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Appraisal of ranibizumab and pegaptanib for the treatment of age-related macular degeneration

Dear Mr Feinmann,

Thank you for giving me the opportunity to comment on the additional analysis commissioned by NICE. As I understand the committee is proposing moving to a final decision without any further consultation I would first like to reemphasise the following main points regarding these treatments which are:

1) They are the only clinically effective treatment for all forms of wet age related macular degeneration (AMD). If treatment is restricted to "predominantly classic " wet AMD the majority of patients with wet AMD will be denied access to the only clinically effective treatment available. This will have a massive impact on these patients' quality of life and I strongly believe therefore all forms of wet AMD should be treated with anti-vegf drugs. As randomised clinical trial data demonstrates that ranibizumab is currently the most effective drug I would strongly recommend it being approved. However there may be clinical situations where pegaptanib may also be useful particularly as new clinical data emerges. For example, ongoing studies are evaluating whether a combination of initial treatment with ranibizumab and subsequent treatment with pegaptanib would be safer and as effective as using ranibizumab as a single agent. I therefore would also support approval for pegaptanib while accepting that in most current situations ranibizumab will be the chosen drug.

2) At the first appraisal meeting a second eye treatment policy was suggested and this was recommended because of comparsions with only treating second eyes which had bilateral cataract. I want to emphasise that the situation for only treating second eyes of patients with wet AMD is very different from cataract patients. If a

second eye wet AMD patient has a poor response to treatment then you cannot go back and revive the first eye. This is very different from cataract surgery where the non-treated eye is healthy and so if there is a complication with the second eye, the first untreated eye can be revived with surgery. A second eye treatment policy for wet AMD does not have this luxury. If the second eye does not respond to treatment (as some will not) the first eye will already have been irrevocably damaged. Thus a second eye policy will definitely condemn many AMD patients to blindness in both eyes.

Perhaps the main criticism regarding this new data is that that there is no summary or interpretation of the numerous tables. As clinical experts and other patient representatives are being denied access to the next NICE meeting the impression is being created that the review process is not transparent. How can I really comment on this additional data when I do not know how the committee will interpret this non-summarised data? The reliance on complicated health economic modelling with multiple assumptions denies non-professional health economists from fully engaging in this review process. I like other commentators therefore recommend that a second ACD be held where clinical commentators and patient representatives can be present. However my specific comments are:

Regarding the SHTAC report:

a) Re one or both eyes - it is confined to estimating the cost of treating two rather than one - and shows that the cost rises sharply over the first few years and declines thereafter. The analysis has not proceeded to estimate the outcomes, QALYs or ICERs to do with treating both eyes - which was requested but not provided .
b) changing the other assumptions makes relatively little difference to the ICER

Regarding the Decision Support Unit report:

a) Use of the Pfizer model but with the costs used in the other models showed that the latter costs raised the ICER sharply indicating that the Pfizer model costings are suspect
b) the ICER was moderately sensitive to the utility values and the costs of blindness.
c) that starting visual acuity was important in establishing the cost effectiveness of pegaptanib, giving a subgroup with a relatively acceptable ICER.
d) that a review of the utility literature indicated no links between depression and AMD.
The papers say nothing about the risks of limiting treatment to the second eye - even though SHTAC was asked to consider the cost effectiveness of this it has not done so - yet.

I hope this information is helpful to the committee and again I must emphasise that anti-vegf drugs represent the first clinically effective treatment for wet AMD. I hope NICE can support their introduction into the NHS in England and thus also remove the inequality in provision which currently exists between England and Scotland for this devastating disease.

Yours sincerely,

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