



# CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

**Subject Photodynamic Therapy for Ocular Conditions**

**Effective Date ..... 1/15/2010**  
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**Coverage Policy Number ..... 0036**

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## Hyperlink to Related Coverage Policies

Artificial Retinal Devices  
 Bevacizumab (Avastin®)  
 Photocoagulation Laser Treatment of Macular Drusen  
 Proton Beam Therapy for Ocular Melanoma, Ocular Hemangiomas and Macular Degeneration  
 Transpupillary Thermal Therapy (TTT) for Choroidal Tumors and Macular Degeneration

## INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2010 CIGNA

## Coverage Policy

**CIGNA covers photodynamic therapy with verteporfin (Visudyne®) for ANY of the following indications:**

- age-related macular degeneration (AMD) with predominantly classic subfoveal choroidal neovascularization (CNV) when the area of the lesion comprises  $\geq 50\%$  of the lesion baseline
- pathological myopia
- presumed ocular histoplasmosis

## General Background

Photodynamic therapy (PDT) is a two-step drug and device procedure used for the treatment of defined ocular conditions. The patient is given an intravenous injection of a photosensitizing dye (i.e., verteporfin/Visudyne®) which is activated in the vessels by a low-energy laser. The dye then binds with low-density lipoproteins generating reactive oxygen species that accumulate in neovascular and neoplastic tissue. This accumulation leads to the destruction of the vascular endothelial tissue resulting in platelet aggregation and vessel thrombosis. Although the vessels typically close shortly after treatment, they can become reperfused within the

next three months. Studies have documented the safety and effectiveness of repeat verteporfin treatments every three months when leakage is seen on follow-up fluorescein angiography (Chan, et al., 2005; Atebara and Thall, 2004).

### **U.S. Food and Drug Administration (FDA)**

Visudyne therapy is approved by the FDA premarket approval (PMA) process as a two-step combination drug and device treatment for patients with predominantly (i.e.,  $\geq 50\%$ ) classic, subfoveal CNV AMD, pathological myopia or presumed ocular histoplasmosis. The FDA's decision included approval of verteporfin for injection, along with PMA of two Class III laser systems for photoactivation of verteporfin: the Coherent Opal Photoactivator™ Laser Console and LaserLink Adapter (Lumenis, Inc., Santa Clara, CA) and the Zeiss VISULAS 690s® laser and VISULINK PDT adapter (Carl Zeiss, Inc., Thornwood, NY). Other approved devices include the Ceralas™ I laser and Ceralink slit lamp adapter (QLT, Inc., Vancouver, British Columbia, Canada) (FDA, 2000; FDA, 2005).

### **Age-Related Macular Degeneration**

Age-related macular degeneration (AMD) may be characterized by the growth of immature blood vessels from the choroid (i.e., choroidal neovascularization [CNV]) that leak blood and fluid creating lesions under the central part of the retina below the fovea (i.e., subfoveal). Classic lesions are clearly delineated on fluorescein angiography and leak fluorescein evenly. Predominantly classic lesions occupy  $\geq 50\%$  of the lesion baseline (Wormald, et al., 2007; Verteporfin Roundtable Participants, 2005).

Treatment for AMD depends upon the stage of the disease and the type of AMD. Early AMD exhibiting no clinical signs may be observed without medical or surgical intervention. Antioxidant vitamins and mineral supplements are used for the treatment of intermediate and advanced AMD. For advanced conditions, thermal laser photocoagulation, or intravitreal injection of pegaptanib (Macugen), ranibizumab (Lucentis) or bevacizumab (Avastin) are also available treatment options. PDT is indicated for the treatment of AMD with predominantly classic subfoveal choroidal neovascularization (CNV) when the area of the lesion comprises  $\geq 50\%$  of the lesion baseline (AAO, 2008).

**Literature Review:** Systematic reviews (Chou, et al., 2009; Wormald, et al., 2007; Pauleikhoff, 2005; Meads and Hyde, 2004), randomized controlled trials (Azab, et al., 2005; Bressler, et al., 2005; Michels, et al., 2005; Schmidt-Erfurth, et al., 2004; Blumenkranz, et al., 2002; Verteporfin in Photodynamic Therapy Study Group, 2001), and case series (Mataix, et al., 2009; Potter, et al., 2007; Tewari, et al., 2007; Sharma, et al., 2004) support the use of PDT with verteporfin for the treatment of predominantly ( $\geq 50\%$ ) classic subfoveal choroidal neovascularization (CNV) caused by AMD. In general, the randomized controlled trials conducted compared PDT to placebo and reported significantly less visual loss following PDT. PDT also reduced or stop fluorescein leakage and restricted lesion growth. Studies comparing PDT to other treatment modalities are lacking. PDT is reported to result in less retinal scarring compared to laser photocoagulation (Chou, et al., 2009).

In a technology appraisal guidance, the National Institute for Clinical Excellence (NICE), (United Kingdom) (2003) recommends PDT for the treatment of wet AMD with a diagnosis of classic with no occult subfoveal CNV and best-corrected visual acuity 6/60 or better. NICE does not recommend PDT for the treatment of AMD when some occult CNV is present.

### **Pathological Myopia**

Pathological myopia (PM) or high myopia is a rare form of shortsightedness in which the eyeball is abnormally long, stretching the retina and the sclera of the eye. This greater axial length may cause areas of atrophy and/or cracks in the retina leading to leakage of blood. PM is often accompanied by CNV, chorioretinal atrophy, and retinal detachment. Historically, treatment options for PM have included laser photocoagulation, macular translocation and submacular surgery with poor results, including immediate, permanent loss of visual acuity. PDT has been shown to be effective in stabilizing and retarding the progression of visual deterioration in PM with CNV (Chan, et al., 2005; Lam, et al., 2004).

**Literature Review:** The evidence in randomized controlled trials (Costa, et al., 2006), nonrandomized comparative studies (Hayashi, et al., 2008), case series (Hussain, et al., 2008; Pece, et al., 2007; Krebs, et al., 2005; Lam, et al., 2004), and retrospective reviews (Glacet-Bernard, et al., 2007) support the use of PDT for the treatment of PM. There are a limited number of studies comparing PDT to other treatment modalities.

### **Presumed Ocular Histoplasmosis Syndrome**

Presumed ocular histoplasmosis syndrome (POHS) is a chronic intraocular inflammation caused by the fungus *histoplasma capsulatum*. Normally, patients are unaware of the disease process until they begin to develop visual disturbances from CNV. Depending on the stage and location of the disease, treatment options may include corticosteroids, laser photocoagulation, submacular surgery, and photodynamic therapy. PDT is indicated for the treatment of POHS because of its ability to selectively treat the target area while preserving surrounding tissue (Oliver, et al., 2005).

**Literature Review:** Although the evidence is primarily in the form of case series (Rosenfeld, et al., 2004; Saperstein, et al., 2002; Sickenberg, et al., 2000) and retrospective reviews (Shah, et al., 2005; Liu JC, et al., 2004), PDT is considered an accepted treatment option for this condition. Following the treatment of POHS with PDT, the studies reported stabilization, and/or improved visual acuity, and/or absence of fluorescein leakage. Studies comparing PDT to other established treatment modalities for POHS are lacking.

### **Other Indications**

PDT has been proposed for the treatment of other ocular conditions including: minimally classic lesions, occult lesions, juxtafoveal lesions, extrafoveal lesions, neovascular glaucoma, corneal neovascularization, CNV secondary to vascular retinochoroidal diseases (e.g., choroiditis, retinochoroiditis, angioid streaks), CNV with macular dystrophy and diseases without CNV (e.g., choroidal hemangioma and melanoma, retinal hemangioma and hamartoma, central serous chorioretinopathy (CSCR), and angiomatous lesions), and polypoidal choroidal vasculopathy. However, studies have primarily been in the form of nonrandomized, small case series and case reports with short-term follow-up and variable, nonsignificant outcomes (Tsuchiya, et al., 2009; Mennel, et al., 2007; Yoon, et al., 2007; Ruiz-Moreno, et al., 2006).

**Literature Review:** To compare the outcomes of treatment, Kaiser et al. (2009) randomly assigned 244 patients to PDT and 120 patients to placebo for the treatment of AMD with subfoveal occult with no classic CNV. Follow-up visits and subsequent therapy occurred for up to 24 months. During the first 12 months of the study, the PDT group received an average of 2.9 treatments compared to 3.3 treatments in the placebo group. Between month 12 and 24, the PDT group received an addition 1.3 treatments compared to 1.7 treatments in the placebo group. Although less loss of visual acuity was reported in the PDT group, the differences were not statistically significant ( $p=0.256$  at 12 months and  $p=0.138$  at 24 months). With the exception of infusion-related pain following PDT ( $p<0.01$ ), there were no statistically significant differences in reported adverse events between the two groups.

Chan et al. (2008) recruited 63 patients to participate in a randomized controlled trial evaluating the efficacy of PDT ( $n=63$ ) for the treatment of acute central serous chorioretinopathy (CSC) of three months or less duration. Subjects had impaired vision, subretinal fluid, and angiographic leakage. Patients were randomized to either treatment with PDT using half-dose verteporfin ( $n=43$ ) or to placebo ( $n=21$ ). At the 12-month follow-up visit, a significant difference was seen in the complete resolution of macular subretinal fluid in 37 eyes in the PDT group compared to 11 eyes in the placebo group ( $p=0.001$ ). The mean logarithm of the minimum angle of resolution, mean lines of best corrected vision acuity, and vision stability/improvement were also significantly improved in the PDT group ( $p=0.008$ ;  $p=0.002$ ;  $p=0.009$ , respectively). The PDT group had significantly better outcomes in the mean central foveal thickness seen on optical coherence tomography ( $p=0.001$ ). No complications or adverse events were experienced. Author-noted limitations included the small sample size, smaller number of eyes in the placebo group vs. the PDT group, use of half-dose verteporfin, exclusion of patients with secondary CSC, and the lack of angiography performed at the 12-month follow-up.

### **Professional Societies/Organizations**

The 2008 American Academy of Ophthalmology management guidelines for the treatment of AMD recommends PDT for the treatment of subfoveal CNV, new or recurrent, with a  $> 50\%$  classic lesion and an entire lesion of  $\leq 5400$  microns in greatest linear diameter. PDT may also be considered for the treatment of occult CNV with vision  $< 20/50$  or CNV with lesion  $< 4$  Macular Photocoagulation Study (MPS) disc areas when vision is  $> 20/50$ .

In 2005, the Verteporfin Roundtable Participants, including input from the American Society of Retina Specialists, the Macula Society, and the Retina Society, updated their guidelines on PDT for the treatment of CNV due to AMD and other causes. Viable candidates for PDT include those whose CNV is associated with AMD, pathologic myopia or other causes in which the outcome of lack of treatment would be more detrimental than PDT itself. Verteporfin therapy is recommended to treat eyes that present with a subfoveal lesion with

predominantly classic CNV (area of classic CNV occupying  $\geq 50\%$  of the area of the entire lesion at baseline). Lesion location should be subfoveal or may be considered for juxtafoveal lesions if the lesion is so close to the fovea that laser photocoagulation might be more harmful than beneficial. For pathological myopia, lesion composition should not influence patient selection for PDT because it has not shown to influence the outcomes of the therapy. According to the authors, PDT should be initiated within one week of the initial diagnostic fluorescein angiogram. Re-treatment may be indicated every three months if there is evidence of fluorescein leakage on revisits.

### Summary

Evidence in the published, peer-reviewed, scientific literature supports the use of photodynamic therapy (PDT) for the treatment of age-related macular degeneration (AMD) with predominantly classic subfoveal choroidal neovascularization (CNV) when the area of the lesion comprises  $\geq 50\%$  of the lesion baseline, pathological myopia, and presumed ocular histoplasmosis.

There is insufficient evidence in the peer-reviewed literature to support the use of PDT for the treatment of other ocular conditions (e.g., minimally classic lesions, occult lesions, juxtafoveal lesions, extrafoveal lesions, angioid streaks and neovascular glaucoma).

## Coding/Billing Information

**Note:** This list of codes may not be all-inclusive.

**Covered when medically necessary:**

CPT <sup>®*</sup> Codes	Description
67221	Destruction of localized lesion of choroid (eg, choroidal neovascularization); Photodynamic therapy (includes intravenous infusion)
67225	Destruction of localized lesion of choroid (eg, choroidal neovascularization); Photodynamic therapy, second eye, at single session, (list separately in addition to code for primary eye treatment).

HCPCS Codes	Description
J3396	Injection, verteporfin, 0.1 mg

ICD-9-CM Diagnosis Codes	Description
115.02	Infection by <i>Histoplasma capsulatum</i> , retinitis
115.92	Unspecified Histoplasmosis retinitis
360.21	Progressive high (degenerative) myopia
362.16	Retinal neovascularization NOS
362.50	Macular degeneration (senile) of retina, unspecified
362.51	Nonexudative senile macular degeneration of retina
362.52	Exudative senile macular degeneration

\*Current Procedural Terminology (CPT<sup>®</sup>) © 2010 American Medical Association: Chicago, IL.

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## Policy History

<b>Pre-Merger Organizations</b>	<b>Last Review Date</b>	<b>Policy Number</b>	<b>Title</b>
CIGNA HealthCare	1/15/2008	0036	Photodynamic Therapy for Ocular Conditions

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