

09-V0000-01

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## Subject: Prosthetic Eyes and Lens Implants

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<a href="#">Position Statement</a>	<a href="#">Billing/Coding</a>	<a href="#">Reimbursement</a>	<a href="#">Program Exceptions</a>	<a href="#">Definitions</a>	<a href="#">Related Guidelines</a>
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### DESCRIPTION:

Prosthetics are artificial substitutes that replace all or part of a body organ or replace all or part of the function of a permanently inoperative, absent, or malfunctioning body part whether surgically implanted or worn as an anatomic supplement.

The lens of the eye is considered an internal body organ. Prosthetics replacing the lens of an eye include post-surgical lenses used during convalescence from eye surgery in which the lens of an eye was removed.

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 (ie, 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 Boston Ocular Surface Prosthesis, which is the prosthetic device used in PROSE, received premarket approval from the U.S. Food and Drug Administration (FDA) in 1994.

## **POSITION STATEMENT:**

**Note:** Coverage for prosthetic lenses (lens implants) is subject to the member's benefit terms, limitations and maximums.

**Prosthetic lenses (lens implants) meet the definition of medical necessity** when they perform the function of the human lenses in the absence of human lenses due to surgery, injury, disease, or congenital anomaly.

The following may be eligible for coverage:

- **Corneal contact lenses** (V2500, V2501, V2502, V2503, V2510, V2511, V2512, V2513)
- **Corneal rigid contact lenses** may be covered when provided for the treatment of [keratoconus](#) ICD-10 codes (H18.601 – H18.629, Q13.4).
- **Hydrophilic contact lenses** (V2520, V2521, V2522, V2523) used as moist corneal bandages for the treatment of conditions such as:
  - Bullous [keratopathy](#)
  - Dry eyes
  - Corneal ulcers and erosion
  - Keratitis
  - Corneal edema
  - Descemetocoele
  - Corneal ectasis
  - Mooren's ulcer
  - Anterior corneal dystrophy
  - Neurotrophic keratoconjunctivitis; **OR**
  - Prescribed as a prosthetic lens for the aphakic patient.
- **[Gas impermeable scleral contact lenses](#)** (V2530) when prescribed as a prosthetic device to support surrounding orbital tissue of a shrunken and sightless eye or when prescribed for the treatment of dry eye (failure of lacrimal gland to produce enough tears).
- **Rigid gas permeable scleral contact lenses** (S0515, V2531) **meet the definition of medical necessity** for members 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, postsurgical 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, postocular surface tumor excision, postglaucoma filtering surgery) with pain and/or decreased visual acuity.

Use of a rigid gas permeable scleral lenses for any other condition **do not meet the definition of medical necessity.**

- **Intraocular lenses** (V2630, V2631, V2632) when implanted by surgery (66982, 66983, 66984, 66985, 66986), any technique, for [aphakia](#).

There are three categories of [intraocular lenses](#):

1. Anterior chamber lenses

- The anterior chamber angle fixation lens is indicated where there is no iris (i.e., congenital or traumatic aniridia) or where there is an unusually large opening in the iris (i.e., as in some iridectomies).
- When one of these indications exists, the anterior chamber angle fixation lens is the only intraocular lens that would be covered.

2. Iris supported lenses

3. Posterior chamber lenses.

- **Temporary cataract lenses** (92358) Only one pair is covered (temporary contact lenses are non-covered).
- **Permanent cataract lenses** (V2100, V2101, V2102, V2103, V2104, V2105, V2106, V2107, V2108, V2109, V2110, V2111, V2112, V2113, V2114, V2115, V2118, V2121, V2199, V2200, V2201, V2202, V2203, V2204, V2205, V2206, V2207, V2208, V2209, V2210, V2211, V2212, V2213, V2214, V2215, V2218, V2219, V2220, V2221, V2299, V2300, V2301, V2302, V2303, V2304, V2305, V2306, V2307, V2308, V2309, V2310, V2311, V2312, V2313, V2314, V2315, V2318, V2319, V2320, V2321, V2399, V2410, V2430, V2499).

One pair of lenses (or frames with lenses), any type, is covered as a prosthesis if an intraocular lens has been implanted.

**Prosthetic eyes** (V2623, V2624, V2625, V2626, V2627, and V2629) for replacement of the human organ **meets the definition of medical necessity** when prescribed by a physician (M.D. or D.O.) or by an optometrist (O.D.).

### Replacement and Repair

Replacement of eye prostheses is eligible for coverage when the replacement is required due to one of the following:

- Loss\*
- Irreparable damage\*
- Wear\*\*
- Change in the patient's condition.\*\*

**\*Replacements** resulting from loss or irreparable damage may be reimbursed without a physician's order when coverage requirements were met for the original prosthesis.

**\*\*Replacements** resulting from wear or a change in the patient's condition must be supported by a current physician's order.

Replacement of frames must be documented for medical necessity.

Reimbursement for the repair of eye prostheses is not to exceed the cost of replacement.

Prosthetic lenses are not eligible for coverage when provided for correction of ordinary refractive errors in the non-diseased eye. Based on the member's individual contract benefit, services are excluded when provided for the diagnosis or treatment of vision problems, including but not limited to the following:

- Surgical procedure performed primarily to correct or improve myopia or other refractive disorders (e.g., radial keratotomy, PRK and LASIK), which are not a direct consequence of trauma or prior ophthalmic surgery;
- Examinations;
- Exercises or visual training;
- Glasses and contact lenses and their fitting.

Accommodating intraocular lens implants, in conjunction with cataract surgery or in the absence of cataracts, **do not meet the definition of medical necessity** when compared as an alternative to standard intra-ocular lenses.

## **BILLING/CODING INFORMATION:**

See section entitled [POSITION STATEMENT](#).

### **CPT Coding:**

92071	Fitting of contact lens for treatment of ocular surface disease
92072	Fitting of contact lens for management of keratoconus, initial fitting

### **HCPCS Coding:**

Q1004	New technology, intraocular lens, category 4 as defined in Federal Register notice
Q1005	New technology, intraocular lens, category 5 as defined in Federal Register notice
S0500	Disposable contact lens, per lens
S0504	Single vision prescription lens (safety, athletic, or sunglass), per lens
S0506	Bifocal vision prescription lens (safety, athletic, or sunglass), per lens
S0508	Trifocal vision prescription lens (safety, athletic, or sunglass), per lens
S0510	Non-prescription lens (safety, athletic, or sunglass), per lens
S0512	Daily wear specialty contact lens, per lens
S0514	Color contact lens, per lens
S0515	Scleral lens, liquid bandage device, per lens
S0516	Safety eyeglass frames
S0518	Sunglasses frames
S0580	Polycarbonate lens (List this code in addition to the basic code for the lens)
S0581	Nonstandard lens (List this code in addition to the basic code for the lens)
S0590	Integral lens service, miscellaneous services reported separately

S0592	Comprehensive contact lens evaluation
S0595	Dispensing new spectacle lenses for patient supplied frame
S0596	Phakic intraocular lens for correction of refractive error
V2530	Contact lens, scleral, gas impermeable, per lens
V2531	Contact lens, scleral, gas permeable, per lens
V2700	Balance lens, per lens
V2702	Deluxe lens feature
V2744	Tint, photochromatic, per lens
V2745	Addition to lens; tint, any color, solid, gradient or equal, excludes photochromatic, any lens material, per lens
V2756	Eye glass case
V2760	Scratch resistant coating, per lens
V2761	Mirror coating, any type, solid, gradient or equal, any lens material, per lens
V2762	Polarization, any lens material, per lens
V2781	Progressive lens, per lens
V2782	Lens, index 1.54 to 1.65 plastic or 1.60 to 1.79 glass, excludes polycarbonate, per lens
V2783	Lens, index greater than or equal to 1.66 plastic or greater than or equal to 1.80 glass, excludes polycarbonate, per lens
V2784	Lens, polycarbonate or equal, any index, per lens
V2786	Specialty occupational multifocal lens, per lens
V2787	Astigmatism correcting function of intraocular lens
V2788	Presbyopia correcting function of intraocular lens
V2797	Vision supply, accessory <b>AND/OR</b> service component of another HCPCS vision code

### **REIMBURSEMENT INFORMATION:**

See section entitled **POSITION STATEMENT**.

Replacement for eye prostheses is limited to 3 within 12-months. Services in excess of this limitation are subject to medical review of documentation in support of medical necessity. The following information may be required documentation to support medical necessity: attending physician initial assessment, physician history and physical, and physician visit note.

### **LOINC Codes:**

<b>DOCUMENTATION TABLE</b>	<b>LOINC CODES</b>	<b>LOINC TIME FRAME MODIFIER CODE</b>	<b>LOINC TIME FRAME MODIFIER CODES NARRATIVE</b>
Physician Initial Assessment	18736-9	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Attending physician visit note	18733-6	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of

			service for the claim.
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## **PROGRAM EXCEPTIONS:**

**Federal Employee Program (FEP):** Follow FEP guidelines.

**State Account Organization (SAO):** Follow SAO guidelines.

### **Medicare Advantage products:**

The following National Coverage Determinations (NCDs) were reviewed on the last guideline reviewed date: Hydrophilic Contact Lens for Corneal Bandage (80.1), Hydrophilic Contact Lens (80.4), Scleral Shell (80.5), and Intraocular Lenses (IOLs) (80.12) located at cms.gov. No Local Coverage Determination (LCD) was found at the time of the last guideline reviewed date.

## **DEFINITIONS:**

**Aphakia:** absence of the crystalline lens of the eye (e.g., after surgical removal of cataracts).

**Enucleation:** surgical removal of the eye.

**Gas permeable scleral contact lenses** (i.e., ocular surface prostheses): formed with an elevated chamber over the cornea and a haptic base over the sclera.

**Intraocular lens:** artificial lens that may be implanted to replace the natural lens after cataract surgery.

**Keratopathy:** any disease of the cornea.

**Keratoconus:** thinning of the cornea causing a cone-shaped bulging of the cornea, usually bilaterally; can be corrected by glasses, contact lenses, or surgery.

**Pseudophakos:** see intraocular lens.

**Scleral shell (or shield):** contact lens that fits over the entire exposed surface of the eye, opposed to corneal contact lenses that cover only the central non-white area (pupil and iris). When an eye has been rendered sightless and shrunken due to inflammatory disease, a scleral shell may, among other things, prevent the need for surgical [enucleation](#) and prosthetic implant, and acts to support the surrounding orbital tissue.

## **RELATED GUIDELINES:**

[Prosthetics, 09-L0000-05](#)

[Implantation of Intrastromal Corneal Ring Segments, 09-V0000-02](#)

## **OTHER:**

**Note:** The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

## REFERENCES:

1. American Academy of Ophthalmology (AAO). Confronting corneal ulcers. 2012.
2. American Academy of Ophthalmology Refractive Management/Intervention Panel. Refractive errors & refractive surgery. San Francisco (CA): American Academy of Ophthalmology; 2017.
3. American Academy of Ophthalmology. Cataract in the adult eye. Preferred practice pattern. San Francisco (CA): American Academy of Ophthalmology (AAO); 2006.
4. Blue Cross Blue Shield Association Medical Policy. Gass Permeable Scleral Contact Lens 9.03.25, Archived 9/2014.
5. Medicare National Coverage Determinations Manual Chapter 1, Part 1, 80.1 Hydrophilic Contact Lens for Corneal Bandage, 09/14.
6. Medicare National Coverage Determinations Manual Chapter 1, Part 1, 80.4 Hydrophilic Contact Lenses, 09/14.
7. Medicare National Coverage Determinations Manual Chapter 1, Part 1, 80.5 Scleral Shield, 10/03.
8. Medicare National Coverage Determinations Manual Chapter 1, Part 1, 80.12 Intraocular Lenses (IOLs), 10/03.
9. National Institute for Health and Clinical Excellence (NICE). Implantation of accommodating intraocular lenses for cataract. Issue date: February 2007.
10. National Institute for Health and Clinical Excellence (NICE). Interventional Procedures Program. Interventional procedure overview of the implantation of accommodating intraocular lenses during cataract surgery. Originally prepared August 2006.
11. US Food and Drug Administration. Center for Devices and Radiological Health. PMA final decision for September 2004. P030002/S002. CrystaLens™ Model AT-45 Multipiece Silicone Posterior Chamber Accommodating Intraocular Lens (IOL).

## COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy & Coverage Committee on 06/27/19.

## GUIDELINE UPDATE INFORMATION:

11/15/01	Medical Coverage Guideline Reformatted.
10/15/03	Reviewed; no change in coverage statement.
01/01/04	Annual HCPCS coding update.
06/15/04	Unscheduled review with revision consisting of addition of non-coverage statement for “accommodating intraocular lens implants”; MCG name change.
10/01/04	4th Quarter HCPCS coding update; added S0515.
01/01/05	HCPCS coding update; added V2702.
04/01/05	2nd Quarter HCPCS coding update; added S0595.
01/01/06	Annual HCPCS coding update (deleted 92391 – 92396).
02/15/06	Revision consisting of removing V2628 (fabrication and fitting) from the list of codes describing prosthetic eyes.
06/15/06	Scheduled review (consensus) with revision consisting of removal of reimbursement statement regarding coverage of fabrication and fitting of prosthetic eye (V2628).
11/15/06	Revision consisting of adding clarification regarding reimbursement of prosthetic lenses and replacement lenses.

08/15/07	Reviewed; added V2788 to coding section; revised statement regarding accommodating IOL implants; reformatted guideline; updated references.
01/01/08	Annual HCPCS coding update: added V2787.
06/15/09	Scheduled review; no change in position statement; references updated.
11/15/09	Revision consisting of updating coding section (V2781 added).
01/15/10	Revision consisting of updating coding section (V2700 added).
06/15/10	Revision consisting of coding section update (Q1003 – Q1005, V2744, and V2760 added).
10/15/10	Revision; formatting changes.
01/01/11	Revision; related ICD-10 codes added.
04/01/11	2nd Quarter HCPCS coding update: Q1003 deleted.
06/15/11	Scheduled review; position statements unchanged; references updated.
07/01/11	Revision; formatting changes.
04/01/12	1st Quarter HCPCS coding update: S0596 added.
03/15/13	Revision: 66986 added.
05/15/14	Billing/Coding Information section updated; Program Exceptions section updated.
12/15/14	Revision to add criteria for gas permeable scleral lenses; updated Coding section; updated references.
11/01/15	Revision: ICD-9 Codes deleted.
10/15/16	Revision; billing/coding information section updated.
02/20/17	Update; Deleted ICD-9 codes 371.6-371.62 and 743.41.
06/15/17	Review; no change to position statement. Updated description, program exception and references.
07/15/19	Review; no change to position statement. Updated references.