Molina Clinical Policy
Visudyne (verteporfin) Ocular Photodynamic Therapy
Policy No. 308

Last Approval: 08/12/2026
Next Review Due By: August 2027

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/non-neovascular) and wet (exudative/neovascular). Dry AMD is more common and is a precursor to wet AMD in a minority of patients. Wet AMD is less common with faster progression and is distinguished by the development of choroidal neovascularization (CNV), which greatly increases the risk of developing severe irreversible vision loss. Historically, wet AMD was classified as classic, occult, predominately classic, minimally classic, or mixed, based on fluorescein angiographic assessment of choroidal neovascular lesions. 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-vascular endothelial growth factor (anti-VEGF) agents, photodynamic therapy, laser photocoagulation surgery, and smoking cessation counseling for patients who currently smoke. The safety and effectiveness of each treatment are determined by the type and location of the neovascularization (Vavvas 2026; Vemulakonda et al. 2025).

Pathologic myopia and presumed ocular histoplasmosis syndrome (POHS) are other disorders of the eye that can lead to the development of CNV. Anti-VEGF is considered the first-line treatment for neovascular AMD, myopic CNV and POHS complicated by CNV (Akhavanrezayat et al. 2019; Perez et al. 2020; Vemulakonda et al. 2025).

Central serous chorioretinopathy (CSC) is a chorioretinal disease where there is a buildup of fluid under the retina due to choroidal dysfunction, which causes detachment and subsequent loss of visual acuity, blurred central vision and other visual disturbances. Some risk factors include male gender, ages 20-60s, stress, steroid use, hypertension, Type A personality, and genetics. CSC may be classified as acute or chronic. Acute CSC is generally a self-limited condition that resolves in 2 to 3 months, with minimal atrophic changes to the retinal pigment epithelium. Chronic CSC patients continue to have persistent subretinal fluid and atrophy of the retinal pigment epithelium, which could cause permanent damage to the photoreceptors. Treatment is recommended for patients with chronic CSC (Mi et al. 2024).

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, a photosensitizing dye, slows retinal damage associated with AMD. Verteporfin, in combination with nonthermal light, is used to treat primarily classic subfoveal CNV caused by AMD, pathologic myopia, or POHS. PDT with verteporfin is not recommended for use in less severe, dry macular degeneration without neovascularization. PDT has advantages over traditional laser therapies due to its capacity for causing targeted tissue injury (Maytin & Warren 2026; Vavvas 2026).

Visudyne (verteporfin injection) is a light-activated drug used in PDT and 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 most frequently reported adverse events include injection site reactions, pain, inflammation, extravasation, rashes, hemorrhage, and visual disturbances, which occurred in clinical

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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 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 are not well 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 is limited data for longer time periods.

Regulatory Status

Visudyne (verteporfin) was approved by the FDA in 2000 for the treatment of predominantly classic subfoveal CNV caused by AMD. In 2001, its use was expanded to include predominantly classic subfoveal CNV due to pathologic myopia and presumed ocular histoplasmosis through a supplemental new drug application (sNDA). In 2012, verteporfin was granted orphan drug status by the FDA for the treatment of chronic or recurrent CSC, although it has not been FDA-approved for this orphan indication. There is insufficient evidence to indicate Visudyne for the treatment of predominantly occult subfoveal CNV (FDA 2023).

COVERAGE POLICY

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

1. Diagnosis of ONE of the following:
    a. Choroidal neovascularization (CNV), when ALL the following are met:
        i. CNV is confirmed via fluorescein angiography or other appropriate imaging modality if fluorescein angiography is contraindicated
        ii. CNV is secondary to ONE of the following conditions:
            1. Wet age-related macular degeneration (AMD)
            2. Pathologic myopia
            3. Presumed ocular histoplasmosis
        iii. Disease progression after use of anti-VEGF therapy as first-line treatment , clinically significant adverse effects with use, labeled contraindication, or clinical rationale supporting the inappropriateness of anti-VEGF therapy with supporting documentation submitted
    b. Chronic central serous chorioretinopathy, when ALL the following criteria are met:
        i. Duration of 3 months or longer
        ii. Diagnosis is confirmed with fluorescein angiography or other appropriate imaging modality if fluorescein angiography is contraindicated
        iii. Patient use of glucocorticoids has been discontinued

2. Absence of porphyria or other porphyrin-related hypersensitivity

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

Continuation of Therapy

Continuation of therapy may be authorized when ALL the following clinical criteria are met:

1. Reauthorization request is for the same eye as initial authorization
    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.

2. At least 3 months since the previous ocular PDT with Visudyne

3. Member continues to meet coverage criteria

4. Continued need for treatment has been formally assessed with supporting documentation

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5. Required documentation for continuation of therapy:
    a. Positive clinical response to ocular PDT with Visudyne, as evidenced by at least ONE of the following:
        i. Detained neovascularization
        ii. Improvement or stabilization in visual acuity from baseline/prior treatment
        iii. Reduction in the number of episodes of severe visual acuity loss
        iv. Supportive findings from OCT or fluorescein angiography
    b. Clinical evidence of persistent or recurrent disease, as demonstrated by ONE of the following:
        i. Recurrent or persistent choroidal neovascular leakage indicated by recent fluorescein angiography conducted ≥ 3 months after the last treatment
        ii. Recurrent or persistent subretinal fluid associated with chronic central serous chorioretinopathy indicated by fluorescein angiography conducted ≥ 3 months after treatment

        NOTE: Re-treatment is necessary if FA or OCT show any signs of recurrence or persistence of leakage
    c. Member is likely to benefit from re-treatment without being exposed to significant risk according to Prescriber

Limitations and Exclusions

1. Concurrent bilateral treatment with Visudyne is considered **experimental, investigational, and unproven** UNLESS the Member has previously received Visudyne therapy with an acceptable safety profile. Treatment of both eyes concurrently may be considered approximately 3 months after the initial treatment. Documentation is required.

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

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):

- IV infusion: 6 mg/m^2 body surface area (BSA) administered IV over 10 minutes at a rate of 3 mL/min.

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- Light: 50 J/cm^2 of neovascular lesion administered at an intensity of 600 mW/cm^2. 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/m^2 BSA administered every 3 months PER EYE
2. Up to 4 treatments per eye (every 3 months) per year
3. Not to exceed two (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
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)
3. Refer to MHI Policy & Procedure: Specialty Medication Administration Site of Care Policy: MHI Pharm 11

SUMMARY OF MEDICAL EVIDENCE

Randomized Controlled Trials

Chen et al. (2019) completed the BRILLIANCE study, a randomized, double-blind phase III study to demonstrate if ranibizumab treatment guided by either disease activity or BCVA is superior to verteporfin PDT for the treatment of myopic choroidal neovascularization. The study involved 48 centers in 5 countries and enrolled a total of 457 patients with 431 patients completing all 12 months of follow-up. Patients were randomized on a 2:2:1 ratio to three treatment groups: (1) ranibizumab 0.5mg at day 1 and month 1 followed by monthly injections from month 2 to month 12 if stability criterion for BCVA was not achieved (no change in BCVA as compared with 2 preceding monthly visits), (2) ranibizumab 0.5mg at day 1 followed by observation of disease activity and administration of ranibizumab injections if there was vision impairment attributable to intraretinal fluid, subretinal fluid, or active leakage associated with pathologic myopia based on optical coherence tomography or fluorescein angiography, and (3) verteporfin PDT on day 1 followed by verteporfin PDT, ranibizumab 0.5mg, or a combination of verteporfin PDT and ranibizumab 0.5mg based on disease activity criteria. Drug dosing of ranibizumab and verteporfin was based on FDA-approved drug labels. Group 1 (ranibizumab and BCVA) contained 173 patients, group 2 (ranibizumab and disease activity monitoring) contained 175 patients, and group 3 (verteporfin PDT) contained 83 patients. Baseline mean age was 52.0 years (group 1), 51.5 years (group 2), 49.1 years (group 3), and 51.2 years (overall). Baseline mean BCVA was 53.6 letters (group 1), 54.2 letters (group 2), 52.1 letters (group 3), and 53.5 letters (overall). Baseline mean CSFT was 341.3 µm (group 1), 340.7 µm (group 2), 334.8 µm (group 3) and 339.8 µm (overall). The percentage of CNV location for group 1 was 73.1% subfoveal, 8.8% juxtafoveal, and 16.5% extrafoveal. The percentage of CNV location for group 2 was 70.1% subfoveal, 12.0% juxtafoveal, and 17.4% extrafoveal. The percentage of CNV location for group 3 was 70.9% subfoveal, 11.4% juxtafoveal, and 16.2% extrafoveal. Results for BCVA showed that ranibizumab guided by either BCVA or disease activity criteria was statistically superior to verteporfin PDT. The mean average change in BCVA from baseline to month 1 through month 3 was +9.5 letters (group 1), +9.8 letters (group 2), and +4.5 letters (group 3). The mean change in BCVA from baseline to month 12 was +12.0 letters (group 1), +13.1 letters (group 2), and +10.3 letters (group 3). Researchers noted that "most patients in both ranibizumab groups gained ≥10 letters from baseline or reached 84 letters at months 3, 6, or 12." In terms of CSFT, researchers noted that both ranibizumab groups has a rapid and clinically significant decrease from baseline to month 3 followed by a stabilization period that persisted through month 12 and the verteporfin PDT group noted smaller decreases than the ranibizumab groups from baseline to month 1 with a plateau at month 3. Further decreases after month 3 in the verteporfin PDT group were achieved if patients received ranibizumab.

In the PLACE trial (NCT01797861), van Dijk et al. (2018) compared half-dose PDT to high-density subthreshold laser (HSML) for the treatment of patients with chronic central serous chorioretinopathy (cCSC). This was a large, open-label, multi-center prospective randomized controlled study that included 179 patients; of which 89 were randomly assigned to the half dose phototherapy group and 90 were randomly assigned to the high-density subthreshold laser group. The primary outcome was complete resolution of the subretinal fluid at 6 to 8 weeks post

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treatment. The subretinal fluid was also measured as secondary outcome at a final visit 7 to 8 months after treatment. Additional secondary outcomes were functional: best corrected visual acuity (BCVA) and retinal sensitivity as measured by microperimetry, and assessment of quality of life using a 25-question validated questionnaire. On the first post treatment visit patient subretinal fluid was found to be resolved in 51.2% of PDT patients and 13.8% of HSML patients (p <0.001). At the final assessment patients treated with PDT, 67.2% had a resolution of SRF compared to 28.8% in patients treated with HSML (p <0.001). At the final visit, the PDT group had a 4.60 EDTRS letter improvement in BCVA in comparison to a 1.39 letter improvement in the HSML group (P = 0.011). The PDT group also had significantly higher increases in retinal sensitivity than the HSML group at both the first and final evaluation. The improvement in vision-related quality of life for the PDT and HSML groups was similar. The author found that for cCSC half-dose PDT was more effective than HSML, with significantly higher complete resolution of subretinal fluid and functional improvement. Short-term resolution of subretinal fluid was most significantly impacted by half-dose or half- fluence PDT (OR: 20.6; 95% CI: 6.3–66.7; p < 0.0001) and threshold conventional laser therapy (OR: 36.4; 95% CI: 2.0–655.7; p = 0.015) and less significantly by selective retinal therapy (OR: 3.4; 95% CI: 1.7–6.8; p = 0.00075). Conventional laser therapy closes the defect to the retinal pigment epithelium, but photocoagulation carries the risk vision loss, central scotoma, and risk of foveal neovascularization. Selective retinal therapy is based on microlaser technology and is thought to cause retinal pigment epithelium damage without impacting the photoreceptors. Currently selective retinal therapy remains experimental. The authors concluded that half-dose or half-fluence PDT “is the only viable treatment option for patients with cCSC” and is “widely considered the first line and preferred therapy for cCSC.”

Systematic Reviews and Meta-Analyses

Kim et al. (2025) completed a systematic review to assess the safety and efficacy of various therapeutic modalities for CSC. Based on a PubMed search, 31 studies met inclusion criteria. The studies were categorized by treatment modality, including laser-based therapy, intravitreal therapy, laser vs. intravitreal therapy, and systemic therapies, with further distinction between acute and chronic CSC treatments. The level of evidence ratings assigned included 6 level I studies, 23 level II studies, and 2 level III studies. Findings demonstrated that PDT using half-dose verteporfin was effective for acute CSC, significantly reducing subretinal fluid in 95% of patients treated at 12 months, compared to 58% in the observation group (p=0.001). Additionally, central foveal thickness was significantly lower in the PDT-treated group (161 ± 65 µm vs. 278 ± 92 µm, p = 0.001). A comparison of half-dose versus 30% dose PDT revealed better fluid resolution in the half-dose group 94.6% vs. 75.4%, p = 0.004), with noninferiority of the 30%-dose group not demonstrated (the 30% dose was not as effective as the half-dose PDT), The VICI trial, a level I study, found no benefit in mineral corticosteroid antagonism (eplerenone) for cCSR, as visual acuity at 12 months showed no significant difference (79.5 letters in placebo vs. 80.4 in eplerenone, p = 0.24). Evidence supporting intravitreal anti-vascular endothelial growth factor (anti-VEGF) injections and systemic beta-blockers was inconsistent, with no level I studies demonstrating a clear benefit for CSC. However, a small level I study suggested potential efficacy of Helicobacter pylori therapy in CSCR treatment. The review concluded that half-dose PTD is effective for acute CSC in terms of anatomical improvement, but evidence for sustained visual acuity benefits beyond 12 months is limited. Intravitreal anti-VEGF therapy and beta-blockers lack consistent efficacy, and eplerenone has not been shown to be beneficial for cCSC treatment. Meanwhile, Helicobacter pylori eradication therapy may have some anatomic and visual benefits, though further research is needed.

Van Dijk et al. (2023) completed a systematic review with network meta-analysis of the short-term efficacy of multiple treatment modalities for cCSC that were tested in randomized controlled trials (RCTs). Short term treatment efficacies were evaluated and ranked using the network meta-analysis. To be considered chronic, the patient had to have a diagnosis of CSC for at least 3 months or have symptoms that were attributable to CSC for at least 3 months. Only studies that used optical coherence tomography (OCT) to evaluate their patients were included. All interventions were considered if they were randomized for comparison to another group. The comparison was another intervention, a non-treatment control or a placebo treatment. The primary outcome was complete resolution of subretinal fluid based on OCT. Outcomes at 2 months post treatment were, or as close to 2 months were evaluated, but at least within 1 to 3 months post treatment. Risk of bias within the selected studies was evaluated independently by 2 authors, and risk of bias was then compared and discussed with a third author. A total of 17 RCTs were included, totaling 1172 eyes. “Treatments included conventional laser (44 eyes), half-dose or half-fluence (PDT (298 eyes), ranibizumab (16 eyes), antioxidants (50 eyes), mineralocorticoid receptor antagonists (187 eyes), rifampicin (91 eyes), selective retina therapy (67 eyes) and subthreshold micropulse laser (192 eyes)”. Short term resolution of subretinal fluid was most significantly impacted by half-dose or half- fluence PDT (OR: 20.6; 95% CI: 6.3–66.7; p < 0.0001) and threshold conventional laser therapy (OR: 36.4; 95% CI: 2.0–655.7; p = 0.015) and less significantly

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by selective retinal therapy (OR: 3.4; 95% CI: 1.7–6.8; p = 0.00075). Conventional laser therapy closes the defect to the retinal pigment epithelium, but photocoagulation carries the risk vision loss, central scotoma, and risk of foveal neovascularization. Selective retinal therapy is based on microlaser technology and is thought to cause retinal pigment epithelium damage without impacting the photoreceptors. Currently selective retinal therapy remains experimental. The authors concluded that half-dose or half-fluence PDT "is the only viable treatment option for patients with cCSC" and is "widely considered the first line and preferred therapy for cCSC".

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

van den Tillaart (2026) conducted a multicenter, prospective cohort study among participants who were previously enrolled in the PLACE and SPECTRA RCTs, to evaluate the long-term outcomes associated with half-dose PDT for treatment-naïve cCSC. Of 179 eligible participants, 107 (59.8%) completed the long-term follow-up, with a median time of 7.0 years after PDT (range 4.6-10.2 years). Participants were classified as "successful" or "unsuccessful," based on whether their first half-dose of PDT produced subretinal fluid resolution. The first half-dose PDT was successful in 78 patients and unsuccessful in 29 patients. Additional treatments were performed in 14.1% and 89.7% of patients, respectively, during the original PLACE and SPECTRA follow-ups. The primary outcome was best-corrected visual acuity, measured using Early Treatment Diabetic Retinopathy Study letters. Secondary outcomes included retinal sensitivity, measured with microperimetry, subretinal fluid, measured with optical coherence tomography, macular neovascularization seen on angiography, retreatment, and recurrence. At long-term follow-up, mean visual acuity was significantly better in the successful treatment group, with acuity improving from 81.8 $\pm$ 7.9 letters at baseline to 87.2 $\pm$ 8.7 letters at long-term follow-up ($p < 0.001$). In the unsuccessful treatment group, visual acuity increased from 73.4 $\pm$ 12.1 to 77.2 $\pm$ 16.2 letters but without statistical significance ($p = 0.108$). For both groups, mean visual acuity remained stable from first follow-up onward. Subretinal fluid was present in 16.7% and 44.8% of eyes in the successful and unsuccessful treatment groups, respectively ($p = 0.005$). Macular neovascularization was detected in 12.1% of the overall cohort, with no significant difference between groups. Retinal sensitivity improved significantly from baseline to long-term follow-up in the successful group ($p < 0.001$), while no statistically significant improvement was seen for the unsuccessful group. Study limitations include 40% loss of participants to long-term follow-up, limited sample size, variation in follow-up timing, and heterogeneity. The authors concluded that successful first half-dose PDT was associated with favorable anatomical and functional outcomes and were sustained for a median of 7 years. Patients who initially had an unsuccessful response to PDT had lower baseline visual acuity and more persistent fluid and subsequent retreatment; however visual acuity remained stable over time and additional treatment resulted in fluid resolution in most cases.

PDT combined with anti-VEGF Treatment

Sarvepalli et al. (2025) conducted a comprehensive meta-analysis evaluating the role of PDT as an adjunct to anti-VEGF therapy for neovascular age-related macular degeneration (AMD). Analyzing data from 23 studies involving 2,781 eyes, the study found that anti-VEGF + PDT combination therapy significantly improved BCVA at 12 months compared to anti-VEGF monotherapy (mean difference [MD] −0.07; 95% CI −0.12 to −0.01; P = 0.02). Patients in the combination therapy group also required significantly fewer anti-VEGF injections (MD −1.76; 95% CI −1.95 to −1.58; P < 0.0001), suggesting a lower treatment burden. Notably, no significant difference in central retinal thickness was observed between groups at 12 months (MD −3.66; 95% CI −10.28 to 2.98; P = 0.28), indicating that visual improvements may result from mechanisms beyond anatomic resolution. Furthermore, pooled ocular adverse events were similar between groups (MD 0.96; 95% CI 0.68 to 1.36; P = 0.41), suggesting that adding PDT did not compromise safety. These results support the use of PDT as a potentially effective adjunctive therapy in carefully selected patients with neovascular AMD, particularly when balancing visual outcomes and treatment frequency.

Gao et al. (2018) completed a meta-analysis of 16 studies with a total of 1260 participants receiving either anti-VGEF monotherapy (n=587) or anti-VGEF and PDT combination therapy (n=673) for neovascular AMD. Combination therapy consisted of either standard-fluence (50 J/m^2) verteporfin PDT or reduced-fluence (25 J/m^2) verteporfin PDT and anti-VGEF treatment. Retreatment therapy consisted of either verteporfin PDT and anti-VGEF therapy or anti-VGEF therapy alone depending on study. Researchers found that the addition of reduced-fluence PDT to anti-VEGF significantly improved BCVA and central retinal thickness and required fewer subsequent injections in comparison to patients receiving growth factor as monotherapy.

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).

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National and Specialty Organizations

The **American Academy of Ophthalmology (AAO)** published *Age-Related Macular Degeneration Preferred Practice Pattern* (Vemulakonda et al. 2025) that indicates that verteporfin is an approved treatment option; 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 AAO. Current evidence is not conclusive regarding PDT and anti-VEGF combo therapy. The AAO lists 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 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:

- 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 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 AAO states that fluorescein angiography (FA) is used to direct treatment if verteporfin PDT or laser photocoagulation surgery is being considered. FA is used to detect the presence of macular neovascularization, and to determine the extent, type, size, and location of it. Fluorescein crosses the placenta and is present in breastmilk for 72 hours and carries risks such as extravasation and allergic reaction. The AAO also notes that optical coherence tomography is important in diagnosing and managing AMD, including the presence of subretinal and intraretinal fluid and the degree of retinal thickening. Additionally, optical coherence tomography angiography can provide evaluation of the retinal and choroidal vasculature and is becoming more commonly used, but it has not replaced other angiographic methods (Vemulakonda et al. 2025).

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

- Offer OCT to people with suspected late (wet active) AMD. Offer FA to confirm diagnosis if OCT does not exclude neovascular disease. Do not offer FA if clinical examination and OCT exclude neovascularization.
- Offer anti-VEGF therapy for late (wet active) AMD for eyes with visual acuity within specified ranges
- Do not offer PDT as monotherapy or as an adjunct to anti-VEGF as first-line treatment for late (wet active) AMD. Only offer PDT as an adjunct to anti-VEGF as second-line treatment in the context of a clinical trial

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	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, unilateral or bilateral

HCPCS (Healthcare Common Procedure Coding System)

Code	Description
J3396	Injection, verteporfin, 0.1 mg

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.

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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

08/12/2026 Policy revised. Added first-line anti-VEGF and retinal imaging requirements for myopic CNV and presumed ocular histoplasmosis (POHS). Added requirement that POHS must be associated with CNV. Clarified that other imaging modalities may be appropriate if fluorescein angiography is contraindicated. Added continuation of therapy criteria for central serous chorioretinopathy. IRO peer reviewed on July 22, 2026 by a practicing physician board certified in ophthalmology.

08/13/2025 Policy revised. Removed contraindication of concurrent administration of Visudyne and anti-VEGF agent. Updated Overview, Summary of Medical Evidence and References. IRO Peer Review completed July 1, 2025, by a board-certified, practicing Ophthalmologist.

08/14/2024 Policy revised. Added chronic central serous chorioretinopathy as an indication. IRO Peer Review on July 10, 2024, by a practicing physician board-certified in Ophthalmology.

08/09/2023 Policy reviewed. No changes to coverage criteria. Removed Supplemental Information section.

08/10/2022 Policy reviewed and updated. No changes in coverage criteria.

08/11/2021 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 brolucizumab (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 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 place holder due to non-applicability to policy. Intention of policy did not change with this update.

Q4 2020 Policy reviewed. No changes in coverage criteria.

Q4 2019 Policy reviewed. No changes in coverage criteria.

07/10/2018 New policy. IRO Peer Review. 5/18/2018. Practicing Physician. Board certified in Ophthalmology

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