

Policy: MP003

Section: Medical Benefit Policy

Subject: Ocular Photodynamic Therapy Utilizing Verteporfin Visudyne

I. Policy: Ocular Photodynamic Therapy Utilizing Verteporfin (Visudyne)

II. Purpose/Objective:

To provide a policy of coverage regarding Ocular Photodynamic Therapy Utilizing Verteporfin (Visudyne)

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

- (i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- (ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.

- (iii) The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

DESCRIPTION:

Photodynamic therapy is a treatment for choroidal neovascularization secondary to exudative “wet” age related macular degeneration, presumed ocular histoplasmosis and pathologic myopia. A pharmaceutical (Visudyne) is injected into the bloodstream, which binds abnormal retinal blood vessels. A nonthermal laser then activates the drug, resulting in local damage to neovascular endothelium, resulting in vessel occlusion. This then prevents future progression of the condition.

INDICATIONS:

1. Age-related macular degeneration (AMD) with predominately classic subfoveal choroidal neovascularization (CNV) lesions (where the area of classic CNV occupies greater than 50% of the area of the entire lesion) at the initial visit as determined by a fluorescein angiogram; **or**
2. Subfoveal occult lesions with no classic CNV associated with AMD; **or**
3. Subfoveal minimally classic CNV (where the area of classic CNV occupies less than 50% of the area of the entire lesion) associated with AMD; **or**

NOTE: Indications 2 and 3 are considered medically necessary only when:

- a) 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,
 - b) 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.
4. Infection by Histoplasma capsulatum, retinitis; **or**
 5. Progressive high (degenerative) myopia

Note: Indications 4 and 5 are considered medically necessary when the area of classic CNV occupies at least 50% of the area of the entire lesion.

CONTRAINDICATIONS:

- Hypersensitivity to verteporfin or any component of the formula
- Juxtafoveal or extrafoveal CNV lesions (lesions outside the fovea),
- Inability to obtain a fluorescein angiogram,
- Atrophic or “dry” AMD

EXCLUSIONS:

Any diagnosis not listed under Indications section.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Ocular Photodynamic Therapy Utilizing Verteporfin (Visudyne)

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

67225 destruction of localized lesion of choroid (eg, choroidal neovascularization); photodynamic therapy, second eye, at single session
J3396 Injection of Verteporfin, 15mg

ICD10 Codes

H35.3210 ,H35.3211, H35.3212, H35.3213, H35.3220, H35.3221, H35.3222, H35.3223, H35.3230, H35.3231, H35.3232
H35.3233, H35.30 , H35.3110, H35.3111, H35.3112, H35.3113, H35.3114, H35.3120, H35.3121, H35.3122, H35.3123,
H35.3124, H35.3130, H35.3131, H35.3132, H35.3133, H35.3134, B39.4, B39.5, B39.9, H32, 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, H44.21, H44.22, H44.23, H35.711, H35.712, H35.713

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LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

Bressler N, et al., "Photodynamic Therapy of Subfoveal Choroidal Neovascularization in Age-related Macular Degeneration With Verteporfin: One-Year Results of 2 Randomized Clinical Trials – TAP Report 1", *Archives of Ophthalmology*, Vol 117 (10) 1329-1345, Oct 1999.

Miller J, et al, "Photodynamic Therapy With Verteporfin for Choroidal Neovascularization Caused by Age-related Macular degeneration: Results of a Single Treatment in a Phase 1 and 2 Study", *Archives of Ophthalmology*, Vol 117(9), 1161-1173, Sept.1999.

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Henney JE, "New Therapy for Macular Degeneration", *JAMA*, Vol.283(21), p2779, 7 June 2000.

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Uemura A. Thomas MA. "Subretinal Surgery for Choroidal Neovascularization in Patients With High Myopia". *Archives of Ophthalmology*. 118(3):344-350, March 2000.

Sickenberg M, Schmidt-Erfurth U, Miller JW, Pournaras CJ, Zografos L, Piguet B, Donati G, Laqua H, Barbazetto I, Gragoudas ES, Lane A, Birngruber R, van den Bergh H, Strong HA, Manjuris U, Gray T, Fsadni M, Bressler NM, "A Preliminary Study of Photodynamic Therapy Using Verteporfin for Choroidal Neovascularization in Pathologic Myopia, Ocular Histoplasmosis Syndrome, Angioid Streaks, and Idiopathic Causes" *Archives of Ophthalmology*. 118(3):327-336, March 2000.

American Academy of Ophthalmology (AAO). Age-related macular degeneration, AAO Retina/Vitreous PPP Panel. San Francisco CA: AAO, updated January 2015. <https://www.aao.org/preferred-practicepattern/age-related-macular-degeneration-ppp-2015>.

American Academy of Ophthalmology (AAO) Retina/Vitreous Panel. Retina Summary Benchmarks for Preferred Practice Pattern Guideline. San Francisco CA: AAO, October 2016.

Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for Ocular Photodynamic Therapy (OPT) (80.2.1)

Tong Y, Zhao KK, Feng D. 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, et al. Anti-vascular endothelial growth factor for choroidal neovascularization in people with pathological myopia. Cochrane Database Syst Rev. 2016;12:CD011160

Centers for Medicare & Medicaid Services. Ocular Photodynamic Therapy (OPT) (NCD 80.2.1)

This policy will be revised as necessary and reviewed no less than annually.

Devised: 05/16/01

Revised: 8/1/01; 2/02 (Coding); 3/02 (Expanded Indications, added references); 8/03(add notice regarding inadequate angiogram quality); 4/04 criteria update; 5/05 (grammatical changes); 5/06(references), 7/08 (removed Prior Auth)

Reviewed: 03/03, 7/09, 6/10, 6/11, 6/12, 6/13, 6/14, 5/15, 5/16; 5/17, 5/18, 5/19