HSE Prescribing Protocol

Risankizumab (Skyrizi®)

for

the treatment of adult patients with moderately to severely active Crohn's Disease

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 Risankizumab (Skyrizi®) Summary of Product Characteristics (SmPC)
https://www.medicines.ie/medicines/skyrizi-600-mg-concentrate-for-solution-for-infusion-35302/spc

INDICATION FOR USE[1]

TREATMENT	HSE APPROVED INDICATION	ICD10	PROTOCOL CODE
Risankizumab	Treatment of adult patients with moderately to severely active Crohn's Disease who have had an inadequate response, lost response or were intolerant to either conventional therapy* or a biologic therapy¥. Risankizumab is restricted to use by the HSE as a second or subsequent line of therapy following treatment with a lower cost biological therapy¥	K50	Gastro001

*Conventional Therapy:

- 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[1]

Risankizumab	DOSE	ROUTE	DURATION OF THERAPY
Induction	600mg	IV	At week 0, 4 and 8
Maintenance	360mg	Subcutaneously	At week 12 and then every 8 weeks thereafter

ELIGIBILITY CRITERIA

- Patients 18 years or over
- Patients with moderate to severe Crohn's Disease
- 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].

ADVERSE EFFECTS

See SmPC

OTHER INFORMATION

Missed dose[1]
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

REIMBURSEMENT CATEGORY

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

REFERENCES

1. Summary of Product Characteristics, Skyrizi 600mg concentrate for solution for infusion. Available from https://www.medicines.ie/medicines/skyrizi-600-mg-concentrate-for-solution-for-infusion-35302/spc. Accessed on: 18 June2024

APPENDIX

Revision History

Revision Number	Revision Date	Summary of Changes