

Medical Policy Therapeutic Lens

Policy Number: 055

	Commercial and Qualified Health Plans	Mass General Brigham ACO	Medicare Advantage	OneCare	Senior Care Options (SCO)
Authorization required	X	X	Χ	X	X
No Prior Authorization					

Overview

The purpose of this document is to describe the guidelines Mass General Brigham Health Plan utilizes to determine medical appropriateness for therapeutic lenses for Mass General Brigham Health Plan members. The treating specialist must request prior authorization for therapeutic lenses.

Coverage Guidelines

Mass General Brigham Health Plan medical necessity criteria for therapeutic lens (Conventional Contact Lens and Scleral Lens) is determined through a custom subset accessible through InterQual®. To access the criteria, log into Mass General Brigham Health Plan's provider website at MassGeneralBrighamHealthPlan.org and click the InterQual® Criteria Lookup link under the Resources Menu or see below:

For **Conventional Contact Lens** (soft or rigid gas-permeable corneal lens), member meets one of the following:

- Keratoconus or other corneal ectasia, or irregular astigmatism that cannot be corrected with spectacles.
- Anisometropia of more than 3.00 diopters (D); or
- Hyperopia of more than 7.00D; or
- Myopia of more than 7.00D; or
- Post-operative cataract extraction.

Restrictions may apply. Please refer to member handbook.

For **Scleral Lens** or **PROSE** (**Prosthetic Replacement of the Ocular Surface Ecosystem**), member meets ALL of the following criteria as specified below in EITHER item A or item B.

- A. The member has impaired vision, requires medically necessary vision correction, and **conventional glasses or conventional contact lenses are insufficient.** The scleral lens must significantly improve vision; OR
- B. The member requires a moist corneal bandage (scleral lens) for medical treatment of severe ocular surface disease, AND conventional treatments¹ are contraindicated or have failed to treat one of the following conditions (not an all-inclusive list):
 - 1. Severe Dry Eye Disease/Dry Eye Syndrome; or

Corneal transplant surgery (associated with risks)



¹ Conventional treatments, can include the following:

[•] Topical medications for patients with ocular surface disease

[•] Standard contact lenses for patients with corneal ectatic disorders and irregular astigmatism

- 2. Limbal Stem Cell Deficiency; or
- 3. Neurotrophic Keratopathy; or
- 4. Corneal Degenerations and Dystrophies; or
- 5. Extensive corneal scarring after trauma or infection or surgery that leads to blindness and is cosmetically disfiguring; or
- 6. High or irregular astigmatism after trauma, infection or surgery.

Exclusions

- 1. Scleral lens for ordinary refractive error
- 2. Lens for exclusively cosmetic purposes

Medicare Variation

Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for medical necessity determinations for its Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Articles (LCAs), and documentation included in the Medicare manuals are the basis for medical necessity determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan's medical policies are used for medical necessity determinations. At the time of Mass General Brigham Health Plan's most recent policy review, Medicare has the following guidelines:

- NCD: Hydrophilic Contact Lens for Corneal Bandage 80.1
- NCD: Hydrophilic Contact Lenses 80.4
- NCD: Scleral Shell 80.5
- LCD Refractive Lenses (L33793)
- Article Refractive Lenses Policy Article (A52499)

When NCDs and LCDs lack sufficient specificity to ensure consistent medical review and coverage decisions, Mass General Brigham Health Plan applies additional coverage criteria to clarify medical necessity of the requested service. Mass General Brigham Health Plan coverage criteria align with the latest clinical evidence and accepted standards of practice, without contradicting existing determinations, and enhance the clarity of medical necessity criteria, documentation requirements, and clinical indications. Because the NCDs and LCDs listed above lack sufficient specificity to ensure consistent medical review and coverage determinations, Mass General Brigham Health Plan uses the NCDs, LCD, and LCA and the criteria described in this policy to review requests for contact lens, scleral lens, or PROSE.

MassHealth Variation

Mass General Brigham Health Plan uses guidance from MassHealth for medical necessity determinations for its Mass General Brigham ACO members. When there is no guidance from MassHealth for the requested service, Mass General Brigham Health Plan's medical policies are used for medical necessity determinations. At the time of Mass General Brigham Health Plan's most recent policy review, MassHealth had the following guidelines for Therapeutic Lens: 130 CMR 402.000.

OneCare and SCO Variation

Mass General Brigham Health Plan uses guidance from CMS for medical necessity determinations for its OneCare and SCO plan members. NCDs, LCDs, LCAs, and documentation included in the Medicare manuals are



the basis for medical necessity determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan uses medical necessity guidelines from MassHealth. When there is no guidance from CMS or MassHealth, Mass General Brigham Health Plan's medical policies are used for medical necessity determinations.

Definitions

<u>Anisometropia:</u> A condition in which the lenses of the two eyes have different focal lengths and are in different states of myopia (nearsightedness) and hyperopia (farsightedness).

<u>Aphakia:</u> Aphakia is the absence of the lens of the eye, due to surgical removal, a wound, ulcer, or as a condition present at birth (congenital anomaly).

<u>Keratoconus:</u> A degenerative vision disorder that occurs when the normally round cornea becomes thin, and irregular (cone) shaped. This abnormal shape prevents the light entering the eye from being focused correctly on the retina and causes distortion of vision.

<u>LASIK</u>: Eye surgery in which the surface of the cornea is reshaped using a laser, performed to correct certain refractive disorders such as myopia.

<u>PROSE</u>: Prosthetic Replacement of the Ocular Surface Ecosystem (PROSE), a medical treatment for complex corneal disease developed by Boston Foundation for Sight.

<u>Scleral Lens</u>: A contact lens generally worn directly on the sclera, which fits underneath the top and bottom eyelids.

<u>Therapeutic Lens</u>: Lenses that provide visual rehabilitation for diseased or altered eyes.

Codes

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

Authorized Codes	Code Description
	Prescription of optical and physical characteristics of and fitting of contact lens, with medical supervision of adaptation; corneal lens for aphakia, both
92312	eyes
	Prescription of optical and physical characteristics of contact lens, with medical supervision of adaptation and direction of fitting by independent
92314	technician; corneal lens, both eyes except for aphakia
92340	Fitting of spectacles, except for aphakia; monofocal
92341	Fitting of spectacles, except for aphakia; bifocal
92342	Fitting of spectacles, except for aphakia; multifocal, other than bifocal
92352	Fitting of spectacle prosthesis for aphakia; monofocal
92353	Fitting of spectacle prosthesis for aphakia; multifocal
92354	Fitting of spectacle mounted low vision aid; single element system



02255	Fitting of spectacle mounted low vision aid; telescopic or other compound
92355	lens system
	Prosthesis service for aphakia, temporary (disposable or loan, including
92358	materials)
92370	Repair and refitting spectacles; except for aphakia
92371	Repair and refitting spectacles; spectacle prosthesis for aphakia
V2020	Frames, purchases
V2100-V2121	Spectacle Lenses
V2200-V2221	Bifocal, Glass or Plastic
V2300-V2321	Trifocal, Glass or Plastic
V2500-V2510	Contact Lenses Code Range
V2512-V2523	Contact Lenses Code Range
V2530	Contact lens, scleral, gas impermeable, per lens
V2531	Contact lens, scleral, rigid gas permeable, per lens
V2599	Contact lens, other
V2627	Scleral cover shell
S0515	Scleral lens, liquid bandage device, per lens

Summary of Evidence

Scleral lenses represent a significant advancement in therapeutic eye care, serving as sophisticated devices that address various ocular conditions. The extensive research conducted from 2008 to 2023 demonstrates their transformative role in modern ophthalmology, particularly in managing complex corneal and ocular surface conditions. In an observational study, Baudin et al. (2021) and a comprehensive literature review and meta-analysis by Fuller & Wang (2020) have documented significant improvements in quality of life and visual acuity among patients with keratoconus. Formisano et al. (2021), through an observational study, further explored scleral lenses' effectiveness, revealing nuanced insights into their impact on visual quality and intraocular pressure levels.

The physiological implications of scleral lens wear have been carefully documented by recent research. Studies by Schornack et al. (2023) and Shahnazi et al. (2020) found that long-term scleral lens use can lead to slight increases in intraocular pressure, typically ranging from 2-4 mmHg. Shahnazi et al. specifically identified that central corneal thickness can increase by approximately 10-15% post-wear, primarily due to hypoxia and fluid retention beneath the lens. These findings underscore the critical importance of precise lens fitting and regular monitoring, especially for patients with pre-existing ocular conditions.

The development of Prosthetic Replacement of the Ocular Surface Ecosystem (PROSE) therapy has marked a crucial advancement in ocular surface disease treatment. Through a comparative cohort study, DeLoss et al. (2014) found PROSE devices to be equally effective as keratoplasty for corneal ectasia while being less invasive. This therapeutic approach has shown particular promise in pediatric populations, with case series by Kim et al.



(2020) and a retrospective case series by Wang et al. (2019) demonstrating successful outcomes in treating severe conditions such as Stevens-Johnson Syndrome and limbal stem cell deficiency.

Comparative research has consistently highlighted the advantages of scleral lenses over alternative treatments. A randomized controlled trial by Levit et al. (2020) demonstrated their superiority to rigid gas-permeable lenses in advanced keratoconus cases, while a comparative cohort study by Tasci et al. (2023) reported similar advantages over hybrid lenses in moderate to advanced cases. Notably, a retrospective cohort study by Koppen et al. (2018) and an observational study by Ling et al. (2021) have shown that scleral lenses significantly reduce the need for corneal transplantation in severe keratoconus cases, underlining their importance in preventing or delaying surgical intervention.

Advances in fitting techniques have been crucial to scleral lens development. Vincent & Fadel (2019) and Jacobs (2008) highlighted the evolution of fitting methodologies, emphasizing personalized approaches based on corneal and scleral anatomy. They recommended an initial corneal clearance of 200-300 microns, with Vincent & Fadel noting potential reduction to around 150 microns after lens settling. The introduction of advanced imaging technologies like optical coherence tomography (OCT) and scleral topography has revolutionized fitting precision, with success rates improving to over 90% in complex cases.

Recent research has increasingly focused on understanding the physiological impacts and safety considerations of scleral lens use. A narrative review by Vincent & Fadel (2019) provided comprehensive insights into optical considerations for optimal lens design, while studies have demonstrated effectiveness in managing conditions such as chronic graft versus host disease (Schornack et al., 2008) and exposure keratopathy (Chahal et al., 2017). These studies consistently emphasize the need for personalized approach, careful monitoring, and precise fitting to maximize therapeutic benefits.

The implementation of scleral lens therapy is supported by robust healthcare policy frameworks, including Medicare Local Coverage Determinations (Noridian Healthcare Solutions, 2020) and MassHealth Provider Manual guidelines. These policies establish clear criteria for medical necessity and provide frameworks for reimbursement, facilitating broader access to this treatment option.

Scleral lenses have firmly established themselves as an essential tool in modern ophthalmic care, offering effective solutions for various ocular conditions while continually evolving through research and technological advancement. Current research trends indicate continued advancement in understanding and application of scleral lens technology, with focus areas including advanced fitting techniques, long-term outcome studies, and enhanced understanding of physiological impacts. The evidence consistently demonstrates improved patient outcomes, enhanced quality of life, and reduced need for invasive procedures, and MGB Health Plan considers them to be medically necessary as a second-line treatment option for complex ocular conditions.

Effective

January 2026: Annual review. Updated prior authorization table and added variation for OneCare and SCO members. Fixed code disclaimer. Updated LCD and LCA.

March 2025: Ad hoc review. Summary of Evidence added.

November 2024: Annual review. Added language referencing InterQual® subsets and custom criteria. Added NCDs to Medicare Variation. Added MassHealth Variation language. Code table updated.

November 2023: Annual review. Medicare added to table. Exclusion added for lens for cosmetic purposes. Medicare Advantage language added. References updated.

April 2023: Off-cycle review. Statement added regarding member handbook.

February 2023: Codes updated.

December 2022: Annual review. Under PROSE section, removed list of diseases and added statement indicating same conditions as listed under Sclera Lens. References updated.



December 2021: Annual review. Updated PROSE criteria for clarity purposes. References updated. January 2021: Annual review. The following changes were made:

- Updated Coverage Guidelines and Conventional Contact Lens sections.
- Coverage criteria for Sclera Lens clarified and updated:
 - Clarified definition of conventional treatment
 - Removed term "conservative" in regard to treatment
 - o Added "Sjögren's syndrome" as example of Severe Dry Eye Disease
 - Changed "Neurotrophic Keratitis" to "Neurotrophic Keratopathy"
 - Removed "Post-surgery for trigeminal nerve dysfunction" and "Seckles Syndrome"
 - o Added: "Hereditary Sensory and Autonomic Neuropathy"
 - o Clarified and added conditions under Acquired Neurotrophic Keratitis"
 - Added the words "including but not limited to" following Corneal Degenerations and Dystrophies
 - o Added "Salzmann's nodular degeneration" under Corneal Degenerations and Dystrophies
 - o Renamed "Post Operative Astigmatism" to "High or irregular post-operative Astigmatism"
 - Added "deep anterior lamellar keratoplasty (DALK) or patch graft (lamellar keratoplasty)"
 - Added "Corneal intra-stromal implants (Intacs)" and "High or irregular astigmatism after trauma, infection or surgery"
- Under PROSE section, removed the exclusion "Vision problems related to diabetes unless as listed above."
- Updated PROSE section to clarify coverage.
- References updated.

November 2019: Annual review. References updated. Added Post-operative cataract extraction (limited to one set of contact lens per surgery) as a medical condition under conventional contact lens.

October 2018: Annual review

August 2017: Annual Review. Changed name of policy to "Therapeutic Lens". Added coverage criteria for conventional contact lens. Added criteria language on PROSE. Added definitions. Added CPT/HCPCS codes. Updated references.

August 2016: Annual review

August 2015: Annual review

August 2014: Annual review

June 2013: Annual review

June 2012: Effective date

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