

LCD - Implantable Miniature Telescope (IMT) (L33584)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
National Government Services, Inc.	MAC - Part A	06101 - MAC A	J - 06	Illinois
National Government Services, Inc.	MAC - Part B	06102 - MAC B	J - 06	Illinois
National Government Services, Inc.	MAC - Part A	06201 - MAC A	J - 06	Minnesota
National Government Services, Inc.	MAC - Part B	06202 - MAC B	J - 06	Minnesota
National Government Services, Inc.	MAC - Part A	06301 - MAC A	J - 06	Wisconsin
National Government Services, Inc.	MAC - Part B	06302 - MAC B	J - 06	Wisconsin
National Government Services, Inc.	A and B and HHH MAC	13101 - MAC A	J - K	Connecticut
National Government Services, Inc.	A and B and HHH MAC	13102 - MAC B	J - K	Connecticut
National Government Services, Inc.	A and B and HHH MAC	13201 - MAC A	J - K	New York - Entire State
National Government Services, Inc.	A and B and HHH MAC	13202 - MAC B	J - K	New York - Downstate
National Government Services, Inc.	A and B and HHH MAC	13282 - MAC B	J - K	New York - Upstate
National Government Services, Inc.	A and B and HHH MAC	13292 - MAC B	J - K	New York - Queens
National Government Services, Inc.	A and B and HHH MAC	14111 - MAC A	J - K	Maine
National Government Services, Inc.	A and B and HHH MAC	14112 - MAC B	J - K	Maine
National Government Services, Inc.	A and B and HHH MAC	14211 - MAC A	J - K	Massachusetts
National Government Services, Inc.	A and B and HHH MAC	14212 - MAC B	J - K	Massachusetts

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
National Government Services, Inc.	A and B and HHH MAC	14311 - MAC A	J - K	New Hampshire
National Government Services, Inc.	A and B and HHH MAC	14312 - MAC B	J - K	New Hampshire
National Government Services, Inc.	A and B and HHH MAC	14411 - MAC A	J - K	Rhode Island
National Government Services, Inc.	A and B and HHH MAC	14412 - MAC B	J - K	Rhode Island
National Government Services, Inc.	A and B and HHH MAC	14511 - MAC A	J - K	Vermont
National Government Services, Inc.	A and B and HHH MAC	14512 - MAC B	J - K	Vermont

LCD Information

Document Information

LCD ID

L33584

LCD Title

Implantable Miniature Telescope (IMT)

Proposed LCD in Comment Period

N/A

Source Proposed LCD

[DL33584](#)

Original Effective Date

For services performed on or after 10/01/2015

Revision Effective Date

For services performed on or after 10/10/2019

Revision Ending Date

N/A

Retirement Date

N/A

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Notice Period Start Date

09/16/2016

Notice Period End Date

10/31/2016

CMS National Coverage Policy

Language quoted from Centers for Medicare and Medicaid Services (CMS), National Coverage Determinations (NCDs) and coverage provisions in interpretive manuals is italicized throughout the policy. NCDs and coverage provisions in interpretive manuals are not subject to the Local Coverage Determination (LCD) Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See Section 1869(f)(1)(A)(i) of the Social Security Act.

Unless otherwise specified, *italicized* text represents quotation from one or more of the following CMS sources:

Title XVIII of the Social Security Act (SSA):

Section 1862(a)(1)(A) excludes expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Section 1833(e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

CMS Publications:

CMS Transmittal No. 2479, Publication 100-04, *Medicare Claims Processing Manual*, Change Request #7854, May 25, 2012, provides billing instructions for HCPCS codes C1840 and 0308T and the deletion of HCPCS code C9732 under the Ambulatory Surgery Center (ASC) Payment System.

CMS Transmittal No. 2481, Publication 100-04, *Medicare Claims Processing Manual*, Change Request #7844, June 1, 2012 includes CPT code 0308T for an insertion of an ocular telescope prosthesis including removal of crystalline lens which is effective for service performed on or after July 1, 2012.

CMS Transmittal No. 2483, Publication 100-04, *Medicare Claims Processing Manual*, Change Request #7847, June 8, 2012, provides billing instructions for HCPCS codes C1840 and 0308T and the deletion of HCPCS code C9732 under the Hospital Outpatient Prospective Payment System (OPPS).

CMS Transmittal No. 2378, Publication 100-04, *Medicare Claims Processing Manual*, Change Request #7682, December 29, 2011, provides billing instructions for HCPCS codes C1840 and C9732 under the Ambulatory Surgery Center (ASC) Payment System.

CMS Transmittal No. 2376, Publication 100-04, *Medicare Claims Processing Manual*, Change Request #7672, December 29, 2011, provides billing instructions for HCPCS codes C1840 and C9732 under the Hospital Outpatient Prospective Payment System (OPPS).

Coverage Guidance**Coverage Indications, Limitations, and/or Medical Necessity**

Abstract:

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

After review of available peer-reviewed literature, National Government Services has determined that appropriate utilization of the IMT in patients who meet all of the indications detailed below may be payable by Medicare.

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.

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:

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 = 2300 cells/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 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:
 - o Myopia > 6.0 D, Hyperopia > 4.0 D
 - o Axial length < 21 mm
 - o A narrow angle, i.e., < Schaffer grade 2
 - o Cornea stromal or endothelial dystrophies, including guttata
 - o Inflammatory ocular disease
 - o Zonular weakness/instability of crystalline lens, or pseudoexfoliation
 - o Diabetic retinopathy, untreated retinal tears, retinal vascular disease, history of retinal detachment, retinitis pigmentosa
 - o Intraocular tumor
 - o 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)

Other Comments:

The U.S. Food and Drug Administration (FDA) labeling specifies that a cornea specialist perform the IMT, because they are the ophthalmic surgical specialty with the additional surgical training required for advanced corneal procedures such as cornea transplants.

Prior to performing IMT, surgeons must participate in the required portion of the Physician Training Program provided by the device manufacturer.

National Government Services expects adequate follow-up of these patients (to include post-operative follow-up and rehabilitation services) to assure the best possible results for these patients. National Government Services anticipates this may require both short-term and long-term record review.

Summary of Evidence

N/A

Analysis of Evidence (Rationale for Determination)

N/A

General Information

Associated Information

N/A

Sources of Information

This bibliography presents those sources that were obtained during the development of this policy. National

Government Services is not responsible for the continuing viability of Web site addresses listed below.

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U.S. Food and Drug Administration News Release dated July 6, 2010.
<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm218066.htm>. Accessed 12/29/2011.

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VisionCare™ Ophthalmic Technologies Implantable Miniature Telescope (by Dr. Issac Lipshitz) for End-Stage Macular Degeneration Indications for Use/Contraindications Document #10025096 Rev 2 11/2014.

Bibliography

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
10/10/2019	R5	Consistent with Change Request 10901, all coding information, National coverage provisions, and Associated Information (Documentation Requirements, Utilization Guidelines) have been removed from the LCD and placed in the related Billing and Coding Article, A57411. There has been no change in coverage with this LCD revision.	<ul style="list-style-type: none"> Revisions Due To Code Removal
11/01/2016	R4	<p>This LCD was revised and returned to Jurisdiction 6 and Jurisdiction K for public and CAC comment from 06/30/2016 through 08/13/2016.</p> <p>The limitations were revised to align with the contraindications in the latest manufacturer's document dated November 2014.</p> <p>The latest manufacturer's document was added to the "Sources of Information and Basis for Decision" section.</p> <p>ICD-10-CM code H35.32 along with the corresponding explanatory note was removed from the "ICD-10-CM Codes that Support Medical Necessity" section.</p> <p>Due to the annual ICD-10-CM code update for 2017, ICD-10-CM code H35.31 was deleted from the "ICD-10-CM Codes that Support Medical Necessity" section of the LCD. ICD-10-CM codes H35.3114 and H35.3124 were added as the replacement codes.</p>	<ul style="list-style-type: none"> New/Updated Technology Revisions Due To ICD-10-CM Code Changes
01/01/2016	R3	The terminology for CPT code 0308T was revised.	<ul style="list-style-type: none"> Revisions Due To CPT/HCPCS Code Changes
10/01/2015	R2	Minor template language change.	<ul style="list-style-type: none"> Other
10/01/2015	R1	Effective October 8, 2014, Food and Drug Administration (FDA) has lowered the telescope implant eligible age from 75 to 65 years of age. The indication has been revised to reflect this change. The updated Premarket Approval (PMA)	<ul style="list-style-type: none"> New/Updated Technology

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		Supplement dated October 8, 2014 was added to the "Sources of Information and Basis for Decision" section.	

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Articles

[A57411 - Billing and Coding: Implantable Miniature Telescope \(IMT\)](#)

[A55261 - Response to Comments: Implantable Miniature Telescope \(IMT\)](#)

Related National Coverage Documents

N/A

Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS
10/04/2019	10/10/2019 - N/A	Currently in Effect (This Version)
Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.		

Keywords

- Eye
- Blindness