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28th February



National Institute for Health and Clinical Excellence

Dear Ms Farrar

RE: Dexamethasone intravitreal implant for the treatment of macular oedema secondary to retinal vein occlusion

On behalf of the NHS Waltham Forest, I would like to submit our comments on the interim appraisal consultation document for Dexamethasone intravitreal implant for the treatment of macular oedema secondary to retinal vein occlusion in the NHS. Based on the evidence considered, NHS Waltham Forest, is in agreement with the appraisal committee's decision and that this technology does represent a cost effective use of scarce NHS resources at present.

- Dexamethasone has been compared against sham treatment in two phase III studies and demonstrated modest benefits in rate of improvement in visual acuity (15 or more letter improvement in best-corrected visual acuity (BCVA)). It is not clear whether there is a benefit compared to current treatment with intravitreal bevacizumab.
- There were no between group differences in the proportion achieving response at 180 days although more improved with dexamethasone between days 30 to 90.
- **Dexamethasone increased adverse events.** The Committee concluded that there were some concerns about the safety profile of dexamethasone treatment (given that the marketing authorisation is based on two re-treatments but the manufacturer assumed that up to six treatments would be given). The number of re-treatments required in practice remains unknown. During the trials, patients received only two injections of dexamethasone and in the cost-effectiveness models. Re-treatment was assumed to occur at 6-monthly intervals with a maximum of five injections for BRVO and six injections for CRVO. The impact of more than two injections on adverse events is unclear; dexamethasone is delivered with a larger implantation needle than needed for other treatments.
- **Unit costs:** The ERG suggested that administration of dexamethasone could be done on an outpatient basis (£150 per administration) and the unit cost of the implant is £870, a total of £1020.

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- **Demand for treatment:** The manufacturer estimates that approximately 23,000 new patients each year will be eligible for treatment in England and Wales. This estimate accounts for the proportion of people with RVO who would go on to develop macular oedema and then the proportion who would be eligible for dexamethasone treatment. This is approximately 126 new patients per 300,000 population per year. Based on this figure, total annual acquisition and implant costs for an average PCT (not including costs of adverse events) would be £128,520 (126 x £1050).
- **Comparator:** The manufacturer restricted the comparator to observation, arguing that there are no other licensed comparators for this condition and that laser treatment was not appropriate for the subgroups under consideration in their decision problem. The ERG concluded that while it is true that there are no other licensed treatments, the use of bevacizumab is common under the 'specials' regime and there is evidence from case series of bevacizumab for this indication that could have informed the question through an indirect comparison.

Yours sincerely

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