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9th January 2008

Mr Christopher Feinmann
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Dear Christopher,

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

Comments on the NICE 2nd Appraisal from The Royal College of Ophthalmologists

The Royal College of Ophthalmologists have carefully scrutinised the current ACD. We note that a number of the concerns that we expressed following the previous ACD have been addressed, and we welcome these changes.

In particular we are pleased that the Appraisal Committee recommends treatment with ranibizumab:

1. in all types of wet macular degeneration
2. where there is evidence of recent disease progression
3. in the absence of permanent structural damage to the fovea.
4. and where the lesion size is less than or equal to 12 disc areas.

However, we question the relevance of some of the other points made in the second ACD and we list these as follows:

1. The ACD states that the visual acuity cut off for treatment should be better than 6/60 (i.e.6/48 or better) in the eye to be treated. It is our view that this is unjustifiable, as the clinical trials which form the evidence base for Lucentis therapy used a visual acuity cut off of 6/96 or better. We wondered whether the proposed cut off was an error as there is a statement in section 4.3.23 of the ACD that "6/60 was an appropriate level for treatment". We would welcome clarification from the appraisal team that any eye with an acuity of 6/60 or better will be treatable.

2. The ACD also states that a visual acuity of 6/60 is the level where a person is considered legally blind. This is incorrect. The current UK legislation as it stands indicates that an acuity of 6/60 (Snellen) in the better seeing eye is the level at which a person is eligible for registration as partially sighted.

3. We would wish that pegaptanib should be recommended for those patients who are unable to tolerate ranibizumab, through allergy or adverse reaction, or where such treatment with ranibizumab is clinically problematic.

4. We would welcome a statement that treatment with anti-VEGFs including ranibizumab should be limited to units with expertise in the field of treatment and assessment of AMD and have access to the necessary technology – fluorescein angiography and optical coherence tomography.

5. It is hoped that there will be robust on going audit to allow collection of adverse events data. The Royal College of Ophthalmologists recommends on going robust data collection for surveillance of both outcomes and adverse events. The College wishes to be the host organisation of such data collection and management if adequate funding is provided by the Department of Health or other outside source.

6. As some patients may require more treatment than others, and it may be difficult to monitor treatment frequencies for each individual patient, average treatments in particular periods may be easier to determine. This may be helpful if pharmaceutical companies are to pick up costs of 'excess' treatment. A life time cap of 14 treatments with ranibizumab is impractical.

7. Any scheme should be based on the average number of treatments administered to a cohort of patients (e.g. across a PCT) rather than on an individual patient basis. All of the health economic analysis is based on such a population approach; hence it does not make sense to switch to a patient level approach for the scheme. Furthermore, to operate an individual patient based reimbursement scheme would be logistically complex and almost unworkable given the numbers of patients involved.

In order to avoid embarrassment in might be prudent for the consultees to be shown the FAD prior to final publication.

In addition we would hope that the FAD can be implemented without delay.