09-J1000-72
Original Effective Date: 10/19/00

Reviewed: 12/10/14

Revised: 10/01/17

Subject: Verteporfin (Visudyne™) Injection

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Choroidal neovascularization (CNV) develops when newly formed blood vessels from the choroid grow through the Bruch membrane and proliferate under the retina. This often leads to exudation and hemorrhage that ultimately damage the photoreceptors and contribute to visual loss. Subfoveal CNV lesions can be defined as classic or occult according to their appearance of fluorescein angiography. Classic CNV membranes are clearly delineated and leak fluorescein uniformly, while occult membranes are often hidden or their extent is hard to delineate, and fluorescein leakage is patchy. Some lesions may have both classic and occult components. Available therapeutic options for CNV include photodynamic therapy, antioxidants, thermal laser photocoagulation, corticosteroids, and vascular endothelial growth factor inhibitors.

Verteporfin (Visudyne®) was approved by the U.S. Food and Drug Administration (FDA) for the treatment of predominately classic subfoveal CNV associated with wet age-related macular degeneration, pathologic myopia, or ocular histoplasmosis. Although first approved in April 2000, verteporfin has more recently been designated as an organ drug for the treatment of chronic or recurrent central serous chorioretinopathy. Verteporfin in combination with photodynamic therapy causes local damage to the neovascular endothelium and produces vessel occlusion.

POSITION STATEMENT:

Verteporfin **meets the definition of medical necessity** for members meeting **ALL** of the following criteria:

1. Indication for use is predominately classic (i.e., greater than or equal to 50% classic) subfoveal choroidal neovascularization associated with any of the following conditions:

    a. Age-related macular degeneration

    b. Pathologic myopia

    c. Presumed ocular histoplasmosis

2. Use will be in combination with photodynamic therapy

3. The dose does not exceed 6 mg/m2 per treatment

Duration of approval: 1 year

Verteporfin **meets the definition of medical necessity** when used for the following designated Orphan Drug indication (http://www.fda.gov/orphan/designat/list.htm):

1. Treatment of chronic or recurrent central serous chorioretinopathy

Duration of approval: 1 year

Verteporfin is **not considered a medical necessity** for members with predominately occult subfoveal choroidal neovascularization.

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

FDA-approved

6 mg/m2 IV every 3 months as needed; administer light delivery 15 minutes after the start of the infusion

Drug Availability

15 mg single-use vial

PRECAUTIONS:

Boxed Warning

None

Contraindications

Porphyria or a known hypersensitivity to any component of this preparation

Precautions/Warnings

- Avoid use in moderate to severe hepatic disease or impairment
- Avoid extravasation and skin and ocular exposure

BILLING/CODING INFORMATION:

HCPCS Coding:

J3396	Injection, Verteporfin, 0.1 mg

ICD-10 Diagnosis Codes That Support Medical Necessity:

B39.4	Histoplasmosis capsulate, unspecified
B39.5	Histoplasmosis duboisii
B39.9	Histoplasmosis, unspecified
H32	Chorioretinal disorders in diseases classified elsewhere
H35.3210 – H35.3293	Exudative age-related macular degeneration
H44.2A1	Degenerative myopia with choroidal neovascularization, right eye
H44.2A2	Degenerative myopia with choroidal neovascularization, left eye
H44.2A3	Degenerative myopia with choroidal neovascularization, bilateral eye
H44.2A9	Degenerative myopia with choroidal neovascularization, unspecified eye

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

Medicare Advantage:

- The following National Coverage Determination (NCD) was reviewed on the last guideline revised date: Verteporfin (80.3.1) located at cms.gov.

- The following Local Coverage Determination (LCD) was reviewed on the last guideline revised date: Ocular Photodynamic Therapy (OPT) with VERTEPORFIN (L29239) located at fcso.com.

DEFINITIONS:

No guideline specific definitions apply.

RELATED GUIDELINES:

Transpupillary Thermotherapy (TTT), 01-92000-20

Photocoagulation of Macular Drusen, 01-92000-21

Pegaptanib (Macugen®), 09-J0000-56

Ranibizumab (Lucentis®), 09-J0000-70

OTHER:

None applicable.

REFERENCES:

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2. Clinical Pharmacology [Internet]. Tampa (FL): Gold Standard, Inc.; 2014 [cited 2014 Nov 15]. Available from: http://www.clinicalpharmacology.com/.
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4. DRUGDEX® System [Internet]. Greenwood Village (CO): Thomson Micromedex; Updated periodically [cited 2014 Nov 15]. Available from: http://www.thomsonhc.com/.
5. Orphan Drug Designations and Approval [Internet]. Silver Spring (MD): US Food and Drug Administration; 2014 [cited 2014 Nov 15]. Available from: http://www.accessdata.fda.gov/scripts/opdlisting/oopd/index.cfm/.
6. QLT Ophthalmics, Inc. Visudyne (verteporfin for injection) injection, powder, lyophilized, for solution. 2010 [cited 2014 Nov 15]. In: DailyMed [Internet]. Bethesda (MD): National Library of Medicine. Available from: http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=31512723-9ff0-4e18-aa3a-55ab833038c6/.
7. Wormald R, Evans JR, Smeeth LL, Henshaw KS. Photodynamic therapy for neovascular age-related macular degeneration. Cochrane Database of Systematic Reviews 2007, Issue 3. Art. No.: CD002030. DOI: 10.1002/14651858.CD002030.pub3.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Coverage Committee on 12/10/14.

GUIDELINE UPDATE INFORMATION:

10/19/00	Medical Coverage Guideline developed.
04/15/02	Revised Medical Coverage Guideline name to include Subfoveal Choroidal Neovascularization. Revised policy statement. Expanded list of covered diagnoses. Added code G0186. Deleted code 0016T and 0017T.
06/15/02	Revised policy statement. Deleted diagnosis code 362.50.
01/01/03	2003 HCPCS update.
06/15/03	Annual review. Added statement for repeat (limitation) RDT.
09/17/03	Changed "CNV occupies greater than 50%" to "equals 50%". Added the following to the non-covered section of the guideline: a diagnosis of AMD with occult or no classic CNV lesions, and the use of OPT with verteporfin for the types of AMD (e.g., patients with minimally classic CNV lesions, atrophic, or dry AMD).
05/15/04	Updated references.
01/01/05	HCPCS update. Added J3396. Deleted J3395.
05/15/05	Revised name of MCG, changed name to Visudyne™ (Verteporfin) for Subfoveal Choridal Neovascularization. Revised when services are covered and not covered sections. Deleted ICD-9 diagnoses: ocular histoplasmosis (115.92) and progressive high (degenerative) myopia (malignant myopia) (360.21). Added the statement to ICD-9 diagnosis: exudative senile macular degeneration ("leakage in macular blood vessels with loss of visual acuity"). Revised reimbursement statement, deleted infusion and added administration of Verteporfin and revise re-treatment statement. Added cross-reference to Macugen® to the related guidelines section. Updated references.
05/15/06	Revise when services are not covered; delete the following: subfoveal occult with no classic CNV and minimally classic CNV lesions, where the area of classic CNV occupies less than 50% of the area of the entire lesion. Added atrophic, or dry AMD. Deleted experimental/investigational statement for photocoagulation feeder vessel technique. Added ICD-9 diagnoses: 115.02, 115.92, 360.21, and 362.50. Added program exception for Medicare Advantage products. Updated references.
05/15/07	Scheduled review; no change in coverage statement; reformatted guideline; updated CPT/HCPCS and ICD-9 codes in the Medicare Advantage Products section; updated references.
07/15/08	Scheduled review; no change in position statement. Revise description section. Update references.

06/15/09	Scheduled review; no change in position statement. Update references.
06/15/10	Annual review; no change in position statement. Updated references.
10/15/10	Revision; related ICD-10 codes added.
03/15/12	Scheduled review. Position statement maintained. Revised description section and updated references.
09/15/12	Review and revision to guideline; consisting of reformatting, updating description, dosage and administration, exceptions and references and adding a precautions section.
01/15/14	Review and revision to guideline; consisting of reformatting and revising description, dosage and administration, position statement, precautions/warnings and references.
01/15/15	Review and revision to guideline; consisting of updating references.
03/15/15	Revision to guideline; update LCD number.
11/01/15	Revision: ICD-9 Codes deleted.
10/01/16	Revision: ICD-10 code updates
10/01/17	New ICD-10 codes.