

Corporate Medical Policy

Epiretinal Radiation Therapy for Age-Related Macular Degeneration

File Name:	epiretinal_radiation_therapy_for_age-related_macular_degeneration
Origination:	1/2010
Last CAP Review:	6/2018
Next CAP Review:	6/2019
Last Review:	6/2018

Description of Procedure or Service

Epiretinal radiation describes the intraocular administration of radiation to the choroidal vascular bed of the retina to treat age-related macular degeneration (AMD).

Age-related macular degeneration (AMD) is the leading cause of legal blindness in individuals older than age 60 in developed nations. AMD is characterized in its earliest stages by minimal visual impairment and the presence of large drusen and other pigmentary abnormalities on ophthalmoscopic examination. 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.

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

The NeoVista Epi-Rad90™ Ophthalmic System is a form of brachytherapy developed to treat CNV by focal delivery of 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 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 believed to be 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.

PBT is a type of external radiation that uses charged atomic particles (protons or helium ions) to target a given area. PBT differs from conventional electromagnetic (photon) radiotherapy in that, with PBT, there is less scatter as the particle beams pass through tissue to deposit ionizing energy at precise depths (Bragg peak). The theoretical advantage of PBT 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.

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Regulatory Status

There are no devices specifically approved by the U.S. Food and Drug Administration (FDA) for this procedure. An investigational device exemption (IDE) has been granted by FDA for a phase III 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 FDA. This is a category B procedure.

Related Policies:

Charged Particle Radiotherapy
Radiosurgery, Stereotactic Approach

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

Intraocular radiation therapy for the treatment of choroidal neovascularization is considered **investigational**. BCBSNC does not cover investigational services.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Epiretinal Radiation Therapy for Age-Related Macular Degeneration is covered

Not applicable.

When Epiretinal Radiation Therapy for Age-Related Macular Degeneration is not covered

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

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

For individuals who have CNV due to AMD, who receive brachytherapy, the evidence includes 2 randomized controlled trials (RCTs) comparing brachytherapy plus vascular endothelial growth factor (VEGF) versus VEGF 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

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did not attain noninferiority for visual 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 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 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 VEGF treatments at 12- and 24-month intervals, but no significant differences versus controls for changes in visual acuity. The evidence is insufficient to determine the effects of the technology on health outcomes.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbnsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 0190T, 67036

CPT code 0190T is to be used in conjunction with 67036

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

ClinicalTrials.gov: A service of the U.S. National Institutes of Health. A study of Strontium90 Beta Radiation with Lucentis to treat Age-Related Macular Degeneration (CABERNET) retrieved on December 11, 2009 from <http://clinicaltrials.gov/ct2/show/NCT00454389?term=CABERNET&rank=1>

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.20, 7/10/08.

Senior Medical Director review - 12/09.

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.20, 2/10/2011

Specialty Matched Consultant Advisory Panel Review -6/2011.

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.20, 2/9/12

Specialty Matched Consultant Advisory Panel Review- 6/2012

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.20, 2/14/13

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.20, 2/13/14

Specialty Matched Consultant Advisory Panel Review- 6/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.20, 2/12/15

Specialty Matched Consultant Advisory Panel review- 6/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.20, 3/10/16

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Specialty Matched Consultant Advisory Panel review- 6/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.20, 3/9/17

Specialty Matched Consultant Advisory Panel review- 6/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.20, 3/8/18

Specialty Matched Consultant Advisory Panel review- 6/2018

Policy Implementation/Update Information

- 99/99 Revised: Coding revisions – Implement Info
- 1/5/10 New policy issued. Epiretinal Radiation Therapy for Age-Related Macular Degeneration is considered investigational. (pmo)
- 6/22/10 Policy Number(s) removed (amw)
- 7/19/11 Specialty Matched Consultant Advisory Panel review 6/29/2011. References added. Policy statement unchanged. (lpr)
- 7/10/12 Specialty Matched Consultant Advisory Panel review 6/20/2012. Policy guidelines updated. No change to policy statement. Reference added. (lpr)
- 4/1/13 Added investigational indication to When Not Covered section regarding proton beam therapy: “Intraocular proton beam therapy for the treatment of choroidal neovascularization is considered investigational.” Updated Policy Guidelines section. Reference added. Medical director review 3/2013. Notification given 4/1/2013 for effective date 7/1/2013. (lpr)
- 4/1/14 Added investigational indication to “When Not Covered” section regarding stereotactic radiation therapy: Sterotactic radiation therapy for the treatment of choroidal neovascularization is considered **investigational**. Updated Policy Guidelines section. Reference added. Medical director review 3/2014. Notification 4/1/14 for effective date 6/10/14. (lpr)
- 7/15/14 Specialty matched consultant advisory panel review 6/24/2014. No change to policy statement. (lpr)
- 3/31/15 Reference added. (lpr)
- 7/28/15 Specialty Matched Consultant Advisory Panel review 6/24/2015. No change to policy statement. (lpr)
- 4/29/16 Updated Description, Regulatory status and Policy Guidelines sections. Clarification added as to type of radiation therapy used, but policy intent unchanged. (lpr)
- 7/26/16 Specialty Matched Consultant Advisory Panel review 6/29/2016. No change to policy statement. (lpr)
- 4/28/17 Updated Policy Guidelines section. Reference added. No change to policy statement. (lpr)
- 7/28/17 Specialty Matched Consultant Advisory Panel review 6/28/2017. No change to policy statement. (lpr)
- 8/10/18 Specialty Matched Consultant Advisory Panel review 6/2018. No change to policy statement. Reference added. (lpr)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment

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and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.