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Healthcare Improvement Scotland | SMC Advice on new medicines

Advice document
SMC2850

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: For the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic treatment.

Guselkumab offers an additional treatment choice in the therapeutic class of interleukin 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 fully human immunoglobulin G1 lambda (IgG1λ) monoclonal antibody that binds to interleukin 23 and myeloid cells expressing Fc-gamma receptor 1 (CD64), with in vitro demonstration of its ability to block IL-23 and bind to CD64. It is administered as either an intravenous infusion (200 mg) or subcutaneous injection (400 mg) (given as two consecutive injections of 200 mg each) for the induction doses (at weeks 0, 4 and 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. Further details are included in the summary of product characteristics (SPC). Consideration should be given to discontinuing treatment in patients who have shown no evidence of therapeutic benefit after 24 weeks of treatment.[1]

1.2. Relevant comparator

Risankizumab (Skyrizi®) is another interleukin inhibitor that has previously been accepted for use by SMC for the treatment of people 16 years and older with moderately to severely active Crohn's disease who have had an inadequate response to, lost response to, or were intolerant to conventional therapy or a biologic treatment, or if such therapies are not advisable (SMC2534).[2] The submitting company considered that risankizumab is the most relevant comparator for guselkumab in the indication under review. Clinical experts consulted by SMC broadly agreed that risankizumab is the most relevant comparator.

2. Summary of Clinical Evidence

2.1. Evidence to support comparable efficacy with relevant comparators

The efficacy and safety data for guselkumab versus placebo or ustekinumab are derived from the double-blind, treat-through, phase III studies (GALAXI-2/-3 [placebo and active-controlled] and GRAVITI [placebo-controlled] in patients with Crohn's disease who have had an inadequate response, lost response to, or were intolerant to either conventional therapy or a biologic treatment.[3, 4]

GALAXI-2/-3 and GRAVITI met their co-primary outcomes, showing guselkumab superiority over placebo for clinical and endoscopic outcomes. Results were broadly consistent across subgroups regardless of prior failure of biological treatments. Key secondary endpoints results showed that guselkumab is superior to ustekinumab for many key endoscopic and clinical measures.[3, 4]

There is no direct evidence comparing guselkumab with risankizumab, therefore, the company presented a published global network meta-analysis (NMA).[5] In the NMA, data for guselkumab 100 and 200 mg subcutaneous injection were from GALAXI-1, GALAXI-2 and GALAXI-3

studies.[4,6] Data for risankizumab efficacy were from three studies; ADVANCE, MOTIVATE, FORTIFY which were randomised, double-blind, placebo-controlled studies.[7, 8]

The results of the NMA suggest no significant differences between guselkumab and risankizumab and these results were consistent across subgroups regardless of prior failure of biological treatments.[5] Notwithstanding the limitations inherent in the NMA, the results provide reasonable assurance that guselkumab is at least as effective as risankizumab in this indication.

Overall, the findings support guselkumab as an additional treatment option in patients with Crohn's disease who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic treatment.

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 www.medicines.org.uk. Last updated 23 May 2025.

2. AbbVie Ltd. Skyrizi 600 mg concentrate for solution for infusion. Summary of product characteristics. Electronic Medicines Compendium www.medicines.org.uk. Last updated 27 March 2025.

3. Hart A, Panaccione R, Steinwurz F, Danese S, Hisamatsu T, Cao Q*, et al.* Efficacy and Safety of Guselkumab Subcutaneous Induction and Maintenance in Participants With Moderately to Severely Active Crohn's Disease: Results From the Phase 3 GRAVITI Study. Gastroenterology. 2025.

4. Panaccione. Efficacy and safety of intravenous induction and subcutaneous maintenance treatment with guselkumab in participants with Crohn's disease: results of two phase 3, randomised, double-blind, placebo-controlled, and head-to-head versus ustekinumab, 48-week trials (GALAXI 2 & 3). Lancet2024.

5. Disher T, Naessens D, Sanon M, Bonner A, Ellis J, Bartlett M*, et al.* One-Year Efficacy of Guselkumab Versus Advanced Therapies for the Treatment of Moderately to Severely Active Crohn's Disease: A Network Meta-Analysis. Advances in Therapy. 2025.

6. William J. Sandborn GRDH, Walter Reinisch, Julián Panés, Daphne Chan, Susana Gonzalez, Kathleen Weisel, Matthew Germinaro, Mary Ellen Frustaci, Zijiang Yang, Omoniyi J. Adedokun, Chenglong Han, Remo Panaccione, Tadakazu Hisamatsu, Silvio Danese, David T. Rubin, Bruce E. Sands, Anita Afzali, Jane M. Andrews, Brian G. Feagan,. Guselkumab for the Treatment of Crohn's Disease: Induction Results From the Phase 2 GALAXI-1 Study,. Gastroenterology,.162(6):1650-64.e8.

7. Ferrante M PR, Baert F, Bossuyt P, Colombel JF, Danese S, Dubinsky M, Feagan BG, Hisamatsu T, Lim A, Lindsay JO, Loftus EV Jr, Panés J, Peyrin-Biroulet L, Ran Z, Rubin DT, Sandborn WJ, Schreiber S, Neimark E, Song A, Kligys K, Pang Y, Pivorunas V, Berg S, Duan WR, Huang B, Kalabic J, Liao X, Robinson A, Wallace K, D'Haens G. . Risankizumab as maintenance therapy for moderately to severely active Crohn's disease: results from the multicentre, randomised, double-blind, placebo-controlled, withdrawal phase 3 FORTIFY maintenance trial. Lancet. 2022.

8. D'Haens G PR, Baert F, Bossuyt P, Colombel JF, Danese S, Dubinsky M, Feagan BG, Hisamatsu T, Lim A, Lindsay JO, Loftus EV Jr, Panés J, Peyrin-Biroulet L, Ran Z, Rubin DT,

Sandborn WJ, Schreiber S, Neimark E, Song A, Kligys K, Pang Y, Pivorunas V, Berg S, Duan WR, Huang B, Kalabic J, Liao X, Robinson A, Wallace K, Ferrante M. . Risankizumab as induction therapy for Crohn's disease: results from the phase 3 ADVANCE and MOTIVATE induction trials. Lancet. 2022.

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.