Geisinger

Geisinger Health Plan Policies and Procedure Manual

Policy: MP003

Section: Medical Benefit Policy

Subject: Ocular Photodynamic Therapy Utilizing Verteporfin Visudyne

Applicable Lines of Business

Commercial	**X**	**CHIP**	**X**
Medicare	**X**	**ACA**	**X**
Medicaid	**X**		

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
Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.

- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- 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. Subfoveal CNV secondary to Infection by Histoplasma capsulatum, retinitis; **or**
5. Subfoveal CNV secondary to 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.

FOR MEDICAID BUSINESS SEGMENT:
Visudyne is subject to the Statewide PDL. Determination of medical necessity must be determined using DHS prior authorization guidelines.

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.

Medicaid Business Segment:
Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

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.***

67221	destruction of localized lesion of choroid (e.g. choroidal neovascularization); photodynamic therapy
67225	destruction of localized lesion of choroid (eg, choroidal neovascularization); photodynamic therapy, second eye, at single session
J3396	Injection of Verteporfin, 15mg

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

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 Subfovial Choroidal Neovascularization in Age-related Macular Degeneration With Verteprofin: 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 Vertrprofin 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.

"Photodynamic Therapy of Subfoveal Choroidal neovascularization in Age-related Macular degeneration with Vertrporfin", One Year Results of 2 Randomized Clinical trials – TAP report 1, *Archives of Ophthalmology*, Vol 117, Oct. 1999 pp 1329-1344.

"Photodynamic Therapy (PDT), A New Treatment for Age-Related Macular Degeneration (AMD), The Wilmer Technology Assessment Center.

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, BirngruberR, van den Bergh H, Strong HA, Manjuris U, Gray T, Fsadni M, BresslerNM, "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)

Silva R, Arias L, Nunes S, et al. Efficacy and Safety of Intravitreal Aflibercept Treat and Extend for Polypoidal Choroidal Vasculopathy in the ATLANTIC Study: A Randomized Clinical Trial. Ophthalmologica. 2022; 245(1): 80-90

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); 5/21 (Indication clarification)

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, 5/20, 5/22, 5/23, 5/24

CMS UM Oversight Committee Approval: 12/23, 7/24

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at https://www.geisinger.org/health-plan/providers/ghp-clinical-policies

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.