National Institute for Health and Care Excellence

Health Technology Evaluation

Bimekizumab for treating axial spondyloarthritis
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	AbbVie	No comments	No action required
	UCB Pharma (company)	UCB will submit using the STA cost-comparison route. UCB intends to submit both ID4010 and ID4011 as a single submission for axial spondyloarthritis (axSpA) in line with the population evaluated for TA718 (ixekizumab in axSpA).	ID4010 and ID4011 have now been merged as a single cost-comparison appraisal under the PATT (Proportionate Approach to Technology Appraisals) streamlined cost comparison process.
	Novartis	We consider the proposed appraisal & evaluation route suggested as appropriate.	ID4010 and ID4011 have now been merged

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			as a single cost-comparison appraisal.
Wording	AbbVie	No comments	No action required
	UCB Pharma	The background section should cover both nr-axSpA and AS, in line with a joint submission for axSpA. It may be helpful to describe axSpA as the umbrella condition, with nr-axSpA and AS as the subtypes and then further relate axSpA to associated diseases such as plaque psoriasis, psoriatic arthritis, hidradenitis suppurativa, and other heterogeneous but related diseases. The background section does not include non-radiographic axSpA (nr-axSpA) as belonging to the group of conditions. It should be included as it is the most closely related to AS.	The merged final scope has been updated to include information on both non-radiographic axSpA and Ankylosing Spondylitis.
	Novartis	We consider the proposed wording appropriate.	Thank you for your comment.
Additional comments on the draft remit	AbbVie	N/a	No action required
	UCB Pharma	UCB will submit using the STA cost-comparison route. The reference comparator will be ixekizumab. Ixekizumab was one of the comparators in the Fast Track Appraisal of bimekizumab in plaque psoriasis (TA723). Bimekizumab, is an immunoglobin G1 monoclonal antibody that selectively inhibits both interleukin 17A and interleukin 17F, while ixekizumab selectively inhibits interleukin 17A. Ixekizumab is approved in all subpopulations listed in the draft NICE scope. Ixekizumab is the most similar drug to bimekizumab in mechanism of action and efficacy. UCB intends to submit as one submission for ID4010 and ID4011 in line with TA718 (ixekizumab in axSpA) guidance population. Making one submission is also in line with NICE's Proportionate Approach to Technology Assessment (PATT) principles.	Thank you for your comment. ID4010 and ID4011 have now been merged as a single cost-comparison appraisal.

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	Novartis	No comment	No action required.

Comment 2: the draft scope

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Background information	AbbVie	In paragraph four, please add the NICE recommendation for Upadacitinib: Upadacitinib is recommended as an option for treating active ankylosing spondylitis that is not controlled well enough with conventional therapy in adults, only if: • tumour necrosis factor (TNF)-alpha inhibitors are not suitable or do not control the condition well enough [TA829]	Thank you for your comment. The paragraph describing existing treatment options in ankylosing spondylitis has been amended to reference TA829 and upadacitinib.
	UCB Pharma	The background section should cover both nr-axSpA and AS, in line with a joint submission for axSpA. The final scope from TA718 should be used as the template for the final scope in a joint appraisal covering ID4010 and ID4011.	Thank you for your comment. The background section has been amended to reflect this.
	Novartis	No comment	No action required
Population	AbbVie	No comments	No action required
	UCB Pharma	UCB plans to submit one submission for ID4010 and ID4011 for axSpA. Ankylosing spondylitis (AS, also known as radiographic axSpA) and non-	Thank you for your comment. The

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		radiographic axSpA (nr-axSpA) are frequently considered to be subgroups of one disease spectrum. UCB advisory boards and statements from committee experts have indicated that looking at these populations as subgroups of one axSpA population is appropriate. Bimekizumab demonstrates similar efficacy across the axSpA disease spectrum, regardless of previous biologic use (see Deodhar et al. 2022, and van der Heijde et al. 2022).	population section of the scope now reflects this.
	Novartis	No comment	No action required
Subgroups	AbbVie	No comments	No action required
	UCB Pharma	In line with the comment above, one STA cost-comparison submission for axSpA with the following subgroups should be considered when evaluating the clinical efficacy: • AS, biologic disease-modifying anti-rheumatic drug (bDMARD)-naive • AS, bDMARD-experienced • Nr-axSpA, bDMARD-naïve **Nr-axSpA, bDMARD-experienced**	Thank you for your comment. The appraisal committee will consider any relevant subgroups for which there are evidence during the course of the appraisal.
	Novartis	No comment	No action required
Comparators	AbbVie	NICE have now issued the final guidance for Upadacitinib for active ankylosing spondylitis [TA829] (https://www.nice.org.uk/guidance/ta829/chapter/1-Recommendations)	Thank you for your comment. The final scope has been amended to reflect this.
	UCB Pharma	Tofacitinib has restrictions based on an Medicines and Healthcare products Regulatory Agency (MHRA) black label warning: *"Tofacitinib should not be used in patients older than 65 years of age, people who are current or past smokers, or individuals with other cardiovascular (such as diabetes or coronary artery disease) or malignancy risk factors unless there are no*	Thank you for your comment. The technology appraisal process will consider all evidence when deciding on appropriate

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		suitable treatment alternatives." Tofacitinib should not be assessed outside of the population allowed by the MHRA black label warning The European Medicines Agency (EMA) has recently released a draft opinion suggesting that all Janus kinase (JAK) inhibitors carry risk in line with the MHRA black label warning for tofacitinib. The Information for healthcare professionals states: • *"EMA concluded that the identified risks apply to all JAK inhibitors approved for the treatment of chronic inflammatory disorders.* • *These medicines (Xeljanz, Cibinqo, Olumaint [sic], Rinvoq and Jyseleca) should only be used in the following patients if no suitable treatment alternatives are available: those aged 65 years or above, those who are current or past long-time smokers, those with a history of atherosclerotic cardiovascular disease or other cardiovascular risk factors, or those with other malignancy risk factors. Cautious use is also recommended in patients with known risk factors for VTE other than those listed above.* • *If JAK inhibitors are needed in patients with these risk factors, a lower dose may be recommended, depending on the medicine, the indication and the specific risk factor.* • *Healthcare professionals should discuss the risks associated with JAK inhibitors with their patients.* • *It is recommended that healthcare professionals carry out periodic examinations of their patients' skin to check for skin cancer, particularly for patients at risk for skin cancer."* These statements from the MHRA and EMA indicate that JAK inhibitors should only be considered in a small subgroup of the population in which bimekizumab will be considered. JAK inhibitors, tofacitinib, and upadacitinib, should be clearly limited to this subgroup in the scope.	comparators to include in the appraisal.

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		We recognise that TA829 (upadacitinib in AS) does not reference these limitations when recommending upadacitinib in AS. However, clinical experts consulted by UCB through multiple advisory boards have consistently listed regulatory warnings such as the EMA warning above for JAK inhibitors as a class and the Medicines and Healthcare products Regulatory Agency (MHRA) black label warning for tofacitinib as a concern that influences prescribing decisions for JAK inhibitors.	
	Novartis	Comparators seem appropriate.	No action required
Outcomes	AbbVie	No comments	No action required
	UCB Pharma	The outcomes listed are appropriate for a cost-utility analysis but are not all aligned with an STA cost-comparison. Notably, health-related quality of life does not feature in an STA cost-comparison analysis.	Thank you for your comment. The final scope has been amended to reflect this.
	Novartis	No comment	No action required
Equality	AbbVie	No comments	No action required
	UCB Pharma	In 2021,a policy paper published by the Department of Health and Social Care highlighted the need to improve women's health outcomes. Nr-axSpA is more prevalent in females than males (Baraliakos and Braun 2015), and females typically have a worse response to TNF-α inhibitors than males Rusman et al. 2017.	Thank you for your comment. This will be included on the Equalities Impact Assessment form for this appraisal.
	Novartis	No comment	No action required

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Questions for consultation	AbbVie	No comments	No action required
	UCB Pharma	No comments	No action required
	Novartis (non radiographic axial spondyloarthritis)	Where do you consider bimekizumab will fit into the existing care pathway for non-radiographic axial spondyloarthritis? **Novartis: We would expect bimekizumab to be positioned alongside other treatments recommended by NICE for treating non-radiographic axial spondyloarthritis?** Are the comparators and outcomes for bimekizumab considered appropriate? **Novartis: See above.** Would bimekizumab be a candidate for managed access? **Novartis: No comment.** Do you consider that the use of bimekizumab can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation? **Novartis: No comment.** Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.	Thank you for your further comments. These will be considered during the appraisal process.

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		Novartis: No comment. 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: • could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which bimekizumab will be licensed; **Novartis: No comment.** • 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; **Novartis: No comment.** • could have any adverse impact on people with a particular disability or disabilities. **Novartis: No comment.** NICE intends to evaluate this technology through its Single Technology Appraisal process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on NICE's health technology evaluation processes is available at	

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		https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation). NICE's health technology evaluations: the manual states the methods to be used where a cost comparison case is made. • Would it be appropriate to use the cost-comparison methodology for this topic **Novartis: Given the range of subpopulations within the remit of the appraisal, we consider the STA process will be more appropriate than a cost comparison.** • Is the new technology likely to be similar in its clinical efficacy and resource use to any of the comparators? **Novartis: No comment.** • Is the primary outcome that was measured in the trial or used to drive the model for the comparators still clinically relevant? **Novartis: No comment.** • Is there any substantial new evidence for the comparator technologies that has not been considered? Are there any important ongoing trials reporting in the next year? **Novartis: No comment.**	

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	Novartis (ankylosing spondylitis)	**Questions for consultation** Do you consider the population of adults with moderate-to-severe active ankylosing spondylitis to be appropriate for this appraisal? **Novartis: No comment.** Where do you consider bimekizumab will fit into the existing care pathway for active ankylosing spondylitis? **Novartis: We would expect bimekizumab to be positioned alongside other treatments recommended by NICE for treating ankylosing spondylitis.** Would bimekizumab be a candidate for managed access? **Novartis: No comment.** Do you consider that the use of bimekizumab can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation? **Novartis: No comment.** Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits. **Novartis: No comment.**	Thank you for your further comments. These will be considered during the appraisal process.

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		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: • **could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which bimekizumab will be licensed;** **Novartis: No comment.** • **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;** **Novartis: No comment.** • **could have any adverse impact on people with a particular disability or disabilities.** **Novartis: No comment.** NICE intends to evaluate this technology through its Single Technology Appraisal process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on NICE's health	

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		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). NICE's health technology evaluations: the manual states the methods to be used where a cost comparison case is made. • Would it be appropriate to use the cost-comparison methodology for this topic? **Novartis: Given the range of subpopulations within the remit of the appraisal, we consider the STA process will be more appropriate than a cost comparison.** • Is the new technology likely to be similar in its clinical efficacy and resource use to any of the comparators? **Novartis: No comment.** • Is the primary outcome that was measured in the trial or used to drive the model for the comparators still clinically relevant? **Novartis: No comment.** • Is there any substantial new evidence for the comparator technologies that has not been considered? Are there any important ongoing trials reporting in the next year?	

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		Novartis: Abstract entitled: '*Secukinumab 150 mg improves signs and symptoms of active ankylosing spondylitis in TNF inhibitor (TNFi)-naïve patients and those previously exposed to TNFi therapy***' submitted to BSR 2023. Contains data from MEASURE 1 and MEASURE 2 trial.** **Decision on whether this submission will be published & presented at BSR 2023 expected to be received in JAN 2023**	

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

NASS