

PRIOR AUTHORIZATION

FOR YOUR CROHN'S DISEASE AND ULCERATIVE COLITIS PATIENTS

If you've determined that Skyrizi is the appropriate treatment for your patient, help get access by following these prior authorization tips.

1

Always include patient diagnosis

Adult patients with moderately to severely active Crohn's disease
Adult patients with moderately to severely active Ulcerative Colitis.

2

Include

Physician's certification stating tuberculosis (TB) status or result of a TB detection test.

3

Document medical necessity by a letter including claims history and/or submission of medical records. Please refer to the QR code to download an example of medical necessity letter (under access and reimbursement forms).

Some medical plans may require documentation of prior therapy, contraindication, or intolerance to: corticosteroid or immunomodulator.



Resources available at: <https://www.skyrizihcprr.com/access-and-support>

Be sure to submit all required patient information in order to receive a timely approval

This resource is for reference only and it demonstrates high-level Pre-Authorization commonalities in Puerto Rico. Providers are encouraged to contact third-party payers for specific information about their coverage policies.

INDICATIONS¹

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 CONSIDERATIONS¹

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.

LEARN MORE AT [SKYRIZIHCPPR.COM](https://www.skyrizihcprr.com)

Please see additional Important Safety Information on next page.

Please see accompanying full [Prescribing Information](#), or visit https://www.rxabbvie.com/pdf/Skyrizi_pi.pdf.

IMPORTANT SAFETY INFORMATION

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.

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

Please see accompanying full **Prescribing Information**, or visit https://www.rxabbvie.com/pdf/Skyrizi_pi.pdf.

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