Skyrizi® COMPLETE

THE **FORMULARY EXCEPTION** REQUEST LETTER

For Commercial Insurance Insurance

INDICATIONS[1]

Plaque Psoriasis: SKYRIZI is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

Psoriatic Arthritis: SKYRIZI is indicated for the treatment of active psoriatic arthritis in adults.

Crohn's Disease: SKYRIZI is indicated for the treatment of moderately to severely active Crohn's disease 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, 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 5.

Please click here for full Prescribing Information.

Skyrizi®
risankizumab-rzaa

WRITING A **FORMULARY EXCEPTION** REQUEST LETTER

A formulary exception is a type of coverage determination used when a drug is not included on a health plan's formulary or is subject to a National Drug Code (NDC) block. A formulary exception request letter may be able to help a patient gain access by outlining the reasons why a treatment is necessary to meet the medical needs of the patient.

Formulary exception request letter submission process

1. The formulary exception request letter **may originate from you**, **your patient**, **or your patient's legal representative**.*
2. Typically, your patient's **medical records** and a **letter of medical necessity (LMN)** are submitted with the letter.
3. **Both** you and your patient **should sign** the letter.

- Plans frequently provide specific formulary exception request templates that must be used when making the request. These forms may be downloaded from each plan's website
- Follow the plan's requirements when requesting SKYRIZI; otherwise, treatment may be delayed†

*Please note for Medicare Part D subscribers: Under the Medicare Part D prescription drug benefit program, a Part D plan enrollee, the enrollee's representative, or the enrollee's doctor or other prescriber can request a coverage determination, including a request for a tiering or formulary exception. A request for a coverage determination can be made orally or in writing. An enrollee, the enrollee's representative, or the enrollee's prescriber may submit a written request for a coverage determination in any format.

†Please note that the Centers for Medicare & Medicaid Services (CMS) has developed "REQUEST FOR MEDICARE PRESCRIPTION DRUG COVERAGE DETERMINATION" model forms that are posted on its website. For more information, visit https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Exceptions

Please see Indications and Important Safety Information on page 5.

Please click here for full Prescribing Information.

Skyrizi® COMPLETE

Skyrizi®
risankizumab-rzaa

WRITING A FORMULARY EXCEPTION LETTER AND **WHAT TO INCLUDE**

Make sure you include all of the information highlighted in red on the sample letter shown on page 4; otherwise, your request could be denied.

Additional documents:

- Letter of medical necessity
- Statement of financial hardship, written by your patient
- Recent photo(s) of the impacted area(s)
- If this letter serves as an appeal, include the case number from the denial letter, a copy of the denial letter, and a written response to the denial

For support in person or over the phone, call an Access Specialist at 1.877.COMPLETE (1.877.266.7538)

Please see Indications and Important Safety Information on page 5.

Please click here for full Prescribing Information.

Skyrizi® COMPLETE

Skyrizi®
risankizumab-rzaa

SAMPLE **FORMULARY EXCEPTION** REQUEST LETTER

This is an example of a letter you can use when your desired treatment option is not included on a health plan's formulary or is subject to an NDC block. This step may require you to submit an LMN with the formulary exception request letter.

[Date]
[Prior authorization department]
[Name of health plan]
[Mailing address]

Re: [Patient's name]
[Plan identification number]
[Date of birth]

To whom it may concern:

My name is [HCP's name], and I am a [board-certified medical specialty] [NPI]. I am writing to request a formulary exception for my patient, [patient's name], who is currently a member of [name of health plan].*

The prescription is for [product, dosage, and frequency], which is medically appropriate and necessary for this patient who has been diagnosed with [condition], [ICD code(s)]. Therefore, I am requesting that the plan remove any relevant NDC blocks, so that [product] can be made available to my patient as a preferred medication.

Patient's history, diagnosis, condition, and symptoms*:

Duration of illness_____

__Abdominal pain/cramping
__Bowel urgency
__Fatigue
__Frequent stools
__ Nausea/vomiting
__Weight loss
__Corticosteroid use
__Biologic use
Duration of use_____
Specify biologic_____
Duration of use_____

Past Treatment(s)†	Start/Stop Dates	Reason(s) for Discontinuing
[Drug name]	[MM/YY] - [MM/YY]	[Please list side effects, lack of efficacy, etc]
[Drug name]	[MM/YY] - [MM/YY]	[Please list side effects, lack of efficacy, etc]

[Include the main reason for requesting this formulary exception].

A Letter of Medical Necessity and pertinent medical records are enclosed, which offer additional support for the formulary exception request for [product].

Please contact me, [name], at [telephone number] for a peer-to-peer review. I would be pleased to speak about why a [product] formulary exception is necessary for [patient's name]'s treatment of [diagnosis].

Sincerely,

[Physician's name and signature]
[Physician's medical specialty] [NPI]
[Physician's practice name]
[Phone #] [Fax #]
Encl: [Medical records, clinical trial information, photo(s), Letter of Medical Necessity]

*Include patient's medical records and supporting documentation, including clinical evaluation, scoring forms, and photos of affected areas.
†Identify drug name, strength, dosage form, and therapeutic outcome.

If this appeal has previously been denied, consider adding:

This is a formulary exception appeal. I have included a copy of the original denial letter and medical notes in response to the denial.

Attach the following:

- A copy of the denial letter
- Medical notes, written by the prescribing physician, in response to the denial letter

This information is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Providers are encouraged to contact third-party payers for specific information about their coverage policies. For more information, please call an Access Specialist at 1.877.COMPLETE (1.877.266.7538).

The sample template shown is for patients who have Crohn's disease. Digital templates for all SKYRIZI indications are available at CompletePro.com and SkyriziHCP.com

LMN=letter of medical necessity; NDC=National Drug Code.

Please see Indications and Important Safety Information on page 5.

Please click here for full Prescribing Information.

Skyrizi® COMPLETE

Skyrizi®
risankizumab-rzaa

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

INDICATIONS[1]

- **Plaque Psoriasis:** SKYRIZI is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.
- **Psoriatic Arthritis:** SKYRIZI is indicated for the treatment of active psoriatic arthritis in adults.
- **Crohn's Disease:** SKYRIZI is indicated for the treatment of moderately to severely active Crohn's disease 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 Crohn's 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, 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 (≥1%) adverse reactions associated with SKYRIZI in plaque psoriasis and psoriatic arthritis include upper respiratory infections, headache, fatigue, injection site reactions, and tinea infections.

In psoriatic arthritis phase 3 trials, the incidence of hepatic events was higher with SKYRIZI compared to placebo.

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

Dosage Forms and Strengths: SKYRIZI is available in a 150 mg/mL prefilled syringe and pen, a 600 mg/10 mL intravenous infusion, and a 360 mg/2.4 mL single-dose prefilled cartridge with on-body injector.

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

Please click here for full Prescribing Information.

abbvie

US-SKZG-210862 June 2022

Skyrizi®
risankizumab-rzaa