

## Pharmacotherapeutic report (t=4) on ranibizumab (Lucentis®) for the treatment of neovascular (wet) age-related macular degeneration (AMD)

**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.** Treatment with ranibizumab is more effective than treatment with photodynamic therapy with (light-activated) verteporfin or treatment with pegaptanib. Data from a head-to-head clinical trial has shown that the improvement in visual acuity did not differ statistically between ranibizumab and bevacizumab.

**Unintended effects.** The most common reported side effect of ranibizumab, pegaptanib and bevacizumab are ocular adverse reactions. An indirect comparison between ranibizumab and verteporfin did not show clinically relevant differences. Data from clinical studies and observational studies did not prove that the unintended effects of intravitreal bevacizumab are different from intravitreal ranibizumab.

**Experience.** Sufficient experience has been gained with ranibizumab and bevacizumab. Photodynamic therapy with (light-activated) verteporfin and intravitreal pegaptanib are rarely used in current clinical practise.

**Applicability.** There are no major differences in applicability between ranibizumab, pegaptanib and bevacizumab. The applicability of verteporfin is more limited.

**Ease of use.** There are differences between the use of intravitreal injection of ranibizumab (treatment is resumed when monitoring indicates loss of visual acuity due to AMD; max. 12 injections per year) and verteporfin (treatment is resumed in the event of recurrent CNV leakage; max. 4 treatments per year) and pegaptanib (fixed dosing schedule; nine treatments per year). There is no EMA approved dosing scheduled for intravitreal injections of bevacizumab.

**Final conclusion.** The conclusion on t=0 was that ranibizumab could be used for the treatment of minimally classic, predominantly classic and occult subfoveal neovascular AMD. Due to its greater efficacy and the improved quality-of-life, ranibizumab has an added therapeutic value compared to photodynamic therapy with verteporfin and treatment with pegaptanib. An indirect comparison has shown that the effects of ranibizumab and bevacizumab are comparable. Data from clinical trials and observational studies which were published between t=0 and t=4 agree with the conclusion drawn at t=0. In addition, a head-to-head clinical trial has shown that the intended and unintended effects of ranibizumab are comparable with those of bevacizumab. With regard to the treatment of visual impairment due to AMD, ranibizumab has an added therapeutic value in comparison with photodynamic therapy with verteporfin and in comparison with pegaptanib.

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