Medical Policy

The Implantable Miniature Telescope (IMT)

Policy Number: PG0351 Last Reviewed Date: 03/01/2025 Last Revised: 03/01/2025 HMO AND PPO ELITE (MEDICARE ADVANTAGE) MARKETPLACE

M PARAMOUNT

GUIDELINES:

- This policy does not certify benefits or authorization of benefits, which is designated by each
 individual policyholder terms, conditions, exclusions, and limitations contract. It does not constitute
 a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific
 policy will supersede this general policy when group supplementary plan document or individual
 plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.

SCOPE:

X Professional

Facility

DESCRIPTION:

Age-related macular degeneration (AMD), a global disease that causes blindness, is becoming increasingly prevalent and has no effective cure. 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 Implantable Miniature Telescope (IMT) is a telescope prosthetic device that replaces the natural lens in one eye of patients with bilateral, advanced age-related macular degeneration (AMD) to enlarge the retinal image to such a degree that it is visualized outside of vision-impairing central scotomas. It does not cure AMD.

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.

POLICY:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

• The Implantable Miniature Telescope (0308T) requires prior authorization for Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans.

COVERAGE CRITERIA:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

The Implantable Miniature Telescope is considered medically reasonable and necessary for monocular implantation to improve vision for patients who meet ALL the following criteria:

- 65 years of age or older; and
- Have stable, severe-to-profound central vision impairment (best corrected distance visual acuity 20/160 to 20/800) caused by blind spots (bilateral central scotoma) associated with end stage AMD as

determined by fluorescein angiography (findings of geographic atrophy or disciform scar with foveal involvement); and

- Evidence of a visually significant cataract (grade 2 or higher); and
- Have adequate peripheral vision in the eye not scheduled for surgery; and
- No active wet AMD (no sign of active choroidal neovascularization in either eye); and
- Have no sign of eye disease other than well controlled glaucoma; and
- Have not been treated for wet AMD in the previous 6 months; and
- Achieve at least a 5-letter improvement on the Early Treatment Diabetic Retinopathy Study (ETDRS) visual acuity chart in the eye scheduled for surgery using an external telescope; and
- Agree to undergo 2 to 4 pre-surgical training sessions with a low vision specialist (optometrist or occupational therapist) in the use of an external telescope sufficient for assessment and for the member to make an informed decision; and
- Agree to participate in postoperative visual rehabilitation with a low vision specialist; and
- Complete and agree to the 'Acceptance of Risk and Informed Consent Agreement' provided in the device labeling documentation.

Limitations:

Implantation of the intraocular telescope is contraindicated in patients:

- 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 endothelial cell density requirements (age 65 to < 70 min. cell density = 2300cells/mm²; age 70 to < 75 min. cell density = 2000 cells/mm²; age 75 or greater min. cell density = 1800 cells/mm²)
- 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 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 intraocular telescope implantation
- with a history of steroid-responsive rise in intraocular pressure, uncontrolled glaucoma, or preoperative IOP > 22 mmHg, 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</p>
 - A narrow angle, i.e., < Schaffer grade 2</p>
 - > 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, history of retinal detachment, retinitis pigmentosa
 - Intraocular tumor
 - Optic nerve disease
- 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
 - actively wet age-related macular degeneration (ARMD)

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CODING/BILLING INFORMATION:

The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

services rendered.		
CPT CODE		
0308T	Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis	
HCPCS CODE		
C1840	Lens, intraocular (telescopic)	
ICD-10 CODES		
H35.3110	Nonexudative age-related macular degeneration, right eye, stage unspecified	
H35.3111	Nonexudative age-related macular degeneration, right eye, early dry stage	
H35.3112	Nonexudative age-related macular degeneration, right eye, intermediate dry stage	
H35.3113	Nonexudative age-related macular degeneration, right eye, advanced atrophic without subfoveal involvement	
H35.3114	Nonexudative age-related macular degeneration, right eye, advanced atrophic with subfoveal involvement	
H35.3120	Nonexudative age-related macular degeneration, left eye, stage unspecified	
H35.3121	Nonexudative age-related macular degeneration, left eye, early dry stage	
H35.3122	Nonexudative age-related macular degeneration, left eye, intermediate dry stage	
H35.3123	Nonexudative age-related macular degeneration, left eye, advanced atrophic without subfoveal involvement	
H35.3124	Nonexudative age-related macular degeneration, left eye, advanced atrophic with subfoveal involvement	
H35.3130	Nonexudative age-related macular degeneration, bilateral, stage unspecified	
H35.3131	Nonexudative age-related macular degeneration, bilateral, early dry stage	
H35.3132	Nonexudative age-related macular degeneration, bilateral, intermediate dry stage	
H35.3133	Nonexudative age-related macular degeneration, bilateral, advanced atrophic without subfoveal involvement	
H35.3134	Nonexudative age-related macular degeneration, bilateral, advanced atrophic with subfoveal involvement	

REVISION HISTORY EXPLANATION: ORIGINAL EFFECTIVE DATE: 11/12/2015

Date	Explanation & Changes
11/12/2015	 Policy created to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
10/28/2016	 Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
10/27/2017	 The Implantable Miniature Telescope (0308T) is now covered with prior authorization for HMO, PPO, & Individual Marketplace Added ICD-10 codes H35.3114 & H35.3124 per CMS guidelines
	 Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
10/25/2018	 Added ICD-10 codes H35.3110, H35.3111, H35.3112, H35.3113, H35.3120, H35.3121, H35.3122, H35.3123, H35.3130, H35.3131, H35.3132, H35.3133, H35.3134 per CMS guidelines
	 Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
12/22/2020	Medical policy placed on the new Paramount Medical Policy Format
02/23/2023	Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023
PC0351_03/01	

03/01/2024	Medical policy reviewed and updated to reflect the most current clinical evidence
03/01/025	 Medical Policy reviewed and updated to reflect the most current clinical evidence

Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to

https://www.paramounthealthcare.com/providers/medical-policies/policy-library

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services <u>https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals</u> <u>Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs</u>

National Physician Fee Schedule Relative Value File Calendar Year XXXX, Centers for Medicare & Medicaid Services (CMS) <u>https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files</u>

NCCI Policy Manual for Medicare Services, current version, Chapter 1, General Correct Coding Policies <u>https://www.cms.gov/files/document/medicare-ncci-policy-manual-2023-chapter-1.pdf</u>

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services https://www.ama-assn.org/amaone/cpt-current-procedural-terminology

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets <u>https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update</u>

Centers for Medicare & Medicaid Services (CMS), ICD-10-CM Official Guidelines for Coding and Reporting <u>https://www.cms.gov/medicare/coding/icd10</u>

Centers of Medicare & Medicaid Services (CMS), Medicare Claims Processing Manual, Chapter 23-Fee Schedule administration and coding Requirements <u>https://www.cms.gov/Regulations-and-Guidance/Manuals/downloads/clm104c23.pdf</u>

Centers for Medicare & Medicaid Services (CMS), National Correct Coding Initiative (NCCI) Policy Manual for Medicare Services <u>https://www.cms.gov/medicare-medicaid-coordination/national-correct-coding-initiative-ncci/ncci-medicare</u>

Center for Medicare and Medicaid Services, Medicare NCCI Medically Unlikely Edits (MUEs) <u>https://www.cms.gov/medicare/coding-billing/national-correct-coding-initiative-ncci-edits/medically-unlikely-edits</u> U.S. Preventive Services Task Force, <u>https://www.uspreventiveservicestaskforce.org/uspstf/</u>

Hayes, Inc., <u>https://www.hayesinc.com/</u>

Industry Standard Review