NICE National Institute for Health and Care Excellence

NICE guidance

Mirikizumab for previously treated moderately to severely active Crohn's disease

Technology appraisal guidance
Published: 10 July 2025

www.nice.org.uk/guidance/ta1080

Your responsibility

The recommendations in this guidance represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, health professionals are expected to take this guidance fully into account, alongside the individual needs, preferences and values of their patients. The application of the recommendations in this guidance is at the discretion of health professionals and their individual patients and do not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to provide the funding required to enable the guidance to be applied when individual health professionals and their patients wish to use it, in accordance with the NHS Constitution. They should do so in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

1 Recommendations

1.1 Mirikizumab can be used as an option to treat moderately to severely active Crohn's disease in adults, only if:

- the disease has not responded well enough or stopped responding to a previous biological treatment, or
- a previous biological treatment was not tolerated, or
- tumour necrosis factor (TNF)-alpha inhibitors are not suitable.

Mirikizumab can only be used if the company provides it according to the commercial arrangement.

1.2 If people with the condition and their healthcare professional consider mirikizumab to be 1 of a range of suitable treatments, after discussing the advantages and disadvantages of all the options, the least expensive should be used. 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 healthcare professional consider it appropriate to stop.

What this means in practice

Mirikizumab must be funded in the NHS in England for the condition and population in the recommendations, if it is considered the most suitable treatment option. Mirikizumab must be funded in England within 30 days of final publication of this guidance.

There is enough evidence to show that mirikizumab provides benefits and value for money, so it can be used routinely across the NHS in this population.

NICE has produced tools and resources to support implementation of this guidance.

Why these recommendations were made

Usual treatment for moderately to severely active Crohn's disease includes biological treatments such as TNF-alpha inhibitors, risankizumab, ustekinumab and vedolizumab. Mirikizumab is another biological treatment.

Clinical trial evidence shows that mirikizumab works as well as ustekinumab in reducing symptoms and achieving disease remission. Indirect comparisons of mirikizumab with other biological treatments are uncertain. But, together with clinical expert opinion, there is enough evidence that mirikizumab is likely to work as well as risankizumab. Clinical expert opinion also suggests that mirikizumab would be used at the same point in the treatment pathway as risankizumab.

To be recommended as a treatment option, mirikizumab needs to cost less or have similar costs to 1 relevant comparator recommended in a published NICE technology appraisal guidance (see NICE's cost-comparison methods). A cost comparison suggests the costs for mirikizumab are similar to or lower than risankizumab, which is recommended after biological treatment has not worked well enough, stopped working or was not tolerated, or when TNF-alpha inhibitors are unsuitable. So, mirikizumab can be used for this population.

For all evidence see the committee papers. For more information on NICE's evaluation of risankizumab, see the committee discussion section in NICE's technology appraisal guidance on risankizumab.

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 Crohn's disease 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 of the 300-mg concentrate solution for infusion used for induction treatment is £2,056.56 (excluding VAT, BNF online, accessed April 2025). The list price of 1 pre-filled pen of 200 mg plus 1 pre-filled pen of 100 mg for subcutaneous injection as maintenance treatment is £2,398.33 (excluding VAT, company communication).

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.

Carbon Reduction Plan

2.5 For information, the Carbon Reduction Plan for UK carbon emissions is published on Eli Lilly's webpage on environmental sustainability.

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 90 days of its date of publication. Because mirikizumab 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 60 days 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 Crohn's disease and the healthcare professional 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

Evaluation committee members

The highly specialised technologies committee is a standing advisory committee of NICE. This topic was considered as a cost-comparison evaluation by the lead team of the highly specialised technologies committee, which includes the chair and vice chair.

The chair and vice chair were 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 and vice chair

Dr Paul Arundel and Professor Iolo Doull
Chair and vice 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, a project manager and an associate director.

Alex Sampson
Technical lead

Zoe Charles
Technical adviser

Jennifer Upton
Project manager

Janet Robertson

Associate director

ISBN: 978-1-4731-7096-4