

Navigating prior authorizations

Prior authorizations—helpful process tips

When your office conducts the benefit investigation process, determine whether the payer requires precertification or a prior authorization (PA) for the prescribed product for approval. PA requests to establish medical necessity may be submitted to request coverage of a prescription drug.

Be sure to complete all required fields in order to receive a timely response. In addition to the form, you may need to send a letter of medical necessity (LMN) to further explain the need for the product of choice.



Checklist for requesting a PA



Before beginning the process, confirm that the patient's insurance has not changed since the last visit



Ask what information or form is necessary. Some payers require:

- Payer-specific forms
- History of past tests and results
- Patient medical records with appropriate chart notes
- Letter of medical necessity



Inquire about how long the process will take once the necessary forms and documentation are submitted



Complete all sections of the PA form and any supplemental material, including all required forms, such as the Complete Enrollment and Prescription form



Determine if the information can be phoned in, faxed, emailed, or submitted through the payer's website



Update your patient on the PA request, in case they receive a call or mail from their insurance company

Keep track of the process:

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



Keep a copy of everything submitted for the PA



Log any calls your facility makes about the request. Note the name of the person you spoke with



Follow up with 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. Also note the expiration date of the PA

For support in person or over the phone, call an Access Specialist at 1.877.COMPLETE (1.877.266.7538).

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.

Please see Important Safety Information, including BOXED WARNING on Serious Infections, Malignancy, and Thrombosis, on page 2.

Please click here for accompanying full Prescribing Information.

Indication and Important Safety Information for RINVOQ™ (upadacitinib)

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

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 full Prescribing Information.

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