



Llywodraeth Cynulliad Cymru
Welsh Assembly Government

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Dear Chris

Pegaptanib (macugen) and ranibizumab (lucentis) for the treatment of wet age-related macular degeneration (AMD)

Thank you for giving the Welsh Assembly Government the opportunity to comment on NICE's Appraisal Consultation Document in connection with the above appraisal. We would like to make the following questions/points in response to the consultation.

We very much welcome the Appraisal Committee's decision to remove the recommendation relating to the treatment of wet AMD for the second eye only. We agree with the Committee's statement at paragraph 4.3.17 that if treatment was given to the second eye only, then this could result in a lost opportunity to preserve vision in the first-presenting eye, and that the second eye could be affected by an untreatable cause of visual loss or might not respond to anti-VEGs.

We are not convinced by the reasoning for basing costs upon delivery of treatment on the basis of 75% day case and 25% outpatient treatment modules (paragraph 4.3.1.6). The costs are based upon 24 injections of ranibizumab over two years and this might (as is acknowledged in the ACD) be an overestimate. Therefore, costs of ranibizumab 12 injections per year over two years = £18300 per patient, whereas 8 injections in year 1 and 6 in year two = £10700 per patient would appear to be more appropriate.

There appears to be some ambivalence and unsupported evidence as to what happens to the visual state and visual acuity if treatment is stopped after two years. We do not believe this necessitates any research commissioned in this area, and is more a case of collating the data. Further analysis would be required to address the comments made in paragraph 4.3.8 as to the numbers of patients who experience rapid deterioration in vision after cessation of treatment.

We agree with the proposed recommendations (paragraph 6.1), especially the need to consider the cost effectiveness of ranibizumab compared with bevacizumab (avastin). This again raises the issue of undertaking trials in this area to compare not just the cost effectiveness but also the outcomes in terms of visual gain in acuity and safety, including potential side effects.

Whilst the preliminary recommendations in paragraph 1.2 are noted, from the RCT results given in paragraph 4.3.3, it follows from the recommendation under 1.3 that further evaluation of the results of treatment with pegaptanib should be ongoing.

We note the Department of Health's concerns about the recommendation for the manufacturer to pay the cost after 14 injections, as they consider that this might increase the administrative burden on to the NHS. We would be interested to learn what safeguards are proposed with regard to continuing funding of treatment, beyond the 14 injections if considered to be clinically necessary, as this suggestion was made by the manufacturer.

We consider a review of guidance on the technology in December 2010 to be appropriate.

Yours sincerely

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