
Medical Policy



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***Current Policy Effective Date: 5/1/25**
(See policy history boxes for previous effective dates)

Title: Corneal Liquid Bandage Lens for Corneal Epithelial Defects/Scleral Lenses

Description/Background

Individuals suffering from chronic severe corneal disease (causing persistent epithelial defects or PEDs) that has not responded to conventional treatment face a lifetime of pain and limited vision, to the point of eventual total blindness. Some of the symptoms associated with PEDs include eye pain, severe dryness, excessive tearing, extreme sensitivity to light (photophobia), inflammation of the eye and blurry vision.

Some conditions which may result in persistent ocular surface disease include, but are not limited to:

- Chemical, thermal or traumatic injury
- Congenital eyelid defects
- Herpes zoster
- Keratoconus
- Neurotrophic keratopathy (a degenerative disease of the corneal epithelium and stroma that results from impaired corneal innervation)
- Ocular graft versus host disease
- Reactions to various drug treatment regimens
- Refractive surgery, including LASIK surgery
- Sjögren's syndrome
- Stevens-Johnson syndrome
- Other disorders and dystrophies

Conventional treatment of PEDs have include the use of include prophylactic topical antibiotic drops or ointments, non-preserved ocular lubricants, eye-patching, and bandage contact lenses. In extremely difficult cases, oral doxycycline, autologous serum, and the surgical application of an amniotic membrane, tarsorrhaphy or a conjunctival flap are used alone or in

combination. Corneal transplantation is not an option for some of these patients because many of them have lost the ability to heal their corneas properly, either due to inherent conditions such as neurotrophic keratopathy or as a result of severe trauma.

There are a number of patients with PEDs who continue to exhibit symptoms despite the use of different treatment modalities. In the past, many of these patients were faced with the prospect of unrelenting pain and eventual blindness. Different systems have been developed in an attempt to cover the cornea to act as a type of scleral “liquid bandage” by protecting the cornea and promoting corneal healing,

There are two types of devices which can function as corneal bandages:

- Therapeutic soft contact lenses
- Rigid gas-permeable scleral contact lenses (RGP-ScCLs); 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.

Therapeutic Soft Contact Lenses

Prior to the use of therapeutic soft contact lenses, the only option for protecting a patient’s eyes following damage was pressure patching. Many practitioners now use soft, disposable contact lenses as initial treatment to temporarily “bandage” the eye which has been compromised due to abrasions. They are typically made of silicone hydrogels which allow for proper oxygenation of the eye surface. They are used as bandages for pain management and to help encourage re-epithelialization or wound closure following trauma, disease, persistent epithelial defect or following surgical procedures to the eye. These soft lenses are worn directly against the cornea and are prescribed for the treatment of acute or chronic corneal pathology such as persistent epithelial defects (PEDs). Many types of soft tissue lenses are available for therapeutic use (e.g., Focus® Night & Day® Lens). These lenses are normally worn on an extended or continuous basis to provide for optimal healing. They reduce pain caused by exposure and prevent the lid from disrupting the healing phase.

Rigid Gas Permeable Lenses/Scleral Lenses

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. A 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 fitted 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. The Rose K2 XL lens (Menicon, Japan) is a semi-scleral lens.

The choice of type and brand of therapeutic corneal bandages and scleral lenses is dependent on the type of condition and the preference of the individual treating physician.

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. The first generation Rose K™ lens received FDA approval in 1995. FDA product code: HQD

Medical Policy Statement

The use of either rigid gas-permeable scleral contact lenses or therapeutic soft (hydrophilic) contact lenses as corneal liquid bandages is considered established for individuals who meet patient selection criteria. They are considered a useful therapeutic option for selected patients.

Inclusionary and Exclusionary Guidelines

Note: measuring and fitting of these therapeutic lenses may take several sessions at the provider's office. The patient may have to undergo a number of fittings using trial lenses until the best match for the patient's needs is found.

The choice of gas-permeable vs soft contact lenses is dependent on the patient's disease process and physician determination of the appropriate therapy.

Inclusions:

Therapeutic soft (hydrophilic) contact lenses or gas-permeable fluid ventilated scleral lenses (e.g., Boston Scleral Lens) when used as moist corneal liquid bandages are considered established for patients who meet both of the following criteria:

- The individual has *persistent epithelial defects* (PEDs) of the cornea with documented, disabling symptoms (e.g., pain, photophobia) that have not responded to medical intervention, including topical medications or standard spectacle or contact lens fitting AND
- The individual has any of the following conditions for which surgery is undesirable and/or contraindicated (note: this list may not be all-inclusive):
 - Corneal stem cell deficiencies:
 - Stevens-Johnson disease (a syndrome of systemic, as well as more severe, mucocutaneous lesions that results in corneal opacities, perforations, and/or blindness)
 - TEN (toxic epidermal neurolysis)
 - Conditions that result from a chemical and/or traumatic injury, including but not limited to:
 - Previous surgical procedures
 - Acquired aniridia
 - Recurrent corneal erosion
 - Exposure keratitis
 - Lacrimal and/or meibomian gland obliteration

- Superior limbal keratoconjunctivitis
- Inflammatory corneal degeneration
- Keratoconus
- PED resulting from superior limbic keratotomy
- Neurotrophic (anesthetic) corneas
 - From acquired causes, including but not limited to:
 - Corneal denervation that is related to acoustic neuroma surgery
 - Trigeminal ganglionectomy
 - Herpes simplex/zoster of the cornea
 - Complications of diabetes
 - Idiopathic corneal stem cell deficiency
 - From congenital causes, including but not limited to:
 - Seckle's syndrome
 - Congenital corneal anesthesia
 - Congenital eyelid defect(s)
 - Congenital dysautonomia (e.g., Riley-Day syndrome)
- Severe dry eyes (keratoconjunctivitis sicca) due to
 - Sjögren syndrome
 - Graft vs. host disease (GVH)
 - Post-radiation treatment
 - Eye surgery
 - Severe meibomian gland deficiency
- Corneal disorders associated with:
 - Systemic autoimmune diseases
 - Rheumatoid arthritis
 - Dermatological disorders such as atopic dermatitis, epidermolysis bullosa, epidermal dysplasia);

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

92499	S0515	V2531	V2627
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Other codes (investigational, not medically necessary, etc.):

N/A

Rationale

HYDROPHILIC SOFT CONTACT LENSES

Hydrophilic soft contact lenses have been used for many years as “bandages” for patients with a variety of corneal and ocular surface diseases. In 2002, Lim et al evaluated the Bausch & Lomb PureVision contact lens as a continuous wear contact lens for therapeutic indications in a prospective open-ended non-randomized clinical trial.¹¹ Patients with a variety of corneal and ocular surface disease conditions presenting at the Singapore National Eye Centre who required therapeutic continuous contact lens wear were enrolled in the trial. Therapeutic indications for the contact lenses included pain relief, corneal protection, and enhancement of

corneal wound healing. Success or failure of specific treatment indications was assessed in all cases, with evaluation of lens performance and fit characteristics, and the presence of ocular complications or lens-related complications was noted.

There were 54 patients (54 eyes), and the mean duration of continuous contact lens wear was 1.1 months. Conditions treated included post-surgical indications (n = 36) (post-keratoplasty or ocular surface transplantation, post-LASIK or PRK surgery) bullous keratopathy (n = 7), chemical burns (n = 3), epithelial abrasions or recurrent corneal erosion syndromes (n = 3), corneal perforations (n = 3), neurotrophic ulcer (n = 1), and corneal laceration (n = 1). For the indication of corneal healing (40 eyes), improved healing was noted in 38 eyes (96%), with full healing occurring in 33 eyes (83%). For pain relief (28 eyes), 27 patients (96%) had considerable or complete pain relief, and the remaining patient reported partial pain relief. For corneal protection (21 eyes), lens wear was fully protective in all cases. The lens performance and fitting characteristics surpassed any previous therapeutic lenses used by the investigators. Complications related to contact lens wear were limited to one case of a culture-negative corneal infiltrate requiring cessation of therapeutic lens wear and one case of a loosely fit lens.

The results showed that the PureVision contact lens exhibited good safety and efficacy when utilized as a continuous wear therapeutic lens. With the theoretical advantage of increased oxygen transmissibility reducing the risk of hypoxia-related complications, this new lens may be one step closer to the ideal therapeutic contact lens.

In 2007, Russo et al published a small study to determine the safety and efficacy of the Focus NIGHT & DAY (CIBA Vision, Duluth, GA) silicone hydrogel contact lens in the management of refractory, moderate to severe dry eye signs and symptoms secondary to graft-versus-host disease (GVHD).¹² Seven patients with GVHD and moderate to severe dry eye disease as determined by the Ocular Surface Disease Index (OSDI) questionnaire were fitted with a near plano Focus NIGHT & DAY soft contact lens (SCL) used on a 7-night continuous-wear basis. Visual acuity, objective measures of dry eye disease (i.e., Schirmer I, tear breakup time, and corneal fluorescein staining), and OSDI scores were compared before SCL wear and after 1 week and 1 month of SCL wear.

The results showed significant improvement in subjective assessment of dry eye symptoms (initial vs. 1-month OSDI score, 76.8 +/- 13.6 vs. 31.2 +/- 17.8, $P < 0.0005$, paired t test). In addition, patients had significant improvement in best-corrected visual acuity after 1 month of SCL wear (initial vs. 1-month logMAR visual acuity for the right eye, 0.23 +/- 0.050 vs. 0.04 +/- 0.027, $P < 0.007$; initial vs. 1-month logMAR visual acuity for the left eye, 0.22 +/- 0.049 vs. 0.04 +/- 0.020, $P < 0.007$, analysis of variance, Dunnett post hoc). There were no significant changes in results of Schirmer I testing, corneal fluorescein staining, or tear breakup time. No adverse events or complications of SCL wear were observed.

GAS PERMEABLE SCLERAL CONTACT LENS

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 palsy, 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], 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.

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 1 or both eyes. Of those fitted with 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, 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 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.

In 2012, Baran et al 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 noncandidates 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 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).

In 2007, Jacobs and Rosenthal published patient-reported outcomes from 33 consecutive patients with severe dry eye from chronic 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, 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, 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 et al 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), post keratoplasty astigmatism (30%), and pellucid marginal degeneration (7%). Patients gained a mean of 3.5 lines of vision 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 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. A 2014 report by the same authors described the successful fitting of the Jupiter scleral lens in 188 eyes of 115 patients.⁸ The most common indications were undifferentiated ocular surface disease, exposure keratopathy, and neurotrophic keratopathy. The goals of treatment, achieved in all but 2 patients, were improved ocular comfort, ocular surface protection, and resolution of epitheliopathy. Visual acuity improved from 20/42 to 20/26. Of the patients with at least 12 months of follow-up, 63% reported continued lens wear and 37% had discontinued lens wear.

Procornea Scleral Lens

Visser et al reported a prospective study of the indications and clinical performance of the Procornea lens in 2007.⁹ 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 post-penetrating 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 corneae (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 Sjögren 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.

Government Regulations

National

CMS NCD 80.1 – Hydrophilic Contact Lens for Corneal Bandage

“Some hydrophilic contact lenses are used as moist corneal bandages for the treatment of acute or chronic corneal pathology, such as bullous keratopathy, dry eyes, corneal ulcers and erosion, keratitis, corneal edema, descemetocoele, corneal ectasis, Mooren’s ulcer, anterior corneal dystrophy, neurotrophic keratoconjunctivitis and for other therapeutic reasons.”

Indications and Limitations of Coverage

Payment may be made under §1861(s)(2) of the Act for a hydrophilic contact lens approved by the Food and Drug Administration (FDA) and used as a supply incident to a physician’s service. Payment for the lens is included in the payment for the physician’s service to which the lens is incident. Contractors are authorized to accept an FDA letter of approval or other FDA published material as evidence of FDA approval. (See §80.4 of the NCD Manual for coverage of a hydrophilic contact lens as a prosthetic device.)”

CMS NCD 80.4 – Hydrophilic Contact Lenses

Indications and Limitations of Coverage

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.

Medicare Administrative Contractors are authorized to accept a Food and Drug Administration (FDA) letter of approval or other FDA-published material as evidence of FDA approval. (See §80.1 for coverage of a hydrophilic lens as a corneal bandage.)

CMS NCD 80.5 – Scleral Shell (CIM 65.3)

“Scleral shell (or shield) 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 under §1861(s)(8) of the Act.”

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.”

Medicare does not reimburse for code S0515.

Local:

There is no WPS LCD on this topic.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Corneal Collagen Cross-linking
- Corneal Hysteresis Determination by Air Impulse Stimulation

References

1. 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. PMID 15894881
2. Stason WB, Razavi M, Jacobs DS, et al. Clinical benefits of the Boston Ocular Surface Prosthesis. *Am J Ophthalmol*. Jan 2010;149(1):54-61. PMID 19878920
3. Baran I, Bradley JA, Alipour F, et al. PROSE treatment of corneal ectasia. *Cont Lens Anterior Eye*. May 24 2012;35(5):222-227. PMID 22633003
4. Jacobs DS, Rosenthal P. Boston scleral lens prosthetic device for treatment of severe dry eye in chronic graft-versus-host disease. *Cornea*. Dec 2007;26(10):1195-1199. PMID 18043175
5. Jupiter DG, Katz HR. Management of irregular astigmatism with rigid gas permeable contact lenses. *CLAO J*. Jan 2000;26(1):14-17. PMID 10656303
6. 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. PMID 22543730
7. Schornack MM, Patel SV. Scleral lenses in the management of keratoconus. *Eye Contact Lens*. Jan 2010;36(1):39-44. PMID 20009945
8. Schornack MM, Pyle J, Patel SV. Scleral lenses in the management of ocular surface disease. *Ophthalmology*. Jul 2014;121(7):1398-1405. PMID 24630687
9. Visser ES, Visser R, van Lier HJ, et al. Modern scleral lenses part I: clinical features. *Eye Contact Lens*. Jan 2007;33(1):13-20. PMID 17224674
10. American Academy of Ophthalmology (AAO). Confronting corneal ulcers. 2012; <http://www.aao.org/publications/eyenet/201207/feature.cfm> . Accessed January 2025.
11. Lim I, Tan DT and Chan WK. Therapeutic use of Bausch & Lomb PureVision contact lenses. *CLAO J* 2001 Oct;27(4): 179-85. (10)
12. Russo PA, Bouchard CS, Galasso JM. Extended-wear silicone hydrogel soft contact lenses in the management of moderate to severe dry eye signs and symptoms secondary to graft-versus-host disease. *Eye Contact Lens*. 2007 May;33(3):144-7. (11)
13. Blue Cross Blue Shield Association. Gas Permeable Scleral Contact Lens. Medical Policy Reference Manual. Policy #9.03.25, Issue 9:2014, original policy date 9/1/11, archived 9/11/15.
14. Centers for Medicare & Medicaid Service (CMS). National Coverage Determination (NCD). 80.1. National Coverage Determination (NCD) for Hydrophilic Contact Lens For Corneal Bandage. Effective date 12/1994. Available at < http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=136&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=Michigan&Keyword=corneal+bandage&KeywordLookUp=Title&KeywordSearchType=And&ncd_id=80.1&ncd_version=1&basket=ncd%25253A80%25252E1%25253A1%25253Ahydrophilic+Contact+Lens+For+Corneal+Bandage&bc=gAAAAABAAAAAAA%3d%3d& > (January 2025).

15. Centers for Medicare & Medicaid Services (CMS) National Coverage Determination, NCD), 80.5: NCD for Scleral Shell, available at < https://www.cms.gov/manuals/downMds/ncd103c1_Part1.pdf >, page 93, accessed January 2025. National Coverage Determination Manual. Rev. 206, 04/03/18.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through January 2025, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
3/1/11	12/14/10	1/14/11	Joint policy established
11/1/13	8/22/13	8/27/13	Routine review
5/1/15	2/17/15	2/27/15	Routine maintenance. Updated references, consolidated inclusionary guidelines. No change in policy status.
5/1/16	2/16/16	2/16/16	Routine maintenance.
5/1/17	2/21/17	2/21/17	Routine maintenance.
5/1/18	2/20/18	2/20/18	Routine policy maintenance, no change in status.
5/1/19	2/19/19		Routine policy maintenance. No change in status.
5/1/20	2/18/20		Routine policy maintenance. No change in policy status.
5/1/21	2/16/21		Routine policy maintenance. No change in policy status.
5/1/22	2/15/22		Routine policy maintenance, no change in policy status.
5/1/23	2/21/23		Routine policy maintenance, no change in policy status. (ds)
5/1/24	2/20/24		Routine policy maintenance, no change in status. Vendor managed: N/A (ds)
5/1/25	2/18/25		Routine policy maintenance, no change in status. Vendor managed: N/A

Next Review Date: 1st Qtr. 2026

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY:
CORNEAL LIQUID BANDAGE LENS FOR CORNEAL EPITHELIAL DEFECTS /SCLERAL
LENSES

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; criteria apply.
BCNA (Medicare Advantage)	See government section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.