Medical Policy

Utilization Management and Clinical Medical Policy

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Verteporfin [Visudyne®]	**MP-RX-FP-101-23**	☒ **MMM MA** ☒ **MMM MultiHealth**	**11/30/2023** **Last Review Date:** **10/21/2026**	**10/21/2026** **Frequently Revision:** **Annual**

Service Category:

- ☐ Anesthesia
- ☐ Surgery
- ☐ Radiology Procedures
- ☐ Pathology and Laboratory Procedures
- ☐ Medicine Services and Procedures
- ☐ Evaluation and Management Services
- ☐ DME/Prosthetics or Supplies
- ☒ Other: Part B Drugs

Service Description:

This document addresses the use of Verteporfin [Visudyne®] , a photoenhancer approved by the Food and Drug Administration (FDA) for the treatment of patients with predominantly classic subfoveal choroidal neovascularization (CNV) due to age-related macular degeneration (AMD), pathologic myopia or presumed ocular histoplasmosis.

Background Information:

Verteporfin, a benzoporphyrin derivative, is an intravenous lipophilic photosensitive drug with an absorption peak of approximately 690 nm. Verteporfin was first approved by the Food and Drug Administration on April 12, 2000, and subsequently approved for inclusion in the United States Pharmacopoeia on July 18, 2000, meeting Medicare's definition of a drug as defined under §1861(t)(1) of the Social Security Act. Under the applicable Medicare National Coverage Determination (NCD), verteporfin is covered only when used in conjunction with ocular photodynamic therapy (OPT) and furnished intravenously incident to a physician's service.

Verteporfin is a photosensitizing agent composed of two regioisomers. It accumulates preferentially in neovasculature, including choroidal neovasculature. Activation of verteporfin by nonthermal light at a wavelentght of 689 nanometers ± 3 nm in the presence of oxygen generates highly reactive, short-lived singlet oxygen and reactive oxygen radicals. The activated particles cause local damage to neovascular endothelium and subsequent vessel occlusion. Damaged endothelium releases procoagulant and vasoactive factors causing platelet aggregation, fibrin clot formation, and vasoconstriction. These factors contribute to the temporary occlusion of choroidal neovascularization

A course of VISUDYNE (verteporfin for injection) therapy is a two-step process requiring administration of both drug and light. The first step is intravenous administration of Visudyne, and the second step is activation of Visudyne with light from a nonthermal diode laser. The physician should re-evaluate the patient 3 months after treatment and if choroidal neovascular leakage is detected on fluorescein angiography, therapy may be repeated.

The greatest linear dimension (GLD) of the lesion should be estimated by fluorescein angiography and color fundus photography. All classic and occult CNV, blood and/or blocked fluorescence, and any serous detachments of the retinal pigment epithelium should be included for this measurement. Fundus cameras with magnification within the range of 2.4-2.6X are recommended. The GLD of the lesion on the fluorescein angiogram must be corrected for the magnification of the fundus camera to obtain the GLD of the lesion on the retina. The treatment spot size should be 1,000 microns larger than the GLD of the lesion on the retina to allow a 500 micron border, ensuring full coverage of the lesion. The maximum spot size used in the clinical trials was 6,400 microns. The nasal edge of the treatment spot must be positioned at least 200 microns from the temporal edge of the optic disc, even if this will result in lack of photoactivation of CNV within 200 microns of the optic nerve.

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Choroidal neovascularization (CNV): is part of the spectrum of exudative age-related macular degeneration (AMD) that consists of an abnormal growth of vessels from the choroidal vasculature to the neurosensory retina through the Bruch's membrane. CNV can also develop in a number of other conditions such as myopic degeneration, chronic central serous chorioretinopathy, macular telangiectasia type 2, various white dot syndromes and other uveitic processes, and some choroidal tumors. Leakage of retinal edema and hemorrhage from CNV threatens visual acuity.

Pathologic myopia: represents a subgroup of myopia and affects up to 3% of the world population. [2] Vision loss related to pathologic myopia is of great clinical significance as it can be progressive, irreversible and affects individuals during their most productive years. High myopia is defined as refractive error of at least -6.00D or an axial length of 26.5mm or more[2]. The definition of pathologic myopia in early studies has been inconsistent and mostly revolved around a combination of refractive error and axial length, which may simply reflect a high degree of myopia. Additionally, there was no clear evidence for the cutoff values chosen. In recent years, the definition of pathologic myopia has shifted to "the presence of myopic maculopathy equal to or more severe than diffuse chorioretinal atrophy."[3] Myopic maculopathy includes diffuse chorioretinal atrophy, patchy chorioretinal atrophy, lacquer cracks, myopic choroidal neovascularization (myopic CNV), and CNV-related macular atrophy.

Approved Indications

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

Nationally Covered Indications (NCD)

Effective April 1, 2004, OPT with verteporfin is covered for patients with a diagnosis of neovascular age-related macular degeneration (AMD) with:

A. Predominately classic subfoveal choroidal neovascularization (CNV) lesions (where the area of classic CNV occupies ≥ 50% of the area of the entire lesion) at the initial visit as determined by a fluorescein angiogram (FA). (CNV lesions are comprised of classic and/or occult components.) Subsequent follow-up visits require either an optical coherence tomography (effective April 3, 2013) or an FA (effective April 1, 2004) to assess treatment response.

   There are no requirements regarding visual acuity, lesion size, and number of retreatments when treating predominantly classic lesions.

B. Subfoveal occult with no classic CNV associated with AMD.
C. Subfoveal minimally classic CNV (where the are\\\\\\a of classic\\\\\ \C\NV occupies < 50% of the area of the entire lesion) associated with AMD.

The above 2 indications are considered reasonable and necessary only when:

1. The 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. The 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

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examination chart), lesion growth (an increase in at least 1 disk area), or the appearance of blood associated with the lesion.

Nationally Non-Covered Indications

Other uses of OPT with verteporfin to treat AMD not already addressed by the Centers for Medicare & Medicaid Services will continue to be non-covered. These include, but are not limited to, the following AMD indications:

A. Juxtafoveal or extrafoveal CNV lesions (lesions outside the fovea);
B. Inability to obtain an FA; OR
C. Atrophic or "dry" AMD.

Other Uses

A. The OPT with verteporfin for other ocular indications, such as pathologic myopia or presumed ocular histoplasmosis syndrome, continue to be eligible for local coverage determinations through individual Medicare Administrative Contractor discretion.

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

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Medical Necessity Guidelines:

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Verteporfin (Visudyne®)

A. Criteria For Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

Requests for Verteporfin therapy may be approved if the following criteria are met:

i. Individual is receiving verteporfin in conjunction with ocular photodynamic therapy (OPT); **AND**

ii. Individual meets one of the following (A, B or C):

A. Neovascular age-related macular degeneration (AMD) with one of the following subfoveal CNV lesions documented by fluorescein angiography (FA); **AND**

1. Predominantly classic subfoveal choroidal neovascularization (CNV), where the area of classic CNV occupies ≥ 50% of the area of the entire lesion; **OR**
2. Subfoveal occult with no classic CNV associated with AMD; **OR**
3. Subfoveal minimally classic CNV, where the area of classic CNV occupies < 50% of the area of the entire lesion, associated with AMD;

AND

4. For subfoveal occult with no classic CNV or subfoveal minimally classic CNV associated with AMD, documentation confirms both of the following:
   a. Lesion size is small, defined as 4 disk areas or less in size at the time of initial treatment or within the 3 months prior to initial treatment; **AND**
   b. The lesion has shown evidence of progression within the 3 months prior to initial treatment, documented by deterioration of visual acuity of at least 5 letters on a standard eye examination chart, lesion growth of at least 1 disk area, or the appearance of blood associated with the lesion;

OR

B. Predominantly classic subfoveal choroidal neovascularization due to pathologic myopia; **OR**

C. Predominantly classic subfoveal choroidal neovascularization due to presumed ocular histoplasmosis syndrome; **AND**

iii. Prescriber Specialties:

A. Ophthalmologist; **OR**

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B. Retina specialist.

B. Criteria For Continuation of Therapy

Continuation requests for Visudyne may be approved if the following criteria are met:

i. Individual continues to meet the applicable initial approval criteria; **AND**
ii. Documentation is provided to show clinical benefit or disease stabilization compared to baseline, including but not limited to stabilization of visual acuity, reduction or stabilization of CNV leakage, lesion stability, or other objective ophthalmologic improvement; **AND**
iii. For AMD, follow-up documentation includes optical coherence tomography (OCT) or fluorescein angiography (FA) to assess treatment response; **AND**
iv. If repeat treatment is requested, documentation supports persistent or recurrent CNV leakage or active lesion requiring retreatment.

C. Authorization Duration

i. Initial Approval Duration: 3 months
ii. Reauthorization Approval Duration: 3 months

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

i. Skin Cancer; **OR**
ii. Atrophic or "dry" age-related macular degeneration; **OR**
iii. Juxtafoveal or extrafoveal CNV lesions associated with AMD; **OR**
iv. Inability to obtain fluorescein angiography when required to determine initial lesion characteristics; **OR**
v. Other uses of OPT with verteporfin to treat AMD not addressed as nationally covered under CMS NCD 80.3.1; **OR**
vi. When the above criteria are not met and for all other indications.

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Limits or Restrictions:

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Drug	Recommended Dosage	Limit
Verteporfin (Visudyne) 15 mg single-dose vial	• 6mg/m^2 body surface area IV	3 months (1 dose)
Exceptions		
• A course of Visudyne (verteporfin for injection) therapy is a two-step process requiring administration of both drug and light. o The first step is the administration of Visudyne. o The second step is the activation of Visudyne with light from a nonthermal diode laser. • The physician should re-evaluate the patient 3 months after treatment and if choroidal neovascular leakage is detected on fluorescein angiography, therapy may be repeated.		

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Codes Information:

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

ICD-10 Diagnostic Codes:

Codes	Description
B39.4	Histoplasmosis capsulati, unspecified (American histoplasmosis)
B39.5	Histoplasmosis duboisii (African histoplasmosis)
B39.9	Histoplasmosis, unspecified
H32	Chorioretinal disorders in diseases classified elsewhere
H35.3211	Exudative age-related macular degeneration with active choroidal neovascularization RIGHT EYE
H35.3221	Exudative age-related macular degeneration with active choroidal neovascularization LEFT EYE
H35.3231	Exudative age-related macular degeneration with active choroidal neovascularization BILATERAL
H35.3291	Exudative age-related macular degeneration with active choroidal neovascularization UNSPECIFIED EYE
H44.21	Degenerative myopia RIGHT EYE
H44.22	Degenerative myopia LEFT EYE
H44.23	Degenerative myopia BILATERAL
H44.20	Degenerative myopia UNSPECIFIED EYE

Note: For presumed ocular histoplasmosis syndrome, B39.4, B39.5, or B39.9 must be used in conjunction with H32. The applicable histoplasmosis code should be listed first, followed by H32.

HCPCS Codes:

Codes	Description
J3396	Injection, verteporfin, 0.1 mg

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Reference Information:

1. Bausch & Lomb Incorporated. Visudyne® (verteporfin for injection), for intravenous use: Prescribing Information. Revised February 2023. Accessed July 7, 2026.
2. Bausch & Lomb Incorporated. *Visudyne® (verteporfin for injection): Billing and Coding Guide*. Accessed July 7, 2026.
3. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) 80.3.1: Verteporfin. Effective April 3, 2013. Accessed July 7, 2026.
4. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) 80.2.1: Ocular Photodynamic Therapy (OPT). Effective April 3, 2013. Accessed July 7, 2026.
5. Product Information: Visudyne intravenous injection, verteporfin intravenous injection. Novartis Pharmaceuticals Corporation (per FDA), East Hanover, NJ, 2016.
6. Product Information: Visudyne intravenous injection, verteporfin intravenous injection. Bausch Health US LLC (per FDA), Bridgewater, NJ, 2021.
7. Product Information: Visudyne injection, verteporfin injection. Novartis Pharmaceuticals Corporation, East Hanover, NJ, 2004.
8. Product Information: Visudyne intravenous injection, verteporfin intravenous injection. Novartis Pharmaceuticals Corporation (per FDA), East Hanover, NJ, 2012.
9. Product Information: Visudyne, verteporfin for injection. QLT PhotoTherapeutics, Seattle, WA, 2000.
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11. Choroidal Neovascularization: OCT Angiography Findings - EyeWiki. (n.d.). Eyewiki.aao.org. Retrieved July 12, 2023, from ttps://eyewiki.aao.org/Choroidal_Neovascularization:_OCT_Angiography_Findings#Clinical_findings
12. Micromedex Solutions: Verteporfin, retrieved July 12,2023 from: https://www.micromedexsolutions.com/micromedex2/librarian/PFDefaultActionId/evidencexpert.DoIntegratedSearch?navitem=topHome&isToolPage=true#

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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Policy History:

Type of Review	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review	Updated the medical policy to align with the current FDA-approved indication and applicable CMS NCD coverage language for verteporfin with ocular photodynamic therapy. Revised initial approval criteria to specify use in conjunction with ocular photodynamic therapy and to define covered subfoveal CNV scenarios associated with age-related macular degeneration, pathologic myopia, and presumed ocular histoplasmosis syndrome. Removed the requirement for therapeutic failure to anti-VEGF therapy because it is not included in the FDA-approved indication or CMS NCD coverage criteria for verteporfin/OPT. Updated continuation criteria to require documentation of clinical benefit, disease stabilization, or persistent/recurrent CNV activity supporting retreatment. Added nationally non-covered AMD indications to Conditions Not Covered and updated ICD-10 coding to include presumed ocular histoplasmosis syndrome-related codes. Added recommended dosage and clarified the two-step process of Visudyne therapy. Coding reviewed: added ICD-10 codes H32, B39.4, B39.5, and B39.9. Updated reference information and incorporated new policy template.	10/15/2026	10/21/2026
Annual Review	Minimal changes; word formatting. Coding reviewed: No changes.	9/5/2025	9/16/2025
Annual Review	Added: therapeutic alternatives section, Federal Statement. Wording and formatting changes. Coding Reviewed: No Changes.	3/14/2025	4/2/2025
Policy Inception	Elevance Health's Medical Policy adoption.	N/A	11/30/2023