

Submitting an Appeal Letter



Support

For case-specific or general access support, call your **Field Reimbursement Manager**, or call **1.877.COMPLETE** (1.877.266.7538)

Please see **Indications and Important Safety Information**, including **Boxed Warning on Serious Infections, Mortality, Malignancies, Major Adverse Cardiovascular Events, and Thrombosis**, on pages 5 and 6.

Please visit https://www.rxabbvie.com/pdf/rinvoq_pi.pdf for full **Prescribing Information**.



Submitting an appeal letter

- **While going through the prescription fulfillment process to get your patient on RINVOQ, you may have to submit an appeal letter.**

An appeal letter outlines the reasons why a treatment is necessary to meet the medical needs of your patient. RINVOQ Complete can help avoid lapses in coverage and ensure your patients stay on track with their prescribed treatment plan.



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.

You may receive a denial if the PA* form has been filled out incorrectly. If this is the case, you may be able to resubmit the PA form once the errors have been corrected. Otherwise, an appeal letter may be necessary.

*PA, prior authorization.



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Submitting an appeal letter

■ Your patient's appeal could be denied for failure to include all the information highlighted in red below and on the sample letter shown on the next page.

- A copy of your patient's relevant medical records
- Recent photos, x-rays, or other imaging of the impacted area(s)
- Supportive literature
- 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 time frame typically begins when the request is received by the plan sponsor. However, if the request involves an exception request, the adjudication time frame begins when the plan sponsor receives the physician's supporting statement. These are standard time frames, but timing varies by plan and may differ from the information presented here.



■ SAFETY CONSIDERATIONS FOR RINVOQ/RINVOQ LQ (upadacitinib)¹

SERIOUS INFECTIONS: Patients treated with RINVOQ* are at increased risk of serious bacterial (including tuberculosis [TB]), fungal, viral, and opportunistic infections leading to hospitalization or death. 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 inhibitor (JAKi) in a study comparing another JAKi with tumor necrosis factor (TNF) blockers in rheumatoid arthritis (RA) patients ≥ 50 years with ≥ 1 CV risk factor.

MALIGNANCIES: Malignancies have occurred in RINVOQ-treated patients. A higher rate of lymphomas and lung cancer (in current or past smokers) was observed with another JAKi when compared with TNF blockers in RA patients.

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MAJOR ADVERSE CARDIOVASCULAR EVENTS: A higher rate of CV death, myocardial infarction, and stroke was observed with a JAKi in a study comparing another JAKi with TNF blockers in RA patients ≥ 50 years with ≥ 1 CV risk factor. History of smoking increases risk.

THROMBOSES: Deep venous thrombosis, pulmonary embolism, and arterial thrombosis have occurred in patients treated for inflammatory conditions with JAK inhibitors, including RINVOQ. A higher rate of thrombosis was observed with another JAKi when compared with TNF blockers in RA patients.

HYPERSENSITIVITY: RINVOQ is contraindicated in patients with hypersensitivity to RINVOQ or its excipients.

OTHER SERIOUS ADVERSE REACTIONS: Hypersensitivity Reactions, Gastrointestinal Perforations, Laboratory Abnormalities, and Embryo-Fetal Toxicity.

*Unless otherwise stated, "RINVOQ" in the SAFETY CONSIDERATIONS refers to RINVOQ and RINVOQ LQ.



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 [HCP's 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 #]

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Appeal letter tips

- ✓ 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.
- ✓ **If you want to try to expedite the appeal process, include:**
I am requesting an expedited review on behalf of my patient.

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 Field Reimbursement Manager at **1.877.COMPLETE** (1.877.266.7538).

Digital version available at
CompletePro.com and RINVOQHCP.com

SAFETY CONSIDERATIONS FOR RINVOQ/RINVOQ LQ (upadacitinib)¹

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INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR RINVOQ/RINVOQ LQ (upadacitinib)

INDICATIONS¹

RINVOQ is indicated for the treatment of:

- **Moderately to severely active rheumatoid arthritis (RA)** in adults who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers.
- **Active ankylosing spondylitis (AS)** in adults who have had an inadequate response or intolerance to one or more TNF blockers.
- **Active non-radiographic axial spondyloarthritis (nr-axSpA)** with objective signs of inflammation in adults who have had an inadequate response or intolerance to TNF blocker therapy.
- **Giant cell arteritis (GCA)** in adults.

Limitations of Use: RINVOQ is not recommended for use in combination with other Janus kinase (JAK) inhibitors, biologic disease-modifying antirheumatic drugs (bDMARDs), or with potent immunosuppressants such as azathioprine and cyclosporine.

- **Refractory, moderate to severe atopic dermatitis (AD)** 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 is inadvisable.

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

- **Moderately to severely active ulcerative colitis (UC)** in adults who have had an inadequate response or intolerance to one or more TNF blockers.
- **Moderately to severely active Crohn's disease (CD)** in adults who have had an inadequate response or intolerance to one or more TNF blockers.

Limitations of Use: RINVOQ is not recommended for use in combination with other JAK inhibitors, biological therapies for ulcerative colitis or Crohn's disease, or with potent immunosuppressants such as azathioprine and cyclosporine.

RINVOQ/RINVOQ LQ is indicated for the treatment of:

- **Active psoriatic arthritis (PsA)** in adults and pediatric patients 2 years of age and older who have had an inadequate response or intolerance to one or more TNF blockers.
- **Active polyarticular juvenile idiopathic arthritis (pJIA)** in patients 2 years of age and older who have had an inadequate response or intolerance to one or more TNF blockers.

Limitations of Use: RINVOQ/RINVOQ LQ is not recommended for use in combination with other JAK inhibitors, bDMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine.

IMPORTANT SAFETY INFORMATION FOR RINVOQ/RINVOQ LQ (upadacitinib)¹

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.

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

Please see additional **Important Safety Information**, including **Boxed Warning on Thrombosis**, on page 6.

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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 ≥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 (MACE)

In a large, randomized, postmarketing study comparing another JAK inhibitor with TNF blockers in RA patients ≥50 years old with at least one CV risk factor, a higher rate of 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.



INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR RINVOQ/RINVOQ LQ (upadacitinib) (CONTINUED)

THROMBOSIS

Thromboses, including deep venous thrombosis, pulmonary embolism, and arterial thrombosis, have occurred in patients treated for inflammatory conditions with JAK inhibitors, including RINVOQ. 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 ≥ 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.

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. Monitor RINVOQ-treated patients who may be at risk for GI perforation (e.g., patients with a history of diverticulitis and patients taking NSAIDs or corticosteroids). 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/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-treated patients. 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-treated patients. 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

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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 prophylactic varicella zoster or herpes zoster vaccinations, in agreement with current immunization guidelines.

MEDICATION RESIDUE IN STOOL

Reports of medication residue in stool or ostomy output have occurred in patients taking RINVOQ. Most reports described anatomic or functional GI conditions with shortened GI transit times. Instruct patients to contact their healthcare provider if medication residue is observed repeatedly. Monitor patients clinically and consider alternative treatment if there is an inadequate therapeutic response.

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 were upper respiratory tract infections, herpes zoster, herpes simplex, bronchitis, nausea, cough, pyrexia, acne, headache, peripheral edema, increased blood creatine phosphokinase, hypersensitivity, folliculitis, abdominal pain, increased weight, influenza, fatigue, neutropenia, myalgia, influenza-like illness, elevated liver enzymes, rash, and anemia.

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, 30 mg, and 45 mg extended-release tablets. RINVOQ LQ is available in a 1 mg/mL oral solution.

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

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