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 coverage
- 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 an Access Specialist at 1.877.COMPLETE (1.877.266.7538).

Please see Important Safety Information, including BOXED WARNING on Serious Infections, Malignancy, and Thrombosis, on page 4. Please click here for accompanying full Prescribing Information.





Sample appeal letter

[Date]	Re: [Patient's name]	
[Prior authorization department]	[Plan identification number]	
[Name of health plan]	[Date of birth]	
[Mailing address]		
— 1 1		
To whom it may concern:		Make sure you match
	rd-certified medical specialty] [NPI] writing on behalf of my patient, roduct name] [generic]. [Patient Name] has been under my care for symptoms].	the language from the denial letter
believe that [product, dosage, frequency] is	al is [copy reason verbatim from the plan's denial letter]. However, we s the appropriate treatment for my patient. In support of our e have provided an overview of my patient's relevant clinical history	
below.		Note here if you are including a lat
[Provide a brief medical history, including of Classification of Diseases (ICD) code(s)].	diagnosis, allergies, existing comorbidities, and International	Note here if you are including a let of medical necessity along with yo
	er treatments. Insert your recommendation summary here, including likely prognosis or disease progression without treatment with	appeal letter.
[List of pertinent medical records] are enclu for [product name]. Please consider covera	osed, which offer additional support for the formulary exception request age of [product name] for my patient.	If you want to try to expedite the
	[telephone number] or [patient's name] at [phone number] for any a look forward to receiving your timely response and approval of this	appeal process, include:
Sincerely,		I am requesting an expedited revie
		on behalf of my patient.
[Physician's name and signature]		
[Physician's medical specialty]		
[Physician's NPI]		
[Physician's practice name]		
[Phone #]		This information is presented for informational
[Fax #]		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 polici For more information, please call an Access
		Specialist at 1.877.COMPLETE (1.877.266.7538).

Digital version available at CompletePro.com and RINVOQHCP.com.

SAFETY CONSIDERATIONS¹

Serious Infections: Patients treated with RINVOQ are at increased risk for developing serious infections that may lead to hospitalization or death. These infections include tuberculosis (TB), invasive fungal, bacterial, viral, and other infections due to opportunistic pathogens. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Malignancy: Lymphoma and other malignancies have been observed in RINVOQ-treated patients.

Thrombosis: Thrombosis, including deep vein thrombosis, pulmonary embolism, and arterial thrombosis have occurred in patients treated with Janus kinase inhibitors used to treat inflammatory conditions.

Other Serious Adverse Reactions: Patients treated with RINVOQ also may be at risk for other serious adverse reactions, including gastrointestinal perforations, neutropenia, lymphopenia, anemia, lipid elevations, liver enzyme elevations, and embryo-fetal toxicity.

Please see additional Important Safety Information, including BOXED WARNING on Serious Infections, Malignancy, and Thrombosis, on page 4.

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Sample appeal letter (cont'd)



Your patient's appeal could be denied for failure to include in the letter all the information highlighted in red.

Supplemental documentation may include:

- A copy of your patient's relevant medical records A summary of your recommendation
- A recent x-ray (or other imaging) of the impacted area(s)
- A summary of your recommendation at the end of the letter
- A letter of medical necessity (LMN)



Appealing a step edit/step therapy?

If this appeal letter is intended to appeal a plan's step edit therapy requirement, 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 relevant medical records are also included in response to the denial.

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



Once you have submitted the letter with any supporting documentation, the payer must review and decide on coverage.

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.





for non-urgent care



for services already provided

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INDICATION¹

RINVOQ is indicated for the treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate.

Limitation of Use: Use of RINVOQ in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine, is not recommended.

IMPORTANT SAFETY INFORMATION¹ SERIOUS INFECTIONS

Patients treated with RINVOQ are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. If a serious infection develops, interrupt RINVOQ until the infection is controlled.

Reported infections include:

- Active tuberculosis (TB), which may present with pulmonary or extrapulmonary disease. Test patients for latent TB before RINVOQ use and during therapy. Consider treatment for latent infection prior to RINVOQ use.
- Invasive fungal infections, including cryptococcosis and pneumocystosis.
- Bacterial, viral, including herpes zoster, and other infections due to opportunistic pathogens.

Carefully consider the risks and benefits of treatment with RINVOQ prior to initiating therapy in patients with chronic or recurrent infection. Monitor patients closely for the development of signs and symptoms of infection during and after treatment with RINVOQ, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

MALIGNANCY

Lymphoma and other malignancies have been observed in patients treated with RINVOQ. Consider the risks and benefits of treatment with RINVOQ prior to initiating therapy in patients with a known malignancy other than a successfully treated non-melanoma skin cancer (NMSC) or in patients who develop a malignancy. NMSCs have been reported in patients treated with RINVOQ. Periodic skin examination is recommended for patients who are at increased risk for skin cancer.

THROMBOSIS

abbvie

Thrombosis, including deep venous thrombosis, pulmonary embolism, and arterial thrombosis have occurred in patients treated with Janus kinase inhibitors used to treat inflammatory conditions. Many of these adverse events were serious and some resulted in death. Consider the risks and benefits prior to treating patients who may be at increased risk. Patients with symptoms of thrombosis should be promptly evaluated.

GASTROINTESTINAL PERFORATIONS

Gastrointestinal perforations have been reported in clinical studies with RINVOQ, although the role of JAK inhibition in these events is not known. In these studies, many patients with rheumatoid arthritis were receiving background therapy with nonsteroidal anti-inflammatory drugs (NSAIDs). RINVOQ should be used with caution in patients who may be at increased risk for gastrointestinal perforation. Promptly evaluate patients presenting with new onset abdominal symptoms for early identification of gastrointestinal perforation.

LABORATORY ABNORMALITIES

Neutropenia

Treatment with RINVOQ was associated with an increased incidence of neutropenia (absolute neutrophil count [ANC] <1000 cells/mm³). Treatment with RINVOQ is not recommended in patients with an ANC <1000 cells/mm³. Evaluate neutrophil counts at baseline and thereafter according to routine patient management.

Lymphopenia

Absolute lymphocyte counts (ALC) <500 cells/mm³ were reported in RINVOQ clinical studies. Treatment with RINVOQ is not recommended in patients with an ALC <500 cells/mm³. Evaluate at baseline and thereafter according to routine patient management.

Anemia

Decreases in hemoglobin levels to <8 g/dL were reported in RINVOQ clinical studies. Treatment should not be initiated or should be interrupted in patients with hemoglobin levels <8 g/dL. Evaluate at baseline and thereafter according to routine patient management.

Lipids

Treatment with RINVOQ was associated with increases in lipid parameters, including total cholesterol, low-density lipoprotein (LDL) cholesterol, and high-density lipoprotein (HDL) cholesterol. Manage patients according to clinical guidelines for the management of hyperlipidemia. Evaluate 12 weeks after initiation of treatment and thereafter according to the clinical guidelines for hyperlipidemia.

Liver enzyme elevations

Treatment with RINVOQ was associated with increased incidence of liver enzyme elevation compared to placebo. Evaluate at baseline and thereafter according to routine patient management. Prompt investigation of the cause of liver enzyme elevation is recommended to identify potential cases of drug-induced liver injury. If increases in aspartate aminotransferase (AST) or alanine aminotransferase (ALT) are observed during routine patient management and drug-induced liver injury is suspected, RINVOQ should be interrupted until this diagnosis is excluded.

EMBRYO-FETAL TOXICITY

Based on animal studies, RINVOQ may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with RINVOQ and for 4 weeks after the final dose. Verify pregnancy status of females of reproductive potential prior to starting treatment with RINVOQ.

VACCINATION

Use of live, attenuated vaccines during, or immediately prior to, RINVOQ therapy is not recommended. Prior to initiating RINVOQ, patients should be brought up to date on all immunizations, including prophylactic zoster vaccinations, in agreement with current immunization guidelines.

LACTATION

There are no data on the presence of RINVOQ in human milk, the effects on the breastfed infant, or the effects on milk production. Available data in animals have shown the excretion of RINVOQ in milk. Advise patients that breastfeeding is not recommended during treatment with RINVOQ and for 6 days after the last dose.

HEPATIC IMPAIRMENT

RINVOQ is not recommended in patients with severe hepatic impairment.

ADVERSE REACTIONS

The most common adverse reactions in RINVOQ clinical trials (≥1%) were: upper respiratory tract infection, nausea, cough, and pyrexia.

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

Please click here for accompanying <u>full Prescribing Information</u>.

