Skyrizi® COMPLETE

SUBMITTING AN **APPEAL LETTER**

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.

Please click here for full Prescribing Information.

Skyrizi®
risankizumab-rzaa

SUBMITTING AN **APPEAL LETTER**

An appeal letter outlines the reasons why a treatment is necessary to meet the medical needs of your patient.

You may want to submit an appeal letter if the payer:

- Denied payment
- Claimed treatment was not medically necessary
- Said the prescription is not covered by your patient's benefits

Depending on the reason for the denial, different materials and additional steps may be required, such as a formulary exception.

For support in person or over the phone, call a Field 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.

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SAMPLE **APPEAL LETTER**

[Date]

Re: [Patient's name]

[Prior authorization department]

[Plan identification number]

[Name of health plan]

[Date of birth]

[Mailing address]

To whom it may concern:

My name is [HCPs name] and I am a [board-certified medical specialty] [NPI] writing on behalf of my patient, [Patient Name], to request coverage for [product name] [generic]. [Patient Name] has been under my care for [X months] for the treatment of [disease or symptoms].

We understand that the reason for your denial is [copy reason verbatim from the plan's denial letter]. However, we believe that [product, dosage, frequency] is the appropriate treatment for my patient. In support of our recommendation for [product] treatment, we have provided an overview of my patient's relevant clinical history below.

[Provide a brief medical history, including diagnosis, allergies, existing comorbidities, and International Classification of Diseases (ICD) code(s)].

[Discuss rationale for using product vs other treatments. Insert your recommendation summary here, including your professional opinion of your patient's likely prognosis or disease progression without treatment with product].

[List of pertinent medical records] are enclosed, which offer additional support for the formulary exception request for [product name]. Please consider coverage of [product name] for my patient.

Please feel free to contact me, [name], at [telephone number] or [patient's name] at [phone number] for any additional information you may require. We look forward to receiving your timely response and approval of this claim.

Sincerely,

[Physician's name and signature]

[Physician's medical specialty]

[Physician's NPI]

[Physician's practice name]

[Phone #]

[Fax #]

Make sure you match the language from the denial letter.

Note here if you are including a letter of medical necessity along with your appeal 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

For Medicare beneficiaries, there are specific requirements that need to be met for the HCP to be considered a legal representative of the patient in an appeal. For additional information, please visit https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev

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WRITING AN APPEAL 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 appeal could be denied.

Supplemental documentation may include:

- A copy of your patient's records
- Recent photo(s) of the impacted area(s)
- A summary of your recommendation at the end of the letter
- A letter of medical necessity

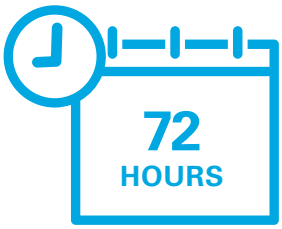
Appealing a step edit?

If this appeal letter is intended to appeal a plan's step edit therapy requirement, you should consider including the following information in your letter:

This is our [add level of request] *coverage authorization appeal. A copy of the most recent denial letter is attached for reference. My patient's medical records are also included in response to the denial.*

[Statement indicating why these step edit therapy requirements are inappropriate for this patient.]

Now that you have submitted the letter with any supporting documentation, the payer must review and decide on coverage within*:



for urgent care

for non-urgent care

for services already provided

*The adjudication timeframes generally begin when the request is received by the plan sponsor. However, if the request involves an exception request, the adjudication timeframe begins when the plan sponsor receives the physician's supporting statement. These are standard timeframes, but timing varies by plan and may differ from the information presented here.

Please see Indications and Important Safety Information on page 5.

Please click here for full Prescribing Information.

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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.

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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 (≥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

Skyrizi® risankizumab-rzaa

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