Medical Coverage Policies

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Epiretinal Radiation Therapy for Age-Related Macular Degeneration

EFFECTIVE DATE 07/21/2009 LAST UPDATED 08/03/2010

Description:

Epiretinal radiation describes the administration of radiation to the choroidal vascular bed of the retina to treat age-related macular degeneration (AMD). AMD is characterized in its earliest stages by minimal visual impairment and the presence of large drusen and other pigmentary abnormalities. Two distinctively different forms of degeneration may be observed. The first, called the atrophic or areolar or dry form, evolves slowly. Atrophic AMD is the most common form of degeneration and may be a precursor of the more visually impairing exudative neovascular form, also referred to as disciform or wet AMD. The wet form is distinguished from the atrophic form by the development of choroidal neovascularization (CNV) and serous or hemorrhagic detachment of the retinal pigment epithelium. Risk of developing severe irreversible loss of vision is greatly increased by the presence of CNV.

The Epi-Rad90[™] Ophthalmic System is an epiretinal radiation delivery device developed to treat wet AMD. Using a standard vitrectomy procedure, the cannula tip of a handheld (pipette-like) surgical device is inserted into the vitreous cavity and positioned under visual guidance over the target lesion. The radiation source (strontium-90) is advanced down the cannula until it reaches the tip, which is then held in place over the lesion for a "prescribed" time to deliver focused radiation. The system is designed to deliver a one-time peak dose of beta particle energy (24 Gy) for a target area 3 mm in depth and up to 5.4 mm in diameter. This is below the dose that is toxic to the retina and optic nerve, and radiation exposure outside of the target area is expected to be minimal. An investigational device exemption (IDE) has been granted by the U.S. Food and Drug Administration (FDA) for a phase III multicenter trial to provide data for application to the FDA; this is a category B procedure.

Epiretinal radiation therapy for all uses is considered not medically necessary due to lack of peerreviewed publications.

Medical Criteria:

Not applicable.

Policy:

Epiretinal radiation therapy for age-related macular degeneration is considered **not medically necessary** as there is insufficient clinical evidence to support its efficacy.

Coverage:

Benefits may vary between groups and contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement, or RIte Care contract for the applicable *Services Not Medically Necessary* benefits/coverage.

Coding:

The following CPT category III code is considered not medically necessary:

0190T

Published:

Provider Update, October 2009 *Provider Update,* October 2010

References:

American Academy of Ophthalmology (AAO). Age-related macular degeneration. Site referenced on 6/14/10: <u>http://one.aao.org/SearchResults.aspx?q=age%20related%20macular%20</u> <u>degeneration&t=o&type=0</u>.

Stevenson MR, Hart PM, Chakravarthy U, MacKenzie G, Bird AC, Owens SL, Chisholm IH, Houston RF, McCulloch DW, Plowman N. *Visual functioning and quality of life in the SubFoveal Radiotherapy Study (SFRADS): SFRADS report 2.* British Journal of Ophthalmology;2005;89:1045–1051.

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