RINVOQ® COMPLETE

# NAVIGATING PRIOR AUTHORIZATIONS

## FOR PATIENTS WHO ARE PRESCRIBED RINVOQ

**For patients with moderately to severely active Crohn's disease or ulcerative colitis**

### INDICATIONS[1]

**RINVOQ is indicated for the treatment of adults with:**

- **Moderately to severely active Crohn's disease** who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers.
- **Moderately to severely active ulcerative colitis** 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 Janus kinase (JAK) inhibitors, biological therapies for Crohn's disease or ulcerative colitis, or with potent immunosuppressants such as azathioprine and cyclosporine.

### SAFETY CONSIDERATIONS[1]

**Serious Infections: RINVOQ-treated patients 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.**

**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.**

**Thrombosis: Deep venous thrombosis, pulmonary embolism, and arterial thrombosis have occurred in patients treated with JAK inhibitors used to treat inflammatory conditions. 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.

**Please see additional Important Safety Information, including BOXED WARNING on Serious Infections, Mortality, Malignancies, Major Adverse Cardiovascular Events, and Thrombosis, on pages 6 and 7.**

**Please click here for full Prescribing Information.**

RINVOQ® upadacitinib

# Navigating prior authorization requirements for patients who are prescribed RINVOQ

## A prior authorization may be required by the payer

When prescribing RINVOQ for your patient, determine whether the payer requires a prior authorization (PA). PA requirements may vary by payer, so check with your patient's health plan for an accurate list of requirements before submitting the request. Ensure that diagnosis, disease severity, prior therapies tried, dosing, duration, and clinical testing are documented to help **avoid potential denials due to missing or incomplete information**.

**You may obtain the PA form through one of the following:**

- Health plan's website
- CoverMyMeds®
- Specialty Pharmacy
- Field Access Specialist

*The following table provides an overview of common payer PA requirements and is for illustrative purposes only. As such, it (1) may include certain PA criteria which are not necessary for a specific payer and (2) may not include all necessary PA requirements for a specific payer.*

## Ensure you document the following in your PA submission and chart notes (as applicable):

| Example PA Criteria | Example Information to Include |
|---|---|
| Patient's diagnosis, using the appropriate ICD-10-CM code(s)[2]* | **K50.0-K50.019** Crohn's disease of small intestine<br>**K50.1-K50.119** Crohn's disease of large intestine<br>**K50.8-K50.819** Crohn's disease of both small and large intestine<br>**K50.9-K50.919** Crohn's disease, unspecified<br>**K51** Ulcerative colitis<br>**K51.8** Other ulcerative colitis<br>**K51.9** Ulcerative colitis, unspecified |
| Patient's disease and severity (moderate or severe) | Active or erosive disease, such as:<br>• Prominent symptoms, including but not limited to: fever, weight loss, abdominal pain and tenderness, intermittent nausea and vomiting, anemia, bleeding, diarrhea, internal fistula, intestinal obstruction, megacolon, involvement in upper gastrointestinal tract, stricturing disease, perianal disease or other enterocutaneous fistula, extraintestinal manifestations<br>• Hospitalization due to Crohn's disease<br>• Fecal markers (fecal calprotectin), serum markers (C-reactive protein), and/or endoscopic assessment<br>• Monitoring: pain, fatigue, stool frequency, and/or rectal bleeding |

*Chart continues on following page*

ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification.

*The codes shown are only suggestions and may vary by patient.

This information is presented for informational purposes only and is not intended to provide reimbursement or legal advice. The information presented here does not guarantee payment or coverage. Providers are encouraged to contact third-party payers for specific information about their coverage policies.

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# Navigating prior authorization requirements for patients who are prescribed RINVOQ

## A prior authorization may be required by the payer (cont'd)

*The following table provides an overview of common payer PA requirements and is for illustrative purposes only. As such, it (1) may include certain PA criteria which are not necessary for a specific payer and (2) may not include all necessary PA requirements for a specific payer. Some medications listed below are not approved for moderate to severe Crohn's disease or ulcerative colitis.*

### Ensure you document the following in your PA submission and chart notes (as applicable):

| Example PA Criteria | Example Information to Include |
|---|---|
| ✓ Inadequate response or contraindication to current and prior therapies, documenting the treatment name, dose, duration, and date of each therapy:<br>• Note any applicable inadequate responses to **all** prior therapy requirements, not just the most recent therapy<br>• Note any plan-specific duration (eg, for at least 3 months) and treatment period requirements (eg, within last 12 months) | **Please list all previously tried and failed conventional and biologic therapies, including:**<br>**Conventional or systemic therapies**<br>• Corticosteroids<br>– prednisone<br>– prednisolone<br>– methylprednisolone<br>– budesonide<br>• Conventional systemic therapies/ immunosuppressants/ immunomodulators<br>– azathioprine<br>– 6-mercaptopurine<br>– methotrexate<br>• 5-aminosalicylates<br>– sulfasalazine<br>– mesalamine<br>– olsalazine<br>– balsalazide<br>**Tumor necrosis factor (TNF) inhibitors**<br>• Humira® (adalimumab) and biosimilars<br>• Remicade® (infliximab) and biosimilars<br>• Cimzia® (certolizumab pegol)<br>**Biologics and synthetic DMARDs**<br>• Stelara® (ustekinumab)<br>• Entyvio® (vedolizumab)<br>• Xeljanz® (tofacitinib)<br>• Omvoh™ (mirikizumab-mrkz)<br>• Velsipity™ (etrasimod)<br>*This is not a comprehensive list* |
| ✓ Testing results for clinical parameters, if required by payer | • Tuberculosis (TB) test<br>• Liver enzymes<br>• Complete blood count (CBC)<br>• Bilirubin |
| ✓ Confirmation of discontinuation of previous immunosuppressants or biologics | • Not to be used in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants |

**It is important to submit documentation for all required information and chart notes with the PA form to support a timely decision from the payer**

JAK, Janus kinase; PA, prior authorization.

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# Potential reasons for coverage denials

## Incomplete information or lack of documentation may lead to a denial for RINVOQ

Below are some of the most **common causes for denial**. Be sure to double-check your documentation when submitting the initial PA request to avoid these common causes for denial:

- **Lack of step therapy documentation** demonstrating previous therapies tried and failed
  - Names of all conventional therapies and targeted immunomodulators, including TNFs, tried and failed
  - Duration of prior therapies (eg, 3 month trial and intolerance to TNF inhibitor)
  - Notes on contraindications or intolerances to other therapies required by the plan
- **Failure to confirm that RINVOQ is not currently being used** in combination with other biologic or targeted synthetic drugs or immunosuppressants, such as azathioprine or cyclosporine
- **Did not adhere to quantity limits for induction dosing** (12 weeks for Crohn's disease and 8 weeks for ulcerative colitis)
- **Lack of documentation for health plan's clinical testing criteria** (eg, recent [within 6 months of therapy request] TB test, CBC)
- **Lack of documentation** supporting diagnosis or disease severity (eg, evidence of severe disease, hospitalization)

**For virtual or in-person support, call your Field Access Specialist, or call 1.877.COMPLETE (1.877.266.7538)**

**SAFETY CONSIDERATIONS**[1]

**Serious Infections: RINVOQ-treated patients 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.**

**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.**

**Thrombosis: Deep venous thrombosis, pulmonary embolism, and arterial thrombosis have occurred in patients treated with JAK inhibitors used to treat inflammatory conditions. 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.

CBC, complete blood count; PA, prior authorization; TB, tuberculosis; TNF, tumor necrosis factor.

**Please see Indications and additional Important Safety Information, including BOXED WARNING on Serious Infections, Mortality, Malignancies, Major Adverse Cardiovascular Events, and Thrombosis, on pages 6 and 7.**

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# Prior authorization best practices

## Some suggested best practices for PAs

When requesting a PA, it is important to have all of the necessary information and documentation.

- Before beginning the process, confirm that insurance coverage has not changed since the patient's last visit
- Complete all sections of the PA form(s) and provide any supplemental documentation required
- Determine how the information should be submitted to the payer (fax, electronic PA, portal or website, etc)
- Inquire about the timing of the process once the request is submitted, and update your patient on the request status

**Tips to keep track of the PA process:**

**Log the date and time of calls,**
who you spoke with, and their contact information

**Keep a copy**
of all PA documentation

**Follow up with the payer**
if your facility does not receive notification of the decision in a timely manner

**Record the PA approval code and date**
in the patient's medical record

**Reminders:**

- Responses to PA requests are generally received within **72 hours after submission**
- If the patient is transitioning dosage strengths, a **separate PA may be required**
- Make note of when a **PA authorization might expire**. If it expires before the end of your patient's treatment, you may need to submit the PA again to continue their coverage

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PA, prior authorization.

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RINVOQ® COMPLETE

RINVOQ® upadacitinib

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

## INDICATIONS[1]

**RINVOQ is indicated for the treatment of adults with:**

- **Moderately to severely active Crohn's disease** who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers.
- **Moderately to severely active ulcerative colitis** 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 Janus kinase (JAK) inhibitors, biological therapies for Crohn's disease or ulcerative colitis, or with potent immunosuppressants such as azathioprine and cyclosporine.

## IMPORTANT SAFETY INFORMATION[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.**

**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

**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 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 ≥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.

**Please see additional Important Safety Information on page 7.**

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RINVOQ® upadacitinib

# Important Safety Information for RINVOQ® (upadacitinib)[1] (cont'd)

## GASTROINTESTINAL PERFORATIONS

Gastrointestinal (GI) perforations have been reported in clinical trials with RINVOQ. Monitor RINVOQ-treated patients who may be at risk for gastrointestinal 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/mm$^3$). Treatment with RINVOQ is not recommended in patients with an ANC <1000 cells/mm$^3$. Evaluate neutrophil counts at baseline and thereafter according to routine patient management.

### Lymphopenia

Absolute lymphocyte counts (ALC) <500 cells/mm$^3$ were reported in RINVOQ-treated patients. Treatment with RINVOQ is not recommended in patients with an ALC <500 cells/mm$^3$. 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 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, 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.

**References: 1.** RINVOQ [package insert]. North Chicago, IL: AbbVie Inc. **2.** Centers for Medicare & Medicaid Services. 2024 ICD-10-CM. 2024 Code Tables, Tabular and Index. Updated June 29, 2023. Accessed December 19, 2023. https://www.cms.gov/files/zip/2024-code-tables-tabular-and-index-updated-06/29/2023.zip

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