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MSD

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Dear Meindert,

MSD thanks NICE for the opportunity to comment on the Appraisal Consultation Document (ACD). We acknowledge that the preliminary recommendation made by the Appraisal Committee maintains patient and clinician access to biologic DMARDs for the treatment of severe active rheumatoid arthritis (RA), in line with previous NICE guidance on these medicines.

We note that the Appraisal Committee has determined that the median cost-effectiveness estimate for biologic DMARDs likely falls between the Assessment Group base-case ICER for patients with severe disease (£41,600) and the Assessment Group ICER for patients with severe disease and the fastest HAQ progression (£25,300). A similar range of values was presented for moderate RA (base-case: £51,100 and fastest HAQ progression: £28,500) which suggested that biologic DMARDs could also be a cost-effectiveness intervention for moderate disease; however, the Appraisal Committee has concluded that the fastest HAQ progression analysis is not applicable to these patients. This appears to contradict the statements made by clinical experts who explained that "the initial DAS score does not define patients who progress fastest" or impact the likelihood of patients failing to respond to intensive conventional DMARD treatment who then require additional treatment options. Considering this, it is not clear why DAS score is still used to define eligibility for treatment.

Access to these effective medicines was originally restricted to patients with severe RA due to cost implications, and it was acknowledged that those decisions would be reviewed at a later date with a view to widening access to a population with moderate RA. It is disappointing that this opportunity to widen access has been lost, especially when the cost of these drugs has reduced in real terms due to inflation since the original recommendations were made. The implication of losing this opportunity is that patients in the UK still have reduced access compared to their counterparts in other parts of Europe, with less stringent eligibility requirements[1]. Given the considerations outlined in this response, MSD urges the Appraisal Committee to revisit the issue of access to patients with moderate RA.

Finally, Section 3.11 of the ACD states that for infliximab biosimilars "the contraindications, adverse reactions and administration schedule are the same as for infliximab". MSD would like to note that both infliximab biosimilars have black triangles, indicating the need for increased safety monitoring, whereas Remicade does not. The safety profile of both infliximab biosimilars is being continually assessed through the use of registries and post-marketing assessment, and very limited data exist on the safety of biosimilar infliximab when switching from Remicade.

Kind regards,

[redacted]

[1] Kiely P. DAS28 criteria for initiation of biologics in early RA: a clinician's view (2012). Available: http://www.rheumatology.org.uk/includes/documents/cm_docs/2012/1/1210_das28_criteria_for_initiation_of_biologics_in_early_ra_a_clinicians_view.pdf; Accessed: 06/07/15