



Cigna Medical Coverage Policy

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Subject Intraocular Lens Implant

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INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna companies including plans formerly administered by Great-West Healthcare, which is now a part of Cigna. Coverage Policies are intended to provide guidance in interpreting certain **standard** Cigna benefit plans. 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 supercedes** 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. 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. Proprietary information of Cigna. Copyright ©2013 Cigna

Coverage Policy

Coverage for services for or related to routine refraction and the surgical treatment of refractive errors is specifically excluded under many benefit plans. Please refer to the applicable benefit plan document to determine benefit availability, and the terms and conditions of coverage.

Cigna covers a standard monofocal intraocular lens (IOL) implant as 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 3 diopters or greater, and uncorrectable vision with the use of glasses or contact lenses

Cigna does not cover ANY of the following classes of premium intraocular lens implants for ANY indication, including aphakia, because each is intended to reduce the need for reading glasses and thus considered a convenience item and not medically necessary. 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 (this list may not be all inclusive):

- presbyopia correcting IOL (e.g., Array® Model SA40, ReZoom™, AcrySof® ReStor®, Tecnis ZM900, Crystalens™ Model AT-45, Crystalens HD™, Crystalens Aspheric Optic™)

- astigmatism correcting IOL (e.g., Toric IOLs)
- phakic IOL (e.g., ARTISAN[®], STAR Visian ICL[™])

Cigna does not cover a clear lens extraction intraocular lens implant (i.e., monofocal IOL, multifocal IOL, or accommodating IOL) for the correction of refractive error because it is considered not medically necessary.

General Background

Intraocular lens (IOL) implants are lenses used to replace the existing natural lens of the eye and are used to treat aphakia. Aphakia is the absence of the natural lens which may result from extraction of the lens (e.g., cataract surgery), penetrating trauma, or from congenital conditions. Procedures for which IOLs are commonly implanted include cataract surgery and clear lens extraction for the correction of refractive errors. Posterior chamber IOLs are most commonly used although an iris supported or anterior chamber lens may also be used. Other conditions for which IOLs may be implanted include anisometropia that is uncorrectable with other the use of eyeglasses or contacts and subluxation or displacement of the lens.

Monofocal IOLs are considered the standard lens for replacement and usually require corrective lenses or eyeglasses after surgery for reading and near vision tasks. However, various types of intraocular lens implants are available and now include presbyopia correcting IOLs (i.e., multifocal and pseudoaccommodating). Presbyopia correcting IOLs are intended to reduce the need for eyeglasses or contact lenses that are commonly needed to provide near, intermediate and distant vision after a standard monofocal IOL is inserted.

Other recent technological advancements to intraocular lens development include the development of aspheric lenses, toric lenses and ultraviolet light absorbing lenses. Several of these features may be applied to either monofocal or multifocal lenses, and in some cases, to accommodating IOLs. Aspheric lenses are slightly flatter and reduce spherical aberration and other optical aberration. Toric lenses reduce eyeglass dependence due to astigmatism (American Academy of Ophthalmology, 2006). Ultraviolet (UV) light absorbing lenses are made out of special materials that absorb UV and blue light, which are intended to protect the retina from the harmful effects of UV light.

U.S. Food and Drug Administration (FDA)

IOL implants are considered prosthetic devices and regulated by the FDA as Class III devices and are approved through the premarket approval process.

Cataract Conditions

A cataract is a hardening or opacification (clouding) of the normally transparent crystalline lens within the eye, located behind the pupil. This condition usually occurs 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 (IOL) within the capsular bag. 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 patient. Monofocal IOLs are considered the standard and meet the basic functional needs of an individual who undergoes cataract removal.

Anisometropia

Anisometropia is a condition that may be congenital or acquired in which the refractive state of the eyes is unequal. Anisometropia of up to 2.5 diopters is generally well tolerated with higher degrees requiring treatment. Early detection and correction are necessary for normal visual development to occur; uncorrected anisometropia can lead to amblyopia. Symptoms associated with anisometropia may include diplopia, difficulty reading, and poor depth perception. Although in some cases eyeglasses and/or contacts may correct the anisometropia, surgery with IOL replacement is indicated when the condition is uncorrectable with the use of eyeglasses or contacts.

Monofocal IOLs

Monofocal IOLs have a fixed or single focal point and are the current standard of treatment for lens replacement. A standard monofocal IOL is a lens that provides good vision at one focal point which can be set for distance, intermediate or near vision. With a fixed focusing power set for one specific distance, typically distance vision, eyeglasses are commonly required for reading or near vision tasks.

Several monofocal IOLs have been approved by the FDA and include but are not limited to the following:

- Staar Toric IOL (Star Surgical, Monrovia, CA) an astigmatism correcting IOL
- Tecnis[®] (Z9000, Z9001, ZA9003, Abbott Medical Optics [AMO], Santa Anna, CA), an aspheric IOL
- AcrySof Toric IOL (Alcon Surgical, Fort Worth, TX), a toric UV absorbing IOL
- AcrySof[®] IQ IOL (Alcon Surgical, Fort Worth, TX), an aspheric IOL with UV and blue light filtering capabilities
- AcrySof Natural (Alcon Surgical, Fort Worth, TX), a UV and blue light filtering IOL
- SofPort AO IOL (Bausch & Lomb, Rochester, NY), an IOL with two aspheric surfaces
- SofPort AO IOL with Violet Shield Technology (Bausch & Lomb, Rochester, NY) an aspheric IOL that absorbs UV and high-energy violet light
- Akreos[™], an aspheric and Akreos[™] Advance Optics Aspheric Lens (Bausch & Lomb, Rochester, NY) an aspheric UV absorbing IOL

Presbyopia Correcting IOL

More recently, presbyopia correcting lenses (i.e., multifocal, pseudoaccommodating) with or without additional features (e.g., toric, aspheric, ultraviolet protection), have been developed to improve visual acuity and may be referred to as premium IOLs. Multifocal IOLs offer both distant and near vision. The pseudoaccommodating IOLs, (also referred to as dynamic IOLs), offers near, intermediate and distant vision. Overall, the intent of multifocal and pseudoaccommodating lenses is to provide distant to near vision capability when compared to the use of a monofocal IOL, and to reduce dependence on eyeglasses following cataract surgery. Premium IOLs are generally considered not medically necessary.

Multifocal IOL: Multifocal IOLs are designed to provide distance and near vision simultaneously and offer multiple focal points within the IOL. They are considered an optional lens for patients in need of cataract surgery and may be classified as refractive or diffractive, depending on the technology of the lens. Diffractive lenses act similar to a bifocal; refractive lenses apply differing refractive powers to concentric portions of the lens. In general, this multifocal lens structure focuses light rays from both distance and near. The lens does not restore good intermediate vision. Despite the improvement in near vision adverse events associated with these lenses include increased glare and halos at night, variable loss of clarity, and loss of low-contrast acuity. Individuals should be counseled regarding potential adverse events and effects on overall quality of life.

Various multifocal lenses have been approved by the FDA within the last few years and include but are not limited to the following:

- Array[®] Model SA40 (Advanced Medical Optics [AMO], Santa Ana, CA) with multifocal rings/zones
- ReZoom[™] (AMO) (a second generation lens to the Array) with Balanced View Optics[™] technology distributing light over five optic zones
- AcrySof[®] ReStor[®] (Alcon Surgical, Fort Worth, TX) an apodized diffractive lens
- Tecnis ZM900 and ZMAOO (AMO, Santa Ana, CA), a multifocal aspheric IOL

Both subjective and objective outcomes resulting from the use of multifocal IOLs have been reported in the peer-reviewed, published scientific literature. Several authors have relied on patient questionnaires and surveys for measuring outcomes; some results improved patient satisfaction with multifocal IOLs in comparison to monofocal lenses (Cilino, et al., 2008; Vingolo, et al., 2007; Chiam, et al., 2006; Kohnen, et al., 2006; Souza, et al., 2006; Sallet, 2006; Lane, et al., 2006; Javitt and Steinert, 2000) although other authors noted no difference in patient satisfaction (Nijkamp, et al., 2004). Some of the published data demonstrates improved visual acuity with the use of these lenses when compared to a monofocal lens (Alio, et al., 2011a; Packer, et al., 2010; Cilino, et al., 2008; Sen et al., 2004). Leyland and Zinocola, 2003 (Cochrane review) reported that unaided near vision was improved with the use of multifocal lenses, and the total freedom from use of eyeglasses was seen more often with the use of multifocal lenses. However, there was no statistical difference between the use of multifocal and monofocal IOLs related to best corrected visual acuity.

The National Institute for Health and Clinical Excellence (NICE, United Kingdom) (2008) published an interventional procedural guidance for multifocal lens implantation and reported there were no major safety concerns with the use of multifocal IOLs. According to the guidance document, the current evidence regarding efficacy demonstrated that these lenses can provide good near and distance vision without the need for spectacles; however, the authors noted they have been associated with a variety of potential visual disturbances.

While the evidence in the published scientific literature supports safety and efficacy of multifocal lenses, the evidence has failed to demonstrate superiority of multifocal lenses compared to monofocal lenses and conventional eyewear. Despite their common use in clinical practice, these lenses are intended to reduce one's independence for eyeglasses following cataract surgery, and are therefore considered not medically necessary.

PseudoAccommodating IOL: Pseudoaccommodating IOLs have been proposed as an alternative to standard monofocal and multifocal lenses; these IOLs may also be referred to as dynamic lenses. Dynamic IOLs are designed to change position in the eye with accommodative efforts (AAO, 2006). These lenses are designed to provide good distance, intermediate and near vision. It is the only type of IOL that theoretically improves visual acuity by providing a continuous range of vision. Pseudoaccommodating lenses are intended to reduce one's dependence on postoperative corrective eyeglasses. The pseudoaccommodating IOL interacts with the ciliary muscles and zonules and has hinges at both ends of the lens to facilitate the forward and backward movement, supposedly allowing variable focus capability.

Pseudoaccommodating IOLs that have been granted FDA approval include the Crystalens™ Model AT-45 Pseudoaccommodating Intraocular Lens (eyeonics, Inc., Aliso Viejo, CA) and updated versions of the device, Crystalens Model AT-50SE, Crystalens HD™ and the Crystalens Aspheric Optic™. These lenses are intended for implantation following cataract removal in adults only.

Other accommodative IOLs currently in clinical trials include the Accommodative 1CU (HumanOptics, Erlangen, Germany), Smartlens™ (Medennium, Irvine, CA), and a dual optic accommodating lens, the Sarfarazi (Bausch and Lomb, Rochester, NY) and Synchrony (Visiogen, Inc., Irvine, CA).

Evidence in the medical literature evaluating accommodating lens technology consists mainly of few randomized controlled trials, nonrandomized trials, case series, meta-analysis and systematic reviews. Some clinical trials support improved visual acuity when compared to a standard monofocal or multifocal lens when measuring short-term outcomes (Harmon, et al., 2008; Macsai, et al., 2006; Cummings, et al., 2006; Alio, et al., 2004; Cummings, et al., 2001). Although the lens is intended to provide near, intermediate and distant vision without eyeglasses, patients still require corrective lenses after implantation. Long-term outcomes supporting the safety and efficacy of accommodating technology and the stability of the lens have not been demonstrated. According to an interventional procedural guidance from NICE (2007), despite evidence supporting short-term safety and efficacy, there is inadequate evidence that the procedure achieves accommodation. However, despite the lack of robust and convincing data regarding long-term safety, efficacy and durability of the device, accommodating IOLs are often recommended to individuals undergoing cataract surgery. Nonetheless, these lenses are intended to reduce the need for eyeglasses post cataract surgery and are considered not medically necessary.

Phakic Intraocular Lenses

Another type of intraocular lens, a phakic intraocular lens, is a synthetic lens placed within the eye on top of the iris or underneath and is used to correct refractive error. The lens sits on top of the natural lens of the eye. These lenses may be also placed in the posterior or anterior chamber of the eye. Phakic lenses are approved by the US Food and Drug Administration (FDA) for correction of nearsightedness (myopia). Two lenses currently available include the ARTISAN®, (OPHTEC USA, Boca Raton, FL) also referred to as Verisyse™; and STAR Visian ICL™ (STAR Surgical Co., Monrovia, CA). ARTISAN is a lens that is fixed to the iris and STAR Visian ICL is a lens that sits in the posterior chamber of the eye. Although phakic lenses are indicated for the correction of refractive errors these lenses are considered not medically necessary because the correction of refractive errors can be achieved with eyeglasses or contact lenses.

Clear Lens Extraction (CLE)

Presbyopia is the aging change of the lens that begins in patients during their early 40's and results in a need for reading glasses. It affects 100% of the population during the normal human life span (Coleman, 2003). The

process results in a farsightedness as a result of decreased stretching involving the lens of the eye. The lens becomes stiff and is unable to change shape. Various forms of treatment may be performed in hopes of restoring the natural focusing ability to the lens and include bifocals, trifocals, monovision contact lenses, bifocal contact lenses and modified monovision. Corrective surgery for presbyopia includes laser-assisted in-situ keratomileusis (LASIK), photorefractive keratectomy (PRK) and a clear lens extraction (CLE) combined with an intraocular lens replacement, all of which are refractive surgeries to correct vision defects.

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. The replacement lens may be monofocal, multifocal or pseudoaccommodating, and may or may not have additional deluxe features. Several studies have supported the safety and effectiveness of clear lens extraction using multifocal intraocular lenses (Packer, et al., 2002; Dick, et al., 2002; Jacobi, et al., 2002). However, refractive surgical procedures are considered not medically necessary because the correction of refractive errors can be achieved with eyeglasses or contact lenses.

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

Summary

Presbyopia correcting lenses such as multifocal and pseudoaccommodative intraocular lenses (IOLs), with or without deluxe features, have been considered an alternative to monofocal lenses, with the intent of reducing one's dependence on eyeglasses, particularly following cataract removal. Evidence in the published, peer-reviewed scientific literature generally supports improved visual acuity in near, intermediate and distant fields; resulting in a decreased need for eyeglasses with the use of these lenses. Long-term safety, efficacy and durability, particularly for the accommodating IOL, have not been demonstrated in the medical literature. Generally, IOLs intended primarily for reducing an individual's dependence on eyeglasses following cataract removal and for other aphakic conditions are not considered medically necessary. Monofocal IOLs are the standard treatment for replacement of the crystalline lens during cataract surgery. Intraocular lens replacement for the treatment of presbyopia (e.g., clear lens extraction) and other refractive correction is considered not medically necessary.

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

Covered when medically necessary:

| CPT[®]* Codes | Description |
|-------------------------------|--|
| 66982 | Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, 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 (1 stage procedure) |
| 66984 | Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, 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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| HCPCS Codes | Description |
|--------------------|--|
| C1780 | Lens, intraocular (new technology) |
| Q1003 | New technology intraocular lens category 3 (reduced spherical aberration)(Code deleted 04/01/2011) |
| V2630 | Anterior chamber intraocular lens |
| V2631 | Iris supported intraocular lens |
| V2632 | Posterior chamber intraocular lens |

| Revenue Codes[†] | Description |
|----------------------------------|--------------------|
| 0276 | Intraocular lens |

| ICD-9-CM Diagnosis Codes | Description |
|---------------------------------|--|
| 366.00-366.09 | Infantile, juvenile and presenile cataract |
| 366.10-366.19 | Senile cataract |
| 366.20-366.23 | Traumatic cataract |
| 366.30-366.34 | Cataract secondary to ocular disorders |
| 366.41-366.46 | Cataract associated with other disorders |
| 366.50-366.53 | After-cataract |
| 366.8 | Other cataract |
| 366.9 | Unspecified cataract |
| 367.31 | Anisometropia |
| 379.31 | Aphakia |
| 379.32 | Subluxation of the lens |
| 379.33 | Anterior dislocation of lens |
| 379.34 | Posterior dislocation of lens |
| 743.30-743.39 | Congenital cataract and lens anomalies |
| 996.53 | Mechanical complication of other specified prosthetic device, implant, and graft, due to ocular lens implant |
| V43.1 | Organ or tissue replaced by other means, lens |
| V45.61 | Cataract extraction status |

Not Medically Necessary/Not Covered:

| ICD-9-CM Diagnosis Codes | Description |
|---------------------------------|--|
| 367.0 | Unspecified disorder of refraction and accommodation |
| 367.1 | Myopia |
| 367.20-367.22 | Astigmatism |
| 367.32 | Aniseikonia |
| 367.4 | Presbyopia |
| 367.51-367.53 | Disorders of accommodation |

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| | |
|---------------|--|
| 367.81-367.89 | Other disorders of refraction and accommodation |
| 367.9 | Unspecified disorder of refraction and accommodation |
| | All other codes |

Premium Intraocular Lens Implant

Not Medically Necessary/Not Covered

| 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 (Code effective 04/01/2012) |
| V2787 | Astigmatism correcting function of intraocular lens |
| V2788 | Presbyopia correcting function of intraocular lens |

| Revenue Codes[†] | Description |
|--------------------------------------|--------------------|
| 0276 | Intraocular lens |

| ICD-9-CM Diagnosis Codes | Description |
|---|--------------------|
| | All codes |

New Technology Intraocular Lens Implants

Covered when medically necessary only when used to report a standard monofocal intraocular lens implant. Not medically necessary/not covered 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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