NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Final draft guidance

Risankizumab for treating moderately to severely active ulcerative colitis

1 Recommendations

1.1 Risankizumab is recommended as an option for treating moderately to severely active ulcerative colitis in adults when conventional or biological treatment cannot be tolerated, or the condition has not responded well enough or has lost response to treatment, only if:

- a tumour necrosis factor (TNF)-alpha inhibitor has not worked (that is the condition has not responded well enough or has lost response to treatment) or
- a TNF-alpha inhibitor cannot be tolerated or is not suitable, and
- the company provides it according to the commercial arrangement (see section 2).

1.2 If people with the condition and their clinicians consider risankizumab to be 1 of a range of suitable treatments (including ustekinumab), after discussing the advantages and disadvantages of all the options, use the least expensive. Take into account the administration costs, dosage, price per dose and commercial arrangements.

1.3 These recommendations are not intended to affect treatment with risankizumab that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.

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Why these recommendations were made

TNF-alpha inhibitors are the most used biological treatments for moderately to severely active ulcerative colitis. When TNF-alpha inhibitors have not worked, or are not tolerated, one of the treatment options is ustekinumab. Risankizumab works in a similar way to ustekinumab and would be offered to the same population.

Clinical trial evidence shows that risankizumab is more effective than placebo for treatment moderately to severely active ulcerative colitis. Risankizumab has not been directly compared with ustekinumab in a clinical trial. But an indirect comparison suggests that it is similarly effective.

A cost comparison suggests risankizumab has similar costs to ustekinumab. Using NICE's cost comparison methods, risankizumab only needs to cost less or have similar costs to 1 relevant comparator to be recommended as a treatment option. So risankizumab is recommended.

For all evidence see the committee papers. To see how NICE evaluated ustekinumab refer to the committee discussion section in NICE's technology appraisal guidance on ustekinumab.

2 Information about risankizumab

Anticipated marketing authorisation indication

2.1 Risankizumab (Skyrizi, AbbVie) does not have a marketing authorisation in Great Britain yet. The Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion recommending the granting of a marketing authorisation for risankizumab, intended for treating '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'.

Dosage in the marketing authorisation

2.2 The dosage schedule will be available in the summary of product characteristics for risankizumab.

Price

2.3 The list price of risankizumab is £3,326.09 for a 600 mg vial of concentrate for solution for intravenous infusion (excluding VAT; BNF online accessed June 2024). The list prices for the 180 mg and 360 mg doses of solution for injection for fixed-dose subcutaneous administration are confidential and cannot be reported here.

2.4 The company has a commercial arrangement. This makes risankizumab available to the NHS with a discount. The size of the discount is commercial in confidence. It is the company's responsibility to let relevant NHS organisations know details of the discount.

3 Implementation

3.1 Section 7 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires integrated care boards, NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this evaluation within 3 months of its date of publication. Because risankizumab has been recommended through the cost-comparison process, NHS England and integrated care boards have agreed to provide funding to implement this guidance 30 days after publication.

3.2 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal guidance recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide

funding and resources for it within 2 months of the first publication of the final draft guidance.

3.3 When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a patient has previously treated moderately to severely active ulcerative colitis and the doctor responsible for their care thinks that risankizumab is the right treatment, it should be available for use, in line with NICE's recommendations.

4 Evaluation committee members and NICE project team

Evaluation committee members

This topic was considered by the chair and vice chair of NICE's highly specialised technologies evaluation committee.

Committee members are asked to declare any interests in the technology being evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

Chair

Paul Arundel
Chair, highly specialised technologies evaluation committee

NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser and a project manager.

Alex Sampson
Technical lead

Zoe Charles

Technical adviser

Jeremy Powell

Project manager

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