

Section 1: Appraisal Committee's preliminary recommendations

We believe that NICE should approve ranibizumab for the treatment of macular oedema secondary to retinal vein occlusion (RVO).

This is essential for RVO patients where dexamethasone (Ozurdex) is contraindicated, which includes those with:

- advanced glaucoma which cannot be adequately controlled by medicinal products alone
- previous raised intraocular pressure with steroids
- hypersensitivity to dexamethasone
- active or suspected ocular or periocular infection

Ranibizumab is an important treatment option for patients with macular oedema secondary to central retinal vein occlusion (CRVO). This type of RVO is the most severe and grid laser photocoagulation is not effective in this subgroup.

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Section 4: Consideration of the evidence

(a) Comment on the comparator:

We are concerned that Avastin is being used as a comparator in this appraisal. There is still insufficient data to draw firm conclusions on the comparative safety of this drug in the treatment of wet AMD. Like the Royal College of Ophthalmologists, we feel the Medicines and Healthcare Products Regulatory Agency and NICE must review the use of Avastin in the treatment of this condition.

We also believe it is vital that a national body is identified to take responsibility for risk management and pharmacovigilance to monitor the ongoing usage of Avastin in the eye.

(b) Comment on the Committee's quality of life assumption:

The Evidence Review Group and Committee both assume that a patient's quality of life only improves if their best corrected visual acuity (BCVA) improves by 20 letters or more. However, patients and experts tell us that a gain of 10 letters or more is significant and clinically meaningful. Therefore, we believe the quality of life benefits have been underestimated.

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