Cost-effectiveness of Ozurdex® in the treatment of macular oedema following Retinal Vein Occlusion.

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Summary

1. Ozurdex® (dexamethasone 700 μg intravitreal implant in applicator) is indicated for the treatment of macular oedema (ME) following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO). It is administered in the hospital setting only. Allergan submitted a dossier for its evaluation for reimbursement to the NCPE in November 2011.

2. The submission basecase compares Ozurdex® to observation (no treatment) in RVO overall and in three subgroups; patients with CRVO; BRVO with macular haemorrhage; and BRVO with previous laser. A cost utility analysis was submitted based on data from the GENEVA study. This was done from the perspective of the payer and using a life time horizon.

3. Data from the large GENEVA study (n=1267) (comprised of identical studies (008 and 009) in (a) CRVO and (b) BRVO) is presented which compares Ozurdex® to sham (placebo). Ten per cent of patients overall received laser treatment (of which 90% were BRVO and were 10% of CRVO). The primary outcomes differ in the studies due to guidance given by regulatory authorities. The European Medicines Agency (EMA) used the proportion of patients with a Best Corrected Visual Acuity (BCVA) improvement of 15 or more letters from baseline at Day 180 (Study 009) and Day 90 (Study 008). For study 008 (n=599) a significant result was achieved at day 90; 22.4% of the Ozurdex® group and 12.4% of the sham group achieved a 15-letter change from baseline (p=0.008). For study 009 (n=668) a statistically significant difference was not observed at day 180 between the Ozurdex® group and the sham group; 23.5% vs. 17% respectively. Cumulative response curves indicate that the dexamethasone 700mcg and 350mcg groups reached a 15 letter improvement significantly faster than those receiving sham treatments.

4. ICERs were presented for RVO, BRVO with macular haemorrhage, BRVO with previous laser treatment and CRVO vs. observation. The ICERs were: RVO €23,332/QALY; BRVO with macular haemorrhage €23,541/QALY; BRVO with previous laser € 9,110/QALY; and CRVO €22,028/QALY.

5. Probabilistic analysis indicates that at a willingness to pay of €20,000/QALY, Ozurdex® has a probability of cost-effectiveness of 34.6% and at a willingness to pay of €45,000 has a probability of cost-effectiveness of 91.9%.

6. The scenario analysis indicates that assuming a visual decline of 1.5% per 6 months in place of stabilisation increases the ICER for all RVO to €24,208/QALY, for CRVO €22,926/QALY, for BRVO with macular haemorrhage €24,321/QALY and for BRVO with previous laser treatment €9,201/QALY. Assumptions in relation to transition probabilities increases the ICER to €45,727/QALY and assuming that 79% of patients with BRVO receive five injections and 86% of patients with CRVO receive six injections increases the ICER to €38,973/QALY.

7. The budget impact for RVO estimates a cost of €429,157 in year 1 which increases to an annual budget impact at year 5 of €3,356,564. The cumulative budget impact is €9,219,005 by year 5. This is based on a market share for Ozurdex® of 10% in year 1 increasing to 50% by year 5.

8. At a threshold of €20,000 per QALY, the 10 year Population EVPI (PEVPI) was €1.74 million. The impact of changing the threshold is considerable; the PEVPI ranges from €14.9 million (at €0 per QALY) to €0.005 million (at €100,000 per QALY).

9. We believe that at the submitted price, Ozurdex® cannot be considered cost-effective therapy for the treatment of macular oedema following retinal vein occlusion.