

Berkshire Priorities Committee

Policy Statement 50 Photodynamic Therapy (with Verteporfin)

Date of Issue October 2002

Berkshire Priorities Committee recommends the use of PDT with verteporfin for the treatment of subfoveal predominantly classic choroidal neovascularization (CNV) due to age-related macular degeneration within Berkshire.

Age-related macular degeneration (AMD) produces profound visual disabilityⁱ because it involves loss of function of the macula, the part of the eye where vision is keenest. There are two forms of AMD, "wet" and "dry". The wet form of AMD is associated with growth of fragile, abnormal blood vessels under the retina (choroidal neovascularization or CNV), which leak, bleed then scar. It is responsible for 90% of the severe visual disability associated with AMDⁱⁱ and seven out of ten eyes with lesions under the centre of the macula (the fovea) are legally blind within two years of diagnosisⁱⁱⁱ.

Clinical effectiveness

Evidence of the effectiveness of PDT with verteporfin comes from two multicentre, randomised controlled clinical trials (the TAP studies) the outcomes of which were so similar, that the data were combined and published as one year and two year reports. The Cochrane Review Group evaluated the TAP studies as high quality^{iv}.

Vision outcomes were significantly better in treated than untreated eyes throughout the two-year study period and they were corroborated by fluorescein angiographic evidence of an impact on disease progression. The benefits of treatment were achieved with an average of seven treatments over three years. Beneficial outcomes were seen across the whole population with subfoveal CNV with a classic component but were stronger in predominantly classic lesions (classic CNV occupying at least half of the lesion).

For the primary outcome measure of avoidance of moderate vision loss (fewer than 15 letters or five lines lost on an ETDRS chart) treatment was effective at 12 months in 67% of treated patients *versus* 39% untreated patients ($p < 0.001$). This benefit was sustained to two years (59% of treated patients *versus* 31% untreated patients: $p < 0.001$). It is for this sub-group of wet AMD patients with predominantly classic CNV that PDT with verteporfin is proposed.

Effectiveness analysis for PDT with verteporfin, based on the outcomes of the TAP studies, compares favourably with trials of other interventions. To prevent one person with predominantly classic lesions suffering moderate vision loss (three or more lines of vision) it is necessary to treat four (3.6) people. Equivalent analyses for other interventions are five for diabetic retinopathy, 19 for sickle cell retinopathy, 15 for diabetes and complications, 128 for treatment of diastolic blood pressure of 90 to 100mm Hg and 1075 for breast examination plus mammography^v.

This statement will be reviewed in the light of new evidence of guidance from NICE.ⁱ

ⁱ. Bressler NM, Gills JP. Age-related macular degeneration. *BR Med J* 2000; 321: 1425- 1427.

ⁱⁱ. Ferris III FL, Fine SL, Hyman L. Age-related macular degeneration and blindness due to neovascular maculopathy. *Arch Ophthalmol* 1984; 102: 1640-1642.

ⁱⁱⁱ. Bressler SB, Bressler NM, Fine SL et al. Natural course of choroidal neovascular membranes within the foveal avascular zone in senile macular degeneration. *AM J Ophthalmol* 1982; 93: 157-163.

ⁱⁱⁱⁱ. Bressler NM, Gills JP. Age-related macular degeneration. *BR Med J* 2000; 321: 1425-1427.

^{iv}. Wormald R, Evans J, Smeeth L. Photodynamic therapy for neovascular age-related macular degeneration (Cochrane Review). In: The Cochrane Library, Issue 3, 2001. Oxford: Update Software/

^v. Sharma S. Update in retina: Photodynamic therapy for the treatment of subfoveal choroidal neovascularization secondary to age-related macular degeneration. *Can J Ophthalmol* 2001; 36: 7-10.