Clinical Policy: Verteporfin (Visudyne)

Reference Number: PA.CP.PHAR.187
Effective Date: 01/18
Last Review Date: 07/18

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for verteporfin (Visudyne®).

FDA Approved Indication(s)
Visudyne is indicated for the treatment of patients with predominantly classic subfoveal choroidal neovascularization (CNV) due to:

- Age-related macular degeneration (AMD)
- Pathologic myopia
- Presumed ocular histoplasmosis

Limitation(s) of use: There is insufficient evidence to indicate Visudyne for the treatment of predominantly occult subfoveal choroidal neovascularization.

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness® that Visudyne is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Choroidal Neovascularization (must meet all)**:**

1. Diagnosis of subfoveal CNV due to one of the following (a, b, or c):
   a. AMD;
   b. Pathologic myopia;
   c. Presumed ocular histoplasmosis;
2. Prescribed by or in consultation with an ophthalmologist;
3. Age ≥ 18 years;
4. For AMD, member meets one of the following (a or b):
   a. Failure of a trial of bevacizumab unless contraindicated or clinically significant adverse effects are experienced;
   b. Disease has progressed after use of a vascular endothelial growth factor (VEGF) as first-line treatment;
5. For CNV due to pathologic myopia, failure of a trial of bevacizumab or Lucentis unless contraindicated or clinically significant adverse effects are experienced;
6. Dose does not exceed 6 mg/m^2 body surface area.

Approval duration: 3 months (1 dose)

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. Classic Subfoveal Choroidal Neovascularization (must meet all)**:**

1. Previously received medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy as evidenced by one of the following (a, b, c, or d):
   a. Detained neovascularization;
   b. Improvement in visual acuity;
   c. Maintenance of corrected visual acuity from prior treatment;
   d. Supportive findings from optical coherence tomography or fluorescein angiography;
3. Recent fluorescein angiography, conducted at least 3 months after the last treatment, shows recurrent or persistent choroidal neovascular leakage;

If request is for a dose increase, new dose does not exceed 6 mg/m2 body surface

Approval duration: 3 months (1 dose)

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Refer to PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53 or evidence of coverage document;

Background

Description/Mechanism of Action:

Visudyne (verteporfin) is a light-activated drug used in photodynamic therapy. Visudyne therapy is a two-stage process requiring administration of both verteporfin for injection and nonthermal red lights. Verteporfin is transported in the plasma primarily by lipoproteins. 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, resulting in vessel occlusion. Damaged endothelium is known to release procoagulant and vasoactive factors through the lipo-oxygenase (leukotriene) and cyclooxygenase (eicosanoids such as thromboxane) pathways, resulting in platelet aggregation, fibrin clot formation and vasoconstriction. Verteporfin appears to somewhat preferentially accumulate in neovasculature, including choroidal neovasculature. However, animal models indicate that the drug is also present in the retina. Therefore, there may be collateral damage to retinal structures following photoactivation including the retinal pigmented epithelium and outer nuclear layer of the retina. The temporary occlusion of CNV following Visudyne therapy has been confirmed in humans by fluorescein angiography.

Formulations:

Single-use vial: lyophilized dark green cake containing 15 mg verteporfin for reconstitution

Appendices

Appendix A: Abbreviation Key

AMD: age-related macular degeneration
CNV: choroidal neovascularization
VEGF: vascular endothelial growth factor

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3396	Injection, verteporfin, 0.1 mg

Reviews, Revisions, and Approvals	Date	Approval Date
Added specialist requirement. Removed fluorescein angiography for diagnosis due to addition of specialist. Added age limit. Expanded VEGF requirement for AMD and pathologic myopia specifically to bevacizumab or other VEGF inhibitors. Added redirection to Lucentis for mCNV due to clinical superiority. Removed allowed indication for occult CNV per limitation of use. References reviewed and updated.	02/18	

References

1. Visudyne Prescribing Information. Bridgewater, NJ: Valeant Ophthalmics; June 2016. Available at: www.visudyne.com. Accessed November 14, 2017.
2. American Academy of Ophthalmology Retina/Vitreous Panel. Preferred Practice Pattern® Guidelines. Age-Related Macular Degeneration. San Francisco, CA: American Academy of Ophthalmology; January 2015. Available at www.aao.org/ppp. Accessed February 24, 2017.
3. Matri LE, Chebil A, Kort F. Current and emerging treatment options for myopic choroidal neovascularization. Clin Ophthalmol. 2015; 9: 733-744.
4. Diaz RI, Sigler EJ, Rafieetary MR, Calzada JI. Ocular histoplasmosis syndrome. Surv Ophthalm. 2015; 60(4): 279-295.