Visudyne® (verteporfin)

Humana

Pharmacy Coverage Policy

Effective Date: January 01, 2024
Revision Date: June 26, 2024
Review Date: June 19, 2024
Line of Business: Medicaid - Louisiana
Policy Type: Prior Authorization

Products Affected
Visudyne intravenous solution

Listed Indications
Age-related Macular Degeneration
Presumed Ocular Histoplasmosis
Pathologic Myopia

Age-related Macular Degeneration	
Does the member meet all of the following criteria?	
Criteria #1	Diagnosed with neovascular (wet) age-related macular degeneration
Criteria #2	Has had prior therapy, contraindication, or intolerance to bevacizumab intravitreal injection.
Approval Duration	
Initial	Visudyne (verteporfin) will be approved in plan year duration or as determined through clinical review.
Renewal	Visudyne (verteporfin) will be approved in plan year duration or as determined through clinical review.

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Presumed Ocular Histoplasmosis	
Does the member meet all of the following criteria?	
Criteria #1	Diagnosed with presumed ocular histoplasmosis.
Approval Duration	
Initial	Visudyne (verteporfin) will be approved in plan year duration or as determined through clinical review.
Renewal	Visudyne (verteporfin) will be approved in plan year duration or as determined through clinical review.

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Pathologic Myopia	
Does the member meet all of the following criteria?	
Criteria #1	Diagnosed with pathologic myopia.
Approval Duration	
Initial	Visudyne (verteporfin) will be approved in plan year duration or as determined through clinical review.
Renewal	Visudyne (verteporfin) will be approved in plan year duration or as determined through clinical review.

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Background

This is a prior authorization policy about Visudyne (verteporfin).

Visudyne (verteporfin for injection) is an ophthalmic agent. It is a light-activated drug used in photodynamic therapy.

Visudyne (verteporfin for injection) therapy is a two-stage process requiring administration of both verteporfin for injection and nonthermal red light. Verteporfin is transported in the plasma primarily by lipoproteins. Once verteporfin is activated by light in the presence of oxygen, highly

reactive, short-lived singlet oxygen and reactive oxygen radicals are generated. Light activation of verteporfin results in local damage to neovascular endothelium, resulting in vessel occlusion. Damaged endothelium is known to release procoagulant and vasoactive factors through the lipo-oxygenase (leukotriene) and cyclo-oxygenase (eicosanoids such as thromboxane) pathways, resulting in platelet aggregation, fibrin clot formation and vasoconstriction. Verteporfin appears to somewhat preferentially accumulate in neovasculature, including choroidal neovasculature. However, animal models indicate that the drug is also present in the retina. Therefore, there may be collateral damage to retinal structures following photoactivation including the retinal pigmented epithelium and outer nuclear layer of the retina. The temporary occlusion of choroidal neovascularization (CNV) following Visudyne therapy has been confirmed in humans by fluorescein angiography.

Visudyne (verteporfin for injection) is indicated for the treatment of: Age-related macular degeneration, associated with classic subfoveal choroidal neovascularization; Presumed Ocular Histoplasmosis associated with classic subfoveal choroidal neovascularization; Pathologic Myopia; associated with classic subfoveal choroidal neovascularization.

Verteporfin is available as Visudyne for injection in a 15 mg lyophilized single use vial.

Age-related macular degeneration (AMD) is a major cause of painless central vision loss and is a leading cause of blindness in people over 60.

- Dry AMD is associated with atrophic cell death of the central retina or macula, which is required for fine vision used for activities such as reading, driving or recognizing faces. Approximately 10-20% of patients with dry AMD eventually progress to wet AMD.
- Wet AMD is associated with growth of abnormal blood vessels under the macula. These new blood vessels tend to be very fragile and often leak blood and fluid and cause scar tissue that destroys the central retina. The blood and fluid raise the macula from its normal place at the back of the eye. Damage to the macula occurs rapidly and results in a deterioration of sight over a period of months to years.

Between 80% to 90% of AMD is dry, yet more than 80% of the visual loss attributable to AMD is caused by the wet form.

Presumed ocular histoplasmosis is characterized by peripheral atrophic chorioretinal scars, peripapillary scarring, and maculopathy. This condition is believed to be secondary to exposure to Histoplasma capsulatum, although this fungus rarely has been isolated or cultured from an eye with the typically associated clinical findings. Visual loss in POHS is secondary to the development of macular choroidal neovascularization (CNV).

Pathologic, or degenerative, myopia typically develops by age 12 in those with an extraordinarily elongated eyeball. About two percent of Americans are afflicted. The stretching of the eyeball worsens with age and can result in a progressive and severe loss of vision. Compounding the problem in many cases is an abnormal growth of new blood vessels (neovascularization) beneath the macula.

- Patients who experience severe decrease of vision of ≥4 lines within one week after treatment with Visudyne should not be retreated, at least until their vision completely recovers to pretreatment levels and the potential benefits and risks of subsequent treatment are carefully considered by the treating physician.
- Examples of other products used to treat AMD include Avastin (compendia listed indication), Lucentis, and Macugen.
- For concurrent bilateral treatment (CBT); if patient already received previous therapy in one eye with acceptable safety profile, both eyes can be treated concurrently following a single verteporfin administration.
- The physician should reevaluate the patient every three months and if choroidal neovascular leakage is detected on fluorescein angiography, therapy should be repeated.

Visudyne should not be used in the following:

- Hypersensitivity to any component of the preparation.
- Patients with porphyria.

Warnings/Precautions

- Patients should avoid bright light for 5 days after injection.
- Visudyne (verteporfin) should be used with caution in patients with moderate to severe hepatic impairment.
- Use precaution to avoid extravasation (stop infusion immediately if it occurs).
- Safety and efficacy of use for longer than 2 years has not been established.
- Patients who experience severe decrease of vision of 4 lines or more within 1 week following treatment, should not be retreated, at least until vision completely recovers to pretreatment levels and the benefits outweigh the risks.

Provider Claim Codes

For medically billed requests, please visit www.humana.com/PAL. Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

Medical Terms

Visudyne; verteporfin; Age-Related Macular Degeneration; AMD; Presumed Ocular Histoplasmosis, Pathologic Myopia, Intravenous; Pharmacy

References

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