

# 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 Indications and Important Safety Information, including **BOXED WARNING** on **SERIOUS INFECTIONS, MORTALITY, MALIGNANCY, MAJOR ADVERSE CARDIOVASCULAR EVENTS (MACE)**, and **THROMBOSIS**, on pages 3 and 4.

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

**RINVOQ<sup>®</sup> COMPLETE**



# Sample letter of 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] [NP] 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 NP]  
[Physician's practice name]  
[Phone #]  
[Fax #]

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



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.

**Mortality:** A higher rate of all-cause mortality, including sudden cardiovascular (CV) death, was observed with a Janus kinase (JAK) inhibitor in a study comparing another JAK inhibitor with tumor necrosis factor (TNF) blockers in rheumatoid arthritis (RA) patients  $\geq 50$  years of age with at least one CV risk factor.

**Malignancies:** Lymphoma and other malignancies have been observed in RINVOQ-treated patients. A higher rate of malignancies (excluding non-melanoma skin cancer [NMSC]), lymphomas, and lung cancer (in current or past smokers) was observed with another JAK inhibitor when compared with TNF blockers in RA patients. Patients who are current or past smokers are at additional increased risk.

Please see Indications and additional Important Safety Information, including BOXED WARNING on SERIOUS INFECTIONS, MORTALITY, MALIGNANCY, MAJOR ADVERSE CARDIOVASCULAR EVENTS (MACE), and THROMBOSIS, on pages 3 and 4.

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

**RINVOQ<sup>®</sup> COMPLETE**



# Indications and Important Safety Information for RINVOQ® (upadacitinib)

## INDICATIONS<sup>1</sup>

RINVOQ is indicated for the treatment of:

- **Moderately to severely active rheumatoid arthritis** in adults who have had an inadequate response or intolerance to one or more TNF blockers.
- **Active psoriatic arthritis** in adults who have had an inadequate response or intolerance to one or more TNF blockers.

**Limitations 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.

- **Refractory, moderate to severe atopic dermatitis** in adults and pediatric patients 12 years of age and older whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable.

**Limitations of Use:** RINVOQ is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.

## 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 TB 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.

### MORTALITY

In a large, randomized, postmarketing safety study comparing another Janus kinase (JAK) inhibitor with tumor necrosis factor (TNF) blockers in rheumatoid arthritis (RA) patients  $\geq 50$  years old with at least one

cardiovascular (CV) risk factor, a higher rate of all-cause mortality, including sudden CV death, was observed with the JAK inhibitor. Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with RINVOQ.

### MALIGNANCIES

Lymphoma and other malignancies have been observed in patients treated with RINVOQ.

In a large, randomized, postmarketing safety study comparing another JAK inhibitor with TNF blockers in RA patients, a higher rate of malignancies (excluding non-melanoma skin cancer [NMSC]), lymphomas, and lung cancer (in current or past smokers) was observed with the JAK inhibitor. Patients who are current or past smokers are at additional increased risk.

With RINVOQ, consider the benefits and risks for the individual patient prior to initiating or continuing therapy, particularly in patients with a known malignancy (other than a successfully treated NMSC), patients who develop a malignancy when on treatment, and patients who are current or past smokers. NMSCs have been reported in patients treated with RINVOQ. Periodic skin examination is recommended for patients who are at increased risk for skin cancer. Advise patients to limit sunlight exposure by wearing protective clothing and using sunscreen.

### MAJOR ADVERSE CARDIOVASCULAR EVENTS

In a large, randomized, postmarketing study comparing another JAK inhibitor with TNF blockers in RA patients  $\geq 50$  years old with at least one CV risk factor, a higher rate of major adverse cardiovascular events (MACE) (defined as cardiovascular death, myocardial infarction, and stroke) was observed with the JAK inhibitor. Patients who are current or past smokers are at additional increased risk. Discontinue RINVOQ in patients that have experienced a myocardial infarction or stroke.

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with RINVOQ, particularly in patients who are current or past smokers and patients with other CV risk factors. Patients should be informed about the symptoms of serious CV events and the steps to take if they occur.

### THROMBOSIS

Thrombosis, including deep venous thrombosis, pulmonary embolism, and arterial thrombosis have occurred in patients treated with JAK inhibitors used to treat inflammatory conditions. Many of these adverse events were serious and some resulted in death.

In a large, randomized, postmarketing study comparing another JAK inhibitor to TNF blockers in RA patients  $\geq 50$  years old with at least one CV risk factor, a higher rate of thrombosis was observed with the JAK inhibitor. Avoid RINVOQ in patients at risk. Patients with symptoms of thrombosis should discontinue RINVOQ and be promptly evaluated.

DMARDs, disease-modifying antirheumatic drugs; JAK, Janus kinase; TNF, tumor necrosis factor.

Please see additional Important Safety Information continued on page 4.

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



# Important Safety Information for RINVOQ<sup>®</sup> (upadacitinib)<sup>1</sup> (cont'd)

## **HYPERSENSITIVITY**

RINVOQ is **contraindicated** in patients with known hypersensitivity to upadacitinib or any of its excipients. Serious hypersensitivity reactions, such as anaphylaxis and angioedema, were reported in patients receiving RINVOQ in clinical trials. If a clinically significant hypersensitivity reaction occurs, discontinue RINVOQ and institute appropriate therapy.

## **GASTROINTESTINAL PERFORATIONS**

Gastrointestinal (GI) perforations have been reported in clinical trials with RINVOQ. In these trials, many patients with RA were receiving background therapy with nonsteroidal anti-inflammatory drugs (NSAIDs). Monitor RINVOQ-treated patients who may be at risk for gastrointestinal perforation (e.g., patients with a history of diverticulitis or taking NSAIDs). Promptly evaluate patients presenting with new onset abdominal pain for early identification of GI 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 patients 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 findings in 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**

Avoid use of live vaccines during, or immediately prior to, RINVOQ therapy. Prior to initiating RINVOQ, patients should be brought up to date on all immunizations, including varicella zoster or prophylactic herpes 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 for use in patients with severe hepatic impairment.

## **ADVERSE REACTIONS**

The most common adverse reactions in RINVOQ clinical trials (≥1%) were upper respiratory tract infections, herpes zoster, herpes simplex, bronchitis, nausea, cough, pyrexia, acne, headache, blood creatine phosphokinase increased, hypersensitivity, folliculitis, abdominal pain, increased weight, influenza, fatigue, neutropenia, myalgia, and influenza-like illness.

Inform patients that retinal detachment has been reported in clinical trials with RINVOQ. Advise patients to immediately inform their healthcare provider if they develop any sudden changes in vision while receiving RINVOQ.

**Dosage Forms and Strengths:** RINVOQ is available in 15 mg and 30 mg extended-release tablets.

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

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

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