

MEDICAL POLICY



SUBJECT: PHOTODYNAMIC THERAPY FOR SUBFOVEAL CHOROIDAL NEOVASCULARIZATION	EFFECTIVE DATE: 07/20/00 REVISED DATE: 01/17/02, 10/16/02, 09/18/03, 09/16/04, 07/21/05, 05/18/06, 03/15/07, 03/20/08 ARCHIVED DATE: 03/19/09 EDITED DATE: 03/18/10, 03/17/11, 03/15/12, 03/21/13, 03/20/14, 03/19/15, 03/17/16, 03/16/17, 03/15/18
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<ul style="list-style-type: none">• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i>• <i>If a commercial product, including an Essential Plan product, covers a specific service, medical policy criteria apply to the benefit.</i>• <i>If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</i>	

POLICY STATEMENT:

- I. Based upon our criteria and assessment of peer-reviewed literature, photodynamic therapy with verteporfin has been medically proven effective and therefore **medically appropriate** for patients with a diagnosis of subfoveal choroidal neovascularization (CNV) associated with the following conditions:
 - A. Age-related macular degeneration;
 - B. Pathologic myopia;
 - C. Chronic central serous chorioretinopathy;
 - D. Choroidal hemangioma; or
 - E. Ocular histoplasmosis syndrome.
- II. Based upon our criteria and assessment of peer-reviewed literature, photodynamic therapy with Verteporfin as yet, has not demonstrated a benefit to patient outcomes and is considered **investigational** as a treatment for patients with CNV for any other ophthalmologic condition not listed above.

Refer to Corporate Medical Policy # 8.01.08 regarding Photodynamic Therapy for Malignant Conditions.

Refer to Corporate Medical Policy #11.01.03 Experimental and Investigational Services.

Refer to FLRx drug policy regarding Neovascular (Wet) Age Related Macular Degeneration (Magugen®:pegaptanib, Lucentis®: ranibizumab, Avastin®: bevacizumab).

POLICY GUIDELINES:

- I. Photodynamic therapy with verteporfin must be administered by an ophthalmologist who has completed a fellowship in vitreoretinal diseases and surgery.
- II. The specialist should evaluate the patient every 3 months. Repeat PDT therapy may be necessary to achieve optimal visual acuity if the abnormal blood vessels re-leak. On the average, 3-4 treatments are necessary during the first year of therapy with approximately 2 treatments during the second year.
- III. Verteporfin photodynamic therapy combined with ranibizumab/Lucentis or bevacizumab/Avastin will be considered in patients with predominantly classic lesions. Refer to FLRx drug policy regarding *Neovascular (Wet) Age Related Macular Degeneration (Magugen®:pegaptanib, Lucentis®: ranibizumab, Avastin®: bevacizumab)*.
- IV. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

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DESCRIPTION:

Age-related macular degeneration (AMD) is a major cause of severe vision loss in people older than age 65 years. There are 2 forms of AMD: wet and dry. The dry form is the most common form and is characterized by yellow deposits in the retina, called “drusen”. The dry form can progress to the wet form, which is more aggressive and severe. Wet or exudative AMD is caused by the growth of abnormal leaky blood vessels (choroidal neovascularization or CNV) that eventually damage the macula. The macula is the area of the eye responsible for central vision, which is essential for most visual activities, including reading, driving, and recognizing faces. CNV associated with wet AMD may include classic or occult neovascular leakage patterns. Classic CNV is distinct or well demarcated during fluorescein angiography whereas occult CNV is obscured or poorly demarcated on fluorescein angiography.

Choroidal neovascularization due to pathologic myopia is caused by abnormal blood vessels that grow under the center of the retina as a result of the abnormal elongation of the back of the eye associated with severe near-sightedness or myopia. Pathologic myopia generally occurs among people over 30 years of age and can result in a progressive loss of vision.

Ocular histoplasmosis syndrome (OHS) is thought to be caused by *Histoplasma capsulatum* (a fungus found in the dust and soil of river valley regions) which is inhaled into the lungs and then spreads to the choroid layer of the eye forming scar tissue. In later years, OHS develops when the scar tissue forms fragile, abnormal blood vessels known as choroidal neovascularization. OHS is also known as Presumed OHS due to the fact that the fungus is rarely isolated or cultured from the eye.

Central serous chorioretinopathy refers to an idiopathic disease in which there is a serous detachment of the macula due to leakage of fluid from the choriocapillaris through the retinal pigment epithelium. This condition is avascular; however, neovascularization can occur as a secondary complication. Although central serous chorioretinopathy often resolves spontaneously in 3 to 4 months, chronic or recurrent central serous chorioretinopathy can result in progressive decline of visual acuity. Central serous chorioretinopathy has been treated with medication and laser photocoagulation, but these treatments have limited efficacy.

Choroidal hemangioma is 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.

Photodynamic therapy is a treatment modality designed to selectively occlude neovascular tissue. Therapy consists of intravenous injection of a photosensitizing agent followed by irradiation of the neovascular tissue with non-thermal light. It is thought that when the light activates the photosensitizer, it generates singlet oxygen, which leads to the selective destruction of new blood vessels.

Visudyne (verteporfin) is the only FDA approved intravenous photosensitizing agent for the treatment of patients with choroidal neovascularization. Visudyne photodynamic therapy is a two-step process: it is injected intravenously and rapidly accumulates in the abnormal vessels in the eye. Activation of Visudyne by the non-thermal laser (usually within 5 minutes of the injection) results in a reduction in the growth and leakage of these abnormal blood vessels and a corresponding reduction or stabilization of vision loss, with minimal effects on the surrounding normal tissue.

RATIONALE:

Visudyne (verteporfin) is the only FDA approved intravenous photosensitizing agent for the treatment of patients with choroidal neovascularization. The FDA approved indications include classic CNV secondary to wet AMD, pathologic myopia and ocular histoplasmosis syndrome.

Several clinical trials are currently underway investigating other photosensitizing agents in the treatment of subfoveal CNV. Publications of the TAP clinical trial have reported that photodynamic therapy can safely reduce the risk of vision loss in patients with age-related macular degeneration characterized by choroidal neovascularization up to 2 years

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following the initial treatment. In an extension trial of the TAP trial, patients' visual acuity was found to remain stable between the 24th and 36th month of follow-up, while the number of treatments required continued to decrease (1.4 treatments in the third year compared to 3.4 and 2.1 treatments received in the first and second years, respectively).

The VIP trial primarily focused on the safety and efficacy of PDT in patients with predominantly occult lesions. While there was no significant difference in vision loss between the treatment and placebo group in the first 12 months, by 24 months a significantly lower percentage of those patients in the treatment group had lost vision. A second arm of the VIP trial investigated patients with CNV due to pathologic myopia. Beneficial outcomes regarding visual acuity were noted at 12 months (86% of verteporfin-treated patients lost less than 3 lines of vision, compared to 67% of patients receiving sham treatment).

The FDA's 2001 decision to expand Visudyne therapy for ocular histoplasmosis was based on findings of a case study of 26 patients. Patients treated with verteporfin demonstrated a reduction in the number of episodes of severe visual acuity loss compared to historical control data.

A recent analysis of the TAP and VIP studies found correlation between lesion size of minimally classic CNV and efficacy of verteporfin treatment. Patients with minimally classic CNV with lesions 4 disc sizes or smaller treated with verteporfin have a better visual acuity outcome after treatment than patients with larger areas of CNV. Preliminary results of the VIM study also support the use of verteporfin treatment in patients with minimally classic CNV with small disc areas.

Quality evidence on use of PDT for central serous chorioretinopathy is limited. The available evidence indicates substantial numbers of adverse events with standard PDT. Reduced-dose PDT may result in improved anatomical outcomes for acute central serous chorioretinopathy, but clinically significant improvements in visual acuity have not been shown for this self-limiting disease. For chronic central serous chorioretinopathy, recent comparative studies of reduced fluence and reduced-dose PDT suggest a possible beneficial effect of this treatment.

PDT has been reported to induce complete and irreversible occlusion of the microvasculature, although this may require more than one treatment. Several case series demonstrated encouraging visual and anatomical outcomes in 150 patients with circumscribed choroidal hemangioma who were treated with various PDT regimens.

Based on numerous case reports and case series, PDT is being used in an attempt to decrease CNV of many different etiologies. For example, PDT has been reported to slow down, but not prevent or reverse, the progression of disease of CNV associated with polypoidal choroidal vasculopathy, angioid streaks, and inflammatory chorioretinal disease. There is insufficient evidence to support the use of PDT as monotherapy or in combination therapy for these other ophthalmologic disorders. As a result, PDT is considered investigational for ophthalmologic disorders other than AMD, chronic central serous chorioretinopathy, choroidal hemangioma, pathologic myopia, or presumed ocular histoplasmosis.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

CPT:	67221	Destruction of localized lesion of choroid (eg, choroidal neovascularization); photodynamic therapy (includes intravenous infusion)
	67225	photodynamic therapy, second eye, at single session (List separately in addition to code for primary eye treatment)

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HCPCS:	J3396	Injection, verteporfin, 0.1 mg
	115.92	Occult histoplasmosis
ICD10:	H35.051- H35.059	Retinal neovascularization, eye (code range)
	H35.32	Exudative age-related macular degeneration
	H44.20-H44.23	Degenerative myopia, eye (code range)

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*key article

KEY WORDS:

Age-related macular degeneration, AMD, Visudyne, Verteporfin.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for ocular photodynamic therapy and a Local Coverage Determination (LCD), Drugs and Biologics. Please refer to the following NCD and LCD websites for Medicare members:

NCD: <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=349&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York++Upstate&CptHcpcsCode=36514&bc=gAAAABAAAA&>

LCD: [https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33394&ContrId=298&ver=35&ContrVer=1&CtrctrSelected=298*1&Ctrctr=298&name=National+Government+Services%2c+Inc.+\(13201%2c+A+and+B+and+HHH+MAC%2c+J++K\)&s=All&DocType=Active&bc=AggAAAQAAAA&](https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33394&ContrId=298&ver=35&ContrVer=1&CtrctrSelected=298*1&Ctrctr=298&name=National+Government+Services%2c+Inc.+(13201%2c+A+and+B+and+HHH+MAC%2c+J++K)&s=All&DocType=Active&bc=AggAAAQAAAA&)