

MEDICAL POLICY



SUBJECT: INTRAOCULAR LENS (IOL) IMPLANTS	EFFECTIVE DATE: 10/27/05 REVISED DATE: 08/31/06, 08/23/07, 08/28/08, 10/28/09, 10/28/10, 12/08/11, 10/25/12, 10/24/13, 10/23/14, 10/28/15, 10/27/16, 10/26/17, 10/25/18
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<ul style="list-style-type: none">• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i>• <i>If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.</i>• <i>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.</i>	

POLICY STATEMENT:

- I. Based upon our criteria and assessment of peer-reviewed literature, the use of a *monofocal (spherical or aspheric)* intraocular lens (IOL) as replacement of the natural crystalline lens of the eye following cataract extraction is considered **medically appropriate**.
- II. Based upon our criteria and assessment of peer reviewed literature, the use of a *multifocal IOL, an astigmatism-correcting lens, or an accommodating/trifocal IOL* following cataract extraction is considered **not medically necessary** as no superior medical benefit for these lenses has been demonstrated over the monofocal IOL other than decreasing the need for corrective eye wear.

POLICY GUIDELINES:

In a manner similar to the Centers for Medicare and Medicaid Services (CMS), patients/members may choose to receive an astigmatism-correcting, multifocal or accommodating IOL (*please refer to the CMS synopsis at the end of this policy*). Patients/members must sign a beneficiary notice waiver and agree to assume liability for the additional expense of the multifocal or accommodating lens. Reimbursement will be provided for only the cost of a standard or monofocal IOL. Patients/ members should be apprised of this option by their eye surgeon prior to the cataract extraction surgery.

DESCRIPTION:

The eye functions much like a camera with two lenses. The first lens is the cornea, a clear membrane that covers the front of the eye. The second lens is the eye's natural crystalline lens, which is located behind the pupil. The cornea is responsible for about 70 percent of the eye's focusing power, while the natural lens "fine-tunes" the image before it is focused on the retina at the back of the eye. The natural lens accomplishes this fine-tuning function by changing shape to accommodate both near objects and those that are further away. Ciliary muscles and zonules are attached to the lens and are responsible for its ability to change shape. A cataract is a hardening and opacification of the normally transparent crystalline lens within the eye. Cataract formation usually occurs as part of the aging process, but may also be congenital in nature. Rarely, a cataract may form when related to trauma or inflammation of the eye or may also result from the use of some medications. Cataracts may result in progressive loss of vision with the degree of loss depending on the location, size and density of the cataract. The primary indication for cataract surgery is that visual function no longer meets the patient's needs and also that there is a reasonable likelihood of vision improvement with the procedure. The current cataract procedure of choice is an extracapsular technique (removes only the lens) with the implantation of an intraocular lens.

IOLs are used to replace the natural lens and restore the optical focusing power of the eye. The more common replacement lenses include monofocal, multifocal or accommodating IOLs.

Monofocal IOLs are the current standard of treatment. This type of IOL usually has a fixed focusing power, which provides good distance vision, sometimes intermediate vision, but does not correct the patient's near vision as the full accommodating ability of the eye is lost. Thus, the placement of a monofocal IOL usually requires corrective lenses or eyeglasses after surgery for reading and near vision tasks. While a traditional fixed monofocal IOL is spherical (the front surface is uniformly curved), an *aspheric* monofocal IOL is slightly flatter in the periphery, allowing for a better contrast

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sensitivity and a reduction in visual aberrations. The advent of aspheric IOLs has enhanced the quality of visual outcome for monofocal lenses.

Multifocal IOLs are designed to provide distance and near vision and are referred to as pseudoaccommodative lenses or dynamic lenses. The multifocal IOL structure allows light rays to be focused from both distance and near. This type of lens does not restore good intermediate vision, but the need for eyeglasses for near vision correction appears to be much less with the use of multifocal IOLs compared to the monofocal IOL. Reports of increased glare, halos at night, variable loss of clarity and low contrast acuity have been reported by patients with the use of multifocal IOLs, creating patient dissatisfaction with the multifocal IOL variety.

Accommodating or trifocal IOLs are designed to provide good distance, intermediate, and near vision. The accommodating IOL has hinges at both ends to facilitate forward and backward movement and interacts with the eye's ciliary muscles and zonules allowing variable focus capability. This type of lens allows patients to see a continuous range of vision and greatly reduces the need for postoperative corrective lenses. Multifocal and accommodating IOLs are sometimes referred to as presbyopia-correcting IOLs.

Astigmatism-correcting IOLs, also known as toric IOLs provide correction or reduction of pre-existing astigmatism (astigmatism that was present before cataract surgery) by incorporating a special curvature into the IOL. Prior to the advent of toric IOLs, pre-existing astigmatism could only be corrected by making limbal relaxing incisions into the cornea during cataract surgery to change its curvature, or by wearing astigmatism correcting eyeglasses after surgery.

RATIONALE:

The numerous IOLs mentioned in the rationale section are examples and may not be an all-inclusive listing of FDA approved devices.

There are several fixed monofocal (e.g., Bausch & Lomb Akreos posterior fixed monofocal IOL, Akreos AO Micro Incision Lens Model MI60L, AcrySof SA60AT monofocal intraocular lens, AcrySof MA60AC, Alcon MZ30BD, and the Hydroview hydrogel foldable posterior IOL) and aspheric monofocal IOLs (e.g., AcrySof® IQ IOL, Tecnis® Z9000, Z9001, Z9002, ZA9003, SofPort AO IOL, Sofport LI61AO Akreos AO Aspheric IOL, AcrySof SN60WF, Hoya PY-60AD, Tecnis AMO Aspheric IOL ZCB00, and Acrysof IQ SN60WS) that have received FDA approval.

The multifocal IOL, AMO Array has been FDA approved since 1997 and is approved for use in persons age 60 or older in whom a cataractous lens has been removed and who may benefit from not having to use reading glasses for near vision. AcrySof ReSTOR, a multifocal IOL which uses apodized diffractive technology, received FDA approval in March of 2005. Clinical studies reported that 80% of patients who received this IOL did not require corrective lenses after cataract surgery. ReZOOM (Advanced medical Optics), a multifocal IOL, which allows distribution of light over 5 optical zones to provide near, intermediate, and distance vision also received FDA approval in March 2005. The European trial investigating its efficacy reported that 93% of patients receiving the ReZOOM implant never or occasionally reported needing glasses. The TECNIS ® multifocal foldable silicone and acrylic IOL received FDA approval January 2009.

In November 2003, Eyeonics received FDA approval for Crystalens Model AT-45 a single-optic accommodating posterior chamber IOL. This device is recommended for the primary implantation in the capsular bag of the eye for the visual correction of aphakia in adult patients in whom cataracts have been removed. Visiogen's Synchrony, a dual-optic accommodating IOL and Tetraflex IOL (Lenstec) are currently being investigated in US clinical trials.

A Cochrane review (2003, 2006), comparing multifocal to monofocal lenses post cataract surgery, found no statistical difference between the use of these IOL related to best corrected visual acuity, though unaided near vision was improved with the use of multifocal lenses. Review of the literature found no studies to support that the pseudo-accommodating or accommodating lens technology is superior to standard use of monofocal IOLs. The long-term stability of the accommodative effect of these lenses is unknown and some patients may still require corrective lenses after the multifocal or accommodative lenses are placed. A 2012 update of the Cochrane review by D Calladine and colleagues noted that there was moderate quality evidence that similar distance acuity is achieved with both types of lenses. There

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was also evidence that people with multifocal lenses had better near vision but methodological and statistical heterogeneity meant that they did not calculate a pooled estimate for effect on near vision. Total freedom from use of glasses was achieved more frequently with multifocal than monofocal IOLs. Adverse subjective visual phenomena, particularly haloes, or rings around lights, were more prevalent and more troublesome in participants with the multifocal IOL and there was evidence of reduced contrast sensitivity with the multifocal lenses. They concluded multifocal IOLs are effective at improving near vision relative to monofocal IOLs. Whether that improvement outweighs the adverse effects of multifocal IOLs will vary between patients. Motivation to achieve spectacle independence is likely to be the deciding factor.

Several models of astigmatism-correcting IOLS have FDA approval: Acrysof® Toric IOL (models: SN60T3, SN60T4, and SN60T5), manufactured by Alcon Laboratories, Inc.; and Silicon 1P Toric IOL (models: AA4203TF and AA4203TL), manufactured by STAAR Surgical. While studies have shown that the use of toric IOLs for the correction of astigmatism can decrease spectacle dependence, there is no evidence to support their superiority and necessity over the use of corrective eyewear (glasses or contacts).

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>	66982	Extracapsular cataract removal with insertion of intraocular lens prosthesis (one stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (e.g., iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage
	66983	Intracapsular cataract extraction with insertion of intraocular lens prosthesis (one stage procedure)
	66984	Extracapsular cataract removal with insertion of intraocular lens prosthesis (one stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification)
	66985	Insertion of intraocular lens prosthesis (secondary implant), not associated with concurrent cataract removal
	66986	Exchange of intraocular lens

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<u>HCPCS:</u>	C1780	Lens, intraocular (new technology)
	V2630	Anterior chamber intraocular lens
	V2631	Iris supported intraocular lens
	V2632	Posterior chamber intraocular lens
	V2787 (NMN)	Astigmatism-correcting function of an intraocular lens
	V2788 (NMN)	Presbyopia correcting function of an intraocular lens

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ICD10:	E08.36	Diabetes mellitus due to underlying condition with diabetic cataract
	E09.36	Drug or chemical induced diabetes mellitus with diabetic cataract
	E10.36	Type 1 diabetes mellitus with diabetic cataract
	E11.36	Type 2 diabetes mellitus with diabetic cataract
	E13.36	Other specified diabetes mellitus with diabetic cataract
	H25.011-H25.9	Age related cataract, code range
	H26.001-H26.09	Infantile and juvenile cataract, code range
	H26.101-H26.139	Traumatic cataract, code range
	H26.20	Unspecified complicated cataract
	H26.211-H26.219	Cataract with neovascularization, code range
	H26.221-H26.229	Cataract secondary to ocular disorders (degenerative) (inflammatory) , code range
	H26.231-H26.239	Glaucomatous flecks (subcapsular), code range
	H26.411-H26.419	Soemmering's ring, code range
	H26.30-H26.33	Drug-induced cataract, code range
	H26.40	Unspecified secondary cataract
	H26.491-H26.499	Other secondary cataract, code range
	H26.8	Other specified cataract
	H26.9	Unspecified cataract
	H28	Cataract in diseases classified elsewhere

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* Key article

KEY WORDS:

Accommodating, Aspheric, Astigmatism-correcting, Crystalens, dynamic, Monofocal, Multifocal, pseudoaccommodating, toric.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for intraocular lenses. Please refer to the following NCD website for Medicare Members:

<http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=239&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York++Upstate&CptHcpcsCode=36514&bc=gAAAABAAAA&>