www.scottishmedicines.org.uk

Advice document
SMC2686

risankizumab solution for injection in cartridge and concentrate for solution for infusion (Skyrizi®)

AbbVie Ltd

06 December 2024

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

risankizumab (Skyrizi®) is accepted for use within NHSScotland.

Indication under review: for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to, lost response to, or were intolerant to conventional therapy or a biologic therapy.

Risankizumab offers an additional treatment choice in the therapeutic class of interleukin inhibitors.

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

Published 13 January 2025

1. Clinical Context

1.1. Medicine background

Risankizumab is a humanised IgG1 monoclonal antibody that binds to the p19 subunit of interleukin 23. For ulcerative colitis (UC), the recommended induction dose is 1,200 mg administered by intravenous infusion at weeks 0, 4 and 8. Starting at week 12 and every 8 weeks thereafter, the recommended maintenance dose is 180 mg or 360 mg administered by subcutaneous injection for patients with or without adequate therapeutic response, respectively. See the Summary of Product Characteristics for further details.[1-3]

1.2. Relevant comparator(s)

Risankizumab is classified as an interleukin inhibitor. Ustekinumab is another interleukin inhibitor that has previously been accepted for use by SMC for the treatment of adult patients with moderately to severely active UC 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 (SMC2250). The submitting company considered ustekinumab to be the most relevant comparator in the indication under review.

2. Summary of Clinical Evidence

2.1. Evidence to support comparable efficacy with relevant comparators

There is no direct evidence comparing risankizumab with ustekinumab. Evidence regarding the efficacy and safety of risankizumab is provided from two randomised, double-blind, placebo-controlled phase III studies, INSPIRE and COMMAND. The INSPIRE study was conducted in adults with moderately to severely active UC who had demonstrated intolerance or inadequate response to conventional therapy, or advanced therapy including one or more biologics, Janus kinase (JAK) inhibitors and/or sphingosine 1-phosphate (S1P) receptor modulators . At week 12, risankizumab induced clinical remission in a significantly greater proportion of patients compared with placebo. Patients who achieved a clinical response at week 12 or after a second 12-week reinduction period could enrol in the maintenance study (COMMAND). Clinical remission at 52 weeks was achieved in a significantly greater proportion of patients in the risankizumab groups compared with placebo.[1-6]

The submitting company performed Bayesian network meta-analyses (NMA) to assess the relative efficacy and safety of risankizumab versus ustekinumab in adults with moderately to severely active UC. The NMA results suggested that efficacy and safety outcomes were generally comparable between risankizumab and ustekinumab.

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 the company considered that 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.

*Other data were also assessed but remain confidential.**

References

1. AbbVie Ltd. Risankizumab 180 mg solution for injection in cartridge (Skyrizi®) Summary of product characteristics. Electronic Medicines Compendium www.medicines.org.uk Last updated 28 August 2024.
2. AbbVie Ltd. Risankizumab 360 mg solution for injection in cartridge (Skyrizi®) Summary of product characteristics. Electronic Medicines Compendium www.medicines.org.uk Last updated 23 August 2024.
3. AbbVie Ltd. Risankizumab 600 mg concentrate for solution for infusion (Skyrizi®) Summary of product characteristics. Electronic Medicines Compendium www.medicines.org.uk Last updated 23 August 2024.
4. Risankizumab Induction Therapy in Patients With Moderately to Severely Active Ulcerative Colitis: Efficacy and Safety in the Randomized Phase 3 INSPIRE Study. Gastroenterol Hepatol (N Y). 2023;19(12 Suppl 9):9-10.
5. Louis E, Panaccione R, Parkes G, Peyrin-Biroulet L, Ferrante M, Hisamatsu T*, et al.* OP06 Risankizumab Maintenance Therapy in Patients With Moderately to Severely Active Ulcerative Colitis: Efficacy and Safety in the Randomised Phase 3 COMMAND Study. Journal of Crohn's and Colitis. 2024;18(Supplement_1):i10-i2. 10.1093/ecco-jcc/jjad212.0006
6. ClinicalTrials.gov. A Multicenter, Randomized, Double-Blind, Placebo Controlled Induction Study to Evaluate the Efficacy and Safety of Risankizumab in Participants With Moderately to Severely Active Ulcerative Colitis (NCT03398148). [cited 30 August 2024]; Available from: https://clinicaltrials.gov/study/NCT03398148.

This assessment is based on data submitted by the applicant company up to and including 24 October 2024.

**Agreement between the Association of the British Pharmaceutical Industry (ABPI) and the SMC on guidelines for the release of company data into the public domain during a health technology appraisal:*https://www.scottishmedicines.org.uk/about-us/policies-publications/

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.