**National Institute for Health and Care Excellence**

**Health Technology Evaluation**

# Guselkumab for previously treated moderately to severely active Crohn's disease [ID6238]

**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 |
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| Appropriateness of an evaluation and proposed evaluation route | J&J Innovative Medicine | 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.<br>Guselkumab has been selected to be appraised as a cost comparison. |
| | Crohn's & Colitis UK | We agree with the appropriateness and the appraisal route. | Thank you for your comment. No changes required to the scope. |
| Wording | J&J Innovative Medicine | The wording of the remit is appropriate | Thank you for your comment. No changes required to the scope. |

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| | Crohn's & Colitis UK | Yes. Currently, 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. No changes required to the scope. |
| Timing issues | J&J Innovative Medicine | There are approximately 500,000 people in the UK living with inflammatory bowel disease.[1] Crohn's disease 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]<br>The efficacy and safety of guselkumab as a treatment option for Crohn's disease has been demonstrated in Phase 3 trials.[3] If recommended by NICE, guselkumab would be the only treatment option for the population relevant to this appraisal that does not require an infusion setting to initiate treatment. Timely NICE guidance for the use of guselkumab in Crohn's disease would allow eligible patients to initiate treatment in a timely manner and may alleviate the waiting list times in the gastroenterology setting.<br><br>References:<br>1. Crohn's & Colitis UK. Available at: https://crohnsandcolitis.org.uk/our-work/our-strategy/our-full-strategy. Accessed 30 May 2024.<br>2. LCP Health Analytics. NHS Waitlist Tracker. Available at: https://waitinglist.health.lcp.com/ Accessed 30 May 2024.<br>3. Panaccione R et al. Efficacy and Safety of Guselkumab Therapy in Patients with Moderately to Severely Active Crohn's Disease: Results of the GALAXI 2 & 3 Phase 3 Studies. Lecture presented at Digestive Disease Week 2024, May 18 - 21, 2024. | Thank you for your comment. NICE aims to publish guidance as soon as possible after the company receives the marketing authorisation and introduces the technology in the UK. NICE has scheduled this topic into its work programme. |
| | Crohn's & Colitis UK | More than a quarter of people with Crohn's or colitis wait over a year for diagnosis, with almost half ending up in Accident and Emergency | Thank you for your comment. NICE aims to |

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| | | 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.<br><br>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). | publish guidance as soon as possible after the company receives the marketing authorisation and introduces the technology in the UK. NICE has scheduled this topic into its work programme. |
| Additional comments on the draft remit | J&J Innovative Medicine | J&J Innovative Medicine has no further comments on the draft remit. | No changes required to the scope. |
| | Crohn's & Colitis UK | N/A | No changes required to the scope. |

**Comment 2: the draft scope**

| Section | Consultee/ Commentator | Comments [sic] | Action |
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| Background information | J&J Innovative Medicine | The background information is appropriate and accurate. | Thank you for your comment. No changes required to the scope. |
| | 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. | Thank you for your comment.<br>Extreme tiredness has already been included |

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| | | We would like to see fatigue and anaemia included, as these are often overlooked but have a significant impact on people's life.<br><br>Care for Crohn's disease has moved towards delivering personalised care and support, and not just remission, with a greater focus on the holistic needs of people with Crohn's, including dietetic and psychological support.<br><br>We would point out that the current guideline for Crohn's disease is not aligned with the IBD Standards or the most up-to-date British Society of Gastroenterology IBD guideline. | as a symptom. Anaemia has been added as a symptom in the background section.<br><br>The background section of the scope provides a brief overview of the disease. More detailed information will be provided at the submission stage.<br><br>Guselkumab will be appraised independently of the NICE guidelines on Crohn's disease. |
| Population | J&J Innovative Medicine | The population is defined appropriately in line with the anticipated marketing authorisation: [redacted] | Thank you for your comment. No changes required to the scope. |
| | Crohn's & Colitis UK | We agree with the population included in the scope | Thank you for your comment. No changes required to the scope. |

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| Subgroups | J&J Innovative Medicine | 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. Subgroups have been removed following the decision to appraise guselkumab as a cost comparison. |
| | Crohn's & Colitis UK | We agree with the sub-groups included in the scope | Thank you for your comment. Subgroups have been removed following the decision to appraise guselkumab as a cost comparison. |
| Comparators | J&J Innovative Medicine | 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, risankizumab or upadacitinib.<br><br>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 Crohn's disease treatment pathway. | Thank you for your comment. A cost comparison case can be made if a health technology is likely to provide similar or greater health benefits at similar or lower cost than technologies recommended in published NICE technology appraisal guidance for the same indication. |

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| | | | The scope has been amended to remove “best supportive care” from the list of comparators. |
| | Crohn’s & Colitis UK | Conventional therapy (which can include drug treatment with conventional corticosteroids alone or in combination with azathioprine, mercaptopurine or methotrexate; aminosalicylates; budesonide alone or in combination with azathioprine, mercaptopurine or methotrexate) | Thank you for your comment. Because of the company’s target population and the decision to appraise guselkumab as a cost comparison, conventional therapy is not an appropriate comparator. |
| Outcomes | J&J Innovative Medicine | The outcomes listed are appropriate. | Thank you for your comment. No changes required to the scope. |
| | Crohn’s & Colitis UK | We would ask the Committee to consider additions of:<br>• Improved medicine adherence and self-management.<br>• Patient experience and outcomes.<br>• Hospital readmission and emergency admissions. | Thank you for your comment. Hospitalisation and health-related quality of life have been included in the outcomes. The list of outcomes is not |

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| | | | 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.<br><br>No changes required to the scope. |
| Equality | J&J Innovative Medicine | 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]<br><br>More than a quarter of people with Crohn's and Colitis had to wait over a year for diagnosis, with almost half 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.<br><br>References:<br>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- | Thank you for your comments.<br><br>We have noted your comments on the equality impact assessment (EIA) form.<br><br>The methods of administration will be discussed during the appraisal.<br><br>No changes required to the scope. |

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| | | about-crohns-and-colitis/employment-and-education/employment-a-guide-for-employees Accessed: 03 June 2024.<br>2. Written evidence from Crohn's & Colitis UK DYE0019 Available at: https://committees.parliament.uk/writtenevidence/129236/html Accessed: 03 June 2024.<br>**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.** | |
| | 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.<br><br>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.<br>We have noted your comments on the equality impact assessment (EIA) form.<br>During the appraisal it will be discussed if all benefits of guselkumab were captured in the cost-effectiveness analyses.<br>No changes required to the scope. |
| Other considerations | J&J Innovative Medicine | No additional comments. | No changes required to the scope. |
| Questions for consultation | J&J Innovative Medicine | **Q1. Where do you consider guselkumab will fit into the existing care pathway for moderately to severely active Crohn's disease?** | Thank you for your comments. |

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| | | **Would guselkumab be used as an alternative to:**<br>• **Tumour necrosis factor-alpha inhibitors (infliximab and adalimumab); or**<br>• **Vedolizumab, ustekinumab, risankizumab and upadactinib; or**<br>• **all of the above**<br>**Or would it be used after these treatments already available in the NHS?**<br><br>Response: Based on the suggested cost comparison appraisal route and the NICE guidance for relevant comparators guselkumab is likely to be positioned as a second-line biologic therapy and expected to be considered as an alternative to vedolizumab and risankizumab. It is also likely to be used in patients who do not respond well or have lost response to a biologic such as TNF-α inhibitors, or in patients for whom TNF-α inhibitors are not suitable or contraindicated.<br><br>**Q2. Would guselkumab be a candidate for managed access?**<br><br>Response: J&J Innovative Medicine do not consider guselkumab to be a candidate for managed access.<br><br>**Q3. 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?** | Guselkumab will be appraised within its marketing authorisation or a population for whom the company provides evidence if this is narrower than the marketing authorisation.<br><br>No changes required to the scope.<br><br>No changes required to the scope. |

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| | | **Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.**<br><br>Response: J&J Innovative medicine have not identified any health-related benefits that would not be captured within a QALY calculation.<br><br>**Q4. NICE is considering evaluating this technology through its cost comparison evaluation process.**<br>**Please provide comments on the appropriateness of appraising this topic through this process.**<br><br>Response: J&J Innovative Medicine believe that guselkumab is appropriate for appraisal via cost comparison vs risankizumab and vedolizumab for the following reasons:<br><br>- 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.<br>- Guselkumab is likely to be similar in its clinical effectiveness and resource use to these comparators.<br>- Guselkumab will be used in the same place in the treatment pathway as the comparators.<br>- Guselkumab will be used to treat the same population as the comparators.<br>- Overall, guselkumab is likely to offer similar or improved health benefits compared with the comparators. | Guselkumab has been selected to be appraised as a cost comparison. |

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| Additional comments on the draft scope | J&J Innovative Medicine | J&J Innovative Medicine has no further comments on the draft scope. | No changes required to the scope |

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

AbbVie (only comments on provisional stakeholder list)
Takeda