Corneal and Scleral Contact Lenses
Clinical Coverage Criteria

Overview

Therapeutic corneal and scleral contact lenses are intended to manage ocular pathology beyond simple refractive disorders. They offer therapeutic benefits by creating a barrier, providing hydration, and aiding in wound healing on the corneal surface. Scleral lenses vault the cornea to decrease mechanical corneal touch, provide a tear reservoir to improve signs and symptoms of dry eye, and provide optical correction of regular and irregular astigmatism similar to other rigid gas permeable lenses.

Policy

This Policy applies to the following Fallon Health products:

☒ Fallon Medicare Plus, Fallon Medicare Plus Central (Medicare Advantage)

☒ MassHealth ACO

☒ NaviCare HMO SNP (Dual Eligible Medicare Advantage and MassHealth)

☒ NaviCare SCO (MassHealth-only)

☒ PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)

☒ Community Care (Commercial/Exchange)

Prior authorization is not required for medically necessary corneal and scleral contact lenses. Healthcare providers must include relevant and specific information in the member's medical records to document medical necessity.

Fallon Health Clinical Coverage Criteria

Fallon Health Clinical Coverage Criteria apply to Community Care members.

Corneal contact lenses

Gas permeable contact lenses (also known as rigid gas permeable contact lenses or "hard contact lenses") and soft (hydrophilic) contact lenses may be considered medically necessary:

- For the treatment of aphakia;
- Following a corneal transplant, for up to one year, if medically necessary;
- For the treatment of keratoconus or other corneal ectasia that cannot be adequately corrected with spectacle lenses; and
- As a moist corneal bandage for the treatment of acute or chronic corneal pathology, such as bullous keratopathy, dry eyes, corneal ulcers and erosion, keratitis, corneal edema, descemetocele, corneal ectasis, Mooren's ulcer, anterior corneal dystrophy, or neurotrophic keratoconjunctivitis.

Scleral contact lenses

Gas-permeable scleral contact lenses, also known as rigid gas-permeable scleral contact lenses (HCPCS code V2531), such as BostonSight Scleral Lens (PROSE) and Jupiter Scleral Lens, may be considered medically necessary for one of the following conditions that has not responded to standard medical treatment including aggressive lubrication, punctal occlusion and corneal contact lenses:

- Corneal ectatic disorders or corneal ectasia (e.g., keratoconus, keratoglubus, pellucid marginal degeneration, Terrien's marginal degeneration, Fuchs' superficial marginal keratitis, post-surgical ectasia);

- Corneal scarring and/or vascularization;
- Irregular corneal astigmatism (e.g., after keratoplasty or other corneal surgery); and
- Ocular surface disease (e.g., severe dry eye, persistent epithelial defects, neurotrophic keratopathy, exposure keratopathy, graft vs. host disease, sequelae of Stevens Johnson syndrome, mucus membrane pemphigoid, post-ocular surface tumor excision, post-glaucoma filtering surgery) with pain and/or decreased visual acuity.

Medicare Variation

Routine Eye Exams, Eye Refractions and Eyeglasses and Contact Lenses for the Correction of Errors of Refraction

Eye examinations, eye refractions and eyeglasses and contact lenses for the correction of errors of refraction, such as myopia (nearsightedness), hyperopia (farsightedness), astigmatism and presbyopia are statutorily excluded by Original Medicare, however, some members may have coverage for routine eye care through Fallon Health. Refer to the member's Evidence of Coverage to determine coverage for routine eye exams, eye refractions and eyeglasses and contact lenses for the correction of errors of refraction.

Medicare has three NCDs related to contact and scleral lenses. National Government Services, Inc., the Part A and B Medicare Administrative Contractor (MAC) with jurisdiction in the Plan's service area, does not have any LCDs related to contact and scleral lenses. Noridian Healthcare Solutions, LLC, the Durable Medical Equipment (DME) MAC with jurisdiction in the Plan's service area has LCD for Refractive Lenses (Medicare Coverage Database search 03/22/2025). Coverage criteria corneal and scleral contact lenses are fully established by Medicare; therefore, the Plan's coverage criteria are no applicable.

- NCD Hydrophilic Contact Lens ror Corneal Bandage 80.1 - Some hydrophilic contact lenses are used as moist corneal bandages for the treatment of acute or chronic corneal pathology. Note: Payment for the lens is included in the payment for the physician's service to which the lens is incident.
- NCD Hydrophilic Contact Lenses 80.4 - Hydrophilic contact lenses are eyeglasses within the meaning of the exclusion in §1862(a)(7) of the Social Security Act and are not covered when used in the treatment of non-diseased eyes with spherical ametropia, refractive astigmatism and/or corneal astigmatism. Payment may be made under the prosthetic device benefit, however, for hydrophilic contact lenses when prescribed for an aphakic patient.
- NCD Scleral Shell 80.5 - Scleral shell is a catchall term for different types of hard scleral contact lenses. A scleral shell fits over the entire exposed surface of the eye as opposed to a corneal contact lens which covers only the central non-white area encompassing the pupil and iris.
    - Where an eye has been rendered sightless and shrunken by inflammatory disease, a scleral shell may, among other things, obviate the need for surgical enucleation and prosthetic implant and act to support the surrounding orbital tissue. In such a case, the device serves essentially as an artificial eye. In this situation, payment may be made for a scleral shell.
    - Scleral shells are occasionally used in combination with artificial tears in the treatment of dry eye of diverse etiology. Tears ordinarily dry at a rapid rate and are continually replaced by the lacrimal gland. When the lacrimal gland fails, the half-life of artificial tears may be greatly prolonged by the use of the scleral contact lens as a protective barrier against the drying action of the atmosphere. Thus, the difficult and sometimes hazardous process of frequent installation of artificial tears may be avoided. The lens acts in this instance to substitute, in part, for the functioning of the diseased lacrimal gland and would be covered as a prosthetic device in the rare case when it is used in the treatment of dry eye.

Noridian Healthcare Solutions, LLC, the Durable Medical Equipment (DME) MAC with jurisdiction in the Plan's service area has and LCD for Refractive Lenses L33793.

Refractive lenses are covered under the prosthetic devices benefit category (Social Security Act §1861(s)(8)). In order for refractive lenses to be eligible for reimbursement, the reasonable and necessary requirements set out in the LCD for Refractive Lenses (L33793) must be met. In addition, there are specific statutory payment policy requirements discussed below, that also must be met.

Refractive lenses are covered when they are used to restore the vision normally provided by the natural lens of the eye of an individual lacking the organic lens because of surgical removal or congenital absence. Covered diagnoses are limited to pseudophakia (condition in which the natural lens has been replaced with an artificial intraocular lens [IOL]), aphakia (condition in which the natural lens has been removed but there is no IOL), and congenital aphakia. Lenses provided for other diagnoses will be denied as noncovered.

For members who are aphakic (i.e., who have had a cataract removed but do not have an implanted intraocular lens (IOL) or who have congenital absence of the lens), the following lenses or combinations of lenses are covered when determined to be medically necessary:

1. Bifocal lenses in frames; or
2. Lenses in frames for far vision and lenses in frames for near vision; or
3. When a contact lens(es) for far vision is prescribed (including cases of binocular and monocular aphakia), payment will be made for the contact lens(es), and lens(es) in frames for near vision to be worn at the same time as the contact lens(es) and lenses in frames to be worn when the contacts have been removed.

For aphakic members (i.e., those who do not have an IOL), replacement lenses are covered when they are medically necessary.

For members who are pseudophakic (i.e., those who have an IOL), coverage is limited to one pair of eyeglasses or contact lenses after each cataract surgery with insertion of an IOL. Replacement frames, eyeglass lenses and contact lenses are noncovered. see **Post Cataract Surgery Eyeglasses and Contact Lenses** below for information about coverage of the initial pair of lenses.

Statutory coverage criteria for refractive lenses are specified in the related Policy Article (Refractive Lenses - Policy Article A52499).

Post Cataract Surgery Eyeglasses and Contact Lenses
One pair of eyeglasses or contact lenses are covered after each cataract surgery, with the insertion of a conventional intraocular lens (IOL).

Replacement frames, eyeglass lenses and contact lenses are noncovered. If a member has a cataract extraction with IOL insertion in one eye, subsequently has a cataract extraction with IOL insertion in the other eye and does not receive eyeglasses or contact lenses between the two surgical procedures, Medicare covers only one pair of eyeglasses or contact lenses after the second surgery. If a member has a pair of eyeglasses, has a cataract extraction with IOL insertion, and receives only new lenses but not new frames after the surgery, the benefit would not cover new frames at a later date (unless it follows subsequent cataract extraction in the other eye).

PROSE Device
PROSE (BostonSight, Needham, MA) devices are designed to rest on the sclera or white part of the eye and are used to treat ocular surface diseases, including some types of dry eye. The correct HCPCS coding for this item is determined based upon the condition(s) being treated. When the PROSE® device is used as a treatment for either of the following indications listed below, the correct HCPCS code to use is V2627 (scleral cover shell):

- Treatment of an eye rendered sightless and shrunken by inflammatory disease; or,
- Treatment of "dry eye" where the PROSE device serves as a substitute for the function of the diseased lacrimal gland.

When the PROSE device is used for any conditions other than those listed above, the device must be coded with HCPCS code V2531 (contact lens, scleral, gas permeable, per lens) and is subject to the Medicare refractive lens statutory coverage exclusion.

MassHealth Variation

Fallon Health covers corneal and scleral contact lenses, when medically necessary, as a medical treatment for medical conditions, such as keratoconus, and bandage lenses.

1. Hard, soft (hydrophilic) or gas-permeable (rigid gas-permeable scleral) contact lenses are covered, when medically necessary, as a medical treatment for one the following conditions:
   a. Postoperative cataract extraction,
   b. Keratoconus or other corneal ectasia that cannot be adequately corrected with spectacle lenses, or
   c. Anisometropia of more than 3.00 diopters (D), or
   d. Myopia of more than 7.00D, or
   e. Hyperopia of more than 7.00D.
2. Therapeutic (bandage) rigid, gas-permeable scleral lenses (V2531) for one of the following conditions that has not responded to standard medical treatment including aggressive lubrication, punctal occlusion and corneal contact lenses:
   a. Corneal ectatic disorders or corneal ectasia (e.g., keratoconus, keratoglubus, pellucid marginal degeneration, Terrien's marginal degeneration, Fuchs' superficial marginal keratitis, post-surgical ectasia);
   b. Corneal scarring and/or vascularization;
   c. Irregular corneal astigmatism (e.g., after keratoplasty or other corneal surgery);
   d. Ocular surface disease (e.g., severe dry eye, persistent epithelial defects, neurotrophic keratopathy, exposure keratopathy, graft vs. host disease, sequelae of Stevens Johnson syndrome, mucus membrane pemphigoid, post-ocular surface tumor excision, post-glaucoma filtering surgery) with pain and/or decreased visual acuity.

Any condition that warrants the use of hard, soft, rigid, gas-permeable, or therapeutic contact lenses must be fully documented in the member's medical record.

Reference: MassHealth Program Regulations 130 CMR 402.433 (eff 02-02-2024).

Exclusions

- Contact lenses to correct errors of refraction (i.e., nearsightedness (myopia), farsightedness (hyperopia), astigmatism, or presbyopia.
- Use of corneal or scleral contact lenses for the treatment of conditions not listed as covered.

Summary of Evidence

Therapeutic corneal bandage lenses, also known as bandage contact lenses, are used to promote healing, relieve pain, and protect the cornea after surgery, injury, or disease, by creating a protective environment for the cornea to heal properly.

There are two types of lenses which can function as therapeutic corneal bandage lenses:

- Therapeutic soft (hydrophilic) contact lenses
- Rigid gas-permeable scleral contact lenses. Gas permeable scleral contact lenses, which are also known as ocular surface prostheses, are formed with an elevated chamber over the cornea and a haptic base over the sclera.

Scleral lenses

Individuals with signs of surface disease and symptoms who have failed traditional therapies are ideal candidates for scleral lens therapy. There are many patients with ocular surface disease who could potentially benefit from scleral lenses. The Tear Film and Ocular Surface Society (TFOS) Dry Eye Workshop II (DEWS II) report defined and classified patients based on their symptoms and signs of ocular surface disease (Craig et al., 2017, Jones et al., 2017). The prescription of scleral lenses for the management of corneal irregularity, uncomplicated refractive error, and ocular surface disease is increasing. The large diameter of the medical device

completely covers the cornea protecting it with a fluid reservoir creating an ideal ocular surface environment and making these lenses particularly useful for ocular surface disease. The Scleral Lenses in Current Ophthalmic Practice Evaluation (SCOPE) study group in 2015 reported that 16% of scleral lenses are currently being prescribed for ocular surface disease, 74% for corneal irregularity, and 10% for uncomplicated refractive error (Nau et al.,2017).

Scleral lenses are rigid gas permeable lenses that vault the cornea while landing gently on the sclera and overlying conjunctival tissue. Scleral lenses differ from corneal gas permeable lenses based on lens diameter and fitting characteristics. Corneal gas permeable contact lenses are supported exclusively by the cornea and do not extend past the limbus. Scleral lenses are large-diameter gas permeable contact lenses that are supported by a tear reservoir, rest on the conjunctival tissue overlying the sclera, and vault the cornea and limbus. Scleral lenses are unique when compared to corneal gas permeable contact lenses in that they maintain a fluid reservoir between the back surface of the contact lens and the front surface of the eye (Harthan and Shorter, 2018).

While there are many potential benefits of scleral lenses for patients with ocular surface disease, they are not generally recommended as the initial therapy. In the past, therapeutic soft lenses have been recommended as a primary therapeutic lens option for some ocular surface conditions due to well-described fitting processes of soft contact lenses, the wide availability of the lenses, and well-documented results in the literature. There are also therapeutic soft lenses that are approved by US Food and Drug Administration for overnight or extended wear. These lenses are inexpensive and readily available, and multiple reports have shown the clinical benefits of them for patients with chronic ocular graft-versus-host disease (GVHD). However, for patients with significant ocular surface disease such as nonhealing epithelial defects, scleral lenses have proven to be beneficial in retaining a fluid-ventilated design allowing oxygenated precorneal fluid reservoir providing continuous corneal hydration with minimal corneal contact. Patients who are diabetic, are immunocompromised, or have non-healing epithelial defects should be closely monitored for potential complications related to scleral lens use. Concomitant prophylactic antibiotic use can be considered in patients using therapeutic lenses; however, their use remains controversial (Harthan and Shorter, 2018)

The overall goal when fitting patients with scleral lenses for ocular surface disease is to mitigate symptoms, and several case series have demonstrated that patients experience relief from or resolution of dryness, pain, irritation, and photophobia when wearing scleral lenses. The 2017 TFOS DEWS II report recommended therapeutic contact lenses (soft bandage contact lenses and rigid scleral lenses) in Step 3 of the management and treatment recommendations for dry eye disease (Jones et al., 2017).

BostonSight PROSE (Prosthetic Replacement of the Ocular Surface Ecosystem)
BostonSight PROSE (Prosthetic Replacement of the Ocular Surface Ecosystem) is an iterative and integrated medical treatment model that restores vision, promotes healing, reduces symptoms, and improves the quality of life for patients with complex corneal disease. The prosthetic devices used in PROSE treatment are approved by the US Food and Drug Administration (FDA) for therapeutic use for the management of a distorted corneal surface (from corneal degenerations, corneal dystrophies, and corneal scarring from surgery, infection, or trauma) and for therapeutic use in eyes with ocular surface disease (from dry eye, limbal stem cell deficiency, disorders of the skin, i.e. ectodermal dysplasia, neurotrophic keratitis, and corneal exposure). Approval from the FDA was first obtained in 1994 and has been updated as recently as August 14, 2024 (FDA, 2024). PROSE treatment has been reported to be effective and safe in managing a variety of ocular conditions including, but not limited to, ocular surface disease, corneal ectasia, and post-surgical corneas. The diameter of devices used in PROSE treatment can range between 13- and 23-mm. PROSE devices have a central optic zone, a transitional zone, and a peripheral haptic zone. The computer assisted and software designed device is made using a computerized lathe machine in-house at the BostonSight manufacturing laboratory in Needham, Massachusetts (AAO. EyeWiki. BostonSight PROSE, 2025).

A retrospective analysis of 875 eyes (538 patients) fitted with a Boston scleral lens was reported in 2005 by Rosenthal (founder and president of the nonprofit Boston Foundation for Sight) and Croteau. Rigid gas-permeable corneal contact lenses either were not tolerated or were contraindicated in all eyes. Patients who failed a trial period were not fitted and were excluded from this study. Follow-up ranged from 2 months to 18 years. Of 501 eyes that were fitted primarily to improve vision, 262 had corneal ectasia, and 130 eyes were fitted due to 6 inadequate best corrected visual acuity (BCVA) after penetrating keratoplasty. The primary indication was to maintain the integrity of the corneal epithelium in 374 eyes with severe ocular surface disease including corneal stem-cell disorders (Stevens Johnson syndrome, corneal ectasia, chemical, ocular cicatricial pemphigoid, aniridia), neurotrophic corneas (congenital corneal anesthesia, acquired cranial nerve V paresis, after acoustic neuroma surgery, after trigeminal ganglionectomy, after herpes simplex keratitis, after herpes zoster keratitis), and severe dry eye syndrome (graft vs host disease), Sjögren syndrome, corneal ectasia, rheumatoid arthritis, radiation), dermatological-associated disorders, exposure, and corneal neuropathic pain. Scleral lenses were found to improve vision, promote healing of persistent epithelial defect, and in patients with dry eye syndrome, reduce ocular pain and disabling photophobia. Attenuation of symptoms was insufficient to continue wearing the prosthesis in eyes with neuropathic pain and in eyes with corneal edema before fitting (Rosenthal and Croteau, 2005).

Jacobs and Rosenthal published results of a patient survey in 33 consecutive patients with severe dry eye from chronic graft-versus-host disease (GVHD) who were fitted with the Boston scleral lens. All patients had been previously treated with various conventional therapies including punctal occlusion, topical cyclosporine, topical and systemic steroids, and partial tarsorrhaphy. The questionnaire results were obtained between 1 week and greater than 2 years after the lenses were dispensed. All but 1 patient reported a reduction in eye pain with 27 patients (82%) reporting that pain was moderately to greatly reduced. Photophobia was resolved or greatly improved in 20 patients (62%). Ninety-one percent of patients reported moderate to great improvement in quality of life, with 20 of 24 patients (83%) reporting moderate to outstanding improvement in driving and 25 of 28 patients (89%) reporting moderate to outstanding improvement in reading. Two patients (6%) reported that they were not wearing their lenses on a regular basis. One had discontinued because of no improvement while the other discontinued wear because of improvement in symptoms over the prior 4 months (Jacobs and Rosenthal, 2007).

In 2010, Stason et al. conducted a prospective case series of 101 patients with severe corneal ectasia, irregular astigmatism, or ocular surface disease who had failed therapies and were seen at the Boston Foundation for Sight between January 1 and June 30, 2006. Of the 101 patients, 80 were fitted with a prosthesis in one or both eyes, and follow-up Visual Functioning Questionnaire data were obtained in 69 eyes. Fitting was not completed or was deferred in 21 patients. At 6-month follow-up after fitting, best-corrected visual acuity (BCVA) improved by a change in mean logarithm of the angle of resolution (logMAR) units of -0.39 (converted from Snellen) with a change of - 0.54 logMAR units in patients with ectasia or astigmatism and -0.22 logMAR in patients with ocular surface disease. Mean composite visual functioning scores increased from 57.0 to 77.8 ($P < .0001$). Improvements in composite Visual Functioning Questionnaire scores were similar in patients with ectasia or ocular surface disease; but vision-related subscores improved more in patients with ectasia, whereas subscores for ocular pain, role difficulties, and dependency improved more in patients with ocular surface disease.

Baran et al., 2012 conducted a retrospective chart review of 59 patients with corneal ectasia seen in consultation at the Boston Foundation for Sight. The primary diagnosis was keratoconus in 83% of patients (98 eyes), post refractive ectasia in 11.9% (15 patients, 21 eyes) and pellucid marginal degeneration (PMD) in 5.1%. Sixteen eyes were non-candidates because conventional correction was adequate. Trial devices were inserted but not dispensed for 13 eyes. No eyes were excluded for severity of ectasia. In the remaining 89 eyes, satisfactory fit was achieved, and a device was dispensed. Device wear at 6 months was documented in 78/89 eyes (88%). National Eye Institute (NEI) Visual Function Questionnaire (VFQ)-25 score improved 27.6 points ($p<0.001$) on a 100-point scale in patients wearing a device at 6 months.

Jupiter Scleral Lens (Visionary Optics, LLC)
According to the manufacturer (Visionary Optics) website, the Europa Scleral Lens is a second-generation Jupiter Scleral Lens with enhancements for successfully managing patients with a wide range of irregular corneal conditions and ocular surface disease.

Jupiter and Katz (2000) measured improvement in best corrected visual acuity with rigid gas-permeable contact lenses compared to best corrected spectacle vision in 29 patients (48 eyes) with irregular astigmatism. The corneal diagnosis included keratoconus, post-keratoplasty, pellucid marginal degeneration, interstitial keratitis, traumatic scarring, trachoma, rosacea keratitis, keratoglobus, Terrien degeneration, measles keratitis, post-lamellar keratectomy, microbial keratitis, herpes simplex keratitis, post-cataract surgery astigmatism, post-epikeratophakia, post radial keratotomy, and Wegener granulomatosis. In this study, Patients with 20/20 spectacle visual acuity achieved, on average, no improvement in visual acuity with RGP contact lenses. Patients with 20/25-20/30 spectacle visual acuity achieved a one-line average improvement. Patients with 20/40 spectacle visual acuity achieved a 2-line average improvement, patients with 20/50 to 20/200 achieved a 4-line average improvement, and patients with 20/400 achieved a 6-line average improvement with the scleral lens. In this study, rigid gas-permeable contact lenses provided a significant improvement in visual acuity compared to spectacle correction.

Pecego et al., 2012, conducted a retrospective case review of 63 patients (107 eyes) who were fitted with the Jupiter sclera lens at the UC Davis Eye Center. The most common primary diagnosis was keratoconus (63% of eyes), followed by post-keratoplasty astigmatism (30%), and pellucid marginal degeneration (7%). Patients gained a mean of 3.5 Snellen lines of vision (SD=2.6) compared with previous contact lens or glasses correction. A mean of 3.2 lenses per eye were needed to obtain the ideal sclera lens, with a mean number of returns to clinic visits of 6.2 over a period of 3 to 17 months. After at least 3 months of wear, 78% of patients reported the lenses to be comfortable, with wear discontinued in 25 eyes (23%).

Schornack and Patel (2010) performed a single center retrospective chart review of the initial 32 patients (52 eyes) with keratoconus evaluated for the Jupiter Scleral Lens. All patients were referred for scleral lens evaluation after exhausting other nonsurgical options for visual correction. Of these, 12 patients (20 eyes) decided not to pursue scleral lens wear after initial evaluation. One patient (2 eyes) abandoned the fitting process after cataract surgery. The remaining 19 patients (30 eyes) were fit successfully. The average number of lenses ordered per eye was 1.5. The fitting process required an average of 2.8 visits. Standard lenses were prescribed for 23 eyes, and custom designs were needed for 7 eyes. Median best-corrected visual acuity improved from 20/40 (mean, 20/76) before scleral lens fitting to 20/20 (mean, 20/30) after fitting. Follow-up ranged from 3 to 32 months.

Schornack et al., 2014, reported on the management of ocular surface disease from a database of patients evaluated for scleral lens wear at the Mayo Clinic (Rochester, MN). Between June 1, 2006, and November 30, 2011, 212 patients (346 eyes) with ocular surface disease were evaluated for potential scleral lens treatment. Of these patients, 77 (130 eyes) chose not to pursue scleral lens fitting after initial evaluation. In an additional 20 patients (28 eyes), the fitting process was initiated but not completed. This left 115 subjects (188 eyes) who were successfully fit with scleral lenses for management of ocular surface diseases during this time period. All eyes were fit with Jupiter scleral lenses, with the initial diagnostic lens selected according to the manufacturer's fitting guide. Successful fitting required an average of 3 visits (2-6 visits) for completion. Eighty-six subjects (75%) achieved successful scleral lens wear with 3 or fewer visits (initial evaluation and 1 or 2 follow-up examinations), and scleral lens fitting was completed in 4 visits in an additional 23 subjects (20%). Undifferentiated dry eye syndrome (DES), neurotrophic keratopathy, and exposure keratopathy were the indications for scleral lens fitting in more than 50% of cases. The most common forms of prior intervention were lubricant drops (86%) and punctal occlusion (62%), and an average of 3.2 (range, 0-8) forms of intervention had been tried before scleral lens evaluation.

Mean duration of follow-up for subjects who were successfully fit with scleral lenses was 32 months (range, 1-83 months). At last follow-up, 71 subjects (63%) reported continued lens wear, and 44 subjects had discontinued scleral lens wear. Overall mean duration of lens wear was 20 months (range, 1-78 months). Mean duration of lens wear was 24 months (range, 1-78 months) in subjects who were wearing lenses at the most recent follow-up and 13 months (range, 1-44 months) in subjects who had discontinued lens wear. The specific therapeutic goals of improved comfort, protection of the ocular surface, and resolution of epitheliopathy were achieved in all but 2 subjects. Best visual acuity improved from 0.32±0.37 logMAR (mean ± standard deviation; Snellen equivalent, 20/42) with habitual correction to 0.12±0.19 logMAR (Snellen equivalent, 20/26) with scleral lenses ($P < 0.001$). The lens-fitting process was incomplete in 20 subjects (28 eyes), and the most common reason for abandoning the fitting process was difficulty with lens application and removal. Of 83 patients (138 eyes) with at least 12 months follow-up after the completion of scleral lens fitting, lenses were still being worn in more than half the cases at last follow-up, although the proportion varied by indication. Handling was the most common reason for discontinuing lens wear. Of note, a number of patients with conditions other than undifferentiated DES were able to maintain stable ocular surfaces with less aggressive forms of intervention after scleral lens therapy.

Analysis of Evidence (Rationale for Determination)

The therapeutic effects of corneal and scleral contact lenses have been well documented. Individuals with signs of surface disease and symptoms who have failed traditional therapies are ideal candidates for contact lens therapy. While scleral lenses are often reserved as a later option when traditional therapies have failed, they are an important tool to heal the corneal epithelial and improve patient comfort as recommended in the 2017 TFOS DEWS II report.

Coding

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

Code	Description
92071	Fitting of contact lens for treatment of ocular surface disease
92072	Fitting of contact lens for management of keratoconus, initial fitting
92310	Prescription of optical and physical characteristics of and fitting of contact lens, with medical supervision of adaptation; corneal lens, both eyes, except for aphakia
92311	Prescription of optical and physical characteristics of and fitting of contact lens, with medical supervision of adaptation; corneal lens for aphakia, 1 eye
92312	Prescription of optical and physical characteristics of and fitting of contact lens, with medical supervision of adaptation; corneal lens for aphakia, both eyes
92313	Prescription of optical and physical characteristics of and fitting of contact lens, with medical supervision of adaptation; corneoscleral lens
92314	Prescription of optical and physical characteristics of contact lens, with medical supervision of adaptation and direction of fitting by independent technician; corneal lens, both eyes except for aphakia
92315	Prescription of optical and physical characteristics of contact lens, with medical supervision of adaptation and direction of fitting by independent technician; corneal lens for aphakia, 1 eye
92316	Prescription of optical and physical characteristics of contact lens, with medical supervision of adaptation and direction of fitting by independent technician; corneal lens for aphakia, both eyes
92317	Prescription of optical and physical characteristics of contact lens, with medical supervision of adaptation and direction of fitting by independent technician; corneoscleral lens

92325	Modification of contact lens (separate procedure), with medical supervision of adaptation
92326	Replacement of contact lens

Code	Description
V2500	Contact lens, PMMA, spherical, per lens
V2501	Contact lens, PMMA, toric or prism ballast, per lens
V2502	Contact lens, PMMA, bifocal, per lens
V2503	Contact lens, PMMA, color vision deficiency, per lens
V2510	Contact lens, gas permeable, spherical, per lens
V2511	Contact lens, gas permeable, toric, prism ballast, per lens
V2512	Contact lens, gas permeable, bifocal, per lens
V2513	Contact lens, gas permeable, extended wear, per lens
V2520	Contact lens, hydrophilic, spherical, per lens
V2521	Contact lens, hydrophilic, toric, or prism ballast, per lens
V2522	Contact lens, hydrophilic, bifocal, per lens
V2523	Contact lens, hydrophilic, extended wear, per lens
V2524	Contact lens, hydrophilic, spherical, photochromic additive, per lens
V2525	Contact lens, hydrophilic, dual focus, per lens
V2530	Contact lens, scleral, gas impermeable, per lens (for contact lens modification, see CPT Level I code 92325)
V2531	Contact lens, scleral, gas permeable, per lens (for contact lens modification, see CPT Level I code 92325)
V2599	Contact lens, other type

References

1. Jacobs DS, Rosenthal P. Boston scleral lens prosthetic device for treatment of severe dry eye in chronic graft-versus-host disease. *Cornea*. 2007 Dec; 26(10):1195-9.
2. Takahide K, et al. Use of fluid-ventilated, gas-permeable scleral lens for management of kerato-conjunctivitis sicca secondary to chronic graft-versus-host disease. *Biol Blood Marrow Transplant*. 2007 Sep; 13(9):1016-21.
3. Stason WB, et al. Clinical Benefits of the Boston Ocular Surface Prosthesis. *Am J Ophthalmol*. 2010 Jan; 149(1):54-61.
4. Medicare National Coverage Determination (NCD) for Scleral Shell (80.5).
5. Medicare National Coverage Determination (NCD) for Hydrophilic Contact Lens For Corneal Bandage (80.1).
6. Medicare National Coverage Determination for Hydrophilic Contact Lenses (80.4).
7. Noridian Health Care Solutions LLC. Local Coverage Determination (LCD) for Refractive Lenses (L33793). Original effective date October 1, 2015. Revision effective date October 1, 2020.
8. Downie LE, Lindsay RG. Contact lens management of keratoconus. *Clin Exp Optom*. 2015 Jul;98(4):299-311.
9. Bavinger JC, DeLoss K, Mian SI. Scleral lens use in dry eye syndrome. *Curr Opin Ophthalmol*. 2015 Jul;26(4):319-24.
10. Schornack MM. Scleral lenses: a literature review. *Eye Contact Lens*. 2015 Jan;41(1):3-11.
11. Dimit R, Gire A, Pflugfelder SC, Bergmanson JP. Patient ocular conditions and clinical outcomes using a PROSE scleral device. *Cont Lens Anterior Eye*. 2013 Aug;36(4):159-63.
12. Bergmanson JP, Walker MK, Johnson LA. Assessing Scleral Contact Lens Satisfaction in a Keratoconus Population. *Optom Vis Sci*. 2016 May 26.
13. Parra AS, Roth BM, Nguyen TM, et. al. Assessment of the Prosthetic Replacement of Ocular Surface Ecosystem (PROSE) scleral lens on visual acuity for corneal irregularity and ocular surface disease. *Ocul Surf*. 2018 Apr;16(2):254-258.
14. Koppen C, Kreps EO, Anthonissen L, et.al. Scleral Lenses Reduce the Need for Corneal Transplants in Severe Keratoconus. *Am J Ophthalmol*. 2018 Jan;185:43-47.

15. Schear MJ, Ibrahim K, Winokur J, Busuioc C, Udell I, Steiner A. Treatment Limitations With PROSE (Prosthetic Replacement of the Ocular Surface Ecosystem): One Centers Experience. *Eye Contact Lens*. 2019 Sep;45(5):315-317.
16. Rosenthal P, Croteau A. Fluid-ventilated, gas-permeable scleral contact lens is an effective option for managing severe ocular surface disease and many corneal disorders that would otherwise require penetrating keratoplasty. *Eye Contact Lens*. May 2005;31(3):130-134.
17. Baran I, Bradley JA, Alipour F, et al. PROSE treatment of corneal ectasia. *Cont Lens Anterior Eye*. May 24 2012;35(5):222-227.
18. Harthan JS, Shorter E. Therapeutic uses of scleral contact lenses for ocular surface disease: patient selection and special considerations. *Clin Optom (Auckl)*. 2018 Jul 11;10:65-74.
19. Craig JP, Nichols KK, Akpek EK, et al. TFOS DEWS II definition and classification report. *Ocul Surf*. 2017;15:276–283.
20. Jones L, Downie LE, Korb D, et al. TFOS DEWS II management and therapy report. *Ocul Surf*. 2017;15:575–628.
21. Nau CB, Harthan J, Shorter E, et al. Demographic Characteristics and Prescribing Patterns of Scleral Lens Fitters: The SCOPE Study. *Eye Contact Lens*. 2018 Sep;44 Suppl 1:S265-S272.
22. Jupiter DG, Katz HR. Management of irregular astigmatism with rigid gas permeable contact lenses. *CLAO J*. Jan 2000;26(1):14-17.
23. Pecego M, Barnett M, Mannis MJ, et al. Jupiter Scleral Lenses: the UC Davis Eye Center experience. *Eye Contact Lens*. May 2012;38(3):179-182.
24. Schornack MM. Scleral lenses: a literature review. Eye Contact Lens. 2015;41(1):3–11.
25. Schornack MM, Patel SV. Scleral lenses in the management of keratoconus. *Eye Contact Lens*. 2010 Jan;36(1):39-44.
26. Schornack MM, Pyle J, Patel SV. Scleral lenses in the management of ocular surface disease. *Ophthalmology*. 2014;121(7):1398–405.
27. Ruiz-Lozano RE, Gomez-Elizondo DE, Colorado-Zavala MF, et al. Update on indications, complications, and outcomes of scleral contact lenses. *Med Hypothesis Discov Innov Ophthalmol*. 2022 Feb 24;10(4):165-178.
28. American Academy of Ophthalmology. EyeWiki. BostonSight PROSE (Prosthetic Replacement of the Ocular Surface Ecosystem) and Scleral Contact Lenses. Last Review: January 5, 2025. Available at: https://eyewiki.org/BostonSight_PROSE_(Prosthetic_Replacement_of_the_Ocular_Surface_Ecosystem)_and_Scleral_Contact_Lenses#:~:text=PROSE%20is%20reported%20to%20be,decreased%20the%20rate%20of%20keratoplasty. Accessed 04/08/2025.
29. U.S. Food & Drug Administration. BostonSight® Specialty Lenses. Boston Foundation for Sight, Inc. D/B/A BostonSight. Product Code HQD. 510(k) Number K241571. Decision Date 08/14/2024. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K241571. Accessed 04/08/2025.

Policy history

Origination date:	01/1994
Review/Approval(s):	Utilization and Care Management Committee: 03/2001, 06/2003 Benefit Oversight Committee: 01/1994, 08/2005 Technology Assessment Committee: 03/2001, 06/2003, 07/23/2014 updated new template, combined with Scleral Lens Liquid Bandage policy, updated references) 07/22/2015 (updated coding and references) 06/22/2016 (clarified language regarding prior authorization, updated references), 07/26/2017 (clarified codes V2521 and V2523 are not covered, updated references), 06/27/2018 (updated references), 06/26/2019 (updated references), 06/15/2021 (Added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section), 03/25/2025 (annual review; added sections for Medicare Variation and MassHealth Variation).

Utilization Management Committee 4/15/2025 (annual review; approved).

Instructions for Use

Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Fallon Health generally follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

For plan members enrolled in NaviCare, Fallon Health first follow's CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.