VHA Office of Integrated Veteran Care
Clinical Determination and Indication
Cataract Extraction and Intraocular Lens Implant

CDI Number: 00004

Original Effective Date: June 1, 2024

Last Revision Date: June 1, 2024

I. Disclaimer

This document is currently in draft and is intended to be used as a reference for non-VA providers and not intended to replace clinical judgment when determining care pathways. These guidelines do not guarantee benefits or constitute medical advice.

II. Clinical Determinations and Indications

a. Indications

i. Indications for Cataract Extraction

Cataract extraction is considered **medically necessary** when **ANY** of the following criteria are met:

- The presence of a cataract and ALL of the following documented by a preoperative examination:
  - Visual impairment that interferes with one or more of the following:
    - Activities of daily living (ADL)
    - Obtaining or maintaining a license to drive a motorized vehicle,
    - Obtaining or maintaining a license to work
    - Eye function as indicated by one or more of the following:
      - Clinically significant glare disability
      - Monocular diplopia
      - Visual disparity between two eyes
  - Confirmation that cataract is the cause for the visual impairment
- Visual impairment not correctable by glasses or other non-surgical measures
- Significant anisometropia in the presence of a cataract
- Inability to visualize the fundus behind the cataract, due to lens opacity, which is interfering with diagnosis or therapeutic treatments in the eye at risk
- Presence of a cataract-induced disease

  - Phacolysis or Phaco-anaphylaxis, where the lens causes inflammation or secondary glaucoma
  - Phacomorphic glaucoma where there is an increase in size of the lens, worsening angle closure glaucoma
- A significant cataract is present in a patient who will be undergoing concurrent surgery in the same eye, and the surgeon identifies that a decreased morbidity of single stage surgery is of significant benefit over surgery on separate dates

ii. Indications for Complex Cataract Surgery

Complex cataract surgery is considered **medically necessary** when **ANY** of the following criteria are met:

- Miotic pupil needing use of a mechanical iris expansion device to adequately visualize the lens
- Pre-existing zonular weakness requiring use of capsular tension rings or segments or intraocular suturing of the intraocular lens
- Mature cataract requiring dye for visualization of capsulorrhexis

iii. Indications for Standard Monofocal Intraocular Lens Implant

Intraocular lens implant with a Food and Drug Administration (FDA) approved standard monofocal intraocular lens (IOL) is considered **medically necessary** for the following:

- Following cataract extraction
- Trauma to the eye which has damaged the lens
- Congenital cataract
- Congenital aphakia
- Lens subluxation/displacement
- Anisometropia of 2 diopters or greater, and uncorrectable vision with the use of glasses or contact lenses

iv. Indications for a Premium Monofocal Astigmatism-Correcting (Toric) Intraocular Lens Implant

Intraocular lens implant with an FDA approved premium monofocal astigmatism-correcting (toric) IOL is considered **medically necessary** when the following criteria are met:

- Due to the variability of IOLs, surgeons must follow manufacturer's clinical criteria and recommendations

v. Indications for Replacement of a Previously Implanted Intraocular Lens

Replacement of a previously implanted IOL is considered **medically necessary** when **ANY** of the following causes the previously implanted intraocular lens to be ineffective:

- Anatomical change
- Inflammatory response
- Mechanical failure
- Post-surgical intolerable refractive error

b. Limitations/Exclusions

i. Cataract Extraction and IOL Implant

For all conditions/indications not listed in section II.a. of this document, cataract extraction with IOL implant is considered **not medically necessary** due to insufficient evidence of efficacy and safety.

Laser or incisional refractive surgery during cataract extraction is considered **not medically necessary**, however a non-refractive Laser-Assisted Cataract Surgery (LACS) technique may be employed by the surgeon, if clinically indicated.

ii. Intraocular Lens

The following are intended to reduce the need for reading glasses and/or contact lenses after cataract extraction, and thus are considered a convenience item and **considered not medically necessary:**

- Multifocal IOLs
  - Premium accommodating (presbyopia-correcting) IOLs
  - Pseudo-accommodating IOLs
  - Extended depth of focus (EDOF) IOLs

c. Description of Treatment

Phacoemulsification is the predominant surgical procedure to safely and effectively remove a cataract from the eye performed by an ophthalmologist. This method uses an ultrasonic handpiece that produces ultrasound energy to break the cataract into smaller particles, which are then aspirated through the handpiece.

After the cataract is removed, an artificial lens is implanted to replace the natural lens. An IOL is a small, clear lens that is used to replace the surgically removed lens during cataract surgery. The IOL may be placed in various locations in the eye, which includes within the capsular bag as a posterior chamber lens, in the ciliary sulcus as a sulcus lens, or in the anterior

chamber, anterior to the iris, as an anterior chamber lens. The goal of the IOL is to improve vision.

Alternative treatment options for cataracts includes non-surgical visual aids for reading including magnifiers, tinted lenses, refractive correction and pupillary dilation for small central cataracts.

Per the recommendation of the Society for Ambulatory Anesthesia (SAMBA), cataract extraction with intraocular lens implant is considered a low-risk procedure and may be safely performed at freestanding ambulatory surgery centers. Refer to SAMBA's position statement for further details related to place of service.

III. Background and Supporting Information

The following information is for reference purposes only in accordance with the medical benefits package outlined in 38 C.F.R. § 17.38 (b). Each subsection supports VA's determinations for medical necessity and alignment with generally accepted standards of medical practice.

a. Background Information

Visual images are produced when light enters the eye. As light passes through the crystalline lens, light is focused onto the retina in the back part of the eye, which generates nerve impulses that is transmitted to the brain. During the natural aging process, the crystalline lens, normally transparent, becomes cloudy through an unknown phenomenon. As the clouding of the lens worsens over time, it decreases vision and may lead to eventual blindness if left untreated. Other causes of cataracts, besides aging, include congenital diseases due to genetic variations, trauma from both blunt and penetrating eye injuries, electrocution, chemical burns, exposure to radiation, and even some metabolic diseases like uncontrolled diabetes.

Currently, there is no treatment to prevent the development or progression of cataracts and vision impairment due to cataracts cannot be corrected with glasses. Cataract surgery is the only definitive treatment to improve vision for someone with cataracts and is the most common indication for an intraocular lens (IOL) implant. Intraocular lenses are artificial lenses, usually made from silicone or acrylic, that replace the natural lens of the eye, restoring vision to the patient.

Astigmatism

Astigmatism is a common eye condition that causes blurred vision or areas of distorted vision due to an irregularly shaped cornea. Blurred vision may be alone or in combination with myopia or hyperopia. This uneven curvature of the cornea causes a refractive error, resulting in light not being able to bend

properly and focus on the retina. Other common symptoms may include eye strain, headache, squinting to see clearly, and eye discomfort.

Intraocular Lenses

There are various types of IOLs, and a lens may also have monofocal or multifocal options. Standard lenses are the most common type of lens used to replace the natural lens post-cataract extraction. Premium lenses are also available options, and these include the astigmatism-correcting (toric) lens and the presbyopia-correcting (accommodating) lens. Most IOLs are made of special material that absorb ultraviolet light.

Standard IOLs meet an individual's basic functional needs for vision. A monofocal IOL has a fixed focal length and provides clear vision at a single distance. Glasses may be required to assist with either near or distance vision post-intraocular lens placement.

Astigmatism-correcting IOLs (toric lenses) are a type of premium IOL that have different powers in different meridians, which makes these IOLs different from spherical IOLs. These IOLs mimic the accommodation of the natural lens, which helps focus both distant and near images onto the retina. Astigmatism correcting IOLs have both cylinder power and spherical power. When an astigmatism-correcting (toric) IOL of the appropriate cylinder power is inserted into the eye and rotated into the correct axis, it can correct the patient's corneal astigmatism. The intention of the toric lens is to correct astigmatism and reduce the need for reading glasses or contact lenses post-surgery.

b. Research, Clinical Trials, and Evidence Summaries

The American Academy of Ophthalmology's Cataract in the Adult Eye Preferred Practice Pattern guidelines are based on the best available evidence of literature and scientific data that identify characteristics and components of quality eye care. It provides guidance for the pattern of practice for cataract surgery care, including patients with astigmatism and the use of toric IOLs.

The evidence of literature supports that monofocal IOLs, including monofocal toric IOLs, are safe and effective implants that improve visual acuity in patients post cataract extraction and had lower residual astigmatism. There is limited evidence that multifocal IOLs are considered medically necessary as research has shown that the main motivation to choose a multifocal IOL is spectacle independence.

A 2016 systematic review and meta-analysis by Kessel et. al. evaluated 13 randomized controlled trials and found high-quality evidence that visual acuity was better in the toric IOL group and provided greater spectacle

independence with lower residual astigmatism. There was moderate quality evidence that toric IOL was not associated with an increased risk of complications.

A 2019 systematic review and meta-analysis by Cao et. al. assessed 21 randomized controlled trials to compare multifocal IOLs to monofocal IOLs and evaluated visual acuity, contrast sensitivity, and adverse events. The team concluded that compared to monofocal IOLs, the multifocal IOLs gave patients better near and intermediate vision and were more likely to be spectacle free. Patients with multifocal IOLs however had a higher risk for adverse events, which included risk of glare and halos.

The Evidence-based Synthesis Program (ESP) Center prepared a report (Comparative Effectiveness of Multifocal, Accommodative, and Monofocal Intraocular Lenses for Cataract Surgery and Lens Replacement) for the Department of Veterans Affairs, Veterans Health Administration in 2019 that compared the effectiveness of multifocal, accommodative, and monofocal IOLs for cataract surgery. The assessment found that multifocal IOLs compared to monofocal IOLs had better uncorrected near vision outcomes, and a greater proportion of patients who are spectacle independent, however there was low evidence to support that multifocal IOLs resulted in better visual acuity and quality of life than monofocal IOLs. The analysis also found that multifocal IOLs are associated with worse contrast sensitivity and had a greater risk of glare and halos.

Rajan et. al.'s (2021) review of literature supports that cataract surgery, a low-risk surgery, may be performed safely at freestanding ambulatory surgery centers (ASCs) on patients of higher risk who would normally not qualify for a more invasive procedure at the same facility. The Society for Ambulatory Anesthesia (SAMBA) recommends that ASA-PS 4 patients with stable comorbidities who can tolerate cataract surgery with topical or regional anesthesia and no or minimal sedation may safely undergo cataract surgery in a free-standing ASC.

c. U.S. Food & Drug Administration (FDA) Information

VA generally only approves use of medical devices that have received at least FDA clearance for 510(k) Premarket Notification. The FDA has determined these Class II devices are substantially equivalent (SE) to legally marketed predicate devices and may be marketed in the U.S.

To search for devices that have received FDA 510(k) clearance or Premarket Approval (PMA), please visit the FDA Devices database.

d. Medicare Coverage Determinations

Available Medicare coverage determinations are listed below as a resource. VA and Medicare are governed by separate laws and regulations; thus, VA coverage determinations may be different.

i. Cataract Extraction

NCD Number	Name	Original/Revision Effective Date
80.10	Phaco-Emulsification Procedure - Cataract Extraction	N/A

LCD Number	Contractor	Original/Revision Effective Date
L33954	CGS Administrators, LLC	01/05/2023
L38926	First Coast Service Options, Inc.	07/11/2021
L34203	Noridian Healthcare Solutions, LLC	10/01/2019
L37027	Noridian Healthcare Solutions, LLC	10/01/2019
L35091	Novitas Solutions Inc.	07/11/2021
L34413	Palmetto GBA	05/26/2022

ii. Intraocular Lenses (IOLs)

NCD Number	Name	Original/Revision Effective Date
80.12	Intraocular Lenses (IOLs)	05/19/1997

LCD Number	Contractor	Original/Revision Effective Date
None	N/A	N/A

- NCD: National Coverage Determination
- LCD: Local Coverage Determination

IV. Definitions

Term	Definition
Anisometropia	Visual disparity existing between the two eyes
Aphakic	The absence of the lens within the eye due to surgical removal or congenital absence
Cornea	The clear window in front of the eye that helps protect the interior of the eyeball
Corneal Ectasia	Weakening of the cornea causes it to bulge and protrude forward, resulting in distorted vision
Diopter	A unit used to measure correction, or the focusing power of the lens a person's eye requires

Term	Definition
Hyperopia	Also known as farsightedness where a person can see distant objects well but has difficulty focusing on up close objects. In this refractive error, the light rays entering the eye focus behind the retina due to the eyeball being shorter than normal
Lens Subluxation	A partially displaced lens but remains within the lens space
Myopia	Also known as nearsightedness where a person will have difficulty reading road signs and seeing distant objects clearly. It is the most common refractive error where light rays focus at a point in front of the retina due to the eyeball being too long
Refraction	The bending of light rays. The cornea and the lens of the eye bend light rays to focus on the retina
Refractive Error	Size and shape-related abnormalities of the eye that affect the ability of the eye to focus light on the retina
Retina	A layer at the back of the eyeball made up of light-sensitive cells that transmits light information via nerve impulses to the brain

V. References

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VI. CDI History/Revision Information

- Explanation of changes to the CDI

Revision Type	Date of Revision	Update(s) Made to CDI
	MM/DD/YYYY	•
	MM/DD/YYYY	•