Clinical Policy: Implantable Miniature Telescope for Age Related Macular Degeneration

Reference Number: HNCA.CP.MP.517

Coding Implications

Last Review Date: 11/22

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

The implantable miniature telescope (IMT) was the first technology approved by the U.S. FDA on July 6, 2010 for end-stage age related macular degeneration (AMD). The telescopic implant is designed to improve visual acuity by reducing the impact of the central blind spot caused by AMD.

Policy/Criteria

I. It is the policy of Health Net of California that a monocular IMT for individuals ≥ 65 years of age, is **medically necessary** for members for the following indications based on the FDA approval parameters:

A. End Stage AMD when all of the following criteria are met:

1. Other treatments for AMD, including drug therapy no longer help;
2. No previous cataract surgery in the eye in which the telescope will be implanted;
3. Stable, severe to profound vision impairment based on best corrected vision. Snellen visual acuity is 20/160 to 20/800 caused by bilateral central scotomas associated with end-stage AMD;
4. Fluorescein angiography results of geographic atrophy or disciform scar with foveal involvement;
5. Evidence of visually significant cataract (i.e., ≥ grade 2);
6. Adequate peripheral vision in the eye not scheduled for surgery
7. No evidence of active wet AMD;
8. Individual understands and participates in two to four sessions of pre-surgery external telescope training and agrees to participate in postoperative visual training with a low vision specialist;
9. Achieve a five letter improvement on the 'Early Treatment of Diabetic Retinopathy Study' chart with an external telescope
10. There are no contraindications such as Stargardt's macular dystrophy, corneal stromal or endothelial dystrophy, inflammatory ocular disease, diabetic retinopathy, history of retinal detachment, intraocular tumor or retinitis pigmentosa, uncontrolled glaucoma, intraocular tumor.

II. It is the policy of Health Net of California that an IMT is **investigational** for all indications other than those specified above.

Background

AMD affects central vision, is the leading cause of legal blindness in adults ≥ 60, and affects over 10 million people in the U.S. Although an estimated 80% of AMD patients have non-neovascular or atrophic AMD, the neovascular form is responsible for nearly 90% of the severe

central visual acuity loss associated with AMD. The primary risk factors for the development of advanced AMD include increasing age, ethnicity, cigarette smoking and genetic factors.

The IMT is a small telescope that is surgically implanted in the posterior chamber of one eye to replace the natural lens and provides twofold to threefold magnification. It is implanted in one eye, with the nonimplanted eye used for peripheral vision. Due to the risk of corneal endothelial cell loss which may lead to the need or corneal transplant, the patient must meet specific criteria, including adequate peripheral vision before surgery and willingness to enroll in a visual training or rehabilitation program.

The U.S. Food and Drug Administration (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. In October 2014, the FDA expanded the age limit for the IMT from 75 to 65 years of age or older

A multicenter clinical trial enrolled 217 patients (mean age 76 years) with AMD and moderate-to-profound bilateral central visual acuity loss (20/80-20/800). 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 best-corrected distance visual acuity, quality of life, ocular complications from surgery, adverse events, and endothelial cell density (ECD). Follow-up in an extension study was 60 months. Long-term results show substantial retention of improvement in best-corrected distance visual acuity for both groups. Younger patients retained more vision than their older counterparts and had fewer adverse events. ECD loss was less in group 1 than in group 2 (35% versus 40%, respectively). [3]

American Academy of Ophthalmology (AAO)
The 2019 AAO Preferred Practice Patterns guidelines on age-related macular degeneration state that an implantable miniature telescope (IMT) is an FDA-approved device that may be effective for screened, phakic, motivated patients with end-stage AMD.

National Institute for Health and Clinical Excellence
A National Institute for Health and Care Excellence (NICE) guidance for miniature lens system implantation for advanced age-related macular degeneration states that evidence on the efficacy of miniature lens system implantation for advanced age-related macular degeneration (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. (NICE 2016).

Coding Implications
This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2015, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for

informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT® Codes	Description
0308T	Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis

HCPCS Codes	Description
N/A	

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

ICD-10-CM Code	Description
H35.31xx	Nonexudative age-related macular degeneration
H53.411	Scotoma involving central area, left eye
H53.412	Scotoma involving central area, right eye
H53.421	Scotoma of blind spot area, right eye
H53.422	Scotoma of blind spot area, left eye

Reviews, Revisions, and Approvals	Date	Approval Date
Policy Adopted from Health Net NMP #517 Implantable Miniature Telescope Screening for Age Related Macular Degeneration	11/16	11/16
Reviewed – no changes	11/17	11/17
Minor revisions, added references	11/18	11/18
Added contraindications and reference to FDA	11/19	11/19
Updated references, no changes	11/20	11/20
No changes, added information on FDA approval to background	11/21	11/21
No changes	11/22	11/22

References

1. American Academy of Ophthalmology (AAO). Preferred Practice Pattern. Age-Related Macular Degeneration. Update Jan 2015. Available at: http://www.aao.org/preferred-practice-pattern/age-related-macular-degeneration-ppp-2015
2. Arroyo JG. Age Related Macular Degeneration. Treatment and Prevention. UpToDate. 3/1/2016.
3. 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 Jun 17; 9:1099-107.

4. Brown GC, Brown MM, Lieske HB, et al. Comparative effectiveness and cost-effectiveness of the implantable miniature telescope. Ophthalmology. 2011;118(9):1834-1843.
5. Colby KA, Chang DF, Stulting RD, Lane SS. Surgical placement of an optical prosthetic device for end-stage macular degeneration: The implantable miniature telescope. Arch Ophthalmol. 2007;125(8):1118-1121.
6. Falkner CI, Leitich H, Frommlet F, et al. The end of submacular surgery for age-related macular degeneration: A meta-analysis. Graef Archiv Clin Exper Ophthal. 2007;245(4):490-501.
7. Geltzer A, Turalba A, Vedula SS. Surgical implantation of steroids with antiangiogenic characteristics for treating neovascular age-related macular degeneration. Cochrane Database Syst Rev. 2007;(4):CD005022.
8. Hudson HL, Stulting RD, Heier JS, et al. (2008) Implantable Telescope for End-Stage Age-related Macular Degeneration: Long-term Visual Acuity and Safety Outcomes J Ophthalmol, 146:664–673.
9. Lane SS, Kuppermann BD. The implantable miniature telescope for macular degeneration. Curr Opin Ophthalmol. 2006;17(1):94-98.
10. National Institute for Clinical Excellence (NICE). Implantation of miniature lens systems for advanced age-related macular degeneration. Interventional Procedure Guidance 272. London, UK: NICE; August 2008.
11. National Institute for Health and Clinical Excellence (NICE). Miniature lens system implantation for advanced age-related macular degeneration. Interventional procedures guidance [IPG565]. September 2016.
12. Primo SA. Implantable miniature telescope: Lessons learned. Optometry. 2010;81(2):86-93.
13. U.S. Food and Drug Administration (FDA). FDA approves first implantable miniature telescope to improve sight of AMD patients. FDA News Release. Rockville, MD: FDA; July 6, 2010.
14. U.S. Food and Drug Administration (FDA). http://www.accessdata.fda.gov/cdrh_docs/pdf5/P050034b.pdf.
15. VisionCare Ophthalmic Technologies, Inc. VisionCare's implantable miniature telescope (by Dr. Isaac Lipshiz). Professional Use Information. Saratoga, CA: VisionCare Ophthalmic Technologies; 2010.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical

practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs,

and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.