MEDICAL POLICY

POLICY TITLE	**INTRAOCULAR RADIOTHERAPY FOR AGE-RELATED MACULAR DEGENERATION**
POLICY NUMBER	**MP 2.389**

CLINICAL BENEFIT	☒ MINIMIZE SAFETY RISK OR CONCERN. ☐ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**5/1/2024**

I. POLICY

The following interventions for choroidal neovascularization are considered **investigational**.

- Intraocular placement of a radiation source (brachytherapy)
- Proton beam therapy
- Stereotactic radiotherapy

There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-reference:

MP 4.008 Photodynamic or Photocoagulation Therapy for Choroidal Neovascularization

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies .

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III. DESCRIPTION/BACKGROUND

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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-time peak 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 (see cross references)

For those whose visual loss impairs their ability to perform daily tasks, low-vision rehabilitative services offer resources to compensate for deficits.

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.

IV. RATIONALE

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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.

V. DEFINITIONS TOP

NA

VI. BENEFIT VARIATIONS TOP

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER TOP

Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION TOP

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational, therefore not covered:

Procedure Codes							
67299							

IX. REFERENCES

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12. *Park SS, Daftari I, Phillips T, et al. Three-year follow-up of a pilot study of ranibizumab combined with proton beam irradiation as treatment for exudative age-related macular degeneration. Retina. May 2012; 32(5): 956-66. PMID 22183743*
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X. POLICY HISTORY

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MP 2.389	10/5/2023 New policy created

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