



## FEP Medical Policy Manual

### FEP 9.03.20 Intraocular Radiotherapy for Age-Related Macular Degeneration

**Effective Policy Date: July 1, 2022**

**Original Policy Date: March 2012**

**Related Policies:**

None

## Intraocular Radiotherapy for Age-Related Macular Degeneration

### Description

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

#### OBJECTIVE

The objective of this evidence review is to determine whether the use of intraocular brachytherapy, proton beam therapy, or stereotactic radiosurgery improves the net health outcome for patients with choroidal neovascularization due to age-related macular dystrophy.

## 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**.

## POLICY GUIDELINES

None

## BENEFIT APPLICATION

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

## FDA 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.

## RATIONALE

### 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.

## SUPPLEMENTAL INFORMATION

### Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in "Supplemental Information" if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines

that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

## American Academy of Ophthalmology

In 2015, the American Academy of Ophthalmology updated its evidence-based preferred practice pattern on age-related macular degeneration.<sup>17</sup> For extrafoveal choroidal neovascularization, radiotherapy was not recommended (SIGN grade: III; GRADE assessment: moderate level of evidence, strong recommendation).

In their 2019 Preferred Practice Pattern (updated as of November 2021) for age-related macular degeneration, the Academy states that current data is insufficient "to demonstrate clinical efficacy" of radiation therapy for extrafoveal choroidal neovascularization.<sup>18</sup>

## 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."<sup>19</sup> 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. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

## REFERENCES

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## POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
March 2012	New policy	
June 2013	Replace 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	Replace 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	Replace policy	Policy was updated with literature, updating reference 10. No changes to the policy statements.
September 2016	Replace 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	Replace policy	Policy updated with literature review through January 8, 2018; references 3 and 16-17 added. Policy statements unchanged.
June 2019	Replace policy	Policy updated with literature review through January 6, 2019; no references added. Policy statements unchanged.
June 2020	Replace policy	Policy updated with literature review through January 13, 2020; AAO practice statement updated. Policy statements unchanged.
June 2021	Replace policy	Policy updated with literature review through February 2, 2021; references added. Policy statements unchanged.
June 2022	Replace policy	Policy updated with literature review through December 20, 2021; no references added. Policy statements unchanged.

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.