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| **Title:** | **Photodynamic therapy with verteporfin (PDT-V) for age-related macular degeneration July 2001** |
| **Agency:** | Medical Services Advisory Committee (MSAC)<br>Commonwealth Department of Health and Ageing<br>GPO Box 9848 Canberra ACT 2601 Australia<br>**http://www.msac.gov.au** |
| **Reference:** | **MSAC application 1039. Assessment report ISSN 1443-7120** |

To assess the safety and effectiveness of the service and under what circumstances public funding should be supported for the service.

**Conclusions and results**

*Safety* Randomised controlled trials indicate a relatively high and precise number of adverse events (1 in 7) including visual disturbance (22%), injection site events (16%), infusion-related back pain (2.5%), allergic reactions (2%), and photosensitivity reactions (3.5%). Incidence of adverse events with Fluorescein angiography (which is used to assess eligibility PDT-V) is measured at 4.5% (case studies, surveys and other studies of lower evidence levels).

*Effectiveness* PDT-V was more effective than placebo in patients with classic choriodal neovascularisation (CNV) in reducing loss of less than 15 letters after an average of 5.6 treatment over 24 months. 4 patients with classic CNV need to be treated to produce one positive result (only 2 where there is no evidence of occult CNV). PDT-V did not reverse visual loss. PDT-V was not more effective than placebo for less typical lesions, patients with occult CNV and patients who were current smokers.

*Cost-effectiveness* Modeling suggests a cost per vision year gained of $6,100-$35,400 based on assumed clinical advantages and associated offsets. PDT-V funding is estimated to cost $10-$30M in the first year, $16-36M in the second year and $13.6M per annum in subsequent years when only new patients are being treated. This assumes diagnosis is accurate. However, the difficulty of diagnosing patients may mean additional costs.

**This draft report does not include recommendations.**

**Method**

MSAC conducted a systematic review of the biomedical literature from 1966 to April 2001 accessing biomedical electronic databases, the Internet and international health technology agency websites.. Effectiveness was assessed using a randomised controlled trial of 609 patients that compared verteporfin with placebo in PDT for patients with neovascular AMD. Cost effectiveness assessment is based on modeling by the applicant of cost-per vision year gained for different clinical scenarios that compare PDT-V and placebo (and includes sensitivity analysis). Aggregate costings assume that the stock of current patients would be cleared in 2 years.

Prepared by the Centre for Clinical Effectiveness, Australia