HSE Prescribing Protocol

for the treatment of adult patients with moderately to severely active Ulcerative Colitis

Risankizumab (Skyrizi®)

Mirikizumab (Omvoh®)

This document is intended for use by healthcare professionals only.

This guideline should be used in conjunction with the full prescribing and administration details in the Summary of Product Characteristics (SmPC)

Risankizumab (Skyrizi®) https://www.ema.europa.eu/en/documents/product-information/skyrizi-epar-product-information_en.pdf

Mirikizumab (Omvoh®) https://www.ema.europa.eu/en/documents/product-information/omvoh-epar-product-information_en.pdf

INDICATION FOR USE

TREATMENT	HSE APPROVED INDICATION	ICD10	PROTOCOL CODE
Risankizumab[1]	Treatment of adult patients with moderately to severely active Ulcerative Colitis (UC) who have had an inadequate response to, lost response to, or were intolerant to conventional* or a biologic therapy¥. Reimbursement is restricted to use as a subsequent line of therapy following treatment with a lower cost biologic therapy¥.	K51	Gastro002a
Mirikizumab[2]	Treatment of adult patients with moderately to severely active Ulcerative Colitis (UC) who have had an inadequate response to, lost response to, or were intolerant to conventional* or a biologic therapy¥. Reimbursement is restricted to use as a subsequent line of therapy following treatment with a lower cost biologic therapy¥.	K51	Gastro002b

*Conventional Therapy (for UC):

- Thiopurines (azathioprine or 6-mercaptopurine) +/- allopurinol
- Methotrexate (subcutaneous or oral)

¥First line Biological therapy Options:

- Infliximab
- Adalimumab
- Ustekinumab
- Vedolizumab

Please contact your pharmacy department for pricing arrangements for relevant agent(s).

TREATMENT

Ulcerative Colitis

Risankizumab	DOSE	ROUTE	DURATION OF THERAPY
Induction	1200mg	IV	At week 0, 4 and 8
Maintenance	Based on individual patient presentation*	Subcutaneously	At week 12 and then every 8 weeks thereafter

*A dose of 180 mg administered by subcutaneous injection is recommended for patients with adequate improvement in disease activity after induction
A dose of 360 mg administered by subcutaneous injection is recommended for patients with inadequate improvement in disease activity after induction (See SmPC for further information)

Mirikizumab	DOSE	ROUTE	DURATION OF THERAPY
Induction	300mg	IV	At weeks 0, 4 and 8
Maintenance	200mg	Subcutaneously	At week 12 and then every 4 weeks thereafter

ELIGIBILITY CRITERIA

- Patients 18 years or over
- Patients with moderate to severe Ulcerative Colitis
- Patients who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic therapy (as defined above)

EXCLUSION CRITERIA

Patients who do not meet the eligibility criteria

CONTRAINDICATIONS

- Hypersensitivity to the active substance or to any of the excipients listed in SmPC
- Clinically important active infections as per SmPC

BASELINE TESTS AND MONITORING

As stipulated by the clinical team.

SPECIAL WARNINGS AND PRECAUTION FOR USE

See SmPC

STOPPING CRITERIA

Consideration should be given to discontinuing treatment in patients who have shown no evidence of therapeutic benefit by week 24.[1,2]

ADVERSE EFFECTS

See SmPC

OTHER INFORMATION

Missed dose[1,2]

If a dose is missed, the dose should be administered as soon as possible. Thereafter, dosing should be resumed at the regular scheduled time

DRUG INTERACTIONS

See SmPC

ATC CODE

Immunosuppressants, interleukin inhibitors

L04AC18 Risankizumab

L04AC24 Mirikizumab

REIMBURSEMENT CATEGORY

Induction: Risankizumab (Skyrizi®) 600mg concentrate for solution for infusion is managed within local hospital budget
Maintenance: Risankizumab (Skyrizi®) 180mg or 360mg solution for injection in cartridge are available via High Tech Hub arrangements

Induction: Mirikizumab (Omvoh®) 300 mg concentrate for solution for infusion is managed within local hospital budget
Maintenance: Mirikizumab (Omvoh®) 200 mg by subcutaneous injection every 4 weeks after completion of induction dosing. Mirikizumab (Omvoh®) 100mg pre-filled pen x 2 is available via High Tech Hub arrangements

REFERENCES

1. Summary of Product Characteristics, Skyrizi 600mg concentrate for solution for infusion. Available from https://www.ema.europa.eu/en/documents/product-information/skyrizi-epar-product-information_en.pdf Accessed on: 04 September 2025
2. Summary of Product Characteristics, Omvoh 300mg concentrate for solution for infusion. Available from https://www.ema.europa.eu/en/documents/product-information/omvoh-epar-product-information_en.pdf Accessed on: 04 September 2025

APPENDIX

Revision History

Revision Number	Revision Date	Summary of Changes