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11/01/2008

**Pegaptanib and ranibizumab for treatment of age-related macular degeneration (AMD)**

**Response to the Appraisal Consultation Document issued on 7 December 2007**

Dear Mr Feinmann,

Thank you for providing the opportunity to respond to the second ACD issued by NICE on the use of pegaptanib and ranibizumab.

In my opinion, the recommendations made in the second ACD are broadly speaking acceptable. However, similar to other consultees I believe that a number of changes and additions are required to ensure that the Final Appraisal Determination will meet the needs of patients. In particular I would welcome:

1.1. The approval of pegaptanib as second-line treatment

1.2. A lower treatment threshold with patients being treated in line with the recommendations of the Royal College of Ophthalmologists

1.3. The FAD to be issued quickly

1.4. The speedy implementation of NICE's guidance and greater efforts by NICE's implementation unit to monitor and enforce the implementation deadline.

1.5. A recommendation that Primary Care Trusts provide the necessary funding to introduce appropriate infrastructure and not just the price of the drug.

1.6. Clarification of NICE's position with regard to Primary Care Trusts which commission an Anti-VEGF service using bevacizumab rather than with ranibizumab or pegaptanib.

## **The decision not to recommend the approval of pegaptanib**

2. I believe that clinicians and their patients should have the option to choose what treatment is in the patient's best interest. Certainly at present ranibizumab will be the preferred treatment choice for most patients. However, some patients with wet AMD may not be able to tolerate ranibizumab, have an allergic reaction to this drug or may have a history of heart disease or stroke. One or more of these factors may make pegaptanib the preferred treatment option.

In addition I am aware of research combining ranibizumab and pegaptanib in the same treatment pathway. In this research, patients are initially given ranibizumab resulting in vision improvement and then they are maintained with pegaptanib which stabilises their vision at the improved level. This research is not published yet but merely presented at scientific meetings. However possibly this may be a safer option for patients with cerebrovascular or cardiovascular disease if it shows equal benefit to treatment with ranibizumab alone. Therefore it would be useful at this stage to have pegaptanib available as an option for treatment so that clinicians could quickly respond to changes in treatment protocols as new evidence from clinical trials becomes available.

## **The treatment threshold**

3. Throughout the ACD a visual acuity of 6/60 is equated with the threshold for legal blindness in the UK. Most significantly the fact that 6/60 is presumed to be the threshold for legal blindness is used as a justification to set the eligibility threshold for treatment at better than 6/60 (effectively 6/48).

4. 6/60 is the threshold for being registered as partially sighted, not blind. The threshold for being registered as blind is 3/60. I believe that the false assumption that 6/60 is the threshold for legal blindness has confused the committee's thinking. I would like to remind NICE that the eligibility threshold for PDT is 6/60 or better, that the Scottish Medicines Consortium has set no eligibility threshold for ranibizumab and a threshold of 6/60 or better for pegaptanib. Significantly, the Royal College of Ophthalmologists recommends that treatment should be considered until a patient's visual acuity falls persistently below 6/96 (or logMar 1.2). Evidence and clinical experience show that providing there is not irreversible sub-foveal scarring patients vision can recover even from these very low levels of vision with resolution of retinal fluid.

5. At present many patients only present with their second eye once they have significant vision loss. Given the chance of improvement in vision through treatment with ranibizumab patients should be given access to treatment even if that is the case. I support the Royal College position and urge NICE to revise its eligibility criteria accordingly.

## **Speedy adoption of FAD**

6. I urge NICE to issue the FAD for this appraisal as quickly as possible ensuring that it is likely to be acceptable to all key stakeholders to avoid the risk of an

appeal. By the time the Appraisal Committee meets again on 13 February 2008 it will have been two years since the draft scope for the appraisal was issued. Because of the delays that occurred throughout the decision-making process hundreds of people will have lost their sight unnecessarily or had to pay for private treatment at a time of life when they could justifiably expect the NHS to provide sight saving treatment. By adopting its FAD quickly NICE can ensure that we do not have to add hundreds more to that list.

## **Implementation**

7. I welcome the fact that the ACD is recommending the usual three-month period for the implementation of the guidance on pegaptanib and ranibizumab. I urge the Committee not to lengthen that period. My and other doctors experiences with the nine-month timescale for the implementation of the final guidance on PDT have shown that many PCTs and Local Health Boards will delay implementation for as long as possible, often missing the deadline altogether. A longer implementation period will remove urgency from their internal decision-making and will again result in unnecessary sight loss.

8. In addition, I would like to raise the issue of treatment standards. Given the high cost of treatment PCTs and Local Health Boards may be tempted to lower the standard of care by allowing under-qualified staff to perform the injections. In the interest of patient safety I feel that the FAD should contain a requirement to follow Royal College of Ophthalmologists' treatment guidelines.

9. I would also welcome a recommendation that Primary Care Trusts provide the necessary funding to introduce appropriate infrastructure as per Royal College of Ophthalmology guidelines and not just the price of the drug. Otherwise it may prove impossible for hospital trusts to provide this treatment. My personal experience is that some Primary Care Trusts will only pay for the drug costs. This is similar to paying for a scalpel but not the operating theatre or surgeon.

10. Finally, I would also welcome clarification of NICE's position regarding Primary Care Trusts who commission an Anti-VEGF service using bevacizumab as the drug choice rather than ranibizumab or pegaptanib. If this occurs will these Primary Care Trusts face financial penalties for not introducing NICE guidance? Or will NICE consider this is satisfactory? Clarification of this from NICE would greatly help planning of anti-VEGF macular degeneration services around the country.

Thank you for your careful appraisal of this technology and for your response to the feedback to the first ACD.

Best wishes,

Yours sincerely,

Andrew Lotery MD FRCOphth

