Skyrizi®
risankizumab-rzaa

For adults with: moderately to severely active Crohn's disease or moderately to severely active ulcerative colitis (UC)[1]

DOSING & MONITORING GUIDE

IL-23i=interleukin-23 inhibitor.

INDICATIONS[1]

Crohn's Disease: SKYRIZI is indicated for the treatment of moderately to severely active Crohn's disease in adults.
Ulcerative Colitis: SKYRIZI is indicated for the treatment of moderately to severely active ulcerative colitis in adults.

SAFETY CONSIDERATIONS[1]

SKYRIZI is contraindicated in patients with a history of serious hypersensitivity reaction to risankizumab-rzaa or any of its excipients. Serious hypersensitivity reactions, including anaphylaxis, have been reported with use of SKYRIZI. If a serious hypersensitivity reaction occurs, discontinue SKYRIZI and initiate appropriate therapy immediately. SKYRIZI may increase the risk of infection. Instruct patients to report signs or symptoms of clinically important infection during treatment. Should such an infection occur, discontinue SKYRIZI until infection resolves. Evaluate patients for tuberculosis infection prior to initiating treatment with SKYRIZI. Drug-induced liver injury was reported in a patient with Crohn's disease during induction dosing of SKYRIZI. For the treatment of Crohn's disease and ulcerative colitis, evaluate liver enzymes and bilirubin at baseline and during induction (12 weeks). Interrupt treatment with SKYRIZI if drug-induced liver injury is suspected, until this diagnosis is excluded. Avoid use of live vaccines in SKYRIZI patients.

Please see additional Important Safety Information on page 6. Please see full Prescribing Information.

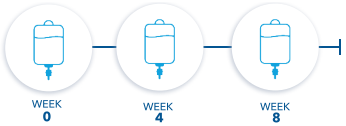
2-MONTH MAINTENANCE DOSING AFTER 3 IV INFUSIONS FOR CROHN'S OR UC

INDUCTION[1]

3 IV Infusions

600 mg per dose in Crohn's

1200 mg per dose in UC

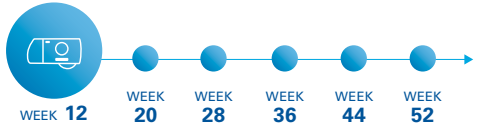


Administer each dose of SKYRIZI over at least 1 hour for Crohn's and 2 hours for UC

Crohn's dose: 1 carton of SKYRIZI 600 mg/10 mL: **NDC 0074-5015-01**
UC dose: 2 cartons of SKYRIZI 600 mg/10 mL: **NDC 0074-5015-01**

MAINTENANCE[1]

6 SC Doses Per Year
(180 mg/1.2 mL or 360 mg/2.4 mL)



Use the lowest effective dosage to maintain therapeutic response

On-Body Injector (OBI) with SKYRIZI prefilled cartridge for SC injection

SKYRIZI 180 mg/1.2 mL: **NDC 0074-1065-01** (kit)
SKYRIZI 360 mg/2.4 mL: **NDC 0074-1070-01** (kit)

FLEXIBILITY OF MAINTENANCE DOSE ADMINISTRATION[1]

IN OFFICE

OR

AT HOME

IV=intravenous; SC=subcutaneous; UC=ulcerative colitis.

ADMINISTRATION CONSIDERATIONS[1]

SKYRIZI (risankizumab-rzaa) is intended for use under the guidance and supervision of a healthcare professional (HCP). SKYRIZI vial for intravenous administration is intended for administration by an HCP. Prior to starting therapy, please refer to the Dosage and Administration section of the Prescribing Information for complete information on how to initiate, prepare, and administer SKYRIZI. Patients may self-inject SKYRIZI using the On-Body Injector with prefilled cartridge after training in subcutaneous injection technique. Provide proper training to patients and/or caregivers on the subcutaneous injection technique of SKYRIZI according to the Instructions for Use.[1]

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Skyrizi® COMPLETE

ENROLL PATIENTS FOR SKYRIZI COMPLETE SUPPORT

Skyrizi Complete is here for your patients offering 1:1 support through every stage of the treatment experience.
Visit the Skyrizi Complete page here or **scan the QR code** to access the enrollment form and fax to **1.678.727.0690**.

1-2-3 SUPPORT THROUGH THE TREATMENT EXPERIENCE

1

ONE person supporting patient access and reimbursement for your office

Field Access Specialist

2

Patient access* and education through **TWO** treatment phases

Infusion (Induction)

OBI (Maintenance)

Nurse Ambassador†

3

The only‡ savings program with **THREE** potential ways to save

$0

1. Infusion-related costs
2. SKYRIZI (Infusion and OBI)
3. Required lab testing

Commercially insured eligible patients may pay as little as zero dollars per treatment. See savings program terms and conditions in footnotes.§

*Patient access and education includes processes and information around patient coverage through BV and PA for both the infusion and OBI.
†Nurse Ambassadors are provided by AbbVie and do not provide medical advice or work under the direction of the prescribing health care professional (HCP). They are trained to direct patients to speak with their HCP about any treatment-related questions, including further referrals.
‡Based on review of public information as of 12/2023.
§Eligibility: Available to patients with commercial insurance coverage for SKYRIZI® (risankizumab-rzaa) who meet eligibility criteria. This co-pay assistance program is not available to patients receiving prescription reimbursement under any federal, state, or government-funded insurance programs (for example, Medicare [including Part D], Medicare Advantage, Medigap, Medicaid, TRICARE, Department of Defense, or Veterans Affairs programs) or where prohibited by law. Offer subject to change or termination without notice. Restrictions, including monthly maximums, may apply. This is not health insurance. **For full Terms and Conditions, visit SKYRIZISavingsCard.com or call 1.866.SKYRIZI for additional information. For full Terms and Conditions for SKYRIZI Crohn's Disease and Ulcerative Colitis patients, visit www.skyrizi.com/savings-card-terms or call 1.866.SKYRIZI for additional information.** To learn about AbbVie's privacy practices and your privacy choices, visit **https://abbv.ie/corpprivacy**.

BV=benefits verification; OBI=On-Body Injector; PA=prior authorization; UC=ulcerative colitis.

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Skyrizi®
risankizumab-rzaa

LAB MONITORING TREATMENT CONSIDERATIONS FOR CROHN'S AND UC

PERFORM LAB TESTING FOR[1]:

	Check lab values	Treatment should NOT be INITIATED or CONTINUED if:	Additional considerations
Laboratory Parameters Liver enzymes* Bilirubin	Evaluate at baseline and during induction (for at least 12 weeks). Monitor thereafter according to routine patient management.	Drug-induced liver injury is suspected, until this diagnosis is excluded.	Consider other treatment options in patients with evidence of liver cirrhosis. Prompt investigation of the cause of liver enzyme elevation is recommended to identify potential cases of drug-induced liver injury.

*Liver enzymes include ALT and AST.

ALT=alanine aminotransferase; AST=aspartate aminotransferase; UC=ulcerative colitis.

Infections: SKYRIZI (risankizumab-rzaa) may increase the risk of infections. Instruct patients to seek medical advice if signs or symptoms of clinically important infection occur. If such an infection develops, monitor the patient closely and do not administer SKYRIZI until the infection resolves.

Tuberculosis (TB): Evaluate for TB infection prior to initiating treatment with SKYRIZI.

Vaccinations: Complete all age-appropriate vaccinations according to current immunization guidelines prior to initiating treatment with SKYRIZI.

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After training, empower patients to take control of their treatment experience

THE OBI: SKYRIZI (risankizumab-rzaa) PREFILLED CARTRIDGE FOR SC INJECTION

The SKYRIZI **Instructions for Use** includes the full set of detailed instructions on the preparation and administration of SKYRIZI. Instruct patients to read before administration.

STORAGE:

MUST BE REFRIGERATED.

Store SKYRIZI in the refrigerator between 36°F to 46°F (2°C to 8°C)

Keep SKYRIZI in the original carton to protect from light and physical damage until time to use.

PREPARATION:

When ready to use, take the carton out of the refrigerator and leave it at room temperature, out of direct sunlight, for at least 45 minutes up to 90 minutes to allow SKYRIZI to warm.

The OBI will not work if left at room temperature for less than 45 minutes.

Do not remove the On-Body Injector or prefilled cartridge from the carton while allowing SKYRIZI to reach room temperature.

OBI=On-Body Injector; SC=subcutaneous.

Have patients call your office or **1.866.SKYRIZI** (**1.866.759.7494**) if they need help or do not know how to proceed.

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IMPORTANT SAFETY INFORMATION[1]

Hypersensitivity Reactions

SKYRIZI® (risankizumab-rzaa) is contraindicated in patients with a history of serious hypersensitivity reaction to risankizumab-rzaa or any of the excipients. Serious hypersensitivity reactions, including anaphylaxis, have been reported with the use of SKYRIZI. If a serious hypersensitivity reaction occurs, discontinue SKYRIZI and initiate appropriate therapy immediately.

Infection

SKYRIZI may increase the risk of infection. Do not initiate treatment with SKYRIZI in patients with a clinically important active infection until it resolves or is adequately treated.

In patients with a chronic infection or a history of recurrent infection, consider the risks and benefits prior to prescribing SKYRIZI. Instruct patients to seek medical advice if signs or symptoms of clinically important infection occur. If a patient develops such an infection or is not responding to standard therapy, closely monitor and discontinue SKYRIZI until the infection resolves.

Tuberculosis (TB)

Prior to initiating treatment with SKYRIZI, evaluate for TB infection and consider treatment in patients with latent or active TB for whom an adequate course of treatment cannot be confirmed. Monitor patients for signs and symptoms of active TB during and after SKYRIZI treatment. Do not administer SKYRIZI to patients with active TB.

Hepatotoxicity in Treatment of Inflammatory Bowel Disease

Drug-induced liver injury was reported in a patient with Crohn's disease who was hospitalized for a rash during induction dosing of SKYRIZI. For the treatment of Crohn's disease and ulcerative colitis, evaluate liver enzymes and bilirubin at baseline and during induction (12 weeks); monitor thereafter according to routine patient management. Consider an alternate treatment for patients with evidence of liver cirrhosis. Interrupt treatment if drug-induced liver injury is suspected, until this diagnosis is excluded. Instruct your patient to seek immediate medical attention if they experience symptoms suggestive of hepatic dysfunction.

Administration of Vaccines

Avoid use of live vaccines in patients treated with SKYRIZI. Medications that interact with the immune system may increase the risk of infection following administration of live vaccines. Prior to initiating SKYRIZI, complete all age-appropriate vaccinations according to current immunization guidelines.

Adverse Reactions

Most common (>3%) adverse reactions associated with SKYRIZI in Crohn's disease are upper respiratory infections, headache, and arthralgia in induction, and arthralgia, abdominal pain, injection site reactions, anemia, pyrexia, back pain, arthropathy, and urinary tract infection in maintenance.

Most common (≥3%) adverse reactions associated with SKYRIZI in ulcerative colitis are arthralgia in induction, and arthralgia, pyrexia, injection site reactions, and rash in maintenance.

Lipid Elevations: Increases from baseline and increases relative to placebo were observed at Week 4 and remained stable to Week 12 in patients treated with SKYRIZI in Crohn's disease. Lipid elevations observed in patients with ulcerative colitis were similar to those in Crohn's disease.

Dosage Forms and Strengths: SKYRIZI (risankizumab-rzaa) is available in a 600 mg/10 mL single-dose vial for intravenous infusion and a 180 mg/1.2 mL or 360 mg/2.4 mL single-dose prefilled cartridge with on-body injector.

Please see full Prescribing Information.

Reference: 1. SKYRIZI [package insert]. North Chicago, IL: AbbVie Inc.

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