National Institute for Health and Care Excellence

Cost Comparison Appraisal

Bimekizumab for treating active psoriatic arthritis [ID4009]

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	UCB	UCB will submit using the STA cost-comparison route.	Thank you for your comment. No change to scope required.
	Novartis	We consider the proposed appraisal & evaluation route suggested as appropriate.	Thank you for your comment. No change to scope required.
	Psoriasis and Psoriatic Arthritis Alliance	Yes, it's appropriate [to refer this topic for evaluation].	Thank you for your comment. No change to scope required.
Wording	Psoriasis and Psoriatic Arthritis Alliance	Reflects the condition. Although a clear steer to what is classed a 'best supportive care' would be helpful.	Thank you for your comment. Best supportive care is a standard term used in NICE scopes to define

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			any treatment provided other than the specific comparator treatments listed. No change to scope required.
	Psoriasis Association	Yes [the wording of the remit is appropriate].	Thank you for your comment. No change to scope required.
Timing issues	Psoriasis Association	Not urgent owing to no marketing authorisation yet. However there remains unmet need for many people suffering from PsA and so all new therapies coming to the market are welcomed by patients. We would welcome an appraisal at the earliest stage NICE can accommodate it within its work programme. However, owing to the use of Bimekizumab in psoriasis, it may be considered a candidate for managed access.	Thank you for your comment. NICE has scheduled this topic into its work programme. No change to scope required.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Janssen	We have noticed that the recommended population for risankizumab has not been fully described as per guidance in NICE TA803 and additionally this has not been reflected in the appropriate comparator lists.	Thank you for your comment. The background section of the scope aims to provide a brief summary of the disease and how it is managed, it is not intended to be exhaustive in its detail.

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			The guidance for risankizumab has been described accurately as being recommended for people with moderate to severe psoriasis, but without the detailed criteria regarding the percentage of body surface area affected or PASI score. No change to scope required.
	Abbvie	There is an error in paragraph 5 of the background information. Its states: "…*upadacitinib are recommended when a person has peripheral arthritis with 3 or more tender joints and 3 or more swollen joints, moderate to severe psoriasis and their disease has not responded well enough to, or they cannot tolerate, 2 conventional DMARDs and at least 1 biological DMARD, and when treatment with TNF-alpha inhibitors is contraindicated but would otherwise be considered*…" This is not the correct NICE recommendation for upadacitinib and should instead state: "…*upadacitinib are recommended when a person has peripheral arthritis with 3 or more tender joints and 3 or more swollen joints and their disease has not responded well enough to, or they cannot tolerate, 2 conventional DMARDs and at least 1 biological DMARD, and when treatment with TNF-alpha inhibitors is contraindicated but would otherwise be considered*" (TA768)	Thank you for your comment. The background section of the scope has been updated to reflect this.

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	Psoriasis and Psoriatic Arthritis Alliance	The prevalence is probably higher than 1 in 5. More likely 1 in 4, which is the conclusion in the paper *Alinaghi F, Calov M, Kristensen LE, Gladman DD, Coates LC, Jullien D, Gottlieb AB, Gisondi P, Wu JJ, Thyssen JP, Egeberg A. Prevalence of psoriatic arthritis in patients with psoriasis: A systematic review and meta-analysis of observational and clinical studies. J Am Acad Dermatol. 2019 Jan;80(1):251-265.e19. doi: 10.1016/j.jaad.2018.06.027. Epub 2018 Jun 19. PMID: 29928910*.	Thank you for your comment. This paper cites a prevalence of PsA in patients with psoriasis of 19.7% overall, and 19.4% for the UK. No change to scope required, but the reference has been added.
Population	UCB	The population in the scope is appropriate.	Thank you for your comment. No change to scope required.
	Psoriasis and Psoriatic Arthritis Alliance	Yes, assuming it matches the licence indication.	Thank you for your comment. No change to scope required.
	Psoriasis Association	Yes – the population is defined appropriately to our knowledge. As ever with PsA some consideration may be given to concomitant skin psoriasis involvement, however severity of skin involvement does not correlate with severity of joint involvement therefore one should not depend on the other for access to relevant therapies.	Thank you for your comment. Please see response to UCB regarding subgroups in the section below. No change to scope required.
Subgroups	UCB	An important subgroup in PsA is patients with plaque psoriasis. As the majority of PsA patients have plaque psoriasis prior to developing PsA, the effectiveness of treatments on PSO symptoms will be part of UCB's efficacy analysis in the company submission.	Thank you for your comment. Possible subgroups to be

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			considered have been added to the scope.
	Abbvie	1. For the last subgroup in the draft scope: For people whose disease has not responded adequately to conventional DMARDs and 1 or more biological DMARDs, or for whom these are not tolerated: • Guselkumab • Risankizumab • Best supportive care • Upadacitinib Please remove Risankizumab from this subgroup 2. Risankizumab NICE recommendation For people whose disease has not responded well enough to 2 conventional DMARDs and at least 1 biological DMARD, only if they have moderate to severe psoriasis (a body surface area of at least 3% affected by plaque psoriasis and a Psoriasis Area and Severity Index [PASI] score greater than 10)	Thank you for your comment. The comparator section of the scope has been updated to reflect this.
	Psoriasis and Psoriatic Arthritis Alliance	In those with psoriasis too.	Thank you for your comment. Possible subgroups to be considered have been added to the scope.
Comparators	UCB	Tofacitinib has restrictions based on an 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 suitable treatment alternatives." Tofacitinib should not be assessed outside of the population allowed by the MHRA black label warning.	Thank you for your comment. The scope lists all possible comparators for each subgroup, and is intended to be broadly

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		Similarly, 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 above. 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. The JAK inhibitors, tofacitinib and upadacitinib, should be clearly limited to this subgroup in the scope.	inclusive of all possible comparators currently recommended as treatment options. No change to scope required. Thank you for your comment. The background section of the scope correctly specifies the guidance restrictions for risankizumab. The comparator section is a

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		We note that TA803 risankizumab guidance limits risankizumab to people with “moderate to severe psoriasis (a body surface area of at least 3% affected by plaque psoriasis and a Psoriasis Area and Severity Index [PASI] score greater than 10)”. The scope should reflect these restrictions on risankizumab.	summary list that does not include this level of detail. No change to scope required.
	Janssen	As correctly described in the background section and based on NICE Technology appraisal guidance 815, guselkumab is recommended when a person has active psoriatic arthritis and their disease has not responded well enough to, or they cannot tolerate, 2 conventional DMARDs and at least 1 biological DMARD or when treatment with tumour necrosis factor (TNF)-alpha inhibitors are contraindicated but would otherwise be considered. Based on the above, guselkumab should be additionally included as a comparator in the group after 1 or more TNF-alpha inhibitors; therefore, please include guselkumab to the following group: For people whose disease has not responded adequately to conventional DMARDs and 1 or more TNF-alpha inhibitors.	Thank you for your comment. The recommendation in TA815 is when TNF-alpha inhibitors are contraindicated, not for when the disease has not responded adequately to TNF-alpha inhibitors. No change to scope required.
	Abbvie	For the first subgroup in the draft scope: For people whose disease has not responded adequately to at least 2 conventional DMARDs: • Biological DMARDs (with or without methotrexate including etanercept, adalimumab, infliximab, golimumab, certolizumab pegol, ixekizumab and secukinumab) • Apremilast • Tofacitinib • Upadacitinib	Thank you for your comment. The order of treatments in this summary list is not intended to represent clinical practice. No change to scope required.

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		As per clinical practice, TNF inhibitors are the dominant comparator in this subgroup	
	Psoriasis Association	Yes [the comparators are appropriate].	Thank you for your comment. No change to scope required.
	Psoriasis and Psoriatic Arthritis Alliance	Yes, looks to cover the range of comparators, a clear idea of what is classed as 'best supportive care' would be helpful.	Thank you for your comment. Please refer to response in the 'wording' section above. No change to scope required.
Outcomes	UCB	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. No change to scope required.
	Psoriasis Association	Pain is not listed as a separate outcome measure, but is of great importance to patients. Fatigue is also an area of concern for patients – is this covered under 'health-related quality of life'?	Thank you for your comment. The outcomes are kept broad to allow flexibility. The list is not intended to be exhaustive. Pain is covered by ACR response under disease activity outcomes. Fatigue is considered to be covered under 'health-related quality of

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			life. No change to scope required.
	Psoriasis and Psoriatic Arthritis Alliance	Pain score? Psychological impact of chronic disease? Fatigue is a common symptom, so might to be useful to identify the scoring test that will cover those too, such as PsArc. There is an old publication that lists these. *Wong PC, Leung YY, Li EK, Tam LS. Measuring disease activity in psoriatic arthritis. Int J Rheumatol. 2012;2012:839425. doi: 10.1155/2012/839425. Epub 2012 Dec 25. PMID: 23319952; PMCID: PMC3540792.* Also a literature review paper from 2018 *Tucker LJ, Coates LC, Helliwell PS. Assessing Disease Activity in Psoriatic Arthritis: A Literature Review. Rheumatol Ther. 2019 Mar;6(1):23-32. doi: 10.1007/s40744-018-0132-4. Epub 2018 Nov 23. PMID: 30471015; PMCID: PMC6393266.*	Thank you for your comment. Please see the response to Psoriasis Association above. No change to scope required.
Equality	Psoriasis and Psoriatic Arthritis Alliance	Nothing that is part of the current legislation. Although a wider point might be to look at the changing identification of the population and see if those match inclusion/exclusion criteria for the trial and subsequent recommendation.	Thank you for your comment. No change to scope required.
Other considerations	Psoriasis and Psoriatic Arthritis Alliance	How affective is the drug in pre-menopausal woman. It could be argued that without data it that group, there is no efficacy data to make a recommendation, therefore potential for discrimination?	Thank you for your comment. No change to scope required.
	Psoriasis Association	The performance of the homecare delivery company proposed to be used by the manufacturer (or real-world experience of the performance of homecare delivery companies used by the manufacturer). Drugs can only work if patients receive them and are educated in their use in a timely fashion. Poor performance in this area renders the drug ineffective and the cost analysis inappropriate when looking at time to respond, maintenance of response etc.	Thank you for your comment. No change to scope required.
Questions for consultation	Novartis	Where do you consider bimekizumab will fit into the existing care pathway for active psoriatic arthritis?	

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		Novartis: We would expect bimekizumab to be positioned alongside other treatments recommended by NICE for psoriatic arthritis, i.e., for patients whose disease has not responded to adequate trials of at least 2 standard DMARDs. 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.**	Thank you for your comment. No change to scope required. Thank you for your comment. No change to scope required.
	Psoriasis and Psoriatic Arthritis Alliance	*Where do you consider bimekizumab will fit into the existing care pathway for active psoriatic arthritis?* **Same position as current similar technologies.** *Would bimekizumab be a candidate for managed access?* **No** *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?* **Already approved in psoriasis, so combined benefit with psoriatic arthritis could help with cost effectiveness**.	Thank you for your comment. No change to scope required. Thank you for your comment. No change to scope required.