Medical Policy

Subject:	Presbyopia and Astigmatism-Correcting Intraocular Lenses		
Document #:	SURG.00061	**Publish Date:**	04/10/2024
Status:	Reviewed	**Last Review Date:**	02/15/2024

Description/Scope

This document addresses the use of presbyopia-correcting intraocular lenses and astigmatism-correcting intraocular lenses. The use of presbyopia-correcting intraocular lenses and astigmatism-correcting intraocular lenses as alternatives to monofocal intraocular lenses is considered to be predominately for comfort and convenience, to eliminate the need for glasses or contact lenses.

Note: Please see the following related document for additional information:

- CG-SURG-77 Refractive Surgery

Position Statement

Not Medically Necessary:

The use of presbyopia-correcting intraocular lenses is considered **not medically necessary** for all indications.

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Additional required information

- **A. Submit the rationale used to preliminarily indicate the service is experimental/investigational**
  - **1. Include peer-reviewed journal articles in PDF format with links to the online articles**
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The use of astigmatism-correcting intraocular lenses is considered **not medically necessary** for all indications.

Rationale

Conventional monofocal intraocular lenses are designed with a fixed optical power to provide primarily distance vision, and thus these lenses are not designed to simultaneously correct the presbyopia, which is part of the natural process of aging seen in most adults undergoing cataract surgery. Therefore, individuals after cataract surgery who have presbyopia may continue to wear glasses or contact lenses for near vision and individuals with pre-existing astigmatism may require glasses or contact lenses for optimal vision following cataract extraction as well. Intraocular lenses are now available for the visual correction of presbyopia and astigmatism following cataract surgery.

Following cataract surgery, the unaffected eye may still retain some accommodative ability and individuals may not like wearing eyeglasses. A study by Mesci and colleagues (2010) attempted to determine whether a unilateral multifocal intraocular lens had an additive effect on binocular vision (the ability to use both eyes to see a single image). Four groups of individuals (n=87) had implants following cataract surgery. The safety and efficacy of four different types of implants were studied; 24 individuals had monofocal implants (group 1), 21 individuals had accommodating implants (group 2), 22 individuals had diffractive multifocal implants (group 3), and 20 individuals had refractive multifocal implants (group 4). Follow-up exams occurred postoperatively at 1 week, 2 weeks, 1, 3, 6, 9, 12, 14, and 18 months. Eighteen (18) months after surgery, refractions, monocular distance and near best-corrected visual acuity were measured along with distance-corrected near and intermediate visual acuity, monocular and binocular distance, and intermediate and near uncorrected visual acuity. Between groups 2, 3, and 4, there was no difference observed in the distance and near best-corrected visual acuities. The multifocal groups (3 and 4) had better near vision than groups 1 and 2. No difference was observed in the near visual acuity of groups 3 and 4. And while this study showed the multifocal groups (3 and 4) had higher rates of eyeglass independence, better stereopsis

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and satisfactory vision than the monofocal and accommodating intraocular lenses (groups 1 and 2), this study is limited by the lack of randomization.

In a 2002 study by Till, 81 individuals had cataract surgery and implantation of an astigmatism-correcting intraocular lens. After a mean follow-up of 23 weeks, an estimated 20% of the individuals with astigmatism achieved good vision and reduced their need for distance glasses. Mendicute and colleagues (2008) evaluated the results of astigmatism-correcting intraocular lens implantation following cataract surgery in individuals with preexisting astigmatism. They studied 30 eyes of 15 individuals. The eyes in this study had a 70% reduction in astigmatism after astigmatism-correcting intraocular lens implantation. However, the authors also concluded that further studies with longer follow-up should continue to evaluate the efficacy of this intraocular lens in cataract surgery.

In 2012, Agresta and colleagues reported on a systematic review which evaluated the efficacy of multifocal intraocular lenses in individuals with presbyotic cataracts. A total of 29 studies met inclusion criteria. Uncorrected distance visual acuity was reported by 26 studies and uncorrected near visual acuity was reported by 25 studies. Gains in improvement for uncorrected distance visual acuity were greater than uncorrected near visual acuity. Limitations of the studies included differences in measurements of quality of life, spectacle independence and visual disturbances. There was a lack of consistency in reporting these outcomes and a lack of a validated instrument to measure these outcomes. And while this systematic review analyzed studies which reported improvements in uncorrected visual acuity in participants with cataracts and presbyopia, further analysis is needed to report on spectacle independence and quality of life with consistent measurement of outcomes.

In a 2019 prospective case series by Chang and colleagues, the authors reported on 36 individuals who had insertion of bilateral multifocal intraocular lens implants following cataract surgery or refractive lens exchange. Participants were evaluated following surgery for visual acuity, visual quality and ease of performance of daily tasks postoperatively. At the 6-month visit, the mean (± standard deviation) monocular uncorrected visual acuity at

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distance was 0.01 ± 0.12, intermediate was 0.26 ± 0.17, and near was 0.09 ± 0.08. At the 3- and 6-month visits, a questionnaire on visual quality and ease of performance of daily tasks was administered. There were 33 participants who rated themselves as satisfied/very satisfied with the uncorrected vision, and 30 participants had complete spectacle independence. There were 35 participants who reported it was easy/very easy for them to perform distance activities without optical correction, 24 participants reported it easy/very easy to perform intermediate activities without optical correction, and 25 participants reported it was easy/very easy for them to perform near activities without optical correction, Halo was reported by 21 participants, glare was reported by 21 participants, and none of the participants reported double images. There were no intraoperative complications reported. While this study reports on corrected vision following multifocal intraocular lens implantation, halo and glare was a common occurrence.

Trifocal intraocular lenses are being studied and have been developed in order to improve the quality of vision at intermediate distances. A 2020 retrospective study by Alfonso and colleagues reported on 40 participants who received a trifocal intraocular lens and were assessed for far, intermediate, and near visual acuity and distance photopic contrast sensitivity. With a 6-month follow-up, monocular distance Snellen decimal uncorrected distance visual acuity was 0.85 ± 0.19 (ranging from 0.25 to 1.25), and best-corrected distance visual acuity was 0.94 ± 0.10 (ranging from 0.70 to 1.25). Binocularly, the uncorrected distance visual acuity was 0.95 ± 0.13 (ranging from 0.50 to 1.25) and best-corrected distance visual acuity was 0.99 ± 0.08 (ranging from 0.80 to 1.25). The near distance monocular Snellen decimal for uncorrected near visual acuity was 0.71 ± 0.10 (ranging from 0.50 to 0.80) and best distance-corrected near visual acuity was 0.72 ± 0.10 (ranging from 0.50 to 0.8). Binocularly, the uncorrected near visual acuity was 0.84 ± 0.12 (ranging from 0.63 to 1.00) and best distance-corrected near visual acuity was 0.85 ± 0.13 (ranging from 0.63 to 1.00). All participants showed a cumulative binocular distance-corrected visual acuity of 0.8 or better (Snellen decimal visual acuity) at a distance with 31 participants having a value of 1.0 (20/20). The near and intermediate distance values changed depending on the distance evaluated. Overall, the participants showed a cumulative distance-corrected visual acuity of 0.5 (20/40) or better when measured at 30, 40, 50, 60, and 70 cm. The study has limitations which include the short follow-up period.

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In a 2020 prospective case series study by Bianchi, the author reported on the safety and effectiveness of a multifocal intraocular lens implant following cataract surgery in 240 participants. Participants were evaluated 12 months following surgery for spherical equivalent, refractive accuracy, uncorrected distance visual acuity, intermediate visual acuity, near visual acuity, binocular defocus curve, corneal endothelial cell density, central corneal thickness, and intraocular pressure. The spherical equivalent mean preoperative spherical equivalent preoperatively was 2.0 ± 2.18 D which decreased to -0.04 ± 0.28 D after surgery. Refractive accuracy showed 82.9 % of eyes obtained spherical equivalent values between -0.5 and 0.5 D. None of the participants experienced loss of lines of vision and uncorrected distance visual acuity and 58.1% had 20/20 vision with 40.2% achieving 20/25 vision. The intermediate visual acuity showed that all participants could see a computer screen at 70cm one year following surgery. Binocular near visual acuity obtained was J1 for 72.5% and J2 for 27.5% of participants. Binocular defocus curve showed 0.04 logMAR for -3.0 D (near sight), 0.09 logMAR for -1.5 D (intermediate sight) and 0.03 logMAR for 0 D (distance sight). Mean corneal endothelial cell density decreased by 226.08 ± 11.63 cell/mm2. Mean central corneal thickness increased by 6.62 ± micrometer. Intraocular pressure remained stable one year following surgery. A satisfaction survey was also evaluated following surgery where 92% of participants obtained spectacle independence and 87% of participants denied "halos." No surgical complications were reported. While there was a high percentage of participants with spectacle independence and improved vision, the lenses continue to be predominantly a comfort or convenience item. The authors also conclude that "a longer follow-up period is necessary to confirm the results from the present study."

A 2021 prospective study by Gabrić and colleagues reported on clinical outcomes in 103 participants who had bilateral cataract surgery with implantation of a presbyopia-correcting IOL. Visual outcomes were measured by uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), uncorrected near visual acuity (UNVA), and distance-corrected near visual acuity (DCNVA). Daily visual function was self-reported using the Catquest-9SF questionnaire. Follow-up was 3 months. The majority of participants achieved binocular postoperative UDVA and UNVA of 0.00 logMAR (20/20 vision), 96.1% and 91.3% of participants, respectively.

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After surgery, a reduction in contrast from 25% to 10% led to a statistically significant decrease in UNVA in both eyes ($p<0.001$). The mean score of the Catquest-9SF questionnaire increased significantly after surgery ($p<0.001$), indicating improved perception by participants of their visual function. Although the authors concluded that this presbyopia-correcting IOL provided effective visual rehabilitation, limitations of the study include its non-randomized case study nature and lack of a comparison group or controls. Only one specific type of IOL was tested; future studies are needed to confirm the benefits of this particular IOL over other similar products. In addition, participant selection was limited to only those who fell within an average IOL power delivery range.

A 2022 systematic review and meta-analysis performed by Cho and colleagues compared the outcomes of presbyopia-correcting IOL. The authors included 27 randomized controlled trials encompassing 2605 participants and compared binocular visual outcomes using visual acuity and glare, halo, and spectacle independence. For near distance, trifocal and bifocal diffractive lenses showed higher values than the other lens types. Multifocal IOLs showed better probability than monofocal IOLs. UNVA was evaluated from 11 studies. There were 3 IOLs that had consistently higher probability of ranking when compared to monofocal or new-generation bifocal IOLs. UDVA was evaluated in 23 studies. The comparison between monofocal IOL and other IOL revealed small mean differences compared to other distances. Variability in outcome measurements between the studies made glare or halos as measures of visual acuity difficult. There were 7 studies which addressed spectacle independence. The old-generation bifocal diffractive and bifocal refractive IOLs showed a high-risk ratio of independence when compared to monofocal IOLs. Limitations include studies with varied measurements of visual acuity, lack of objective measurements of glare, halos, and spectacle independence in the studies, and some of the included studies did not provide information regarding randomization methods which leads to concern about bias risk.

Several intraocular lenses have received Food and Drug Administration (FDA) approval through the premarket approval (PMA) process. The Crystalens™ (Eyeonics, Inc., Aliso Viejo, CA) received FDA approval through the PMA process on November 14, 2003. The FDA-labeled indication reads as follows: “The Crystalens is an accommodating intraocular lens (IOL) that is intended for primary implantation in the capsular bag of the eye for

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the visual correction of aphakia in adult patients in whom a cataractous lens has been removed." Insertion of the accommodating intraocular lens requires a distinct surgical procedure. The FDA approval was based on a prospective nonrandomized study of 324 participants followed for 1 year; 90% of the population was Caucasian with a mean age of 69.7 years (FDA, 2003). The device was not studied in younger adults or children. The clinical effectiveness endpoint was visual performance at near, intermediate and distance. A total of 93.5% achieved visual acuities of 20/32 or better, uncorrected at near, distance or intermediate 1 year after surgery. Individuals were surveyed regarding their use of spectacles; 73% stated they either did not wear spectacles or only wore them rarely. No long-term follow up is available. Eyeonics was acquired by Bausch & Lomb (Rochester, NY) in January 2008.

The AcrySof® ReSTOR® Apodized Diffractive Optic Posterior Chamber multifocal intraocular lens (Alcon Research Ltd., Fort Worth, TX) received approval through the PMA process on March 21, 2005. This device, implanted in the capsular bag, is intended for the visual correction of aphakia secondary to removal of a cataractous lens in adults with and without presbyopia, who desire near, intermediate and distance vision with increased spectacle independence. The FDA approval was based on a study of 802 individuals enrolled in a trial to determine the safety of the ReSTOR intraocular lens. A total of 760 individuals were evaluated at 1 year. Of these, 566 first eyes were implanted with the ReSTOR intraocular lens and 194 first eyes were implanted with a monofocal control intraocular lens. Of the first eyes implanted with each lens model, the fellow eye was also implanted with the same lens model in 549 eyes and 181 eyes (monofocal control). Mean contrast acuities and contrast sensitivity were clinically equivalent between the ReSTOR intraocular lens and the monofocal control group. Glare/flare, problems with night vision, and halos were reported significantly ($p<0.05$) more often by the ReSTOR individuals compared to monofocal control group.

The ReZoom™ intraocular lens (Advanced Medical Optics, Inc. Santa Ana, CA) is a second-generation refractive, multifocal lens, which received supplemental approval through the PMA process on March 23, 2005. This lens distributes light over five optic zones arranged in concentric circles to provide near and distant vision. The device, implanted in the capsular bag, is intended for visual correction of aphakia in persons 60 years or older in whom a

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cataractous lens has been removed and who desire near vision without reading spectacles and increased spectacle independence over a range of distances. FDA approval was based on a clinical trial of a first generation multifocal lens, the ARRAY® Multifocal Silicone Posterior Chamber Lens. Using a prospective, nonrandomized design, 456 eyes (456 individuals) were implanted with the ARRAY intraocular lens. Both historic and prospective controls (n=102) were used. Results indicate the ARRAY provides comparable distance and intermediate vision compared to monofocal intraocular lens with increased near vision. Under low contrast conditions, i.e., driving at night or in poor visibility, visual acuity is reduced compared to a monofocal lens. The supplemental approvals beginning in 2008 now show ReZoom as the trade name. The ReZoom has not been clinically evaluated. Advanced Medical Optics (AMO) was acquired by Abbott (Park, Illinois) in February 2009.

In August 2019, the AcrySof IQ PanOptix Trifocal Intraocular Lens (Alcon Laboratories, Inc. Fort Worth, TX) was given PMA approval by the FDA. The intended use of the device is for the visual correction of aphakia, in adults with less than 1 diopter of pre-existing corneal astigmatism, in whom a cataractous lens has been removed.

Background/Overview

Clouding of the lens of the eye is common in older persons and rarely is seen in newborn children. This condition is generally known as "cataracts," but more specifically as "adult cataracts" when present in previously unaffected adults and as "congenital cataracts" when present in newborn infants. The only available treatment for cataracts at this time is surgical replacement of the affected lens with an artificial lens. These artificial lenses are usually of fixed power (monofocal) and require the use of reading glasses for near vision. Presbyopia-correcting intraocular lenses, including, but not limited to, accommodating and multifocal intraocular lenses, are designed to restore a fuller range of near, intermediate and far distance vision as compared to monofocal intraocular lenses. Astigmatism-correcting lenses are designed to reduce the need for glasses for clear distance vision following cataract surgery.

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Standard Intraocular Lenses
Standard prosthetic intraocular lenses are small polymer discs designed to have the same optical properties as an individual's natural lens, and are used to replace diseased lenses removed during cataract surgery. The normal lens is attached to muscles in the eye, which alter the shape of the lens to focus the eye on objects at various distances. Standard prosthetic lenses cannot duplicate this function (accommodation).

Accommodating Lenses
Accommodating intraocular lenses have been proposed as an alternative to standard lens prostheses. These lenses are designed to work with the muscles of the eye to reproduce the focusing function of the lens, by changing the position of the lens rather than changing its shape. Accommodating intraocular lenses are made of similar polymers as standard lens prostheses, and have additional features, referred to as "hinges", allowing the prosthesis to move with the eye naturally to provide visual focusing for near, intermediate, and distance vision. At this time, accommodating intraocular lenses have not been discussed as an alternative treatment for congenital cataracts and only adult cataracts have been studied. The majority of individuals with adult cataracts also require corrective lenses to correct the presbyopia (lack of accommodation) created by a fixed monofocal prosthetic lens. The use of accommodating intraocular lenses may simultaneously correct presbyopia and thus eliminate the need for reading glasses.

Multifocal Lenses
Multifocal intraocular lenses use apodized diffractive technology which responds to how wide or small the pupil might be to provide near, intermediate, and distance vision. Twelve concentric steps of gradually decreasing step heights allocate energy based on lighting conditions and activity, creating a full range of quality vision.

Definitions

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Accommodation: The ability of the eye to increase its focusing power. As an object is viewed closer up, greater focusing power is needed to continue to see it clearly.

Aphakia: The absence of the lens of the eye.

Apodization: The gradual reduction or blending of the diffractive step heights.

Astigmatism: A common form of visual impairment in which part of an image is blurred, due to an irregularity in the curvature of the front surface of the eye, the cornea.

Cataract: Cloudiness of the natural lens inside the eye which can blur vision.

Cornea: The clear, transparent cover over the iris and pupil on the front part of the eye. The cornea is the first part of the eye that bends (or refracts) the light and provides most of the focusing power of the eye.

Crystalline (natural) lens: The eye's natural lens that bends light (refracts) to provide some of the focusing power of the eye. The eye's natural lens is able to change shape allowing the eye to focus at different distances.

Diffraction: The spreading of light, occurring when light passes through discontinuities (i.e., steps or edges). In an optical system, light can be diffracted to form multiple focal points or images.

Intraocular lens: A lens made of silicone, plastic or acrylic material surgically implanted inside the eye.

Presbyopia: A type of age-associated refractive error resulting in progressive loss of focusing power of the lens of the eye which can cause difficulty seeing objects at near distance, or close-up.

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Stereopsis: The ability to see objects as three-dimensional and the judge their distance in space by putting together mental imagines from both eyes.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Not Medically Necessary:

HCPCS

V2787	Astigmatism correcting function of intraocular lens
V2788	Presbyopia correcting function of intraocular lens

ICD-10 Diagnosis

All diagnoses

References

Peer Reviewed Publications:

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10. Macsai MS, Padnick-Silver L, et al. Visual outcomes after accommodating intraocular lens implantation. J Cataract Refract Surg. 2006; 32(4):628-633.
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Websites for Additional Information

1. National Library of Medicine. Medical Encyclopedia: Cataracts. Updated August 4, 2023. Available at: http://www.nlm.nih.gov/medlineplus/ency/article/001001.htm. Accessed on December 22, 2023.

Index

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Accommodating Intraocular Lens
AcrySof IQ PanOptix Trifocal Intraocular Lens
ACRYSOF Toric Posterior Chamber Intraocular Lens
Astigmatism-Correcting Intraocular Lens
Crystalens
enVista®
Multifocal Intraocular Lens
Presbyopia-Correcting Intraocular Lens
ReSTOR
ReZoom
Staar Toric (astigmatism correcting) IOL implant
TECNIS Multifocal Foldable Silicone and Acrylic Intraocular Lenses
TECNIS Symfony®
Trulign Toric IOL

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.

Document History

Status	Date	Action
Reviewed	02/15/2024	MPTAC review. Revised Description/Scope, Rationale, References, and Websites for Additional Information sections.
Reviewed	02/16/2023	MPTAC review. Updated Rationale and References sections.
Reviewed	02/17/2022	MPTAC review. Updated Rationale and References sections.

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Reviewed	02/11/2021	MPTAC review. Updated Rationale and References sections.
Reviewed	02/20/2020	MPTAC review. Updated Rationale, References and Index sections.
Reviewed	03/21/2019	MPTAC review. Updated Rationale, Background/Overview, Definitions, References, and Index sections.
Reviewed	03/22/2018	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date." Updated Rationale and References sections.
Reviewed	05/04/2017	MPTAC review. Updated References and Index sections.
Reviewed	05/05/2016	MPTAC review. Updated Description/Scope, Background/Overview, and References sections. Removed ICD-9 codes from Coding section.
Reviewed	05/07/2015	MPTAC review. Updated References.
Reviewed	05/15/2014	MPTAC review. Updated Index.
Reviewed	05/09/2013	MPTAC review. Updated Rationale and References.
Reviewed	05/10/2012	MPTAC review. Updated References.
Reviewed	05/19/2011	MPTAC review. Updated Rationale, References and Index.
Reviewed	05/13/2010	MPTAC review. No change to Position Statement.
Revised	05/21/2009	MPTAC review. Added cross reference to SURG.00009. Updated Rationale, Definitions, Coding, References and Web Sites. Title change to Presbyopia and Astigmatism-Correcting Intraocular Lenses. Revision of not medically necessary statement to include astigmatism-correcting intraocular lenses.
Reviewed	05/15/2008	MPTAC review. References updated.
Reviewed	05/17/2007	MPTAC review. Rationale and References updated. Coding updated; removed HCPCS code V2702.
Revised	06/08/2006	MPTAC review. Title changed to Presbyopia-Correcting Intraocular Lenses. Multifocal Lenses added as an example of presbyopia-correcting IOLs. Position revised from investigational/not medically necessary to not medically necessary.

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	11/18/2005	Added reference for Centers for Medicare and Medicaid Services (CMS) – National Coverage Determination (NCD).
Reviewed	09/22/2005	MPTAC review. Revision based on Pre-Merger Anthem and Pre-Merger WellPoint Harmonization.

Pre-Merger Organizations	Last Review Date	Document Number	Title
Anthem, Inc.	10/28/2004	SURG.00061	Accommodating Intraocular Lens
WellPoint Health Networks, Inc.			No Document

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