

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: 6/2011
Next CAP Review: 6/2012
Last Review: 6/2011

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). 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.

The NeoVista Epi-Rad90™ Ophthalmic System has been 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 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. An investigational device exemption (IDE) has been granted by the U.S. Food and Drug Administration (FDA) for a phase III multicenter trial to provide data for application to the FDA; this is a category B procedure.

*****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

BCBSNC will not provide coverage for Intraocular Placement of a Radiation Source for the Treatment of Choroidal Neovascularization because it 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

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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

Epiretinal Radiation Therapy for Age-related Macular Degeneration is considered **investigational**. BCBSNC does not provide coverage for investigational services.

Policy Guidelines

The phase III, CNV secondary to AMD treated with beta radiation epiretinal therapy (CABERNET) trial is a multi-center, randomized, controlled study to evaluate the safety and efficacy of beta radiation epiretinal therapy combined with 2 injections of ranibizumab (Lucentis®) versus ranibizumab alone. This study is ongoing, but not recruiting subjects and is projected to enroll 450 subjects with AMD-related wet CNV from international locations in addition to 30 sites in the United States. Final data collection for the primary outcome measure is expected to be completed in 2010. The projected study completion date is 2011.

There is no reliable, long-term evidence from well-designed, well-executed randomized controlled trials on the effectiveness of epiretinal radiation therapy in the treatment of wet AMD. It is uncertain whether epiretinal radiation therapy offers any additional benefit compared to standard treatment, such as treatment with anti-vascular endothelial growth factors.

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.bcbsnc.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

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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.

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)

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