FEP 9.03.20 Intraocular Radiotherapy for Age-Related Macular Degeneration

Effective Date: July 15, 2018

Related Policies:
6.01.10 Stereotactic Radiosurgery and Stereotactic Body Radiotherapy
8.01.10 Charged-Particle (Proton or Helium Ion) Radiotherapy
9.03.08 Photodynamic Therapy for Choroidal Neovascularization

Intraocular Radiotherapy for Age-Related Macular Degeneration

Description

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

FDA REGULATORY STATUS

No devices are specifically approved by the U.S. Food and Drug Administration for intraocular radiation. An investigational device exemption was granted by the Food and Drug Administration 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 Food and Drug Administration. This is a category B procedure.

POLICY STATEMENT

Intraocular placement of a radiation source (brachytherapy) for the treatment of choroidal neovascularization is considered **investigational**.

Proton beam therapy for the treatment of choroidal neovascularization is considered **investigational**.

Stereotactic radiotherapy for the treatment of choroidal neovascularization is considered **investigational**.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

RATIONALE

Summary of Evidence

For individuals who have CNV due to AMD who receive brachytherapy, the evidence includes 2 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 the effects of the technology on health outcomes.

For individuals who have CNV due to AMD who receive PBT, 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 the effects of the technology on health outcomes.

For individuals who have CNV due to AMD 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 vs controls for changes in visual acuity. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American Academy of Ophthalmology

In 2015, the American Academy of Ophthalmology updated its evidenced-based preferred practice pattern on age-related macular degeneration.[15] For extrafoveal choroidal neovascularization, radiotherapy was not recommended (SIGN grade: III; GRADE assessment: moderate level of evidence, strong recommendation).

National Institute for Health and Care Excellence

The 2011 guidance from the National Institute for Health and Care Excellence stated that current evidence on the efficacy of epiretinal brachytherapy for wet age-related macular degeneration is "inadequate and limited to small numbers of patients."[16] For safety, "vitrectomy has well-recognised complications and there is a possibility of subsequent radiation retinopathy." The Institute concluded that wet age-related macular degeneration should only be used for "research."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES

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POLICY HISTORY

Date	Action	Description
March 2012	New Policy	
June 2013	Update Policy	Policy updated with literature review, references updated and reordered, investigational statement added on proton beam therapy and policy title change to “Intraocular Radiation Therapy” from “Epiretinal Radiation Therapy”
June 2014	Update Policy	Policy was updated with literature review adding references 6, 7, 9 and 10. No change was made to the policy statement. The summary was revised with no change to the intent.
June 2015	Update Policy	Policy was updated with literature, updating reference 10. No changes to the policy statements.
September 2016	Update Policy	Policy updated with literature review; references 12 and 14 added. Policy statements clarified as to type of radiation therapy used, but intent unchanged.
June 2018	Update Policy	Policy updated with literature review through January 8, 2018; references 3 and 16-17 added. Policy statements unchanged.