Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Verteporfin [Visudyne®]	MP-RX-FP-101-23	☒ MMM MA ☒ MMM Multihealth

Service Category

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

Service Description

This document addresses the use of Verteporfin [Visudyne®] , a photoenhancer approved by the Food and Drug Administration (FDA) for the treatment of 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 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. Verteporfin is only covered when used in conjunction with ocular photodynamic therapy (OPT) when furnished intravenously incident to a physician's service.

Verteporfin is a photosensitizing agent composed of two regioisomers.[6] It accumulates preferentially in neo vasculature, including choroidal neo vasculature.[6] Activation of verteporfin by nonthermal light (689 nanometers wavelength) in the presence of oxygen generates highly reactive, short-lived singlet oxygen and reactive oxygen radicals.[6] The activated particles cause local damage to neovascular endothelium and subsequent vessel occlusion.[6] Damaged endothelium releases procoagulant and vasoactive factors causing platelet aggregation, fibrin clot formation, and vasoconstriction.[6] 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 physician should re-evaluate the patient 3 months after treatment and if choroidal neovascular leakage is detected on fluorescein angiography, therapy may be repeated. Lesion Size Determination 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. Spot Size Determination 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

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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.

Definitions and Measures

Mechanism of action: VISUDYNE (verteporfin for injection) therapy is a two-stage process requiring administration of both verteporfin for injection and nonthermal red light. Verteporfin is transported in the plasma primarily by lipoproteins. Once verteporfin is activated by light in the presence of oxygen, highly reactive, short-lived singlet oxygen and reactive oxygen radicals are generated. Light activation of verteporfin results in local damage to neovascular endothelium, resulting in vessel occlusion. Damaged endothelium is known to release procoagulant and vasoactive factors through the lipoxygenase (leukotriene) and cyclooxygenase (eicosanoids such as thromboxane) pathways, resulting in platelet aggregation, fibrin clot formation and vasoconstriction. Verteporfin appears to somewhat preferentially accumulate in neovasculature, including choroidal neovasculature. However, animal models indicate that the drug is also present in the retina. Therefore, there may be collateral damage to retinal structures following 41 42 4 8 photoactivation including the retinal pigmented epithelium and outer nuclear layer of the retina. The temporary occlusion of the CNV following VISUDYNE therapy has been confirmed in humans by fluorescein angiography.

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.

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Nationally Covered Indications (NDC)

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 access 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 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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Applicable Codes

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.

HCPCS	Description
J3396	Injection, verteporfin, 0.1 mg

ICD-10	Description
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

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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.

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

Verteporfin [Visudyne®]

A. Criteria for Initial approval

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

i. Diagnosis:
   A. Age related macular degeneration - Choroidal retinal neovascularization **OR**
   B. Choroidal retinal neovascularization - Myopia, Pathologic **OR**
   C. Choroidal retinal neovascularization - Ocular histoplasmosis syndrome, Presumed; **AND**

ii. Prescriber Specialties:
   A. Ophthalmologist; **OR**
   B. Retinologist; **AND**

iii. Therapeutic failure to vascular endothelial growth factor (VEGF) as first-line treatment.

B. Criteria for Continuation of Therapy

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

i. Physician must document member is responding positively to therapy.

C. 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

D. Authorization Duration

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

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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	Limit
Verteporfin (Visudyne)	3 months (1 dose)
Exceptions	
None	

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2. HIGHLIGHTS OF PRESCRIBING INFORMATION. (n.d.) Verteporfin. Retrieved July 12, 2023, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/021119s027lbl.pdf
3. Product Information: VISUDYNE(R) intravenous injection, verteporfin intravenous injection. Novartis Pharmaceuticals Corporation (per FDA), East Hanover, NJ, 2016.
4. Product Information: VISUDYNE(R) intravenous injection, verteporfin intravenous injection. Bausch Health US LLC (per FDA), Bridgewater, NJ, 2021.
5. Product Information: VISUDYNE(R) injection, verteporfin injection. Novartis Pharmaceuticals Corporation, East Hanover, NJ, 2004.
6. Product Information: VISUDYNE(R) intravenous injection, verteporfin intravenous injection. Novartis Pharmaceuticals Corporation (per FDA), East Hanover, NJ, 2012.
7. Product Information: Visudyne™, verteporfin for injection. QLT PhotoTherapeutics, Seattle, WA, 2000.
8. Ohno-Matsui K. Pathologic myopia. Asia Pac J Ophthalmol 2016;5: 415–423.
9. 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
10. 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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Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review 9/2/2025	Minimal changes; word formatting. Coding reviewed: No changes.	9/5/2025	9/16/2025
Annual Review 9/27/24	Added: therapeutic alternatives section, Federal Statement. Wording and formatting changes. Coding Reviewed: No Changes.	3/14/2025	4/2/2025
Policy Inception 9/27/2023	Elevance Health's Medical Policy adoption.	N/A	11/30/2023