



National Institute for Health and Clinical Excellence

Pegaptanib and ranibizumab for the treatment of age-related macular degeneration

Royal College of Nursing

Introduction

With a membership of over 400,000 registered nurses, midwives, health visitors, nursing students, health care assistants and nurse cadets, the Royal College of Nursing (RCN) is the voice of nursing across the UK and the largest professional union of nursing staff in the world. The RCN promotes patient and nursing interests on a wide range of issues by working closely with Government, the UK parliaments and other national and European political institutions, trade unions, professional bodies and voluntary organisations.

The RCN welcomes the opportunity to review and comment on the report of the additional analyses and Decision Support Unit for the technology appraisal of Pegaptanib and Ranibizumab for the treatment of age-related macular degeneration.

RCN Response

Having read the appraisal documents we note how comprehensive and vast the information presented to us is and commend NICE for their efforts. Despite this we still feel disillusioned, frustrated and weary with this lengthy protracted process.

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We are aware that we have to work with often limited resources and that as NHS clinicians we must be accountable for the best use of finances for the greater good. But as nurses faced daily with desperate patients, trying to remain independent as their vision is failing; it is frustrating that we are yet again faced with pages and pages of models of cost effectiveness model based on yet more assumptions. None of us will ever know the true long term cost to the NHS until we implement and monitor these new treatments.

We know from clinical trials that ranibizumab, the intravitreal treatment which targets all isotypes of vascular endothelial growth factor (VEGF), for the first time in the history of AMD treatments, results in a significant increase in visual acuity in patients with neovascular AMD. Overall, antiangiogenic approaches provide vision maintenance in over 90% and substantial improvement in 25–40% of patients.

The revised costings around ranibizumab are much more realistic for both the first and second year and take into account the visits that include assessment only costs rather than treatment only for a full year period.

In terms of patient experience: AMD is a very distressing and debilitating eye condition and from clinical experience there is a vast difference between what is deemed clinically significant to health care professionals and also in terms of vision outcomes to what is often very different to the patient experience. Meeting other patients with this condition and time spent in explanation is found to be extremely valuable to the patients and their families. This unfortunately is very difficult to measure and quantify.

The primary purpose of disease management in AMD is to minimize visual loss and related physical and emotional impairment and to optimize vision related quality of life. The time has come to allow experienced retinal specialists, who during the past decade through monitoring and treating patients with AMD, have developed an in-depth understanding of what is best for individual patients and CNV lesion subtypes.

We note from the report that re-modeling took into account the fact that patients do not require a full assessment and treatment at every monthly visit but will require some form of monitoring visit. We agree that this is a sensible approach but would be cautious in

assuming that this reduced frequency regime based on the PRONTO study is representative of the wider population as there were only 37 patients in the study and from one centre.

Despite this word of caution, it is believed by many clinicians who have a vast amount of experience in this field, that combination of antiVEGF with occlusive therapies like photodynamic therapy (PDT) potentially offers a reduction of re-treatment frequency and long-term maintenance of the treatment benefit which is what we all wish for.

We are confident that leaving the decision with the retinal specialist will result in the most cost effective use of NHS money. They will choose the most effective treatment plan based on an individual patient by patient basis as is everyday common practice.

This individualized planning, together with monitoring visits allowing treatment as required when leakage activity and or lesion growth recurs, offers maximal systemic and ocular safety and the most practical management of patient numbers in the NHS.

Pegaptanib sodium stabilizes vision in some groups of patients and has been observed to have shown improvement in a small number of patients.

We also note that despite pegaptanib treated patients showing a treatment benefit after 2yrs over patients receiving only 1 year of pegaptanib treatment; a mean of 16 out of 17 possible injections were administered to patients over 24 months. The therapeutic benefit has been demonstrated comparable to the one obtained with PDT monotherapy, with a lower number of treatments needed with PDT. Therefore, reluctantly we accept the findings that this may not be a cost effective option for the NHS.

However, all the cost effective analysis in the report was based on predominately classic CNV subtypes whereas both pegaptanib and ranibizumab are suitable for a wider spectrum of lesions and the prognosis appears to be independent of lesion size and composition.

The current unmet need of patients suffering from occult CNV must be addressed and we yet again urge NICE to consider this group by allowing all CNV lesion types to benefit from NHS treatment.

To exclude this group would be devastating both for patients and for clinicians. We will still have the unenviable distressing job of informing our patients of their inevitable poor prognosis, sight loss and thus their independence!