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11 November 2019

Dear [redacted]

Re: Final Appraisal Document – erenumab for preventing migraine [ID1188]

Thank you for your letter of 1 November 2019, responding to my initial scrutiny views. This letter is my final decision on initial scrutiny.

Ground 1(a): In making the assessment that preceded the recommendation, NICE has failed to act fairly

1. **The Committee failed to ensure that a sufficient number of clinical experts were consulted about the decision**
2. **The Committee failed to properly take into account the evidence of the clinical experts and professional bodies**
3. **The Committee failed to present a properly balanced assessment of the arguments of a commentator who had a clear conflict of interest**

I am grateful for your confirmation that you do not wish to offer further evidence on these points. For the reasons given in my initial scrutiny letter I will not be referring them to the appeal panel.

Ground 2: the recommendation is unreasonable in the light of the evidence submitted to NICE

4. **The Committee unreasonably failed to consider the impact of positive stopping rules on the cost-effectiveness of erenumab for patients with chronic migraine**

Already agreed to be a valid appeal point.

5. **The Committee unreasonably ignored the opinions of clinical experts and professional bodies on the clinical effectiveness of erenumab and its burden versus its comparator in judging its cost-effectiveness for patients with chronic migraine**

I note your additional comments concerning the FAD's failure to apply an administration utility decrement and confirm this issue will be referred to the appeal panel.

6. **The Committee unreasonably failed to consider the cost-effectiveness of erenumab versus best supportive care in those who had failed to benefit from the comparator drug in patients with chronic migraine**

Thank you for your further comments on this point. On reflection I agree that the argument that the Committee were obliged as a minimum to ask the sponsor to model alternative treatment pathways is valid, assuming as I do for present purposes that it is correct that there is no consensus on where in the treatment pathway CGRP antibody treatment sits.

Therefore the valid appeal points are 4, 5 as it relates to an administration utility decrement, and 6 as it relates to a failure to ask the sponsor for analysis of alternative treatment sequences. Where there are multiple appellants, NICE shares the valid appeal grounds of each appellant with the other appellants to assist with preparation for the hearing. In this case you are the only appellant and so this will not apply.

I believe NICE will have been in touch to make arrangements for the appeal hearing.

Many thanks

Yours sincerely

Tim Irish

Vice-Chair

National Institute for Health and Care Excellence