



Gas Permeable Scleral Contact Lens

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Next Review: 11/2014

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for gas permeable scleral contact lens when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered

Rigid gas permeable scleral lens may be considered **medically necessary** for patients who have not responded to topical medications or standard spectacle or contact lens fitting, for the following conditions:

- Corneal ectatic disorders (e.g., keratoconus, keratoglobus, 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);
- 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.

When Policy Topic is not covered

Rigid gas permeable scleral lens not meeting the medical necessity criteria above are considered **not medically necessary**.

Considerations

There are CPT codes for prescription and fitting of corneoscleral lens (92313 and 92317) which depend on the level of involvement of the physician.

Insertion of a gas permeable scleral contact lens might be reported with the unlisted ophthalmological service or procedure code (92499). Modification of contact lens may be reported using CPT code 92325 when performed separately.

There are specific HCPCS codes for scleral lenses:

- S0515 Scleral lens, liquid bandage device, per lens
- V2531 Contact lens, sclera, gas permeable, per lens

Description of Procedure or Service

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 contact lenses are being evaluated in patients with corneal disease, including keratoconus, Stevens-Johnson syndrome, chronic ocular graft-versus-host disease, and in patients with reduced visual acuity after penetrating keratoplasty or other types of eye surgery.

Background

Scleral contact lenses create an elevated chamber over the cornea that can be filled with artificial tears. The base or haptic is fit over the less sensitive sclera. Scleral contact lens has been proposed to provide optical correction, mechanical protection, relief of symptoms, and facilitation of healing for a variety of corneal conditions. Specifically, the scleral contact lens may neutralize corneal surface irregularities and, by covering the corneal surface in a reservoir of oxygenated artificial tears, function as a liquid bandage for corneal surface disease. This may be called prosthetic replacement of the ocular surface ecosystem (PROSE).

The development of materials with high gas permeability and technologic innovations in design and manufacturing has stimulated the use of scleral lenses. The Boston Ocular Surface Prosthesis (Boston Foundation for Sight) is a scleral contact lens that is custom fit using computer-aided design and manufacturing (i.e., computerized lathe). Another design is the Jupiter mini-scleral gas permeable contact lens (Medlens Innovations and Essilor Contact Lens). The Jupiter scleral lens is fit using a diagnostic lens series. The Procornea (Eerbeek) scleral lens was developed in Europe. There are 4 variations of the Procornea: spherical, front-surface toric, back-surface toric, and bitoric. Lenses are cut with submicron lathing from a blank.

Regulatory Status

The Boston Ocular Surface Prosthesis, which is the prosthetic device used in PROSE [prosthetic replacement of the ocular surface ecosystem], was approved by the U.S. Food and Drug Administration (FDA) in 1994.

Rationale

Searches of the MEDLINE database through July 15, 2013 identified case series with gas permeable scleral contact lens. The largest series are described below.

Boston Ocular Surface Prosthesis

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. (1) 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 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 (GVHD), Sjogren 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.

In 2010, Stason et al. reported use of the Boston Ocular Surface Prosthesis in a series of 101 patients with corneal disease who had not responded satisfactorily to conventional treatments and were seen at a tertiary care clinic. (2) The fitting procedure was not completed or was deferred in 21 patients; 80 patients were fitted with a prosthesis in one or both eyes. Of those fitted with a prosthesis, the principal eye diagnosis was corneal ectasia or irregular astigmatism in 42 patients and ocular surface disease (e.g. dry eye syndrome, chronic GVHD) in 38 patients. Sixteen patients had undergone a previous corneal transplantation, and 3 had undergone laser in situ keratomileusis (LASIK). About half were experiencing photophobia and one third reported eye pain at baseline. 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) of -0.39 with a change of -0.54 logMAR units in patients with ectasia or astigmatism and -

0.22 logMAR in patients with ocular surface disease. For all 141 fitted eyes, 27% had no significant change in vision, 35% gained 1 line, 23% gained 2 lines, and 14% gained 3 lines or more. Mean composite visual functioning scores on the Visual Functioning Questionnaire (VFQ) increased from 57.0 to 77.8 for patients who received a prosthesis (measured in 69 of 80 patients) and were not significantly improved in patients (measured in 12 of 21 patients) who did not (from 65.1 to 69.3). There was significant improvement in all of the vision-related subscales on the VFQ, which included the categories of vision, activities, and ocular pain (from 49.9 at baseline to 72.8 with a prosthesis). Lower baseline VFQ scores were strong predictors of subsequent improvement in visual functioning. The report concluded that controlled clinical studies will be needed to confirm the effectiveness of the Boston Ocular Surface Prosthesis and to compare it with corneal transplantation, tarsorrhaphy, or other techniques in patients with advanced ectasia or ocular surface disease.

Baran and colleagues from the Boston Foundation for Sight reported 6-month outcomes from prosthetic replacement of the ocular surface ecosystem (PROSE) treatment in a series of 59 patients with corneal ectasia. (3) The primary diagnosis was keratoconus in 83% of patients (98 eyes). Fifteen patients (21 eyes) had previously undergone penetrating keratoplasty. Sixteen of the 118 eyes were considered non-candidates because conventional correction was adequate. No devices were dispensed in another 13 eyes due to little improvement in vision during the 6-hour trial period (n=12) or low endothelial cell count (n=1). There was significant improvement in visual acuity; of 102 candidate eyes, 95 (93.1%) achieved visual acuity of 20/40 or better. At mean 9-month follow-up, the sclera contact lens was being worn in 88% of the 89 eyes that had a satisfactory fit. For patients still wearing a device at follow-up, the National Eye Institute Visual Function Questionnaire (NEI VFQ-25) score improved by 27.6 points on a 100-point scale. Reasons for not wearing the device included discomfort (n=4), lack of motivation to follow the insertion and removal regimen (n=2), and limited improvement in visual acuity (n=1).

Jacobs and Rosenthal published patient-reported outcomes from 33 consecutive patients with severe dry eye from chronic graft-versus-host disease (GVHD) who were fitted with the Boston scleral lens. (4) 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 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.

Jupiter Scleral Lens

In 2000, Jupiter and Katz reported the management of irregular astigmatism in 48 eyes (29 patients) with rigid gas-permeable contact lenses. (5) The corneal diagnosis included keratoconus, postkeratoplasty, pellucid marginal degeneration, interstitial keratitis, traumatic scarring, trachoma, rosacea keratitis, keratoglobus, Terrien's degeneration, measles keratitis, postlamellar keratectomy, microbial keratitis, herpes simplex keratitis, postcataract surgery astigmatism, postepikeratophakia, post raidal keratotomy, and Wegener's granulomatosis. In this study, nearly one third of the patients with irregular astigmatism had BCVA of 20/25 or better with spectacles. 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.

Pecego and colleagues reported a series of 63 patients (107 eyes) who were fitted with the Jupiter sclera lens. (6) The most common primary diagnoses included keratoconus (42% of eyes), postkeratoplasty astigmatism (30%), and pellucid marginal degeneration (7%). Patients gained a mean of 3.5 lines of vision compared to 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 return 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 described use of the Jupiter scleral lens in a retrospective review of patients with keratoconus in 2010. (7) Of 209 patients evaluated for possible scleral lens wear, 52 eyes of 32 patients (15%) had keratoconus and were included in the report. The primary reason for scleral lens evaluation was contact lens intolerance. At the time of presentation, 16 patients were wearing spectacle correction, 8 were wearing corneal rigid gas-permeable lenses, 1 was wearing hydrogel toric lenses, 3 were wearing piggyback systems, and 4 were wearing no correction. Successive diagnostic lens were placed until a lens was applied that had complete limbal and corneal clearance and had a fluid reservoir depth between 0.15 and 0.4 mm. At follow-up visits, revised lenses were ordered as needed to achieve optimal vision, comfort, and fit. The authors noted that at the time of publication, no specific fitting guidelines for scleral lenses have been validated or published. After the initial consultation, 12 patients (20 eyes) chose not to proceed with the fitting process primarily due to a lack of visual benefit compared with habitual correction. Nineteen patients (30 eyes) were fit with Jupiter lens in an average of 2.8 visits (range, 2-4) with an average of 1.5 lenses (range, 1-3). Standard lens designs were prescribed for 23 eyes (77%), and 7 eyes required a custom design to optimize the scleral lens fit. With an average follow-up of 22.5 months (range, 5-34 months), the median BCVA improved in these eyes from 20/40 at baseline to 20/20 with the scleral lens, with an average improvement of 2.9 lines.

Procornea Scleral Lens

Visser et al. reported a prospective study of the indications and clinical performance of the Procornea lens in 2007. (8) All of the 178 patients (284 eyes) included in the study had been referred to the tertiary clinic for one of a variety of corneal conditions that had not responded to other contact lenses or therapeutic management. Patients with either fit or early wearing failure were excluded from the study. About half of the patients (50.4%) were diagnosed with keratoconus and 19.7% were postpenetrating keratoplasty. Other forms of irregular corneal surface included eyes with scars related to herpes simplex keratitis (n=8), other forms of keratitis (n=2), trauma (n=5), irradiation (n=3), pellucid marginal degeneration (n=7), pterygium (n=2), and macula cornea (n=1). There were 4 types of corneal dystrophy: map-dot-fingerprint (n=5), Fuchs' endothelial (n=2), Reis-Bucklers (n=2), and lattice (n=1). Primary keratitis sicca was diagnosed in 4 eyes, neurotrophic keratitis in 7, ocular cicatricial pemphigoid in 2 eyes, and Sjogren syndrome in 2 eyes. The primary indication was for visual correction in 249 (87.7%) eyes. Median visual acuity was 20/100 without a scleral lens and 20/28 with the lens.

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 1 physician specialty society and 3 academic medical centers while this policy was under review in 2011. The input supported the medical necessity of the rigid gas permeable scleral contact lens for corneal ectatic disorders, corneal scarring and/or vascularization, irregular corneal astigmatism, and ocular surface disease with pain and/or decreased visual acuity in cases that had failures of all other available treatments (i.e., topical medications or standard contact lens fittings). One reviewer commented that the prosthesis can help to avoid potentially blinding complications with ocular surface disease and that the alternative for patients with keratoconus and other forms of irregular astigmatism would be cornea transplant surgery, which involves a lifetime of close medical monitoring and significant risk.

Summary

The literature on gas permeable scleral contact lenses consists of a number of large case series that enrolled more than 100 patients. The largest series was a retrospective review of more than 538 patients with more than 40 different clinical indications who were fitted with the Boston Ocular Surface Prosthesis. These case series report an improvement in health outcomes in patients who have failed all

other available treatments. These uncontrolled studies are suggestive of benefit, but the lack of controlled trials precludes a definite conclusion on treatment benefit.

Clinical input was obtained and supports the medical necessity of the gas permeable scleral contact lens in cases of corneal ectatic disorders, corneal scarring and/or vascularization, irregular corneal astigmatism, and ocular surface disease with pain and/or decreased visual acuity when all other available treatments have failed. For patients with ocular surface diseases who have not responded adequately to topical medications, there is a lack of alternative treatments. For patients with corneal ectatic disorders and irregular astigmatism who have failed standard contact lens, the alternative of corneal transplant surgery is associated with risks. Therefore, the gas permeable scleral contact lens may be considered medically necessary in these patient populations.

Medicare National Coverage

There is no national coverage determination.

References

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Billing Coding/Physician Documentation Information

92071 Fitting of contact lens for treatment of ocular surface disease
92072 Fitting of contact lens for management of keratoconus, initial fitting
92313 Prescription of optical and physical characteristics of and fitting of contact lens, with medical supervision of adaptation; corneoscleral lens
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
92499 Unlisted ophthalmological service or procedure
S0515 Scleral lens, liquid bandage device, per lens
V2531 Contact lens, scleral, gas permeable, per lens (for contact lens modification, see 92325)

Additional Policy Key Words

N/A

Policy Implementation/Update Information

11/1/11 New policy; considered medically necessary when all other treatments have failed
1/1/12 Coding updated
11/1/12 No policy statement changes.
11/1/13 No policy statement changes.

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