

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Age-Related Macular Degeneration (AMD) is a degenerative disease of the retina that leads to the loss of central vision. Two main types of AMD exist: dry (atrophic) and wet (exudative). Dry AMD, the more common type of AMD, progresses more slowly than wet AMD and is distinguished by small yellow lipid debris deposits beneath the retina. It is frequently a precursor of exudative (wet) AMD. The wet form, which is less common and progresses faster, is distinguished by the development of choroidal neovascularization (CNV), which greatly increases the risk of developing severe irreversible vision loss. Although non-neovascular or dry AMD accounts for approximately 80% of AMD patients, the neovascular form is responsible for the majority of the severe central visual acuity loss associated with AMD. The three types of lesions associated with wet AMD are classic, occult, and minimally classic; however, choroidal neovascular lesions are classified as classic or occult based on fluorescein angiographic assessments. CNV disrupts the anatomy of the retinal pigment epithelium-photoreceptor complex, leaks serum and sometimes blood, and is frequently accompanied by irreversible scar formation, which is associated with photoreceptor loss. AMD management options include observation and early detection, antioxidant vitamin and mineral supplements, intravitreal injection of anti-VEGF agents, photodynamic therapy, laser photocoagulation surgery, and smoking cessation counseling for patients who currently smoke (AAO, 2019). The safety and effectiveness of each treatment are determined by the type and location of the neovascularization (Boyd, 2020).

Photodynamic therapy (PDT) is a technique that involves the use of a photosensitizing agent that causes localized and selective tissue damage when activated by light of a specific wavelength. In patients with predominantly classic choroidal neovascular lesions, PDT with verteporfin slows retinal damage associated with AMD. Verteporfin, in combination with nonthermal light, is used to treat primarily classic subfoveal CNV caused by AMD. PDT with verteporfin is not recommended for use in less severe, dry macular degeneration without neovascularization. With the increased use of anti-VEGF therapy, the role of PDT has been reduced. Patients who do not respond to initial anti-VEGF therapies should consider PDT (with or without intravitreal bevacizumab, aflibercept, or ranibizumab).

Visudyne (verteporfin injection), a light-activated drug used in PDT, was approved by the FDA in April 2000 for the treatment of predominantly classic subfoveal CNV caused by AMD, pathologic myopia, or suspected ocular histoplasmosis. Once verteporfin has been activated by light in the presence of oxygen, highly reactive, short-lived reactive oxygen radicals are produced. Light activation of verteporfin causes local damage to neovascular endothelium, which leads to vessel blockage. A course of verteporfin therapy requires the administration of both verteporfin for injection and non-thermal red light. The first stage is a 10-minute intravenous infusion of verteporfin, followed by 83 seconds of nonthermal low-intensity light five minutes later. PDT has advantages over traditional laser therapies due to its capacity for causing targeted tissue injury. PDT has advantages over conventional laser treatments due to its ability to cause selective tissue injury. The ability to affect CNV selectively is due to preferential localization of the photosensitizer dye to the CNV complex and irradiation of the complex with light levels far lower than required for thermal injury. The most frequently reported adverse events in verteporfin clinical trials include injection site reactions, pain, inflammation, extravasation, rashes, hemorrhage, and visual disturbances, which occurred in clinical trials at a rate ranging from 10% to 30% of patients. Verteporfin is contraindicated in patients with porphyria or hypersensitivity to any component of the verteporfin preparation. Re-treatment may be indicated as

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frequently as every 3 months based on the appearance of leakage on fluorescein angiography. However, the appropriate frequency of repeat treatments and the number of total treatments a patient may require during the course of clinical management of their neovascular AMD are not defined. There is also no clear definition of treatment failure and, as a result, no method for determining when treatment should be discontinued. The current data suggest that PDT with verteporfin is beneficial for up to 2 years; however, there are no data for longer time periods.

COVERAGE POLICY

Ocular PDT utilizing Visudyne in the treatment of adult patients **may be considered medically necessary** when **ALL** of the following clinical criteria are met:

1. Diagnosis of subfoveal CNV due to **ONE** of the following:
 - a. AMD; **OR**
 - b. Pathologic myopia; **OR**
 - c. Presumed ocular histoplasmosis

AND

2. Member meets **ONE** of the following with documentation [**A, B, OR C**]
 - A. Predominantly *classic* subfoveal CNV (wet macular degeneration; classic component comprises > 50% of the entire lesion area)
 - a. Diagnosis of neovascular *wet* AMD; **AND**
Informational Note: PDT with verteporfin is not recommended for use in the less severe, dry form of macular degeneration in which neovascularization is not present (AHFS, 2021).
 - b. Predominantly classic subfoveal CNV where the area of *classic* CNV[†] occupies at least 50% of the entire lesion (with the greatest linear dimension equal to or less than 7000-7500 microns) as demonstrated by a fluorescein angiogram. [†]*CNV lesions comprised of classic and/or occult components.*
Informational Note: PDT with verteporfin was not associated with clinical benefit in patients in which the classic component comprised less than 50% of the area of the lesion (AHFS, 2021).

OR

- B. Presentation of **ONE (1)** of the following:
 - a. Subfoveal occult with no classic CNV associated with AMD; **OR**
 - b. Subfoveal minimally classic CNV [where the area of classic CNV occupies < 50% of the area of the entire lesion] associated with AMD; **AND**
 - c. Documentation of the following:
 1. Lesions are small (4 disk areas or less in size) at the time of initial treatment or within the 3 months prior to initial treatment; **AND**
 2. Lesions have shown evidence of progression within the 3 months prior to initial treatment. Evidence of progression must be documented by deterioration of visual acuity (at least 5 letters on a standard eye examination chart), lesion growth (an increase in at least 1 disk area), or the appearance of blood associated with the lesion.

OR

- C. Predominantly classic subfoveal CNV [when the area of classic CNV occupies at least 50% of the area of the entire lesion] associated with macular degeneration, secondary to **ONE** of the following:
 1. Infection by *Histoplasma capsulatum*, retinitis; **OR**
 2. Pathologic myopia; Progressive high (degenerative) myopia.

NOTE: Subsequent requests require either an OCT report or a fluorescein angiogram to assess treatment response and should include the description of the lesion (e.g., predominantly classic), unless there is a documented history of fluorescein allergy

AND

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3. Disease progression after use of an anti-VEGF as first-line treatment. Documentation with date(s) of failed therapy or clinical event required.

NOTE: Avastin (bevacizumab); Lucentis (ranibizumab); Eylea (aflibercept); Macugen (pegaptanib); Beovu (brolucizumab), etc.

EXCEPTIONS: Clinically significant adverse effects, labeled contraindication, or clinical rationale supporting the inappropriateness to VEGF Inhibitor therapies. Documentation required.

AND

4. Requested Visudyne therapy will be used in combination with PDT. NOTE: Ocular PDT is only authorized when used in conjunction with verteporfin.

AND

5. Visudyne is NOT prescribed for, or intended for concurrent or combination with, ANY of the following treatments or conditions:

- a. Bilateral treatment UNLESS member had previous verteporfin therapy, with an acceptable safety profile, then treatment of both eyes concurrently (approximately 3 months after the initial treatment) may be considered. Documentation required.

Informational Note: Use in more than one eye has not been studied; however, it is recommended that initial treatment in patients requiring treatment in both eyes should be applied to the more aggressive lesion first. Then after safe and effective treatment to the initial eye, the second eye may be treated 1 week later. After approximately 3 months and an acceptable safety profile with initial treatment, both eyes may be treated concurrently.

AND

- b. Concurrent or combination therapy with VEGF Inhibitors [Avastin (bevacizumab); Lucentis (ranibizumab); Eylea (aflibercept); Macugen (pegaptanib); Beovu (brolucizumab), etc.]

Informational Note: The AAO guideline states that verteporfin is still an approved option for AMD, although VEGF is still the preferred therapy. Data do not support combination therapy of the two (AAO, 2015). This consensus matches that of the European Society of Retina Specialists (Schmidt-Erfurth, 2014).

Informational Note: A review of 6 trials comparing ranibizumab monotherapy to a combination with PDT showed no difference between the two groups for 1) central retinal thickness reduction; 2) number of patients with >0 lines gained; 3) tolerance; and 4) adverse events. Monotherapy actually had more patients with 3 or more lines gained and better visual acuity correction (Si, 2014).

AND

6. Other documentation required:
 - a. Member has been informed about the potential adverse effects of Ocular PDT with Visudyne; **AND**
 - b. Requested therapy for use in affected eye (right eye or left eye); **AND**
 - c. Total calculated drug dose (mg) of the PDT drug to be administered and the member's body surface area on which the dose of the drug is based.

CONTINUATION OF THERAPY

1. Reauthorization request is for the same eye as initial authorization AND 3 months since the previous Ocular PDT with Visudyne.

NOTE: The continuation of therapy criteria applies only to the same previously treated eye. If member has developed condition in an untreated eye, a new request should be submitted and meet all initial coverage criteria.

AND

2. Member continues to meet coverage criteria AND continued need for treatment has been formally assessed and documentation submitted for review

AND

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3. Required documentation for continuation of therapy:
 - a. Positive clinical response to Visudyne as evidenced by at least ONE of the following:
 1. Detained neovascularization; **OR**
 2. Improvement or stabilization in visual acuity from baseline/prior treatment; **OR**
 3. Reduction in the number of episodes of severe visual acuity loss; **OR**
 4. Supportive findings from OCT or fluorescein angiography.

AND

- b. Clinical evidence of deterioration as demonstrated by persistent fluorescein leakage from CNV: Recurrent or persistent choroidal neovascular leakage indicated by a recent fluorescein angiography *conducted at least 3 months after the last treatment*.

NOTE: Re-treatment is necessary if FA or OCT show any signs of recurrence or persistence of leakage.

AND

- c. Member is likely to benefit from re-treatment without being exposed to significant risk according to Prescriber.

LIMITATIONS AND EXCLUSIONS

The following are considered **contraindications/exclusions** based on insufficient evidence:

1. Hypersensitivity to verteporfin or any component of the formulation
2. Porphyria or other porphyrin-related hypersensitivity
3. Atrophic or “dry” AMD
4. Inability to obtain an adequate, legible fluorescein angiogram or OCT to document CNV (including difficulty with venous access). Exception: Member has a documented history of fluorescein allergy.
5. No evidence of CNV leakage (as determined by fluorescein angiography or OCT)
6. Unacceptable toxicity from the agent, including extravasation, decrease in visual acuity, etc.

The following are considered **experimental, investigational and unproven** based on insufficient evidence:

1. Any indications other than those listed above
2. Central Serous Chorioretinopathy (CSCR)

Note: Currently, there are no FDA approved therapeutic options for managing this condition. Although half-fluence PDT has been considered as a viable option for treatment, there is no general consensus in regard to the use of this option for managing chronic CSCR.

Note: Lai et al. (2016) investigated the long-term efficacy and prognostic factors of half-dose PDT in chronic CSCR; however, the study was based on a retrospective evaluation of past data. A review of the PubMed database yields mostly retrospective studies and case series. There is currently not enough evidence to support the use of Visudyne/PDT for this indication.

3. Simultaneous use of Visudyne in *combination with anti-angiogenic agents* for the treatment of CNV due to AMD: Safety and effectiveness of such combination therapy has not been established.

DURATION OF APPROVAL: Initial authorization: 6 months; Continuation of therapy: 1 year

PRESCRIBER REQUIREMENTS: Prescribed by board-certified ophthalmologists or retinal specialist experienced in the treatment of retinal diseases. Treatment and monitoring must be retained by the Prescriber/Specialist.

AGE RESTRICTIONS: 18 years of age or older

DOSING CONSIDERATIONS: A course of verteporfin therapy is a 2-step process requiring administration of both drug and light. The first step is the intravenous (IV) infusion of verteporfin. The second step is the activation of verteporfin with light from a nonthermal diode laser. Detailed instructions can be found in the manufacturer's labeling. Subfoveal choroidal neovascularization (in adults):

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- IV infusion: 6 mg/m² body surface area (BSA) administered IV over 10 minutes at a rate of 3 mL/min.
- Light: 50 J/cm² of neovascular lesion administered at an intensity of 600 mW/cm². This dose is administered over 83 seconds.
- Duration of therapy: The health care provider should reevaluate the patient every 3 months and if choroidal neovascular leakage is detected on fluorescein angiography, therapy should be repeated.

QUANTITY LIMITATIONS

1. Total calculated dose (mg) of the PDT drug to be administered and the member's BSA on which the dose of the drug is based does not exceed **6 mg/m² BSA administered every 3 months PER EYE; AND**
2. Up to 4 treatments per eye (every 3 months) per year **AND NOT TO EXCEED TWO (2) YEARS.**

Informational Note: Safety and efficacy have not been established of use for longer than 2 years.

ADMINISTRATION

1. Visudyne PDT is considered a provider-administered procedure to be performed in a provider office, outpatient setting by a qualified ophthalmologist experienced in intravitreal injections; **AND**
2. Documentation of the following information required for review and submission of requests for subsequent treatment(s): Dose and frequency; **AND** Treated eye(s) (right/ left/both); **AND**
3. Refer to MHI Policy & Procedure: Specialty Medication Administration Site of Care Policy: MHI Pharm 11.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DRUG INFORMATION

ROUTE OF ADMINISTRATION: Intravenous (IV) infusion

DRUG CLASS: Ophthalmic Agent; Photosensitizing Agents

FDA-APPROVED USES: Subfoveal choroidal neovascularization

Treatment of predominantly classic subfoveal choroidal neovascularization due to age-related macular degeneration, pathologic myopia, or presumed ocular histoplasmosis.

Limitations of use: There is insufficient evidence to indicate verteporfin for the treatment of predominately occult subfoveal choroidal neovascularization.

COMPENDIAL APPROVED OFF-LABELED USES: None

SUMMARY OF MEDICAL EVIDENCE

PDT with verteporfin has been evaluated in 2 double-blind, placebo-controlled studies in patients with classic-containing subfoveal choroidal neovascularization secondary to AMD. Patients enrolled in these studies were randomized (2:1 randomization) to receive verteporfin or placebo followed by activation with nonthermal laser light; treatment with the same regimen was repeated every 3 months in patients with leakage from classic or occult lesions as determined by fluorescein angiogram. Results of these studies at 12 and 24 months indicate that multiple treatments with PDT that includes verteporfin improved or maintained visual acuity, contrast sensitivity, and fluorescein angiographic outcomes in patients with predominantly classic choroidal neovascular lesions (classic component comprised 50% or more of the area of the entire lesion). At 12 or 24 months, 67 or 59% of verteporfin-treated patients with predominantly classic choroidal neovascular lesions had lost less than 3 lines (15 letters on the Early Treatment of Diabetic Retinopathy Study chart) of visual acuity compared with 40 or 31% of placebo-treated patients, respectively (TAP Report 1 and 2). Visual acuity loss of 6 lines or more was experienced by 12 or 15% of

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verteporfin-treated patients versus 34 or 36% of placebo-treated patients at 12 or 24 months, respectively. Approximately 77 or 27% of verteporfin- or placebo-treated patients, respectively, with classic lesions (no occult lesions) had lost less than 3 lines of visual acuity at 12 months.

The **ANCHOR** (**AN**ti-VEGF Antibody for the Treatment of Predominantly Classic **CHOR**oidal Neovascularization in AMD) trial found that 96.4% of patients treated with Lucentis 0.5 mg lost fewer than 15 letters at 12 months compared to 64.3% of patients treated with Visudyne. Intraocular inflammation was more common in Lucentis 0.5 mg patients (15%) than in Visudyne patients (2.8%). (Kaiser et al., 2007).

RADIANCE, a Phase 3, 12-month, multicenter, randomized, double-masked, active-controlled trial, compared Visudyne PDT (vPDT) to Lucentis for the treatment of myopic CNV. Wolf S, et al. (2014) noted that, regardless of retreatment criteria, ranibizumab treatment provided superior BCVA gains versus vPDT up to month 3. Up to month 6, ranibizumab treatment guided by disease activity criteria was non-inferior to VA stabilization criteria. Individualized ranibizumab treatment was effective in improving and maintaining BCVA in patients with myopic CNV over a 12-month period and was generally well tolerated. (Wolf et al., 2014).

A Cochrane review of 3 studies (n = 1,022) compared verteporfin therapy with controls (5% dextrose in water). Participants underwent five treatments over a two-year period. The intervention group had a 23% (significantly) lower chance of losing at least 3 lines of visual acuity, and a 38% (significantly) lower risk of losing at least 6 lines, after treatment concluded. Approximately 2% of individuals experience acute severe visual acuity loss (Wormald, 2007). A Cochrane review of 5 trials indicated that treatment with the vascular endothelial growth factor medication ranibizumab resulted in fewer patients losing at least 15 letters than verteporfin. Furthermore, the combination of the two therapies was more effective than verteporfin alone (Solomon et al., 2019 & 2014).

Verteporfin therapy for AMD was reported to have better outcomes (measured in visual gain or loss) when compared to controls, however it did not produce better outcomes when compared to the VEGF medication ranibizumab as concluded by a systematic review of 10 randomized controlled trials (RCTs) (Virgili et al., 2011).

PDT combined with VEGF Treatment

Gao et al. (2018) concluded in a meta-analysis of 16 studies (n=587) that the addition of PDT to anti-VEGF significantly improved visual acuity and central retinal thickness and required fewer subsequent injections in comparison to patients receiving growth factor as monotherapy.

Solomon et al. (2014) compared VEGF (using any of three drugs) with PDT or sham treatment in a Cochrane review of 12 RCTs (n = 5,496) and reported that more subjects in each type of VEGF resulted in more with an increase of at least 15 letters and more with a vision of 20/200 or better. In a more recent Cochrane review, Solomon et al. (2019) concluded that while anti-VEGF has become the gold standard for treating macular degeneration, combining VEGF with PDT is warranted.

Ba et al. (2015) conducted a systematic review of 12 RCTs and concluded that adding combined intravitreal ranibizumab and PDT to intravitreal ranibizumab monotherapy increased visual acuity by an average of 2.74 letters in 5 trials (n = 418).

Si et al. (2014) concluded no difference between the two groups in terms of 1) central retinal thickness reduction; 2) number of patients with >0 lines gained; 3) tolerance; and 4) adverse events, according to a review of six trials that compared ranibizumab alone to a combination with PDT. Monotherapy resulted in more patients gaining three or more lines and improved visual acuity correction.

National and Specialty Organizations

The American Academy of Ophthalmology (AAO) guidelines (published in 2015, updated in 2019) indicate that verteporfin is an approved treatment option for AMD, however VEGF remains the preferred therapy. Intravitreal injectable therapy with anti-VEGF agents (e.g., aflibercept, bevacizumab, and ranibizumab) is the most effective approach to manage neovascular AMD and represents the first line of treatment, according to the American Academy of Ophthalmology (2019). Current evidence is not conclusive regarding PDT and anti-VEGF combo therapy (AAO, 2019). This consensus is consistent with that of the European Society of Retina Specialists (Schmidt-Erfurth, 2014).

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The AAO 2015 AMD preferred practice pattern guideline listed verteporfin PDT as an FDA-approved treatment option for subfoveal AMD lesions and primarily classic CNV. Anti-VEGF treatments are now the first-line treatment and stabilization option for the majority of AMD cases. Verteporfin PDT is a less prevalent treatment for neovascular AMD; according to recommendations, the following diagnoses are eligible for verteporfin PDT:

- Macular CNV, new or recurrent, where the classic component is >50% of the lesion and the entire lesion is ≤5400 µm in greatest linear diameter
- Occult CNV may be considered for PDT with vision <20/50 or if the CNV is <4 MPS [macular photocoagulation study] disc areas in size when the vision is >20/50
- Juxtafoveal CNV is an off-label indication for PDT but may be considered in select cases.

The National Institute for Health and Care Excellence (NICE) (2018) revised its previous guidance on the use of PDT for AMD to include the following recommendations:

- Recommend *against* using PDT as monotherapy for late (wet) AMD and as first-line adjuvant therapy to anti-VEGF medications for late (wet) AMD; and
- In a clinical trial setting, PDT was recommended as a second-line adjunctive therapy to anti-VEGF therapies for late (wet) AMD.

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT	Description
67221	Destruction of localized lesion of choroid (e.g., choroidal neovascularization); photodynamic therapy (includes intravenous infusion)
67225	Destruction of localized lesion of choroid (e.g., choroidal neovascularization); photodynamic therapy, second eye, at single session (List separately in addition to code for primary eye treatment)
92235	Fluorescein angiography (includes multi-frame imaging) with interpretation and report

HCPCS	Description
J3396	Injection, verteporfin, 0.1 mg [not covered in combination with intravitreal anti-hyphenangiogenic agents]

AVAILABLE DOSAGE FORMS: 15 mg (2 mg/mL after reconstitution) single-use vial; for IV infusion only

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

- 8/10/2022 Policy reviewed and updated. No changes in coverage position. Updated references.
- 8/11/2021 Policy revised. IRO Peer Review. 7/1/2021. Practicing Physician. Board certified in Ophthalmology. Notable revisions include:
- Added CMS section outlining CMS NCD for Verteporfin
 - Added 'Diagnosis of subfoveal CNV due to ONE of the following: AMD; Pathologic myopia; or Presumed ocular histoplasmosis' in the initial coverage criteria #2 under the 'Diagnosis/Indication' criteria:
 - Added brolicizumab (Beovu) where anti-VEGF is referenced
 - In reauthorization/continuation section, #2 under 'Labs/Reports/Documentation' added criteria: 'Positive clinical response to Visudyne as evidenced by at least ONE of the following: Detained neovascularization; Improvement or stabilization in visual acuity from baseline/prior treatment; Reduction in the number of episodes of severe visual acuity

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- loss; or Supportive findings from OCT or fluorescein angiography'
- In reauthorization/continuation section, under #4 the 'Discontinuation of Treatment' criteria, added: Absence of unacceptable toxicity from the agent, including extravasation, decrease in visual acuity, etc.
- Removed the following from the policy: #2 'Compliance' criteria placeholder due to non-applicability to policy. Intention of policy did not change with this update.

Q4 2020 Policy reviewed and updated, no changes in coverage criteria, updated references.

Q4 2019 Policy reviewed and updated, no changes in coverage criteria, updated references.

7/10/2018 New policy. IRO Peer Review. 5/18/2018. Practicing Physician. Board certified in Ophthalmology

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Government Agencies

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6. United States Food and Drug Administration (FDA). Orphan drug designations and approval Available from [FDA](#). Accessed June 2022.

Prescribing Information and Drug Compendia

1. American Society of Health-System Pharmacists. AHFS Drug Information® - 2022nd Ed. Bethesda, MD. American Society of Health-System Pharmacists. ISBN-10: 1-58528-684-2, ISBN-13: 978-1-58528-684-3. ISSN: 8756-6028. STAT!Ref Online Electronic Medical Library. Available from [AHFS](#). Published 2022. Accessed July 2022. Registration and login required.
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4. Visudyne (verteporfin) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals; July 2021.

Peer Reviewed Publications

1. Ba J, Peng RS, Xu D, et al. Intravitreal anti-VEGF injections for treating wet age-related macular degeneration: a systematic review and meta-analysis. *Drug Des Devel Ther*. 2015;9:5397-405. doi: 10.2147/DDDT.S86269. Accessed July 2022.
2. Gao Y, Yu T, Zhang Y, Dang G. Anti-VEGF monotherapy versus photodynamic therapy and anti-VEGF combination treatment for neovascular age-related macular degeneration: A meta-analysis. *Invest Ophthalmol Vis Sci*. 2018 Aug 1;59(10):4307-4317. doi: 10.1167/iovs.17-23747. PMID: 30372759. Accessed July 2022.
3. Kaiser PK, Brown DM, Zhang K, et al. Ranibizumab for predominantly classic neovascular age-related macular degeneration: Subgroup analysis of first-year ANCHOR results. *Am J Ophthalmol*. 2007 Dec;144(6):850-857. doi: 10.1016/j.ajo.2007.08.012. Accessed July 2022.
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Policy No. 308

Last Approval: 8/10/2022

Next Review Due By: August 2023



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APPENDIX

Reserved for State specific information. Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.