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## Therapeutic Lenses, Scleral Shell

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Related Policies (if applicable)
None

### Disclaimer

**Carefully check state regulations and/or the member contract.**

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

### Legislative Mandates

**EXCEPTION:** For HCSC members residing in the state of Arkansas, § 23-79-1502 relating to craniofacial anomaly corrective surgery, requires coverage and benefits for reconstructive surgery and related medical care for a person of any age who is diagnosed as having a craniofacial anomaly if the surgery and treatment are medically necessary to improve a functional impairment that results from the craniofacial anomaly. Coverage shall also be required, annually, for Sclera contact lenses, including coatings, office visits, an ocular impression of each eye, and any additional tests or procedures that are medically necessary for a craniofacial patient. Coverage shall also be required every two [2] years, two [2] hearing aids and two [2] hearing aid molds for each ear; this includes behind the ear, in the ear, wearable bone conductions, surgically implanted bone conduction services, and cochlear implants. Medical care coverage required includes coverage for reconstructive surgery, dental care, and vision care. This applies to the following: Fully Insured Group, Student, Small Group, Mid-Market, Large Group, HMO, EPO, PPO, POS. Unless indicated by the group, this mandate or coverage will not apply to ASO groups.

### Coverage

**NOTE 1:** Eyeglasses and contact lenses are generally a vision benefit and therefore not included as a medical contract benefit. Check the member's contract carefully for vision benefit.

### **Therapeutic Lenses**

Eyeglasses and contact lenses **may be considered medically necessary** under a member's medical benefit plan as prosthetics for the following indications:

1. Eyeglasses, intraocular lenses, or contact lenses as a prosthetic device following cataract surgery when covered by the benefit contract.
2. Eyeglasses or contact lenses when initially prescribed to correct a vision change that is a direct result of accidental bodily injury.
3. Eyeglasses or contact lenses to correct ocular surface disease resulting in pain and/or decreased visual acuity (e.g., bullous keratopathy, corneal erosions, corneal ulcers, exposure keratopathy, graft vs host disease, keratitis, keratopathy, mucus membrane pemphigoid, neurotrophic, persistent epithelial defects, post glaucoma filtering surgery, postocular surface tumor excision, sequelae of Stevens Johnson syndrome, severe dry eye).
4. Contact lenses for the non-surgical correction of the cornea. (e.g., keratoconus, keratoglobus, pellucid marginal degeneration, Terrien marginal degeneration, Fuch's superficial marginal keratitis, postsurgical ectasia and/or other causes of acquired irregular astigmatism which cannot be corrected by glasses).
5. Contact lenses for corneal scars or post penetrating keratoplasty (PKP).

**NOTE 2:** Bandage lenses may require frequent changes and may be used on a short or long-term basis. The procedure includes the fitting of the lens, as well as replacement of the lens.

Sunglasses **are considered not medically necessary** if provided in addition to regular cataract glasses or lenses.

Deluxe frames and deluxe lens features, including but not limited to tinting, mirror coating, progressive lens and scratch resistant coating, are convenience items and **are considered not medically necessary**.

Contact lenses or combination of contact lenses and eyeglasses **are considered not medically necessary** for the treatment of pseudophakia.

Contact lenses or glasses for the treatment of refractive errors **are not considered a covered benefit**, except under the provisions of a vision benefit contract.

### **Scleral Shell**

Scleral shells **may be considered medically necessary:**

1. When used as an artificial eye or for corneal coverage when the eye has been rendered sightless, shrunken and/or deformed. This may include coverage for phthisis and disfiguring cornea opacity in people who are not candidates for corneal transplantation; OR
2. For premature babies and/or children whose eyes did not develop properly or completely and using a scleral shell will allow the bone structure of the eye socket as well as the eyelid

to develop correctly during growth.

A scleral shell when used for any other indication, including: to improve the appearance of a discolored eye **is considered not medically necessary.**

## Policy Guidelines

None.

## Description

The term “therapeutic” is derived from the Greek word “therapeuein” meaning to take care of, or to heal. The term “therapeutic” is often used as if it applied to a specific type of contact lens, when in reality, nearly every lens type can be used in a therapeutic capacity. Therapeutic contact lenses are designed to manage other ocular pathology beyond simple refractive disorders and have become an effective tool in the management of a wide variety of ophthalmic disorders. Therapeutic contact lenses (TCLs) may be used for the relief of ocular pain, promotion of corneal healing, mechanical protection and support, maintenance of corneal epithelial hydration, and drug delivery. (1)

### Glossary of Terms

- **Astigmatism:** Distorted vision resulting from an irregularly curved cornea, the clear covering of the eyeball. (2)
- **Artificial eye:** Prosthetic device resembling the anterior surface of a normal eyeball. It is fitted under the upper and lower eyelid of an eye that has been removed. (3)
- **Bandage lenses:** Soft contact lens worn on a diseased or injured cornea to protect or treat it while it heals (e.g. after a corneal abrasion or keratoplasty). (3)
- **Bullous keratopathy:** Edema of the corneal stroma and epithelium resulting in formation of bullae on the corneal surface. It occurs in Fuchs epithelial dystrophy, advanced glaucoma and iridocyclitis, endothelial failure, and sometimes after intraocular lens (IOL) implantation. (3)
- **Cataract:** Opacity of the lens of the eye or its capsule or both. Cataract may result from injuries to the eye, exposure to heat or radiation, or inherited factors. (3)
- **Contact lens:** Lightweight corrective, cosmetic or therapeutic device that is usually placed directly onto either the cornea, or the cornea and sclera of the eye. (3) Examples of TCLs may include corneal liquid bandage lens, Boston scleral lens and scleral shell contact lens.
- **Cornea:** Transparent part of the eye that covers the front portion of the eye. It covers the pupil, iris and anterior chamber of the eye. The cornea’s main function is to focus the light that enters the eye. The cornea tends to repair itself quickly from minor abrasions, however, deeper abrasions may lead to scar formation causing the cornea to lose transparency, leading to visual impairment. (4)
- **Corneal abrasion:** Scratch or scrape on the eye’s cornea. (5)

- Corneal ectasia: Corneal ectasia is a noninflammatory condition encompassing both naturally occurring and surgically induced corneal thinning and protrusion. Types of cornea ectasia include keratoconus, pellucid marginal degeneration, keratoglobus, post keratorefractive ectasia and wound ectasia after surgical intervention. (6)
- Corneal ectatic disorders: A group of uncommon, noninflammatory, eye disorders characterized by bilateral thinning of the central, paracentral, or peripheral cornea. Disorders include the following conditions: Keratoconus, Keratoglobus, Pellucid marginal degeneration, Posterior keratoconus, Post-LASIK ectasia, and Terrien's marginal degeneration. Treatment options include contact lenses and intrastromal corneal ring segments for correcting refractive errors caused by irregular corneal surface, corneal collagen cross-linking to strengthen a weak and ectatic cornea, or corneal transplant for advanced cases. (3)
- Corneal erosion: When the epithelium does not stay attached correctly to the corneal tissue below, including the layer called the Bowman's layer or the basement membrane. (5)
- Corneal scar: When the cornea becomes damaged through disease, infection, or injury, the resulting scar(s) can interfere with vision by blocking or distorting light as it enters the eye. (7)
- Corneal transplantation: Surgical procedure to replace part of the cornea with corneal tissue from a donor (keratoplasty, PKP, corneal transplantation). Keratoplasty is indicated for a number of serious corneal conditions (e.g., scarring, edema, thinning, and distortion). Lamellar keratoplasty is a partial thickness corneal grafting. Penetrating keratoplasty is full thickness corneal grafting. (8)
- Corneal ulcers: Open sore (ulceration) on the cornea. Also, known as ulcerative keratitis. (3)
- Dry eye: Condition which there is insufficient tears to lubricate and nourish the eye. Tears are necessary for maintaining the health of the anterior surface of the eye and for providing clear vision. People with dry eyes either do not produce enough tears or have a poor quality of tears. The most common form of dry eyes is due to an inadequate amount of the water layer of tears. This condition, called keratoconjunctivitis sicca (KCS), is also referred to as dry eye syndrome. Dry eyes can occur due to many factors including but not limited to age, gender, medication use, medical conditions, and environmental conditions. (9)
- Endothelium: Single layer of cells located between the stroma and the aqueous humor. The endothelium works as a pump, expelling excess water back into the eye as it is absorbed into the stroma. Without this specialized function, the stroma would become waterlogged, creating a hazy and opaque cornea and reducing vision. (7)
- Epithelium: Most superficial layer of the cornea, the epithelium stops outside matter from entering the eye. This layer of the cornea also absorbs oxygen and nutrients from tears. (7)
- Exposure keratopathy: Condition caused by the cornea constantly being exposed to the atmosphere. (10)
- Graft-versus-host disease (GVHD): Complication that may occur in which cells from the transplanted tissue of a donor (allogeneic) initiate an immunologic attack on the cells and tissue of the recipient. GVHD does not occur when someone receives his or her own cells during a transplant (autologous). (3)

- Keratitis: Inflammation of the cornea, the clear, dome-shaped tissue on the anterior portion of the eye that covers the pupil and iris. Keratitis may or may not be associated with an infection. Noninfectious keratitis can be caused by a relatively minor injury, wearing your contact lenses too long or other diseases. Infectious keratitis can be caused by bacteria, viruses, fungi and parasites. (11)
- Keratoconus: Distorted curvature of the cornea. (2)
- Keratoglobus: Degenerative non-inflammatory disorder of the eye in which structural changes within the cornea cause it to become extremely thin and change to a more globular shape than its normal gradual curve. This disorder causes corneal thinning, primarily at the margins, resulting in a spherical, slightly enlarged eye. (3)
- Keratopathy: Non-inflammatory disease of the cornea (3)
- Mucous membrane pemphigoid (MMP): Mucous membrane pemphigoid (MMP) is a rare, chronic, autoimmune, subepithelial blistering and erosive disease that affects the mucosal surfaces of the mouth (gingiva, movable mucosa, tongue, and palate), eyes, nose, nasopharynx, hypopharynx, larynx, esophagus, genitals, and/or anus. Limited cutaneous involvement (typically localized to the head, neck, or upper trunk) also may be present. The oral cavity is the most common site of mucous membrane pemphigoid (MMP). Patients with extraoral mucous membrane pemphigoid (MMP; ocular, nasal, laryngeal, esophageal, or anogenital MMP) are considered to be at high risk for developing serious functional limitations as a consequence of mucosal inflammation and scarring. The exact cause of MMP is unknown. (12)
- Ectasia: Expansion of a hollow or tubular organ. (13)
- Hyperopia: Farsightedness; difficulty seeing close objects clearly. (2)
- Myopia: Nearsightedness; difficulty in seeing distant objects clearly. (2)
- Opacity: Quality or state of a body that makes it impervious to the rays of light or an opaque spot in a normally transparent structure (e.g., lens of the eye). (13)
- Pellucid marginal degeneration (PMD): Progressive condition in which thinning occurs over many years, resulting in a crescent shaped band of inferior corneal thinning approaching 20% of normal thickness. It can cause severe deterioration in visual function. Patients who undergo refractive surgery with PMD can have deleterious results. (14)
- Penetrating keratoplasty (PKP): The entire thickness of the cornea is removed and replaced by transparent corneal tissue. Another name for corneal transplantation. (3)
- Phthisis bulbi: Wasting and shrinkage of the eyeball following destructive diseases of the eye. (13)
- Presbyopia: Refractive error which leads to difficulty in reading or seeing at arm's length; it is linked to aging and occurs almost universally. (2)
- Pseudophakia: Eye in which the natural lens is replaced with an IOL. (3)
- Refractive error: Common eye disorder that occurs when the eye cannot clearly focus the images from the outside world resulting in blurred vision, which is sometimes so severe that it causes visual impairment. The four most common refractive errors are myopia, hyperopia, astigmatism, and presbyopia. (2)
- Scleral shell: Prosthetic device that fits over the entire exposed surface of the eye, unlike a corneal contact lens that only covers the white area encompassing the pupil and iris. A

scleral shell may, among other things, obviate the need for surgical enucleation and prosthetic implant and act to support the surrounding orbital tissue when an eye has been rendered sightless and shrunken by inflammatory disease. (15)

- Stevens Johnson syndrome: Rare, serious disorder of the skin and mucous membranes usually triggered by a reaction to a medication or an infection. Symptoms may include blisters on the skin and the mucous membranes of the mouth, nose, eyes and genitals. Treatment focuses on eliminating the underlying cause, controlling symptoms and minimizing complications. (16)
- Stroma: Middle and thickest layer of the cornea and is found behind the epithelium. It is made up mostly of water and proteins that give it an elastic but solid form. (7)
- Terrien marginal degeneration: Ocular condition that is essentially a painless, bilateral peripheral corneal thinning disorder, characterized by intact epithelium overlying areas of thinning and by irregular astigmatism. (3)

## Rationale

This medical policy was created in September 2002 and has been updated regularly with searches of the PubMed database. The most recent literature review was performed through October 7, 2022.

Medical policies assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical uses of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

No recent randomized controlled trials (RCT'S) or meta-analyses on the use of therapeutic lenses or scleral shells were identified. Current available evidence consists primarily of case

series and small non-randomized trials. The overall goal of therapeutic glasses and contacts is to delay or prevent corneal transplantation.

### **Professional Guidelines and Position Statements**

In 2012, the American Academy of Ophthalmology (AAO) published a paper reviewing the uses of scleral contact lenses. (17) Researchers reported success using scleral lenses for a wide range of ocular conditions to include patients with corneal disease, keratoconus, Pellucid marginal degeneration (PMD), Stevens Johnson syndrome, chronic graft versus host disease (GVHD), and in patients with reduced visual acuity post penetrating keratoplasty or other types of ocular surgery. It allows contact lenses as a treatment option for improving vision without surgery once the bacterial infection is resolved and the ulcer is scarred over.

In 2018, the AAO published a preferred practice pattern evaluating the diagnosis and treatment of corneal edema and Opacification. (18) It states that for corneal edema microcystic, or bullous epithelial disease may produce discomfort or pain, necessitating the placement of a bandage lens to alleviate these symptoms. Although many lenses may be used, thin lenses with high water content and high oxygen diffusion coefficients (i.e., Dk levels) are thought to be most advantages. Generally, a flat lens that will have some movement on blinking is desirable. If there is concomitant dry eye disease, preservative-free artificial tears may be necessary to facilitate sufficient movement of the lens. For corneal opacification, A rigid gas permeable (RGP) lens, or hybrid or scleral lens when greater stability is needed will often improve vision when surface irregularity is a factor; such lenses may preclude the need for more invasive procedures.

In 2018, the AAO published recommendations for severe dry eye syndrome (19) which states that rigid gas permeable scleral lenses have been used successfully in the treatment of severe dry eye syndrome for years. Widespread use of scleral lenses may be limited by fitting difficulties (particularly in the presence of conjunctival cicatrization), patient willingness and ability to wear the lenses and high costs. Soft contact lenses may provide symptomatic relief in selected cases, particularly in the setting of filamentary keratitis. The use of contact lenses must be tempered by the risk of corneal infection.

In 2019, the AAO published a benchmark for corneal ectasia (20) that affirms therapy is tailored to the individual patient, depending on the visual impairment and a risk/benefit analysis of each treatment option(s). Vision can be corrected with eyeglasses but contact lenses may be required as keratoconus progresses to correct vision and reduce distortion. Rigid corneal gas permeable contact lenses can mask corneal irregularities. Hybrid contact lenses provide higher oxygen permeability and greater RGP/hydrogel junction strength. Piggyback contact lenses may be employed for greater comfort and less epithelial disruption. Scleral lenses may be indicated when RGP and/or hybrid contact lenses fail. The AAO benchmark also list contact lenses as an approved treatment modality for severe dry eye syndrome.

In 2021, the AAO updated their preferred practice pattern for cataracts in the adult patient. (21) The AAO states, management of a visually significant cataract is primarily surgical.

However, there are nonsurgical means for managing the symptoms of cataract before surgery is necessary. Changes to glasses and contact lens prescriptions can often be made to account for refractive

shifts in the early stages of cataract development. Low-vision devices can maximize remaining vision pending cataract surgery or allow surgery to be deferred in patients at high risk of complications.

### Centers for Medicare and Medicaid Services (CMS)

CMS (15) supports the use of scleral shell when the eye has been rendered sightless and shrunken by inflammatory disease to obviate the need for surgical enucleation and prosthetic implant and to support the surrounding orbital tissue. In this situation, the scleral shell serves essentially as an artificial eye.

Scleral shells are occasionally used in combination with artificial tears in the treatment of "dry eye". When the lacrimal gland fails, the half-life of artificial tears may be greatly prolonged using scleral contact lens as a protective barrier against the drying action of the atmosphere. Occasionally, a scleral shell may avoid the frequent installation of artificial tears. In this situation, the scleral shell acts a prosthetic device in the rare case when it is used in the treatment of "dry eye." (15)

## Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

<b>CPT Codes</b>	92071, 92072, 92310, 92311, 92312, 92313, 92314, 92315, 92316, 92317, 92352, 92353, 92358, 92499
<b>HCPCS Codes</b>	L8610, Q1004, Q1005, S0500, S0512, S0580, S0581, S0590, S0592, V2020, V2025, V2100, V2101, V2102, V2103, V2104, V2105, V2106, V2107, V2108, V2109, V2110, V2111, V2112, V2113, V2114, V2115, V2118, V2121, V2199, V2200, V2201, V2202, V2203, V2204, V2205, V2206, V2207, V2208, V2209, V2210, V2211, V2212, V2213, V2214, V2215, V2218, V2219, V2220, V2221, V2299, V2300, V2301, V2302, V2303, V2304, V2305, V2306, V2307, V2308, V2309, V2310, V2311, V2312, V2313, V2314, V2315, V2318, V2319, V2320, V2321, V2399, V2410, V2430, V2499, V2500, V2501, V2502, V2503, V2510, V2511, V2512, V2513, V2520, V2521, V2522, V2523, V2524, V2526, V2530, V2531, V2599, V2627, V2702, V2782, V2783, V2784, V2786, V2799



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## Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) **does** have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been **changed** since this medical policy document was written. See Medicare's National Coverage at <<http://www.cms.hhs.gov>>.

## Policy History/Revision

Date	Description of Change
05/01/2023	Reviewed. No changes.
12/01/2022	Document updated with literature review. Coverage unchanged. References 4 and 12 added, others removed.
01/01/2022	Reviewed. No changes.
05/01/2021	Documents updated with literature review. The following changes were made to Coverage: 1) Added "A scleral shell when used for any other indication, including: to improve the appearance of a discolored eye is considered not medically necessary", and 2) Modified not medically necessary statement on deluxe lens feature to now include deluxe frames as well. References updated.
01/15/2019	Reviewed. No changes.
03/15/2018	Document updated with literature review. Coverage unchanged.
07/01/2016	Reviewed. No changes.
06/01/2015	Document updated with literature review. The following changes were made to Coverage: 1) Eyeglasses or contact lenses to correct ocular surface disease resulting in pain and/or decreased visual acuity (e.g., exposure keratopathy, graft vs host disease, keratopathy, mucus membrane pemphigoid, neurotrophic, persistent epithelial defects, post glaucoma filtering surgery, postocular surface tumor excision, sequelae of Stevens Johnson syndrome,

	severe dry eye; 2) Added the following indications as non-surgical correction of the cornea ( e.g., keratoglobus, pellucid marginal degeneration, Terrien marginal degeneration, Fuch’s superficial marginal keratitis, postsurgical ectasia; 3) Expanded terminology of deluxe lens features to state “Deluxe lens features, including but not limited to tinting, mirror coating, progressive lens and scratch resistant coating, are considered convenience items and are considered not medically necessary.” Policy description, references and rationale completely revised.
11/01/2012	Literature reviewed. No change
10/15/2009	CPT/HCPCS code(s) updated
04/01/2009	CPT/HCPCS code(s) updated
04/15/2008	Policy reviewed without literature review; new review date only. This policy is no longer scheduled for routine literature review and update.
08/15/2007	Revised/updated entire document