

## Ocular Photodynamic Therapy

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<b>Approved By:</b>	Highmark Health Options – Market Leadership
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### Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

### POLICY STATEMENT

Highmark Health Options may provide coverage under the medical surgical benefits of the Company's Medicaid products for medically necessary treatments of wet age-related macular degeneration and advanced, end-stage age-related macular degeneration.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

### DEFINITIONS

**Highmark Health Options (HHO)** – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently serves Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan and Health Plan Plus members.

**Ocular Photodynamic Therapy (PDT)** – A form of treatment for certain types of ophthalmic diseases characterized by neovascularization (e.g., age-related wet macular degeneration) that uses a combination of a photosensitizing drug and non-thermal laser light to treat diseased tissue. The treatment takes approximately 20 minutes and can be performed in a doctor's office.

**Transpupillary Thermotherapy (TTT)** – A technique in which low level heat is delivered through the pupil using a modified diode laser. TTT is designed to gently heat subfoveal choroidal lesions while limiting damage to the overlying retinal pigment epithelium

## **POLICY POSITION**

### **Verteporfin PDT**

Verteporfin PDT as monotherapy may be considered medically necessary as a treatment of choroidal neovascularization (CNV) associated with ANY of the following conditions:

- Age-related macular degeneration with EITHER:
  - Classic subfoveal CNV; or
  - Predominantly classic subfoveal CNV; or
- Chronic central serous chorioretinopathy; or
- Choroidal hemangioma; or
- Occult neovascularization; or
- Pathologic myopia; or
- Presumed ocular histoplasmosis.

If CNV leakage is detected on fluorescein angiography, subsequent verteporfin PDT may be considered medically necessary.

Verteporfin PDT as monotherapy for other ophthalmic disorders not meeting the criteria indicated in this policy is considered experimental/investigational and therefore, non-covered because the safety and/ or effectiveness of this service cannot be established by the available published peer-reviewed literature.

Verteporfin PDT when used in combination with one (1) or more anti-vascular endothelial growth factor therapies is considered experimental/investigational as a treatment of CNV and, therefore, is non-covered because the safety and/ or effectiveness of this service cannot be established by the available published peer-reviewed literature when associated with ANY of the following conditions:

- Age-related macular degeneration; or
- Pathologic myopia; or
- Presumed ocular histoplasmosis; or
- Central serous chorioretinopathy; or
- Choroidal hemangioma; or
- Other ophthalmologic disorders.

### **Transpupillary Thermotherapy (TTT)**

TTT may be considered medically necessary for EITHER of the following indications:

- Retinoblastoma involving less than half (50%) of the retina, and without associated vitreal or subretinal seeds at the time of thermotherapy; or
- Small (2 to 3 mm) choroidal melanomas located posterior in the globe.

TTT not meeting the criteria as indicated in this policy is considered experimental/investigational and, therefore, noncovered because the safety and/ or effectiveness of this service cannot be established by the available published peer-reviewed literature.

### **Noncovered Services**

Other drugs for ocular PDT and other procedures, such as photocoagulation (feeder vessel technique) are considered experimental/investigational and, therefore, noncovered because the safety and/ or effectiveness of this service cannot be established by the available published peer-reviewed literature.

Experimental/investigational (E/I) services are not covered regardless of place of service.

Ocular PDT or Transpupillary Thermotherapy is typically an outpatient procedure which is only eligible for coverage as an inpatient procedure in special circumstances, including, but not limited to, the presence of a comorbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

### **Professional and Facility Claims**

This policy is applied on a post-payment basis for Professional claims. The services will pay on initial processing and are subject to retrospective review.

Note the following pre-payment applications within the body of the bulletin:

- The diagnosis codes are applied on a pre-payment basis for procedure codes: 67221, 67225 and J3396.

**Note:** Photocoagulation feeder vessel technique (G0186) is considered experimental/investigational and, therefore, noncovered and applies to Professional claims.

## **PROFESSIONAL STATEMENTS AND SOCIETAL POSITIONS GUIDELINES**

### **National Institute of Health and Excellence – 2018**

In 2018, the National Institute for Health and Care Excellence updated its 2003 guidance on the use of photodynamic therapy for age-related macular degeneration. The Institute made the following recommendations:

- Recommends against use of photodynamic therapy as monotherapy for late (wet) age-related macular degeneration and against use of photodynamic therapy as first-line adjunctive therapy to anti-vascular endothelial growth factor therapies for late (wet) age-related macular degeneration
- Recommends for photodynamic therapy as second-line adjunctive therapy to anti-vascular endothelial growth factor therapies for late (wet) age-related macular degeneration in a trial setting.

### **American Academy of Ophthalmology – 2015**

A 2015 preferred practice pattern guideline on age-related macular degeneration from the American Academy of Ophthalmology has described verteporfin photodynamic therapy as a treatment option approved by the U.S. Food and Drug Administration for subfoveal lesions and predominantly classic choroidal neovascularization (choroidal neovascularization) related to age-related macular degeneration.

The 2015 update stated that anti-vascular endothelial growth factor therapies have become first-line therapy for treating and stabilizing most cases of age-related macular degeneration. Verteporfin photodynamic therapy is a less commonly used treatment for neovascular age-related macular degeneration; recommendations stated that the following diagnoses are eligible for verteporfin photodynamic therapy:

- “Macular choroidal neovascularization, new or recurrent, where the classic component is greater than 50% of the lesion and the entire lesion is  $\leq 5400 \mu\text{m}$  in greatest linear diameter
- Occult choroidal neovascularization may be considered for PDT [photodynamic therapy] with vision less than 20/50 or if the choroidal neovascularization is Less than 4 MPS [macular photocoagulation study] disc areas in size when the vision is greater than 20/50

- Juxtafoveal choroidal neovascularization is an off-label indication for PDT but may be considered in select cases.”

### National Comprehensive Cancer Network – 2020

#### Ocular Photodynamic Therapy

- There is no recommendation to treat uveal melanoma with ocular PDT mentioned in the NCCN guidelines.

#### Transpupillary Thermotherapy

- Consider additional treatment with resection, laser ablation, transpupillary thermotherapy, or cryotherapy if concerned that adequate response was not achieved from initial radiation.
- For small recurrences in [individuals] who cannot undergo radiation therapy or surgery, transpupillary thermotherapy is recommended.

### PROCEDURE CODES

Table	Style
67221	Destruction Of Localized Lesion Of Choroid (e.g., Choridal Neovascularization); Photodynamic Therapy 9 includes Intravenous Infusion)
67225	Destruction Of Localized Lesion Of Choroid (e.g., Choridal Neovascularization); Photodynamic Therapy, Second Eye, At Single Session (list Separately In Addition To Code For Primary Eye Treatment)
J3396	Injection, Verteporfin, 0.1 Mg

### Non-covered Procedure Code(s)

Code	Description
G0186	Destruction Of Localized Lesion Of Choroid (for Example, Choridal Neovascularization); Photocoagulation, Feeder Vessel Technique (one Or More Sessions)

### Eligible Diagnosis Codes for Procedure Codes 67221, 67225 and J3396

B39.4	B39.5	B39.9	D18.09	H32
H35.051	H35.052	H35.053	H35.059	H35.30
H35.3210	H35.3211	H35.3212	H35.3213	H35.3220
H35.3221	H35.3222	H35.3223	H35.3230	H35.3231
H35.3232	H35.3233	H35.3290	H35.3291	H35.3292
H35.3293	H35.711	H35.712	H35.713	H35.719
H44.20	H44.21	H44.22	H44.23	H44.2A1
H44.2A2	H44.2A3	H44.2B1	H44.2B2	H44.2B3
H44.2C1	H44.2C2	H44.2C3	H44.2D1	H44.2D2
H44.2D3	H44.2E1	H44.2E2	H44.2E3	

## References

- American Academy of Ophthalmology Retina/Vitrous Panel. Preferred Practice Pattern® Guidelines. Age-related macular degeneration. San Francisco, CA. 2015.
- Salehi M, Wenick As, Law HA, Evans JR, Gehlerbach P. interventions for central serous chorioretinopathy: A network meta-analysis. *Cochrane Database Sys Rev*. 2015;22(12)CD01184d1.
- Atik A, Hu Y, Yu H, et al. Changes in macular sensitivity after hal-dose photodynamic therapy for chronic central serous chorioretinopathy. *BMC Ophthalmology*. 2017;17:140.
- Cheng CK, Chang CK, Peng CH. Comparison of photodynamic therapy using half-dose off verteporfin or half-fluence of laser light for the treatment of CCSC. *Retina*. 2017;37(2):325-333.
- Fabian I, Stacey A, Papastefanou V, et al. Primary photodynamic therapy with verteporfin for small pigmented posterior pole choroidal melanoma. *Eye*. 2017;31:519-528.
- Rundle P. Photodynamic therapy for eys cancer. *Biomedicines*. 2017;5:69.
- Blasi M, Pagliara M, Lanza A, et al. Photodynamic therapy in ocular oncology. *Biomedicines*. 2018;6:17.
- Ba J, Peng RS, Xu D, Li YH, Shi H, et al. Intravitreal anti-VEGF injections for treating wet age-related macular degeneration: a systematic review and meta-analysis. *Drug Des Devel Ther*. 2015;9:5397-5405.
- Semeraro F, Russo A, Delcassi L, Romano MR, Rinaldi M, et al. Treatment of exudative age-related macular degeneration with ranibizumab combined with ketorolac eyedrops or photodynamic therapy. *Retina*. 2015;35(8):1547-1554.
- Tang K, Si JK, Guo DD, Cui Y, Du YX, et al. Ranibizumab alone or in combination with photodynamic therapy vs photodynamic therapy for polypoidal choroidal vasculopathy: a systematic review and meta-analysis. *Int J Ophthalmol*. 2015;8(5):1056-1066.
- Zhao M, Zhang F, Chen Y, Dai H, Qu J, et al. A 50% vs 30% dose of verteporfin (photodynamic therapy) for acute central serous chorioretinopathy: one-year results of a randomized clinical trial. *JAMA Ophthalmol*. 2015;133(3):333-340.
- Tong Y, Zhao KK, Feng D, Biswal M, Zhao PQ, et al. Comparison of the efficacy of anti-VEGF monotherapy versus PDT and intravitreal anti-VEGF combination treatment in AMD: a Meta-analysis and systematic review. *Int J Ophthalmol*. 2016;9(7):1028-1037.
- Zhu Y, Zhang T, Xu G, Zhang T. Anti-vascular endothelial growth factor for choroidal neovascularization in people with pathological myopia. *Cochrane Database Syst Rev*. 2016;12:CD011160.
- Hayes, Inc. Hayes Health Assessment. *Photodynamic Therapy with Verteporfin (Visudyne) for Choroidal Hemangioma*. Lansdale, PA: Hayes, Inc. 08/29/2018.
- Lee JH, Lee WK. One-year results of adjunctive photodynamic therapy for type 1 neovascularization associated with thickened choroid. *Retina*. 2016;36(5):889-895.
- Rinaldi M, Semeraro F, Chiosi F, et al. Reduced-fluence verteporfin photodynamic therapy plus ranibizumab for choroidal neovascularization in pathologic myopia. *Graefes Arch Clin Exp Ophthalmol*. 2017;255(3):529-539.

American Academy of Ophthalmology Retina Panel. Age-related macular degeneration PPP. 2015. Accessed September 01, 2020.

National Institute for Health and Care Excellence (NICE). Age-related macular degeneration [NG82]. Accessed September 01, 2020.

National Comprehensive Cancer Network (NCCN). NCCN clinical practice guidelines in oncology: Uveal melanoma. Version 1.2020.

Rao R, Honavar SG. Retinoblastoma. *Indian J Pediatr.* 2017;84(12):937-944.

Mendoza PR, Grossniklaus HE. Therapeutic options for retinoblastoma. *Cancer Control.* 2016;23(2):99-109.

**POLICY UPDATE HISTORY**

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