
Medical Policy



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Joint Medical Policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and is therefore subject to change.

***Current Policy Effective Date: 7/1/18**
(See policy history boxes for previous effective dates)

Title: Implantable Miniature Telescope for the Treatment of End-Stage Age-Related Wet Macular Degeneration

Description / Background

Age-related macular degeneration, often called AMD or ARMD, is the leading cause of vision loss and blindness among Americans who are age 65 and older. AMD is caused by degeneration of the macula, which is the part of the retina responsible for the sharp, central vision needed to read or drive. Because the macula is affected in AMD, central vision loss may occur. End-stage AMD is the most advanced form of age-related macular degeneration and results in a loss of central vision, or a blind spot, which is uncorrectable by glasses, drugs or cataract surgery.

There are several methods used in the treatment AMD, including medical and surgical approaches. On July 6, 2010, VisionCare Ophthalmic Technologies, Inc., a developer of advanced visual prosthetic devices, announced that the U.S. Food and Drug Administration (FDA) had approved the company's Implantable Miniature Telescope (IMT), developed by Dr. Isaac Lipshitz, to improve vision in patient 75 years and older with stable, nonfoveal sparing, untreatable, bilateral, age-related macular degeneration (AMD) with severe-to-profound vision impairment (when vision impairment has not changed over time) caused by blind spots (bilateral central scotoma). VisionCare's telescope implant is integral to a new patient care program, CentraSight, for treating patients with end-stage macular degeneration.

According to the VisionCare website, "The implantable telescope technology platform is based on wide-angle micro-optics that, in combination with the optics of the cornea, creates a telephoto system that magnifies objects in view. The telescope implant is surgically placed in the capsular bag after removal of the eye's lens. Implantation inside the eye allows the patient to see using natural eye movements in both stationary and dynamic environments. The implantable telescope technology platform incorporates wide-angle micro-optical lenses in a Galilean telescope design. The device, along with the cornea, enlarges images in front of the eye approximately 2.2 to 2.7 times their normal size, depending on the model of the implant used. The magnification allows central images to be projected onto healthy perimacular areas of the retina instead of the macula alone, where the breakdown of receptors and loss of vision

has occurred. This helps reduce the blind spot and allows the patient to distinguish and discern images that have been unrecognizable or difficult to see.”

The IMT device is surgically implanted in the posterior chamber of the eye after removal of the eye’s lens and is designed to be implanted in one eye only. The implanted eye provides central vision, while the non-implanted eye is used for peripheral vision. The device provides higher resolution images to the central retina and its telephoto effect also allows more to be seen in the central visual field. The device is used for both near and distance activities, with objects being brought into focus by standard spectacles.

Prior to implantation, patients must agree to undergo training with an external telescope with a low vision specialist to determine whether adequate improvement in vision with the external telescope can be obtained and to verify if the patient has adequate peripheral vision in the eye that would not be implanted. Patients must also agree to participate in a post-operative visual training program.

Implantation of the prosthesis is performed under local anesthesia. The natural lens of the eye is removed through a small incision at the limbus (the area where cornea meets the sclera) and the new lens system inserted. The artificial lens systems can consist of miniature telescope prosthesis or a combination of lenses implanted either in the capsular bag of the native lens, or one in front of and one behind the iris. The exact technique for implantation varies according to the system being used. Viscoelastic fluid is used during the implantation process to facilitate the insertion and is then removed by irrigation or aspiration. The eye then processes images according to which lens system is used. If a single lens is used, images in the treated eye are enlarged by the implanted lens system and focused on the macula, while the other eye is used for peripheral vision. If a system of two separate lenses is used, the lenses are rotationally aligned to deflect a magnified image away from the most damaged part of the macular and towards a less damaged area. After the implantation procedure, patients are usually required to undergo a period of visual rehabilitation.

Regulatory Status:

The VisionCare Implantable Miniature Telescope received United States Food and Drug Administration in July 2010 for patients meeting strict patient selection criteria. Effective October 8, 2014, FDA lowered the telescope implant eligible age from 75 to 65 years of age. The device, as modified, will be marketed under the trade name implantable miniature telescope™ (by Dr. Isaac Lipshitz) (IMT) models wide angle 2.2x and 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 bilateral central scotomas associated with end-stage age-related macular degeneration.

Medical Policy Statement

The safety and effectiveness of the implantable miniature telescope for the treatment of end stage, age-related wet macular degeneration have been established. It is a useful therapeutic option for patients meeting specified criteria.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

Inclusions:

The intraocular telescope is indicated for *monocular* implantation to improve vision in patients with age-related wet macular degeneration who meet *all* of the following guidelines as specified by the FDA*:

- Patient must be greater than or equal to 65 years of age (effective 10/8/14)
- Have stable severe to profound vision impairment (best-corrected distance visual acuity 20/160 to 20/800) caused by bilateral central scotoma associated with untreatable end-stage age-related macular degeneration.
- Have retinal findings of geographic atrophy or disciform scar with foveal involvement, as determined by fluorescein angiography
- Have untreatable end-stage, non-exudative, age-related macular degeneration
- Have evidence of visually significant cataract ($\geq$ Grade 2)
- Agree to undergo pre-surgery training and assessment (typically 2 to 4 sessions) with low vision specialists in the use of an external telescope sufficient for patient assessment and for the patient to make an informed decision regarding the potential risks and benefits of the IMT
- Achieve at least 5-letter improvement on the Early Treatment of Diabetic Retinopathy Study (ETDRS) chart with an external telescope during the pre-implant evaluation
- Have adequate peripheral vision in the eye not scheduled for surgery
- Complete and agree to the "Acceptance of risk and informed consent agreement" provided in the device labeling documentation
- Agree to participate in post-implant visual training with a low vision specialist

Exclusions:

- Due to significantly increased risk of corneal endothelial cell loss, patients should not be considered for implantation if they have a minimum endothelial cell density of <2000 for age 65-84, or <1800 for patients 85 or greater, or
- Anterior chamber depths of <3.0 mm, or
- Corneal guttae
- Patients not meeting all selection guidelines above

****Inclusions taken from FDA guidelines.***

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

Established codes:

C1840

0308T

Rationale

In the United Kingdom, the 2008 National Institute for Clinical Excellence (NICE) guidance on implantable miniature lens systems for the treatment of ARMD states that "Evidence on the

efficacy of implantation of miniature lens systems for advanced age-related macular degeneration (AMD) shows that the procedure can improve both vision and quality of life in the short-term. Short-term safety data 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."

The NICE guidance included a non-randomized study and a case series study as part of the evidence review. In the non-randomized study of 217 patients, 67% and 68% of eyes with an implanted lens system improved by three or more lines of best-corrected distance and near visual acuity, respectively, compared with 13% and 33% of non-implanted fellow at 1-year follow-up. Loss of 2 or more lines of best-corrected distance visual acuity was reported in 2% of implanted eyes and nine percent of fellow eyes at 1-year follow-up. Two patients developed corneal decompensation and underwent device removal and corneal transplantation more than one year after the initial surgery and five percent of the procedures were aborted due to complications (e.g., posterior capsule rupture and choroidal effusion and/or hemorrhage). In a case series study of 35 patients (40 eyes), the best-corrected distance visual acuity improved in all patients after a mean of 20 months. Other complications in the non-randomized study and case series study included increased intraocular pressure requiring treatment (28%) and corneal edema (25%). Two specialists reported corneal endothelial cell loss as an adverse event. They considered additional theoretical complications to include corneal decomposition and corneal and macular edema. One specialist advisor commented that the procedure has more risks than standard cataract surgery.

Two-year results from a prospective, multicenter phase 1 and 2 trial of 217 patients were published in November 2008.

AMD patients with moderate to profound bilateral impairment of their central vision received the third generation of the telescope implant, with integrated wide-angle micro-optics, and it greatly improved visual acuity and patient satisfaction rates. The wide-angle feature doubled the field of view when compared with the earlier mid-study results.

Two years after implantation, 60% of telescope-implanted study eyes gained 3 lines or more of visual acuity, compared with 10% of fellow eye controls. The 3x model produced even greater improvement—an average of 3.6 lines. Median visual acuity improvement was more than three lines better in telescope-implanted eyes than fellow eyes undergoing cataract surgery and IOL implantation. Patients with end-stage AMD who have cataract surgery gain mostly peripheral vision, whereas, in this study, the benefits were to central vision. It is assumed that the telescopic device was responsible for this effect.

In March 2009, the FDA Ophthalmic Devices Advisory Panel recommended, with certain conditions, approval of the premarket application for the IMT.

Hudson et al reported on a prospective, open label multi-center clinical trial of VisionCare's IMT-002 evaluated the safety and efficacy of the implant in patients with bilateral, end-stage ARMD. The study enrolled a total of 217 patients with ARMD who had moderate to profound bilateral central visual acuity loss (20/80 to 20/800) resulting from bilateral untreatable geographic atrophy, disciform scars, or both. Eleven eyes did not receive the device because of an aborted procedure. The IMT was implanted in the capsular bag after lens extraction. Study patients participated in 6 visual rehabilitation visits after surgery. Ninety percent met or

exceeded the visual acuity end-point defined as an improvement in 2 lines or more in either near or distance best corrected acuity at the 1-year follow-up. According to the Visual Function Questionnaire provided by the National Eye Institute, mean quality-of-life and the Activities of Daily Life scale improved by more than 7 points from baseline on 7 of 8 relevant subscales. Mean endothelial cell density (ECD) loss at 3 months was 20% and 25% at 12 months. The decrease in ECD was found to be related to post-surgical edema. There was no evidence that endothelial cell loss accelerated by ongoing endothelial trauma after the implant was inserted. The conclusion reached was that the IMT can improve visual acuity and quality of life in patients with moderate-to-profound visual impairment due to bilateral, end-stage ARMD.

An article by Brown et al. in 2011 on the comparative effectiveness and cost effectiveness of the implantable miniature telescope concluded that the insertion of the telescope prosthesis in appropriately selected patients considerably improves quality of life and at the same time is cost-effective. According to the study, the ocular-related direct medical cost savings resulted from not having to treat patients for depression from inability to see, decreased injuries from interference with activities of daily living due to poor vision, and so forth are included in the article. All costs were reported in 2010 US dollars.

In 2015, Boyer and colleagues published a study to evaluate the long-term results of an implantable miniature telescope (IMT) in patients with bilateral, end-stage, age-related macular degeneration. The study enrolled 217 patients with AMD and moderate to profound bilateral central visual acuity loss. A subgroup analysis was performed with stratification for age (patient age 65 to < 75 years [group 1] and patient age $\geq$ 75 years [group 2], with a comparative evaluation of change in best-corrected distance visual acuity (BCDVA), quality of life, ocular complications from surgery, adverse events, and endothelial cell density. Follow-up in an extension study was 60 months.

The authors concluded that the long-term results show substantial retention of improvement in BCDVA. Chronic ECD loss was consistent with that reported for conventional intraocular lenses. The IMT performed as well in group 1 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, the authors found that patients younger than 65 years also fared better than those in group 2 and retained more vision with fewer adverse events through month 60.

Certain patients with end-stage ARMD who have failed all other treatments suffer such severe to profound vision loss such that their quality of life is impaired and their activities are largely curtailed. The implantation of the IMT gives these patients a chance to resume some of their normal activities. In addition, this surgery is likely to be offered to a very small subset of patients due to strict patient selection criteria. Therefore, the implantation of the miniature telescope is a reasonable alternative to total vision loss in patients who meet the patient selection criteria.

Government Regulations

National:

There is no current NCD on the IMT procedure. Centers for Medicare and Medicaid Services (CMS) had granted transitional pass-through payment status and established a billing code for

the Implantable Miniature Telescope under the Hospital Outpatient Prospective Payment System. The new pass-through code, C1840, is effective October 1, 2011 and will enable outpatient facilities to obtain reimbursement for the telescope implant for covered procedures.

Local:

WPS LCD Local Coverage Determination (LCD) for Implantable Miniature Telescope (IMT) (L32792), effective 7/16/12, retired 7/1/13:

Indications:

The intraocular telescope 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 bilateral central scotoma associated with untreatable end-stage age-related macular degeneration.

(***The FDA reduced the age requirement to 65 effective 10/8/14))

Patients must:

- Have retinal findings of geographic atrophy or disciform scar with foveal involvement, as determined by fluorescein angiography
- Have untreatable end-stage, non-exudative, age-related macular degeneration
- Have evidence of visually significant cataract (≥ Grade 2)
- Agree to undergo pre-surgery training and assessment (typically 2 to 4 sessions) with low vision specialists in the use of an external telescope sufficient for patient assessment and for the patient to make an informed decision regarding the potential risks and benefits of the IMT
- Achieve at least 5-letter improvement on the ETDRS chart with an external telescope during the pre-implant evaluation
- Have adequate peripheral vision in the eye not scheduled for surgery
- Complete and agree to the "Acceptance of risk and informed consent agreement" provided in the device labeling documentation
- Agree to participate in post-implant visual training with a low vision specialist

Limitations:

- Due to significantly increased risk of corneal endothelial cell loss, patients should not be considered for implantation if they have a minimum endothelial cell density of <2000 for age 65-84, or <1800 for patients 85 or greater, or
- Anterior chamber depths of <3.0 mm, or
- Corneal guttae

Michigan Department of Health and Human Services (MDHHS):

There is no professional fee available at this time for the insertion of ocular telescope prosthesis including removal of crystalline lens. There is no Medicaid policy on this topic. Reimbursement would be reviewed on an individual consideration basis.

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

Related Policies

- Epiretinal Radiation Treatment for Wet Age-Related Macular Degeneration
 - Photocoagulation of Macular Drusen
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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through December 2017, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
1/1/11	11/8/10	10/27/10	Joint policy established
12/1/12	9/27/12	9/27/12	Policy status changed from experimental/investigational to established. New codes added.
5/1/15	2/17/15	2/27/15	Update of established service. Updated inclusionary criteria to indicate that the patient must be at least 65 years of age (formerly 75). Age change effective 10/8/14.
7/1/16	4/19/16	4/19/16	Routine policy maintenance. Updated references and rationale.
7/1/17	4/18/17	4/18/17	Routine maintenance. No change in policy status.
7/1/18	4/17/18	4/17/18	Routine policy maintenance. Recommend retirement.

Next Review Date: This is an established policy and no longer subject to routine review.

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: IMPLANTABLE MINIATURE TELESCOPE FOR THE TREATMENT OF END-STAGE
WET AGE-RELATED MACULAR DEGENERATION

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; criteria apply
BCNA (Medicare Advantage)	Covered; criteria apply
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

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