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Advice document
SMC2848

guselkumab solution for injection in pre-filled pen and concentrate for solution for infusion (Tremfya®)

Johnson & Johnson

10 October 2025

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and, following review by the SMC executive, advises NHS Boards and Area Drug and Therapeutics Committees (ADTCs) on its use in NHSScotland. The advice is summarised as follows:

ADVICE: following an abbreviated submission

guselkumab (Tremfya®) is accepted for use within NHSScotland.

Indication under review: Treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy, a biologic treatment, or a Janus kinase (JAK) inhibitor.

Guselkumab offers an additional treatment choice in the therapeutic class of interkeukin inhibitors in this setting.

This advice applies only in the context of approved NHSScotland Patient Access Scheme (PAS) arrangements delivering the cost-effectiveness results upon which the decision was based, or PAS/ list prices that are equivalent or lower.

Chair
Scottish Medicines Consortium

1. Clinical Context

1.1. Medicine background

Guselkumab is a human monoclonal antibody that binds selectively to the interleukin 23 (IL-23) protein with high specificity and affinity through the antigen binding site. Guselkumab has demonstrated in vitro blocking of IL-23 and binding to CD64.

The induction dose is:

- 200 mg administered by intravenous (IV) infusion at Week 0, Week 4 and Week 8.

Or

- 400 mg administered by subcutaneous injection (SC) (given as two consecutive injections of 200 mg each) at Week 0, Week 4 and Week 8.

After completion of the induction dose regimen, the recommended maintenance dose starting at Week 16 is 100 mg administered by subcutaneous injection every 8 weeks. Alternatively, for patients who do not show adequate therapeutic benefit to induction treatment according to clinical judgement, a maintenance dose of 200 mg administered by subcutaneous injection starting at Week 12 and every 4 weeks thereafter, may be considered. Consideration should be given to discontinuing treatment in patients who have shown no evidence of therapeutic benefit after 24 weeks of treatment. Further details are included in the summary of product characteristics (SPC).[1, 2]

1.2. Relevant comparator(s)

The company considers that the relevant comparators are risankizumab and mirikizumab. Risankizumab and mirikizumab are also IL-23 inhibitors, accepted for use by SMC for adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with lost response to, or were intolerant to either conventional therapy or a biologic treatment. Ustekinumab, an IL-12 and IL-23 inhibitor, has also been accepted for use by SMC for adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with lost response to, or were intolerant to either conventional therapy or a biologic or have medical contraindications to such therapies.

2. Summary of Clinical Evidence

2.1. Evidence to support comparable efficacy with relevant comparators

Guselkumab has not been compared directly with a relevant active comparator. Evidence for the efficacy and safety of guselkumab for the indication under review comes from QUASAR and ASTRO. QUASAR and ASTRO were randomised phase III, double-blind, placebo-controlled, parallel-group studies in adults with moderately to severely active ulcerative colitis who had an inadequate response, loss of response or intolerance to conventional therapy, biologics or JAK inhibitors. Results indicated guselkumab was significantly superior to placebo for the primary

outcomes: clinical remission at week 12 (induction) and week 44 (maintenance, QUASAR only). For the secondary outcomes of symptomatic remission and clinical response, results significantly favour guselkumab over placebo.[3-5]

The company provided a network meta-analysis (NMA) to compare the efficacy and safety against relevant comparators, risankizumab and mirikizumab.

The company found no significant differences between guselkumab, risankizumab or mirikizumab for both outcomes of one-year clinical response and one-year clinical remission. Safety profile was consistent and aligned with other approved indications, with no additional safety concerns.

Overall, the NMA supports the assumption that guselkumab has similar clinical benefit to risankizumab and mirikizumab.

3. Company Estimate of Eligible Population, Uptake and Budget Impact

3.1. Company's number of patients assumed to be eligible for treatment

SMC is unable to publish the estimated patient numbers as these were commercial in confidence.

3.2. Budget Impact assumption

Medicines reviewed under the abbreviated submissions process are estimated to have a limited net budget impact and resource allocation across NHS Scotland.

References

1. Janssen-Cilag Ltd (a Johnson & Johnson Company). Tremfya 200 mg PushPen solution for injection in pre-filled pen. Summary of product characteristics. Electronic Medicines Compendium https://mhraproducts4853.blob.core.windows.net/docs/a5ade3e85482e51c0964a0b3e16b6ff7405e1ba5. Last updated 19 August 2025.

2. Janssen-Cilag Ltd (a Johnson & Johnson Company). Tremfya 200 mg concentrate for solution for infusion. Summary of product characteristics. Electronic Medicines Compendium https://mhraproducts4853.blob.core.windows.net/docs/159c89dc62d57b3106a37bb742572e16133011c1. Last updated 23 May 2025.

3. Peyrin-Biroulet L, Allegretti JR, Danese S, Germinaro M, Baker T, Alvarez Y, et al. OP10 Efficacy and safety of subcutaneous guselkumab induction therapy in patients with Ulcerative Colitis: Results through week 12 from the phase 3 ASTRO study. Journal of Crohn's and Colitis. 2025;19(Supplement_1):i19-i20.

4. Peyrin-Biroulet L, Allegretti JR, Rubin DT, Bressler B, Germinaro M, Huang KG, et al. Guselkumab in Patients With Moderately to Severely Active Ulcerative Colitis: QUASAR Phase 2b Induction Study. Gastroenterology. 2023;165(6):1443-57. Epub 2023/09/03.

5. Rubin DT, Allegretti JR, Panés J, Shipitofsky N, Yarandi SS, Huang KG, et al. Guselkumab in patients with moderately to severely active ulcerative colitis (QUASAR): phase 3 double-blind, randomised, placebo-controlled induction and maintenance studies. Lancet. 2025;405(10472):33-49. Epub 2024/12/21.

This assessment is based on data submitted by the applicant company up to and including 29 September 2025.

Medicine prices are those available at the time the papers were issued to SMC for consideration. SMC is aware that for some hospital-only products national or local contracts may be in place for comparator products that can significantly reduce the acquisition cost to Health Boards. These contract prices are commercial in confidence and cannot be put in the public domain, including via the SMC Detailed Advice Document. Area Drug and Therapeutics Committees and NHS Boards are therefore asked to consider contract pricing when reviewing advice on medicines accepted by SMC.

Patient access schemes: A patient access scheme is a scheme proposed by a pharmaceutical company in order to improve the cost-effectiveness of a medicine and enable patients to receive access to cost-effective innovative medicines. A Patient Access Scheme Assessment Group (PASAG), established under the auspices of NHS National Services Scotland reviews and advises NHSScotland on the feasibility of proposed schemes for implementation. The PASAG operates separately from SMC in order to maintain the integrity and independence of the assessment process of the SMC. When SMC accepts a medicine for use in NHSScotland on the basis of a patient access scheme that has been considered feasible by PASAG, a set of guidance

notes on the operation of the scheme will be circulated to Area Drug and Therapeutics Committees and NHS Boards prior to publication of SMC advice.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice is based on the estimation of at least similar comparative efficacy and limited net budget impact compared with other medicinal products, within the same therapeutic class, that are in routine use within NHSScotland.

This advice represents the view of the Scottish Medicines Consortium and was arrived at after evaluation of the evidence submitted by the company. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.