csas
Commissioning Support
Appraisals Service

www.sph.nhs.uk/appraisals
**Tel:** +44 (0)1865 334787
**Email:** askappraisals@sph.nhs.uk

15 October 2012

National Institute for Health and Clinical Excellence

Dear Jeremy,

**RE: Ranibizumab for the treatment of diabetic macular oedema**

On behalf of Commissioning Support, Appraisals Service (CSAS), Solutions for Public Health, I would like to submit our comments on the appraisal consultation document for ranibizumab for the treatment of diabetic macular oedema. We are in agreement with the recommendation in the ACD to recommend ranibizumab for this indication only if the person has a central retinal thickness of 400 micrometres or more and the manufacturer provides ranibizumab with the discount agreed as part of the patient access scheme (as revised in 2012). On the basis of the evidence considered it is likely that this treatment can be considered clinically and cost effective in real life clinical practice.

- **Ranibizumab gave the greatest improvement in people with thicker retinas and more severe visual impairment at baseline.** In one large trial (RESTORE), gains in BCVA with ranibizumab were greatest in the subgroup of people with central foveal thickness greater than 300 micrometres.
- **Ranibizumab improves visual acuity compared to laser photocoagulation alone, but there is no additional benefit of adding laser to ranibizumab.** The two larger of four trials (RESTORE and DRCR.net) found that, for the whole treatment population, ranibizumab improved BCVA over 2 years, but there was no evidence for a benefit in adding laser to ranibizumab.
- **Uncertainties remain over whether the trial data is relevant to the eligible UK population**. There were uncertainties over whether the glycaemic control and use of laser photocoagulation in the trials accurately reflected what would be seen in UK clinical practice.
- **Ranibizumab could be considered a cost effective use of NHS resources in the subgroup of people with thicker retinas.** The ICER when accounting for treatment in both eyes had been estimated at between £27,999 and £36,089 per QALY depending on the utility values used, but the Committee concluded that the most plausible ICER for the subgroup of people with thicker retinas was likely to be below £25,000 per QALY.
- **The manufacturer's revised model used more plausible assumptions than those used in the economic model submitted for TA237.** The manufacturer's revised model produced an ICER of £13,322 per QALY for treating both eyes in people with thicker retinas. This ICER would be likely to increase depending on characteristics of the treatment population but it still expected to be below £25,000 per QALY.

csas
Commissioning Support
Appraisals Service

www.sph.nhs.uk/appraisals
**Tel:** +44 (0)1865 334787
**Email:** askappraisals@sph.nhs.uk

- **The manufacturer has agreed a patient access scheme.** The scheme will make ranibizumab available with a discount, the details of which are commercial in confidence.
- **The Committee had no concerns regarding the safety of ranibizumab.** The included studies have not assessed safety outcomes, but found no difference in the rate of adverse events.
- **Bevacizumab was not compared to ranibizumab**. Bevacizumab was listed as a comparator in the scope but the manufacturer did not compare clinical effectiveness despite the ERG noting that a recent head-to-head trial of ranibizumab and bevacizumab for age-related macular degeneration (CATT) showed equivalent efficacy between the two technologies. The committee agreed with the manufacturer that a cost effectiveness analysis was not possible as the costs associated with preparing and administering bevacizumab, (e.g. dose and number of injections required) was not readily available. The committee proposed that further research directly comparing the clinical and cost effectiveness of ranibizumab and bevacizumab in people with DMO should be conducted.

If you require any further information please contact me directly: Phone: 01865 334723, email XXXXX.XXXXXXXXXXXXXXXXXXXXX

Yours sincerely

XX XXXXXX XXXXXX

XXXXXXXXXXXXXXXXXXXX

XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX,

XXXXXXXXXXXXXXXXXXXXXXX

Email: XXXXXXXXXXXXXXXXXX

XXXXXX XXXXXX-XXXX

XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXXXXXXXXXX

Tel: XXXXXXXXXXX

Email: XXXXXXXXXXXXXXXXXXXXXXXXXX