

## Clinical Policy: Verteporfin (Visudyne)

Reference Number: CP.PHAR.187

Effective Date: 03/16

Last Review Date: 03/17

[Coding Implications](#)  
[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### Description

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

### Policy/Criteria

It is the policy of health plans affiliated with Centene Corporation® that Visudyne is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Subfoveal Choroidal Neovascularization (must meet all):

1. Diagnosis of subfoveal choroidal neovascularization (CNV) confirmed by recent fluorescein angiography and classified as one of the following (a or b):
  - a. Predominantly classic CNV (classic [well-demarcated] CNV comprises > 50% of the entire lesion area);
  - b. Occult CNV (poorly defined CNV with indistinct or poorly demarcated boundaries), and either vision < 20/50 or CNV size < 4 macular photocoagulation study disc areas;
2. The CNV is due to one of the following (a, b, or c):
  - a. Age-related macular degeneration (AMD);
  - b. Pathologic myopia;
  - c. Presumed ocular histoplasmosis;
3. Failure of an anti-vascular endothelial growth factor (VEGF) medication (e.g., aflibercept, bevacizumab, pegaptanib, ranibizumab) unless contraindicated or clinically significant adverse effects are experienced.

**Approval duration: 3 months (1 dose)**

##### B. Other diagnoses/indications: Refer to CP.PHAR.57 - Global Biopharm Policy.

#### II. Continued Approval

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

1. Previously received medication via Centene benefit or member has previously met all initial approval criteria;
2. Documentation of positive response to therapy (e.g., detained neovascularization, improvement/stabilization of visual acuity, supportive findings on 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.

**Approval duration: 3 months (1 dose)**

**B. Other diagnoses/indications (must meet 1 or 2):**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy;
2. Refer to CP.PHAR.57 - Global Biopharm Policy.

**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

*FDA Approved Indication:*

Visudyne (verteporfin) is light-activated drug/intravenous injectable indicated for the treatment of patients with:

- Predominantly classic subfoveal CNV due to:
  - AMD; or
  - pathologic myopia; or
  - presumed ocular histoplasmosis

Limitations of use:

- There is insufficient evidence to indicate Visudyne for the treatment of predominantly occult subfoveal CNV.

**Appendices**

**Appendix A: Abbreviation Key**

AMD: age-related macular degeneration

CNV: choroidal neovascularization

VEGF: vascular endothelial growth factor

**Coding Implications**

**CLINICAL POLICY**  
Verteporfin

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
Format: policy converted to new template and split from CP.PHAR.39 AMD Retinal Disorder Treatments. Criteria: added age and max dose; added criteria for classic and occult CMV per AAO AMD guidelines; removed restriction that occult, which is off-label, only be used in the presence of AMD; removed monotherapy requirement as Visudyne is sometimes used with anti-VEGF medications in nonresponsive cases; changed approval duration to 3 months per PI; removed requests for documentation.	03/16	03/16
Removed age restriction. Removed restriction that lesion must be $\leq$ 5400 microns in greatest linear diameter for predominantly classic CNV. Added definition for occult CNV. Added option for contraindication/clinically significant adverse effects to anti-VEGF trial requirement. Removed max dose criterion, and instead incorporated dosing as a quantity limit (1 dose per 3 month approval period). Removed safety criteria. For continuation: Modified “Currently receiving...” to “Previously received...” to account for as needed dosing. Added requirement for documentation of positive response to therapy. Specified that FA should be at least 3 months after the last treatment.	03/17	03/17

**References**

1. Visudyne Prescribing Information. Bridgewater, NJ: Valeant Ophthalmics; June 2016. Available at: [www.visudyne.com](http://www.visudyne.com). Accessed February 27, 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](http://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 Ophthalmol. 2015; 60(4): 279-295.

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status;

evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**Note: For Medicare members**, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

## CLINICAL POLICY

### Verteporfin



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