



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

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Subject **Intraocular Lens Implant**

Table of Contents

Coverage Policy	1
General Background	1
Coding/Billing Information	4
References	5
Policy History	10

Hyperlink to Related Coverage Policies

Corneal Remodeling

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), 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 participant'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 participant'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 group 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. Proprietary information of CIGNA. Copyright ©2009 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 to meet the basic functional needs of an individual who undergoes removal of the crystalline lens as part of cataract surgery.

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

- presbyopia correcting IOL (i.e., multifocal, accommodating IOL)
- astigmatism correcting IOL (i.e., toric IOL)
- clear lens extraction IOL

General Background

Replacement of the natural lens of the eye is required to restore vision in cases where the lens has been surgically removed. Intraocular lens (IOL) implants are lenses used to replace the existing natural lens of the eye. Two procedures for which IOLs are commonly implanted include cataract surgery and clear lens extraction for the correction of refractive errors.

For cataract removal, monofocal IOLs are considered the standard lens 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 accommodating). Presbyopia correcting IOLs are intended to provide near, intermediate and distant vision without the need for eyeglasses or contact lenses.

Other recent technological advancements to intraocular lens development include the development of aspheric lenses, toric lenses and ultraviolet 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 improve contrast sensitivity, decrease halos and improve optical quality, such as night driving performance. Toric lenses decrease 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)

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

Intraocular Lens Implant for the Treatment of Cataract

A cataract is a hardening and 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.

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.

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, accommodating) 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 accommodating IOLs, (also referred

to as dynamic IOLs), offers near, intermediate and distant vision. Overall, the intent of multifocal and accommodating lenses is to provide distant to near vision capability when compared to the use of a monofocal IOL, and to reduce dependence on eyeglass 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 act as pseudoaccommodative lenses. 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 (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.

Accommodating IOL: Accommodating 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. Accommodating lenses are intended to reduce one's dependence on postoperative corrective eyeglasses. The accommodating 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.

Accommodating IOLs that have been granted FDA approval include the Crystalens™ Model AT-45 Accommodating Intraocular Lens (eyeonics, Inc., Aliso Viejo, CA) and an updated version of the device, Crystalens Model AT-50SE. Both 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 obviate the need for eyeglasses post cataract surgery and are considered not medically necessary.

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 accommodating, 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 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 accommodative 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 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. Overall, IOLs intended for reducing an individual's dependence on eyeglasses following cataract removal are not considered medically necessary. Monofocal IOLs are the standard treatment for replacement of the crystalline lens as part of cataract surgery. In addition, clear lens extraction intraocular lens replacement for the treatment of presbyopia or for refractive correction is considered not medically necessary.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when 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
C1780	Lens, intraocular (new technology)
Q1003	New technology intraocular lens category 3 (reduced spherical aberration)
V2632	Posterior chamber intraocular lens

ICD-9-CM Diagnosis Codes	Description
366.00- 366.23	Cataract
366.30	Unspecified cataracta complicata
366.31*	Cataract secondary to glaucomatous flecks (subcapsular)
366.32*	Cataract in inflammatory ocular disorders
366.33*	Cataract with ocular neovascularization
366.34*	Cataract in degenerative ocular disorders
366.41*	Diabetic cataract
366.42*	Tetanic cataract
366.43*	Myotonic cataract
366.44*	Cataract associated with other syndromes
366.45	Toxic cataract
366.46	Cataract associated with radiation and other physical influences
366.8	Other cataract
366.9	Unspecified cataract
367.51	Paresis of accommodation

***Must first code underlying condition.**

Not Medically Necessary/Not Covered:

HCPCS Codes	Description
V2788	Presbyopia correcting function of intraocular lens
V2787	Astigmatism correcting function of intraocular lens
V2797	Vision supply, accessory and/or service component of another HCPCS vision code

***Current Procedural Terminology (CPT®) © 2008 American Medical Association: Chicago, IL.**

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Policy History

<u>Pre-Merger Organizations</u>	<u>Last Review Date</u>	<u>Policy Number</u>	<u>Title</u>
CIGNA HealthCare	8/15/2007	0125	Intraocular Lens Implant

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