

# Submitting a letter of medical necessity



## You may need to provide a letter of medical necessity (LMN) if:

- Your patient's claim was denied and you are submitting an appeal letter
- You are requesting a formulary exception or tiering exception to get access for your patient



## Make sure you have the following for an efficient submission of your letter of medical necessity:

- Patient's insurance policy/ID number
- Case ID number if a decision has already been rendered
- Patient's full name, plan identification number, and date of birth
- A brief medical history, including diagnosis, allergies, existing comorbidities, and International Classification of Diseases (ICD) code(s)
- Clinical support for your recommendation
- Your office contact information

**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 3.

Please click [here](#) for accompanying full Prescribing Information.

# Sample letter of medical necessity

Ask the payer whether a specific form is required to help establish medical necessity.



[Date]  
[Payer Name]  
[Payer Address]  
Attn: [Appeals Department]  
Re: [Patient Name]  
[Policy ID/Group Number]  
[Date of Service]

To whom it may concern:

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

I am writing this letter for medical necessity because after working with [Patient name], I believe that [product name] is the best treatment for this patient, and it's important that a formulary exception be made.

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

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

[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 contact me at [telephone number] to answer any pending questions. I would be pleased to speak to the medical necessity of [product name] for [patient's name]'s [diagnosis].

Thank you in advance for your attention to this request.

Sincerely,

[Physician Name and signature]  
[Physician's medical specialty]  
[Physician's NPI]  
[Physician's practice name]  
[Phone #]  
[Fax #]

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](http://CompletePro.com) and [RINVOQHCP.com](http://RINVOQHCP.com).

## SAFETY CONSIDERATIONS<sup>1</sup>

**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 3.

Please click [here](#) for accompanying full Prescribing Information.

# Indication and Important Safety Information for RINVOQ™ (upadacitinib)

## INDICATION<sup>1</sup>

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 INFORMATION<sup>1</sup>

### 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

**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/mm<sup>3</sup>). Treatment with RINVOQ is not recommended in patients with an ANC <1000 cells/mm<sup>3</sup>. Evaluate neutrophil counts at baseline and thereafter according to routine patient management.

### Lymphopenia

Absolute lymphocyte counts (ALC) <500 cells/mm<sup>3</sup> were reported in RINVOQ clinical studies. Treatment with RINVOQ is not recommended in patients with an ALC <500 cells/mm<sup>3</sup>. 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 [full Prescribing Information](#).

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