HEALTH TECHNOLOGY APPRAISAL: NICE Health Technology Appraisal - 2nd Appraisal Consultation Document (ACD) On Ranibizumab and pegaptinib for age related macular degeneration	
TO: NICE	**FROM: NHS Quality Improvement Scotland**

i) Whether you consider that all the relevant evidence has been taken into account.
Yes this appears to be complete

ii) Whether you consider that the summaries of clinical and cost effectiveness are
reasonable interpretations of the evidence.
This is an improvement over the initial NICE doc.
and recognises the need to treat 1st and 2nd eyes and now is more in line with SMC advice.

[redacted]
14.01.08

I welcome the recommendations issued in December 2007.

The Committee has thoroughly considered the clinical effectiveness and made the most reasonable and sensible conclusions for which I congratulate them. Many of the concerns of the previous consultation have been addressed, particularly that it is recommended for first eyes with wet AMD.
The effectiveness of Ranibizumab is undisputed and the agreement that the manufacturer will meet the cost of treatments beyond 14 injections is welcome.

I have only relatively minor concerns and list them below.

1. There is a need to limit treatment to those who will benefit most. I am concerned that treatment will be limited to patients with a best corrected visual acuity better than 6/60 and that there is no level of defined visual loss before commencement of treatment. The trials included best-corrected visual acuity between 6/12 and 6/96 and it would be reasonable to follow this criterion. Many patients with a visual acuity of 6/60 would benefit, and many with occult CNV with good acuities remain stable for long periods and some resolve spontaneously. It is rare for subfoveal CNV to have good vision and I would therefore advise treatment being limited to patients with a degree of defined visual loss e.g. visual loss of between 6/12 and 6/90.

2. The criterion of 'no permanent structural damage' needs to be clearly defined. It is almost impossible not to have some degree of structural damage in AMD. I think what is essentially meant by this criterion is that patients with significant subretinal fibrosis (implying CNV which has progressed to fibrosis and which is therefore fairly long standing) should not be treated. This should be clearly stated.
3. In considering clinical effectiveness Ranibizumab is clearly the drug of choice and is the preferred agent in comparison with pegaptanib. I agree that Pegaptanib should not be recommended.
4. 1.3 deals with patients currently receiving pegaptanib. Such patients should have the opportunity to convert to ranibizumab particularly for 2nd eye involvement.
5. The cost analysis based on 14 injections over 2 years is reasonable. This will provide treatment for at least 2 years. The manufacturer's offer to pay for injections beyond 14 treatments may prove difficult to administer and requires further clarity. The comments regarding additional costs (para 4.3.21) for such additional treatments are appropriate
6. The non drug costs (i.e. the costs of administration and monitoring) are still overestimated in my opinion. There should encouragement to establish the procedure as an Outpatient procedure (75% day case is far too high)
7. Proposed recommendations for Research – assessment of the cost effectiveness of ranibizumab compared to bevacizumab and the long term effects of anti-VEGF therapy are the most pressing research needs. There is also a need to identify which subtypes of occult respond best. We recognise different types of occult CNV e.g. retinal angiomatous proliferation (RAP) lesions which account for about 30% of occult lesions, serous PEDs, etc, and this should be indicated in the recommendations. I expect different forms of occult respond better than others.

[redacted]
14.01.08

Nil response from [redacted] as he is on annual leave.

Basically all the pertinent points I feel worthy of mention are included in the response of the RCOphth. There is only one other very important point relevant to Scotland which is, our course, that the SMC **have** approved Macugen and so clinicians in Scotland do retain some autonomy regarding the selection of what they feel is the best drug to use for any individual patients. When NICE issued their FAD, it will be interesting to see if they do eventually approve Macugen use in principle as well as Lucentis after considering all the responses from the consultees.

[redacted]

Reviewer 1.

iii) Whether you consider that all the relevant evidence has been taken into account.

The summaries relate to the evidence provided

iv) Whether you consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence..

I consider that the summaries interpret the evidence provided succinctly

iii) Whether 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 recommendations on use or not use are sound based on the evidence – however the recommendation regarding the dose-capping scheme will require further discussion between SGHD and NHS QIS.

iv) Whether you consider that there are any potential policy implications for SGHD?

Yes – the dose capping scheme will need to be considered in the context of the policy on alternative pricing schemes which is being developed.

14/01/08