

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Final draft guidance

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

## 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 (see [section 2](#)).

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 to treat moderately to severely active Crohn's disease, if it is considered the most suitable treatment option, and:

- a previous biological treatment has not worked well enough, has stopped working, or was not tolerated, or
- TNF-alpha inhibitors are unsuitable.

Because mirikizumab has been recommended through the cost-comparison process, it 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.

**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

Final draft guidance – Mirikizumab for previously treated moderately to severely active Crohn's disease

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 confidential.
- 2.4 The company has a commercial arrangement (simple discount patient access scheme). This makes mirikizumab available to the NHS with a discount. The size of the discount is commercial in confidence.

## Carbon Reduction Plan

- 2.5 Information on the Carbon Reduction Plan for UK carbon emissions for Eli Lilly will be included here when guidance is published.

## 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: [to be added at publication]