Skyrizi® COMPLETE

NAVIGATING **PRIOR AUTHORIZATIONS** FOR PATIENTS WHO ARE PRESCRIBED SKYRIZI

For patients with moderately to severely active Crohn's disease or moderately to severely active ulcerative colitis

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 click here for full Prescribing Information.

Skyrizi®
risankizumab-rzaa

NAVIGATING PRIOR AUTHORIZATIONS FOR PATIENTS WHO ARE PRESCRIBED SKYRIZI

A prior authorization may be required by the payer

When prescribing SKYRIZI for your patient, determine whether the payer requires prior authorizations (PAs) for both SKYRIZI via intravenous (IV) and SKYRIZI On-Body Injector (OBI) treatment. IV and OBI treatment may be covered under separate medical and pharmacy benefits and require individual PAs. PA requirements may vary by payer, so check with your patient's health plan for an accurate list of requirements before submitting the request. Ensure that diagnosis, disease severity, prior therapies tried, dosing, duration, and clinical testing are documented to help **avoid potential denials due to missing or incomplete information.**

You may obtain the PA form through one of the following:

- Health plan's website
- CoverMyMeds®
- Specialty Pharmacy
- Field Access Specialist

The following table provides an overview of common payer PA requirements and is for illustrative purposes only. As such, it (1) may include certain PA criteria which are not necessary for a specific payer and (2) may not include all necessary PA requirements for a specific payer.

Ensure you document the following in your PA submission and chart notes (as applicable):

Example PA Criteria	Example Information to Include
Patient's diagnosis, using the appropriate ICD-10-CM code(s)[2]*	**K50.0-K50.019** Crohn's disease of small intestine **K50.1-K50.119** Crohn's disease of large intestine **K50.8-K50.819** Crohn's disease of both small and large intestine **K50.9-K50.919** Crohn's disease, unspecified **K51.0-K51.019** Ulcerative pancolitis **K51.2-K51.219** Ulcerative proctitis **K51.3-K51.319** Ulcerative rectosigmoiditis **K51.4-K51.419** Inflammatory polyps of colon **K51.5-K51.519** Left sided colitis **K51.8-K51.919** Other ulcerative colitis or unspecified
Patient's disease and severity (moderate or severe)	Active or erosive disease, such as: • Prominent symptoms include, but are not limited to: fever, weight loss, abdominal pain and tenderness, intermittent nausea and vomiting, anemia, bleeding, diarrhea, internal fistula, intestinal obstruction, megacolon, involvement in upper gastrointestinal tract, stricturing disease, perianal disease or other enterocutaneous fistula, extraintestinal manifestations, deep ulcers, or prior surgical resection • Hospitalization due to Crohn's disease • Fecal markers (fecal calprotectin), serum markers (C-reactive protein), and/or endoscopic assessment • Monitoring: pain, fatigue, stool frequency, and/or rectal bleeding

Chart continues on following page

ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.

*The codes shown are only suggestions and may vary by patient.

This information is presented for informational purposes only and is not intended to provide reimbursement or legal advice. The information presented here does not guarantee payment or coverage. Providers are encouraged to contact third-party payers for specific information about their coverage policies.

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NAVIGATING PRIOR AUTHORIZATIONS FOR PATIENTS WHO ARE PRESCRIBED SKYRIZI (CONT'D)

A prior authorization may be required by the payer

The following table provides an overview of common payer PA requirements and is for illustrative purposes only. As such, it (1) may include certain PA criteria which are not necessary for a specific payer and (2) may not include all necessary PA requirements for a specific payer. Some medications listed below are not approved for moderately to severely active Crohn's disease or moderately to severely active ulcerative colitis.

Ensure you document the following in your PA submission and chart notes (as applicable):

Example PA Criteria	Example Information to Include
Inadequate response or contraindication to current and prior therapies, documenting the treatment name, dose, duration, and date of each therapy: • Note any applicable inadequate responses to **all** prior therapy requirements, not just the most recent therapy • Note any plan-specific duration (eg, for at least 3 months) and treatment period requirements (eg, within the last 12 months)	**Please list all previously tried and failed conventional and biologic therapies, which may include:** **Conventional** • Corticosteroids – prednisone – prednisolone – methylprednisolone – budesonide • Conventional systemic therapies/ immunosuppressants/immunomodulators – azathioprine – methotrexate – 6-mercaptopurine • 5-aminosalicylates – sulfasalazine – mesalamine – olsalazine – balsalazide *This is not a comprehensive list* **Biologics** • Humira® (adalimumab) and biosimilars • Cimzia® (certolizumab pegol) • Remicade® (infliximab) and biosimilars • Stelara® (ustekinumab) • Entyvio® (vedolizumab) • Xeljanz® (tofacitinib) • Omvoh™ (mirikizumab-mrkz) • Velsipity™ (etrasimod) • Tysabri® (natalizumab)
Testing results for clinical parameters, if required by payer	• Tuberculosis (TB) test • Liver enzymes • Complete blood count (CBC) • Bilirubin
Proof of induction and response	*For OBI (maintenance therapy)*: Document that all 3 IV induction doses were taken and that the patient responded with an improvement from baseline. Indicate what improvements from baseline were observed.

It is important to submit documentation for all required information and chart notes with the PA form to support a timely decision from the payer

IV=intravenous; OBI=SKYRIZI On-Body Injector; PA=prior authorization.

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POTENTIAL REASONS FOR **COVERAGE DENIALS**

Incomplete information or lack of documentation may lead to a denial for SKYRIZI

Below are some of the most **common causes for denial**. Be sure to double-check your documentation when submitting the initial PA request to avoid these common causes for denial:

- **Lack of documentation of step therapy** demonstrating all previous therapies tried and failed
  - Names of all conventional therapies or biologics tried and failed
  - Duration of prior therapies (eg, 3 month trial of immunosuppressant therapy)
  - Notes on contraindications or intolerances to other therapies required by the plan
- **Failure to confirm that SKYRIZI is not currently being used** in combination with other immunosuppressants, biologic DMARDs or targeted synthetic DMARDs, or JAK inhibitors
- **Lack of documentation for health plan's clinical testing criteria** (eg, recent [within 6 months of therapy request] TB test, CBC)
- **Lack of documentation supporting diagnosis or disease severity**
  - May include medical records with evidence of definitive diagnosis, chronic colitis, severe disease, hospitalization, etc
- **Lack of documentation supporting successful induction therapy** (3 IVs) for approval of maintenance therapy (OBI)
- **Failure to provide proof of response** for reauthorization of maintenance therapy

For virtual or in-person support, call your Field Access Specialist, or call 1.877.COMPLETE (1.877.266.7538)

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.

CBC=complete blood count; DMARD=disease-modifying antirheumatic drug; IV=intravenous; JAK=Janus kinase; OBI=SKYRIZI On-Body Injector; PA=prior authorization; TB=tuberculosis.

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PRIOR AUTHORIZATION **BEST PRACTICES**

Some suggested best practices for PAs

When requesting a PA, it is important to have all of the necessary information and documentation.

- Before beginning the process, confirm that insurance coverage has not changed since the patient's last visit
- To avoid a disruption in therapy, confirm if a medical and pharmacy PA are required and submit both as soon as possible per payer requirements
- Complete all sections of the PA form(s) and provide any supplemental documentation required
- Determine how the information should be submitted to the payer (fax, electronic PA, portal, website, etc)
- Inquire about the timing of the process once the request is submitted, and update your patient on the request status

TIPS TO KEEP TRACK OF THE PA PROCESS

Log the date and time of calls, who you spoke with, and their contact information

Keep a copy of the PA documentation

Follow up with the payer if your facility does not receive notification of the decision in a timely manner

Record the PA approval code and date in the patient's medical record

Reminders:

- Responses to PA requests are generally received within **72 hours after submission**
- Make note of when a **PA authorization might expire.** If it expires before the end of your patient's treatment, you may need to submit the PA again to continue their coverage

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PA=prior authorization.

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INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR SKYRIZI® (risankizumab-rzaa)

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.

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.

References: 1. SKYRIZI [package insert]. North Chicago, IL: AbbVie Inc. **2.** Centers for Medicare & Medicaid Services. 2024 ICD-10-CM. ICD-10-CM tabular list of diseases and injuries. Updated February 1, 2024. Accessed April 23, 2024. https://www.cms.gov/files/zip/2024-code-tables-tabular-and-index-updated-02/01/2024.zip

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