MEDICAL POLICY

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MEDICAL POLICY DETAILS	
Medical Policy Title	**Ocular Photodynamic Therapy**
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Category	**Technology Assessment**
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Product Disclaimer	• *Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) 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.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, photodynamic therapy (PDT) with verteporfin has been medically proven to be effective and, therefore, is considered **medically appropriate** for patients with a diagnosis of subfoveal choroidal neovascularization (CNV) associated with **ANY** of the following conditions:
   A. Age-related macular degeneration (AMD);
   B. Pathologic myopia;
   C. Chronic central serous chorioretinopathy;
   D. Choroidal hemangioma;
   E. Ocular histoplasmosis syndrome.

II. Based upon our criteria and assessment of the peer-reviewed literature, PDT with verteporfin has not demonstrated a benefit to patient outcomes and, therefore, is considered **investigational** as a treatment for patients with CNV for any other ophthalmologic condition not listed above.

Refer to Corporate Medical Policy #8.01.06 Photodynamic Therapy for Malignant Conditions

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

POLICY GUIDELINES

I. PDT 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 three (3) months. Repeat PDT therapy may be necessary to achieve optimal visual acuity, if the abnormal blood vessels re-leak. On average, three (3) to four (4) treatments are necessary during the first year of therapy, with approximately two (2) treatments during the second year.

III. Verteporfin PDT, combined with ranibizumab (Lucentis) or bevacizumab (Avastin), will be considered in patients with predominantly classic lesions.

DESCRIPTION

Age-related macular degeneration (AMD) is a major cause of severe vision loss in people older than age 65 years. There are two 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.

CNV 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, when inhaled into the lungs, 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 CNV. 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 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 three to four 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 (PDT) 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. 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 CNV. Visudyne photodynamic therapy is a two (2) 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 five (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

Several clinical trials are currently underway, investigating other photosensitizing agents in the treatment of subfoveal CNV. Publications of a clinical trial investigating the treatment of age-related macular degeneration with photodynamic therapy, known as the TAP trial, have reported that PDT can safely reduce the risk of vision loss in patients with age-related macular degeneration characterized by CNV, up to two (2) years 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 Verteporfin in Photodynamic Therapy (VIP) trial primarily focused on the safety and efficacy of PDT in patients with predominantly occult lesions. While, in the first 12 months, there was no significant difference in vision loss between the

treatment and placebo group, 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 three (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. The studies appear to establish that patients with minimally classic CNV, who have lesions that are 4-disc sizes or smaller and who are treated with verteporfin, have a better visual acuity outcome after treatment than patients with larger areas of CNV. Preliminary results of the Verteporfin in Minimally Classic CNV due to AMD (VIM) study also support the use of verteporfin treatment in patients with minimally classic CNV with small disc areas.

Quality evidence on the 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 OHS.

CODES

- *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.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
67221	Destruction of localized lesion of choroid (e.g., 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)

HCPCS Codes

Code	Description
J3396	Injection, verteporfin, 0.1 mg

ICD10 Codes

Code	Description
D18.09	Hemangioma of other sites
H35.051-H35.059	Retinal neovascularization, unspecified (code range)
H35.321-H35.3293	Exudative age-related macular degeneration (code range)
H44.20-H44.2A9	Degenerative myopia and Degenerative myopia with choroidal neovascularization (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 (OPT) (#80.2.1). Please refer to the following NCD website for Medicare Members [https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=349&ncdver=2&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&CptHcpcsCode=36514&bc=gAAAABAAAAAA&=] accessed 02/02/24.

There is currently a Local Coverage Determination (LCD) for Drugs and Biologicals, Coverage of, for Label and Off-Label Uses (#L33394). Please refer to the following LCD website for Medicare Members [https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33394&ver=47&CntrctrSelected=298*1&Cntrctr=298&name=National+Government+Services%2c+Inc.+(13201%2c+A+and+B+and+HHH+MAC%2c+J+-+K)&s=All&DocType=Active&bc=AggAAAQBAAAA&=] accessed 02/02/24.