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Intraocular Lens (IOLs) and Implantable Miniature Telescope (IMT)

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

NOTE 1: Generally, the treatment of refractive errors is not considered a covered benefit, except under the provisions of a vision benefit contract. Refer to the individual vision benefit contract for coverage details.

Intraocular Lens
Intraocular lens (IOL) implant with an Food and Drug Administration (FDA) approved conventional monofocal IOL (both aspherical and spherical) **may be considered medically necessary** when used to replace the natural crystalline lens. Some examples may include:

- Following cataract extraction; OR
- Lens damage as a result of trauma to the eye; OR
- Congenital cataract; OR
- Congenital aphakia; OR
- Lens subluxation/displacement; OR

- Anisometropia of 2 diopters or greater, and uncorrectable vision with the use of glasses or contact lenses.

Premium intraocular lens implant (e.g., Toric, multifocal, extended depth of focus [EDOF], light adjustable lenses and/or accommodating lenses/IOLs) **are considered not medically necessary.**

Implantable Miniature Telescope

The Implantable Miniature Telescope™ (IMT) **may be considered medically necessary** for monocular implantation when ALL the following criteria are met:

1. Patient is 65 years or older with stable severe to profound vision impairment caused by blind spots (bilateral central scotoma) associated with end-stage AMD (age-related macular degeneration); AND
2. Patient has evidence of a visually significant cataract (grade 2 or higher); AND
3. Visual acuity is poorer than 20/160, but not worse than 20/800 in both eyes; AND
4. Patient has retinal findings of geographic atrophy or disciform scar with foveal involvement, as determined by fluorescein angiography; AND
5. Patient has undergone training (typically 2 to 4 sessions) with a low vision specialist or optometrist with an external telescope prior to implantation and has been determined to have adequate improvement in vision; AND
6. Patient can achieve at least a 5-letter improvement on the Early Treatment Diabetic Retinopathy Study (ETDRS) chart in the affected eye using an external telescope; AND
7. Patient has adequate peripheral vision in the eye not scheduled for surgery.

NOTE 2: Patients should undergo postoperative training with a low vision specialist after IMT implantation.

NOTE 3: Patient should complete the Acceptance of Risk and Informed Decision Agreement prior to IMT implantation. (Because the IMT is a large device, implantation can lead to extensive loss of corneal endothelial cells. Significant losses in corneal endothelial cells may lead to corneal edema, corneal decompensation, and the need for corneal transplant. To ensure that the risks of IMT implantation are consistently communicated to patients, the Food and Drug Administration and the manufacturer created detailed labeling that includes an Acceptance of Risk and Informed Decision Agreement.)

An intraocular telescope (Implantable Miniature Telescope™) **is considered experimental, investigational and/or unproven** when all the above criteria are not met.

Policy Guidelines

Replacement of a conventional monofocal intraocular (IOL) implant may be medically appropriate when anatomical change, inflammatory response, or mechanical failure renders a previously implanted intraocular lens ineffective or nonfunctional.

Description

Intraocular Lens

Presbyopia is part of the normal aging process in which the eyes lens loses flexibility resulting in an inability to focus on objects. Presbyopia typically occurs in patients during their early 40's due to a change in the aging lens. This change in the lens often results in a need for reading glasses, especially for close-up tasks such as reading. Due to the 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 which may include but are not limited to the use of bifocals, trifocals, progressive lens, monovision contact lenses, bifocal contact lenses, modified monovision lenses and vision correction surgery. Intraocular lens (IOLs) were developed for the visual correction of presbyopia following cataract surgery. (1) IOL implant may also be needed for conditions other than cataract surgery. Less common uses may include trauma to the eye which has damaged the lens; congenital cataract; congenital aphakia; lens subluxation/displacement and significant anisometropia that is uncorrectable with the use of glasses or lenses.

IOLs are small, artificial lenses that are surgically implanted to replace or supplement the eye's natural crystalline lens. Replacement of the natural lens of the eye is utilized to restore vision in cases where the lens is surgically removed (e.g., cataract surgery). (2) Foldable IOLs are now the most commonly used IOLs because they can be implanted through smaller incisions. Foldable IOLs are classified according to their optic material: silicone, hydrophilic acrylic, and hydrophobic acrylic. The choice of IOL is dependent on the physician recommendation and the visual needs of each patient. (3)

<u>Types of Intraocular Lens</u>

Monofocal IOL or conventional IOL

Monofocal lenses or conventional IOLs are the most commonly implanted ocular lenses. The monofocal IOL is designed with one fixed optical power (either long distance, middle distance or short distance) which provides high-quality vision. The use of monofocal IOLs as replacement for the cataract lens will typically require the use of corrective eyeglasses after surgery for near vision tasks such as reading. (2) Monofocal IOLs are the standard lenses used in the majority of cataract surgeries. (4)

Multifocal IOLs

Multifocal IOLs, also known as pseudo accommodative lenses, have more than one focal point and are designed to provide distance and near vision simultaneously. (2) Presbyopia-correcting (near vision correcting) IOLs include, but are not limited to, multifocal IOLs, accommodating, extended depth of focus IOLs and multifocal IOLs. The lenses are designed to restore a fuller range of near, intermediate, and distance vision as compared to monofocal IOLs. Multifocal IOLs have some limitations which may include halos, glare, and starbursts due to the light scatter that naturally occurs when transitioning between near and distance vision and reduced intermediate (mid-range) vision. (5, 6) Popular Food and Drug Administration (FDA)-approved multifocal IOLs include: Tecnis Multifocal IOL (Johnson & Johnson Vision) and AcrySof IQ ReSTOR (Alcon). (7)

Multifocal IOLs are subdivided into 3 subtypes (6):

- Bifocal Diffractive IOLs: A diffractive IOL that creates two distinct images at near and far.
- Trifocal Diffractive IOLs: Is a presbyopia-correcting IOL. Compared to the bifocal diffractive IOL, the trifocal IOL improves intermediate vision by providing a third focus. However, these IOLs are associated with increased halos and reduced distance visual quality when compared to bifocal diffractive IOLs.
- Refractive IOLs: Function by creating multiple focal points that allow for viewing at all distances as they have multiple zones. Refractive IOLs produce good quality distance, intermediate, and near vision but are limited by pupillary diameter because of the zonal design of the lens.

Multifocal lenses have been shown to increase levels of spectacle independence; however, they may be associated with unwanted photic phenomena such as glare, halos, and photic phenomenon. (10)

Accommodating IOLs

Visual accommodation is the ability of the eye to change the convexity of its lens in order to focus on objects over a range of distances (near and far). Accommodating IOLs are designed to work with the ciliary muscle, which controls the lens of the eye, allowing it to flatten or thicken as needed for distant or near vision. Accommodating IOLs are designed to provide good distance, intermediate, and near vision. Traditionally, accommodating IOLs tend to provide sharper distance vision than multifocal lenses, and multifocal IOLs tend to provide more magnifying power for seeing fine print than accommodating IOLs. (8)

Crystalens accommodative IOL was the first FDA-approved accommodating posterior chamber IOL. Information from the manufacturer suggests this lens reduces the need for postoperative corrective lenses following cataract surgery. (6, 9)

Extended Depth of Focus IOL

Extended depth of focus (EDOF) IOL is similar to multifocal lenses. EDOF lenses sharpen near and far vision, but with only one corrective zone, which “extends” to cover both distances. This may mean less effort to re-focus between distances. (2) This technology is proposed for the treatment of presbyopia. In contrast to multifocal IOLs used in treatment of presbyopia, EDOF

lenses work by creating a single elongated focal point to augment the “depth of focus”. Intermediate vision is improved compared to standard bifocal multifocal IOLs, but near vision may only be modestly improved. Additionally, while patients may have better levels of contrast sensitivity and less ocular aberrations, they may experience visual "starbursts." (6, 10) FDA approved examples include the Tecnis Symfony® IOL (Johnson & Johnson Vision/AMO, ZXR00). Extended depth of focus lenses is unique in that they are neither multifocal nor accommodative IOLs. However, the Tecnis Symfony® is a presbyopia-correcting lens and the Tecnis Symfony® Toric IOL addresses both presbyopia and astigmatism. (6, 11) EDOF lenses have been shown to increase levels of spectacle independence; however, they may be associated with unwanted photic phenomena such as glare, halos, and photic phenomenon. (10)

Toric IOLs

A toric IOL is a “premium” IOL that has different optical power and focal length in two orientations perpendicular to each other; it is used to correct astigmatism in addition to nearsightedness (myopia) and farsightedness (hyperopia). The same type of correction can also be done with eyeglasses or contact lenses. (12) Examples of toric IOLs include, but are not limited to the Tecnis Toric IOL (Abbott Medical Optics) and the AcrySof IQ Toric IOL (Alcon). (12)

Phakic IOLs

Unlike other lenses, phakic lens are not associated with cataract surgery. They are permanently implanted into the eye to reduce a person's need for glasses or contact lenses, without removing the natural lens. They are placed just in front of or just behind the iris while preserving the natural crystalline lens. Phakic IOLs function very similarly to contact lenses. (13) Phakic lenses are approved by the FDA for the correction of nearsightedness (myopia) only and include Visian Implantable Collamer Lens (ICL) (Staar Surgical) and Verisyse/ARTISAN (Abbott Medical Optics). (14, 15)

Light-Adjustable IOLs

A light-adjustable lens (LAL) allows the physician to make small adjustments to the implanted lens during several in-office procedures after the initial surgery to improve visual acuity without glasses. It is intended for patients who have astigmatism before surgery and who do not have macular diseases. The device should not be used in patients taking systemic medication that may increase sensitivity to ultraviolet (UV) light. An FDA-approved example is Light Adjustable Lens™ from RxSight®. (16)

Implantable Miniature Telescope (IMT)

The IMT is a small prosthetic device that when surgically implanted through a corneal incision, it provides an enlarged retinal image to improve the central visual field in patients with moderate to profound visual impairment. The IMT is designed to magnify and project images onto a healthy portion of the retina to allow patients to recognize and identify objects that they could not otherwise see. Only one eye is implanted with the IMT so the remaining eye can maintain peripheral vision to assist in providing spatial orientation and mobility. Visual rehabilitation and occupational therapy are necessary to adapt to the device therefore, it is crucial that appropriate candidates are selected for the treatment. IMT implantation can cause

extensive loss of corneal endothelial cells, resulting in the need for device removal and corneal transplant. To ensure that the risks of IMT implantation are consistently communicated to patients, the FDA and the manufacturer created detailed labeling that includes an Acceptance of Risk and Informed Decision Agreement, which patients must complete prior to IMT implantation. Patients must also have a successful trial with an external telescope prior to device implantation. (17-19)

Regulatory Status

Intraocular Lenses (IOLs)

IOL implants are considered prosthetic devices and regulated by the FDA as Class III devices and are approved through the premarket approval (PMA) process. Refer to the U.S. FDA website at <https://www.fda.gov> for specific IOLs and their FDA approved indication(s). FDA Product codes: HQL, MFK, NAA, POE, MJP.

Implantable Miniature Telescope (IMT)

In July 2010, the FDA approved the IMT (Samsara Vision) to improve vision in patients 75 years and older with stable, severe to profound vision impairment caused by bilateral central scotomas associated with end stage age-related macular degeneration (AMD). Per the FDA label, individuals must meet specific criteria in order to be considered to receive an IMT implant. (17) In 2015, the FDA label was expanded to include patients between the ages of 65 and 74, in addition to those 75 and older. Proprietary names include Implantable Miniature Telescope™ (Models Wide Angle 2.2X and Wide Angle 2.7X). (18, 19) FDA Product code: NCJ.

A second generation IMT device (SING IMT™; Samsara Vision) has been developed, although it has not been FDA approved or cleared for marketing in the U.S. (20)

Rationale

Intraocular Lenses

This medical policy is based on guidance from the Centers for Medicare & Medicaid Services (CMS) and Professional Society Guidelines.

This policy considers standard monofocal intraocular lenses (IOL's) as medically appropriate because they restore basic functional vision after the natural lens is removed. Premium IOLs including multifocal, accommodating, and toric IOLs, offer advanced vision correction across multiple distances (distance, intermediate, and near) and can correct astigmatism. The primary intent of premium IOLs is to reduce or eliminate the patient's dependence on glasses and/or contacts after surgery and typically are considered a lifestyle and/or convenience benefit, not a medical necessity.

CMS National Coverage Determination (NCD)

The core of the CMS NCD 80.12, titled "Intraocular Lenses" indicates that CMS covers the insertion of an monofocal IOL during cataract surgery. CMS does not cover the additional costs

associated with more advanced IOLs, such as multifocal, accommodating, or toric lenses, which correct presbyopia or astigmatism. Individuals can choose these premium lenses but are responsible for the cost difference between the basic (monofocal) IOL and the upgraded lens, as well as any additional charges related to the advanced lens. (21, 22)

Professional Guidelines and Position Statements

American Academy of Ophthalmology (AAO)

The AAO website states IOLs other than monofocal, are referred to as "premium" IOLs and are often recommended to individuals undergoing cataract surgery to decrease the individuals need for glasses and/or contacts following cataract surgery. Multifocal, extended depth of focus (EDOF), toric, light-adjustable lenses and accommodative IOLs are considered premium IOLs as they can reduce the need for glasses or contact lenses. These premium IOLs offer enhanced features beyond single-distance correction, with the goal of reducing or eliminating the need for glasses or contacts. (23)

The AAO 2023 Refractive Surgery Preferred Practice Pattern® under intraocular surgery states (24):

- Lenticular surgery using a variety of IOL implants has also been used to address presbyopia. After the crystalline lens is removed, the IOL can be used to provide functional distance vision as well as near vision through monofocal, aspheric, multifocal, accommodative, extended depth of focus, and light-adjustable IOLs. There are advantages and disadvantages to each of these modalities, and the selection of the specific IOL depends on the patient's visual needs, expectations, motivation to be less dependent on eyeglasses, and willingness to accept potential compromises.
- Presbyopia can be managed by using eyeglasses, contact lenses (multifocal, accommodating or EDOF), topical agents, and refractive surgery.

In 2022, the AAO published a preferred practice pattern for cataracts in the adult eye. (25) The AAO offered the following guidance:

- Intraocular lens implantation is the method of choice for correcting aphakia unless there are specific contraindications. Posterior chamber IOL implantation inside the capsular bag is the optimal method for most cases.
  - Cataract surgeons can choose from a wide variety of posterior chamber IOL styles and materials to find an appropriate lens to match their patients' needs. Intraocular lens optic size, shape, haptic configuration, optic edge design, optic and haptic materials, and chromophore content are engineered with a variety of characteristics.
  - Foldable IOLs are commonly used because of their ability to fit through small incisions, and they have largely replaced rigid polymethyl methacrylate (PMMA) posterior chamber IOLs. Foldable IOLs can be made from silicone, hydrophilic acrylic, and hydrophobic acrylic. Surgeons should be familiar with the unique positive and negative features of each IOL type with regard to material, design, and insertion system.
  - Presbyopia correcting IOLs may improve a patient's quality of life by improving near and intermediate vision and decreasing the need for corrective eyewear after cataract surgery, though patient selection is critical. Patients should be informed of the potential

compromise in quality of vision associated with the various choices. These patients were found to have more glare, halos, and reduced contrast sensitivity than patient with monofocal IOLs (good, strong quality of evidence).

In 2021, the AAO published a technology assessment on multifocal and accommodating IOLs for the treatment of presbyopia. (26) Results include:

- Presbyopia-correcting lenses were effective at improving distance and near visual acuity after cataract surgery.
- Near acuity at different focal lengths was related directly to the effective add power of multifocal and extended depth-of-focus (EDOF) IOLs.
- Most multifocal and EDOF lenses that were compared with a control monofocal lens demonstrated that patient-reported spectacle independence was superior to the monofocal lens.
- All patients who had multifocal and EDOF lenses implanted showed decreased contrast sensitivity and reported more visual phenomena as compared with control participants who received monofocal lenses.

The AAO Preferred Practice Pattern® on Amblyopia (also known as "lazy eye") updated in 2024 provides recommendations to include (27):

- Treatment of refractive error alone can improve visual acuity in children who have untreated anisometropic and strabismic amblyopia. Visual acuity of children who have bilateral refractive amblyopia also can substantially improve with refractive correction alone.
- Most children who have moderate amblyopia (20/40 to 20/80) respond to initial treatment consisting of 2 hours of daily patching or weekend atropine.
- Following treatment of amblyopia caused by strabismus, anisometropia or both combined, continued monitoring and treatment, if needed, is associated with long-term stability of the visual acuity improvement.
- Suitable treatment options for amblyopia may include optical correction, patching, pharmacological treatment, optical treatment, Bangerter (translucent) filters, binocular digital therapy, and/or surgery to treat the cause of amblyopia.

In 2017, the AAO published a clinical statement that states that amblyopia, also known as lazy eye, is a medical condition that is typically a preventable and treatable form of vision loss caused by developmental abnormalities of the brain's vision centers. (28) Unless amblyopia is treated promptly during childhood, permanent structural changes occur in the brain of the amblyopic child, resulting in decreased visual function. Current methods of preschool vision screening can identify risk factors (primarily high levels of refractive error and anisometropia) that, if untreated, increase the likelihood of amblyopia developing. Optical correction (i.e., eyeglasses or contact lenses) may be indicated as a part of amblyopia treatment in addition to other modalities, such as patching and/or pharmacologic treatment. Unless amblyopia is treated during childhood, recovery of vision is rarely achieved.

Implantable Miniature Telescope (IMT)

IMT is based on guidance from the FDA label and professional society guidelines.

In July 2010, the FDA approved the IMT through the premarket approval (PMA) process for the models Wide Angle 2.2X and Wide Angle 2.7X. The initial FDA approval was "for monocular implantation to improve vision in patients greater than or equal to 75 years of age with stable severe to profound vision impairment (best corrected distance VA 20/160 to 20/800) caused by bilateral central scotomas associated with end-stage age-related macular degeneration." The FDA also listed numerous additional conditions and contraindications. In October 2014, the FDA expanded the indication for IMT to allow implantation in patients aged 65 years or older. The current coverage is based on the FDA labeled indications. (17-19)

Per the FDA label, the Implantable Miniature Telescope™ (IMT) is indicated in patients 65 to 74 years of age from the current minimum of 75 years, to revise the professional and patient labeling to update the data based on the results out to 8 years post IMT implantation and to revise the acceptance of risk and informed decision agreement as well as the professional and patient labeling, to emphasize that the longer the IMT is in the eye, the greater the potential risk of developing vision-impairing corneal edema which may lead to the need for corneal transplant and possible telescope removal. The device as modified will be marketed under the trade name Implantable Miniature Telescope™ Models wide angle 2.2X an wide angle 2.7X and is indicated for monocular implantation to improve vision in patients greater than or equal to 65 years of age with stable severe to profound vision impairment (best corrected distance visual acuity 20/160 to 20/800) caused by bilaterial central scotomas associated with end-stage age-related macular degeneration. Patients must:

- Have Retinal findings or geographic atrophy or disciform scar with foveal involvement, as determined by fluorescein angiography;
- Have evidence of visually significant cataract (≥GRADE 2);
- Agree to undergo pre-surgical training and assessment (typically 2-4 sessions) with low vision specialist (optometrist or occupational therapist) in the use of an external telescope sufficient for patient assessment and for the patient to make an informed decision
- Achieve at least a 5 letter improvement on the ETDRS (Early Treatment Diabetic Retinopathy Study) chart with an external telescope;
- Have adequate peripheral vision in the eye not scheduled for surgery; and
- Agree to participate in postoperative visual training with a low vision specialist.

The FDA states the patient should complete the Acceptance of Risk and Informed Decision Agreement prior to IMT implantation. (Because the IMT is a large device, implantation can lead to extensive loss of corneal endothelial cells. Significant losses in corneal endothelial cells may lead to corneal edema, corneal decompensation, and the need for corneal transplant. To ensure that the risks of IMT implantation are consistently communicated to patients, the Food and Drug Administration and the manufacturer created detailed labeling that includes an Acceptance of Risk and Informed Decision Agreement.) (17-19)

<u>Professional Guidelines and Position Statements</u>

National Institute for Health and Clinical Excellence (NICE)
In 2016, NICE (29) published evidence-based recommendations on miniature lens system implantation for advanced age-related macular degeneration (AMD). This involves implanting an artificial lens system into one eye only. "Evidence on the efficacy of miniature lens system implantation for advanced AMD shows that the procedure can improve both vision and quality of life in the short term. Data on short-term safety are available for limited numbers of patients. There is currently insufficient long-term evidence on both efficacy and safety. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research."

American Academy of Ophthalmology (AAO)
In 2024, the AAO published their Preferred Practice Pattern for AMD (30) which recognizes IMT as an FDA-approved device that may be effective for screened, phakic, motivated patients with end-stage AMD.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	0308T, 66985, 66986
HCPCS Codes	C1780, C1840, Q1004, Q1005, S0596, V2630, V2631, V2632, V2787, V2788

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
01/01/2026	Document updated. The following changes were made to Coverage: 1) For Intraocular monofocal lens: a) Modified language to include use of an FDA approved intraocular lens (IOL); and b) Modified language to include specific examples of when a natural IOL may need to be replaced although no change to intent; 2) Added “light adjustable” IOL to the existing not medically necessary statement as an example of a premium lens; 3) Moved statement specific to replacement IOLs to the policy guidelines section; 4) For Implantable miniature telescope criteria: a) Removed “untreatable” end-stage AMD to now state “Patient is 65 years or older with stable severe to profound vision impairment caused by blind spots (bilateral central scotoma) associated with end-stage AMD (age-related macular degeneration); and b) Added “typically 2 to 4 sessions with a low vision specialist or optometrist” to the presurgical training. Added references 3, 13-16, 20-23, 25; others updated and/or removed.
06/15/2024	Document updated with literature review. Coverage unchanged. Added references 2, 4, 5, 11, 12, 14, and 25; others updated, some removed.
07/01/2023	Reviewed. No changes.
01/15/2023	Document updated with literature review. The following change was made in Coverage: Added “Premium intraocular lens implant” to describe intraocular lens other than monofocal lens (i.e., Toric, multifocal, extended depth of focus (EDOF), and/or accommodating lenses) to the existing not medically necessary statement although the overall intent is unchanged. Added references 10, 11, 27, 29 and 30; others updated, some removed.
12/01/2021	Reviewed. No changes.
03/15/2021	Document updated with literature review. The following changes were made in Coverage: 1) Added Note 1: Generally, the treatment of refractive errors is not considered a covered benefit, except under the provisions of a vision benefit contract. Refer to the individual vision benefit contract for coverage details. 2) Expanded medically necessary coverage for monofocal intraocular lens to include 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. 3) Added extended depth of focus (EDOF) intraocular lens as not medically necessary 3) Added replacement of a medically necessary monofocal IOL implant when anatomical change, inflammatory response or mechanical failure renders a previously implanted intraocular lens ineffective or nonfunctional as may be considered medically necessary. 4) Added additional criteria to implantable miniature telescope to include: a) Patient has retinal findings of geographic atrophy or disciform scar with foveal involvement, as determined by fluorescein angiography; and b) Patient has adequate peripheral vision in the eye not scheduled for surgery. 5) Added an intraocular telescope (Implantable Miniature Telescope™) as

	experimental, investigational and/or unproven when all the above criteria are not met. Added references 13, 25-27, 30-33, 39, 40, 42-45, 48, 54; several updated.
01/15/2019	Reviewed. No changes.
01/01/2018	Document updated with literature review. Coverage unchanged. Title changed from Intraocular Lens (IOL).
11/15/2016	Reviewed. No changes.
02/15/2016	Document updated with literature review. The following criterion (age requirement) in the Coverage section was updated: The Implantable Miniature Telescope (IMT) may be considered medically necessary for monocular implantation when the following criteria are met: Patient is 65 years or older with stable severe to profound vision impairment caused by blind spots (bilateral central scotoma) associated with untreatable end-stage AMD (age-related macular degeneration).
09/15/2014	Document updated with literature review. Coverage unchanged.
11/15/2012	The following was added: The Implantable Miniature Telescope (IMT) may be considered medically necessary for monocular implantation when the stated criteria are met. The following was changed: Aspherical monofocal intraocular lenses (IOLs) may be considered medically necessary when used to replace the natural crystalline lens of the eye when the natural lens becomes cataractous; Toric intraocular lenses are considered not medically necessary.
12/15/2011	Document updated with literature review. Coverage unchanged, rationale revised.
10/15/2009	CPT/HCPCS code(s) updated
08/15/2008	CPT/HCPCS code(s) updated
06/01/2008	Coverage Revised
01/01/2008	Codes Revised/Added/Deleted
10/15/2007	Revised/Updated Entire Document
07/15/2005	New medical document