

Royal College of Physicians 11 St Andrews Place Regent's Park London NW1 4LE

Tel: +44 (0)20 3075 1560

www.rcplondon.ac.uk

Professor Carole Longson
Director, Centre for Health Technology Evaluation
By email



25 August 2011

Dear Professor Longson

Re: NICE STA: Multiple sclerosis (relapsing-remitting) - fingolimod - ACD

The Royal College of Physicians (RCP) plays a leading role in the delivery of high quality patient care by setting standards of medical practice and promoting clinical excellence. We provide physicians in the United Kingdom and overseas with education, training and support throughout their careers. As an independent body representing over 25,000 Fellows and Members worldwide, we advise and work with government, the public, patients and other professions to improve health and healthcare.

The RCP is grateful for the opportunity to respond to the above ACD consultation. We would like to make the following comments.

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

Our experts 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 believe that 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.

Yours sincerely