NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Final draft guidance

Mirikizumab for treating moderately to severely active ulcerative colitis

1 Recommendations

1.1 Mirikizumab 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 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 mirikizumab to be 1 of a range of suitable treatments (including vedolizumab and 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 mirikizumab that was started in the NHS before this guidance was published. People having treatment outside these recommendations 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, usually people are offered vedolizumab or ustekinumab. Mirikizumab is another biological treatment that would be offered to the same population as these 2 treatments.

Clinical trial evidence shows that mirikizumab is more effective than placebo for treating moderately to severely active ulcerative colitis. However, there are no clinical trials directly comparing mirikizumab with vedolizumab or ustekinumab. An indirect comparison suggests that all 3 treatments are similarly effective.

A cost comparison suggests the costs of mirikizumab are similar or lower to those of vedolizumab and ustekinumab. Using NICE's cost comparison methods, mirikizumab only needs to cost less than 1 relevant comparator to be recommended as a treatment option. So mirikizumab is recommended.

For all evidence see the committee papers. To see what NICE did for vedolizumab and ustekinumab, see the committee discussion section in NICE's technology appraisal guidance on vedolizumab and ustekinumab.

2 Information about mirikizumab

Marketing authorisation indication

2.1 Mirikizumab (Omvoh, Eli Lilly) is indicated for: 'the treatment of 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.'

Dosage in the marketing authorisation

2.2 The dosage schedule is available in the summary of product characteristics for mirikizumab.

Price

2.3 The list price is £2,056.56 (excluding VAT; emc med data browser accessed August 2023) per:

- 300 mg vial of concentrate for solution for infusion
- 2 pack of 100 mg per 1 ml solution for injection pre-filled syringes.

Costs may vary in different settings because of negotiated procurement discounts.

2.4 The company has a commercial arrangement. This makes mirikizumab 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 mirikizumab has been recommended through the cost-comparison process, NHS England and commissioning groups 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 moderately to severely active ulcerative colitis and the doctor responsible for their care thinks that mirikizumab is the right treatment, it should be available for use, in line with NICE's recommendations.

4 Evaluation committee members and NICE project team

Appraisal committee members

The 4 technology appraisal committees are standing advisory committees of NICE. This topic was considered by the chair of committee C and the 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.

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) and a project manager.

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