National Institute for Health and Care Excellence

Health Technology Evaluation

Guselkumab for treating moderately to severely active ulcerative colitis (ID6237)
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	Johnson & Johnson	J&J Innovative Medicine consider this topic appropriate for referral to NICE for appraisal. In line with recent appraisals in inflammatory bowel disease (TA888, TA905, TA925, TA956) and others currently in progress (ID6209, ID6244), we consider it appropriate that this topic be selected for appraisal as a cost comparison.	Thank you for your comment. Guselkumab has been selected to be appraised as a cost comparison. No action needed.
	Crohn's & Colitis UK	We agree with the appropriateness of the appraisal route.	Thank you for your comment. No action needed.
	UK Clinical Pharmacy Association	Appropriate	Thank you for your comment. No action needed.
	AbbVie	No comments	No action needed.

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Wording	Johnson & Johnson	The wording of the remit is appropriate	Thank you for your comment. No action needed.
	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 comments. No action needed.
	UK Clinical Pharmacy Association	Patients who have had inadequate response, lost response to or were intolerant to either a conventional therapy, biological treatment or JAK inhibitor Conventional therapy – defined as steroids and/or immunomodulators should be included in section 'comparators'	Thank you for your comments. Conventional therapies are included in the list of comparators. No action needed.
	AbbVie	No comments	No action needed.
Timing issues	Johnson & Johnson	There are approximately 500,000 people in the UK living with inflammatory bowel disease.[1] Ulcerative colitis remains an incurable condition and patients are experiencing delays in starting treatment. At the time of scoping, the national average waiting time for gastroenterology is 14.1 weeks, with 390,454 people currently waiting for a hospital appointment.[2] The efficacy and safety of guselkumab as a treatment option for ulcerative colitis has been demonstrated in Phase 3 trials.[3] If recommended by NICE, guselkumab would provide an additional treatment option to patients, and the upcoming launch of a subcutaneous induction would offer benefits to the NHS capacity in the long term. Timely NICE guidance for the use of guselkumab in ulcerative colitis would allow eligible patients to initiate treatment in a timely	Thank you for your comments. NICE has scheduled this topic into its work programme. For further details, see the NICE website: https://www.nice.org.uk/guidance/indevelopment/gid-ta11247. No action needed.

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		manner and may alleviate the waiting list times in the gastroenterology setting. References: 1. Crohn's & Colitis UK. Available at: https://crohnsandcolitis.org.uk/our-work/our-strategy/our-full-strategy. Accessed 30 May 2024. 2. LCP Health Analytics. NHS Waitlist Tracker. Available at: https://waitinglist.health.lcp.com/ Accessed 30 May 2024. 3. Rubin DT et al. Efficacy and Safety of Guselkumab as Maintenance Therapy in Patients with Moderately to Severely Active Ulcerative Colitis: Results from the Phase 3 QUASAR Maintenance Study. Presented at Digestive Disease Week 2024, May 18 - 21, 2024.	
	Crohn's & Colitis UK	More than a quarter of people with Crohn's and colitis wait over a year for diagnosis, with almost half ending up in Accident and Emergency Departments (A&E) during this time. Following a diagnosis, many still feel the impact of NHS workforce pressures. Finding an effective treatment early leads to better health outcomes for patients and reduces the risk of needing surgery. There is also a benefit to an additional treatment option that can be administered at home to help reduce pressure on the NHS (i.e. outpatient appointments, day cases, and workforce).	Thank you for your comments. NICE has scheduled this topic into its work programme. For further details, see the NICE website: https://www.nice.org.uk/guidance/indevelopment/gid-ta11247. No action needed.
	UK Clinical Pharmacy Association	Specifically, an addition to mirikizumab and risankizumab (when approved for UC) as all bind to p19 subunit of IL23. Overall another drug available for use in moderate to severely active ulcerative colitis where multiple mechanisms of action now available therefore relative urgency is low.	Thank you for your comments. No action needed.
	AbbVie	No comments	No action needed.

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Additional comments on the draft remit	Johnson & Johnson	J&J Innovative Medicine has no further comments on the draft remit.	No action needed.
	AbbVie	No comments	No action needed.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Johnson & Johnson	The background information is appropriate and accurate.	Thank you for your comment. No action needed.
	Crohn's & Colitis UK	We welcome the recognition that people with IBD are affected by more than just their bowel symptoms, and the recognition that this can impact daily quality of life. 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 colitis, including dietetic and psychological support. 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.	Thank you for your comments. This section of the scope aims to provide a brief overview of the background for the evaluation; additional details may be considered by the appraisal committee. No action needed.
	UK Clinical Pharmacy Association	Ulceration is not a 'symptom' of ulcerative colitis. Complications of ulcerative colitis are less likely to be abscesses (as more associated with Crohn's disease).	Thank you for your comments. The background section has been updated. Specific

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		On page 2 it states that NICE recommends several 'biologic' treatments for moderately to severely active ulcerative colitis but then includes JAK inhibitors and S1P modulators in that list. Initial wording should acknowledge small molecules. QUASAR trial to be noted rather than 'studies in clinical trials'	trials are not referenced in the background section.
	AbbVie	The aim of treatment in active disease also includes mucosal healing (endoscopic, histological). Reference: Ramos L, Teo-Loy J, Acosta M.B., Front Med (Lausanne) 2022; 9: 1102420.	Thank you for your comments. This section of the scope aims to provide a brief overview of the background for the evaluation. No action needed.
Population	Johnson & Johnson	The population is defined appropriately in line with the anticipated marketing authorisation: [redacted]	Thank you for your comment. No action needed.
	Crohn's & Colitis UK	We agree with the population included in the scope.	Thank you for your comment. No action needed.
	UK Clinical Pharmacy Association	Yes Note that at present this can be used ahead of mirikizumab and ustekinumab and those stipulate patients should be intolerant to or lost response to TNF alpha antagonists	Thank you for your comment. No action needed.
	AbbVie	No comments	No action needed.

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Subgroups	Johnson & Johnson	Based on the suggested cost comparison appraisal route, it may not be appropriate to separately consider the subgroups listed in the draft scope.	Thank you for your comment. The subgroups have been removed following the decision to evaluate this topic through the cost comparison route.
	Crohn's & Colitis UK	We agree with the subgroups included in the scope.	Thank you for your comment. The subgroups have been removed following the decision to evaluate this topic through the cost comparison route.
	UK Clinical Pharmacy Association	Appropriate	Thank you for your comment. The subgroups have been removed following the decision to evaluate this topic through the cost comparison route.
	AbbVie	No comments	No action needed.
Comparators	Johnson & Johnson	Based on the suggested cost comparison appraisal route, it may be appropriate to demonstrate cost comparability to at least one of the following treatments according to NICE guidance: vedolizumab, ustekinumab, JAK	Thank you for your comments. Best supportive care is not included in the list of

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		inhibitors (upadacitinib, tofacitinib, filgotinib), S1P receptor modulators (ozanimod, etrasimod), or mirikizumab. J&J Innovative Medicine suggest removal of “Best supportive care” as a treatment option, as this is unlikely to be an alternative to guselkumab for the population relevant to this submission, within the ulcerative colitis treatment pathway.	comparators. No action needed.
	Crohn’s & Colitis UK	We agree with the comparators listed.	Thank you for your comment. No action needed.
	UK Clinical Pharmacy Association	Yes	Thank you for your comment. No action needed.
	AbbVie	Etrasimod has been recommended by NICE (TA956 published on 11 Mar 2024) and is no longer subject to ongoing NICE appraisal.	Thank you for your comment. The scope has been updated to align with the recently published NICE guidance.
	Pfizer	Etrasimod is now recommended (TA956) and therefore the phrase ‘(subject to ongoing appraisal)’ in the comparator section can be removed.	Thank you for your comment. The scope has been updated to align with the recently

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			published NICE guidance.
Outcomes	Johnson & Johnson	The outcomes listed are appropriate.	Thank you for your comment. No action needed.
	Crohn's & Colitis UK	We would ask the Committee to consider additions of: Improved medicine adherence and self-management. Patient experience and outcomes.	Thank you for your comment. Medicine adherence has been added to the list of outcomes. Patient experience are captured under the broad category of health-related quality of life measures.
	UK Clinical Pharmacy Association	Acceptable	Thank you for your comment. No action needed.
	AbbVie	No comments	No action needed.
Equality	Johnson & Johnson	Living with inflammatory bowel disease isn't classed as a disability under the Equality Act. However, it may be classed as a disability depending on the effect it has on a patient's daily life.[1] People living with inflammatory bowel disease often require specialist medications and surgery, hospital admissions, investigations, and outpatient appointments. Relapses are unpredictable in nature, and around 50% of people with Crohn's and Colitis experience at least one flare-up per year.[2] More than a quarter of people with Crohn's and Colitis had to wait over a year for diagnosis, with almost half	Thank you for your comments. Under the Equality Act 2020, inflammatory bowel disease is not a protected characteristic but can be considered

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		ending up in Accident and Emergency Departments (A&E) during this time.[3] Availability of an additional treatment option which can be safely administered at home, may reduce inequalities between people with IBD with varying degrees of disability, and reduce reliance on an overburdened healthcare system. References: 1. Crohn's & Colitis UK, A guide for employees. June 2022. Available at: https://crohnsandcolitis.org.uk/info-support/information-about-crohns-and-colitis/all-information-about-crohns-and-colitis/employment-and-education/employment-a-guide-for-employees Accessed: 03 June 2024. 2. Written evidence from Crohn's & Colitis UK DYE0019 Available at: https://committees.parliament.uk/writtenevidence/129236/html Accessed: 03 June 2024. 3. Crohn's & Colitis UK, Weeks Not Years, April 2023. Available at: https://crohnsandcolitis.org.uk/media/5kefufoj/crohns-colitis-uk_weeks-not-years-briefing.pdf Accessed: 03 June 2024.	under the protected characteristic of "disability". In line with other technology appraisals in ulcerative colitis, equality issues will be considered by the committee during the evaluation. No action 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. There is also an advantage to a further treatment option that can be administered at home, which avoids the need for patients to take time off work or education.	Thank you for your comments. No action needed.
	UK Clinical Pharmacy Association	Three induction infusions will be needed therefore impact to infusion facilities and will affect access to the medication across different areas. Drug acquisition cost compared to other advanced treatments and more specifically other biologic treatments in same class.	Thank you for your comments. No action needed.

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		Important that wording is clear as per previous comments so that differences between integrated care boards/commissioners is limited and positioning can be based on patient factors.	
	AbbVie	No comments	No action needed.
Other considerations	Johnson & Johnson	No additional comments	No action needed.
	AbbVie	No comments	No action needed.
Questions for consultation	Johnson & Johnson	**Q1. Where do you consider guselkumab will fit into the existing care pathway for ulcerative colitis?** Response: Based on the suggested cost comparison appraisal route, the decision problem addressed in our submission, and the NICE recommendation for the key reference comparator, we anticipate that guselkumab will be used for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response, lost response, or were intolerant to either a biologic treatment, or a Janus kinase (JAK) inhibitor. **Q2. Please select from the following, will guselkumab be:** **A. Prescribed in primary care with routine follow-up in primary care** **B. Prescribed in secondary care with routine follow-up in primary care** **C. Prescribed in secondary care with routine follow-up in secondary care** **D. Other (please give details):**	Thank you for your comments. No action needed.

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		For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention. Response: Guselkumab is likely to be prescribed in secondary care, with routine follow-up in secondary care. **Q3. Is there a preferred treatment sequence with biological treatments and/or other advanced therapies (for example JAK inhibitors) after an inadequate response or intolerance to conventional therapy?** Response: Based on the suggested cost comparison appraisal route, it may only be appropriate to consider treatments that are recommended for use after an inadequate response or intolerance to a biologic treatment and/or other advanced therapies (e.g. JAK inhibitors). There is no preferred treatment sequence suggested in the guidelines published by NICE or the British Society of Gastroenterology. In this population of patients, it is expected that any of the following treatment options may be offered, based on the NICE guidance: *Biologic treatments* - vedolizumab (TA342) - ustekinumab (TA633) - mirikizumab (TA925) *Other advanced therapies*	No action needed. No action needed.

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		- tofacitinib (TA547) - filgotinib (TA792) - ozanimod (TA828) - upadacitinib (TA856) - etrasimod (TA956), **Q3. Are all relevant comparators included in the scope? Specifically, should conventional therapy with aminosalicylates, oral corticosteroids and/or immunomodulators be considered a comparator in the evaluation?** Response: Based on the suggested cost comparison appraisal route, we recommend limiting the comparators only to those treatments that are recommended in patients who have had an inadequate response, lost response, or were intolerant to either a biologic treatment, or a Janus kinase (JAK) inhibitor. Conventional therapy with aminosalicylates, oral corticosteroids and/or immunomodulators should not be considered as a comparator in the evaluation, as these are unlikely to be appropriate alternative options for the proposed population. **Q4. Are there specific sub-groups that would particularly benefit from treatment with guselkumab?** Response: Based on the suggested cost comparison appraisal route, it may not be appropriate to separately consider specific sub-groups. **Q5. Would guselkumab be a candidate for managed access?**	The scope has been kept broad and conventional therapies have been kept in the list of comparators. No action needed. Subgroups have been removed. No action needed.

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		Response: J&J Innovative Medicine do not consider guselkumab to be a candidate for managed access. **Q6. Do you consider that the use of guselkumab 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.** Response: J&J Innovative medicine have not identified any health-related benefits that would not be captured within a QALY calculation. **Q7. NICE is considering evaluating this technology through its cost comparison evaluation process. Please provide comments on the appropriateness of appraising this topic through this process.** Response: J&J Innovative Medicine believe that guselkumab is appropriate for appraisal via cost comparison vs mirikizumab and vedolizumab for the following reasons: - Guselkumab is expected to provide similar or greater health benefits, at a similar or lower cost, compared with technologies that have been previously recommended in published NICE guidance for the same indication. - Guselkumab is likely to be similar in its clinical effectiveness and resource use to these comparators.	No action needed. This topic will be appraised through the cost comparison route.

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		- Guselkumab will be used in the same place in the treatment pathway as the comparators. - Guselkumab will be used to treat the same population as the comparators. - Overall, guselkumab is likely to offer similar or improved health benefits compared with the comparators.	
	AbbVie	No comments	No action needed.
Additional comments on the draft scope	Johnson & Johnson	J&J Innovative Medicine has no further comments on the draft scope.	No action needed.
	AbbVie	No comments	No action needed.

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

Bladder and Bowel UK
Guts UK
Takeda UK Ltd