

National Institute for Health and Care Excellence

Health Technology Evaluation

Filgotinib for treating axial spondyloarthritis ID6594

Response to stakeholder organisation comments on the draft remit and draft scope

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 and proposed process

Section	Stakeholder	Comments [sic]	Action
Appropriateness of an evaluation and proposed evaluation route	Alfasigma UK LTD	Alfasigma UK Limited will be making a submission using the cost-comparison route.	Thank you for your comment, no changes are needed.
	UCB Pharma	Yes, we consider this appraisal to be appropriate	Thank you for your comment, no changes are needed.
	AbbVie	AbbVie agrees that filgotinib should be evaluated as a single technology appraisal.	Thank you for your comment. A cost comparison case can be made if a health technology is likely to provide similar or greater health benefits at similar or lower cost than technologies recommended in published NICE technology appraisal guidance for the same indication. NICE will schedule this topic into its work programme as a cost comparison.

Section	Stakeholder	Comments [sic]	Action
	National Axial Spondyloarthritis Society (NASS)	A single technology appraisal is appropriate.	Thank you for your comment. A cost comparison case can be made if a health technology is likely to provide similar or greater health benefits at similar or lower cost than technologies recommended in published NICE technology appraisal guidance for the same indication. NICE will schedule this topic into its work programme as a cost comparison.
Wording	Alfasigma UK LTD	Alfasigma UK Limited agrees that the draft remit reflects the issues that NICE should consider.	Thank you for your comment, no changes are needed.
	UCB Pharma	Yes	Thank you for your comment, no changes are needed.
	AbbVie	The wording of the remit reflects the issue of clinical and cost-effectiveness.	Thank you for your comment, no changes are needed.
	NASS	Yes	Thank you for your comment, no changes are needed.
Timing Issues	Alfasigma UK LTD	No comments	No comment.
	UCB Pharma	No comment	No comment.

Section	Stakeholder	Comments [sic]	Action
	AbbVie	No comments.	No comment.
	NASS	None	Thank you for your comment, no changes are needed.
Additional comments on the draft remit	Alfasigma UK LTD	NA	No comment.
	UCB Pharma	-	No comment.
	AbbVie	No additional comments.	No comment.
	NASS	-	No comment.

Comment 2: the draft scope

Section	Consultee/ Commentat or	Comments [sic]	Action
Background information	Alfasigma UK LTD	<p>The terminology 'ankylosing spondylitis' (AS) is presently prioritised in the 'background' section of the draft scope over 'radiographic axial spondyloarthritis' (r-axSpA). R-axSpA is the terminology used in current clinical practice. In contrast, AS is considered a historic term.</p> <p>As such, Alfasigma UK Limited would apply the term 'r-axSpA' in its submission.</p>	Thank you for your comment, the text was updated as suggested.

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	UCB Pharma	-	No comment.
	AbbVie	AbbVie considers the background information to be factually accurate.	Thank you for your comment, no changes are needed.
	NASS	This is complete	Thank you for your comment, no changes are needed.
Population	Alfasigma UK LTD	Alfasigma UK Limited agrees that the population specified in the draft scope is appropriate.	Thank you for your comment. Please note that we have spelled out the radiographic axial spondyloarthritis and non-radiographic axial spondyloarthritis populations in the population section to highlight the two populations included.
	UCB Pharma	Yes	Thank you for your comment. Please note that we have spelled out the radiographic axial spondyloarthritis and non-radiographic axial spondyloarthritis populations in the population section to highlight the two populations included.
	AbbVie	AbbVie considers that the population is appropriately defined.	Thank you for your comment. Please note that we have spelled out the radiographic axial spondyloarthritis and non-radiographic axial spondyloarthritis

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	NASS	Yes	<p>populations in the population section to highlight the two populations included.</p> <p>Thank you for your comment.</p> <p>Please note that we have spelled out the radiographic axial spondyloarthritis and non-radiographic axial spondyloarthritis populations in the population section to highlight the two populations included.</p>
Subgroups	Alfasigma UK LTD	<p>One STA cost-comparison submission for axSpA with the following subgroups should be considered:</p> <ul style="list-style-type: none"> • R-axSpA biologic disease-modifying anti-rheumatic drug (bDMARD)-naïve • R-axSpA bDMARD-experienced • Non-radiographic axial spondyloarthritis (nr-axSpA), bDMARD-naïve • Nr-axSpA, bDMARD-experienced. 	<p>Thank you for your comment, no change is needed.</p> <p>Please note that the subgroups were updated to represents the UK treatment pathway: <i>If the evidence allows, the following subgroups will be considered with the 2 main populations:</i></p> <ul style="list-style-type: none"> • <i>TNF-inhibitors naïve, and</i> • <i>TNF-inhibitors experienced subgroup.</i>
	UCB Pharma	Among people with axSpA, psoriasis has a prevalence of 10%.	<p>Thank you for your comment, no changes are needed.</p> <p>Please note that the subgroups were updated to represents the UK treatment pathway:</p>

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			<p><i>If the evidence allows, the following subgroups will be considered with the 2 main populations:</i></p> <ul style="list-style-type: none"> • <i>TNF-inhibitors naïve, and</i> • <i>TNF-inhibitors experienced subgroup.</i>
	AbbVie	<p>AbbVie considers that patients with ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-ax-SpA) represent distinct subgroups of interest to the clinical pathway in the UK. Separately, the treatment pathway in the UK distinguishes between patients who are contra-indicated for a tumour necrosis factor inhibitor (TNFi) and all other patients. As such, this also represents a distinct sub-group for assessment.</p>	<p>Thank you for your comment.</p> <p>Please note that we have spelled out the radiographic axial spondyloarthritis and non-radiographic axial spondyloarthritis populations in the population section to highlight the two populations included</p> <p>In addition, please note that the subgroups were updated to represents the UK treatment pathway:</p> <p><i>If the evidence allows, the following subgroups will be considered with the 2 main populations:</i></p> <ul style="list-style-type: none"> • <i>TNF-inhibitors naïve, and</i> • <i>TNF-inhibitors experienced subgroup.</i> <p>No further changes are needed.</p>
	NASS	<p>For those that injecting/using a pen is not appropriate (oral medication)</p>	<p>Thank you for your comment. Other oral medications are available in this population. No changes are needed.</p>

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			<p>Please note that the subgroups were updated to represents the UK treatment pathway: <i>If the evidence allows, the following subgroups will be considered with the 2 main populations:</i></p> <ul style="list-style-type: none"> • <i>TNF-inhibitors naïve, and</i> • <i>TNF-inhibitors experienced subgroup.</i>
Comparators	Alfasigma UK LTD	<p>In the subgroup of patients who are bDMARD-naïve:</p> <ul style="list-style-type: none"> • R-axSpA: adalimumab, certolizumab pegol, etanercept, golimumab, infliximab • Nr-axSpA: adalimumab, certolizumab pegol, etanercept, golimumab <p>In the subgroups of patients for whom bDMARDs are not suitable (e.g. where a bDMARD was received but was not tolerated) or have not controlled the condition well enough:</p> <ul style="list-style-type: none"> • R-axSpA: secukinumab ixekizumab, bimekizumab, upadacitinib, tofacitinib • Nr-axSpA: secukinumab ixekizumab, bimekizumab, upadacitinib <p>*Includes TNF-alpha inhibitors for both r-axSpA and nr-axSpA. This is in line with the NICE recommended treatments for patients that are bDMARD-naïve</p>	<p>Thank you for your comments, no changes are needed.</p> <p>Please note that the subgroups were updated to represents the UK treatment pathway: <i>If the evidence allows, the following subgroups will be considered with the 2 main populations:</i></p> <ul style="list-style-type: none"> • <i>TNF-inhibitors naïve, and</i> • <i>TNF-inhibitors experienced subgroup.</i> <p>Please note where a technology is expected to be evaluated through the cost comparison process, a comparison is only required against one comparator which must be established in practice and have</p>

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			substantial use in the NHS in England for the same indication.
	UCB Pharma	Yes	<p>Thank you for your comments, no changes are needed.</p> <p>Please note where a technology is expected to be evaluated through the cost comparison process, a comparison is only required against one comparator which must be established in practice and have substantial use in the NHS in England for the same indication.</p>
	AbbVie	AbbVie agrees with the list of comparators outlined in the draft scope.	<p>Thank you for your comments, no changes are needed.</p> <p>Please note where a technology is expected to be evaluated through the cost comparison process, a comparison is only required against one comparator which must be established in practice and have substantial use in the NHS in England for the same indication.</p>
	NASS	Yes	<p>Thank you for your comments, no changes are needed.</p> <p>Please note where a technology is expected to be evaluated through the cost comparison process, a comparison is only required against one comparator which must be established in practice and have</p>

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			substantial use in the NHS in England for the same indication.
Outcomes	Alfasigma UK LTD	The outcomes listed are appropriate for a cost-utility analysis but are not all aligned with a cost-comparison submission. Notably, health-related quality of life does not feature in a cost-comparison analysis.	Thank you for your comments. The scope lists outcomes important to patient and carers of patients with this condition. This is not dependent on the economic analysis used, so no changes are needed. Please note fatigue was added to the list.
	UCB Pharma	Yes, appropriate	Thank you for your comment, no changes are needed. Please note fatigue was added to the list.
	AbbVie	AbbVie considers the outcomes listed to be appropriate.	Thank you for your comment, no changes are needed. Please note fatigue was added to the list.
	NASS	Impact on fatigue should be considered.	Thank you for your comment, fatigue was added to the list as suggested.
Equality	Alfasigma UK LTD	No comments	No comment
	UCB Pharma	No comment	No comment

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	AbbVie	No comment.	No comment
	NASS	It is important to consider that this is an oral medication (as are comparator JAK inhibitors) and so may be more appropriate for those with particular disabilities such as learning difficulties, or those who are not able to inject or use a pen. A recommendation for those on lower incomes or in shared accommodation might also be welcomed as there is no need to store in the fridge.	Thanks for your comment. Committee will consider all potential equality issues raised during the appraisal. Please note, your comment was included in the scoping EIA form.
Other considerations	Alfasigma UK LTD	No comments	No comment
	UCB Pharma	No comment	No comment
	AbbVie	No additional comments.	No comment
	NASS	-	No comment.
Questions for consultation	Alfasigma UK LTD	Where do you consider filgotinib will fit into the existing care pathway for the disease? For bDMARD-naïve patients, filgotinib is anticipated to be an alternative to TNF-alpha inhibitors as an initial advanced therapy	Thank you for your comments. Please note, a cost comparison case can be made if a health technology is likely to provide similar or greater health benefits at similar or lower cost than technologies

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		<p>when non-steroidal anti-inflammatory drugs (NSAIDs) have not controlled the condition well enough or are not tolerated.</p> <p>For bDMARD-experienced patients, when TNF-alpha inhibitors are not suitable or have not controlled the condition well enough, filgotinib is expected to be an alternative to other janus kinase (JAK) inhibitors and interleukin 17 (IL-17) inhibitors.</p> <p>Please select from the following, will filgotinib be:</p> <p>A. Prescribed in primary care with routine follow-up in primary care</p> <p>B. Prescribed in secondary care with routine follow-up in primary care</p> <p>C. Prescribed in secondary care with routine follow-up in secondary care</p> <p>D. Other (please give details):</p> <p>For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.</p> <p>Option C will apply to filgotinib in this indication.</p> <p>Would the technology be a candidate for managed access?</p> <p>No comments</p> <p>Do you consider that the use of filgotinib can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?</p> <p>No comments</p>	<p>recommended in published NICE technology appraisal guidance for the same indication. NICE will schedule this topic into its work programme as a cost comparison.</p> <p>Where a technology is expected to be evaluated through the cost comparison process, a comparison is only required against one comparator which must be established in practice and have substantial use in the NHS in England for the same indication.</p> <p>Also, please note that we have spelled out the radiographic axial spondyloarthritis and non- radiographic axial spondyloarthritis populations in the population section to highlight the two populations included.</p> <p>And the subgroups were updated to represent the UK treatment pathway: <i>If the evidence allows, the following subgroups will be considered with the 2 main populations:</i></p> <ul style="list-style-type: none"> • <i>TNF-inhibitors naïve, and</i> • <i>TNF-inhibitors experienced subgroup.</i> <p>No further changes are needed.</p>

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		<p>Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.</p> <p>No comments</p> <p>NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:</p> <ul style="list-style-type: none"> • could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which the treatment will be licenced; • could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology; • could have any adverse impact on people with a particular disability or disabilities. <p>Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.</p> <p>No comments</p>	

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		<p>NICE is considering evaluating this technology through its cost comparison evaluation process. Please provide comments on the appropriateness of appraising this topic through this process. (Information on NICE’s health technology evaluation processes is available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation).</p> <p>Alfasigma believe the cost comparison evaluation process is appropriate for this submission.</p> <p>Technologies can be evaluated through the cost-comparison process if they are expected to provide similar or greater health benefits, at a similar or lower cost, compared with technologies that have been previously recommended (as an option) in published NICE guidance for the same indication. Companies can propose cost-comparison topics to NICE at any stage during topic selection and scoping. NICE will route technologies for evaluation through the cost-comparison process if it is agreed during scoping that the process is an appropriate route to establish the clinical and cost effectiveness of the technology.</p> <p>NICE’s <u>health technology evaluations: the manual</u> states the methods to be used where a cost comparison case is made.</p>	

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		<ul style="list-style-type: none"> • Is the technology likely to be similar in its clinical effectiveness and resource use to any of the comparators? Or in what way is it different to the comparators? [REDACTED] • Will the intervention be used in the same place in the treatment pathway as the comparator(s)? Yes, see comments on comparators. Have there been any major changes to the treatment pathway recently? No If so, please describe. NA • Will the intervention be used to treat the same population as the comparator(s)? Yes, see comments on the comparators. 	

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		<ul style="list-style-type: none"> • Overall is the technology likely to offer similar or improved health benefits compared with the comparators? Yes • Would it be appropriate to use the cost-comparison methodology for this topic? Yes 	
	UCB Pharma	No comment	No comment.
	AbbVie	<p>NICE is considering evaluating this technology through its cost comparison evaluation process:</p> <p>Is the technology likely to be similar in its clinical effectiveness and resource use to any of the comparators? Or in what way is it different to the comparators? AbbVie are not aware of any direct head-to-head studies of filgotinib compared with relevant UK comparators in axial spondyloarthritis (ax-SpA).</p> <p>Will the intervention be used in the same place in the treatment pathway as the comparator(s)? Have there been any major changes to the treatment pathway recently? If so, please describe. It is expected that filgotinib will be used as an alternative to other JAK inhibitors in ax-SpA.</p> <p>Will the intervention be used to treat the same population as the comparator(s)? As above, filgotinib will be used as an alternative to other JAK inhibitors in ax-SpA. This population will consist of patients who</p>	<p>Thank you for your comments.</p> <p>Please note, a cost comparison case can be made if a health technology is likely to provide similar or greater health benefits at similar or lower cost than technologies recommended in published NICE technology appraisal guidance for the same indication. NICE will schedule this topic into its work programme as a cost comparison.</p> <p>Where a technology is expected to be evaluated through the cost comparison process, a comparison is only required against one comparator which must be established in practice and have substantial use in the NHS in England for the same indication.</p> <p>Also, please note that we have spelled out the radiographic axial spondyloarthritis and non- radiographic axial spondyloarthritis</p>

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		<p>are biologic-experienced (2L+) or where TNF inhibitors are contraindicated.</p> <p>Overall is the technology likely to offer similar or improved health benefits compared with the comparators? No comments.</p> <p>Would it be appropriate to use the cost-comparison methodology for this topic? The NICE manual states that “<i>Cost-comparison analyses in a technology appraisal should be used for technologies likely to provide similar health benefits at similar or lower cost than comparator(s) that are recommended in published NICE guidance for the same population</i>”. A decision on whether to use the cost-comparison methodology should therefore consider the clinical effectiveness evidence compared with the relevant comparators outlined above.</p>	<p>populations in the population section to highlight the two populations included.</p> <p>And the subgroups were updated to represents the UK treatment pathway: <i>If the evidence allows, the following subgroups will be considered with the 2 main populations:</i></p> <ul style="list-style-type: none"> • <i>TNF-inhibitors naïve, and</i> • <i>TNF-inhibitors experienced subgroup.</i> <p>No further changes are needed.</p>
	NASS	<p>Where do you consider filgotinib will fit into the existing care pathway for the disease?</p> <p>Please select from the following, will filgotinib be: C. Prescribed in secondary care with routine follow-up in secondary care</p> <p>For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.</p> <p>It does not.</p>	<p>Thank you for your comments.</p> <p>Please note, a cost comparison case can be made if a health technology is likely to provide similar or greater health benefits at similar or lower cost than technologies recommended in published NICE technology appraisal guidance for the same indication. NICE will schedule this topic into its work programme as a cost comparison.</p> <p>Where a technology is expected to be evaluated through the cost comparison process, a comparison is only required</p>

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		<p>Would the technology be a candidate for managed access? N/A for NASS to answer</p> <p>Do you consider that the use of filgotinib can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation? No</p> <p>NICE is considering evaluating this technology through its cost comparison evaluation process. Please provide comments on the appropriateness of appraising this topic through this process. (Information on NICE’s health technology evaluation processes is available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation).</p> <p>Technologies can be evaluated through the cost-comparison process if they are expected to provide similar or greater health benefits, at a similar or lower cost, compared with technologies that have been previously recommended (as an option) in published NICE guidance for the same indication. Companies can propose cost-comparison topics to NICE at any stage during topic selection and scoping. NICE will route technologies for evaluation through the cost-comparison process if it is agreed during scoping that the process is an appropriate</p>	<p>against one comparator which must be established in practice and have substantial use in the NHS in England for the same indication.</p> <p>Also, please note that we have spelled out the radiographic axial spondyloarthritis and non- radiographic axial spondyloarthritis populations in the population section to highlight the two populations included.</p> <p>And the subgroups were updated to represents the UK treatment pathway: <i>If the evidence allows, the following subgroups will be considered with the 2 main populations:</i></p> <ul style="list-style-type: none"> • <i>TNF-inhibitors naïve, and</i> • <i>TNF-inhibitors experienced subgroup.</i> <p>No further changes are needed.</p>

Section	Consultee/ Commentat or	Comments [sic]	Action
		<p>route to establish the clinical and cost effectiveness of the technology.</p> <p>NICE’s <u>health technology evaluations: the manual</u> states the methods to be used where a cost comparison case is made.</p> <ul style="list-style-type: none"> • Is the technology likely to be similar in its clinical effectiveness and resource use to any of the comparators? Or in what way is it different to the comparators? <p>Likely to be similar to other JAK inhibitors</p> <ul style="list-style-type: none"> • Will the intervention be used in the same place in the treatment pathway as the comparator(s)? Have there been any major changes to the treatment pathway recently? If so, please describe. <p>Usual pathway is TNF-inhibitors, IL17-a inhibitors then JAK</p> <ul style="list-style-type: none"> • Will the intervention be used to treat the same population as the comparator(s)? 	

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		<p>It will be used for people along the spectrum of axial spondyloarthritis. Some of the comparitors are only specified as an intervention for radiographic axial SpA (or ankylosing spondylitis).</p> <ul style="list-style-type: none"> • Overall is the technology likely to offer similar or improved health benefits compared with the comparators? <p>N/A</p> <ul style="list-style-type: none"> • Would it be appropriate to use the cost-comparison methodology for this topic? <p>Yes</p>	
Additional comments on the draft scope	Alfasigma UK LTD	No comments	No comment
	UCB Pharma	-	No comment
	AbbVie	No additional comments.	No comment
	NASS	-	No comment

Section	Consultee/ Commentat or	Comments [sic]	Action

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

None.