SKYRIZI PRODUCT FACT SHEET FOR CROHN'S DISEASE AND ULCERATIVE COLITIS INDICATIONS

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.

Images not shown to scale.

Single-dose vial

Single-dose prefilled cartridge with On-Body Injector

PRODUCT OVERVIEW

Dosage and administration[1]	**Crohn's Disease:** The recommended induction dosage is 600 mg administered by intravenous infusion over at least one hour at Week 0, Week 4, and Week 8. The recommended maintenance dosage is 180 mg or 360 mg administered by subcutaneous injection at Week 12, and every 8 weeks thereafter. Use the lowest effective dose needed to maintain therapeutic response. **Ulcerative Colitis:** The recommended induction dosage is 1200 mg administered by intravenous infusion over a period of at least two hours at Week 0, Week 4, and Week 8. The recommended maintenance dosage of SKYRIZI is 180 mg or 360 mg administered by subcutaneous injection at Week 12, and every 8 weeks thereafter. Use the lowest effective dose needed to maintain therapeutic response.
Packaging and NDC number[1]	• 600 mg/10 mL (60 mg/mL) single-dose vial **Carton of 1: 0074-5015-01** • 360 mg/2.4 mL (150 mg/mL) single-dose prefilled cartridge with On-Body injector **Kit: 0074-1070-01** • 180 mg/1.2 mL (150 mg/mL) single-dose prefilled cartridge with On-Body injector **Kit: 0074-1065-01**
Storage and handling[1]	• Store in a refrigerator at 36 °F to 46 °F (2 °C to 8 °C) • Do not shake • Do not freeze • Keep in the original cartons to protect from light • Not made with natural rubber latex
Shipping case dimensions	• Vial: 7.28" x 5.28" x 3.62" • Prefilled cartridge with On-Body Injector: 11.5" x 6.8" x 7.5"
Weight	• Vial: 0.084 lb • Prefilled cartridge with On-Body Injector: 0.49 lb
WAC[2]* (As of April 2024)	• Vial (induction dose): $9,805.92 • Prefilled cartridge with On-Body Injector 6 1 x 180 mg (maintenance dose): $21,017.36 • Prefilled cartridge with On-Body Injector 6 1 x 360 mg (maintenance dose): $21,017.36

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.

NDC=National Drug Code; WAC=wholesale acquisition cost.

*WAC is used as a proxy for retail prices. The actual price paid by patients, third-party payers, and pharmacies may vary and may not correlate with WAC. It does not include discounts, rebates, and any other reductions in price.

Please see additional Important Safety Information on the next page.
Please see accompanying full Prescribing Information.

Skyrizi®
risankizumab-rzaa

POTENTIAL ICD-10-CM DIAGNOSIS CODES[3]

Code	Description	Code	Description	Code	Description
K50.0-K50.019	CD of small intestine	K51.0-K51.019	Ulcerative (chronic) pancolitis	K51.5-K51.519	Left-sided colitis
K50.1-K50.119	CD of large intestine	K51.2-K51.219	Ulcerative (chronic) proctitis	K51.8-K51.819	Other Ulcerative Colitis
K50.8-K50.819	CD of both small and large intestine	K51.3-K51.319	Ulcerative (chronic) rectosigmoiditis	K51.9-K51.919	Ulcerative Colitis, unspecified
K50.9-K50.919	CD, unspecified	K51.4-K51.419	Inflammatory polyps of colon		

IMPORTANT SAFETY INFORMATION FOR SKYRIZI® (risankizumab-rzaa)[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 accompanying full Prescribing Information.

CD=Crohn's Disease; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.

References: 1. SKYRIZI [package insert]. North Chicago, IL: AbbVie Inc. **2.** Data on file, AbbVie Inc. **3.** ICD-10-CM tabular list of diseases and injuries. Centers for Disease Control and Prevention. Accessed April 5, 2024. https://ftp.cdc.gov/pub/health_statistics/nchs/publications/ICD10CM/2022/icd10cm-tabular-2022-April-1.pdf

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