Medica Coverage Policy

Policy Name:	**Photodynamic Therapy with Visudyne® (verteporfin) for Ocular Indications**
Effective Date:	**4/17/2023**

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

Coverage Policy

Note: This policy is no longer scheduled for routine review of the scientific literature.

Verteporfin (Visudyne™) photodynamic therapy using a non-thermal laser **is not investigative** for the treatment of subfoveal choroidal neovascularization (predominantly classic, minimally classic, or occult) when associated with any of the following:

- Wet age-related macular degeneration (AMD)
- Pathologic myopia
- Presumed ocular histoplasmosis syndrome
- Central serous chorioretinopathy
- Polypoidal choroidal vasculopathy
- Choroidal hemangioma.

Verteporfin photodynamic therapy for the treatment of other ocular conditions, including, but not limited to: choroidal melanoma is considered investigative and unproven, and therefore **NOT COVERED**. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Note: See also related Medica coverage policy: *Laser Treatments for Neovascularization Associated with Macular Degeneration.*

Description

The most frequent cause of blindness among people over 60 in the western world is macular degeneration. As macular degeneration progresses, two distinctively different forms may develop. Neovascular, or wet, macular degeneration is the most severe form of the two. Wet macular degeneration results when new blood vessels grow over the posterior of the eye (known as classical choroidal neovascularization [CNV]) and results in blood and serum leaking into the retina. Vascular leakage causes blister formation in the retina and damage to the macular

area, interfering with central vision. Risk of developing severe irreversible loss of vision is greatly increased by the presence of CNV.

Central serous chorioretinopathy (CSC) (also known as central serous retinopathy) is a medical condition that occurs when fluid leaks from capillaries in the choroidal layer between the retina and the outer surface of the eye, causing detachment of the retina. Patients with CSC may experience visual disturbances that include central scotoma, micropsia, reduced visual acuity, and loss of contrast sensitivity. Most episodes of CSC are self-limiting; however, some patients may experience residual visual symptoms despite recovery of visual acuity.

Verteporfin (Visudyne) photodynamic therapy is an alternative to photocoagulation and is used in the clinical, outpatient setting. The photosensitive drug, verteporfin, is administered intravenously and is taken up by lipoprotein receptors within the cells. Following infusion, nonthermal laser light is administered to the eye lesion. This initiates Visudyne activity by which highly reactive, short-lived singlet oxygen and reactive oxygen radicals are produced. This results in local damage to the neovascular endothelium by causing release of procoagulant and vasoactive factors that stimulate massive platelet aggregation, fibrin clot formation and vasoconstriction. Leaking vessels are thereby sealed with minimal adverse effects to surrounding tissue. Due to the recurrence of vascular leaking in virtually all patients, retreatment is an essential component of this therapy. Visudyne therapy can reduce or delay vision loss associated with AMD, but the therapy will not reverse previous vision loss.

Visudyne has also been used to treat CSC. However, complications such as retinal pigment atrophy, secondary choroidal neovascularization, and choroidal ischemia have been reported. Beneficial effects have been demonstrated by reducing the standard dose of Visudyne to half to reduce potential side effects.

As new therapies have evolved, photodynamic therapy with verteporfin it is now typically used as a second-line treatment for neovascular AMD.

FDA Approval
On April 13, 2000, the Visudyne™ two-step combination drug and device treatment process received new drug application (NDA) approval for use in the treatment of macular degeneration in patients with predominantly classic subfoveal choroidal neovascularization. This approval covers verteporfin for injection and two laser systems for photoactivation of verteporfin: the Coherent Opal Photoactivator Laser Console and LaserLink Adapter (Coherent-AMT, Ontario Canada), and the Zeiss VISULAS 690s laser and VISULINK PDT adapter (Zeiss Humphrey Systems, Dublin CA).

On August 22, 2001, the FDA granted additional approval to Visudyne for the treatment of patients with predominantly classical subfoveal choroidal neovascularization due to presumed ocular histoplasmosis syndrome or pathologic myopia.

Currently, verteporfin does not have FDA approval in the treatment of choroidal hemangioma, and use of it for this condition represents an off-label use of the drug.

Prior Authorization
Prior authorization is not required. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.

Coding Considerations

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes

- **J3396** - Injection, verteporfin, 0.1 mg
- **67221** - Destruction of localized lesion of choroid (eg, choroidal neovascularization); photodynamic therapy (includes intravenous infusion)
- **67225** - Destruction of localized lesion of choroid (eg, choroidal neovascularization); photodynamic therapy, second eye, at single session (List separately in addition to code for primary eye treatment)

Original Policy: *Verteporfin (Visudyne™) Photodynamic Therapy for Age-Related Macular Degeneration*

Effective Date: 9/1/2000

Re-Review Date(s):

11/13/2001 – title changed to *Verteporfin (Visudyne™) Photodynamic Therapy for Subfoveal Choroidal Neovascularization*

1/27/2004 – title changes to *Laser Treatments for Neovascularization Associated with Macular Degeneration*

3/27/2007

4/19/2010

12/17/2013 – title changed to *Photodynamic Therapy with Visudyne® (verteporfin) for Ocular Indications*

2/15/2017

2/19/2020

2/15/2023 – Clinical Review Reserve