



MEDICAL COVERAGE GUIDELINES
SECTION: VISION

ORIGINAL EFFECTIVE DATE: 04/16/13
LAST REVIEW DATE: 03/18/14
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

IMPLANTABLE MINIATURE TELESCOPE FOR TREATMENT OF AGE-RELATED MACULAR DEGENERATION

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Implantable Miniature Telescope™ (IMT):

Implantable miniature lens system magnifies images and projects them onto a healthy part of the retina that can still see images. IMT has been investigated to improve vision in end-stage age-related macular degeneration.

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IMPLANTABLE MINIATURE TELESCOPE FOR TREATMENT OF AGE-RELATED MACULAR DEGENERATION (cont.)

Description: (cont.)

Age-Related Macular Degeneration (AMD):

Gradual painless loss of central vision due to a breakdown of a portion of the retina known as the macula.

The non-neovascular form (also known as dry, nonexudative, or atrophic) is more common and progresses slowly, characterized by the accumulation of small, yellowish deposits called drusen that form within the layers of the retina. Non-neovascular AMD may suddenly develop into neovascular AMD.

The neovascular form (also known as wet, exudative or disciform) is characterized by choroidal neovascularization, the proliferation of fine blood vessels at the back of the eye that begin to leak or exude fluid, causing hemorrhage, swelling and scar tissue which may result in permanent central vision loss within days or weeks.

Criteria:

Implantable Miniature Telescope:

- Implantable Miniature Telescope for the treatment of age-related macular degeneration is considered ***experimental or investigational*** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 4. Insufficient evidence to support improvement outside the investigational setting.

Resources:

1. Hudson HL, Lane SS, Heier JS, et al. Implantable miniature telescope for the treatment of visual acuity loss resulting from end-stage age-related macular degeneration: 1-year results. *Ophthalmology*. 2006 Nov 2006;113(11):1987-2001.

FDA Premarket Approval Information for Implantable Miniature Telescope:

- FDA-approved indication: 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.