NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Allergan comment on

Appraisal Consultation Document

Ranibizumab for the treatment of macular oedema secondary to retinal vein occlusion

Has all of the relevant evidence been taken into account?

Yes

Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?

Allegan would like to endorse and reiterate the points made by the ERG with regard to the indirect comparison of Ozurdex to ranibizumab. Allergan agrees that the exploratory indirect comparisons conducted by the ERG and provided by the manufacturer in its economic comparison are biased to favour ranibizumab efficacy because of differing patient characteristics in the RCTs informing the comparison (namely GENEVA for Ozurdex and BRAVO & CRUISE for ranibizumab). These differences included:

- greater duration of macular oedema in both the BRVO and CRVO patient populations of GENEVA versus BRAVO and CRUISE, respectively,
- lower baseline best-corrected visual acuity and larger central retinal thickness measures in both BRAVO and CRUISE versus GENEVA, and
- lack of specific criteria to exclude ischaemic patients in the GENEVA study.

As a result, the ERG cautions (and Allergan agrees) that any differences in efficacy between Ozurdex and ranibizumab presented in the ACD and ERG report should be interpreted with caution. The most appropriate manner to assess the relative efficacy of these two products would be a head to head clinical study.

Are the provisional recommendations sound and a suitable basis for guidance to the NHS?

Yes

Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of gender, race, disability, age, sexual orientation, religion or belief?

No

Are there any equality -related issues that need special consideration and are not covered in the appraisal consultation document?

No