

MEDICAL POLICY

SUBJECT: GAS PERMEABLE SCLERAL CONTACT LENS (E.G., BOSTON OCULAR SURFACE PROSTHESIS)

EFFECTIVE DATE: 11/21/13
REVISED DATE: 11/20/14, 10/15/15, 10/20/16, 10/19/17, 10/18/18

POLICY NUMBER: 9.01.17

CATEGORY: Technology Assessment

PAGE: 1 OF: 4

- *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.*
- *If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.*
- *If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.*

POLICY STATEMENT:

Based upon our criteria and assessment of peer-reviewed literature, an FDA approved gas permeable scleral lens is considered **medically appropriate** for patients who have not responded to topical medications or standard spectacle or contact lens fitting for the following conditions:

- I. Corneal ectatic disorders (e.g., ., keratoconus, keratoglobus, pellucid marginal degeneration, Terrien's marginal degeneration, Fuchs' superficial marginal keratitis, post-surgical ectasia);
- II. Corneal scarring and/or vascularization;
- III. Irregular corneal astigmatism (e.g., after keratoplasty or other corneal surgery); or
- IV. 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.

POLICY GUIDELINES:

- I. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.
- II. Replacement of the lens or lenses that have been damaged or lost due to patient neglect is **ineligible for coverage**.

DESCRIPTION:

Gas permeable scleral contact lenses, which are also known as ocular surface prostheses are made of a highly oxygen permeable polymer. They are unique in their design in that they fit onto and are supported by the sclera, the white portion of the eye. Scleral support is the key to improved comfort compared with corneal lenses because of the lower density of pain fibers in the sclera than in the cornea. In comparison to corneal contact lenses, scleral lenses bulge outward considerably more. The space between the cornea and the lens is filled with artificial tears. The liquid, which is contained in a thin elastic reservoir, conforms to the irregularities of the deformed cornea.

Scleral lenses are noticeably larger than standard gas permeable (GP) corneal contacts and have a diameter equal to or greater than that of soft contact lenses. The smallest scleral lenses are approximately 14.5 mm in diameter, and the largest can be up to 24 mm. Typically, scleral lenses that are 18 mm or smaller are subcategorized as mini-scleral lenses. Another category of gas permeable lenses bridges the size gap between conventional GP lenses and mini-scleral lenses. These lenses, called corneo-scleral lenses, generally are approximately 13 to 15 mm in diameter. Corneo-scleral lenses often are utilized for people who require larger-than-normal GP lenses for greater comfort. They also are frequently used when contact lenses are needed after LASIK or other corneal refractive surgery to correct irregular astigmatism.

Scleral contact lenses have 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.

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). This may be

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called prosthetic replacement of the ocular surface ecosystem (PROSE). 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 (Eerbeeck) 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.

RATIONALE:

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.

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 (Rosenthal, et al. 2005) 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. While there is a lack of controlled trials, the current uncontrolled studies investigating the Boston scleral contact lens are suggestive of a health benefit in patients who otherwise have no alternative treatment (e.g., Stason, et al. 2010; Baran, et al. 2012; Jacobs, et al. 2007).

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

<u>CPT:</u>	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

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<u>HCPCS:</u>	S0515	Scleral lens, liquid bandage device, per lens
	V2531	Contact lens, scleral, gas permeable, per lens

<u>ICD10:</u>	H16.401-H16.449	Corneal neovascularization (code range)
	H17.00-H17.9	Corneal scars and opacities (code range)
	H18.40-H18.49	Corneal degenerations (code range)
	H18.601-H18.629	Keratoconus (code range)
	H18.70-H18.799	Other and unspecified corneal deformities (code range)
	H52.211-H52.219	Irregular astigmatism

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T85.398A-T85.398S Other mechanical complication of other ocular prosthetic devices, implants, and grafts (code range)

REFERENCES:

- Agranat JS, et al. prosthetic replacement of the ocular surface ecosystem: impact at 5 years. Br J Ophthalmol 2016 Sept;100(9):1171-1175.
- Arumugam AO, et al. PROSE for irregular corneas at a tertiary eye care center. Eye Contact Lens 2014 Mar;40(2):71-3.
- Asena L, et al. Clinical outcomes of scleral Misa lenses for visual rehabilitation in patients with pellucid marginal degeneration. Cont Lens Anterior Eye 2016 Dec;39(6):420-424.
- Barnett M, et al. Use of scleral lenses and miniscleral lenses after penetrating keratoplasty. Eye Contact Lens 2016 May;42(3):185-189.
- BlueCross BlueShield Association. Gas Permeable Scleral Contact Lens. Medical Policy Reference Manual Policy #9.03.25. archived 2014 Sep 11.
- Chahal HS, et al. Scleral contact lenses in an academic oculoplastics clinic: epidemiology and emerging considerations. Ophthal Plast Reconstr Surg 2018 May/Jun;34(3):231-236.
- Chahal JS, et al. Prosthetic replacement of the ocular surface ecosystem scleral lens therapy for exposure keratopathy. Eye Contact Lens 2017July;43(4):240-244.
- DeLoss KS, et al. Prosthetic replacement of Ocular Surface Ecosystem (PROSE) scleral device compared to keratoplasty for the treatment of corneal ectasia. Am J Ophthalmol 2014 Nov;158(5):974-82.
- de Luis Eguileor B, et al. Irregular corneas: improve visual function with scleral contact lenses. Eye Contact Lens 2018 May;44(3):159-163.
- Ghosh S, et al. Effects of contact lens wearing on keratoconus: a confocal microscopy observation. Int J Ophthalmol 2017 Feb 18;10(2):228-234
- Hassani,M, et al. A comparison of the visual acuity outcome between Clearkone and RGP lenses. J Curr Ophthalmol 2017 Aug 26;30(1):85-86
- Heur M, et al. Prosthetic replacement of the ocular surface ecosystem scleral lens therapy for patients with ocular symptoms of chronic Stevens-Johnson syndrome. Am J Ophthalmol 2014 Jul;158(1):49-54.
- Kornberg DL, et al. Clinical experience with PROSE fitting: significance of diagnosis and age. Eye Contact Lens 2016 March;42(2):124-128.
- Papakostas TD, et al. Prosthetic replacement of the ocular surface ecosystem as treatment for ocular surface disease in patients with a history of Stevens-Johnson syndrome/toxic epidermal necrolysis. Ophthalmology 2015 Feb;122(2):248-53.
- Rathi VM, et al. Scleral contact lenses in the management of pellucid marginal degeneration. Cont Lens Anterior Eye 2016 June;39(3):217-220.
- Schorrack MM, et al. Scleral lenses in the management of ocular surface disease. Ophthalmology 2014 Jul;121(7):1398-405.
- *Shepard DS, et al. Economic appraisal of the Boston Ocular Surface prosthesis. Am J Ophthalmol 2009 Dec;148(6):860-8.
- *Stason WB, et al. Clinical benefits of the Boston Ocular Surface Prosthesis. Am J Ophthalmol 2010 Jan;149(1):54-61.
- Stoyanova EI, et al. Bandage and scleral contact lenses for ocular graft-versus-host disease after allogeneic haematopoietic stem cell transplantation. Acta Ophthalmol 2015 Nov;93(7):e604.

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Theophanous C, et al. Use of prosthetic replacement of the ocular surface ecosystem scleral lenses in patients with ocular chronic graft-vs-host disease. Biol Blood Marrow Transplant 2015 Dec;21(12):2180-2184.

*Visser ES, et al. Modern scleral lenses part I: clinical features. Eye Contact Lens 2007 Jan;33(1):13-20.

*Visser ES, et al. Modern scleral lenses part II: patient satisfaction. Eye Contact Lens 2007 Jan;33(1):21-25.

Wang Y, et al. Corneal nerve structure and function after long-term wear of fluid-filled scleral lens. Cornea 2015 Apr;34(4):427-32.

Yan P, et al. Patient comfort and visual outcomes of mini-scleral contact lenses. Can J Ophthalmol 2017 Feb;52(1):69-73.

* key article

KEY WORDS:

Boston ocular surface prosthesis, PROSE, Prosthetic replacement of the ocular surface ecosystem, scleral contact lens

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based upon our review, scleral contact lens is not addressed in National or regional CMS coverage determinations or policies. However, the following news release on 9/3/15 noted the following:

PROSE® Device - Correct Coding - Joint DME MAC and PDAC Article

Recently the DME MACs have received questions about the proper coding of the PROSE® device (BostonSight). PROSE® devices are designed to rest on the sclera or white part of the eye and are used to treat ocular surfaces diseases, including some types of "dry eye." This article discusses the correct coding of the PROSE® device.

For Medicare billing purposes 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 certain types of dry eye (see below) the device must be coded as a scleral shell with HCPCS code V2627 (scleral cover shell).

Coverage criteria for scleral shells (V2627) is outlined in the Centers for Medicare & Medicaid Services National Coverage Determination 80.5 (Internet-only Manual 100-3, Chapter 1, Part 1, §80.5). Coverage for V2627 is limited to two conditions:

- Treatment of an eye rendered sightless and shrunken by inflammatory disease; and,
- 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.