National Institute for Health and Care Excellence

Health Technology Evaluation

Risankizumab for people with previously treated moderately to severely active ulcerative colitis [ID6209]
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	The company does not currently possess the necessary data to confirm the appropriateness of evaluating the topic through the cost comparison process. As such, the appropriate evaluation route is single technology appraisal.	Thank you for your comment. This has been scheduled as a single technology appraisal. No change needed.
	Crohn's & Colitis UK	We agree with the appropriateness and the appraisal route.	No change needed.
Wording	AbbVie	Please align the remit to the current marketing authorisation: [redacted]	Thank you for your comment. The wording of the draft remit has been updated to align with the population in the clinical trials.

Section	Stakeholder	Comments [sic]	Action
	Crohn's & Colitis UK	Yes. Currently, there are limited treatment options available in treating moderate to severe ulcerative colitis. It is important that patients have the widest possible options available to them, particularly given what we are increasingly coming to understand in terms of the importance of personalised treatments.	Thank you for your comment. No change needed.
Additional comments on the draft remit	AbbVie	The timing of this evaluation is appropriate.	No change needed.
	Crohn's & Colitis UK	Considering Covid-19 backlog and elective recovery, there is a benefit to an additional treatment option that can be administered at home to potentially reduce infection risk and pressure on the NHS (i.e. outpatient appointments, day cases and workforce).	Thank you for your comment. No change needed.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	AbbVie	The information in the background section is accurate. We would like to add that the aim of treatment, in addition to addressing "symptoms of bloody diarrhoea, urgent need to defecate and abdominal pain, and thereafter to maintain remission", is also mucosal healing, which is measured by endoscopic outcomes.	Thank you for your comment. The wording in the background information section has been updated.
	Crohn's & Colitis UK	We welcome the recognition that people with IBD are affected by more than just their bowel symptoms. We are pleased to see NICE include fatigue and anaemia as these symptoms are often overlooked, despite the significant impact they have on people's lives. Care for ulcerative colitis has moved towards delivering personalised care and support, and not just remission, with a greater focus on the holistic needs of people with ulcerative colitis, including dietetic and psychological support.	Thank you for your comment. This technology appraisal scope includes the most up to date NICE guideline. The scope is intended to give a broad

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		We would point out that the current guideline for ulcerative colitis is not aligned with the IBD Standards or the most up-to-date British Society of Gastroenterology IBD guideline.	overview of the condition and treatment pathway. It is anticipated that established practice for this condition will be further discussed in the appraisal.
Population	AbbVie	We propose wording the population in the same way as the anticipated label. Please amend to the following: [redacted]	Thank you for your comment. The wording of the population has been updated to align with the population in the clinical trials.
	Crohn's & Colitis UK	We agree with the population included in the scope	No change needed.
Subgroups	AbbVie	No comment	No change needed.
	Crohn's & Colitis UK	We agree with the sub-groups included in the scope	No change needed.
Comparators	AbbVie	A comparison with conventional therapies is not required, as risankizumab would be an option for patients who had an inadequate response to or were intolerant to conventional therapy. We also recommend that etrasimod and mirikizumab are not included as comparators, as they are currently not approved for use in, or considered standard of care for, patients with moderately to severely active ulcerative colitis.	Thank you for your comment. Conventional therapy as a comparator has been removed from the scope. Identifying comparators should be inclusive. Hence, etrasimod and

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			mirikizumab are included subject to ongoing NICE evaluations, in line with the current methods for technology appraisal.
	Crohn's & Colitis UK	We would ask the Committee to remove steroids. Steroids are not recommended for maintenance of remission and are associated with a range of side effects (BSG IBD Guideline and IBD Standards 2019)	Thank you for your comment. We have removed conventional therapy as a comparator.
Outcomes	AbbVie	The outcomes listed are broadly appropriate. We propose adding histologic-endoscopic mucosal improvement (HEMI) to the list of outcomes. In addition, we recommend removing 'relapse', as there is no specific outcome measure for relapse within the clinical trials. We also propose the removal of 'nephrotoxicity' from the list, as it was not an adverse event of special interest.	Thank you for your comments. Nephrotoxicity has been removed from the scope as it will be captured in adverse effects of treatment. It is also anticipated that HEMI will be captured in rate of endoscopic improvement.
	Crohn's & Colitis UK	We welcome the inclusion of corticosteroid-free remission in the proposed outcomes. We would ask the Committee to consider additions of: • Patient experience and outcomes • Improved medicine adherence and self-management	Thank you for your comments. The committee will welcome comments from patients regarding their experience through the

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		We also welcome the inclusion of the rate of hospitalisation in the proposed outcomes and encourage the Committee to consider the rate of readmission and emergency admissions within this measure.	appraisal process. No changes made.
Equality	AbbVie	No comment	No change needed.
	Crohn's & Colitis UK	The mode of administration is a benefit for those with disabilities and remote communities in terms of reducing the need for travel to hospital and could potentially improve adherence.	Thank you for your comment. No change needed.
Other considerations	AbbVie	No comment	No change needed.
	Crohn's & Colitis UK	None	No change needed.
Questions for consultation	AbbVie	**Where do you consider risankizumab will fit into the existing care pathway for ulcerative colitis?** We anticipate risankizumab to be used within its marketing authorisation, after conventional therapy, as an alternative to advanced therapies (TNF-alpha inhibitors, JAK inhibitors, ustekinumab, vedolizumab, ozanimod). **Is there a preferred treatment sequence with biologics and/or other advanced therapies (e.g. JAK inhibitors or ozanimod) after an inadequate response or intolerance to conventional therapy?** There are no preferred treatment sequences. **Should conventional therapy with aminosalicylates, oral corticosteroids and/or immunomodulators be considered a comparator in the evaluation?** Conventional therapy should not be considered a comparator in this evaluation.	Thank you for your responses. The scope has been updated, where required.

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		The trial included people who had intolerance or an inadequate response to tofacitinib. Would risankizumab be used after other JAK inhibitors or ozanimod? Risankizumab is expected to be used within its marketing authorisation, after conventional therapy, as an alternative to advanced therapies (TNF-alpha inhibitors, JAK inhibitors, ustekinumab, vedolizumab, ozanimod). **Would risankizumab be a candidate for managed access?** It would not likely be a candidate. **Do you consider that the use of risankizumab can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?** The use of risankizumab could result in benefits in patients who suffer from additional inflammatory conditions, for which risankizumab is also licenced. **Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.** **NICE's health technology evaluations: the manual states the methods to be used where a cost comparison case is made.** • **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?** • **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.**	

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		• **Will the intervention be used to treat the same population as the comparator(s)?** • **Overall is the technology likely to offer similar or improved health benefits compared with the comparators?** • **Would it be appropriate to use the cost-comparison methodology for this topic?** As described above, the company does not possess the necessary data to comment on the cost-comparison approach at this stage. As such, the appropriate evaluation route is single technology appraisal.	
	Crohn's & Colitis UK	None	No change needed.
Additional comments on the draft scope	AbbVie	None	No change needed.
	Crohn's & Colitis UK	None	No change needed.

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

Janssen