Single technology appraisal (STA)

Fingolimod for the treatment of relapsing-remitting multiple sclerosis

Appraisal consultation document

Comments from Prof Carolyn Young

1) Use of only Avonex (a form of beta interferon) as comparator treatment

We agree with the concerns of the Committee that this was not the best comparator, given that the subgroup had been defined by inadequate treatment response on beta interferon.

However, we disagree that "best supportive care" should be the choice of comparator as patients with inadequate response to beta interferon may be switched to another disease modifying treatment *in addition* to best supportive care.

2) Duration of the model for a maximum of 50 years

We do not think there is sufficient evidence that the effects of Fingolimod or avonex can be modelled over 50 years, using the shorter term trial data.

We disagree with the assumption that "The relative risks associated with disease progression and relapse are constant over the entire time horizon." [3.11] as the natural history studies do not support the assertion that risk of relapse or disease progression are constant over many decades.

3) Treatment withdrawal with increasing EDSS score

We feel that a sentence from section 4.3 should be shortened as it does not fully reflect typical practice, and we provide the original sentence with the suggested deletion shown in strikeout: "The Committee understood that clinicians are unlikely to prescribe a different beta interferon after a suboptimal response to the first beta interferon used, and that they are likely to stop treatment for people whose disease progresses above an EDSS score of 6." While we accept that the evidence base for continuing disease modifying treatments at higher EDSS scores is limited and the trials recruited people who were EDSS<6, clinicians consider treatment withdrawal on a case by case basis and may continue for people with EDSS above 6.