Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

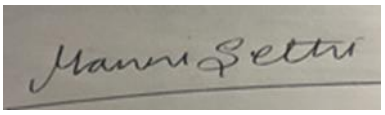
Plan: AmeriHealth Caritas Pennsylvania & Keystone First	**Submission Date**: 3/1/2025
Policy Number: ccp.1077	**Effective Date:** 6/2014 **Revision Date:** 2/2025
Policy Name: Therapeutic contact lenses	

Type of Submission:	Type of Policy:
☐ New Policy	☒ Prior Authorization Policy
☒ Revised Policy*	☐ Base Policy
☐ Annual Review- no revisions	☐ Experimental/Investigational Policy
	☐ Statewide PDL
	☐ Other:

*All revisions to the policy must be highlighted using track changes throughout the document.

Please provide any clarifying information for the policy below:

Please see tracked changes below.

Name of Authorized Individual (Please type or print):	Signature of Authorized Individual:
Manni Sethi, MD, MBA, CHCQM	

Therapeutic contact lenses

Clinical Policy ID: CCP.1077

Recent review date: 2/2025

Next review date: 6/2026

Policy contains: Amniotic membrane transplantation; Boston scleral lens; Hydrophilic contact lens for corneal bandage; Scleral shell lens

Keystone First- CHIP has developed clinical policies to assist with making coverage determinations. Keystone First- CHIP's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First- CHIP, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First- CHIP's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First- CHIP's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First- CHIP will update its clinical policies as necessary. Keystone First- CHIP's clinical policies are not guarantees of payment.

Coverage policy

The use of therapeutic contact lenses is clinically proven and, therefore, may be medically necessary when all of the following criteria are met (American Academy of Ophthalmology, 2022; Lim, 2020; Watson, 2012):

- Use of any of the following lens types:
  - Contact lenses or intra-ocular lenses placed after cataract surgery, as they are considered prostheses unless otherwise specified by the member's benefit plan.
  - Hydrophilic soft contact lenses or gas-permeable fluid ventilated scleral lenses, when used in the management of severe corneal disease.
  - Boston scleral lens when used as a moist corneal bandage if lubricants or drops are not appropriate.
  - Scleral shell contact lenses for the treatment of severe keratoconjunctivitis sicca and/or when the orbit requires greater support because of the loss of corneal strength.

- Correction of any of the following functional impairments:
  - Not able to achieve vision of 20/40 or better, despite best correction with eyeglasses or typical contact lenses.
  - Lenses will delay/prevent the need for corneal transplantation.
  - Will improve performance of activities of daily living.

Amniotic membrane transplantation is clinically proven and, therefore, may be medically necessary on a case-by-case basis for circumstances where there is a severe condition requiring acute treatment, such as (Clare, 2012; Zhao, 2015):

- Chemical, thermal, or radiation injuries.
- Stevens Johnson Syndrome.
- Limbal stem cell failure.

Limitations

All other uses of therapeutic contact lenses are not medically necessary.

Contact lenses for vision correction are subject to benefit plans of the individual member.

The use of contact lenses for treatment of visual perceptual dysfunction, such as dyslexia, has not had consistent results in clinical studies and cannot be considered medically necessary.

Alternative covered services

- Physician office visits.
- Standard covered ocular surgery.
- Standard medical management of corneal disease.

Background

Therapeutic contact lenses are designed to manage other ocular pathology beyond simple refractive disorders. There are several types of therapeutic lenses available for the management of these disorders, consisting of (Gromacki, 2012):

- The corneal liquid bandage lens may be rigid gas permeable scleral contact lenses or a therapeutic contact lens. They are used to treat acute or chronic corneal disease, such as the persistent epithelial defects listed above. These lenses protect the cornea from the drying effects of air and may reduce pain and photophobia. Because such lenses cover the entire cornea with a smooth surface, they may improve vision that results from acute astigmatism.
- The Boston scleral lens was developed through the Boston Foundation for Sight. It is a specially designed fluid-ventilated, gas-permeable contact lens. The design allows a bubble-free reservoir of oxygenated aqueous fluid to cover the corneal surface, at a neutral hydrostatic pressure. This design makes it well suited for severe corneal diseases.
- The scleral shell contact lens covers the entire exposed surface of the eye. For individuals with severe dry eye, such as keratoconjunctivitis, the scleral shell lens can hold artificial tears that have been dropped into the eye. These lenses protect the eye against further drying. The scleral shell also allows support and protection when severe corneal disease has rendered the person blind. Use of the scleral shell may prevent enucleation by providing support for the rest of the eye.
- Amniotic membrane transplantation is performed in cases of severe thermal or chemical burns to the cornea to reduce pain and accelerate healing.

Findings

Most studies on the various medical uses of contact lenses have been single site, with relatively small numbers enrolled. We found no recent meta-analyses of therapeutic contact lenses or head-to-head comparisons between the various products. Reviews of studies of amniotic membrane transplantation have not found sufficient evidence from published, peer-reviewed articles to support its routine use (Clare, 2012).

A review of the professional literature lists pain relief, enhancement of corneal healing, corneal sealing, corneal protection, and drug delivery as indications for use of therapeutic contact lenses. Associated conditions and procedures include painful corneal diseases such as keratopathy; keratectomy; severe dry eye; post–amniotic membrane transplant; sealing corneal perforations; corneal protection from eyelid conditions; and maintaining therapeutic concentrations during ocular drug delivery (Lim, 2020).

A detailed review presents information on new developments in drug-eluting ophthalmic lenses that sustain drug delivery to the eye in treating various ophthalmologic conditions (Toffoletto, 2020).

A survey of patients (n = 659) with dry eye disease using therapeutic contact lenses found a large proportion reported mid-day fogging or clouding of vision (75% for scleral lenses, 62% for soft lenses). Large proportions (72% and 43%) of wearers of these lenses spent over 20 minutes per day on dry eye (Shorter, 2023).

In a systematic review, three of 10 studies assessed outcomes for patients with shield ulcers who later had surgical debridement and amniotic membrane transplantations. One study showed a 94% resolution rate, with a 15% recurrence rate, based on 44 patients. The other two studies only included six patients. No comparison of outcomes was made with patients who did not have amniotic membrane transplantation (Azizi, 2023).

Professional guidelines note the absence of such studies and recommend that providers describe the advantages of various strategies, thus allowing the patient to be an active participant in the clinical judgment (American Academy of Ophthalmology, 2022). There is consensus that patients with corneal pathology that threatens to weaken the architecture of the eye should be treated with appropriate medical therapy and/or supporting contact lenses. The corneal disorders for which contact lenses may become therapeutic include the following conditions:

- Aphakia.
- Prostheses following cataract surgery.
- Stevens-Johnson syndrome, toxic epidermolysis necrosis, chemical burns, or other corneal stem cell deficiencies.
- Congenital anomalies.
- Neurotrophic corneas.
- Keratoconjunctivitis with reduced tear production.
- Corneal involvement of systemic autoimmune disorders.
- Corneal exposure disorders.
- Epidermal ocular disorders.
- Keratoconus associated with irregular astigmatism.

In 2025, we found a systematic review of amniotic membrane grafting for ocular burns (Veldman, 2024) that reviewed nine studies (n = 505). Among these, three key randomized controlled trials (n = 182) demonstrated that amniotic membrane grafting added to medical therapy accelerated healing only in moderate burns. The first study (n = 44 eyes) showed significantly faster epithelial defect reduction at week 1 in moderate burns (7.4 vs 6.2 points), but no benefit in severe burns or later. A second trial (n = 100) reported faster epithelial healing rates (2.5 vs 0.8 mm²/day) in moderate burns only. The final trial studied 45 participants (30 eyes analyzed), finding substantially shorter re-epithelialization time in the treatment group (22 vs 57 days). While these studies showed accelerated healing in moderate ocular surface burns, none demonstrated improvements in severe burns or final visual acuity outcomes, which impacts medical necessity considerations.

References

On January 10, 2025, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “Contact Lenses/therapeutic use”(MeSH), “Contact Lenses, Extended-Wear/therapeutic use”(MeSH), “therapeutic contact lenses,” and “amniotic membrane.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

American Academy of Ophthalmology. Preferred Practice Pattern Panels. Summary Benchmarks – full set – 2022. https://www.aao.org/summary-benchmark-detail/summary-benchmarks-full-set-2020. Published December 2022.

Azizi S, Subhi Y, Rasmussen MLR. Surgical treatment of corneal shield ulcer in vernal keratoconjunctivitis: A systematic review. *J Pers Med*. 2023;13(7):1092. Doi: 10.3390/jpm13071092.

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Lim L, Lim EWL. Therapeutic contact lenses in the treatment of corneal and ocular surface diseases – A review. *Asia Pac J Ophthalmol (Phila)*. 2020;9(6):524-532. Doi: 10.1097/APO.0000000000000331.

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Toffoletto N, Saramago B, Serro AP. Therapeutic ophthalmic lenses: A review. *Pharmaceutics*. 2020;13(1):36. Doi: 10.3390/pharmaceutics13010036.

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Policy updates

12/2013: initial review date and clinical policy effective date: 6/2014

11/2016: Policy references updated.

11/2017: Policy references updated.

1/2018: Policy references updated.

10/2018: Policy references updated.

11/2019: Policy references updated.

2/2021: Policy references updated.

2/2022: Policy references updated.

2/2023: Policy references updated; no new references added.

2/2024: Policy references updated.

2/2025: Policy references updated.