



Louisiana

Photodynamic Therapy for Choroidal Neovascularization

Policy # 00097

Original Effective Date: 06/05/2002

Current Effective Date: 11/09/2020

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services Are Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company considers verteporfin photodynamic therapy (VPDT) as monotherapy as a treatment of choroidal neovascularization (CNV) associated with age-related macular degeneration (AMD), pathologic myopia, presumed ocular histoplasmosis, chronic central serous chorioretinopathy (CSC) or choroidal hemangioma to be **eligible for coverage**.**

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers verteporfin photodynamic therapy (VPDT) as monotherapy for all other ophthalmologic disorders to be **investigational**.*

Based on review of available data, the Company considers verteporfin photodynamic therapy (VPDT) when used in combination with one or more of the anti-vascular endothelial growth factor (anti-VEGF) therapies, i.e., pegaptanib (Macugen®)‡, ranibizumab (Lucentis®)‡, bevacizumab (Avastin®)‡, aflibercept (Eylea™)‡ as a treatment of choroidal neovascularization (CNV) associated with age-related macular degeneration (AMD), pathologic myopia, presumed ocular histoplasmosis, chronic central serous chorioretinopathy (CSC), choroidal hemangioma, or for other ophthalmologic disorders to be **investigational**.*

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Policy Guidelines

U.S. Food and Drug Administration (FDA) labeling for verteporfin indicates that the physician should reevaluate the patient every 3 months and, if choroidal neovascularization leakage is detected on fluorescein angiography, therapy should be repeated. However, total number of treatments is not addressed by FDA. Evidence defining when treatment should stop is not available, but experts have suggested stopping “when the situation is judged to be ‘futile’.” FDA labeling states that the “safety and efficacy of Visudyne beyond 2 years have not been demonstrated.”

Acute central serous chorioretinopathy refers to self-limiting disease that resolves spontaneously over a few months without any treatment. Chronic central serous chorioretinopathy has been defined as a serous macular elevation, visible biomicroscopically or detected by optical coherence tomography, that is associated with retinal pigment epithelial atrophic areas and subtle leaks or ill-defined staining by fluorescein angiography; it does not resolve spontaneously within a few months.

Background/Overview

Vision Loss

Severe vision loss can occur with ocular neovascularization, the growth of abnormal blood vessels in the retina or choroid. Neovascularization occurs in a number of ocular diseases, including age-related macular degeneration.

Age-Related Macular Degeneration

Age-related macular degeneration is a degenerative disease of the retina that results in loss of central vision. Two distinctive forms, known as dry and wet degeneration, may be observed. The dry form (also known as atrophic or areolar) is more common and is often a precursor of the wet form (also known as exudative neovascular or disciform). The wet form is more devastating and characterized by serous or hemorrhagic detachment of the retinal pigment epithelium and development of choroidal neovascularization, which greatly increases the risk of developing severe irreversible loss of vision. Choroidal neovascularization is categorized as classic or occult. Classic choroidal neovascularization appears as an initial lacy pattern of hyperfluorescence followed by more irregular patterns as the dye leaks into the subretinal space. Occult choroidal neovascularization lacks the characteristic angiographic pattern. Classic choroidal neovascularization carries a worse prognosis for vision than occult choroidal neovascularization, suggesting that the proliferative response that

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obscures new vessels may also favorably alter the clinical course of age-related macular degeneration.

Pathologic Myopia

Pathologic myopia refers to an abnormal elongation of the eye associated with severe near-sightedness. It generally occurs among people older than 30 years of age and can result in a progressive, severe loss of vision, frequently related to the development of choroidal neovascularization. Verteporfin photodynamic therapy has also been investigated in patients with choroidal neovascularization related to pathologic myopia. Antivascular endothelial growth factor therapy is now considered a first-line intervention in patients with myopic choroidal neovascularization.

Presumed Ocular Histoplasmosis

Presumed ocular histoplasmosis may be the second most common cause of blindness in patients younger than 50 years of age in certain endemic areas (Ohio and Mississippi River Valleys in the United States). This condition is characterized by a positive skin test for histoplasmosis, miliary opacities of the lungs, tiny choroidal scars, peripapillary disruption of the choriocapillaris, and exudation or hemorrhage from choroidal lesions in or near the macula. The condition is asymptomatic and benign, unless the choroidal neovascularization lesions, which may develop many years after chorioretinal scarring has taken place, affect the macula.

Central Serous Chorioretinopathy

Central serous chorioretinopathy refers to an idiopathic disease in which there is a serous detachment of the macula due to leakage of fluid from the choriocapillaris through the retinal pigment epithelium. This condition is avascular; however, neovascularization can occur as a secondary complication. In most cases, central serous chorioretinopathy resolves spontaneously in 3 to 4 months. However, in a few cases, chronic progression or recurrence can lead to the progressive decline of visual acuity. Central serous chorioretinopathy has been treated with medication and laser photocoagulation, but these treatments have limited efficacy. Multiple definitions have been used in the literature to classify central serous chorioretinopathy as acute or chronic based cutoff time points (eg, persistent fluid for <3, 4 or 6 months) or less frequently based on the timing of treatment. For example, acute central serous chorioretinopathy defined as the first attempted treatment to improve visual acuity, and chronic central serous chorioretinopathy is defined as being refractory to treatment. Further, multiple verteporfin photodynamic therapy strategies that use either reduced-

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dose or half-fluency have been evaluated for the treatment of central serous chorioretinopathy because full-dose verteporfin photodynamic therapy used in age-related macular degeneration has shown a potentially higher risk of developing choroidal ischemia and retinal atrophic changes.

Polypoidal Choroidal Vasculopathy

Polypoidal choroidal vasculopathy arises primarily from abnormal choroidal circulation, resulting in characteristic lesions comprising well-defined vascular networks of vessels ending in polyp-like structures. A less common subtype is polypoidal choroidal neovascularization, and it may be considered a subtype of age-related macular degeneration. Eyes that develop a cluster of grape-like polypoidal dilations are at high risk for severe vision loss.

Choroidal Hemangioma

Choroidal hemangioma is an uncommon, benign vascular tumor, manifesting as an orange-red mass in the posterior pole of the eye. Visual loss may be progressive and irreversible because of chronic foveal detachment.

Angioid Streaks

Angioid streaks result from crack-like breaks in the Bruch membrane (the innermost layer of the choroid) and occur in patients spontaneously or due to blunt trauma or associated with some systemic diseases such as pseudoxanthoma elasticum, Paget disease of bone, or sickle hemoglobinopathy. Vision loss in eyes with angioid streaks occurs most frequently as a result of choroidal neovascularization.

Treatment

Available therapeutic options for choroidal neovascularization include antivascular endothelial growth factor inhibitors, verteporfin photodynamic therapy, antioxidants, thermal laser photocoagulation, and corticosteroids. The safety and efficacy of each treatment depends on the form and location of the neovascularization.

Verteporfin photodynamic therapy is a treatment modality designed to selectively occlude ocular choroidal neovascular tissue. The therapy is a 2-step process, consisting of an injection of the photosensitizer verteporfin, followed 15 minutes later by laser treatment to the targeted sites of retinal neovascularization. The laser treatment selectively damages the vascular endothelium and

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occludes the neovascularized tissue. Patients may be retreated if leakage from choroidal neovascularization persists.

Monotherapy with vascular endothelial growth factor inhibitors is now standard treatment of choroidal neovascularization due to age-related macular degeneration and pathologic myopia. Combining verteporfin photodynamic therapy with antivascular endothelial growth factor inhibitors, concurrently or sequentially, has a biologic basis and has been investigated in multiple trials particularly in the treatment of choroidal neovascularization due to age-related macular degeneration and pathologic myopia.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In 2000, verteporfin (Visudyne[®]; Novartis) ‡, an intravenous photodynamic therapy agent, was approved by the U.S. Food and Drug Administration for the treatment of age-related macular degeneration in patients with predominantly classic subfoveal choroidal neovascularization. Subsequently, in 2001, the indication was expanded to include presumed ocular histoplasmosis and pathologic myopia.

Rationale/Source

Verteporfin photodynamic therapy is a treatment modality designed to selectively occlude ocular choroidal neovascular tissue. The therapy is a 2-step process, consisting of an injection of the photosensitizer verteporfin, followed 15 minutes later by laser treatment to the targeted sites of retinal neovascularization. The laser treatment selectively damages the vascular endothelium, thereby occluding choroidal neovascularization tissue. Patients may be retreated if leakage from choroidal neovascularization persists.

Age-Related Macular Degeneration

For individuals who have classic choroidal neovascularization due to age-related macular degeneration who receive verteporfin photodynamic therapy, the evidence includes randomized controlled trials (RCTs) and systematic reviews of controlled trials. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. Multiple RCTs have supported the superiority of verteporfin photodynamic therapy in reducing vision loss and decreasing

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retinal thickness compared with placebo or sham procedure. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have choroidal neovascularization due to age-related macular degeneration who receive verteporfin photodynamic therapy plus antivascular endothelial growth factor therapy, the evidence includes 2 confirmatory RCTs (and their multiple analyses), multiple smaller RCTs, and a meta-analysis of existing trials. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. This evidence does not demonstrate improvements in visual acuity using combination therapy compared with antivascular endothelial growth factor monotherapy. Combination therapy may reduce the number of intravitreal injections needed, but this result has not been consistently reported across studies. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have choroidal neovascularization due to age-related macular degeneration who receive verteporfin photodynamic therapy plus corticosteroids and/or antivascular endothelial growth factor therapy, the evidence includes 3 small RCTs. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. The evidence does not demonstrate improvements in visual acuity with combination therapy. The evidence is insufficient to determine the effects of the technology on health outcomes.

Pathologic Myopia

For individuals who have choroidal neovascularization due to pathologic myopia who receive verteporfin photodynamic therapy, the evidence includes a subgroup analysis from a large RCT. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. The subgroup analysis showed verteporfin photodynamic therapy was more effective than placebo in preventing vision loss at one year but not in the second year. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Clinical input obtained in 2012 supported the use of verteporfin photodynamic therapy for pathologic myopia, and therefore verteporfin photodynamic therapy may be considered medically necessary for this indication.

For individuals who have choroidal neovascularization due to pathologic myopia who receive verteporfin photodynamic therapy plus antivascular endothelial growth factor therapy, the evidence

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includes a small RCT and a retrospective cohort study. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. The single RCT was likely underpowered to detect a clinically meaningful change in visual acuity outcomes. The retrospective cohort study did not demonstrate improvements in visual acuity with combination treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.

Presumed Ocular Histoplasmosis

For individuals who have choroidal neovascularization due to presumed ocular histoplasmosis who receive verteporfin photodynamic therapy, the evidence includes a small RCT and a prospective cohort study. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. Lack of a control arm in the prospective cohort study and 50% lost to follow-up in the RCT preclude a meaningful interpretation of data of observed improvements in visual acuity outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes. Clinical input obtained in 2012 supported the use of verteporfin photodynamic therapy for presumed ocular histoplasmosis, and therefore verteporfin photodynamic therapy may be considered medically necessary for this indication.

Central Serous Chorioretinopathy

For individuals who have choroidal neovascularization due to acute central serous chorioretinopathy who receive verteporfin photodynamic therapy, the evidence includes 2 RCTs. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. Although the evidence has demonstrated that full and reduced doses of verteporfin photodynamic therapy result in a small improvement in visual acuity outcomes, the improvements did not meet clinically meaningful thresholds. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical input obtained in 2012 supported the use of verteporfin photodynamic therapy for acute central serous chorioretinopathy, and therefore verteporfin photodynamic therapy may be considered medically necessary for this indication.

For individuals who have choroidal neovascularization due to chronic central serous chorioretinopathy who receive verteporfin photodynamic therapy, the evidence includes multiple retrospective studies. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. Although this relatively large body of retrospective studies has shown

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that half-dose verteporfin photodynamic therapy yields positive functional and anatomic outcomes while, at the same time, reducing the potential adverse events associated with conventional verteporfin photodynamic therapy, data from RCTs for multiple verteporfin photodynamic therapy strategies are lacking. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical input obtained in 2012 supported the use of verteporfin photodynamic therapy for chronic central serous chorioretinopathy, and therefore verteporfin photodynamic therapy may be considered medically necessary for this indication.

Polypoidal Choroidal Vasculopathy

For individuals who have choroidal neovascularization due to polypoidal choroidal vasculopathy who receive verteporfin photodynamic therapy, the evidence includes several prospective cohort studies and a meta-analysis of 2 RCTs. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. Prospective cohort studies have reported favorable anatomic and visual acuity outcomes for patients treated with verteporfin photodynamic therapy. However, RCTs comparing verteporfin photodynamic therapy with antivascular endothelial growth factor therapies have reported no statistically significant differences in visual acuity outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have choroidal neovascularization due to polypoidal choroidal vasculopathy who receive verteporfin photodynamic therapy plus antivascular endothelial growth factor therapy, the evidence includes 2 small RCTs, a meta-analysis, and 2 retrospective cohort studies. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. Results of the 2 RCTs failed to demonstrate statistically significant differences in visual acuity outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

Choroidal Hemangioma

For individuals who have choroidal neovascularization due to choroidal hemangioma who receive verteporfin photodynamic therapy, the evidence includes a systematic review of case series and a prospective cohort study. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. Although the prospective cohort suggested a favorable effect of verteporfin photodynamic therapy on various visual acuity and anatomic outcomes in patients with

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choroidal hemangioma, data from RCTs are lacking. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical input obtained in 2012 supported the use of verteporfin photodynamic therapy for choroidal hemangioma, and therefore verteporfin photodynamic therapy may be considered medically necessary for this indication.

Angioid Streaks

For individuals who have choroidal neovascularization due to angioid streaks who receive verteporfin photodynamic therapy, the evidence includes a systematic review of case series. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. Data from multiple case series have shown conflicting results for visual acuity outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

Inflammatory Chorioretinal Conditions

For individuals who have choroidal neovascularization due to inflammatory chorioretinal conditions who receive verteporfin photodynamic therapy, the evidence includes a systematic review of case reports. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. Methodologic limitations limit the conclusions drawn from 15 case reports (total N=115 patients) of multiple disease indications. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 2 physician specialty societies and 2 academic medical centers while this policy was under review in 2012. Input agreed that photodynamic therapy alone is medically necessary for age-related macular degeneration, pathological myopia, presumed ocular histoplasmosis, central serous chorioretinopathy, and choroidal hemangioma. Input was

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mixed on the use of photodynamic therapy for other ophthalmologic disorders. Input agreed that photodynamic therapy used in combination with vascular endothelial growth factor antagonists is investigational for all ophthalmologic disorders.

Practice Guidelines and Position Statements

American Academy of Ophthalmology

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 >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 <20/50 or if the choroidal neovascularization is <4 MPS [macular photocoagulation study] disc areas in size when the vision is >20/50
- Juxtafoveal choroidal neovascularization is an off-label indication for PDT but may be considered in select cases.”

National Institute for Health and Care Excellence

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: it recommended 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; it recommended 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.

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Canadian Agency for Drugs and Technologies in Health

In 2008, the Canadian Agency for Drugs and Technologies in Health released a health technology assessment on the management of neovascular age-related macular degeneration. The Agency concluded that “Overall, the efficacy of antivascular endothelial growth therapies over V-photodynamic therapy is well supported by RCTs [randomized controlled trials]. What remains unclear is whether combination therapy (and which combinations) are superior or merely equal to monotherapy.”

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

Since 2001, use of ocular photodynamic therapy has been covered by Medicare for the treatment predominantly classical subfoveal choroidal neovascularization (ie, occupies $\geq 50\%$ of the area of the entire lesion) associated with age-related macular degeneration only when used in conjunction with verteporfin. However, there was no national Medicare coverage policy for other indications. In 2004, Medicare found evidence to conclude that photodynamic therapy with verteporfin may be “reasonable and necessary” for patients with age-related macular degeneration with “subfoveal occult or minimally classic choroidal neovascularization ...4 disk areas or less in size ... [with] evidence of progression within the three months prior to initial treatment.” Medicare also reiterated that use of ocular photodynamic therapy with verteporfin for indications such as “pathologic myopia or the presumed histoplasmosis syndrome” may be “eligible for coverage through individual contractor discretion.”

Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this review are listed in Table 1.

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Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT01797861	Prospective Randomized Controlled Treatment Trial for Chronic Central Serous Chorioretinopathy (PLACE)	140	May 2017 (completed; no results posted)
NCT02495181	Randomized, Double-masked, Sham-controlled Phase 4 Study, Efficacy, Safety, and Tolerability of Intravitreal Aflibercept Monotherapy Compared to Aflibercept With Adjunctive Photodynamic Therapy in Patients With Polypoidal Choroidal Vasculopathy (ATLANTIC)	50	Dec 2019 (completed; no results posted)
NCT02821520	Initial Versus Delayed PDT Combination With Conbercept in Polypoidal Choroidal Vasculopathy	80	Jun 2019
NCT03079141	Photodynamic Therapy Versus Eplerenone: Treatment Trial for Chronic Central Serous Chorioretinopathy (SPECT)	107	Aug 2021
NCT02452840 ^a	Photodynamic Therapy for PDA in Neovascular Age-Related Macular Degeneration	100	Oct 2022

NCT: national clinical trial; PDT: photodynamic therapy.

^a Denotes industry-sponsored or cosponsored trial.

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- 04/18/2002 Medical Policy Committee review
- 06/05/2002 Managed Care Advisory Council approval
- 06/24/2002 Format revision. No substance change to policy.
- 06/01/2004 Medical Director review
- 06/15/2004 Medical Policy Committee review
- 06/28/2004 Managed Care Advisory Council approval
- 05/03/2005 Medical Director review
- 05/17/2005 Medical Policy Committee review. Format revision. Patient selection criteria added.
- 05/23/2005 Managed Care Advisory Council approval
- 05/03/2006 Medical Director review
- 05/17/2006 Medical Policy Committee approval. Format revision including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
- 04/04/2007 Medical Director review

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04/18/2007	Medical Policy Committee approval. No change to coverage eligibility.
08/06/2008	Medical Director review
08/20/2008	Medical Policy Committee approval. Added Updates from BCBSA to Rationale. Changed the verbiage in the Coverage section from “When Services May Be Eligible for Coverage” to “When Services Are Eligible for Coverage”. Criteria dropped in Coverage section due to redundancy. No change to coverage eligibility.
08/06/2009	Medical Policy Committee approval.
08/26/2009	Medical Policy Implementation Committee approval. No change to coverage eligibility.
08/05/2010	Medical Policy Committee review
08/18/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/04/2011	Medical Policy Committee review
08/17/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/02/2012	Medical Policy Committee review
08/15/2012	Medical Policy Implementation Committee approval. New drug listed under investigational section.
08/01/2013	Medical Policy Committee review
08/21/2013	Medical Policy Implementation Committee approval. PDT monotherapy considered eligible for coverage for central serous chorioretinopathy and choroidal hemangioma added as investigational.
08/07/2014	Medical Policy Committee review
08/20/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/01/2014	Coding updated- code G0186 Destruction of localized lesion of choroid (for example, choroidal neovascularization); photocoagulation, feeder vessel technique (one or more sessions) - added to policy
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
10/08/2015	Medical Policy Committee review
10/21/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/06/2016	Medical Policy Committee review

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- 10/19/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
- 10/05/2017 Medical Policy Committee review
- 10/18/2017 Medical Policy Implementation Committee approval. Added “verteporfin” in front of “photodynamic therapy” in the policy statements and throughout the body of the policy.
- 10/04/2018 Medical Policy Committee review
- 10/17/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 10/03/2019 Medical Policy Committee review
- 10/09/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 10/01/2020 Medical Policy Committee review
- 10/07/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 10/2021

Coding

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Code Type	Code
CPT	67221, 67225
HCPCS	C9257, J0178, J2503, J2778, J3396
ICD-10 Diagnosis	B39.9, D18.09, H32, H35.30, H35.711-H35.719, H44.20-H44.23

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 - 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 - 3. Reference to federal regulations.

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- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

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