Implantable Miniature Telescope (IMT)

Policy Number: MMP222.12
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➲ Instructions for Use

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Related Commercial Medical Policy

- Macular Degeneration Treatment Procedures

Coverage Rationale

Overview

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) in order to enlarge the retinal image to such a degree that it is visualized outside of vision-impairing central scotomas.

CMS National Coverage Determinations (NCDs)

Medicare does not have an National Coverage Determination (NCD) for Implantable Miniature Telescope (IMT).

CMS Local Coverage Determinations (LCDs) and Articles

Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for Implantable Miniature Telescope (IMT).

For coverage guidelines for states/territories with no LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Policy titled Macular Degeneration Treatment Procedures.

In addition to utilizing the commercial policy referenced above in states/territories with no LCDs/LCAs, UnitedHealthcare also uses the criteria in that policy to supplement the general Medicare criteria within the WPS jurisdiction regarding when an implantable miniature telescope is reasonable and necessary. UnitedHealthcare uses the criteria noted above in order to ensure consistency in reviewing the conditions to be met for coverage of an implantable miniature telescope, as well as reviewing when such services may be medically necessary. Use of this criteria to supplement the general provisions noted above provides clinical benefits by helping ensure implantable miniature telescopes are not incorrectly denied when medically appropriate for a particular patient nor incorrectly approved when not reasonable and necessary for a patient. The potential clinical harms of using this criteria may include inappropriately denying an implantable miniature telescope when it is otherwise indicated, which could lead to the member not obtaining improvement in their vision. This may impact their functional independence, activities of daily living, and overall quality of life. The clinical benefits of using this criteria are highly likely to outweigh any clinical harms, including from delayed or decreased access to services, because the criteria is unlikely to lead to circumstances where implantable miniature telescopes are inappropriately denied. In addition, use of the criteria may decrease inappropriate denials by creating a consistent set of review criteria and will provide clinical benefits in helping ensure that the patient obtains an appropriate surgical procedure for the requested indication. Further, use of the criteria should limit the circumstances where implantable miniature telescopes are incorrectly approved, which itself provides benefits because it prevents unnecessary development of adverse events (e.g. ocular complications from surgery, device explant, and malfunction). Additionally, patients undergoing intraocular telescope implant may be at risk of developing persistent unresolved corneal edema (edema that continues), persistent vision impairing corneal edema (continuing corneal edema leading to a loss of best corrected distance visual acuity (BCDVA) > 2-lines from baseline level at last available visit) and may need corneal transplantation.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

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

CPT® is a registered trademark of the American Medical Association

HCPCS Code	Description
C1840	Lens, intraocular (telescopic)

Diagnosis Code	Description
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
H35.3123	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
H35.3133	Nonexudative age-related macular degeneration, bilateral, advanced atrophic without subfoveal involvement
H35.3134	Nonexudative age-related macular degeneration, bilateral, advanced atrophic with subfoveal involvement

Centers for Medicare and Medicaid Services (CMS) Related Documents

After checking the table below and searching the Medicare Coverage Database, if no NCD, LCD, or LCA is found, refer to the criteria as noted in the Coverage Rationale section above.

NCD	LCD	Article	Contractor Type	Contractor Name
Implantable Miniature Telescope (IMT)				
N/A	L35490 Category III Codes	A56902 Billing and Coding: Category III Codes	Part A and B MAC	WPS*
	N/A	A53501 Billing and Coding: Implantable Miniature Telescope (IMT) for Macular Degeneration	Part B MAC	Palmetto

Medicare Administrative Contractor (MAC) with Corresponding States/Territories	
MAC Name (Abbreviation)	**States/Territories**
CGS Administrators, LLC (CGS)	KY, OH
First Coast Service Options, Inc. (First Coast)	FL, PR, VI
National Government Services, Inc. (NGS)	CT, IL, ME, MA, MN, NH, NY, RI, VT, WI
Noridian Healthcare Solutions, LLC (Noridian)	AS, AK, AZ, CA, GU, HI, ID, MT, NV, ND, Northern Mariana Islands, OR, SD, UT, WA, WY
Novitas Solutions, Inc. (Novitas)	AR, CO, DE, LA, MD, MS, NJ, NM, OK, PA, TX, DC

Medicare Administrative Contractor (MAC) with Corresponding States/Territories	
MAC Name (Abbreviation)	**States/Territories**
Palmetto GBA (Palmetto)	AL, GA, NC, SC, TN, VA, WV
Wisconsin Physicians Service Insurance Corporation (WPS)*	IA, IN, KS, MI, MO, NE
*__Note__: Wisconsin Physicians Service Insurance Corporation Contract Number 05901 applies only to WPS Legacy Mutual of Omaha MAC A Providers	

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Implantable Miniature Telescope

The Implantable Miniature Telescope (IMT) received FDA approval, effective July 1, 2010. This device is indicated 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 visual acuity 20/160 to 20/800) caused by bilateral central scotomas associated with end-stage age-related macular degeneration. In October 2014, the FDA expanded the age limit for IMT to 65 years of age or older.

According to the FDA's indications for use of the Implantable Miniature Telescope, patients must:

- Have retinal findings of geographic atrophy or disciform scar with foveal involvement, as determined by fluorescein angiography.
- Have evidence of visually significant cataract (greater 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.

According to the FDA approval letter, a post-approval requirement indicates that the manufacturer must 1) continue follow-up on the patients from its long-term cohort study to provide additional long-term (up to 8 years) safety data and 2) must conduct an additional study of 770 newly enrolled patients to evaluate adverse events for 5 years after implantation. Refer to the following website for more information at: https://www.accessdata.fda.gov/cdrh_docs/pdf5/P050034a.pdf. (Accessed April 16, 2024)

According to the FDA's Summary of Safety and Effectiveness Data (2010), the IMT is contraindicated in patients with any of the following:

- Stargardt's macular dystrophy.
- 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.
- The presence of corneal guttata.
- The minimum age and endothelial cell density requirements are not met.
- 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.
- Evidence of active choroidal neovascularization (CNV) on fluorescein angiography or treatment for CNV within the past six months.
- Any ophthalmic pathology that compromises the patient's peripheral vision in the fellow.
- Previous intraocular or cornea surgery of any kind in the operative eye, including any type of surgery for either refractive or therapeutic purposes.
- Prior or expected ophthalmic related surgery within 30 days preceding intraocular telescope implantation.
- A history of steroid-responsive rise in intraocular pressure, uncontrolled glaucoma, or preoperative intraocular pressure greater than 22 mm Hg, while on maximum medication.
- Known sensitivity to post-operative medications.
- A history of eye rubbing or an ocular condition that predisposes them to eye rubbing.
- The planned operative eye has:

- Myopia greater than 6.0 diopters.
- Hyperopia greater than 4.0 diopters.
- Axial length less than 21 mm.
- A narrow angle (i.e., less than 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.

Refer to the following website for more information at: https://www.accessdata.fda.gov/cdrh_docs/pdf5/P050034b.pdf. (Accessed April 16, 2024)

Policy History/Revision Information

Date	Summary of Changes
07/01/2024	**Title Change/Template Update** • Previously titled *Ocular Telescope* • Reformatted and reorganized policy; transferred content to new template • Changed policy type classification from “Policy Guideline” to “Medical Policy” • Added *FDA* section • Updated *Instructions for Use* **Related Policies** • Added reference link to the UnitedHealthcare Commercial Medical Policy titled *Macular Degeneration Treatment Procedures* • Removed reference link to the UnitedHealthcare Medicare Advantage Policy Guideline titled *Category III CPT Codes* **Coverage Rationale** • Removed language indicating 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; 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 Early Treatment Diabetic Retinopathy Study (ETDRS) chart with an external telescope during the pre-implant evaluation ○ 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 ***Centers for Medicare & Medicaid (CMS) National Coverage Determinations (NCDs)*** • Added language to indicate Medicare does not have a National Coverage Determination (NCD) for Implantable Miniature Telescope (IMT) ***CMS Local Coverage Determinations (LCDs) and Articles*** • Added language to indicate:

Date	Summary of Changes
	○ Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable; for specific LCDs/LCAs, refer to the table [in the *CMS Related Documents* section of the policy] ○ For coverage guidelines for states/territories with no LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Policy titled *Macular Degeneration Treatment Procedures* ○ In addition to utilizing the commercial policy referenced above in states/territories with no LCDs/LCAs, UnitedHealthcare also uses the criteria in that policy to supplement the general Medicare criteria within the Wisconsin Physicians Service Insurance Corporation (WPS) jurisdiction regarding when an implantable miniature telescope is reasonable and necessary ○ UnitedHealthcare uses the criteria noted above: ▪ In order to ensure consistency in reviewing the conditions to be met for coverage of an implantable miniature telescope, as well as reviewing when such services may be medically necessary ▪ To supplement the general provisions noted above provides clinical benefits by helping ensure implantable miniature telescopes are not incorrectly denied when medically appropriate for a particular patient nor incorrectly approved when not reasonable and necessary for a patient ○ The potential clinical harms of using this criteria may include inappropriately denying an implantable miniature telescope when it is otherwise indicated, which could lead to the member not obtaining improvement in their vision; this may impact their functional independence, activities of daily living, and overall quality of life ○ The clinical benefits of using this criteria are highly likely to outweigh any clinical harms, including from delayed or decreased access to services, because the criteria is unlikely to lead to circumstances where implantable miniature telescopes are inappropriately denied; in addition, use of the criteria may decrease inappropriate denials by creating a consistent set of review criteria and will provide clinical benefits in helping ensure that the patient obtains an appropriate surgical procedure for the requested indication ▪ Further, use of the criteria should limit the circumstances where implantable miniature telescopes are incorrectly approved, which itself provides benefits because it prevents unnecessary development of adverse events (e.g., ocular complications from surgery, device explant, and malfunction) ▪ Additionally, patients undergoing intraocular telescope implant may be at risk of developing persistent unresolved corneal edema (edema that continues), persistent vision impairing corneal edema (continuing corneal edema leading to a loss of best corrected distance visual acuity (BCDVA) > 2-lines from baseline level at last available visit) and may need corneal transplantation **CMS Related Documents** • Updated list of documents available in the *Medicare Coverage Database* to reflect the most current information **Supporting Information** • Archived previous policy version MPG222.11

Instructions for Use

The Medicare Advantage Policy documents are generally used to support UnitedHealthcare coverage decisions. It is expected providers retain or have access to appropriate documentation when requested to support coverage. This document may be used as a guide to help determine applicable:

- Medical necessity coverage guidelines; including documentation requirements, and/or
- Medicare coding or billing requirements.

Medicare Advantage Policies are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates. This Policy is provided for informational purposes and does not constitute medical advice. It is intended to serve only as a general reference and is not intended to address every aspect of a clinical situation. Physicians and patients should not rely on this information in making health care decisions. Physicians and patients must exercise their independent clinical discretion and judgment in determining care. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes this policy. For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.

Medicare Advantage Policies are developed as needed, are regularly reviewed, and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policies at any time by publishing a new version on this website. Medicare source materials used to develop these policies may include, but are not limited to, CMS statutes, regulations, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and manuals. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. The information presented in this Policy is believed to be accurate and current as of the date of publication. Where there is a conflict between this document and Medicare source materials, the Medicare source materials apply. Medicare Advantage Policies are the property of UnitedHealthcare. Unauthorized copying, use, and distribution of this information are strictly prohibited.

You are responsible for submission of accurate claims. Medicare Advantage Policies are intended to ensure that coverage decisions are made accurately. UnitedHealthcare Medicare Advantage Policies use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

For members in UnitedHealthcare Medicare Advantage plans where a delegate manages utilization management and prior authorization requirements, the delegate’s requirements need to be followed.