Anthem

Clinical UM Guideline

Subject: Intraocular Telescope
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Description

This document addresses intraocular telescope devices (for example, the Implantable Miniature Telescope™ [IMT] [Samsara Vision, Inc., Far Hills, NJ]). The IMT is used to improve certain cases of severe to profound vision impairment caused by end-stage, age-related macular degeneration (AMD).

Clinical Indications

Medically Necessary:

An intraocular telescope (for example, the Implantable Miniature Telescope) is considered**medically necessary** for monocular implantation to improve vision in individuals 65 years of age or older when all of the following criteria are met:

The individual must:

- Achieve at least a 5-letter improvement on the Early Treatment Diabetic Retinopathy Study chart with an external telescope in the eye scheduled for surgery; **and**
- Agree to undergo pre-surgery training and assessment (typically 2 to 4 sessions) with low vision specialists (optometrist or occupational therapist) in the use of an external telescope sufficient for assessment and for the individual to make an informed decision; **and**
- Agree to participate in postoperative visual training with a low vision specialist;**and**
- Have adequate peripheral vision in the eye not scheduled for surgery;**and**
- Have retinal findings of geographic atrophy or disciform scar with foveal involvement, as determined by fluorescein angiography; **and**
- Have stable, severe to profound vision impairment (best corrected distance visual acuity 20/160 to 20/800) caused by bilateral central scotomas, associated with end-stage age-related macular degeneration; **and**
- Show evidence of visually significant cataract (Grade 2 or more).

Not Medically Necessary:

An intraocular telescope (for example, the Implantable Miniature Telescope) is considered**not medically necessary** when all of the above criteria are not met.

Coding

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

When services may be Medically Necessary when criteria are met:

CPT

0308T	Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis

HCPCS

C1840	Lens, intraocular (telescopic)

ICD-10 Procedure

08RJ30Z	Replacement of right lens with intraocular telescope, percutaneous approach
08RK30Z	Replacement of left lens with intraocular telescope, percutaneous approach

ICD-10 Diagnosis

H35.30	Unspecified macular degeneration
H35.3110-H35.3194	Nonexudative age-related macular degeneration
H35.3210-H35.3293	Exudative age-related macular degeneration
H53.413	Scotoma involving central area, bilateral

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met or for all other diagnoses not listed.

Discussion/General Information

AMD, a global disease that causes blindness, is becoming increasingly prevalent and has no effective cure (Jager, 2008). AMD affects the macula located in the center of the retina. The macula has the highest photoreceptor concentration and is where visual detail is discerned. Wet AMD occurs with the pathological formation of new blood vessels (angiogenesis) behind the retina. These new blood vessels often leak blood and fluid displacing the macula from its normal position at the back of the eye and distorting central vision as a result. Wet AMD is also known as advanced AMD.

The IMT is currently the only intraocular telescope system that is approved by the U.S. Food and Drug Administration (FDA) (Singer, 2012). This device does not treat AMD directly; it works around the AMD. Incoming images are expanded onto the still functioning

part of the macula. The device is about the size of a pea (3.6 mm diameter; 4.4 mm length) and is surgically inserted through an incision in the cornea, and rotated into place. The IMT has two mirrors that are used to enhance and magnify images. Although photoreceptors in the macular area are damaged by wet AMD, the peripheral photoreceptors remain intact. The purpose of the IMT is to magnify an image so that a much larger picture is projected onto the peripheral retina allowing the peripheral photoreceptors to pick it up, so that the image can be seen by the individual. Only one eye can be implanted so that the other eye serves to pick up peripheral vision. Visual rehabilitation and occupational therapy are necessary to adapt to the device, therefore, it is crucial that appropriate candidates are selected for the treatment. There are also concerns with side effects, such as corneal edema, as well as the need for a corneal transplant (1 out of 25), due to damage caused by the IMT. However, for many age 65 years and older, IMT represents an opportunity to restore vision before it is lost completely.

The FDA approved the IMT in July, 2010 for monocular implantation to improve vision in individuals 75 years of age or older with stable, severe to profound vision impairment caused by bilateral central scotomas associated with end-stage AMD. Approval was granted to VisionCare Ophthalmic Technologies Inc. (Saratoga, California), which is now known as Samsara Vision, Inc. In October 2014, the FDA expanded the age limit for the IMT from 75 to 65 years of age or older.

Additionally, the FDA recommends that individuals:

- have retinal findings of geographic atrophy or disciform scar with foveal involvement, as determined by fluorescein angiography;
- have evidence of visually significant cataract (greater than or equal to Grade 2);
- agree to undergo pre-surgery training and assessment (typically 2 to 4 sessions) with low vision specialists (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 Early Treatment Diabetic Retinopathy Study (ETDRS) chart with an external telescope;
- have adequate peripheral vision in the eye not scheduled for surgery;
- agree to participate in postoperative visual training with a low vision specialist.

The initial FDA approval was based on 1-year results of a prospective, open-label, multi-center clinical trial designed to evaluate the safety and efficacy of the IMT (Hudson, 2006). A total of 217 individuals, 55 to 93 years of age (mean age, 76 years) with AMD and moderate to profound bilateral central visual acuity loss (20/80 to 20/800) resulting from bilateral untreatable geographic atrophy, disciform scars, or both were enrolled. Eleven eyes did not receive the device because the procedure was terminated. The IMT was implanted monocular (in one eye) in the capsular bag after lens extraction. Fellow eyes (contralateral) were not implanted to allow for peripheral vision and served as controls. Study subjects participated in six visual rehabilitation visits after surgery. The majority of those subjects (90%) met or exceeded the visual acuity endpoint defined as an improvement in 2 lines or more in either near or distance best corrected visual acuity (BCVA) at the 1-year follow-up. Change in visual acuity was not related to lesion type. Mean endothelial cell density (ECD) loss at 3 months was 20% and 25% at 12 months. The decrease in ECD was correlated with post-surgical edema, and there was no evidence that endothelial cell loss was accelerated by ongoing endothelial trauma after implantation. The authors concluded that, “The population of patients in this investigation experienced clinically meaningful and statistically significant improvements in both visual acuity and quality of life.”

As a condition of approval, the FDA required the manufacturer, VisionCare Ophthalmic Technologies Inc., to conduct two post-approval studies. In 2008, Hudson and colleagues reported results of follow-up evaluations continuing at 18 and 24 months. Main outcome measures included BCVA change from baseline, ECD and morphometry, and incidence of complications. Data from 174 (92.6%) of 188 available subjects were analyzed. Overall, 103 (59.5%) of 173 telescope-implanted eyes gained 3 lines or more (doubling of visual angle) of BCVA compared with 18 (10.3%) of 174 fellow control eyes ($p<0.0001$). Mean BCVA improved 3.6 lines (standard deviation [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. Long-term results showed that the BCVA improvement demonstrated at 1 year was also maintained at 2 years.

A second post-approval study (Boyer and colleagues, 2015) followed participants to 60 months and reported long-term safety and efficacy outcomes. Additionally explored was whether younger subjects had similar or better outcomes after IMT implantation as compared to the older participants. A total of 2 subgroup analyses were performed consisting of group 1 (n=70; subject age 65 to less than 75 years) and group 2 (n=127; subject age 75 years or older). The mean best corrected distance visual acuity (BCDVA) improvement from baseline to 60 months was 2.41 ± 2.69 lines in all subjects, with 2.64 ± 2.55 lines in group 1 and 2.09 ± 2.88 lines in group 2. At the 60-month final follow-up visit, 62% maintained a significant 2-line BCDVA improvement. Significantly higher quality of life scores and fewer adverse events were reported for group 1. Study limitations included a small number of participants as not all original participants chose to continue in the extension study. The authors also reported that, for a small number of participants initially enrolled (n=20) but too small for inclusion in data analysis, “The IMT performed as well in the 20 patients aged 55-65 years as in those aged 65-75 years.”

Currently available evidence in the peer reviewed literature supports the use of the FDA approved IMT, in terms of clinical effectiveness and safety, to improve severe to profound vision impairment caused by end-stage AMD when specific requirements are met.

Some additional information from the FDA is as follows:

Contraindications per product labeling information (2010):

Implantation of the intraocular telescope is contraindicated in individuals:

- with Stargardt's macular dystrophy;
- with central anterior chamber depth (ACD) < 3.0 mm; measurement of the ACD should be taken from the posterior surface of the cornea (endothelium) to the anterior surface of the crystalline lens;
- with the presence of corneal guttata;
- who do not meet the minimum age and ECD requirements;
- with cognitive impairment that would interfere with the ability to understand and complete the Acceptance of Risk and Informed Decision Agreement or prevent proper visual training/rehabilitation with the device;
- who have evidence of active choroidal neovascularization (CNV) on fluorescein angiography or treatment for CNV within the past six months;
- with any ophthalmic pathology that compromises the patient's peripheral vision in the fellow eye;
- with previous intraocular or cornea surgery of any kind in the operative eye, including any type of surgery for either refractive or therapeutic purposes;

- who have prior or expected ophthalmic-related surgery within 30 days preceding IMT implantation;
- with a history of steroid-responsive rise in intraocular pressure (IOP), uncontrolled glaucoma, or preoperative IOP > 22 mm Hg, while on maximum medication;
- with known sensitivity to post-operative medications;
- who have a history of eye rubbing or an ocular condition that predisposes them to eye rubbing;
- in whom the planned operative eye has:
    - Myopia > 6.0 D
    - Hyperopia > 4.0 D
    - Axial length < 21 mm
    - A narrow angle, i.e., < Schaffer grade 2
    - Cornea stromal or endothelial dystrophies, including guttata
    - Inflammatory ocular disease
    - Zonular weakness/instability of crystalline lens, or pseudoexfoliation
    - Diabetic retinopathy
    - Untreated retinal tears
    - Retinal vascular disease
    - Optic nerve disease
    - A history of retinal detachment
    - Intraocular tumor
    - Retinitis pigmentosa;
- in eyes in which both haptics cannot be placed within the capsular bag during surgery, the intraocular telescope should be removed and replaced with a conventional intraocular lens (IOL); sulcus fixation of either one or both haptics increases the risk of severe endothelial cell loss and corneal transplant.

Warnings per product labeling information (2010) include the following:

- Patients undergoing intraocular telescope implant may be at risk of developing persistent unresolved corneal edema (corneal edema that continues), persistent vision-impairing corneal edema (continuing corneal edema leading to a loss of BCDVA > 2-lines from baseline level at last available visit) and may need corneal transplantation. In up to 5 years of follow-up there were:
    - 10 reports of persistent unresolved corneal edema (cumulative probability 9.2%, 95% confidence interval [CI] 3.3%, 15.1%).
    - 8 reports of persistent vision-impairing corneal edema (cumulative probability 6.8%, 95% CI 2.1%, 11.6%). Persistent vision-impairing corneal edema is a subset of persistent unresolved corneal edema.
    - 5 reports of corneal transplant (cumulative probability 4.1%, 95% CI 0.4%, 7.7%). Corneal transplant is a subset of persistent unresolved corneal edema.
- Only cornea specialists should implant the intraocular telescope. A cornea specialist is an ophthalmologist who had fellowship or other specialty training in diseases and surgery of the cornea and who regularly performs corneal surgical procedures such as penetrating keratoplasty.
- The potential for the device to alter the IOP and long-term risk of glaucoma, anterior synechiae, and pigment dispersion are unknown.
- Surgical difficulties at the time of cataract extraction might increase the potential for complications, including persistent bleeding, significant iris damage, uncontrolled positive pressure, or significant vitreous prolapse or loss.
- Secondary surgical intervention may be necessary and include intraocular telescope repositioning, removal, corneal transplant, or intraocular telescope replacement.
- A small percentage of patients (< 4% in the clinical trial) may be dissatisfied to the point that they request and have the device explanted.
- Thermal lasers should be used with extreme caution around the device and never through the glass optical portion. Accidental focus of the laser beam on any glass part could cause glass fracture.
- Patients must be informed that participation in visual training/rehabilitation is necessary to maximize the benefit of the change in visual status.
- The intraocular telescope protrudes slightly through and above the plane of the iris.
- Patients must be informed that eye rubbing must be avoided due to risk of endothelial cell loss. Patients who are persistent eye rubbers are contraindicated.
- The intraocular telescope restricts the patient's peripheral field. The functional field of view will be generally limited to that of the non-implanted eye.

Another device, the Smaller-Incision New-Generation implantable miniature telescope (SING IMT™ [Samsara Vision, Inc., Far Hills, NJ]) is currently under investigation for use in the United States. However, it has not received FDA approval or clearance for marketing in the U.S.

At this time, published data for the SING IMT device is limited. Toro and colleagues (2023) conducted a non-comparative retrospective study evaluating the safety and efficacy of the device in individuals with disciform scars or geographic atrophy at baseline who had stable but severe to profound vision impairment caused by central scotomas associated with end-stage AMD. The individuals had monocular implantation and were followed for 3 months. The outcomes measured were BCDVA, best-corrected distance near visual acuity (CDNVA), incidence of complications, loss of ECD, IOP, and ACD. A total of 24 subjects were included. Outcomes were measured at baseline and postoperatively at day 1, day 15, month 1, and month 3. All the individuals were Caucasian and ranged between 69-91 years old (median age: 76 years). At baseline, all measured outcomes (BCDVA, CDNVA, IOP, ECD and ACD) were comparable between the study and untreated control eyes. At the 1-month and 3-month follow-ups, the mean ACD in the study eyes was not significantly different from the baseline. Regarding IOP, there was a significant decrease ($p<0.05$) in the study eye group from baseline to the 3-month follow-up, however, no between-group differences were reported. There was a statistically significant increase in the study eye group in regard to CDVA and CDNVA ($p<0.0001$ for all) at the 1- and 3-month follow-ups. The authors reported significant ECD loss in the study eye group, however, no p-values were reported. Compared to baseline in the study eye group, at 1 month post-procedure, average ECD loss was 9.6±13.3% ($p=0.0047$) and 10.4±13.3% at 3 months ($p=0.0025$). During the study period, no device malfunctions were reported. Within 30 days of the surgery, 7 subjects had corneal edema, but they all resolved by 2 months post-procedure with pharmacological treatments. A total of 4 subjects had to undergo surgical repositioning of the device due to iris incarceration or iris prolapse. It was noted that almost 70% of the subjects did not report any adverse events but 14 ocular adverse events were reported in 7 subjects (29.17%). The two most common adverse events were each reported by 3 subjects, and they included distorted pupil and inflammatory deposits on the device. No unexpected adverse events were reported and most of the adverse events were resolved with medical or surgical treatments. The authors note that the individuals will continue to be followed and monitored up to 12 months post-procedure. The limitations of this study include low power due to small sample size, short-term follow-up, the retrospective design, and the fact that all the subjects were Caucasian.

At this time, the available evidence regarding the clinical utility of the SING IMT device is limited. Aside from receiving the necessary

regulatory approval from the FDA, further investigation is needed to establish its place in clinical practice.

Definitions

Age-related macular degeneration (AMD): A disease blurring the sharp, central vision needed for "straight-ahead" activities such as reading, sewing, and driving. AMD affects the macula, the part of the eye used for fine detail. In some cases, AMD advances so slowly that people notice little change in their vision and in others, the disease progresses faster and may lead to a loss of vision in both eyes.

Dry AMD also called atrophic AMD: A form of AMD that involves gradual thinning of the macula which happens in 3 stages: early, intermediate, and late. It usually progresses slowly over several years. Any stage of dry AMD can turn into wet AMD.

Wet AMD also called advanced neovascular AMD: A less common type of late AMD that usually causes faster vision loss. It involves the formation of abnormal blood vessels in the back of the eye that leak causing damage to the macula.

Central scotoma: An area of diminished vision corresponding with the point of fixation and interfering with central vision. More commonly known as a blind spot in the center of vision.

Choroidal neovascularization (CNV): A condition characterized by the development of new blood vessels across the back portion of the eye, which may interfere with vision.

Disciform scar: A subretinal scar, most often located in the macular area of the eye.

External telescope: A hand-held or externally worn telescope used to magnify objects.

Fovea: A pit in the retina of the eye which allows for sharp central vision.

Geographic atrophy: Is considered late-stage dry AMD.

Peripheral vision: Vision outside the center of gaze, on the sides.

References

Peer Reviewed Publications:

1. Boyer D, Freund KB, Regillo C, et al. Long-term (60-month) results for the implantable miniature telescope: efficacy and safety outcomes stratified by age in patients with end-stage age-related macular degeneration. Clin Ophthalmol. 2015; 9:1099-1107.
2. Dunbar HMP, Dhawahir-Scala FE. A discussion of commercially available intra-ocular telescopic implants for patients with age-related macular degeneration. Ophthalmol Ther. 2018; 7(1):33-48.
3. Grzybowski A, Wang J, Mao F, Wang D, Wang N. Intraocular vision-improving devices in age-related macular degeneration. Ann Transl Med. 2020; 8(22):1549.
4. Hudson HL, Lane SS, Heier JS, et al; IMT-002 Study Group. Implantable miniature telescope for the treatment of visual acuity loss resulting from end-stage age-related macular degeneration: 1-year results. Ophthalmology. 2006; 113(11):1987-2001.
5. Hudson HL, Stulting RD, Heier JS, et al; IMT002 Study Group. Implantable telescope for end-stage age-related macular degeneration: long-term visual acuity and safety outcomes. Am J Ophthalmol. 2008; 146(5):664-673.
6. Jager RD, Mieler WF, Miller JW. Age-related macular degeneration. N Engl J Med. 2008; 358(24):2606-2617.
7. Singer MA, Amir N, Herro A, et al. Improving quality of life in patients with end-stage age-related macular degeneration: focus on miniature ocular implants. Clin Ophthalmol. 2012; 6:33-39.
8. Toro MD, Vidal-Aroca F, Montemagni M, et al. Three-month safety and efficacy outcomes for the smaller-incision new-generation implantable miniature telescope (SING IMT™). J Clin Med. 2023; 2(2):518.

Government Agency, Medical Society, and Other Authoritative Publications:

1. American Academy of Ophthalmology (AAO). Preferred Practice Pattern® Guidelines. Age-related macular degeneration. San Francisco, CA: American Academy of Ophthalmology; 2019. For additional information visit the AAO website: http://www.aao.org. Accessed on November 14, 2023.
2. Gupta A, Lam J, Custis P, et al. Implantable miniature telescope (IMT) for vision loss due to end-stage age-related macular degeneration. Cochrane Database Syst Rev. 2018; (5):CD011140.
3. U.S. Food and Drug Administration. Center for Devices and Radiological Health (CDRH). Summary of Safety and Effectiveness. Visioncare Implantable Miniature Telescope. P050034. Rockville, MD: FDA. July 1, 2010. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf5/p050034b.pdf. Accessed on November 14, 2023.

Websites for Additional Information

1. National Eye Institute. U.S. National Institutes of Health. Facts about Age-Related Macular Degeneration. Last updated June 22, 2021. Available at: https://nei.nih.gov/health/maculardegen. Accessed on November 14, 2023.

Index

Age-related macular degeneration (AMD)
Implantable Miniature Telescope (IMT)
Intraocular Implant
Intraocular Telescope
Ocular Telescope Prosthesis
SING IMT

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Revised	11/09/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised MN and NMN statements. Revised Description, Discussion/General Information, Definitions, References, Websites for Additional Information, and Index sections.

Reviewed	11/10/2022	MPTAC review. References were updated.
Reviewed	11/11/2021	MPTAC review. The Definitions and References sections were updated.
Reviewed	11/05/2020	MPTAC review. References were updated. Reformatted Coding section.
Reviewed	11/07/2019	MPTAC review. References were updated.
New	01/24/2019	MPTAC review. Moved content of SURG.00136 Intraocular Telescope to a new clinical utilization management guideline document with the same title. Removed acronyms from the Clinical Indications section. The References section was updated.
