National Institute for Health and Care Excellence

Health Technology Evaluation

Mirikizumab for treating moderately to severely active Crohn's disease [ID6244]
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	Eli Lilly	Lilly consider this topic appropriate for referral to NICE for appraisal.	Thank you for your comment. Mirikizumab has been selected to be appraised as a cost comparison.
	Crohn's and Colitis UK	The NICE guideline on Crohn's Disease and Quality Standard on Inflammatory Bowel Disease are outdated and do not reflect current best practices and the experience of people with Crohn's Disease. We would ask that NICE update the guideline and quality standard urgently given it is the basis on which this drug will be appraised.	Thank you for your comment. Mirikizumab will be appraised independently of the NICE guideline on Crohn's Disease and the quality standard on inflammatory bowel disease.

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	Abbvie	No comment	No changes to the scope required.
	Janssen	This technology may be appropriate for appraisal via a NICE PATT (cost comparison) route, in line with recent appraisals in Crohn's Disease (TA888, TA905)	Thank you for your comment. Mirikizumab has been selected to be appraised as a cost comparison.
Wording	Eli Lilly	The wording of the remit is appropriate.	Thank you for your comment. No changes to the scope required.
	Crohn's and Colitis UK	No comments	No changes to the scope required.
	Abbvie	No comments	No changes to the scope required.
	Janssen	No comments	No changes to the scope required.
Timing Issues	Eli Lilly	Crohn's disease (CD) is recognised as an incurable, relapsing-remitting disease, with a considerable burden on patient health-related quality of life (HRQoL).[1-4] Current treatment paradigms are unsatisfactory in addressing the continued unmet need in the CD patient population, with key concerns being the suboptimal treatment outcomes,[5, 6] and the continued experience of severe symptoms despite treatment.[7-10] Additionally, patients may be contraindicated to certain treatment options e.g. tumour necrosis factor-α	Thank you for your comment. NICE has scheduled this topic into its work programme as a cost comparison. For further details, please see the NICE website:

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		(TNFα) inhibitors, and the number of potential treatment options are markedly reduced for these patients. Mirikizumab provides effective and tolerable management of moderate to severe CD and would represent an additional treatment option for this population of patients. Therefore, Lilly considers that timely NICE guidance for the use of mirikizumab in CD would be valuable to patients and to the National Health Service (NHS).	https://www.nice.org.uk/guidance/indevelopment/gid-ta11267 No changes to the scope required.
	Crohn's and Colitis UK	There are limited treatment options available in treating moderate to severe Crohn's disease. 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. NICE has scheduled this topic into its work programme as a cost comparison. For further details, please see the NICE website: https://www.nice.org.uk/guidance/indevelopment/gid-ta11267 No changes to the scope required.
	Abbvie	No comments	No changes to the scope required.
	Janssen	No comments	No changes to the scope required.

Section	Stakeholder	Comments [sic]	Action
Additional comments on the draft remit	Eli Lilly	Lilly has no further comments on the draft remit.	No changes to the scope required.
	Crohn's and Colitis UK	No comments	No changes to the scope required.
	Abbvie	No comments	No changes to the scope required.
	Janssen	No comments	No changes to the scope required.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Eli Lilly	Lilly has no comments on the background information in the draft scope, and consider it an accurate description of the disease background and treatment landscape.	Thank you for your comment. No changes to the scope required.
	Crohn's and Colitis UK	We welcome the inclusion of research commissioned by Crohn's & Colitis UK which estimates that over 500,000 or 1 in 123 people are living with Inflammatory Bowel Disease in the UK, with 1 in 3 diagnosed before the age of 30. We also welcome the references to the impact living with Crohn's Disease can have on quality of life, as the aim of treatment is for people to live their best-possible lives, not just achieve remission.	Thank you for your comment. The background section of the scope provides a brief overview of the disease. More detailed information will be provided at the submission stage.

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		We would welcome further consideration about whether there may be circumstances in which a person with severe Crohn's disease requiring intensive inpatient treatment may benefit from this treatment, in conjunction with other interventions. As currently written the background does not capture the significant unmet need for treatments within this patient cohort.	The remit of this appraisal is to evaluate mirikizumab within its anticipated marketing authorisation. No changes to the scope required.
	Abbvie	No comments	No changes to the scope required.
	Janssen	No comments	No changes to the scope required.
Population	Eli Lilly	The anticipated label for mirikizumab is as follows: [redacted] Therefore, Lilly suggests amending the wording of the proposed population wording to: "Adults with moderate to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic treatment."	Thank you for your comment. The population wording in the scope has been amended as suggested.
	Crohn's and Colitis UK	No comments	No changes to the scope required.

Section	Consultee/ Commentator	Comments [sic]	Action
	Abbvie	No comments	No changes to the scope required.
	Janssen	No comments	No changes to the scope required.
Subgroups	Eli Lilly	Lilly has no comments on the presented subgroups.	Thank you for your comment. Subgroups have been removed following the decision to appraise mirikizumab as a cost comparison.
	Crohn's and Colitis UK	No comments	No changes to the scope required.
	Abbvie	No comments	No changes to the scope required.
	Janssen	No comments	No changes to the scope required.
Comparators	Eli Lilly	Lilly understand that "best supportive care" is more typically referred to as "conventional therapy" in the CD treatment pathway. In alignment with this, and with its use elsewhere in the draft scope, Lilly suggest that any discussion of "best supportive care" in the scope be updated to "conventional therapy". However, as per the anticipated label and as described in the "Population" section above, it is anticipated that mirikizumab will be positioned after	Thank you for your comment. Conventional therapy is not listed as a comparator in the scope because it is anticipated that mirikizumab will be

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		conventional therapy, which is typically prescribed as a first-line treatment for moderate to severely active CD. Therefore, Lilly do not consider that conventional therapy (currently termed “best supportive care”) will be a relevant comparator at the anticipated positioning. All other comparators listed are considered appropriate for this appraisal.	indicated after at least 1 previous therapy. The scope has been amended to remove “best supportive care” from the list of comparators.
	Crohn’s and Colitis UK	No comments	No changes to the scope required.
	Abbvie	No comments	No changes to the scope required.
	Janssen	Should this technology be appraised via a PATT cost comparison route, it may be appropriate to restrict the comparators to other branded medications currently approved and recommended by NICE for Crohn’s disease in patients (e.g. risankizumab and vedolizumab).	Thank you for your comment. Best supportive care has been removed from the list of comparators following the decision to appraise mirikizumab as a cost comparison.
Outcomes	Eli Lilly	Lilly agree that the outcomes listed are appropriate.	Thank you for your comment. No changes to the scope required.

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	Crohn's and Colitis UK	We agree with the outcome measures presented, in particular the health-related quality of life. We would welcome consideration of patient experiences and improved medicine adherence.	Thank you for your comment. The list of outcomes is not intended to be exhaustive at this stage. Where relevant, the organisation is welcome to provide the evidence on all outcomes that are important for people with the condition during the evaluation. No changes to the scope required.
	Abbvie	No comments	No changes to the scope required.
	Janssen	No comments	No changes to the scope required.
Equality	Eli Lilly	No equality issues have been identified.	Thank you for your comment. No changes to the scope required.
	Crohn's and Colitis UK	No comments	No changes to the scope required.

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	Abbvie	No comments	No changes to the scope required.
	Janssen	No comments	No changes to the scope required.
Other considerations	Eli Lilly	No additional comments.	No changes to the scope required.
	Crohn's and Colitis UK	No comments	No changes to the scope required.
	Abbvie	No comments	No changes to the scope required.
	Janssen	No comments	No changes to the scope required.
Questions for consultation	Eli Lilly	**1. Where do you consider mirikizumab will fit into the existing care pathway for Crohn's disease? Would it be used as an alternative to:** • **Tumour necrosis factor-alpha inhibitors (infliximab and adalimumab); or** • **Vedolizumab, ustekinumab, risankizumab and upadactinib** **Or would mirizikumab be used after these treatments already available in the NHS?**	Thank you for your comment. No changes to the scope required.

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		As per the anticipated label, mirikizumab will be positioned similarly to approved biologics such as risankizumab and upadacitinib: as a second-line biologic therapy following treatment with TNFα inhibitors, or as a first-line biologic therapy following conventional therapy in cases of contraindication to, or other unsuitability to receive, TNFα inhibitors. **2. Would mirikizumab be a candidate for managed access?** No, Lilly does not believe mirikizumab would be a suitable candidate for managed access. **3. Do you consider that the use of mirikizumab can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?** **Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.** No health-related benefits that would not be captured within a QALY calculation have been identified. **4. 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.**	

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		• **could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which mirikizumab will be licensed;** • **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.** **Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.** No equality issues have been identified. **5. NICE is considering evaluating this technology through its cost comparison evaluation process.**	
	Crohn's and Colitis UK	No comments	No changes to the scope required.
	Abbvie	**Where do you consider mirikizumab will fit into the existing care pathway for Crohn's disease? Would it be used as an alternative to:** • **Tumour necrosis factor-alpha inhibitors (infliximab and adalimumab); or**	Thank you for your comment. Comparators are kept inclusive to avoid the exclusion of any

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		• **Vedolizumab, ustekinumab, risankizumab and upadactinib** **Or would mirizikumab be used after these treatments already available in the NHS?** Mirikizumab should not be positioned as an alternative to TNF-alpha inhibitors. Instead, mirikizumab should be positioned in later lines of therapy, after TNF-alpha inhibitors.	potentially relevant comparators. Tumour necrosis factor-alpha inhibitors have been kept in the scope. No changes to the scope required.
	Janssen	No comments	No changes to the scope required.
Additional comments on the draft scope	Eli Lilly	Lilly has no further comments on the draft scope	No changes to the scope required.
	Crohn's and Colitis UK	No comments	No changes to the scope required.
	Abbvie	No comments	No changes to the scope required.
	Janssen	No comments	No changes to the scope required.

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

None