



MEDICAL COVERAGE GUIDELINES
SECTION: VISION

ORIGINAL EFFECTIVE DATE: 04/16/13
LAST REVIEW DATE: 03/05/19
LAST CRITERIA REVISION DATE: 07/22/14
ARCHIVE DATE:

PHOTODYNAMIC THERAPY FOR CHOROIDAL NEOVASCULARIZATION

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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PHOTODYNAMIC THERAPY FOR CHOROIDDAL NEOVASCULARIZATION (cont.)

Description:

Photodynamic Therapy (PDT):

Photodynamic therapy (PDT) is a treatment modality designed to selectively occlude ocular choroidal neovascular tissue. The therapy is a 2-step process, consisting initially of an injection of the photosensitizer Visudyne® (verteporfin), followed 15 minutes later by laser treatment to the targeted sites of neovascularization in the retina. The laser treatment selectively damages the vascular endothelium. Individuals may be re-treated if leakage from choroidal neovascularization (CNV) persists. Intravitreal corticosteroids have been investigated as an adjunct to verteporfin PDT.

Anti-Vascular Endothelial Growth Factors (VEGF) Inhibitors:

Antagonists that bind to and inhibit vascular endothelial growth factor (VEGF) to prevent the formation of new blood vessels. Anti-VEGF inhibitors are also referred to as angiogenesis inhibitors.

- Eylea® (aflibercept)
- Lucentis® (ranibizumab)
- Macugen® (pegaptanib sodium)
- Avastin® (bevacizumab)

Age-Related Macular Degeneration (AMD):

Gradual painless loss of central vision due to a breakdown of a portion of the retina known as the macula.

The non-neovascular form (also known as dry, nonexudative, or atrophic) is more common and progresses slowly, characterized by the accumulation of small, yellowish deposits called drusen that form within the layers of the retina. Non-neovascular AMD may suddenly develop into neovascular AMD.

The neovascular form (also known as wet, exudative or disciform) is characterized by choroidal neovascularization, the proliferation of fine blood vessels at the back of the eye that begin to leak or exude fluid, causing hemorrhage, swelling and scar tissue which may result in permanent central vision loss within days or weeks.

Central Serous Chorioretinopathy:

A disease in which a serous detachment of the macula occurs due to leakage of fluid from the choriocapillaris through the retinal pigment epithelium. Choroidal neovascularization may occur as a secondary complication.

Choroidal Hemangioma:

An uncommon, benign vascular tumor, manifesting as an orange-red mass in the posterior pole of the eye. Visual loss may be progressive and irreversible because of chronic foveal detachment.



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Description: (cont.)

Choroidal Neovascularization (CNV):

The proliferative growth of abnormal new blood vessels, called neovascular membranes, originating from the choroid (between the retina and the sclera) that begin to leak or exude fluid, causing hemorrhage, swelling and scar tissue which can lead to rapid irreversible loss of vision.

Pathologic Myopia:

Abnormal elongation of the eye associated with severe near-sightedness. It can result in a progressive, severe loss of vision, frequently related to the development of CNV.

Presumed Ocular Histoplasmosis:

Characterized by tiny choroidal scars, peripapillary scarring and exudation or hemorrhage from choroidal lesions in or near the macula along with a positive skin test for histoplasmosis and miliary opacities of the lungs.

Criteria:

- Photodynamic therapy (Visudyne plus laser) as monotherapy is considered **medically necessary** for treatment of choroidal neovascularization associated with **ANY** of the following conditions:
 1. Age-related macular degeneration
 2. Chronic central serous chorioretinopathy
 3. Choroidal hemangioma
 4. Pathologic myopia
 5. Presumed ocular histoplasmosis

- Photodynamic therapy as monotherapy for all other indications not previously listed; or if above criteria not met is considered **experimental or investigational** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.



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Criteria: (cont.)

- Photodynamic therapy when used in combination with one or more anti-vascular endothelial growth factor (anti-VEGF) therapies for treatment of choroidal neovascularization associated with all other ophthalmologic conditions is considered ***experimental or investigational*** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

These conditions include, *but are not limited to*:

- Age-related macular degeneration
 - Chronic central serous chorioretinopathy
 - Choroidal hemangioma
 - Pathologic myopia
 - Presumed ocular histoplasmosis
- Intravitreal corticosteroid injection as an adjunct to photodynamic therapy is considered ***experimental or investigational*** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 4. Insufficient evidence to support improvement outside the investigational setting.



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Resources:

Literature reviewed 04/17/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

Resources prior to 04/16/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. 9.03.08 BCBS Association Medical Policy Reference Manual. Photodynamic Therapy for Choroidal Neovascularization. Re-issue date 03/08/2018, issue date 12/15/2001.
2. American Academy of Ophthalmology. Age-Related Macular Degeneration Preferred Practice Pattern Guidelines. Updated January 2015.
3. Kiernan DF, Mieler WF. The use of intraocular corticosteroids. *Expert Opin Pharmacother*. Oct 2009;10(15):2511-2525.
4. Sacu S, Varga A, Michels S, et al. Reduced fluence versus standard photodynamic therapy in combination with intravitreal triamcinolone: short-term results of a randomised study. *Br J Ophthalmol*. Oct 2008;92(10):1347-1351.

FDA Premarket Approval Database for Opal Photoactivator™:

- FDA-approved indication: For the treatment of patients with predominantly classic subfoveal choroidal neovascularization due to age-related macular degeneration, pathologic myopia or presumed ocular histoplasmosis.



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Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilinígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idílkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idílkidgo beehaz'áanii hólo díí t'áa hazaadk'ehjí háká a'doowolgo bee haz'á doo baqah ilínígóó. Ata' halne'ígíí kojí' bich'í' hodílnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

