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Advice document
SMC2650

# mirikizumab solution for injection in pre-filled pen and concentrate for solution for infusion (Omvoh®)

## Eli Lilly and Company Ltd

08 March 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

**mirikizumab (Omvoh®)** 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 with, lost response to, or were intolerant to either conventional therapy or a biologic treatment.

Mirikizumab 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**

# 1. Clinical Context

### 1.1. Medicine background

Mirikizumab is a humanised IgG4 monoclonal antibody that binds to the p19 subunit of interleukin 23. It is administered as an intravenous infusion for the induction doses (300 mg at weeks 0, 4 and 8), followed by maintenance doses of 200 mg subcutaneously every 4 weeks.[1]

### 1.2. Relevant comparator(s)

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 ulcerative colitis (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 that ustekinumab and vedolizumab were the most relevant comparators for mirikizumab in the indication under review. Vedolizumab (an integrin inhibitor) has also been accepted for use by SMC 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 tumour necrosis factor-alpha (TNFα) antagonist (SMC1045/15).

# 2. Summary of Clinical Evidence

### 2.1. Evidence to support comparable efficacy with relevant comparators

There is no direct evidence comparing mirikizumab with an active comparator. The efficacy and safety data for mirikizumab versus placebo are derived from two randomised, double-blind, placebo-controlled phase III studies (LUCENT-1 and LUCENT-2) in patients with moderately to severely active UC who had an inadequate response to, loss of response to, or were intolerant to conventional or biologic therapy for UC. After 12 weeks, mirikizumab induced clinical remission in a greater proportion of patients compared with placebo in LUCENT-1. Patients who achieved clinical remission in LUCENT-1 could enter the maintenance study (LUCENT-2). Clinical remission at 40 weeks was achieved in a greater proportion of patients in the mirikizumab group compared with placebo.[2]

The submitting company presented results from a Bayesian network meta-analysis (NMA) comparing mirikizumab with ustekinumab and vedolizumab for several efficacy and safety outcomes in both the biologic-naïve and biologic-failed populations. The NMA supported the assumption that mirikizumab has similar clinical benefit to ustekinumab and vedolizumab in the induction and maintenance phases and did not indicate any differences in serious adverse events between the treatments.

## 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. Eli Lilly and Company Limited, Summary of Product Characteristics, mirikizumab 100 mg solution for injection in pre-filled pen and 300 mg concentrate for solution for infusion. www.medicines.org
2. European Medicines Agency (EMA), European Public Assessment Report, mirikizumab (Omvoh®). EMEA/H/C/005122/0000, published 30 March 2023. Available at: https://www.ema.europa.eu/en/medicines/human/EPAR/omvoh#ema-inpage-item-assessment-history


This assessment is based on data submitted by the applicant company up to and including 05 December 2023.

**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.