MEDICAL POLICY

SUBJECT: GAS PERMEABLE SCLERAL CONTACT LENS (E.G., BOSTON OCULAR SURFACE PROSTHESIS)  
POLICY NUMBER: 9.01.17  
CATEGORY: Technology Assessment  
EFFECTIVE DATE: 11/21/13  
REVISED DATE: 11/20/14, 12/15/15  
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• If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.
• Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.
• Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.

POLICY STATEMENT:
Based upon our criteria and assessment of peer-reviewed literature, a 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 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 (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.

**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:**

*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).

**CPT:**

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

**HCPCS:**

S0515  Scleral lens, liquid bandage device, per lens

V2530  Contact lens, scleral, gas impermeable, per lens

V2531  Contact lens, scleral, gas permeable, per lens

**ICD9:**

367.22  Irregular astigmatism

370.60-360.64  Corneal neovascularization (code range)

371.00-371.04  Corneal scars and opacities (code range)
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**KEY WORDS:**

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

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**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.

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