MSD
Hertford Road
Hoddesdon
Hertfordshire EN11 9BU
UK
Telephone +44 (0) 1992 467272
Facsimile +44 (0) 1992 468175

Vice chair
National Institute for Health and Care Excellence
10 Spring Gardens
London
SW1A 2BU

25 September 2015

Dear

Final Appraisal Determination - Ankylosing spondylitis and axial spondyloarthritis (non-radiographic) - adalimumab, etanercept infliximab and golimumab (inc rev TA143 and TA233) ID694

MSD would like to appeal the above mentioned FAD on the basis that NICE has acted unfairly in making the recommendations. Our detailed arguments are set out below.

Ground 1(a) NICE has Failed to Act Fairly
1.1 NICE has inappropriately used contract prices in analyses

The FAD (specifically sections 4.46 and 4.67) describes analyses performed by the Assessment Group using "contract prices" for biosimilar infliximab which generated an incremental cost-effectiveness ratio.

> *4.46 Following consultation on the preliminary guidance, the companies that market biosimilar infliximab presented updated economic analyses using a range of prices for infliximab to reflect the tendering process that was ongoing at the time of the consultation. Ranges, rather than single prices, were necessary because the process is regional rather than national and may differ between organisations. After the Committee meeting at which these analyses were discussed, NICE was able to confirm with the Commercial Medicines Unit that the tendering process was complete and that the prices presented in the companies' submissions were now available within the NHS. The Assessment Group then recalculated their base-case ICERs for infliximab in ankylosing spondylitis using an acquisition cost of infliximab to reflect the highest price the NHS would need to pay for infliximab (that is, the upper end of the range of acquisition costs for the cheapest product) and the Committee's preferred infusion cost (see section 4.65). Because the contract prices resulting from the tendering process are commercially confidential, the results of this analysis are not presented here (because this could allow the contract prices to be estimated from the ICERs).*
>
> *[...]*
>
> *4.67 The Committee also discussed the new ICERs, presented in response to the appraisal consultation document, by the companies which market biosimilar versions of infliximab. These used lower prices to reflect the tendering process that was taking place during the consultation period. The companies' representatives present at the meeting were able to confirm that the tendering process was complete and that Commercial Medicines Unit contract prices are now available in the NHS. The Committee noted the updated base-case analyses provided by the Assessment group (that included the highest price the NHS would need to pay for infliximab based on the contract prices, and infusion costs based on the national tariff to deliver simple parenteral chemotherapy) and it agreed that these analyses*

MSD
Hertford Road
Hoddesdon
Hertfordshire EN11 9BU
UK
Telephone +44 (0) 1992 467272
Facsimile +44 (0) 1992 468175

showed that the cost-effectiveness of infliximab was within the range considered to be a cost-effective use of NHS resources. The Committee noted section 5.5.2 of the NICE Guide to the methods of technology appraisal (2013) which states: 'When there are nationally available price reductions, for example for medicines procured for use in secondary care through contracts negotiated by the NHS Commercial Medicines Unit, then the reduced price should be used in the reference-case analysis to best reflect the price relevant to the NHS.' The Committee therefore concluded that infliximab could be recommended as an option for treating adults with ankylosing spondylitis whose disease has responded inadequately to, or who cannot tolerate, NSAIDs provided that the infliximab product with the lowest acquisition cost is used. People already receiving infliximab should be able to continue on their existing product.

However, the inclusion of the contract prices for biosimilars is inconsistent with NICE's own 'Guide to the Methods of Technology Appraisal' (2013) because:

- Contract prices for biosimilar infliximabs do not represent "nationally available price reductions" as they are negotiated on a regional basis.
- Further, these contract prices are subject to cyclical tender arrangements with the NHS Commercial Medicines Unit and so there is no guarantee that the prices will remain in place for the duration of NICE guidance.
- There is no clarity or transparency on how the "highest NHS contract price" for biosimilar infliximab was determined.

1.2 The FAD lacks transparency

NICE has acknowledged that contract prices for Remicade are also available through contracts negotiated by the NHS Commercial Medicines Unit (section 3.20). However, no similar analyses were performed using these contract prices, nor were contract prices for any of the other medicines under appraisal taken in to consideration. Thus the process is incomplete and lacks transparency. Further, there was no opportunity for consultation on the new analyses, given that the first time they were presented was in the FAD.

We refer to an earlier letter to NICE dated 10th September 2015 where we highlighted these procedural concerns with a view to avoiding an appeal.

To ensure fairness in the process, sections 4.46 and 4.67 need to be removed from the final Technology Appraisal Guidance issued to the NHS.

In addition, the wording of the recommendation in paragraph 1.1 should be amended from "*Infliximab is recommended only if treatment is started with the least expensive infliximab product*" to "*Start treatment with the least expensive drug (taking into account administration costs, dose needed, and product price per dose). Costs may vary in different settings because of negotiated procurement discounts*", particularly since price reductions are available for Remicade and other biologics, as well as for biosimilar infliximab through contracts negotiated with the NHS Commercial Medicines Unit.

Finally, we note that biosimilars were not included in the final scope for this appraisal, dated 30th May 2014. The first mention of biosimilar infliximab in the NICE supporting documents is in the Assessment Report (published 8th January 2015). The late addition of biosimilars to an existing process after evidence submissions had already been made compounds the unfairness described above.

MSD
Hertford Road
Hoddesdon
Hertfordshire EN11 9BU
UK
Telephone +44 (0) 1992 467272
Facsimile +44 (0) 1992 468175

We kindly ask for an oral hearing to consider this appeal.

Yours sincerely,

, Managing Director of MSD in UK