Diabetes UK's comments on the Appraisal consultation document: Ranibizumab for treating diabetic macular oedema (rapid review of technology appraisal guidance 237)

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical and cost-effectiveness reasonable interpretations of the evidence?
- Are the provisional recommendations sound and a suitable basis for guidance to the NHS?
- Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, gender, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?

Diabetes UK agrees that the relevant evidence has been taken into account and therefore also with the preliminary recommendation of the rapid review (paragraphs 1.1 and 1.2); that ranibizumab will be available as a treatment option for visual impairment due to diabetic macular oedema (DMO) if the person has a central retinal thickness of 400 micrometers or more and the manufacturer provides ranibizumab at a discounted price as part of the Patient Access Scheme.

The relevant evidence in terms of the importance of vision to people with DMO is partially acknowledged in paragraph 4.2; that visual impairment has a substantial negative impact on quality of life, the ability of the person to manage their own condition and on their emotional wellbeing. Further to this, the likely effect of the negative impact on patients' ability to self-manage their condition and the worsening of diabetic complications is described by Williams *et al*:

"Visual impairment as a result of diabetic retinopathy has a significant impact on patients' quality of life, and can compromise their ability to manage successfully their disease, which in turn can have a negative impact on the incidence of other diabetic complications and overall life expectancy."[1]

We note in paragraph 4.11 the Committee's acknowledgment that the manufacturer's revised subgroup analysis of central retinal thickness is based on a post-hoc analysis of the RESTORE trial but also that this analysis was provided in response to comments from clinical experts that laser photocoagulation may be less effective in thicker, more oedematous retinas. The Committee's acknowledgement in paragraph 4.22 of the clinical plausibility of 'a greater relative efficacy of ranibizumab in such people [CRT > 400µm], because it understood that laser photocoagulation may be less effective when used on a thicker retina' and the conclusion that it has received robust evidence demonstrating a subgroup effect in favour of people with thicker retinas are to be welcomed for people with DMO who are less likely to respond to laser photocoagulation.

The provisional recommendations are therefore sound and a suitable basis for guidance to the NHS. As the Committee could not consider a comparison with bevacizumab (paragraph 4.24) the guidance offers consistent access to a subgroup of patients across England and Wales to an anti-vascular endothelial growth factor A drug. This is because, and as stated in paragraph 4.24, bevacizumab is not in routine use throughout the NHS.

No issues of unlawful discrimination were recognised.

[1] Williams *et al* (2004) Epidemiology of diabetic retinopathy and macular oedema: a systematic review. *Eye*, 18, 963-983.