Therapeutic contact lenses

Clinical Policy ID: CCP.1077

Recent review date: 2/2022

Next review date: 6/2023

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

AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas' 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 AmeriHealth Caritas 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. AmeriHealth Caritas' 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. AmeriHealth Caritas' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas' clinical policies are not guarantees of payment.

Coverage policy

The use of therapeutic contact lenses is clinically proven and, therefore, medically necessary when all of the following criteria are met (American Academy of Ophthalmology, 2019; 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, 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.

For Medicare members only

For services performed on or after October 1, 2015, amniotic membrane transplantation for ocular conditions is considered clinically proven and, therefore, medically necessary for any of the following indications (Centers for Medicare & Medicaid Services, 2019):

- Failure of standard therapy for severe ophthalmological conditions demonstrated by ocular surface cell damage or failure and/or inflammation, scarring, or ulceration of the underlying stroma.
- A severe condition requiring acute treatment with amniotic membrane, such as:
    - Chemical, thermal or radiation injuries.
    - Stevens Johnson Syndrome.
    - Limbal stem cell failure.
- Band keratopathy after treatment with other therapy, such as:
    - Surgery.
    - Topical medications
    - Bandage contact lens.
    - Patching.
- Bullous keratopathy associated with an epithelial defect.
- Scleral melting.
- Corneal ulcer following initiation of anti-infective therapy and demonstration of clinical response for the purpose of healing the persistent epithelial defect.
- Conjunctival defects after other therapy, such as surgery or topical medications.
- Corneal melting.
- Recurrent corneal erosions after treatment failure with other therapy, such as:
    - Bandage contact lens.
    - Patching.
    - Topical medications.

Limitations for Medicare members only

Amniotic membrane must have U.S. Food and Drug Administration approval for sutureless applications to eye.

Application for dry eye syndrome is not medically necessary, given no demonstrated impact on long-term outcome.

Cogan’s Dystrophy is not covered unless associated with corneal epithelial removal.

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

A Local Coverage Determination provides guidance when amniotic membrane transplantation is medically necessary (Centers for Medicare & Medicaid Services, 2019). Three National Coverage Determinations state that hydrophilic contact lenses are not necessary for non-diseased eyes, but can be used as corneal bandages; and define scleral shells as a type of contact lens indicated for treating dry eyes when used with artificial tears (Centers for Medicare & Medicaid Services, effective date not posted).

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).

Professional guidelines note the absence of such studies and recommend that the professional describe the advantages of various strategies, thus allowing the patient to be an active participant in the clinical judgment (American Academy of Ophthalmology, 2017). 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.

References

On December 1, 2021, 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 – 2019. https://www.aao.org/summary-benchmark-detail/summary-benchmarks-full-set-2019.

Centers for Medicare & Medicaid Services. Local Coverage Determination. L36237 Amniotic membrane-sutureless placement on the ocular surface. https://www.cms.gov/medicare-coverage-database/new-search/search.aspx. Last revised January 8, 2019.

Centers for Medicare & Medicaid Services. National Coverage Determination manual section 80.1. Hydrophilic contact lens for corneal bandage. https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=136&ncdver=1&DocID=80.1&kq=true&bc=gAAAABAAAAAA&. Effective date not posted.

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Zhao Y, Ma L. Systematic review and meta-analysis on transplantation of ex vivo cultivated limbal epithelial stem cell on amniotic membrane in limbal stem cell deficiency. *Cornea.* 2015;34(5):592-600. Doi: 10.1097/ico.0000000000000398.

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.