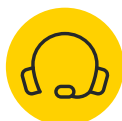


Writing a Formulary Exception Request Letter

for Commercial Insurance



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.



Writing a formulary exception request letter

A formulary exception is a type of coverage determination used when a drug is not included on a health plan's formulary or is subject to a National Drug Code (NDC) block. A formulary exception request letter may be able to help a patient gain access by outlining the reasons why a treatment is necessary to meet the medical needs of the patient.

■ Formulary exception request letter submission process

1

The formulary exception request letter may **originate from you, your patient, or your patient's legal representative.***

2

Typically, your patient's **medical records** and a **letter of medical necessity (LMN)** are submitted with the letter.

3

Both you and your patient **should sign** the letter.

- Plans frequently provide specific formulary exception request templates that must be used when making the request. These forms may be downloaded from each plan's website
- Follow the plan's requirements when requesting product approval; otherwise, treatment may be delayed†

*Please note for Medicare Part D subscribers: Under the Medicare Part D prescription drug benefit program, a Part D plan enrollee, the enrollee's representative, or the enrollee's doctor or other prescriber can request a coverage determination, including a request for a tiering or formulary exception. A request for a coverage determination can be made orally or in writing. An enrollee, the enrollee's representative, or the enrollee's prescriber may submit a written request for a coverage determination in any format.

†Please note that the Centers for Medicare & Medicaid Services (CMS) has developed "REQUEST FOR MEDICARE PRESCRIPTION DRUG COVERAGE DETERMINATION" model forms that are posted on its website. For more information, visit <https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Exceptions>.

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Sample formulary exception request letter

This is an example of a letter you can use when your desired treatment option is not included on a health plan's formulary or is subject to an NDC block. This step may require you to submit an LMN with the formulary exception request letter.

[Date]
[Prior authorization department]
[Name of health plan]
[Mailing address]

Re: [Patient's name]
[Plan identification number]
[Date of birth]

To Whom It May Concern:

My name is [HCP's name], and I am a [board-certified medical specialty] [NPI]. I am writing to request a formulary exception for my patient, [patient's name], who is currently a member of [name of health plan].

The prescription is for [product] [dosage and frequency], which is medically appropriate and necessary for this patient who has been diagnosed with [diagnosis] [ICD code(s)]. Therefore, I am requesting that the plan remove any relevant NDC blocks, so that [product] can be made available to my patient as a preferred medication.

Patient's history and symptoms*:

% of BSA impacted
% of BSA involving only sensitive areas
Duration of illness
Potent immunosuppressant use (Y/N), (specify)
Other DMARD use, (specify)

Past Treatment(s)†	Start/Stop Dates	Reason(s) for Discontinuing
[Drug name]	[MM/YYYY] - [MM/YYYY]	[Please list side effects, lack of efficacy, etc.]
[Drug name]	[MM/YYYY] - [MM/YYYY]	[Please list side effects, lack of efficacy, etc.]

[Include the main reason for requesting this formulary exception].

A letter of medical necessity and pertinent medical records are enclosed, which offer additional support for the formulary exception request for [product].

Please contact me, [HCP name], at [telephone number] for a peer-to-peer review. I would be pleased to speak about why a [product] formulary exception is necessary for [patient's name]'s treatment of [diagnosis].

Sincerely,

[Physician's name and signature] [Patient's name and signature]
[Physician's medical specialty] [Physician's NPI] [Patient's contact information]
[Physician's practice name]
[Phone #] [Fax #]
Enc: [Medical records, clinical trial information, photo(s), letter of medical necessity]

BSA, body surface area; DMARD, disease-modifying antirheumatic drug; NDC, national drug code.
*Include patient's medical records and supporting documentation, including clinical evaluation, scoring forms, and photos of affected areas.
†Identify drug name, strength, dosage form, and therapeutic outcome.

Help for denied request letters



If this request has previously been denied, consider adding:

This is a formulary exception appeal. I have included a copy of the original denial letter and medical notes in response to the denial.

Attach the following:

- A copy of the denial letter
- Medical notes, written by the prescribing physician, in response to the denial letter

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 templates for all RINVOQ indications are available at
CompletePro.com and RINVOQHCP.com

LMN, letter of medical necessity; NDC, National Drug Code.

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.

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.

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.

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Writing a formulary exception letter and what to include

Make sure you include all of the information highlighted in red on the sample letter shown on page 3; otherwise, your appeal could be denied

■ Additional documents

- A letter of medical necessity
- A statement of financial hardship, written by your patient
- Recent photos, x-rays, or other imaging of the impacted area(s)
- If this letter serves as an appeal, include the case number from the denial letter, a copy of the denial letter, and a written response to the denial



Support

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

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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.

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RINVOQ[®]
upadacitinib

RINVOQ[®] LQ
upadacitinib 1 mg/mL
oral solution

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.

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.

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

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

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

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.

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

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, 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.

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