National Institute for Health and Care Excellence

Single Technology Appraisal (STA)

Tofacitinib for treating moderate to severe active rheumatoid arthritis after the failure of disease-modifying anti-rheumatic drugs

Response to consultee and commentator comments on the draft remit and draft scope (pre-referral)

Please note: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Comment 1: the draft remit

Section	Consultee/ Commentator	Comments [sic]	Action
Appropriateness	British Society for Rheumatology	Janus kinase inhibitors are an important new class of drugs being evaluated in RA. There are several JAK inhibitors of which Tofacitinib is one.	Thank you for your comment. No changes to the scope required.
	Merck Sharpe & Dohme	Yes	Thank you for your comment. No changes to the scope required.
	Pfizer	We consider it appropriate for this topic to be referred to NICE for appraisal.	Thank you for your comment. No changes to the scope required.
Wording	British Society for Rheumatology	No issues	Thank you for your comment. No changes to the scope required.

Section	Consultee/ Commentator	Comments [sic]	Action
	Merck Sharpe & Dohme	Yes	Thank you for your comment. No changes to the scope required.
	Pfizer	No comments	Thank you for your comment. No changes to the scope required.
	Roche Products	Roche suggest the remit for this appraisal should be 'adults with moderate to severe, active rheumatoid arthritis'.	Thank you for your comment. We believe that the current broad remit includes the wording suggested and is also reflected in the marketing authorisation.
Timing Issues	British Society for Rheumatology	JAK inhibitors will be a useful addition but unlikely to alter treatment pathways	Thank you for your comment. No changes to the scope required
	Merck Sharpe & Dohme	No comments	Thank you for your comment. No changes to the scope required
	Pfizer	We consider the timing of appraisal to be appropriate	Thank you for your comment. No changes to the scope required

Section	Consultee/ Commentator	Comments [sic]	Action
Additional comments on the draft remit	British Society for Rheumatology	None.	No changes to the scope required
	Merck Sharpe & Dohme	None.	No changes to the scope required
	Pfizer	None.	No changes to the scope required

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	British Society for Rheumatology	This is accurate.	Thank you for your comment. No changes to the scope required
	Merck Sharpe & Dohme	No comments.	No changes to the scope required
	Pfizer	No comments.	No changes to the scope required
The technology/ intervention	British Society for Rheumatology	Accurate description.	Thank you for your comment. No changes to the scope required

Section	Consultee/ Commentator	Comments [sic]	Action
	Merck Sharpe & Dohme	No comments.	No changes to the scope required
	Pfizer	No comments.	No changes to the scope required
Population	British Society for Rheumatology	It would be helpful to establish the numbers of patients who achieve low disease activity or remission.	Thank you for your comment. Disease activity has been included as an outcome in the scope and numbers of patients who achieve low disease activity and remission will most likely be established through the appraisal process depending on evidence submitted by consultees.
	Merck Sharpe & Dohme	Yes the population is defined appropriately.	Thank you for your comment. No changes to the scope required
	Pfizer	No comments.	No changes to the scope required

Section	Consultee/ Commentator	Comments [sic]	Action
Comparators	British Society for Rheumatology	Hydroxychloroquine should be included in the combination group. It is surprising that the combination of methotrexate and leflunomide is included – this is not a recommended combination.	Thank you for your comment. The examples of leflunomide and sulfasalazine have been removed for clarity.
	Merck Sharpe & Dohme	Yes, these are the standard treatments used.	Thank you for your comment. No changes to the scope required
	Pfizer	No comments.	No changes to the scope required
Outcomes	British Society for Rheumatology	Disease activity as defined by DAS or its individual components Physical function as defined by HAQ Joint damage as assessed by radiological progression I doubt that there will be adequate data on extra-articular manifestations	Thank you for your comment. These outcomes are included in the scope. No changes to the scope required
	Merck Sharpe & Dohme	Yes.	Thank you for your comment. No changes to the scope required
	Pfizer	No comments.	No changes to the scope required

Section	Consultee/ Commentator	Comments [sic]	Action
Economic analysis	British Society for Rheumatology	Currently there are many regional access schemes for biologics, it would be important to define cost with biosimilars rather than originator drugs.	Comment noted. No changes to the scope required
	Merck Sharpe & Dohme	No comments.	No changes to the scope required
	Pfizer	Pfizer will submit an economic model that addresses the NICE reference case.	Comment noted. No changes to the scope required
Equality and Diversity	British Society for Rheumatology	No comment.	No changes to the scope required
	Merck Sharpe & Dohme	No inequality issues were identified.	No changes to the scope required
	Pfizer	No comments.	No changes to the scope required
Innovation	British Society for Rheumatology	This is an alternative disease modifying drug.	Thank you for your comment. No changes to the scope required
	Merck Sharpe & Dohme	No comments.	No changes to the scope required
	Pfizer	We believe that tofacitinib can be considered a step change in the management of RA. It has a novel mode of action, as a reversible inhibitor of	Comment noted. The Appraisal Committee

Section	Consultee/ Commentator	Comments [sic]	Action
		the ATP binding site of JAK enzymes with selectivity for JAK1 and 3 and is administered orally, which is supported by data from 6 phase III clinical trials. Results from the clinical programme, which included a broad range of patients provides evidence for the use of tofacitinib at multiple points in the NICE RA treatment pathway, in particular, in patients who are MTX intolerant or resistant. Rapid onset of results were seen as early as 2 weeks in the clinical trial programme and maintained for up to 12 months. Patient Reported Outcomes, including pain, fatigue and sleep improvement from the Tofacitinib clinical programme have shown a significant improvement in a wide range of patient populations.	will discuss the potentially innovative nature of this technology. No changes to the scope required
Other considerations	British Society for Rheumatology	For tofacitinib to be considered a major advance the numbers of patients achieving low disease activity or remission should be greater to justify their cost relative to available biosimilars or compared to triple therapy.	Comment noted. No changes to the scope required
	Merck Sharpe & Dohme	No comments.	No changes to the scope required
	Pfizer	No comments.	No changes to the scope required
Questions for consultation	British Society for Rheumatology	None.	No changes to the scope required
	Merck Sharpe & Dohme	Given that no other Janus Kinase Inhibitors have received positive recommendation for rheumatoid arthritis, it appears to be better suited to a single technology appraisal.	Comment noted. No changes to the scope required

Section	Consultee/ Commentator	Comments [sic]	Action
	Pfizer	No comments.	No changes to the scope required
	Roche Products	As per Roche's response to the Abbreviated Technology Appraisal (ATA) consultation, we have concerns regarding the lack of clinician and patient input into the currently proposed ATA process. Moreover, Roche does not support the current ATA proposal that comparator manufacturers will only receive a summary of the submitting manufacturer's documents. Additionally, it is unclear what the most appropriate comparator would be for tofacitinib to be appraised against via the ATA route.	Comment noted. The ATA process is still being considered by the NICE Board and has not been finalised. No changes to the scope required.
Additional comments on the draft scope	British Society for Rheumatology	None.	No changes to the scope required
	Merck Sharpe & Dohme	None.	No changes to the scope required
	Pfizer	None.	No changes to the scope required

The following consultees/commentators indicated that they had no comments on the draft remit and/or the draft scope

AbbVie
Bristol Myers Squibb
Department of Health