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National Institute for Health and Clinical Excellence

## **Fingolimod for the treatment of relapsing-remitting multiple sclerosis**

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Royal College of Nursing

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### **Introduction**

The Royal College of Nursing (RCN) was invited to review the second Appraisal Consultation Document (ACD) for Fingolimod for the treatment of relapsing-remitting multiple sclerosis

Nurses caring for people with multiple sclerosis reviewed the documents on behalf of the RCN.

### **Appraisal Consultation Document – RCN Response**

The Royal College of Nursing welcomes the opportunity to review this document. The RCN's response to the four questions on which comments were requested is set out below:

i) **Has the relevant evidence has been taken into account?**

Although the evidence considered seems reasonably comprehensive it is still difficult to apply this to everyday clinical practice.

The RCN acknowledges appraisal of process of seeking clinical expert input and note that there were two clinical experts present. We are however, not sure that this fully covered all areas in view of the complexity and unpredictability of this condition.

ii) **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?**

It appears that the actual number of patients contained within fingolimod clinical trials, that would have met the licensed criteria was very small. We consider that this could have made the ability of the Committee to determine clinical and cost effectiveness very difficult. This seems evident in the conclusion that there was no strong evidence that fingolimod was effective for that specific patient group in comparison to Avonex.

In view of this, we would ask that the summaries of the clinical and cost effectiveness of this appraisal should be aligned to the clinical pathway followed by people with multiple sclerosis. The preliminary views on resource impact and implications should be in line with established standard clinical practice.

iii) **Are the provisional recommendations sound and a suitable basis for guidance to the NHS?**

The RCN is disappointed that the Appraisal Committee does not recommend the use of Fingolimod for the treatment of relapse remitting multiple sclerosis. Fingolimod is the first oral medication that has been well tolerated. The clinical management of Multiple Sclerosis is far more complex and unpredictable than demonstrated by the model used and evidence presented.

It is stated that the Committee has taken into consideration the specialist and patient comments, but has gone on to decline its use.

We acknowledge the decision. The document clearly describes the reasoning for the decision. We agree that choice of comparator is crucial, but consider that the selection of Avonex was inappropriate given the marketing authorisation for fingolimod and that the Committee was obliged to limit consideration within the submission. It is frustrating that additional disease modifying treatment is not yet available.

Had standard best practice (ie no treatment) been selected there may have been an ethical argument to suggest that the small number of patients who would fail treatment with other Disease Modifying Treatments (DMTs) should be offered fingolimod.

- iv) **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 gender, race, disability, age, sexual orientation, religion or belief?**

None that we are aware of.

- v) **Are there any equality-related issues that need special consideration that are not covered in the appraisal consultation document?**

We are not aware of any specific issue at this stage. However, it would be helpful to know if NICE will publish the equality analysis for this appraisal. We would also ask that any guidance issued should show that an analysis of equality impact has been considered and that the guidance demonstrates an understanding of issues relating to all the protected characteristics where appropriate.