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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
Monofocal (both aspherical and spherical) intraocular lenses (IOLs) **may be considered medically necessary** for **ANY** of the following conditions:

- When used to replace the natural crystalline lens of the eye when the natural lens becomes cataractous; OR
- Trauma to the eye which has damaged the lens; 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), and/or accommodating lenses/IOLs] **are considered not medically necessary.**

Replacement of Intraocular Lens (IOLs)

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 **may be considered medically necessary**.

Implantable Miniature Telescope (IMT)

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 untreatable 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 with an external telescope prior to implantation and has been determined to have adequate improvement in vision, and adequate peripheral vision in the eye that would not be implanted; 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: Patient 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

None.

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 of 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)

Types of Intraocular Lens

Monofocal IOLs

Monofocal lenses 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 contact lenses or eyeglasses after surgery for near vision tasks such as reading. Monofocal IOLs meet the basic functional needs of an individual who undergoes cataract removal. (2, 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) These lenses are considered an optional lens for patients in need of cataract surgery. 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 far 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 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.

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, also referred to as extended range of vision (EROV) IOL, is a new technology 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 are they accommodative IOLs. However, the TECNIS Symfony® is a presbyopia-correcting lens and the TECNIS Symfony® Toric IOL addresses both presbyopia and astigmatism. (6, 11)

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)

U.S. FDA-approved toric IOLs lenses available in the U.S. include but are not limited to the following IOLs: Tecnis Toric (Abbott Medical Optics) and AcrySof IQ Toric (Alcon). (12)

IOLs other than monofocal, are referred to as “premium” or “deluxe” lenses and are often recommended to individuals undergoing cataract surgery in order to decrease the individuals need for glasses and/or contacts following cataract surgery; however, they are considered not medically necessary.

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. (13, 14)

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. (13) 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). (14) 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.

Rationale

This policy was originally developed in 2005 and has been updated with searches of the PubMed database through April 23, 2024. Following is a summary of the key literature to date.

Intraocular Lenses (IOLs)
In 2005, Marshall et al. (16) performed a prospective randomized patient-masked multicenter study, in which 150 patients received the AcrySof Natural IOL and 147 patients received the AcrySof single-piece IOL as a control. Patients with bilateral age-related cataracts who were willing and able to wait at least 30 days between cataract procedures and had verified normal preoperative color vision were eligible for the study. Standardized surgery included a 4.0 to 5.0 mm capsulorhexis and phacoemulsification. All lenses were inserted in the capsular bag, with verification of in-the-bag placement of both haptics. In all bilateral implantation cases, the same model IOL was used in each eye. Postoperatively, contrast sensitivity and color perception were measured up to 180 days and up to 1 year (for visual acuity; VA) after implantation. No statistically significant differences were discovered between the 2 patient groups in VA, contrast sensitivity evaluated under mesopic and photopic conditions, or the number of patients who passed the Farnsworth D-15 color perception test. There were no lens-related adverse events in either group. The study concluded that the blue-light filtering AcrySof Natural IOL is equivalent to the conventional AcrySof lens in terms of postoperative visual performance. Additional long-term clinical studies are needed to determine whether the IOL provides the theoretical benefits to retinal health.

In 2005, Heatley et al. (17) compared the near visual clinical performance of an accommodative IOL with a standard monofocal IOL in a prospective, randomized study. Thirty patients (60 eyes) with bilateral cataracts (but otherwise normal eyes) were recruited from a single university hospital. Patients were randomized to receive either the 1CU accommodative IOL in their first eye or the Acrysof MA30 monofocal IOL. The alternative lens was then implanted in the second eye 4 to 6 weeks later. At all follow-up visits, a full assessment was made of distance, near and reading visual performance, and accommodative amplitude. Data was evaluated in 30 patients at 6 months and 20 patients at 1 year. At 6 months, no difference was noted in distance-corrected VA between the two IOLs. Of the 1CU eyes, 9 patients (30%) could read J6 or better at a reading speed of 80 words/minute or better. In these 9 patients, the mean difference (MD) in the amplitude of accommodation between the 2 eyes was 0.71 diopters. The accommodative IOL appears to produce improved near vision in some eyes, but it does not work in all eyes, and in eyes where there is apparent accommodation, there is a discrepancy between subjective reading performance and the modest measured increase of accommodative amplitude.

In 2010, Takakura et al. (18) conducted a meta-analysis to compare accommodating IOLs and monofocal IOLs in restoring accommodation in cataract surgery. Because of measurement-scale variations, outcomes were pooled for distance-corrected near visual acuity (DCNVA) as standardized MD with 95% confidence intervals [CIs] and anterior displacement of the lens as weighted MD (95% CI). The meta-analysis comprised 12 randomized controlled studies of 727 eyes. The authors reported that, based on 10 studies that compared DCNVA, accommodating IOLs were favored but failed the test of heterogeneity (I(2)=94%). However, pooling only the 6 homogeneous trials (I(2)=43%) showed no difference (standardized MD, -0.16; 95% CI: -0.56 to 0.25). The authors stated that heterogeneity could not be explained by any characteristic of the study population or methodology. Based on 4 studies that evaluated pilocarpine-induced IOL shift, there was a significant anterior compared with the control (weighted MD, 95% CI: -0.36 -0.47 to -0.24), although the studies were heterogeneous (I(2)=58%). Three of 5 studies mentioning posterior capsule opacification (PCO) reported increased rates in the accommodating IOL group postoperatively. The meta-analysis concluded that there was no clear evidence of near acuity improvement with accommodating IOLs compared to monofocal IOLs. Further randomized controlled studies with standardized methods evaluating adverse effects (e.g., posterior capsular opacification) are needed to clarify the trade-offs.

In 2014, Ong et al. (19) stated that following cataract surgery and IOL implantation, loss of accommodation or post-operative presbyopia occurs and remains a challenge. In a metanalysis, investigators defined (i) the extent to which accommodative IOLs improve unaided near visual function, in comparison with monofocal IOLs; (ii) the extent of compromise to unaided distance VA; and (iii) whether a higher rate of additional complications is associated the use of accommodative IOLs. They searched multiple databases and registries through 2013. Randomized controlled trials (RCTs) that compared implantation of accommodative IOLs to implantation of monofocal IOLs in cataract surgery were included in the analysis. Two authors independently screened search results assessed risk of bias and extracted data. All included trials used the 1CU accommodative IOL for their intervention group. One trial had an additional arm with the AT-45 Crystalens accommodative IOL. Investigators performed a separate analysis comparing 1CU and AT-45 IOL. They included 4 RCTs, including 229 participants (256 eyes), conducted in Germany, Italy, and the UK. The age range of participants was 21 to 87 years. All studies included people who had bilateral cataracts with no pre-existing ocular pathologies. These researchers judged all studies to be at high risk of performance bias. They graded 2 studies with high risk of detection bias and 1 study with high risk of selection bias. Participants who received the accommodative IOLs achieved better DCNVA at 6 months (MD -3.10 Jaeger units; 95% CI: -3.36 to -2.83, 2 studies, 106 people, 136 eyes, moderate quality evidence). Better DCNVA was seen in the accommodative lens group at 12 to 18 months in the 3 trials that reported this time-point but considerable heterogeneity of effect was seen, ranging from 1.3 (95% CI: 0.98 to 1.68; 20 people, 40 eyes) to 6 (95% CI: 4.15 to 7.85; 51 people, 51 eyes) Jaeger units and 0.12 (95% CI: 0.05 to 0.19; 40 people, binocular) logMAR improvement (low quality evidence). The relative effect of the lenses on corrected distant visual acuity (CDVA) was less certain. At 6 months there was a standardized MD of -0.04 standard deviations (SD; 95% CI: -0.37 to 0.30, 2 studies, 106 people, 136 eyes, low quality evidence). At long-term follow-up there was heterogeneity of effect with 18-month data in 2 studies showing that CDVA was

better in the mono-focal group (MD 0.12 logMAR; 95% CI: 0.07 to 0.16, 2 studies, 70 people, 100 eyes) and 1 study that reported data at 12 months finding similar CDVA in the 2 groups (-0.02 logMAR units, 95% CI: -0.06 to 0.02, 51 people) (low quality evidence). The relative effect of the lenses on reading speed and spectacle independence was uncertain. The average reading speed was 11.6 words per minute more in the accommodative lens group, but the 95% CI ranged from 12.2 words less to 35.4 words more (1 study, 40 people, low quality evidence). People with accommodative lenses were more likely to be spectacle-independent but the estimate was very uncertain (RR 8.18; 95% CI: 0.47 to 142.62, 1 study, 40 people, very low-quality evidence). More cases of PCO were seen in accommodative lenses but the effect of the lenses on PCO was uncertain (Peto odds ratio (OR) 2.12; 95% CI: 0.45 to 10.02, 91 people, 2 studies, low quality evidence). People in the accommodative lens group were more likely to require laser capsulotomy (Peto OR 7.96; 95% CI: 2.49 to 25.45, 2 studies, 60 people, 80 eyes, low quality evidence). Glare was reported less frequently with accommodative lenses but the relative effect of the lenses on glare was uncertain (RR any glare 0.78; 95% CI: 0.32 to 1.90, 1 study, 40 people, and RR moderate/severe glare 0.45; 95% CI: 0.04 to 4.60, low quality evidence). The authors concluded that there is moderate-quality evidence that study participants who received accommodative IOLs had a small gain in near VA after 6 months. There is some evidence that distance VA with accommodative lenses may be worse after 12 months but due to low quality of evidence and heterogeneity of effect, the evidence for this is not clearcut. People receiving accommodative lenses had more PCO which may be associated with poorer distance vision. However, the effect of the lenses on PCO was uncertain. They stated that further research is needed to improve the understanding of how accommodative IOLs may affect near visual function, and whether they provide any durable gains. Additional trials, with longer follow-up, comparing different accommodative IOLs, multi-focal IOLs and mono-focal IOLs, would help map out their relative efficacy, and associated late complications. Research is needed on control over capsular fibrosis post-implantation. Risks of bias, heterogeneity of outcome measures and study designs used, and the dominance of one design of accommodative lens in existing trials (the HumanOptics 1CU) mean that these results should be interpreted with caution. They may not be applicable to other accommodative IOL designs.

Duman et al. (2015) evaluated the impact of 4 different IOLs on PCO by comparing the Nd:YAG laser capsulotomy rates. (20) This retrospective study included 4,970 eyes of 4,013 cataract patients who underwent phacoemulsification and IOL implantation between January 2000 and January 2008 by the same surgeon at 1 clinic; 4 different IOLs were assessed. The outcome parameter was the incidence of Nd:YAG laser posterior capsulotomies. An Nd:YAG laser posterior capsulotomy was performed in 153 (3.07%) of the 4,970 eyes. The mean follow-up time was 84 months for all the IOL groups. The percentage of eyes developing PCO was significantly greater for the acrylic hydrophilic IOLs than for the hydrophobic IOLs, although eyes with acrylic hydrophilic IOLs did not require Nd:YAG laser capsulotomy as soon as eyes with acrylic hydrophobic IOLs. There was no difference between the long-term PCO rates when 1- and 3-piece acrylic hydrophobic IOLs were compared or when IOLs made of the same material but with different haptic angles were compared. The authors concluded that in this study, eyes with acrylic hydrophilic IOLs were more likely to develop PCO than those with

acrylic hydrophobic IOLs and the lens design (1-piece versus 3-piece and varying haptic angles) did not affect the PCO rate.

In 2016 de Silva et al. (21) stated that good unaided distance VA is now a realistic expectation following cataract surgery and IOL implantation. However, near vision still requires additional refractive power, typically in the form of reading glasses. Multifocal IOLs claim to allow good vision at a range of distances although, it is unclear whether this benefit outweighs the optical compromises inherent in multifocal IOLs. Investigators evaluated the visual effects of multifocal IOLs in comparison with the current standard treatment of mono-focal lens implantation. They searched multiple databases for available studies through 2016. Researchers did not use any date or language restrictions in the electronic searches. In June 2016, all RCTs comparing a multifocal IOL of any type with a monofocal IOL as a control were included. Both unilateral and bilateral implantation trials were also incorporated. They also considered trials comparing multifocal IOLs with "monovision" where 1 eye was corrected for distance vision and 1 eye was corrected for near vision. Researchers used standard methodological procedures and the "certainty" of the evidence was graded. The authors concluded that multifocal IOLs are effective at improving near vision relative to monofocal IOLs although there is uncertainty as to the size of the effect. Whether that improvement outweighs the adverse effects of multifocal IOLs, such as glare and haloes, will vary between people. Also, the motivation to achieve spectacle independence is likely to be the deciding factor.

In 2019, Chang et al. (22) performed a prospective case series in which the authors reported on 36 subjects who had bilateral multifocal IOL implants inserted following cataract surgery or refractive lens exchange. Participants were evaluated post-surgery for VA, visual quality and ease of performance of daily tasks. At the 6-month visit, the mean (± SD) monocular uncorrected VA at 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 daily tasks was evaluated. 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 subjects, glare was reported by 21 subjects, and none of the participants reported double images. There were no intraoperative complications reported. While this study reports on corrected vision following multifocal IOL implantation, the sample size was small, and halo and glare was a common occurrence.

In 2019, a retrospective study by Alfonso and colleagues (23) reported on 40 participants who received a trifocal IOLs and were assessed for far, intermediate, and near VA and distance photopic contrast sensitivity. With a 6-month follow-up, monocular distance Snellen decimal uncorrected distance VA was 0.85 ± 0.19 (ranging from 0.25 to 1.25), and best-corrected visual acuity (BCVA) was 0.94 ± 0.10 (ranging from 0.70 to 1.25). Binocularly, the uncorrected distance VA was 0.95 ± 0.13 (ranging from 0.50 to 1.25) and BCVA was 0.99 ± 0.08 (ranging from 0.80 to

1.25). The near distance monocular Snellen decimal for uncorrected near VA was 0.71 ± 0.10 (ranging from 0.50 to 0.80) and best DCNVA was 0.72 ± 0.10 (ranging from 0.50 to 0.8). Binocularly, the uncorrected near VA was 0.84 ± 0.12 (ranging from 0.63 to 1.00) and best DCNVA 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 VA) 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 small sample size and short follow-up period.

A prospective, 6-month, multicenter, bilateral, randomized, evaluator- and subject-masked clinical trial in which the FDA approval of Technis Symfony IOL was based on compared 148 cataract patients implanted with the Tecnis Symfony IOL to 151 cataract patients implanted with a monofocal IOL. (24) The study evaluated VA at near, intermediate, and far ranges; contrast sensitivity (the ability to distinguish small differences between light and dark); and adverse events for six months after implantation. Of the patients implanted with the Tecnis Symfony IOL, 77 percent had good vision (20/25), without glasses at intermediate distances, compared to 34 percent of those with the monofocal IOL. For near distances, patients with the Tecnis Symfony IOL were able to read two additional, progressively smaller lines on a standard eye chart than those with the monofocal IOL. Both sets of patients had comparable results for good distance vision. Patients implanted with the Tecnis Symfony IOL may experience worsening of or blurred vision, bleeding, or infection. The device may cause reduced contrast sensitivity that becomes worse under poor visibility conditions such as dim light or fog. Some patients may experience visual halos, glare, or starbursts. The device is not intended for use on patients who have had previous trauma to their eye. Additional long-term data with larger sample sizes are warranted to determine the impact on health outcomes.

In 2022, Cho et al. (25) performed a systematic review and meta-analysis that compared outcomes of presbyopia correcting IOLs. This review included 27 RCTs encompassing 2605 participants. Binocular visual outcomes using visual acuity and glare, halo, and spectacle independence were examined. For near distance, trifocal and bifocal diffractive lenses showed higher values than the other lens types. Multifocal IOLs showed better probability than monofocal IOLs. Uncorrected near visual acuity (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. Uncorrected distant visual acuity (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.

UpToDate

In 2024, UpToDate (26) published guidance related to cataracts in adults which states monofocal and multifocal lenses are equally effective at improving distance visual acuity. Multifocal IOLs can result in better uncorrected near vision when compared with monofocal IOLs, but multifocal IOL users report an increase in visual side effects such as glare or haloes. Toric IOLs can reduce or eliminate the need for astigmatism correction with spectacles or contact lenses. Multifocal, accommodative, and toric IOLs are more expensive than monofocal lenses and are typically offered as "premium" lenses as these lenses reduce dependence on the use of glasses.

Guidelines and Position Statements

American Academy of Ophthalmology (AAO)

In 2022 the AAO published a preferred practice pattern for cataracts in the adult eye. (3) The AAO offered the following recommendations:

- 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.

In 2021, the AAO published a technology assessment on multifocal and accommodating IOLs for the treatment of presbyopia. (27) 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.

In 2022, the AAO Preferred Practice Pattern® on Refractive Errors made the following recommendations (28):
Presbyopia can be managed by using eyeglasses, contact lenses (multifocal, accommodating or EDOF), topical agents, and refractive surgery.

The 2024 AAO Preferred Practice Pattern® on Amblyopia (also known as "lazy eye") provides recommendations to include (29):

- 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, 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. (30) 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.

Summary of Evidence: IOLs

Monofocal IOLs are the standard treatment for replacement of the crystalline lens. Both subjective and objective outcomes resulting from the use of varying types of intraocular lens (IOLs) have been reported in the peer-reviewed, published scientific literature (e.g., contrast sensitivity, glare acuity, pain score, up-close, medium range and distance visual acuity). Evidence in the published, peer-reviewed scientific literature generally supports improved visual acuity (VA) resulting in a decreased need for eyeglasses, with the use of premium lenses (i.e., toric, multifocal, extended depth of focus (EDOF), and/or accommodating IOLs). Generally, premium IOLs used primarily for reducing an individual's dependence on additional vision correction (e.g., eyeglasses) are not considered medically necessary as they are predominately for comfort and convenience and additional vision correction may be required after insertion of these premium lenses.

Implantable Miniature Telescope (IMT)

In July 2010, the Food and Drug Administration (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. Following is the key literature to date. (13-15)

In 2006, Hudson et al. (31) evaluated the safety and efficacy of IMT in patients with bilateral, end-stage age-related macular degeneration (AMD). This prospective, open-label, multicenter clinical trial followed 217 patients (mean age, 76 years) with AMD and a moderate to profound bilateral central VA (20/80-20/800) that resulted from bilateral untreatable atrophy, disciform scars, or both. An IMT was implanted monocularly in the capsular bag after lens extraction. Fellow eyes were not implanted to provide peripheral vision and to serve as a control. Study patients participated in 6 visual rehabilitation visits after surgery. Best-corrected distance visual acuity (BCDVA) and best-corrected near visual acuity (BCNVA), quality-of-life scores from the National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) and the Activities of Daily Life scale, ECD, and incidence of complications and adverse events were evaluated. At 1 year, 67% of implanted eyes achieved a 3-line or more improvement in BCDVA versus 13% of fellow eye controls (P<0.0001). Fifty-three percent of implanted eyes achieved a 3-line or more improvement in both BCDVA and BCNVA versus 10% of fellow eyes (P<0.0001). Mean BCDVA and BCNVA improved 3.5 lines and 3.2 lines, respectively, in implanted eyes versus 0.8 lines and 1.8 lines, respectively, in fellow eyes (P<0.0001). Change in visual acuity was not related to lesion type. Mean NEI VFQ-25 scores improved by more than 7 points from baseline (P<0.01) on 7 of 8 relevant subscales. Eleven eyes did not receive the device because of an aborted procedure. Endothelial cell density (ECD) was reduced by 20% at 3 months and 25% at 1 year. The decrease in ECD was correlated with postsurgical edema (P<0.0001), and there was no evidence that endothelial cell loss is accelerated by ongoing endothelial trauma after implantation. This 1-year study concluded that IMT can improve visual acuity and quality of life in patients with moderate to profound visual impairment caused by bilateral, end-stage AMD.

In 2008 Hudson et al. (32) also evaluated the long-term safety and BCVA results with the use of IMT in patients with end-stage AMD. This was a prospective, open-label clinical trial study with fellow-eye controls. Patients with end-stage AMD (bilateral geographic atrophy or disciform scars; BCVA, 20/80 to 20/800) received the telescope prosthesis at 28 centers. Methods were similar to those described in the one-year results, with follow-up visits continuing at 18 and 24 months. Main outcome measures included BCVA change from baseline, ECD and morphometry, and incidence of complications. At 2 years, data from 174 (92.6%) of 188 available patients were reviewed. Overall, 103 (59.5%) of 173 IMT implanted eyes gained 3 lines or more (doubling of visual angle) of BCVA compared with 18 (10.3%) of 174 fellow control eyes (P < .0001). Mean BCVA improved 3.6 lines (SD, 1.9 lines) and 2.8 lines (SD, 2.3 lines) from baseline

in eyes with the 3X and 2.2X device models, respectively. Mean ECD stabilized through 2 years, with 2.4% mean cell loss occurring from 1 to 2 years. There was no significant change in coefficient of variation or percentage of hexagonal endothelial cells from within 6 months to 2 years after surgery. The most common complication was inflammatory deposits. Overall, the long-term results of the IMT showed substantial BCVA improvement at 1 year is also maintained at 2 years.

In 2015 Boyer and colleagues (33) evaluated the long-term results of an IMT in patients with bilateral, end-stage, AMD. A prospective, open-label, multicenter clinical trial with fellow eye controls enrolled 217 patients (mean age 76 years) with AMD and moderate-to-profound bilateral central visual acuity loss (20/80-20/800) resulting from untreatable geographic atrophy, disciform scars, or both. A subgroup analysis was performed with stratification for age (patient age 65 to <75 years [group 1; n=70] and patient age ≥75 years [group 2; n=127]), with a comparative evaluation of change in BCDVA, quality of life, ocular complications from surgery, adverse events, and ECD. Follow-up in an extension study was 60 months. Data were available for 22, 38, and 31 patients in group 1 and 42, 46, and 32 patients in group 2 at 36, 48, and 60 months, respectively. Mean BCDVA improvement from baseline to 60 months was 2.41±2.69 lines in all patients (n=76), with 2.64±2.55 lines in group 1 and 2.09±2.88 lines in group 2. Quality of life scores were significantly higher in group 1. The most common significant surgery-related ocular complications in group 1 were iritis >30 days after surgery (7/70; 10%) and persistent corneal edema (3/70; 4.3%); and in group 2 were a decrease in BCDVA in the implanted eye or IMT removal (10/127 each; 7.9%), corneal edema >30 days after surgery (9/127; 7.1%), and persistent corneal edema (6/127; 4.7%). Significant adverse events included four corneal transplants, comprising two (2.9%) in group 1 and two (1.6%) in group 2. At 60 months, one patient in group 1 (3.2%) and three patients in group 2 (9.4%) had lost ≥2 lines of vision. The IMT was removed in one (1.4%) and ten (7.9%) patients in group 1 and group 2, respectively. Mean ECD loss was 20% at 3 months. Chronic loss was 3% per year. ECD loss was less in group 1 than in group 2 (35% versus 40%, respectively) at 60 months. Long-term results showed substantial retention of improvement in BDCVA. Chronic ECD loss was consistent with that reported for conventional IOLs. The IMT performed as well in group 1 (the younger group) as it did in group 2 through month 60. Younger patients retained more vision than their older counterparts and had fewer adverse events. Although not a specified outcome for this study, patients younger than 65 years also fared better than those in group 2 and retained more vision with fewer adverse events through month 60.

In 2018, Gupta et al. (34) reported on a Cochrane review to assess the effectiveness and safety of the implantable miniature telescope (IMT) in improving visual acuity and quality of life in people with late or advanced AMD. The selection criteria included RCTs and quasi-randomized trials that compared the IMT versus no IMT. The review included four studies; three were non-randomized studies and there was one ongoing RCT that compared the OriLens intraocular telescope with standard low vision training in eyes with end-stage AMD with results for this study expected in 2020. The authors found no RCT or quasi-RCT and noted that they can draw no conclusion about the effectiveness and safety of the IMT in improving visual acuity in individuals with late or advanced AMD. The authors noted that since the IMT is typically

implanted monocularly based upon which eye has better best-corrected distance visual acuity, randomization between eyes within an individual may not be acceptable and studies are needed that compare outcomes between individuals randomized to the device versus individuals not implanted.

Guidelines and Position Statements

National Institute for Health and Clinical Excellence (NICE)

In 2016, NICE (35) published evidence-based recommendations on miniature lens system implantation for advanced 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 2020, the AAO published their Preferred Practice Pattern for AMD (36) which recognizes IMT as an FDA-approved device that may be effective for screened, phakic, motivated patients with end-stage AMD.

Ongoing and Unpublished Clinical Trials

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

Table 1. Key Clinical Trials

NCT No.	Title	Number of Participants	Estimated Date of Completion
NCT01757132	Post-approval Study of VisionCare's IMT (by Dr. Isaac Lipshitz) in Patients with Bilateral Severe to Profound Central Vision Impairment Assoc. With End-stage ARMD (PAS-01)	770 (enrolled by invitation)	Dec 2028

ARMD: Age-related Macular Degeneration No: Number; IMT: Implantable miniature telescope

Summary of Evidence: IMT

Current evidence of published peer reviewed literature is adequate to permit scientific conclusions regarding the short-term safety and efficacy of implantable miniature telescope (IMT) for the diagnosis of age-related macular degeneration (AMD). Additional long term randomized controlled trials (RCTs) with sufficiently large sample sizes are needed for use of IMT outside of the U.S. FDA labelled indications.

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®) ©2023 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 <http://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
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