# **Medical Policy**



Blue Cross Blue Shield Blue Care Network of Michigan

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Joint Medical Policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. When Centers for Medicare and Medicaid (CMS) coverage rules are not fully developed, this medical policy may be used by BCBSM or BCN Medicare Advantage plans 42 CFR § 422.101 (b)(6). Please reference the appropriate certificate or contract for benefit information. This policy may be updated and is therefore subject to change.

> \*Current Policy Effective Date: 7/1/25 (See policy history boxes for previous effective dates)

# **Title: Cataract Removal Surgery**

#### **Description/Background**

A cataract is a progressive opacity, or cloudiness, of the normally clear lens of the eye that interferes with the individuals vision and the examiners ability to view the fundus. It is a common cause of visual impairment, particularly in the elderly population. The cloudiness and loss of transparency are due to the clustering of proteins within the lens. Cataracts develop gradually, ranging from minor changes in the transparency of the lens to complete opacity. The degree of vision loss depends on the location, size, and density of the cataract. Early-stage cataract formation may not be accompanied by any noticeable effects on vision; however, the later stages of cataract development may significantly decrease visual acuity.

Traditional cataract surgery (phacoemulsification with a manual capsulotomy technique) normally involves a surgeon manually creating a small incision on the side of the cornea with a handheld scalpel. A tiny probe from the phacoemulsification device is inserted and emits ultrasound waves that soften and break up the lens so that it can be removed by suction.

Symptoms of cataract formation may include:

- Clouded, blurred or dim vision
- Increasing difficulty with vision at night
- Sensitivity to light and glare
- Seeing "halos" around lights
- Frequent changes in eyeglass or contact lens prescription
- Fading or yellowing of colors
- Double vision in a single eye

Cataracts affect over 24.4 million Americans age 40 and older, or approximately 1 in every 6 people in this age range. Cataracts are rare in children, and they can affect 1 or both eyes. By

age 75, approximately half of all Americans have cataracts. In the United States, the number of people with cataracts is forecasted to double from 24.4 million to about 50 million by the year 2050. Risk factors associated with the development of cataracts include advancing age, prolonged exposure of the eyes to ultraviolet-B light, diabetes, smoking, and prolonged use of corticosteroid medications. A cataract may also form as a result of trauma to the eye, inflammation, radiation, previous intraocular surgery, or use of some medications. Cataracts are the leading cause of blindness worldwide.

Phaco combined with a manual capsulotomy technique remains the gold standard and most commonly utilized technique for cataract removal surgery. Multiple technologies are being assessed in pursuit of better outcomes by creating a perfectly sized central circular capsulotomy including use of femtosecond lasers, aperture continuous thermal capsulotomy and, capsulaser devices.

#### **Regulatory Status**

The FDA has approved a number of intraocular lens implants to replace the natural lens of the eye after cataract surgery. There are currently no intraocular lens (IOLs) that have received premarket approval from the FDA as safe and effective devices for use in individuals under the age of 18 years. An IOL manufacturer that has received FDA approval for an Investigational Device Exemption for a clinical trial of IOL use in children may sponsor a clinical study in which a physician may act as a clinical investigator and perform IOL implantations, within the study protocol, in children.

Multiple femtosecond laser platforms for use with anterior capsulotomy during cataract surgery have received FDA approval. (e.g., Victus Femtosecond Laser Platform, FEMTO LDV™ Z8 Femtosecond Surgical Laser, Catalys Precision Laser System, LensSx Laser System, Lensar Laser System, Wavelight FS200, Femtec Laser System for Capsulotomy) Product code: OOE

#### **Medical Policy Statement**

The safety and efficacy of cataract removal surgery, with or without intraocular lens (IOL) implantation, has been established. It is considered an effective treatment when clinical criteria are met.

#### **Inclusionary and Exclusionary Guidelines**

#### Inclusions:

Cataract removal surgery (with or without IOL implantation) may be an appropriate treatment for adult members when <u>all</u> the following criteria are met:

- The individual has a decreased ability to carry out activities of daily living such as reading, watching television, driving, or meeting occupational or vocational expectations; **AND**
- The individual has a best corrected visual acuity of <u>20/40 or worse</u> at distance or near; **or** additional testing reveals one of the following:

- Consensual light testing decreases visual acuity by two lines, or
- Glare testing decreases visual acuity by two lines
- Other eye disease(s), such as macular degeneration or diabetic retinopathy, have been ruled out as the only cause of decreased visual function; **AND**
- Significant improvement in visual function can be expected as a result of cataract extraction; **AND**
- The individual has undergone a preoperative ophthalmologic evaluation that includes a comprehensive ophthalmologic exam and ophthalmic biometry; **AND**
- If cataracts exist in both eyes and require surgery, the surgery will be performed on each eye at separate times, usually four to eight weeks apart. **AND**
- The individual has been educated about the risks and benefits of cataract surgery and the alternative(s) to surgery (e.g., avoidance of glare, optimal eyeglass prescription, etc.)

Additional indications for cataract removal may include:

- Lens-induced disease and/or angle closure (phacomorphic glaucoma, phagolytic glaucoma, phacolysis, phacoanaphylaxis and other lens-induced disease may require cataract surgery and the need for extraction may be urgent)
- The need to visualize the fundus (e.g., the individual has diabetes with significant risk of reduced visual acuity from diabetic retinopathy requiring management through visualization for diagnosis or clear media laser therapy)
- Capsular rupture with lens swelling
- Other trauma-induced ocular pathology necessitating surgery
- Reduced contrast sensitivity that correlates with the individuals subjective and objective assessments
- Double vision in the affected eye
- Clinically significant anisometropia in the presence of a cataract
- The lens opacity interferes with optimal diagnosis or management of posterior segment conditions
- Refractory correcting IOLs<sup>a</sup>
- <sup>a</sup> Refractory correcting IOLs are considered deluxe items and are therefore considered not medically necessary. Individuals must be advised in advance that deluxe, or enhancement items are the financial responsibility of the member. It is the providers responsibility to obtain a signed copy of the Advanced Notice of Member Responsibility (ANMR) form from the member and bill with the appropriate modifiers. Failure to appropriately execute an ANMR form and bill with the correct modifiers will cause the claim to reject. The provider will be liable for the item and/or service and the member may not be billed.

For pediatric members, cataract removal surgery **<u>without IOL implantation<sup>b</sup></u>** may be considered an appropriate treatment when any of the following criteria are met:

- Dense central opacity larger than 3 mm in diameter
- In partial cataracts, surgery is indicated when the visual acuity is less than 6/18 or, in preverbal children, when fixation is poor
- Capsular rupture with lens swelling
- Other trauma-induced ocular pathology necessitating cataract surgery

<sup>b</sup> IOL implants are not FDA approved for children under the age of 18 years.

#### Exclusions:

For adult members:

- Glasses or visual aids provide functional vision satisfactory to the individuals needs and desires
- Surgery is <u>not</u> expected to improve visual function, and no other indication for lens removal exists
- The individual cannot safely undergo surgery because of coexisting medical or ocular conditions
- Functional improvement is unlikely due to concomitant disease
- Active proliferative diabetic retinopathy (unless cataract removal is necessary to allow visualization of the retina)
- The presence of rubeosis iridis and/or neovascular glaucoma

For pediatric members:

- IOLs have not received regulatory approval for use in children under the age of 18 years
- The presence of a severe life-limiting disease
- Cases of severe microphthalmia (corneal diameter less than 5 mm)
- Cases in which the retina is irreparably detached, or the posterior segment is disorganized
- The presence of untreated retinoblastoma

**CPT/HCPCS Level II Codes** (Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)

Established	codes:				
66820	66821	66830	66840	66850	66852
66920	66930	66940	66982	66983	66984
66987	66988				

#### Other codes (investigational, not medically necessary, etc.):

N/A

*Note: The above code(s) may not be covered by all contracts or certificates. Please consult customer or provider inquiry resources at BCBSM or BCN to verify coverage.* 

### Rationale

Although cataract formation is often attributed to the aging process, a cataract may develop at any age. An adult with cataracts may experience a decreased ability to carry out his/her activities of daily living (ADLs), including a reduction in the ability to read, drive, and perform work duties. There is an increased risk of accidental injury (e.g., falls) associated with cataracts.

A cataract may be successfully treated via surgical extraction. Cataract surgery involves removing the clouded lens and replacing it with an artificial intraocular lens implant (IOL).

Individuals who are not candidates for IOLs may need to wear eyeglasses or contact lenses once the cataract is removed. Cataract surgery is typically performed on 1 eye at a time in an outpatient setting, with a few weeks between surgeries.

Currently, there are 2 principal types of cataract surgeries: phacoemulsification (phaco) and conventional extracapsular cataract extraction. Both of these techniques usually involve the insertion of an IOL.

Phaco is the most commonly performed cataract surgery. This technique involves a small (2-3 mm) incision that may be made in different locations, including the cornea, limbus, or sclera of the eye. A probe is inserted through the incision to supply ultrasonic waves to break-up and emulsify the crystalline lens, and then the lens remnants are removed with suction. The small incision may or may not require sutures.

Extracapsular cataract extraction uses a larger incision (10-12 mm) that usually requires sutures. Conventional extracapsular cataract extraction involves manual removal of the lens through a large (usually 10-12 mm) incision made in the cornea or sclera. Although it requires a larger incision and the use of stitches, the conventional method may be indicated for individuals with very rigid cataracts or when phaco surgery is not indicated.

The goal of this surgery is to restore an individual's visual acuity and level of functioning. Indications for surgery are usually based on the level of Snellen visual acuity and have been divided into 2 groups: those with visual acuity of 20/40 or better and those with 20/50 or worse.

In individuals with 20/40 visual acuity or better, special attention should be paid to the individuals complaints of decreased vision during specific tasks, monocular diplopia or polyopia, or large refractive difference between the eyes. Despite 20/40 visual acuity or better, impairment due to any of these factors may indicate a need for surgery.

In individuals whose visual acuity is reduced to worse than 20/40, surgical intervention is more likely to be appropriate because of reduced ability or inability to perform daily tasks.

The 20/40 visual acuity threshold is used to determine post-operative success. The U.S. Food and Drug Administration (FDA) uses this value as an assessment parameter in the approval of IOLs and other vision devices. Lastly, most states, including Michigan, require a visual acuity level of 20/40 for unrestricted motor vehicle operation.

There are numerous studies in the peer-reviewed literature demonstrating that physical function, mental health, emotional well-being, safety, and overall quality of life can be enhanced when visual function is restored by cataract extraction. Various professional societies, such as the American Academy of Eye Surgeons and the American Academy of Ophthalmology, provide recommendations and practice guidelines for cataract removal surgery.

#### Presbyopia (Refractory) Correcting Intraocular Lens

The use of presbyopia-correcting IOLs and astigmatism-correcting IOLs as alternatives to monofocal IOLs are considered to be predominately for comfort and convenience, (i.e.,

to eliminate the need for spectacles or contact lenses). The available peer-reviewed literature has failed to establish the superiority of presbyopia-correcting IOLs and astigmatism-correcting IOLs, in terms of safety and long-term benefit over monofocal IOLs and conventional eyewear.

#### ONGOING AND UNPUBLISHED CLINICAL TRIALS

Some currently ongoing and unpublished trials that might influence this review are listed in Table 1.

#### Table 1. Summary of Key Active Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT01547442	Artisan Aphakia Lens for the Correction of Aphakia in Children –	300	Dec 2025
	Phase III		
NCT: National clinical trial			

#### Government Regulations National:

National Coverage Determination (NCD) for Phaco-Emulsification Procedure - Cataract Extraction (80.10) Pub: 100-3, Version 1: Longstanding NCD; Effective date of this version has not been posted.

#### Indications and Limitations of Coverage

In view of recommendations of authoritative sources in the field of ophthalmology, the subject technique is viewed as an accepted procedure for removal of cataracts. Accordingly, program reimbursement may be made for necessary services furnished in connection with cataract extraction utilizing the phaco-emulsification procedure.

#### NCD: Intraocular Lenses (IOLs) (80.12) Pub 100-3, Version 1: Effective date: 5/19/1997

#### Indications and Limitations of Coverage

Intraocular lens implantation services, as well as the lens itself, may be covered if reasonable and necessary for the individual. Implantation services may include hospital, surgical, and other medical services, including pre-implantation ultrasound (A-scan) eye measurement of one or both eyes.

# Medicare Learning Network Matters (CMS): Fact Sheet - Medicare Vision Services ICN 907165 (2023)

Presbyopia and astigmatism are common eye problems which are corrected by presbyopiacorrecting Intraocular Lenses (P-C IOLs) and astigmatism-correcting IOLs (A-C IOLs). A P-C IOL or A-C IOL are 2 separate items or services:

- Implantable conventional IOL (not P-C or A-C)— Medicare covers
- Surgical correction, eyeglasses, or contact lenses to correct presbyopia or astigmatism— Medicare doesn't cover

When a beneficiary requests a P-C or A-C IOL instead of a conventional IOL, inform the beneficiary before the procedure that Medicare does not pay for the physician and facility services specific to the insertion, adjustment, or other subsequent treatments that are attributable to the functionality of the P-C or A-C IOLs.

Medicare Learning Network Matters (CMS) MM3927: Implementation of the Centers for Medicare & Medicaid Services (CMS) Ruling 05-01 Regarding Presbyopia-Correcting Intraocular Lenses (IOLs) for Medicare Beneficiaries. Effective May 2, 2005. Updated February 11, 2013

#### Coverage Ruling

Payment for conventional IOLs furnished in an outpatient setting is covered by Medicare. However, providers have generally not offered beneficiaries presbyopia correcting IOLs because the costs for this advanced technology substantially exceed Medicare's payment.

This ruling by CMS clarifies that a beneficiary may request insertion of a presbyopia correcting IOL in place of a conventional IOL following cataract surgery.

The beneficiary is responsible for payment of that portion of the charge for the presbyopia correcting IOL and associated services that exceed the charge for insertion of a conventional IOL following cataract surgery.

#### Laser-Assisted Cataract Surgery and CMS Rulings 05-01 and 1536-R

Per CMS Ruling 05-01, issued May 3, 2005, Medicare will allow beneficiaries to pay additional charges (which are non-covered by Medicare as these additional charges are not part of a Medicare benefit category) associated with insertion of a presbyopia correcting intraocular lens (PC-IOL) following cataract surgery. Per CMS-Ruling 1536-R, effective for services on and after January 22, 2007, Medicare will allow beneficiaries to pay additional charges (which are non-covered by Medicare as these additional charges are not part of a Medicare benefit category) for insertion of an astigmatism correcting intraocular lens (AC-IOL). These rulings allow the beneficiary to pay additional charges for two specific categories of non-covered services:

- The portion of the facility or physician's charge for the PC-IOL or AC-IOL that exceeds the facility or physician's charge for insertion of a conventional intraocular lens (IOL) following cataract surgery.
- Facility or physician charges for resources required for fitting and vision acuity testing of a PC-IOL or AC-IOL that exceeds the facility or physician charges for resources furnished for a conventional IOL following cataract surgery.

Medicare coverage and payment for cataract surgery is the same irrespective of whether the surgery is performed using conventional surgical techniques or a bladeless, computer-controlled laser. Under either method, Medicare will cover and pay for the cataract removal and insertion of a conventional intraocular lens. If the bladeless, computer-controlled laser cataract surgery includes implantation of a PC-IOL or AC-IOL, only charges for those non-covered services specified above may be charged to the beneficiary.

# CMS Manual System. Pub 100-4; Transmittal 1228. Instructions for Implementation of CMS 1536-R; Astigmatism-Correcting Intraocular Lens (A-C IOLs). Effective: January 22, 2007; Updated August 27, 2012

Medicare will pay the same amount for cataract extraction with Astigmatism-Correcting IOL insertion that it pays for cataract extraction with conventional IOL insertion.

The beneficiary is responsible for payment of that portion of the hospital or ambulatory surgery center charge for the procedure that exceeds the facility's usual charge for cataract extraction and insertion of a conventional IOL following cataract surgery, as well as any fees that exceed the physician's usual charge to perform a cataract extraction with insertion of a conventional IOL.

#### Coverage policy:

The Social Security Act specifically excludes eyeglasses and contact lenses from coverage, with an exception for one pair of eyeglasses or contact lenses covered as a prosthetic device furnished after each cataract surgery with insertion of an IOL. In addition, there is no Medicare benefit category to allow payment for the surgical correction or cylindrical lenses of eyeglasses or contact lenses that may be required to compensate for the imperfect curvature of the cornea (astigmatism).

#### Local:

#### Cataract Surgery (L39905). Effective 10/13/24

#### **Coverage Indications**

In the clinical presence of cataract(s), cataract surgery is considered medically necessary when the following conditions or circumstances exists, and are clearly documented in the medical record:

- After comprehensive medical eye evaluation AND
- Consideration of the risk factors for undergoing the planned anesthesia, AND
- Informed consent from the patient or the patient's health care power of attorney after discussing the risks, benefits, and expected outcomes of surgery, including the anticipated refractive outcome, AND
- Outcome measures of cataract surgery such as visual acuity, accuracy of refractive correction, occurrence of significant operative and postoperative complications shall be recorded post-operatively, AND
- The cataract is causing visual impairment that is not correctable with a tolerable change in glasses or contact lenses, resulting in the inability to perform Activities of Daily Living such as, but not limited to, driving, reading, watching television, and/or meeting vocational or recreational needs, OR
- The lens opacity interferes with optimal diagnosis or management of posterior segment conditions (e.g., diabetic retinopathy or macular degeneration), OR
- As a treatment of vision threatening cataract induced complications (e.g., the lens induces or risks angle closure, uveitis, dislocation of the lens), OR
- During vitrectomy procedures, the lens interferes with the performance of vitreoretinal surgery, as in the case of proliferative vitreoretinopathy, complicated retinal detachments, and severe proliferative diabetic retinopathy, OR
- There is a high probability of accelerating cataract development because of a concomitant or subsequent procedure (e.g., pars plana vitrectomy, iridocyclectomy, procedure for ocular trauma) and treatments such as external beam irradiation, OR
- There is clinically significant anisometropia or aniseikonia that exists because of lens extraction in the first eye (despite satisfactorily corrected monocular visual acuity), OR
- There is lens injury with potential lens swelling (traumatic cataract)

#### **Coverage Limitations**

- Cataract surgery is not reasonable and necessary when all the above criteria are not fulfilled. AND
- Cataract surgery can only be performed once for the same eye.

#### Complex cataract surgery

#### Coverage Indications:

Complex cataract surgery will be considered medically reasonable and necessary when there is one of the following:

- A miotic pupil that will not dilate sufficiently requiring the use of a mechanical iris expansion device (Iris retractors through four additional incisions, Beehler expansion device, or Malyugin ring) to adequately visualize the lens in the posterior chamber of the eye, OR
- Pre-existing zonular weakness requiring use of capsular tension rings or segments or intraocular suturing of the intraocular lens, OR
- Pediatric cataract surgery, intraoperatively difficult because of an anterior capsule that is more difficult to tear, cortex that is more difficult to remove needing a primary posterior capsulotomy or capsulorrhexis, OR
- Mature cataract requiring dye for visualization of capsulorrhexis.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

## **Related Policies**

N/A

#### References

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 2/4/25, the date the research was completed.

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
1/1/13	10/16/12	10/16/12	Joint policy established
5/1/14	2/24/14	3/3/14	Routine maintenance
7/1/15	4/24/15	5/8/15	Routine maintenance
7/1/16	4/19/16	4/19/16	Routine maintenance
7/1/17	4/18/17	4/18/17	Routine maintenance
7/1/18	4/17/18	4/17/18	Routine maintenance
7/1/19	4/16/19		Routine maintenance
7/1/20	5/19/20		<ul> <li>Routine maintenance</li> <li>66987, 66988 added to policy – code update</li> <li>BCBSM only policy - Presbyopia (Refractory) Correcting Intraocular Lens (IOLs) incorporated</li> </ul>
7/1/21	4/20/21		Routine maintenance
7/1/22	4/19/22		Routine maintenance
7/1/23	4/18/23		<ul><li> Routine maintenance (slp)</li><li> Vendor managed: N/A</li></ul>
7/1/24	4/16/24		<ul><li> Routine maintenance (slp)</li><li> Vendor managed: N/A</li></ul>
7/1/25	4/15/25		<ul><li> Routine maintenance (slp)</li><li> Vendor managed: N/A</li></ul>

# Joint BCBSM/BCN Medical Policy History

Next Review Date: 2<sup>nd</sup> Qtr, 2025

#### BLUE CARE NETWORK BENEFIT COVERAGE POLICY: CATARACT REMOVAL SURGERY

I. Coverage Determination:

Commercial HMO (includes Self- Funded groups unless otherwise specified)	Covered, criteria apply
BCNA (Medicare Advantage)	Refer to the Medicare information under the
	Government Regulations section of this policy.
BCN65 (Medicare	Coinsurance covered if primary Medicare covers
Complementary)	the service.

#### II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.