National Institute for Health and Care Excellence

Single Technology Appraisal (STA)

Risankizumab for previously treated active psoriatic arthritis

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	AbbVie	Yes, it is appropriate to refer this topic for appraisal.	Thank you for your comment. No action required.
	Novartis	We consider the proposed appraisal appropriate.	Thank you for your comment. No action required.
	Psoriasis and Psoriatic Arthritis Alliance	Yes [it is appropriate to refer this topic for appraisal].	Thank you for your comment. No action required.
	Psoriasis Association	Yes [it is appropriate to refer this topic for appraisal].	Thank you for your comment. No action required.
Wording	AbbVie	Yes, the wording of the remit is appropriate.	Thank you for your comment. No action required.

Section	Consultee/ Commentator	Comments [sic]	Action
	Novartis	No comment	Thank you. No action required.
	Psoriasis and Psoriatic Arthritis Alliance	The wording is appropriate.	Thank you for your comment. No action required.
	Psoriasis Association	Yes [the wording of the remit reflects the issues of clinical and cost effectiveness about this technology or technologies that NICE should consider].	Thank you for your comment. No action required.
Timing Issues	AbbVie	No comment	Thank you. No action required.
	Novartis	No comment	Thank you. No action required.
	Psoriasis and Psoriatic Arthritis Alliance	No particular urgency [of this appraisal to the NHS].	Thank you for your comment. No action required.
	Psoriasis Association	Not urgent, 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.	Thank you for your comment. NICE has scheduled this topic into its work programme. No action required.
Additional comments on	AbbVie	N/A	Thank you. No action required.

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the draft remit	Novartis	No comment	Thank you. No action required.
	Psoriasis and Psoriatic Arthritis Alliance	N/A	Thank you. No action required.
	Psoriasis Association	N/A	Thank you. No action required.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	AbbVie	No comment	Thank you. No action required.
	Novartis	No comment	Thank you. No action required.
	Psoriasis and Psoriatic Arthritis Alliance	I don't think the background has reflected the impact that psoriatic arthritis has on an individual, their family and carers. Disability is possible and that can affect many aspects of an individual's life, not least education and the ability to work. Relationships and future plans are all restricted by having an arthritis. Pain and fatigue are symptoms that bother patients. 50% of those with psoriatic arthritis have nail involvement, which along with the psoriatic arthritis creates many issues with dexterity, and can create many problems related to personal care, dressing and basic activities, where hands are needed. Grip or lack of, also creates issues such as holding items and	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

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		fundamental tasks needed in a modern world, including the use of keyboards or switches. All of these restrictions cause frustration and make individuals feel helpless and dependent on other's help, which in turn causes a psychological impact.	detail. No changes were made to the scope.
	Psoriasis Association	N/A	Thank you. No action required.
The technology/ intervention	AbbVie	Yes [the description of the technology is accurate].	Thank you for your comment. No action required.
	Novartis	No comment	Thank you. No action required.
	Psoriasis and Psoriatic Arthritis Alliance	Yes [the description of the technology is accurate].	Thank you for your comment. No action required.
	Psoriasis Association	N/A	Thank you. No action required.
Population	AbbVie	AbbVie request that this wording be updated to be consistent with the wording used in recent appraisals, as follows: 'Adults with active psoriatic arthritis whose disease has not responded adequately to previous biological therapies or conventional synthetic DMARDs, or for whom biological therapies or conventional synthetic DMARDs are not tolerated or for whom DMARDs are contraindicated'.	Thank you for your comment. The scope has been updated.
	Novartis	No comment	Thank you. No action required.

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	Psoriasis and Psoriatic Arthritis Alliance	Yes [the population is defined appropriately].	Thank you for your comment. No action 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	Thank you for your comment. The presence or severity of concomitant psoriasis has been already included in the 'Other considerations' section. No action required.
Comparators	AbbVie	Section 6.2 of the NICE methods guide states that "the Committee will normally be guided by established practice in the NHS when identifying the appropriate comparator(s)". The draft scope currently includes upadacitinib and guselkumab, both of which are currently being appraised by NICE. Please note that these medicines are not established NHS practice and should therefore not be regarded as comparators.	Thank you for your comment. The comparators listed in the scope represent treatments used for previously treated psoriatic arthritis in NHS clinical practice. These comparators are consistent with previous scopes, including the scope for guselkumab and the ongoing appraisal of upadacitinib

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			(ID2690). Guselkumab, is now recommended for previously treated psoriatic arthritis in NICE Technology Appraisal 711. The scope has been updated to reflect this. Upadacitinib may be an established treatment option by the time of the first committee discussion of risankizumab. Upadacitinib has therefore been included as a comparator, subject to ongoing NICE appraisal.
	Novartis	No comment	Thank you. No action required.
	Psoriasis and Psoriatic Arthritis Alliance	Yes [these are the standard treatments currently used in the NHS with which the technology should be compared].	Thank you for your comment. No action required.

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	Psoriasis Association	Yes these are the standard treatments. No one alternative can be described as 'best supportive care' owing to the individual needs of patients (co-morbidities, suitability and tolerability of the treatments)	Thank you for your comment. No action required.
Outcomes	AbbVie	No comment	Thank you. No action required.
	Novartis	No comment	Thank you. No action required.
	Psoriasis and Psoriatic Arthritis Alliance	Perhaps include nail scores and any benefit to psoriasis	Thank you for your comment. The outcomes are kept broad to allow flexibility. Therefore, nail scores have not been included in the scope specifically. Additionally, subgroups by presence or severity of concomitant psoriasis have been included in the 'Other considerations' section. No change was made to the scope.
	Psoriasis	Pain is not listed as a separate outcome measure, but is of great	Thank you for your

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	Association	importance to patients. Fatigue is also an area of concern for patients – is this covered under 'health-related quality of life'?	comment. Pain is covered by ACR response under disease activity outcomes. Fatigue is considered to be covered under 'health-related quality of life. No changes were made to the scope.
Economic analysis	AbbVie	No comment	Thank you. No action required.
	Novartis	No comment	Thank you. No action required.
	Psoriasis and Psoriatic Arthritis Alliance	No comments	Thank you. No action required.
	Psoriasis Association	N/A	Thank you. No action required.
Equality and Diversity	AbbVie	No comment	Thank you. No action required.
	Novartis	No comment	Thank you. No action required.

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	Psoriasis and Psoriatic Arthritis Alliance	None under the legislation.	Thank you for your comment. No action required.
	Psoriasis Association	N/A	Thank you. No action required.
Other considerations	AbbVie	No comment	Thank you. No action required.
	Novartis	No comment	Thank you. No action required.
	Psoriasis and Psoriatic Arthritis Alliance	None	Thank you. No action required.
	Psoriasis Association	N/A	Thank you. No action required.
Innovation	AbbVie	Risankizumab belongs to a new class of targeted medicines for PsA called interleukin-23 (IL-23) inhibitors that selectively block IL-23 by binding to its p19 subunit. IL-23 is a driver of bone erosion, synovitis and enthesitis, which causes symptoms and disability in PsA. The KEEPsAKE-1 and KEEPsAKE-2 Phase 3 trial results demonstrate improvements in disease activity across joint and skin symptoms among Psoriatic Arthritis (PsA) patients. In these studies, the rates of patients discontinuing risankizumab were very low (<1%) and the safety profile of Risankizumab through week 24 was	Thank you for your comment. The appraisal committee will consider the extent to which risankizumab is innovative in its decision making. No action required.

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		generally consistent with safety findings in previous studies in psoriasis. Risankizumab provides increased treatment options. The heterogeneity of psoriatic arthritis and the presence of comorbidities means that there is not a “one size fits all” in terms of which treatment will work for patients, for how long and with manageable side effects. The limitations of current treatment classes include the negative impact of IL-12 inhibition on host immunity; the cardiac and other contraindications associated with Anti-TNFs; the inability to use IL-17 inhibitors in patients with co-existing inflammatory bowel diseases (IBD) such as Crohn’s disease and ulcerative colitis due to contraindications. The innovative potential of Risankizumab in psoriatic arthritis can be summarised as follows: • **Unique Mechanism of Action** targeting IL-23. Of note is that IL-23 inhibitors are not the same: differences in binding affinity, half life and efficacy have been demonstrated. • Risankizumab has demonstrated **improvement in both joint and skin** symptoms, which is important for a chronic life-long condition such as PsA, requiring therapies with long-lasting efficacy. **Reduced Dosing Frequency**: Risankizumab will be the only IL-23 inhibitor licensed in PsA with **12 weekly** (i.e. just 4 injections a year) maintenance dosing administered with one injection. This may improve treatment adherence when compared to other biologics which are given weekly or fortnightly.	
	Novartis	No comment	Thank you. No action required.

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	Psoriasis and Psoriatic Arthritis Alliance	None	Thank you. No action required.
	Psoriasis Association	At the time of submitting this response, there is not another IL-23 antibody approved for use in PsA, therefore it is targeting a different chemical pathway so could be considered to be innovative.	Thank you for your comment. The appraisal committee will consider the extent to which risankizumab is innovative in its decision making. No action required.
Questions for consultation	AbbVie	N/A	Thank you. No action required.
	Novartis	No comment	Thank you. No action required.
	Psoriasis and Psoriatic Arthritis Alliance	Nothing further to add	Thank you. No action required.
	Psoriasis Association	N/A	Thank you. No action required.
Additional comments on the draft scope	AbbVie	The draft scope includes some information on the **burden of disease** and this is further elaborated as follows: • The burden of the psoriasis aspect of psoriatic arthritis is often	Thank you for your comment. The background section of the scope aims to

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		underestimated, and the efficacy in managing the skin aspect of psoriatic arthritis directly affects HRQoL. • Patients with skin involvement in PsA possess significantly worse patient global assessment scores and increased healthcare resource ultilization.[1] • The burden of PsA affecting enthesitis/dactylitis leads to significant reduction of QoL • Patients with psoriatic arthritis have a higher incidence of co-morbid conditions. Inflammatory Bowel Disease (IBD) rates are higher in patients with psoriatic arthritis. • PsA is a lifelong chronic disease in which patients go on to fail current advanced therapies. Risankizumab provides data in patients as a first line advanced therapy and after advanced therapy failures, thereby increasing the range of treatment options for patients with this lifelong, relapsing and remitting disease. 1.Rheumatol Ther. 2018 Dec; 5(2): 423–436. Published online 2018 Jul 6. doi: 10.1007/s40744-018-0120-8	provide a brief summary of the disease and how it is managed, it is not intended to be exhaustive in its detail. No changes were made to the scope.
	Novartis	No comment	Thank you. No action required.
	Psoriasis and Psoriatic Arthritis Alliance	No [additional comments].	Thank you. No action required.

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	Psoriasis Association	N/A	Thank you. No action required.

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

Amgen
Pfizer