



**OCULAR PHOTODYNAMIC THERAPY
WITH VISUDYNE (VERTEPORFIN)
HS-031**



Harmony Behavioral Health, Inc.

Harmony Behavioral Health of Florida, Inc.

Harmony Health Plan of Illinois, Inc.

HealthEase of Florida, Inc.

*'Ohana Health Plan, a plan offered by
WellCare Health Insurance of Arizona, Inc.*

WellCare Health Insurance of Illinois, Inc.

WellCare Health Insurance of New York, Inc.

WellCare Health Plans of New Jersey, Inc.

WellCare of Florida, Inc.

WellCare of Connecticut, Inc.

WellCare of Georgia, Inc.

WellCare of Kentucky, Inc.

WellCare of Louisiana, Inc.

WellCare of New York, Inc.

WellCare of Ohio, Inc.

WellCare of Texas, Inc.

WellCare Prescription Insurance, Inc.

**Ocular Photodynamic
Therapy with Visudyne
(verteporfin)**

Policy Number: HS-031

Original Effective Date: 7/3/2008

**Revised Date(s): 7/23/2009; 7/28/2010;
8/2/2011**

DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

BACKGROUND

Age-Related Macular Degeneration

Age-related macular degeneration (AMD) is the leading cause of blindness in individuals age 60 years and older. In the United States, fifteen million people have been diagnosed with AMD, and it is estimated that an additional two million new cases are diagnosed annually. There are two types of AMD, “dry” and “wet.” Dry, atrophic, or non-neovascular AMD is characterized by small yellow lipid debris deposits beneath the retina. Dry AMD makes up 90% of all AMD cases and normally does not result in severe vision loss. The concern with dry AMD is that it can progress to wet AMD, creating progressive visual disturbances. Wet, or neovascular, AMD is characterized by choroidal neovascularization (CNV), the growth of immature blood vessels from the choroid. This leads to blood leakage from the vessels, which in turn causes scarring, blind spots and disturbances of central vision. Wet AMD comprises 10–15% of diagnosed cases of macular degeneration and 90% of resulting vision loss and blindness. If left untreated, complete blindness may develop within five years. The three lesion types associated with wet AMD are classic (25%), occult (40%) and minimally classic or mixed (35%). Classic lesions are clearly delineated on fluorescein angiography and leak fluorescein evenly. Occult lesions can be hard to detect and create an uneven fluorescein appearance. Minimally classic lesions are a combination of classic and occult types (Wormald, et al., 2005). Predominantly classic lesions occupy > 50% of the lesion baseline, while minimally classic lesions occupy < 50% of the lesion baseline. Diagnosis of AMD is based upon information obtained from patient history, physical examination and, when appropriate, fluorescein angiography. 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) may be the treatment of choice. Photodynamic therapy is indicated for the treatment of AMD with predominantly classic subfoveal choroidal neovascularization (CNV) when the area of the lesion comprises > 50% of the lesion baseline (AAO, 2007).

Ocular Histoplasmosis

Ocular histoplasmosis is a chronic intraocular inflammation caused by the fungus *histoplasma capsulatum*. The fungus is acquired by inhalation of soil and material polluted by bat or bird droppings. Once inhaled, the fungus infects the lungs and is circulated throughout the body via the blood stream, infecting other organs (i.e., disseminated histoplasmosis). Histoplasmosis is endemic in the United States in the Ohio-Mississippi River Valley. In this geographic area, up to 80 million people, 20–50 years of age, are at risk for acquiring the disease. Ocular histoplasmosis is the most common form of disseminated histoplasmosis.

Clinical findings of ocular histoplasmosis include a macular lesion from the presence of CNV, peripapillary atrophy and choroidal scars. Normally, the patients are unaware of the disease process until they begin to develop visual disturbances from CNV. Once CNV develops, visual prognosis is poor. 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 ocular histoplasmosis with CNV involvement because of its ability to selectively damage the target area and not destroy surrounding tissue (Oliver, et al., 2005).

Pathologic Myopia

Pathological myopia (PM) is a rare form of shortsightedness in which the eyeball continues to grow, becoming 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. The cracks allow for new blood vessel growth that can lead to blood and serum leakage. PM occurs most often in people of Chinese, Japanese, Middle Eastern or Jewish descent. The condition is seen in 9–21% of the Asian population as opposed to 2–4% in the white population (Chan, et al., 2005).

Pathological myopia is the seventh leading cause of legal blindness in Americans. Twin and family studies support

a genetic contribution to the development of myopia, especially the more severe forms (Walling, 2002). Pathological myopia can develop at any age, but most frequently occurs between the ages of 30 and 40 years. As many as 50,000 people per year are diagnosed with CNV associated with pathological myopia. Treatment options for PM have included laser photocoagulation, macular translocation and submacular surgery with poor results, including immediate, permanent loss of additional visual acuity. PDT has been shown to be effective in stabilizing and retarding the progression of visual deterioration in PM with CNV (Lam, et al., 2004).

Photodynamic Therapy

Photodynamic therapy is a two-stage process requiring 1) administration of Visudyne (verteporfin for injection) and 2) activation of the drug by nonthermal red light (i.e. diode laser). Once verteporfin is activated by light in the presence of oxygen, highly reactive, short-lived singlet oxygen and reactive oxygen radicals are generated. Light activation of verteporfin results in local damage to neovascular endothelium, ultimately resulting in vessel occlusion. Damaged endothelium is known to release procoagulant and vasoactive factors, resulting in platelet aggregation, fibrin clot formation and vasoconstriction. Verteporfin appears to somewhat preferentially accumulate in neovasculature, including choroidal neovasculature. The temporary occlusion of choroidal neovascularization (CNV) following Visudyne therapy can lead to a reduction in vessel leakage, stopping the progression of vision damage due to CNV. The therapeutic occlusion has been confirmed in humans by fluorescein angiography.

Concurrent Bilateral Treatment

Controlled clinical trials with Visudyne only allowed treatment of one eye per patient. In patients who present with eligible lesions in both eyes, physicians should evaluate the potential benefits and risks of treating both eyes concurrently. If the patient has already received previous Visudyne therapy in one eye with an acceptable safety profile, both eyes can be treated concurrently after a single administration of Visudyne. The more aggressive lesion should be treated first, at 15 minutes after the start of infusion. Immediately at the end of light application to the first eye, the laser settings should be adjusted to introduce the treatment parameters for the second eye, with the same light dose and intensity as for the first eye, starting no later than 20 minutes from the start of infusion.

In patients who present for the first time with eligible lesions in both eyes without prior Visudyne therapy, it is prudent to treat only one eye (the most aggressive lesion) at the first course. One week after the first course, if no significant safety issues are identified, the second eye can be treated using the same treatment regimen after a second Visudyne infusion. Approximately 3 months later, both eyes can be evaluated and concurrent treatment following a new Visudyne infusion can be started if both lesions still show evidence of leakage (Novartis, 2007).

POSITION STATEMENT

Photodynamic Therapy with Visudyne (verteporfin) **is considered medically necessary** when all of the following criteria are met:

- Treatment is of subfoveal choroidal neovascularization (CNV) lesions caused by one of the following indications:
 - Aged-related macular degeneration (AMD); OR,
 - Pathologic myopia; OR,
 - Ocular histoplasmosis.
- CNV lesions comprise > 50 % of the lesion baseline (classic CNV)
- Retreatment with photodynamic therapy with Visudyne every three months may be considered medically necessary if:
 - A fluorescein angiogram performed prior to the retreatment indicates recurrence or persistence of vascular leakage.

Photodynamic Therapy with Visudyne **is considered investigational and NOT a covered benefit** for any condition not listed above, including but not limited to:

- CNV secondary to:
 - Choroiditis
 - Angioid streaks
 - Central serous chorioretinopathy
 - Macular dystrophy
 - Parafoveal telangiectasia
 - Retinal angiomatous proliferation
- Idiopathic CNV
- Diseases without CNV

CODING

Covered CPT® Codes

- 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).

Covered HCPCS Code

J3396 Injection, Visudyne (verteporfin), 0.1 mg

Covered ICD-9 Procedure Code

14.29 Destruction of Lesion of Retina and Choroid Not otherwise specified.

Covered ICD-9-CM Diagnosis Codes

- 115.02** Infection by Histoplasma capsulatum, retinitis
- 115.12** Infection by Histoplasmosis duboisii
- 115.92** Histoplasmosis, Unspecified
- 360.21** Progressive high (degenerative) myopia
- 362.16** Choroid / Retinal neovascularization NOS
- 362.51** Macular degeneration; Nonexudative senile, dry
- 362.52** Macular degeneration; Exudative senile, wet

Non Covered ICD-9 Diagnosis Codes This list may not be all inclusive.

- 190.6** Malignant neoplasm of choroid [choroidal melanoma]
- 228.09** Hemangioma of other sites [choroidal]
- 362.15** Retinal telangiectasia [parafoveal]
- 362.29** Other nondiabetic proliferative retinopathy [retinal angiomatous proliferation]
- 362.41** Central serous retinopathy [serous chorioretinopathy]

- 362.50 Macular degeneration (senile), unspecified
- 363.20 Choroiditis / Chorioretinitis, unspecified
- 363.43 Angioid streaks of choroid
- 364.42 Rubeosis iridis
- 371.55 Macular Corneal Dystrophy

*Current Procedural Terminology (CPT) 2010 American Medical Association: Chicago, IL.®©

REFERENCES

Peer Reviewed

1. Chan WM, Ohji M, Lai TY, Liu DT, Tano Y, Lam DS. Choroidal neovascularisation in pathological myopia: an update in management. *Br J Ophthalmol*. 2005 Nov;89(11):1522-8.
2. Hayes. Photodynamic Therapy with Verteporfin (Visudyne) for Neovascular Age related Macular Degeneration. Lansdale, PA: HAYES, Inc.; ©2007 Winifred S. Hayes, Inc. Apr 25, 2007.
3. Lam DS, Chan WM, Liu DT, Fan DS, Lai WW, Chong KK. Photodynamic therapy with verteporfin for subfoveal choroidal neovascularisation of pathologic myopia in Chinese eyes: a prospective series of 1 and 2 year follow up. *Br J Ophthalmol*. 2004 Oct;88(10):1315-9.
4. Oliver A, Ciulla TA, Comer GM. New and classic insights into presumed ocular histoplasmosis syndrome and its treatment. *Curr Opin Ophthalmol*. 2005 Jun;16(3):160-5.
5. Walling A. Shortsightedness: a review of causes and interventions. *AAFP*. Accessed Nov 20, 2007. Available at URL address: <http://www.aafp.org/afp/20020915/tips/1.htm>
6. Wormald R, Evans J, Smeeth L, Henshaw K.. Photodynamic therapy for neovascular age-related macular degeneration. *Cochrane Database Syst Rev*. 2007 Jul 18;(3):CD002030.

Government Agencies, Professional and Medical Organizations

1. American Academy of Ophthalmology. Ophthalmic technology assessment. Photodynamic therapy with verteporfin for age-related macular degeneration. *Ophthalmol*. 2000;107:2314-7.
2. American Academy of Ophthalmology. Preferred practice pattern® age-related macular degeneration. 2006. Accessed Nov 19, 2007. Available at URL address: http://one.aao.org/CE/PracticeGuidelines/PPP_Content.aspx?cid=0e2b5946-d493-4a4a-80fa-6f40841b1405
3. National Institute for Clinical Excellence (NICE). Technology appraisal guidance 68. Photodynamic therapy for age-related macular degeneration. Sep 2003. Accessed Nov 19, 2007. Available at URL address: <http://www.nice.org.uk/guidance/index.jsp?action=byID&o=11512>

Other

1. Visudyne (verteporfin for injection). Prescribing information. Novartis. March 2007.

HISTORY AND REVISIONS

Date	Action
12/1/2011	• New template design approved by MPC.
8/2/2011	• Approved by MPC. No changes.