

Evidence Based Guideline

Photodynamic Therapy, Ocular

File Name:	photodynamic_therapy_ocular
Origination:	3/2001
Last CAP Review:	6/2011
Next CAP Review:	6/2012
Last Review:	6/2011

Description of Procedure or Service

Ocular Photodynamic Therapy is a treatment modality designed to selectively close off new blood vessels that have formed in abnormal positions beneath the retina (choroidal neovascularization or CNV). The therapy is a two-step process, consisting initially of an intravenous (within the vein) injection of a photosensitizing agent (light-activated drug). The drug selectively accumulates in the abnormal blood vessels of the eye. A non-thermal laser is then used to activate the drug as it passes through the abnormal blood vessels and because it does not generate heat, normal vessels are not damaged (the overlying retina and healthy retinal vasculature are not damaged).

Age-related macular degeneration (AMD) is a disease that affects the central vision. It is a common cause of vision loss among people over age of 55. The disease affects the macula, which is located at the center of the retina (the light-sensitive tissue which lines the back of the eye). The macula provides us with central vision and is responsible for the sharp, direct vision needed to read, drive or watch television. The fovea is a small depression in the center of the macula provides the sharpest vision. When the macula is damaged, significant vision loss can occur. There are two types of AMD: "dry" and the more severe "wet" form. Currently, photodynamic therapy is not considered effective as a treatment for "dry" AMD. This discussion will focus on the wet form.

Although wet AMD accounts for only 10% of patients with AMD, 90% of AMD patients with significant vision loss have this form of the disease. Wet AMD is caused by the growth of abnormal new blood vessels under the central part of the retina, the macula (choroidal neovascularization). Because these new blood vessels tend to be very fragile, they will often leak fluid and blood underneath the macula. This leakage causes a blister to form in the retina which lifts the macula from its normal place causing distorted vision.

CNV location is critical because lesions with borders located beneath the center of the fovea indicate the worst prognosis. CNV can be described by its location: (1) extrafoveal (CNV 200 microns or more from the foveal center), (2) juxtafoveal (CNV between 1 and 199 microns from the foveal center). CNV can further be described as "classic" or "occult", based on appearance on fluorescent angiography. For example, classic CNV appears as an initial lacy pattern of hyperfluorescence followed by more irregular patterns as the dye leaks into the subretinal space. Occult CNV lacks the characteristic angiographic pattern, either due to the opacity of coexisting subretinal hemorrhage or, especially in CNV associated with AMD, by a tendency for epithelial cells to proliferate and partially or completely surround the new vessels. Interestingly, lesions consisting only of classic CNV carry a worse visual prognosis than those made up of only occult CNV, suggesting that the proliferative response that obscures new vessels may also favorably alter the clinical course of AMD.

An early symptom of wet AMD is that straight lines appear wavy. This progression eventually leads to scar tissue, distortion and a loss of central vision. The dry form is more common than the wet; however the wet form of the disease usually leads to more serious vision loss.

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Presumed ocular histoplasmosis is a disease caused by the histoplasmosis fungus, which is a soil fungus that gets into the lungs, and then migrates to the eyes. The fungus is present in the Ohio-Mississippi river basin area. For unknown reasons, several decades after the initial infection, the scars left in the vascular layer lining the retina develop abnormal new blood vessels which leak fluid and blood.

Pathologic Myopia refers to an abnormally long eyeball that is associated with severe nearsightedness (A condition in which near objects are seen clearly, but distant objects do not come into proper focus.). This condition strains the eye tissue and causes it to thin. The thinning of the tissue results in decreased circulation that may result in the growth of abnormal new blood which leak fluid and blood.

Angioid Streaks are splits in a layer of the eye which lies deep to the retina known as Bruch's membrane. Unfortunately, angioid streaks may lead to the development of choroidal neovascular membranes. These behave in a fashion similar to those of patients with AMD often causing vision loss due to bleeding, fluid leakage and scarring.

Central Serous Chorioretinopathy consists of one or more "blisters" of fluid (serous detachment) beneath the macula (central portion of the retina). The exact cause is not understood. Fluid from the layer of blood vessels that lie underneath the retina seeps up through the break, causing a small detachment to form under the retina. The condition is avascular; however, neovascularization can occur as a secondary complication. Central Serous Chorioretinopathy may resolve spontaneously or can be treated with medication and laser photocoagulation.

Idiopathic CNV, traumatic CNV and circumscribed choroidal hemangiomas. Idiopathic CNV is relatively rare compared to AMD and tends to occur at a younger age. Idiopathic CNV leads to acute loss of central vision but is not attributed to any known disease process. Traumatic CNV may be related to choroidal rupture, photocoagulation, surgical trauma, etc. Circumscribed choroidal hemangiomas (CCH) are rare, noncancerous growths within the choroid blood vessel layer, which lies beneath the retina.

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

Evidence Based Guideline for Ocular Photodynamic Therapy

Ocular photodynamic therapy may be appropriate as a treatment of choroidal neovascularization that is visually threatening or visually impairing due to **any one** of the following:

- "wet" age-related macular degeneration (AMD), **OR**
- pathologic myopia, **OR**
- presumed ocular histoplasmosis, **OR**
- angioid streaks, **OR**
- idiopathic, **OR**
- trauma, **OR**
- circumscribed choroidal hemangioma.

Medical Evidence regarding Ocular Photodynamic Therapy indicates it is not recommended in the following situations

Ocular Photodynamic Therapy is not recommended if the evidence based guideline criteria listed above is not met.

Photodynamic therapy is not recommended for other ophthalmologic disorders, including, but not limited to, "dry" AMD, choroidal neovascularization secondary to central serous chorioretinopathy and when used in combination with one or more of the anti-vascular endothelial growth factor therapies (anti-VEGF), i.e., pegaptanib (Macugen[®]), ranibizumab (Lucentis[®]), bevacizumab (Avastin[®]), as a treatment of CNV.

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Benefits Application

This evidence based guideline 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 guideline.

Billing/Coding/Physician Documentation Information

This guideline 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 codes: 67221, 67225, J3396

Documentation should include results of fluorescein angiogram.

Scientific Background and Reference Sources

Policies combined for new policy entitled: Photodynamic Therapy

BCBSA Medical Policy Reference Manual, 8/18/2000; 8.01.06

BCBSA TEC Evaluation, 12/2000; Volume 15, No. 18

BCBSA Medical Policy Reference Manual, 12/15/2000; 9.03.08

Specialty Matched Consultant Advisory Panel 11/2001

BCBSA Medical Policy Reference Manual, 11/20/2001, 8.01.36 and 9.03.08

ECRI TARGET™ Fact Sheet "Photodynamic Therapy for wet Age-related Macular Degeneration"

National Eye Institute "Facts About Age-Related Macular Degeneration" August 2002

Photodynamic Therapy Policy separated. New policy name is Photodynamic Therapy, Ocular

ECRI Hotline Response: Photodynamic Therapy with Verteporfin (Visudyne) for Choroidal Neovascularization. January 7, 2003

Specialty Matched Consultant Advisory Panel 3/2003

BCBSA Medical Policy Reference Manual, 9.03.08; 4/29/03

National Institute for Clinical Excellence (NICE). Guidance on the use of photodynamic therapy for age-related macular degeneration. Technology Appraisal 68. London, UK: NICE; September 2003. Available at: <http://www.nice.org.uk/Docref.asp?d=86801>. Accessed November 8, 2004.

U.S. Department of Health and Human Services, Center for Medicare and Medicaid Services (CMS). Decision Memo for Ocular Photodynamic Therapy with Verteporfin for Macular Degeneration (CAG-00066R3). Baltimore, MD: CMS; January 28, 2004. Available at: <http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=101>. Accessed November 8, 2004.

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.08, 4/16/04.

ECRI Target Report #425 (2004, April) Photodynamic therapy (PDT) for wet age-related macular degeneration (AMD). Retrieved on November 8, 2004 from <http://www.target.ecri.org/summary/>

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detail.aspx?doc_id=414&q=%22Age+related+macula+degeneration&anm.

Specialty Matched Consultant Advisory Panel 1/2005

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.08, 6/27/05.

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.08, 12/14/05.

BCBSA Technology Evaluation Center. (2006, January). Current and Evolving Strategies in the Treatment of Age Related Macular Degeneration. Retrieved 1/7/2007 from <http://www.bcbs.com/betterknowledge/tec/tec-assesments-by-topic.html?topics=ophthalmology-eye-disease>

Specialty Matched Consultant Advisory Panel 1/25/07

American Academy of Ophthalmology Retina Panel. Preferred Practice Pattern® Guidelines. Age-Related Macular Degeneration. San Francisco, CA: American Academy of Ophthalmology; 2008. Retrieved on December 17, 2008 from <http://www.aao.org/ppp>

Specialty Matched Consultant Advisory Panel - 4/6/09.

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.08, 4/14/2011

Specialty Matched Consultant Advisory Panel -6/2011

Policy Implementation/Update Information

Policies combined for new policy entitled: Photodynamic Therapy

8/00 New combined policy issued. System coding changes.

3/01 Revised. New section IV added to include criteria for photodynamic therapy for treatment of age-related macular degeneration. Added statement under when extracorporeal photopheresis is not covered.

5/01 Revised. Added eligible criteria for palliative treatment of obstructing endobronchial lesions to Section III.

10/01 Coding format changes.

11/01 Specialty Matched Consultant Advisory Panel. No changes.

3/02 Policy statements revised in both covered and non-covered sections of the, "Photodynamic Therapy for Treatment of Age-related Macular Degeneration" and "Extracorporeal Photopheresis".

1/03 Revised Description Section for clarity and to include presumed ocular histoplasmosis and pathologic myopia. Added codes 67225 and J3395 to Billing and Coding Section.

Photodynamic Therapy Policy separated. New policy name is Photodynamic Therapy, Ocular

11/03 Specialty Matched Consultant Advisory Panel review 3/24/03. Description, Benefits Application and Billing/Coding sections revised. Criteria for coverage expanded to include subfoveal choroidal neovascularization due to Angioid streaks, idiopathic, trauma, circumscribed choroidal hemangioma. Codes 67225 and J3395 added to Billing/Coding section.

1/6/05 First quarter 2005 HCPCS code J3396 added to Billing/Coding section of policy.

1/20/05 Specialty Matched Consultant Advisory Panel review-1/5/05. Under "Description" section, added information regarding occult and classic CNV and central serous chorioretinopathy. Added "choroidal neovascularization secondary to central serous chorioretinopathy." as investigational. Under "Billing/Coding" section, deleted code J3395-code was deleted in 2005 HCPCS. Medical term definitions and reference sources added. Notification given 1/20/05. Effective date 4/7/05.

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- 9/18/06 Medical Policy changed to Evidence Based Guideline. (pmo)
- 2/26/07 Specialty Matched Consultant Advisory Panel review. No changes to guidelines. Reference sources added. (pmo)
- 4/27/09 No changes to guidelines. Reference source added. (pmo)
- 6/22/10 Policy Guideline Number(s) removed (amw)
- 7/19/11 Specialty Matched Consultant Advisory Panel review 6/29/2011. Under “When Recommended” section: removed subfoveal from the statement. Under “When Not Recommended” section: added statement “when used in combination with one or more of the anti-vascular endothelial growth factor therapies (anti-VEGF), i.e., pegaptanib (Macugen[®]), ranibizumab (Lucentis[®]), bevacizumab (Avastin[®]), as a treatment of CNV.” (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.