blue of california

Medical Policy

Photodynamic Therapy for Subfoveal Choroidal Neovascularization	
Type: Medical Necessity and Investigational / Experimental	**Policy Specific Section:** Medicine
Original Policy Date: June 18, 2000	**Effective Date:** June 28, 2013

Definitions of Decision Determinations

Medically Necessary: A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Description

Photodynamic therapy (PDT) is a treatment modality designed to selectively occlude ocular choroidal neovascular tissue. The therapy is a 2-step process, consisting initially of an injection of the photosensitizer verteporfin, followed 15 minutes later by laser treatment to the targeted sites of neovascularization in the retina. The laser treatment selectively damages the vascular

endothelium. Patients may be re-treated if leakage from choroidal neovascularization (CNV) persists.

Policy

Photodynamic therapy with verteporfin (Visudyne®), as monotherapy, may be considered **medically necessary** as a treatment of choroidal neovascularization associated with **any** of the following:

- Age-related macular degeneration
- Chronic central serous chorioretinopathy
- Choroidal hemangioma
- Pathologic myopia
- Presumed ocular histoplasmosis

Photodynamic therapy with verteporfin (Visudyne®), as monotherapy, is considered **investigational** for other ophthalmologic disorders.

Photodynamic therapy with verteporfin (Visudyne®) is considered **investigational**, when used in combination therapy with one or more of the anti-vascular endothelial growth factor therapies, as a treatment of CNV associated with **any** of the following:

- Age-related macular degeneration
- Chronic central serous chorioretinopathy
- Choroidal hemangioma
- Pathologic myopia
- Presumed ocular histoplasmosis
- Other ophthalmologic disorders

Note: See Policy Guidelines for examples of anti-vascular endothelial growth factor therapies.

Policy Guideline

Anti-vascular endothelial growth factor therapy examples:

- Pegatanib (Macugen®)
- Ranibizumab (Lucentis®)
- Bevacizumab (Avastine®)
- Aflibercept (Eylea™)

The U.S. Food and Drug Administration (FDA) labeling for verteporfin indicates that the physician should re-evaluate the patient every 3 months and, if choroidal neovascular leakage is detected on fluorescein angiography, therapy should be repeated. However, the total number of treatments is not addressed by the FDA. Evidence defining when treatment should stop is not available, but expert opinion (convened by Novartis, Visudyne manufacturer) suggested stopping "when the situation is judged to be futile'" (Verteporfin Roundtable Participants 2005). FDA labeling states "safety and efficacy of Visudyne beyond 2 years have not been demonstrated."

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Internal Information

There is an MD Determination Form for this Medical Policy. It can be found on the following Web page:
http://myworkpath.com/healthcareservices/MedicalOperations/PSR_Determination_Pages.htm

Documentation Required for Clinical Review

• Ophthalmologic history and physical or consultation notes including:
  o Current treatment plan
  o Past treatment and treatment response
• Fluorescein angiographic results (initial or subsequent re-treatment)

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.

Click here to view the appendix for this policy

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