Medical Coverage Policy | Intraocular Radiotherapy for Age-Related Macular Degeneration

EFFECTIVE DATE: 12|01|2022
POLICY LAST REVIEWED: 03/20/2024

OVERVIEW
Intraocular radiation, including brachytherapy, proton beam therapy, and stereotactic radiotherapy, are being evaluated to treat choroidal neovascularization associated with age-related macular degeneration.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Medicare Advantage Plans
Intraocular placement of a radiation source (brachytherapy), proton beam therapy and stereotactic radiotherapy for the treatment of choroidal neovascularization is considered not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products
Intraocular placement of a radiation source (brachytherapy), proton beam therapy and stereotactic radiotherapy for the treatment of choroidal neovascularization is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE
Benefits may vary by group/contract. Please refer to the appropriate Member Certificate or Subscriber Agreement for applicable speech therapy benefits/coverage.

BACKGROUND
Age-Related Macular Degeneration
Age-related macular degeneration is the leading cause of legal blindness in individuals older than age 60 in developed nations. Age-related macular degeneration is characterized in its earliest stages by minimal visual impairment and the presence of large drusen and other pigmentary abnormalities on ophthalmoscopic examination. Two distinctive forms of degeneration may be observed. The first, called the atrophic or areolar or dry form, evolves slowly. Atrophic age-related macular degeneration 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 age-related macular degeneration. The wet form is distinguished from the atrophic form by the development of choroidal neovascularization 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 choroidal neovascularization.

Standard Clinical Management
Usual care for neovascular age-related macular degeneration includes intravitreal agents that target vascular endothelial growth factor, including pegaptanib, ranibizumab, bevacizumab, and aflibercept. Photodynamic therapy is an older method that has been largely replaced by anti-vascular endothelial growth factor therapies. The intravitreal therapies may necessitate repeated intravitreal injections. Hence, alternative treatments, such as intraocular radiation, including brachytherapy, proton beam therapy, and stereotactic radiotherapy, are being investigated.

Intraocular Radiotherapy
The NeoVista Epi-Rad90 Ophthalmic System, a brachytherapy device, treats choroidal neovascularization by delivering focal radiation to a subfoveal choroidal neovascular lesion. 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 1-timepeak dose of beta particle energy (24 Gray) for a target area 3 mm in depth and up to 5.4 mm in diameter. This dose is believed to be below that toxic to the retina and optic nerve. Radiation exposure outside of the target area is expected to be minimal.

Proton beam therapy is a type of external radiotherapy that uses charged atomic particles (protons or helium ions) to target a given area. Proton beam therapy differs from conventional electromagnetic (photon) radiotherapy in that, with proton beam therapy, there is less scatter as the particle beams pass through tissue to deposit ionizing energy at precise depths (Bragg peak). The theoretical advantage of proton beam therapy over photon therapy is the ability to deliver higher radiation doses to the target without harm to adjacent normal tissue.

Stereotactic radiotherapy is a nonsurgical procedure performed in an office setting. It uses a robotically controlled device to deliver radiation beams through the inferior sclera to overlap at the macula.

Other Treatments
Other available therapeutic options for age-related macular degeneration not addressed in this evidence review include photodynamic therapy and vascular endothelial growth factor antagonists or angiostatics.

Summary of Evidence
For individuals who have choroidal neovascularization due to age-related macular degeneration who receive brachytherapy, the evidence includes data from a Cochrane review, 2 randomized controlled trials (RCTs) comparing brachytherapy plus vascular endothelial growth factor with vascular endothelial growth factor monotherapy, as well as phase 1/2 trials and case series on the use of brachytherapy. Relevant outcomes are change in disease status, morbid events, functional outcomes, quality of life, medication use, and treatment-related morbidity. Both RCTs showed that brachytherapy did not attain noninferiority for visual acuity outcomes and was associated with a higher proportion of adverse events. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have choroidal neovascularization due to age-related macular degeneration who receive proton beam therapy, the evidence includes a randomized, prospective, sham-controlled trial and a pilot study. Relevant outcomes are change in disease status, morbid events, functional outcomes, quality of life, medication use, and treatment-related morbidity. Recruitment into the RCT was halted for ethical concerns, and available results did not show statistically significant stabilization of visual acuity. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have choroidal neovascularization due to age-related macular degeneration who receive stereotactic radiotherapy, the evidence includes an RCT with sham control. Relevant outcomes are change in disease status, morbid events, functional outcomes, quality of life, medication use, and treatment-related morbidity. The RCT showed a reduction in the number of vascular endothelial growth factor treatments at 12- and 24-month intervals, but no significant differences versus controls for changes in visual acuity. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Regulatory Status
No devices are specifically approved by the U.S. Food and Drug Administration (FDA) for intraocular radiation. An investigational device exemption was granted by the FDA for a phase 3 multicenter trial of the EPI-RAD90™ (now known as Vidion Anti-Neovascular Epimacular Brachytherapy [EMBT] System; NeoVista) to provide data for a device application to the FDA. This is a category B procedure.

CODING

Medicare Advantage Plans and Commercial Products

CPT codes have not been assigned to all of the services or therapies addressed in this policy. Therefore, the following Unlisted procedure code(s) should be used:

67299 Unlisted procedure, posterior segment

RELATED POLICIES

Unlisted Procedures

PUBLISHED

Provider Update, May 2024
Provider Update, July 2023
Provider Update, October 2022

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