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Date: 3rd July 2007.

Christopher Feinmann
National Institute for Health and Clinical Excellence
Peter House
Oxford Street
Manchester
M1 5AN

Dear Mr Feinmann,

**RE: NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE
Single technology appraisal (STA)**

Health technology appraisal: Ranibizumab and Pegaptanib for the treatment of age-related macular degeneration

Appraisal Consultation Document comments:

- 1) Do you consider that all of the relevant evidence has been taken into account?

This appears to be a thorough review of the currently available evidence in addition to which the committee has noted the lack of evidence relating to the lasting effects and best possible maintenance regimens beyond 2 years of treatment (using Ranibizumab). Both evidence of effectiveness and the cost effectiveness evidence appear to have been reviewed in full and the limitations have been noted.

- 2) Do you consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence, and that the preliminary views on the resource impact and implications for the NHS are appropriate?

The cost effectiveness of the treatment regimens under consideration have been fully explored despite the differing methodologies used. However the total cost to the NHS of these treatments, alongside the impact of the underlying condition on NHS budgets overall, has not been fully explored. The costs and opportunity costs need to be more fully assessed prior to implementation of the guidance.

In particular the costs of care other than drug costs will not be negligible in the treated groups, which alongside the ageing population (and therefore an increased incidence of the condition) will see increasing support costs as well as the actual treatment costs which need to be more accurately accounted for.



Chair: John Pierce **Chief Executive:** Trevor Purt
Professional Executive Committee Chair: Dr Nick Dawes

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The Local Strategic Partnership
for the Borough of Rochdale



However the recommendations do include the need for trials of the alternative therapy Bevacizumab which is a cheaper drug, the initial use of which has shown indications of its being as effective as Ranibizumab. The NHS will need to provide the driver for these trials as commercial interests may not do so. The recommendations for additional trials, both of Bevacizumab as an alternative and of the effectiveness of both Bevacizumab and Ranibizumab beyond 2 years, needs to be strengthened.

- 3) Do you consider that the provisional recommendations of the appraisal committee are sound and constitute a suitable basis for the preparation of guidance to the NHS?
- The inclusion criteria relating to the identification of individuals to whom the treatment would be offered is comprehensive, is in line with the evidence reviewed and also matches the views that our local clinicians have given to our commissioning group.
 - The recommendation to no longer offer Pegaptanib is supported by the evidence provided but will have significant cost implications if patients currently on this drug wish to change to Ranibizumab. The recommendation that current treatment can continue at the discretion of the clinician and patient is welcomed
 - The treatment regimens suggested appear to be in line with the evidence and the views of the expert clinicians
 - The recommendation to make funding available to fully implement this within 3 months may be problematic dependant on the timing of the release of the guidance in relation to the planning /commissioning cycle for Trusts
 - The proposed recommendations for further research are welcomed but would be strengthened by the recommendation that treatment with Ranibizumab should be funded as part of a trial to establish one or all of the following:
 - i. Long-term effects of anti-VEGFs
 - ii. The appropriate duration and optimal treatment regimen
 - iii. Evaluation of cost effectiveness (including supporting service costs)
 - The proposed review date of April 2010 may not allow time for outcome of the trials into the long term effects to be available or from trials of Bevacizumab not yet established. Perhaps the optimal treatment regimens should be reviewed then, with the full review taking place in a timescale that allows the other trials to be completed or to have provided their initial interim results.

Yours Sincerely,

[Redacted Signature]



Chair: John Pierce **Chief Executive:** Trevor Purt
Professional Executive Committee Chair: Dr Nick Dawes

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