Clinical Review Criteria

Visudyne with Photodynamic Therapy for Age-Related Wet Macular Degeneration

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Criteria
See main photodynamic therapy criteria document.

The following information was used in the development of this document and is provided as background only. It is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Age-related macular degeneration (AMD) is the most common and most severe cause of vision loss in the U.S. and many developed countries. With increasing life expectancy, the prevalence of AMD (currently about 25%) in people aged 65 years and older will increase significantly, with an enormous social and financial cost. In spite of the significance of this problem, AMD’s pathogenesis remains unclear and is essentially untreatable.

AMD is characterized by two forms: the “dry” and more severe “wet” form. The latter accounts for 15% of all AMD cases, but is responsible for 90% of the severe vision loss associated with this condition. Visual acuity loss usually results from choroidal neovascularization (CNV), the ingrowth of new vessels from the choriocapillaris. These new vessels are accompanied by fibrous tissue that can destroy central visual function over months to years.

Standard treatment of CNV has been with a thermal laser. The drawback of this laser is that in addition to destroying the CNV it destroys the surrounding retinal tissue with immediate vision loss.

Photodynamic Therapy (PDT) utilizing verteporfin (Visudyne; CIBA Vision Corp, Duluth, GA) is a new technology which completed Phase III clinical trials last year and was recently recommended for FDA approval by the Ophthalmic Drugs Subcommittee of the FDA. Verteporfin therapy involves an intravenous administration of verteporfin, a light activated drug. Laser light at the specific wavelength absorbed by Visudyne is then directed to the area of neovascularization and causes preferential closure of these vessels while sparing the overlying retina.

The articles described below evaluate PDT as a treatment for choroidal neovascularization (CNV), the type of late AMD that is the most frequent cause of visual loss.

Health Plan Director’s Group Meeting Recommendation

03/27/02 Based on the fact that no denials for this service have occurred since the creation of the criteria, and that the care process in diagnosis and treatment allows no time for coverage review prior to the procedure, it was recommended that the clinical review criteria should be suspended.

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### Medical Technology Assessment Committee (MTAC)

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<td>6/14/00</td>
<td>The prospect of verteporfin (Visudyne) as a new therapy for subfoveal wet AMD is very promising, in light of the fact AMD is an important public health problem with no currently available treatment that spares destruction of the fovea itself. However, the efficacy and safety of verteporfin cannot be fully determined from the limited evidence provided by these two studies, which were conducted by the same investigators. The findings from the case series are threatened by small sample size and possible observation and selection biases. The findings from both studies are threatened by short length of follow-up, concerns about the generalizability of the findings, and the fact that the investigators would benefit financially from FDA approval of the drug. Further studies, preferably blinded, randomized controlled trials, such as the Verteporfin in Photodynamic Therapy (VIP) Trial (to be completed this Fall), will provide further evidence regarding whether photodynamic therapy with verteporfin can safely and effectively reduce the risk of vision loss in patients with age-related macular degeneration.</td>
<td>The use of Visudyne with Photodynamic Therapy in the treatment of Age-related Macular Degeneration does meet the Group Health Medical Technology Assessment Criteria.</td>
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### Evidence/ Source Documents

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