

Merck Sharp Dohme
Hertford Road
Hoddesdon
Hertfordshire
EN11 9BU

By email to: XXXXXXXXXXXXXXXXXXXX

19 October 2015

Dear XXXXXXXXXX

FAD: Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept for rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed

Thank you for your letter of 8 October. This is my final decision on initial scrutiny.

Ground 1 (a)

1.1(a) The FAD unfairly discriminates against Remicade

Although I have considered your letter carefully I am afraid I still do not consider this to be a valid appeal point. The FAD is clear that the recommendation is to start treatment with the "least expensive" drug. That recommendation ought not to involve any consideration of an ICER, which is a measure of cost effectiveness and not cost. While for present purposes I have to accept that you have feedback that does support your concern, I cannot see that a proper reading of the FAD would lead clinicians to conclude that only biosimilars are recommended, or that biosimilars are to be preferred to Remicade.

It seems to me that the effect of the guidance at the moment of prescription (or the moment of fulfilling the prescription) will be that the clinician or pharmacist will consult a price list, read off the cheapest product whatever it may be taking account of administration costs etc , and supply that. I cannot see that they would refer to the ICER's published in the guidance at all. Certainly any policy that said in terms not to supply Remicade until biosimilars had been tried could not be said to be a result of the guidance. It seems to me that if there is any confusion at present it may be a result of reading the FAD in isolation from a list of the prices available to a Trust, and that once that additional information is available any risk of discrimination (which I am doubtful about in any case) falls away.

Even if that is wrong, and there is a risk of the guidance being misapplied, the Guidance Executive is able to make drafting changes to guidance before it is published, assuming the guidance was passed to them rather than being sent to the appraisal committee for further consideration.

In holding this ground to be invalid, I do not intend that you cannot refer to any evidence of confusion to support your argument under ground 1.2(a)

1.2(a) the FAD lacks transparency

Already accepted as valid.

Grounds 1(b) and 2

No points raised

There will be an oral hearing to consider your appeal ground 1.2(a)

Yours sincerely



National Institute for Health and Care Excellence