Skyrizi® COMPLETE

THE **TIERING EXCEPTION** REQUEST LETTER

For Medicare & TRICARE

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.

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 5.

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Skyrizi®
risankizumab-rzaa

WRITING A **TIERING EXCEPTION** REQUEST LETTER

A tiering exception request letter can help make medication more affordable for patients covered through **Medicaid or TRICARE** who may not be eligible to participate in savings programs but need assistance covering costs. This type of letter can help a patient gain access by outlining the reasons why a treatment is necessary to meet the medical needs of the patient.

Tiering exception request letter submission process

A tiering exception is a type of coverage determination used when a medication is on a plan's formulary but is placed in a nonpreferred tier that has a higher copay or coinsurance. Plans may make a tiering exception when the drug is demonstrated to be medically necessary.

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 tiering 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

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SAMPLE **TIERING EXCEPTION** REQUEST LETTER

This is an example of a letter you can use for patients when the prescribed product is on a health plan's formulary but is placed in a nonpreferred tier that has a higher copay or coinsurance. This step may require you to submit an LMN with the tiering exception request letter.

[Date]
[Formulary director]
[Name of health plan]
[Mailing address]

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

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 tiering 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)].

I am requesting that [product] be made available to my patient as a preferred medication.

In the past, [patient's name] has attempted other treatments for [condition], but those trials have failed due to either inadequate efficacy or lack of tolerability.

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]

The patient's present treatment(s) are as follows:

Current Treatment(s)†	Start Date	Dosage
[Drug name]	[MM/YY]	[XX]
[Drug name]	[MM/YY]	[XX]

Currently, [patient's name] has the following unresolved symptoms:

- [Symptom 1]
- [Symptom 2]

Along with this letter, I have enclosed a copy of my patient's medical records and a Letter of Medical Necessity. The letter describes why [product] is medically necessary for my patient's care over the preferred drugs listed in the plan's formulary.

[Explain why lower-tiered formulary drugs would not be as effective as product].

The reason I am requesting a tiering exception is because the cost associated with [product] assigned tier would present a financial burden to [patient's name]. Furthermore, it prevents my patient from utilizing a medication that will help treat the [condition].

To summarize, I consider [product] to be the best option in successfully treating my patient's [condition]. Please contact me, [name], at [telephone number] to answer any pending questions.

Sincerely,

[Physician's name and signature]
[Physician's medical specialty] [Physician's NPI]
[Physician's practice name]
[Phone #] [Fax #]
Encl: [Medical records, photo(s), Letter of Medical Necessity, statement of financial hardship, case number, written response to denial]

NPI, National Provider Identifier
*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 tiering exception request letter. 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).

Digital version available at CompletePro.com and SkyriziHCP.com

LMN=letter of medical necessity.

Please see Indications and Important Safety Information on page 5.

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WRITING A TIERING EXCEPTION REQUEST LETTER AND **WHAT TO INCLUDE**

Make sure you include all of the information highlighted in red on the sample letter shown on page 3; 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 a Field Access Specialist at 1.877.COMPLETE (1.877.266.7538)

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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.
- **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 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 (≥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, 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 150 mg/mL prefilled syringe and pen, 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 click here for full Prescribing Information.

abbvie

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Skyrizi® risankizumab-rzaa