BlueCross BlueShield of Arizona
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MEDICAL COVERAGE GUIDELINES
SECTION: VISION

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

PHOTODYNAMIC THERAPY FOR CHOROIDAL NEOVASCULARIZATION

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.

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.

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.

PHOTODYNAMIC THERAPY FOR CHOROIDAL NEOVASCULARIZATION (cont.)

Description: (cont.)

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.

- Lucentis® (ranibizumab)
- Macugen® (pegaptanib sodium)
- Eylea® (aflibercept)
- Avastin® (bevacizumab) is an anti-VEGF monoclonal antibody approved for the treatment of metastatic cancers including colorectal and lung cancer. Avastin is the full-length monoclonal antibody from which the Lucentis fragment is derived. Use of Avastin is included in the American Academy of Ophthalmology (AAO) preferred practice pattern for Age-Related Macular Degeneration.[12] Although prospective randomized trials with bevacizumab for AMD have not yet been conducted, community experience demonstrating the beneficial impact on vision have resulted in acceptance as standard in the medical community.

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.

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.

PHOTODYNAMIC THERAPY FOR CHOROIDAL NEOVASCULARIZATION (cont.)

Description: (cont.)

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.

PHOTODYNAMIC THERAPY FOR CHOROIDAL NEOVASCULARIZATION (cont.)

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.

PHOTODYNAMIC THERAPY FOR CHOROIDAL NEOVASCULARIZATION (cont.)

Resources:

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 06/12/2014, issue date 12/15/2001.

2. American Academy of Ophthalmology. Age-Related Macular Degenreation Preferred Practice Pattern Guidelines. 10/2011.

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 Information for Visudyne®:

- 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.

FDA Product Approval Information for Lucentis® (Ranibizumab):

- FDA-approved indication: For the treatment of neovascular (wet) age-related macular degeneration. For the treatment of macular edema following retinal vein occlusion. For the treatment of diabetic macular edema.

FDA Product Approval Information for Macugen® (Pegaptanib Sodium):

- FDA-approved indication: For the treatment of neovascular (wet) age-related macular degeneration. For the treatment of macular edema following retinal vein occlusion.

FDA Product Approval Information for Eylea® (Aflibercept):

- FDA-approved indication: For the treatment of neovascular (wet) age-related macular degeneration. For the treatment of macular edema following Central Retinal Vein Occlusion (CRVO).

PHOTODYNAMIC THERAPY FOR CHOROIDAL NEOVASCULARIZATION (cont.)

Resources: (cont.)

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.