Pharmacotherapeutic report on ranibizumab (Lucentis®) for the treatment of visual impairment due to diabetic macular oedema (DME)

Medicine. Ranibizumab 10 mg/ml solution for intravitreal injection. Each vial contains 2.3 mg of ranibizumab in 0.23 ml solution.

Summary of the therapeutic value

Intended effects. Data from short-term head-to-head trials have shown that patients with visual impairment due to DME who were treated with ranibizumab achieved a greater mean average gain in best-corrected visual acuity (BCVA; 6 ETDRS letters) in comparison with patients treated with laser photocoagulation. In addition, the percentage of patients who gained ≥10 letters and the percentage of patients who gained ≥15 letters was greater during treatment with ranibizumab in comparison with laser. Furthermore, combination therapy of ranibizumab and laser was more effective than laser as monotherapy. The effect of combination therapy with ranibizumab and laser was comparable with ranibizumab. An indirect comparison between ranibizumab and bevacizumab suggest that the intended effects of these agents are comparable.

Unintended effects. The risk of side effects is greater during the initial treatment period with intravitreal injections of ranibizumab and intravitreal injections of bevacizumab in comparison with laser during the same period. However, repeated laser treatment can damage large areas of the retina. There are no data available on side effects during long-term (>1 year) treatment with ranibizumab or bevacizumab. Data from RCTs seem to indicate that the side effects of intravitreal use of ranibizumab are comparable with those during intravitreal use of bevacizumab.

Experience. Sufficient experience has been gained with ranibizumab and bevacizumab and considerable experience with laser.

Applicability. There are no major differences in applicability between ranibizumab, bevacizumab and laser.

Ease of use. There do not seem to be any major differences between intravitreal injection of ranibizumab and (off-label) intravitreal injection of bevacizumab. The method and frequency of laser administration is different.

Final conclusion. Head-to-head trials have shown that, with respect to the intended and unintended effects, ranibizumab is superior to laser for the treatment of patients with visual impairment due to DME.

An indirect comparison between ranibizumab and bevacizumab showed that the intended and unintended effects were comparable between ranibizumab and bevacizumab. Furthermore, there are no major differences in experience, applicability and ease of use.

With regard to treatment of visual impairment due to DME, ranibizumab has an added therapeutic value in comparison with laser photocoagulation.

With regard to treatment of visual impairment due to DME, the therapeutic value of ranibizumab is comparable with that of bevacizumab.

*The original text of the summary of this **CFH-report** was in Dutch. Although great care was taken in translating the text from Dutch to English, the translation may nevertheless have resulted in discrepancies. Rights may only be derived on the basis of the Dutch version of the summary of the CFH-report.*
Furthermore, CVZ points out that only the summary of this report was translated. A proper understanding of all relevant considerations and facts would require familiarity with the Dutch version of this report, including all appendices.