National Institute for Health and Clinical Excellence

Ranibizumab for the treatment of macular oedema caused by retinal vein occlusion (RVO)

Royal College of Nursing

Introduction

The Royal College of Nursing (RCN) was invited to review the Appraisal Consultation Document (ACD) of Ranibizumab for the treatment of macular oedema caused by retinal vein occlusion (RVO).

Nurses caring for people with macular oedema reviewed the documents on behalf of the RCN.

Appraisal Consultation Document – RCN Response

The Royal College of Nursing welcomes the opportunity to review this document. The RCN's response to the key questions on which comments were requested is set out below:

i) **Has the relevant evidence been taken into account?**

The Committee concluded that ranibizumab is an effective treatment for non-ischaemic macular oedema secondary to BRVO and CRVO**.** They state that ranibizumab was associated with statistically significant mean gains in BCVA in the treated eye (for non-ischaemic patients) compared with sham injection for the 6-month treatment phase but we note that

they have excluded ischaemic CRVO. The Committee states that patients with RAPD were excluded from the BRAVO and CRUISE studies but such patients are the extreme end of ischaemia. It is known that some non-ischaemic cases may progress to the ischaemic type but are not ischaemic enough to have a RAPD. Thus, all ischaemic patients should not be excluded only those with positive RAPD.

ii) **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?**

In the cost model, the direct comparison of ranibizumab and dexamethasone implant do not take into full account the known side effects of steroids or the unknown re-treatment frequency of dexamethasone implant. It is well documented that the long-term side effects include cataract and glaucoma, so with increased use of steroids there will be an increased financial burden on the NHS in managing these adverse events. This cost, therefore, should be included in the model.

Also there are some issues around the lack of discussion related to the independent use of photocoagulation as this is identified as having no cost point (see 3.14). There must be a cost associated to this as healthcare professionals have to undertake the treatment and the machine needs maintenance. We would also like to know how the patient's vision is maintained with just laser as opposed to treatment with both.

Further, the information related to the quality of life index does not seem to have been well evaluated. The report indicates that these patients are often younger, so this element is really important as if these individuals cannot work or need care and benefit support for longer, then this is not cost effective (reference to point 3.11 at the end of the page also 3.6).

iii) **Are the provisional recommendations sound and a suitable basis for guidance to the NHS?**

We would question the comparison studies used for bevacizumab versus ranibizumab especially Russo (2009). It was a very small, unmasked study so one cannot say that it was unbiased or evidence based.

iv) **Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of gender, race, disability, age, sexual orientation, religion or belief?**

None that we are aware of.

v) **Are there any equality-related issues that need special consideration that are not covered in the appraisal consultation document?**

We are not aware of any specific issue at this stage. We would also ask that any guidance issued should show that an analysis of equality impact has been considered and that the guidance demonstrates an understanding of issues relating to all the protected characteristics where appropriate.

Conclusion

We would conclude by saying that the current evidence shows that treatment of BRVO and CVRO with ranibizumab offers the greatest promise for patients with a view to improving the management of the condition and vision outcomes. The associated cost of not using this technology should be factored in. In our view, this health technology should be considered for use in the NHS.