RANIBIZUMAB AND PEGAPTENIB FOR THE TREATMENT OF AGE-RELATED MACULAR DEGENERATION (TA 155): IMPACT OF PROPOSED REVISIONS TO THE PATIENTS ACCESS SCHEME

REPORT BY THE DECISION SUPPORT UNIT

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ABOUT THE DECISION SUPPORT UNIT

The Decision Support Unit (DSU) is a collaboration between the Universities of Sheffield, York and Leicester. We also have members at the University of Bristol, London School of Hygiene and Tropical Medicine and Brunel University.

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EXECUTIVE SUMMARY

The DSU has been asked to establish whether the proposed revision to the patient access scheme for ranibizumab in the treatment of age-related macular degeneration, has an adverse impact on the cost-effectiveness estimates used in the development of Technology Appraisal 155. Whilst, there was uncertainty at the time of the appraisal regarding the number of injections required to maintain clinical benefit, the committee considered it likely that ranibizumab would be cost-effective provided that the drug acquisition costs borne by the NHS were limited to the first 14 injections. [redacted] It is therefore unlikely that the revised PAS scheme will have an adverse impact on the expected cost-effectiveness of ranibizumab.

1. INTRODUCTION

In August 2008, NICE issued guidance (TA155) on the use of ranibizumab and pegaptanib for the treatment of age-related macular degeneration[1]. Ranibizumab was recommended under the proviso that the cost of ranibizumab beyond 14 injections was met by the manufacturer. The manufacturer has submitted a proposal to the Department of Health for a revised patient access scheme (PAS) in which the current arrangements are replaced by a simple discount on the price of ranibizumab. The manufacturer has submitted a brief report to NICE in which they claim that the revised PAS has a negligible impact on the cost-effectiveness estimates for ranibizumab[2]. The DSU has been asked to review this claim in the context of the guidance document and economic model issued to support TA155.

2. RELEVANT FACTORS CONSIDERED IN TA155

At the time of the appraisal, there was uncertainty regarding the number of injections required to achieve the clinical efficacy estimates observed in the key trials. The individualised dosing regimen specified in the marketing authorisation was lower than that used in the clinical trials and was expected to result in an average of 8 doses in the first year and 6 doses in the second year. ICERs based on this dosing frequency are reported in section 4.2.4.7 of the FAD[1] and are summarised in Table 1 below. These ICERs also incorporate other changes to the basecase which reflect the committee's preferred scenario for economic modelling including; alternative utility values (Brazier study), splitting the cost of administering the injection between day-case (75%) and outpatient (25%) costs and higher uptake of community care services (from 6% to 17% or 25%). They also assume that only the better-seeing eye is treated, with the ICERs expected to be 50% higher when including treatment of the first eye. The Committee's considerations regarding the number of injections for ranibizumab are described in section 4.3.22 of the FAD[1]. The committee considered that many patients may require more than 14 doses to maintain the benefits of treatment. However, the committee considered it likely that ranibizumab would be cost-effective provided that the drug acquisition costs borne by the NHS were limited to the first 14 injections.

Table 1: Table 1 Cost-effectiveness estimates based on the assessment group model assuming 14 doses of ranibizumab with monthly monitoring [adapted from additional scenario analysis undertaken by the Assessment Group[3]]

Scenario	Incremental cost (£)	Incremental QALY	ICER (£/ QALY)
Predominantly classic lesions treated with ranibizumab, compared with PDT	5,836	0.43	13,671
Predominantly classic lesions treated with ranibizumab, compared with best supportive care	7,196	0.73	9,900
Minimally classic and occult no classic lesions treated with ranibizumab	10,777	0.54	19,904
Notes: Analysis incorporates "Brazier" utilities, Novartis injection cost, uptake of community care at 25% and two years of treatment (14 injections, with monthly monitoring)			

3. THE CURRENT RANIBIZUMAB REIMBURSEMENT SCHEME

Information regarding the current ranibizumab reimbursement scheme has been provided to the Patient Access Scheme Liaison Unit at NICE[4]. [redacted]

4. IMPACT OF REVISED PAS ON THE COST-EFFECTIVENESS ESTIMATES FROM TA155

Cost-effectiveness estimates are based on the expected cost across the whole cohort of patients eligible to receive treatment and therefore the expected costs should be based on the mean number of doses.

[redacted]. The original PAS effectively capped the drug costs at £10,657 per patient (based on 14 doses at the list price of £761.20[1]). [redacted] Monitoring and

administration costs are not affected by the change in the PAS scheme. It is unlikely that the revised PAS scheme will have an adverse impact on the expected cost-effectiveness of ranibizumab. The DSU therefore considers it unlikely that the revised PAS scheme will have an adverse impact on the expected cost-effectiveness of ranibizumab.

5. REFERENCES

1. National Institute for Health and Clinical Excellence. Ranibizumab and pegaptanib for the treatment of age-related macular degeneration. National Institute for Health and Clinical Excellence, London. August 2008.
   Available from http://guidance.nice.org.uk/TA155/Guidance/pdf/English
2. Novartis Pharmaceuticals UK Ltd. Response to NICE Clarification on Update of TA155. Novartis Pharmaceuticals UK Ltd, Surrey. December 2011
3. Southampton Health Technology Assessment Centre. Macular degeneration (age-related) - pegaptanib and ranibizumab: Additional scenario analysis undertaken by the Assessment Group, Southampton Health Technology Assessment Centre (SHTAC) related to consultation on first ACD. The University of Southampton, Southampton. March 2008.
   Available from http://www.nice.org.uk/nicemedia/live/11700/40277/40277.pdf
4. National Institute for Health and Clinical Excellence, Patient access liaison unit. Advice to the Department of Health on a proposed change to a Patient Access Scheme: ranibizumab. National Institute for Health and Clinical Excellence, London. December 2011.