

<b>Clinical Policy Title:</b>	verteporfin
<b>Policy Number:</b>	RxA.554
<b>Drug(s) Applied:</b>	Visudyne®
<b>Original Policy Date:</b>	03/06/2020
<b>Last Review Date:</b>	12/07/2020
<b>Line of Business Policy Applies to:</b>	All lines of business

## Background

Verteporfin (Visudyne®) is a light activated drug used in photodynamic therapy. It 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.

## Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
verteporfin (Visudyne®)	Predominantly classic subfoveal choroidal neovascularization due to age-related macular degeneration, pathologic myopia or presumed ocular histoplasmosis	6 mg/m <sup>2</sup> Body Surface Area IV diluted with 5% dextrose to a final volume of 30 mL infused over 10 minutes	6 mg/m <sup>2</sup> IV

## Dosage Forms

- Vial for reconstitution: 15 mg (2 mg/mL after reconstitution)

## Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

### 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;

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

- c. Presumed ocular histoplasmosis;
- 2. Prescribed by or in consultation with an ophthalmologist;
- 3. Age ≥ 18 years;
- 4. Member has failed an intravitreal anti-vascular endothelial growth factor (VEGF), unless contraindicated or clinically significant adverse effects are experienced;  
*\*Prior authorization may be required.*
- 5. Dose does not exceed 6 mg/m<sup>2</sup> body surface area.

**Approval Duration**

**Commercial:** 3 months (1 dose)

**Medicaid:** 3 months (1 dose)

**II. Continued Therapy Approval**

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

- 1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
- 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;
- 4. If request is for a dose increase, new dose does not exceed 6 mg/m<sup>2</sup> body surface area.

**Approval Duration**

**Commercial:** 3 months (1 dose)

**Medicaid:** 3 months (1 dose)

**III. Appendices**

**APPENDIX A: Abbreviation/Acronym Key**

AMD: age-related macular degeneration

CNV: choroidal neovascularization

FDA: Food and Drug Administration

mCNV: myopic choroidal neovascularization

VEGF: vascular endothelial growth factor

**APPENDIX B: Therapeutic Alternatives**

*Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.*

Drug Name	Dosing Regimen	Maximum Dose
Avastin® (bevacizumab), Mvasi® (bevacizumab- awwb), Zirabev® (bevacizumab-bvzr)	Neovascular (wet) AMD: 1.25 to 2.5 mg administered by intravitreal injection every 4 weeks.	2.5 mg/month
	mCNV: 0.05 mL initial intravitreal injection, followed by monthly evaluation for additional injections as needed.	0.5 mL/month

Eylea® (aflibercept)	Neovascular (wet) AMD: 2 mg (0.05 mL) administered by intravitreal injection once a month for 3 months then 2mg every 2 months.	2 mg/month
Lucentis® (ranibizumab)	Neovascular (wet) AMD: 0.5 mg (0.05 mL) administered by intravitreal injection once a month.  <u>Alternative dosing:</u> Once monthly injections for three months followed by 4-5 doses dispersed among the following 9 months  Or  Treatment may be reduced to one injection every 3 months after the first four injections if monthly injections are not feasible.	0.5 mg/month
	Myopic CNV: 0.5 mg (0.05 mL) administered by intravitreal injection once a month for up to 3 months. Patients may be retreated if needed.	0.5 mg/month
pegaptanib	Neovascular (wet) AMD: 0.3 mg (0.09 mL) administered by intravitreal injection every 6 weeks.	0.3 mg/6 weeks

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

#### **APPENDIX C: Contraindications/Boxed Warnings**

- Contraindication(s):
  - Patients with porphyria or a known hypersensitivity to any component of the Visudyne® preparation.
- Boxed Warning(s):
  - None reported.

#### **APPENDIX D: General Information**

- In the ANti-VEGF Antibody for the Treatment of Predominantly Classic CHORoidal Neovascularisation in AMD (ANCHOR) trial, the number of patients that lost fewer than 15 letters at 12 months was achieved by 96.4% of patients treated with Lucentis 0.5 mg compared to 64.3% of patients treated with Visudyne® (p < 0.001). Rate of intraocular inflammation was higher for patients treated with Lucentis 0.5 mg at 15% compared to Visudyne® at 2.8%.
- In the RADIANCE, a Phase III, 12-month, multicenter, randomized, double-masked, active-controlled trial, Lucentis was compared to vPDT (Visudyne® and photodynamic therapy) for the treatment of mCNV. Lucentis treatment in groups I and II was superior to vPDT based on mean average BCVA change from baseline to month 1 through month 3 (group I: +10.5, group II: +10.6 vs. group III: +2.2 Early Treatment Diabetic Retinopathy Study [ETDRS] letters; both p < 0.0001). Lucentis treatment guided by disease activity was noninferior to VA stabilization-guided retreatment based on mean average BCVA change from baseline to

month 1 through month 6 (group II: +11.7 vs. group I: +11.9 ETDRS letters;  $p < 0.00001$ ). Mean BCVA change from baseline to month 12 was +13.8 (group I), +14.4 (group II), and +9.3 ETDRS letters (group III). At month 12, 63.8% to 65.7% of patients showed resolution of myopic CNV leakage. Patients received a median of 4.0 (group I) and 2.0 (groups II and III) ranibizumab injections over 12 months. No deaths or cases of endophthalmitis and myocardial infarction occurred.

**References**

1. Visudyne® Prescribing Information. Bridgewater, NJ: Valeant Ophthalmics; February 2017. Available at: [www.visudyne.com](http://www.visudyne.com). Accessed October 5, 2020.
2. American Academy of Ophthalmology Retina/Vitreous Panel. Preferred Practice Pattern® Guidelines. Age-Related Macular Degeneration. San Francisco, CA: American Academy of Ophthalmology; September 2019. Available at: [www.aao.org/ppp](http://www.aao.org/ppp). Accessed October 5, 2020.
3. Diaz RI, Sigler EJ, Rafieetary MR, Calzada JI. Ocular histoplasmosis syndrome. *Surv Ophthalmol.* 2015; 60(4): 279-295.
4. Wolf S, Valciuniene VJ, Laganovska G, et al. RADIANCE: a randomized controlled study of ranibizumab in patients with choroidal neovascularization secondary to pathologic myopia. *Ophthalmology* March 2014; 121(3):682-92.e2. doi: 10.1016/j.ophtha.2013.10.023. Epub 2013 Dec 8.
5. Ohno-Matsui K, Ikuno Y, Lai TY, et al. Diagnosis and treatment guideline for myopic choroidal neovascularization due to pathologic myopia. *Progress in Retinal and Eye Research.* 2018; 63: 92-106. <https://doi.org/10.1016/j.preteyeres.2017.10.005>. Accessed October 5, 2020.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: <ol style="list-style-type: none"> <li>1. Policy title table was updated. Line of business policy applies was updated to all lines of business.</li> <li>2. Initial approval criteria I.A.4 updated to include anti-VEGF drug as first-line.</li> <li>3. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance...”.</li> <li>4. Commercial approval duration was updated from “length of benefit” to 3 months for initial and continued approval criteria.</li> <li>5. Appendix A was updated to include VEGF.</li> <li>6. Appendix B for therapeutic alternatives standard verbiage has been updated. Section also updated to</li> </ol>	10/05/2020	12/07/2020

<p>include more specific alternatives and remove discontinued products.</p> <p>7. References were updated.</p>		
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