



# Medical Coverage Policy

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## Intraocular Lens Implant

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### Related Coverage Resources

[Corneal Remodeling](#)

#### **INSTRUCTIONS FOR USE**

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

### Overview

This Coverage Policy addresses intraocular lens (IOL) implant.

### Coverage Policy

**Coverage for the surgical treatment of a refractive error varies across plans. Refer to the customer's benefit plan document for coverage details.**

**Standard monofocal intraocular lens (IOL) implant is considered medically necessary for ANY of the following conditions:**

- following cataract extraction
- trauma to the eye which has damaged the lens
- congenital cataract
- congenital aphakia
- lens subluxation/displacement
- anisometropia of 2 diopters or greater, and uncorrectable vision with the use of glasses or contact lenses

**The following classes of premium intraocular lens implants are intended to reduce the need for reading glasses and thus considered a convenience item and not medically necessary for ANY indication, including aphakia. In addition, many plans exclude the surgical treatment for the correction of a refractive error; therefore these lenses and their implantation are not covered under many health benefit plans:**

- presbyopia correcting IOL
- astigmatism correcting IOL
- phakic IOL

**Intraocular lens implant (i.e., monofocal IOL, multifocal IOL, or accommodating IOL) following clear lens extraction for the correction of refractive error is considered not medically necessary.**

#### **REPLACEMENT**

**Replacement of a medically necessary intraocular lens implant when anatomical change, inflammatory response or mechanical failure renders a previously implanted intraocular lens ineffective or nonfunctional is considered medically necessary.**

## **General Background**

The most common indication for an intraocular lens implant is cataract surgery. Cataracts – hardening or opacification (clouding) of the normally transparent crystalline lens within the eye – usually occur as part of the aging process but may be congenital, traumatic or related to other systemic diseases or medications. The current cataract procedure of choice is an extracapsular technique (removal of only the lens) with implantation of a posterior chamber (behind the iris) intraocular lens within the capsular bag. An intraocular lens (IOL) is a tiny, artificial lens for the eye. It replaces the eye's natural lens that is removed during cataract surgery. Most IOLs are made of silicone or acrylic. They may also be coated with a special material to help protect the eyes from harmful ultraviolet rays. Replacement of the lens restores optical focusing power lost by removal of the natural crystalline lens. The choice of IOL is dependent on physician recommendation and the visual needs of each individual. Monofocal IOLs meet the basic functional needs of an individual who undergoes cataract removal.

Other related vision disorders include:

- refractive error – any of a number of size- and shape-related abnormalities of the eyeball or other components of the eye that affect the normal ability of the eye to focus light on the retina.
- astigmatism – a refractive error caused by an uneven curve in the cornea or lens, so light (an image) fails to come to a single focus on the retina to produce clear vision. Instead, multiple focus points occur, either in front of the retina or behind it or both.
- nearsightedness (i.e., myopia) – a refractive error that occurs when the eyeball is too long, relative to the focusing power of the cornea and lens of the eye. This causes light rays to focus at a point in front of the retina, rather than directly on its surface. A nearsighted person typically will have difficulty reading road signs and seeing distant objects clearly. Myopia is the most common refractive error of the eye. It has become much more prevalent in recent years, purportedly due to eye fatigue from computer use and other extended near vision tasks and possibly genetic predisposition for myopia. Nearsightedness also can be caused by the cornea and/or lens being too curved for the length of the eyeball. In some cases, myopia is due to a combination of these factors.
- farsightedness (i.e., hyperopia) – a refractive error that occurs when light rays entering the eye focus behind the retina, rather than directly on it. A person can see distant objects very well, but has difficulty focusing on objects that are up close. The eyeball of a farsighted person is shorter than normal. Many children are born farsighted, and some of them outgrow it as the eyeball lengthens with normal growth.
- presbyopia – a refractive error that frequently begins at around age 40, when people start having trouble reading small print. It is believed to stem from a gradual thickening and loss of flexibility of the natural lens inside your eye. This differs from astigmatism, nearsightedness and farsightedness, which are related to the shape of the eyeball and are caused by genetic and environmental factors.

- aphakia – the absence of the natural lens which may result from extraction of the lens (e.g., cataract surgery), penetrating trauma, or from congenital conditions.
- anisometropia – refers to the condition in which one eye has a different refractive error than the other. Usually the eye with the least amount of refractive error is the dominant or preferred eye while the other eye may be suppressed and develop amblyopia (lazy eye). Greater degrees of anisometropia or astigmatism result in increased risk and severity of amblyopia.

### **Types of Intraocular lens (IOLs)**

IOLs other than monofocal, referred to as premium or deluxe lenses, are often recommended to individuals undergoing cataract surgery. Premium lenses are intended to reduce the need for vision correction following cataract surgery; however, they are considered not medically necessary.

**Monofocal:** The most common type of lens used with cataract surgery is a monofocal IOL set to focus for up-close, medium range or distance vision. Most people have them set for clear distance vision. Conventional monofocal lenses are spherical, meaning they are designed to provide clear vision at a single focal point (usually far away for good driving vision, for example). With conventional IOLs, typically eyeglasses or contact lenses are also needed in order to use a computer, read or perform other close-up tasks within arm's length.

**Multifocal:** IOLs that provide both distance and near focus at the same time are called multifocal IOLs. The lens has different zones set at different powers. It is designed so that the brain learns to select the right focus automatically. Multifocal IOLs contain added magnification in different parts of the lens to help treat presbyopia, decreasing the need for reading glasses or computer glasses after cataract surgery. Multifocal IOLs tend to provide better near vision than accommodating IOLs, but they also are more likely to cause glare or mildly blurred distance vision. FDA-approved multifocal IOLs include Tecnis Multifocal IOL (Abbott Medical Optics) and AcrySof IQ ReSTOR (Alcon).

**Accommodative:** These lens move or change shape inside your eye, allowing focusing at different distances. Accommodative IOLs expand the range of clear vision with both an aspheric design (as opposed to spherical design of monofocal IOLs) and also flexible "haptics" — the supporting legs that hold the IOL in place inside the eye. These flexible legs allow the accommodating IOL to move forward slightly when looking at near objects, which increases the focusing power of the eye enough to provide better near vision than a conventional monofocal lens. Accommodating IOLs may not provide the same level of magnification for near vision that a multifocal IOL does. FDA-approved accommodating IOLs include Crystalens AO and Trulign Toric IOL, both made by Bausch + Lomb. (The Trulign Toric lens corrects astigmatism as well as presbyopia.)

**Toric:** A toric lens is custom made to correct astigmatism as well as nearsightedness or farsightedness. Astigmatism is a refractive error caused by an uneven curve in the cornea or lens. The toric lens is designed with different powers in different meridians of the lens. They also have alignment markings on the peripheral part of the lens that enable the surgeon to adjust the orientation of the IOL inside the eye for optimal correction. Prior to cataract surgery, the surgeon places temporary markings on the patient's cornea that identify the location of the most curved meridian of the front of the eye. When the toric IOL is implanted during the cataract procedure, the surgeon rotates the IOL so the markings on the IOL are aligned with the markings on the cornea to insure proper astigmatism correction. FDA-approved toric intraocular lenses available in the U.S. include: Tecnis Toric (Abbott Medical Optics), AcrySof IQ Toric (Alcon), Staar Toric IOL (Staar Surgical), and Trulign Toric (Bausch + Lomb).

**Aspheric:** The shape of the natural lens inside the eye may vary in curvature from center to periphery. In other words, the eye's natural lens is aspheric or not spherical. Aspheric IOLs are designed to more closely match the shape and optical quality of the eye's natural lens, and thereby can provide sharper vision, especially in low light conditions. FDA-approved IOLs include: Tecnis Aspheric (Abbott Medical Optics), AcrySof IQ (Alcon), SofPort AO (Bausch + Lomb), and Softec HD (Lenstec).

**Extended Depth of Focus (EDOF):** EDOF IOLs, also referred to as Extended Range of Vision (EROV) IOL, are proposed for the treatment of presbyopia. In contrast to multifocal IOLs used in treatment of presbyopia, EDOF lenses work by creating a single elongated focal point to enhance "range of vision" or "depth of focus". A FDA-approved examples are The TECNIS Symphony® IOL and TECNIS Symphony® Toric IOL. Extended depth of focus lenses are unique in that they are neither multifocals nor are they accommodative IOLs. However, the

TECNIS Symphony® is a presbyopia-correcting lens and the TECNIS Symphony® Toric IOL addresses both presbyopia and astigmatism. The IC-8™ IOL (AcuFocu, Inc., Irvine, CA) and WIOL-CF (Medicem, Czech Republic) are not FDA-approved or available for sale in the United States.

**Light-adjustable:** A light-adjustable lens (LAL) allows the physician to make small adjustments to the implanted lens during several in-office procedures after the initial surgery to improve visual acuity without glasses. It is intended for patients who have astigmatism before surgery and who do not have macular diseases. The device should not be used in patients taking systemic medication that may increase sensitivity to UV light. A FDA-approved example is Light Adjustable Lens™ from RxSight®.

**Phakic:** Unlike the above described lenses, phakic lens are not associated with cataract surgery. They are permanently implanted into the eye to reduce a person's need for glasses or contact lenses, without removing the natural lens. They are placed just in front of or just behind the iris while preserving the natural crystalline lens. This is in contrast to intraocular lenses that are implanted into eyes after the eye's cloudy natural lens has been removed during cataract surgery. Phakic IOLs function very similarly to contact lenses. Phakic lenses are approved by the FDA for the correction of nearsightedness (myopia) only and include Visian Implantable Collamer Lens (ICL) (Staar Surgical) and Verisyse/ARTISAN (Abbott Medical Optics).

### Other IOL Indications

Intraocular lens implant may be needed for conditions other than with cataract surgery. Less common uses include: trauma to the eye which has damaged the lens; congenital cataract; congenital aphakia; lens subluxation/displacement; and significant anisometropia that is uncorrectable with the use of glasses or contact lenses.

- Congenital or infantile cataracts may be unilateral or bilateral. Most unilateral cataracts are not inherited or associated with a systemic disease and are of unknown etiology. The majority of bilateral congenital cataracts not associated with a syndrome have no identifiable cause. Genetic mutation is likely the most common cause.
- Congenital aphakia is a rare anomaly that can be subdivided into two forms: primary and secondary. Histologically, the lens is absent in primary congenital aphakia. In secondary congenital aphakia, the lens has developed but has been resorbed or extruded before or during birth.
- Anisometropia, the condition in which one eye has a different refractive error than the other, can cause amblyopia. The threshold for anisometropia that is enough to cause amblyopia varies depending upon the type of refractive error. The level of anisometropia severity can be categorized into mild (SE difference  $\geq 1.0$  D and  $< 2.0$  D), moderate (SE difference  $\geq 2.0$  D and  $< 3.0$  D), and severe (SE difference  $\geq 3.0$  D) (Lee, et al., 2017; Linke, et al., 2011). Anisometropia is treated with refractive correction. Early detection of refractive anisometropia in children with timely intervention could prevent permanent impairment in binocular vision and stereopsis. Refractive surgery may be performed in children with significant anisometropia who cannot or will not wear refractive correction. In children with extremely high refractive error in one eye only, correction with glasses causes a condition called aniseikonia (difference in image size) such that the eyes cannot function visually together. Secondarily, the children can experience asthenopia (eye fatigue, headache) from this correction and most refuse to wear the glasses. Contact lenses are another option, but they are difficult to insert in uncooperative children, loss is frequent, and they are costly. The consequence of this intolerance/noncompliance is severe amblyopia.

Clear Lens Extraction (CLE) also called refractive lens exchange (RLE) is the removal of a non-cloudy natural lens of the eye with the placement of corrective lenses. The clear lens extraction technique is very similar to cataract extraction. The eye's natural lens is removed and replaced with a prescription intraocular lens. However, refractive surgical procedures are considered not medically necessary because the correction of refractive errors can be achieved with eyeglasses or contact lenses.

### Literature Review

Both subjective and objective outcomes resulting from the use of varying types of IOLs have been reported in the peer-reviewed, published scientific literature (e.g., contrast sensitivity, glare acuity, pain score, up-close, medium range and distance visual acuity). Evidence in the published, peer-reviewed scientific literature generally supports improved visual acuity resulting in a decreased need for eyeglasses, with the use of premium lenses.

Generally, IOLs intended primarily for reducing an individual's dependence on additional vision correction (e.g., eyeglasses) following cataract removal and for other conditions are not considered medically necessary. Additional vision correction may be required after insertion of premium lenses. Monofocal IOLs are the standard treatment for replacement of the crystalline lens during cataract surgery. Intraocular lens replacement for the treatment of presbyopia, myopia, and/or other refractive correction is considered not medically necessary.

For more information on surgical treatment of refractive errors please refer to the Cigna Medical Coverage Policy Corneal Remodeling.

### **Professional Societies/Organizations**

**American Academy of Ophthalmology (AAO):** The AAO Preferred Practice Pattern® on Refractive Errors & Refractive Surgery (November 2017) states under Highlighted Findings and Recommendations for Care:

- Presbyopia can be managed by using eyeglasses or contact lenses (soft, rigid gas-permeable, aspheric bifocal or multifocal). Surgical management of presbyopia includes keratorefractive surgery, corneal inlays, or intraocular lens implantation (multifocal, accommodative, and extended depth of focus lenses).

The AAO Preferred Practice Pattern® on Amblyopia (November 2017) states under Highlighted Findings and Recommendations for Care:

- Treatment of refractive error alone can improve visual acuity in children who have untreated anisometropic and strabismic amblyopia. Visual acuity of children who have bilateral refractive amblyopia also can substantially improve with refractive correction alone.
- Most children who have moderate amblyopia (20/40 to 20/80) respond to initial treatment consisting of 2 hours of daily patching or weekend atropine.
- Following treatment of amblyopia caused by strabismus, anisometropia or both combined, continued monitoring and treatment, if needed, is associated with long-term stability of the visual acuity improvement.
- Suitable treatment options for amblyopia may include optical correction, patching, pharmacological treatment, optical treatment, Bangerter (translucent) filters, and/or surgery to treat the cause of amblyopia.
- Patching may be effective in older children and teenagers, particularly if they have not previously been treated.

The AAO Preferred Practice Pattern® on Cataract in the Adult Eye (October 2016) notes the following:

- The standard of care in cataract surgery in the United States is a small-incision phacoemulsification with foldable intraocular lens (IOL) implantation.
- Intraocular lens technologies and surgical approaches to implanting lenses continue to improve.
- Although numerous complications can occur intraoperatively or postoperatively with cataract surgery, those resulting in permanent loss of vision are rare. Complications specific to the IOL occur infrequently; the most common reasons for explantation of foldable IOLs include dislocation or decentration, glare or optical aberrations, incorrect power, and opacification.

The AAO Clinical Statement 'Amblyopia is a Medical Condition' (April 2017) states that amblyopia is a medical condition that is typically a preventable and treatable form of vision loss caused by developmental abnormalities of the brain's vision centers. Unless amblyopia is treated promptly during childhood, permanent structural changes occur in the brain of the amblyopic child, resulting in decreased visual function. Current methods of preschool vision screening can identify risk factors (primarily high levels of refractive error and anisometropia) that, if untreated, increase the likelihood of amblyopia developing. Therefore, these amblyopia risk factors should also be considered medical conditions. Optical correction such as eyeglasses or contact lenses may be medically indicated as a part of amblyopia treatment in addition to other modalities, such as patching and/or pharmacologic treatment. Unless amblyopia is treated during childhood, recovery of vision is rarely achieved.

**The American Board of Internal Medicine’s (ABIM) Foundation Choosing Wisely® Initiative:** No relevant information found.

**Use Outside of the US**

The National Institute for Health and Clinical Excellence (NICE, United Kingdom) has several previously published related guidelines, all over ten years old.

**Medicare Coverage Determinations**

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	Intraocular Lenses (IOLs) (80.12)	5/19/1997
LCD		No Local Coverage Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.

**Coding/Billing Information**

- Note:** 1) This list of codes may not be all-inclusive.  
 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

**Standard Monofocal Intraocular Lens Implant**

**Considered Medically Necessary when criteria in the applicable policy statements listed above are met:**

CPT®* Codes	Description
66985	Insertion of intraocular lens prosthesis (secondary implant), not associated with concurrent cataract removal
66986	Exchange of intraocular lens

HCPCS Codes	Description
C1780	Lens, intraocular (new technology)
V2630	Anterior chamber intraocular lens
V2631	Iris supported intraocular lens
V2632	Posterior chamber intraocular lens

Revenue Codes†	Description
0276	Intraocular lens

ICD-10-CM Diagnosis Codes	Description
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
H26.001- H26.09	Infantile and juvenile cataract

<b>ICD-10-CM Diagnosis Codes</b>	<b>Description</b>
H26.101- H26.20	Traumatic cataract
H26.211- H26.219	Cataract with neovascularization
H26.221- H26.229	Cataract secondary to ocular disorders (degenerative) (inflammatory)
H26.231- H26.239	Glaucomatous flecks (subcapsular)
H26.30- H26.33	Drug-induced cataract
H26.40- H26.499	Secondary cataract
H26.8	Other specified cataract
H26.9	Unspecified cataract
H27.00- H27.03	Aphakia
H27.10	Unspecified dislocation of lens
H27.111- H27.119	Subluxation of lens
H27.121- H27.129	Anterior dislocation of lens
H27.131- H27.139	Posterior dislocation of lens
H28	Cataract in diseases classified elsewhere
H52.31	Anisometropia
Q12.0- Q12.9	Congenital lens malformation
T85.21XA- T85.21XS	Breakdown (mechanical) of intraocular lens
T85.22XA- T85.22XS	Displacement of intraocular lens
T85.29XA- T85.29XS	Other mechanical complication of intraocular lens
T85.79XA- T85.79XS	Infection and inflammatory reaction due to other internal prosthetic devices, implants and grafts
Z96.1	Presence of intraocular lens
Z98.41- Z98.49	Cataract extraction status

**Considered Not Medically Necessary:**

<b>ICD-10-CM Diagnosis Codes</b>	<b>Description</b>
H52.00- H52.03	Hypermetropia
H52.10- H52.13	Myopia
H52.201- H52.209	Unspecified astigmatism
H52.211- H52.219	Irregular astigmatism

ICD-10-CM Diagnosis Codes	Description
H52.221- H52.229	Regular astigmatism
H52.32	Aniseikonia
H52.4	Presbyopia
H52.511- H52.519	Internal ophthalmoplegia (complete) (total)
H52.521- H52.529	Paresis of accommodation
H52.531- H52.539	Spasm of accommodation
H52.6	Other disorders of refraction
H52.7	Unspecified disorder of refraction
	All other codes

### **Premium Intraocular Lens Implant**

**Considered Not Medically Necessary:**

CPT®* Codes	Description
66985	Insertion of intraocular lens prosthesis (secondary implant), not associated with concurrent cataract removal
66986	Exchange of intraocular lens

HCPCS Codes	Description
S0596	Phakic intraocular lens for correction of refractive error
V2787	Astigmatism correcting function of intraocular lens
V2788	Presbyopia correcting function of intraocular lens

Revenue Codes†	Description
0276	Intraocular lens

ICD-10-CM Diagnosis Codes	Description
	All codes

### **New Technology Intraocular Lens Implants**

**Considered Medically Necessary only when used to report a standard monofocal intraocular lens implant.**

**Considered Not Medically Necessary when used to report premium intraocular lens implants mentioned as such in this policy.**

HCPCS Codes	Description
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



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