspecified eye
H18.891-H18.893	Other specified disorders of cornea, (right, left, bilateral) eye
H18.899	Other specified disorders of cornea, bilateral eye
L51.0	Non-bullous erythema multiforme
L51.1	Stevens-Johnson syndrome
L51.3	Stevens-Johnson syndrome-toxic epidermal necrolysis overlap syndrome
L51.9	Erythema multiforme, unspecified
T26.00XA-T26.92XS	Trauma, burn, corrosion eye, adnexa (see ICD-10 Manual for specific injury codes

## References<sup>2</sup>

- CGS Administrators, LLC. Local Coverage Article. (A53441). "Billing & Coding: Amniotic Membrane Billing Guidelines." Jurisdiction J-J & J-M.
- CGS Administrators, LLC. Local Coverage Determination. (L36237) "Amniotic Membrane – Sutureless Placement on the Ocular Surface". Jurisdiction J-N.
- Behrens A , Doyle JJ , Stern L , et al. "Dysfunctional tear syndrome. A Delphi approach to treatment recommendations." *Cornea* 2006 ;25:9 0-7.
- Bouchard CS, John T. "Amniotic membrane transplantation in the management of severe ocular surface disease: indications and outcomes." *Ocular Surface*. Jul 2004;2(3):201-211.
- Eslani M, Baradaran-Rafii A, et al. "Amniotic Membrane Transplantation in Acute Severe Ocular Chemical Injury: A Randomized Clinical Trial." *Am. Journ. Ophthalmol.* 2019 Mar;199:209-215.
- John T, Tighe S, Sheha H, et al. "Corneal nerve regeneration after self-retained cryopreserved amniotic membrane in dry eye disease." *Journal Ophthalmol.* Aug 15, 2017;2017:6404918.
- Kaufman SC, Jacobs DS, Lee WB, et al. "Options and adjuvants in surgery for pterygium: a report by the American Academy of Ophthalmology." *Ophthalmology*. Jan 2013;120(1):201-208.
- Kheirkhah, AA, Casas, VV, et al. "Sutureless amniotic membrane transplantation for partial limbal stem cell deficiency." *Am. Journal . Ophthalmol.*, 2008 Mar 11;145(5).
- Liu J, Li L, Li X. "Effectiveness of Cryopreserved Amniotic Membrane Transplantation in Corneal Ulceration: A Meta-Analysis." *Cornea*. 2019 Apr;38(4).
- McDonald, MM, Sheha, et al. "Treatment outcomes in the Dry Eye Amniotic Membrane (DREAM) study." *Clin Ophthalmol*, 2018 Apr 20;12:677-681.
- Pachigolla, GG, Prasher, PP, Di Pascuale, et al, "Evaluation of the role of ProKera in the management of ocular surface and orbital disorders." *Eye Contact Lens*, 2009 May 29;35(4).
- Paris Fidos S, Goncalves ED, et al. "Amniotic membrane transplantation versus anterior stromal puncture in bullous keratopathy: a comparative study." *Ophthalmol.* Aug 2013;97(8):980-984.
- Sharma N, Thenarasun SA, Kaur M, et al. "Adjuvant role of amniotic membrane transplantation in acute ocular stevens-johnson syndrome: a randomized control trial." *Ophthalmology*. Mar 2016;123(3):484-491.
- Suri, KK, Kosker, MM, Raber, II, et al, "Sutureless amniotic membrane ProKera for ocular surface disorders: short-term results." *Eye Contact Lens*, 2013 Aug 16;39(5).
- Tamhane A, Vajpayee RB, Biswas NR, et al. "Evaluation of amniotic membrane transplantation as an adjunct to medical therapy as compared with medical therapy alone in acute ocular burns." *Ophthalmology*. 2005 Nov;112(11).
- Tandon, RR, Gupta, et al. "Amniotic membrane transplantation as an adjunct to medical therapy in acute ocular burns." *Brit Journ Ophthalmol*, 2010 Aug 3;95(2).
- Yin HY, Cheng AMS, Tighe S, et al. "Self-retained cryopreserved amniotic membrane for treating severe corneal ulcers: a comparative, retrospective control study." *Sci Rep*. Oct 12 2020; 10(1).

---

<sup>2</sup> Retrieved electronically June 2023

Miller DD, Hasan SA, Simmons NL, Stewart MW. Recurrent corneal erosion: a comprehensive review. Clin Ophthalmol. 2019 Feb 11;13:325-335. doi: 10.2147/OPTH.S157430. PMID: 30809089; PMCID: PMC6376883.

Walkden A. Amniotic Membrane Transplantation in Ophthalmology: An Updated Perspective. Clin Ophthalmol. 2020 Jul 22;14:2057-2072. doi: 10.2147/OPTH.S208008. PMID: 32801614; PMCID: PMC7383023.

### **Review and Approval Change Log**

May 2024	Medical Surgical policy drafted
May 2024	Scope limited to medical surgical prior authorization requirement.
August 2024	Update and review with Dr. Fackler, additional references added.
November 2024	Client UM Committee Approved