

SPECIALTY GUIDELINE MANAGEMENT

VISUDYNE (verteporfin)

POLICY

A. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Visudyne is indicated for the treatment of patients with predominantly classic subfoveal choroidal neovascularization due to age related macular degeneration, pathologic myopia, or presumed ocular histoplasmosis.

Compendial Uses

Occult choroidal neovascularization
Central serious chorioretinopathy
Juxtafoveal retinal telangiectasia
Choroidal hemangioma
Polypoidal choroidal vasculopathy

All other indications are considered experimental/investigational and are not covered benefits.

B. PRESCRIBER RESTRICTION

Visudyne must be prescribed by, or in conjunction with, an ophthalmologist.

C. CRITERIA FOR APPROVAL

1. Ocular Indications

- a. Authorization of 12 months may be granted for members prescribed Visudyne for the any of the following indications:
 - i. Classic subfoveal choroidal neovascularization due to age-related macular degeneration
 - ii. Pathologic myopia
 - iii. Presumed ocular histoplasmosis
 - iv. Occult subfoveal choroidal neovascularization
 - v. Central serious chorioretinopathy
 - vi. Juxtafoveal retinal telangiectasia
 - vii. Choroidal hemangioma
 - viii. Polypoidal choroidal vasculopathy

D. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

E. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

REFERENCES

1. Visudyne [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals; September 2013.
2. American Academy of Ophthalmology Retinal/Vitreous Panel. Preferred Practice Pattern Guidelines. Age-Related Macular Degeneration. San Francisco, CA: American Academy of Ophthalmology; 2014. Available at: www.aao.org/ppp.

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3. Bressler NM, Treatment of Age-Related Macular Degeneration with Photodynamic Therapy (TAP) Study Group. Photodynamic therapy of subfoveal choroidal neovascularization in age-related macular degeneration with verteporfin: two-year results of 2 randomized clinical trials-TAP report 2. *Arch Ophthalmol* 2001;119:198-207.
4. Bae SH, Heo J, Kim C. Low-fluence photodynamic therapy versus ranibizumab for chronic central serous chorioretinopathy: one-year results of a randomized trial. *Ophthalmology* 2014;121(2):558-565.
5. Hershberger VS, Hutchins RK, Laber PW. Photodynamic therapy with verteporfin for subretinal neovascularization secondary to bilateral idiopathic acquired juxtafoveal telangiectasis. *Ophthalmic Surg Lasers Imaging* 2003;34(4):318-320.
6. Chan LW, Hsieh YT. Photodynamic therapy for choroidal hemangioma unresponsive to ranibizumab. *Optom Vis Sci* 2014;91(9):e226-229.
7. Wong, RL and Lai, TY. Polypoidal choroidal vasculopathy: An update on therapeutic approaches. *J Ophthalmic Vis Res* 2013;8(4):359-371.