Multiple sclerosis (relapsing-remitting) - Fingolimod – ACD

1. Has all of the relevant evidence been taken into account?

Answer: Yes but there is a need to extend the evidence using a more appropriate comparator. A weakness of the evidence was using only Avonex in clinical trials. However, the key studies of Fingolimod have been identified and the ACD appears to have given due consideration to clinical, economic, quality of life evidence as well as representations from both clinical specialists and patient experts.

2. Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?

Answer: Yes, but there are aspects of clinical effectiveness that are not captured by using the EDSS scale (as used in this appraisal) and this would include clinical depression, MS fatigue and cognitive changes

In addition, the ACD is primarily considering information from the submission by Novartis rather than published clinical or cost effectiveness studies. We have not had access to this submission so we are not able to determine that the interpretation of this undisclosed evidence is reasonable or not. The modeling techniques employed appear consistent with previous NICE guidance. We agree with the concern expressed in the ACD section 3.18 with the use of Avonex as a comparator and think that the proposed arguments for this concern are entirely reasonable and correct. In addition the ACD explains that the use of Avonex as a comparator further undermines the cost effectiveness modeling for specific defined patient populations which is entirely reasonable. The ACD criticizes the assumed costs for Avonex in section 3.21 and again I agree with this observation.

We agree with the patient expert view (4.2) that patients would welcome an oral medication rather than self-injection and this is consistent with my experience of working with this patient group. We agree with the views of the clinical specialists expressed in section 4.3 and whole heartedly share the disappointment described in 4.4 and 4.7 that Natalizumab was not included as a comparator.

Finally with regards to comparing Fingolimod with Natalizumab - we must remember that this is a relatively new drug and we assume this would not have been available during the research to have been used as a comparator in this instance. Although, it obviously will be a good comparator in the future.

3. Are the provisional recommendations sound and a suitable basis for guidance to the NHS?

Answer: Yes, with the exception of those who have highly active RRMS and rapidly evolving severe MS and are unable to tolerate or undergo infusion therapy and have failed on first line therapies. This group would benefit from receiving Fingolimod.

4. 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?

Answer: No

5. Are there any equality -related issues that need special consideration and are not covered in the appraisal consultation document?

Answer: No.