Pegaptanib & Ranibizumab for the Treatment of Age-related Macular Degeneration

Comments on Appraisal Consultation Document (ACD)

Name of Commentator: [redacted]
on behalf of DHSSPSNI

Conflict of Interest Declaration

Please state if, at any time, you have had any involvement with the health care industry or manufacturers (as listed in the list of stakeholders) in relation to the technology being appraised and have personally received payment or material benefit from that work. If so, please provide details including the date of your last involvement.

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Comments on Pegaptanib & Ranibizumab for the Treatment of Age-related Macular Degeneration

I don't have any substantive comments on the guidance issued on pegaptanib. I agree that the outcomes in the VISION trials show effectiveness in preventing moderate and severe vision loss but were not substantive enough for cost effectiveness.

I have a number of comments on the guidance on ranibizumab.

Restriction to predominantly classic CNV only. Such a restriction is illogical for several reasons.

1. There is increasing evidence that the classification of CNV by proportion of classic does not have any biological significance. This classification was primarily derived to facilitate treatment by laser based therapies where it was important to delineate the margins of the CNV. Also the classification became entrenched into the literature following on from the PDT studies where subgroup analyses showed differences in outcomes by proportion of classic CNV. However NICE themselves accepted that the subgroup analyses in the PDT trials were unlikely to represent true findings and this has been borne out by subsequent trials (VIO study). The morphological grouping of lesions based on proportion of classic CNV did not have any effect on outcomes both with pegaptanib or ranibizumab indicating that lesion subtype is irrelevant with VEGF blockade. Thus it is illogical to restrict treatment to predominantly classic only.
2. The decision to limit treatment to eyes with predominantly classic CNV only is driven by the ICER calculations. As the control arm in MARINA and the PDT treatment arm of ANCHOR (the comparator arms) both suffered equivalent losses of vision it would appear that the Southampton assessment group have made assumptions in their modelling that detract from the effectiveness of ranibizumab in the treatment of eyes without predominantly classic CNV. I do not understand the logic of this approach.

Restriction to second eyes only. This is a cause of great concern for the following reasons

1. If treatment is denied to the first eye with a CNV (lets assume that it is predominantly classic as per current NICE guidance) and the second eye develops some other sight threatening disorder we will have lost the opportunity to treat.
2. If the second eye develops a CNV (40% of patients will have second eye involvement with wet AMD within 5 years) and if this is of the minimally classic or occult type (this is quite possible as there is only a small degree of symmetry between the eyes of a patient with respect to proportion of classic) again one will have lost the opportunity to treat.

Applicability to Northern Ireland

A rebuttal of NICE guidance is clearly needed. Scotland has approved the use of ranibizumab without restriction to type of CNV or whether the disease is bilateral.

- If treatment is to be denied to first eyes, it is important to point out to NICE that all second eyes should be treated regardless of CNV subtype.
- If treatment is to be restricted to predominantly classic only, then both first and second eyes should be allowed treatment.

Numbers in NI. We expect some 780 persons per annum to develop CNV in NI. Of these 70% will be second eyes (approximately a third of people who develop CNV in their first eye do not notice the onset of visual symptoms and present late thus minimising the benefit of any treatment). Based on the data collected over the last 3 years we expect to see between 120 and 140 patients with predominantly classic CNV per annum. Of these more than 2/3rds will have second eye involvement.