

13th December 2011

Dear Sir/Madam,

Please find below comments from the BMJ-TAG on the Appraisal consultation document (ACD) for Ranibizumab for the treatment of macular oedema secondary to retinal vein occlusion.

1. Point 3.19 (pg 15).

- The ACD states that “The ERG considered that the most relevant data for determining the comparative effectiveness of ranibizumab in treating macular oedema secondary to RVO are the data from the period when ranibizumab was given as needed (that is, from month 6).”
- In the ERG report, the ERG comments that it considers data at 6 months (end of the treatment phase) to be the most relevant for patients with MO secondary to CRVO. For patients with MO secondary to BRVO, because of use of concomitant rescue grid laser photocoagulation, the ERG considers data at 3 months to be most informative on the effects of ranibizumab alone.

2. Point 3.21 (pg 16).

- The ACD states “Based on exploratory analyses of the proportion of people whose visual acuity improved by 10 or more ETDRS letters (considered to be clinically meaningful)”.
- In the ERG report, the text describing the outcome of 10 or more letters is highlighted as Academic in Confidence, although the relative risk and confidence intervals are not.

3. Point 3.21 (pg 16).

- The ACD states “The relative risk of achieving a visual acuity improvement of 15 or more ETDRS letters at 3 months was 0.79 (95% CI 0.56 to 1.12) for patients with macular oedema secondary to BRVO, again favouring ranibizumab over dexamethasone intravitreal implant.”
- In the ERG report, the RR of achieving 15 or more ETDRS letters at 3 months is given as 0.56 (95% CI 0.33 to 0.96) for patients with MO secondary to BRVO. The RR presented in point 3.21 is for the relative risk of achieving an improvement of 10 or more letters at 3 months.

4. Point 3.31 (pg 21).

- The ACD states “The ERG conducted a cost-minimisation analysis for ranibizumab versus dexamethasone intravitreal implant...”.
- The ERG carried out a cost-minimisation analysis for ranibizumab versus bevacizumab rather than dexamethasone intravitreal implant.

Please do not hesitate to contact us if you require more information.

Yours faithfully,

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