[Physician’s letterhead]

[Date] Re: [Patient’s name]

[Health plan’s name] [Date of birth]

ATTN: [Department] [Case ID number]

[Health plan’s address] [Date(s) of service]

[City, State ZIP]

**REQUEST:** Authorization for treatment with SKYRIZI® (risankizumab-rzaa)

**DIAGNOSIS:** [Insert diagnosis] [Insert ICD-10-CM Code]

**DOSE AND FREQUENCY:** [Insert dose and frequency]

To whom it may concern,

I am a(n) [insert physician practice area] writing on behalf of my patient, [insert patient name], to request prior authorization approval and to document the medical necessity of SKYRIZI® (risankizumab-rzaa), billed under code
J2327 (“injection, risankizumab-rzaa, intravenous, 1 mg”),1 for the treatment of moderately to severely active ulcerative colitis in adults. My request is supported by the following:

On June 18, 2024, SKYRIZI was approved by the FDA for the treatment of adults with moderately to severely active ulcerative colitis (UC). Please see accompanying full [Prescribing Information](https://www.rxabbvie.com/pdf/skyrizi_pi.pdf) for more information.

**Patient’s Medical History**

[Insert

* Patient’s diagnosis and symptoms
* Date of diagnosis
* Lab results and date
* Current condition
* Previous therapies/procedures
* Dose, duration, and response to previous therapies
* If seeking authorization for a patient transitioning to the SKYRIZI On-Body Injector for maintenance, include documentation of completion of SKYRIZI intravenous (IV) doses for induction

Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the
patient’s medical condition.]

**Summary**

In my clinical opinion, [patient’s name] should receive SKYRIZI for the following reasons:

* [Summary of your professional opinion of the patient’s likely prognosis or disease progression without
treatment with SKYRIZI, including recommendations for why SKYRIZI is appropriate based on the patient’s diagnosis and medical history
* Rationale for not using drugs currently listed on the plan's formulary]

**INDICATION AND IMPORTANT SAFETY INFORMATION FOR SKYRIZI (risankizumab-rzaa)**

**INDICATION2**

SKYRIZI is indicated for the treatment of moderately to severely active ulcerative colitis in adults.

**IMPORTANT SAFETY INFORMATION2**

**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.

**Please see additional Important Safety Information on page 2.**

**Please click here for full** [**Prescribing Information**](https://www.rxabbvie.com/pdf/skyrizi_pi.pdf)**.**

**IMPORTANT SAFETY INFORMATION FOR SKYRIZI (risankizumab-rzaa) (cont’d)**

**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 click here for full** [**Prescribing Information**](https://www.rxabbvie.com/pdf/skyrizi_pi.pdf)**.**

Sincerely,

[Physician’s signature]

Enclosures

[List and attach enclosures, which may include:

Medical records, including medication history

Laboratory work

Other supporting documentation]

**References: 1.** Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) quarterly update. CMS.gov. Updated April 17, 2024. Accessed April 19, 2024. <https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update> **2.** SKYRIZI [package insert]. North Chicago, IL: AbbVie Inc.

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