

Access & Reimbursement

Letter Templates



Please see [Indications](#) and [Important Safety Information](#) for RINVOQ, including **BOXED WARNING** on Serious Infections, Mortality, Malignancies, Major Adverse Cardiovascular Events, and Thrombosis, on pages 17–18.

Please see full [Prescribing Information](#) for RINVOQ, including **BOXED WARNING**, or visit https://www.rxabbvie.com/pdf/rinvoq_pi.pdf

Please see [Important Safety Information](#) for SKYRIZI on page 19. Please see full [Prescribing Information](#) for SKYRIZI or visit https://www.rxabbvie.com/pdf/skyrizi_pi.pdf





SUBMITTING AN APPEAL LETTER

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](#) for RINVOQ, including BOXED WARNING on Serious Infections, Mortality, Malignancies, Major Adverse Cardiovascular Events, and Thrombosis, on pages 17–18. Please see full [Prescribing Information](#) for RINVOQ, including BOXED WARNING, or visit https://www.rxabbvie.com/pdf/rinvoq_pi.pdf

Please see [Important Safety Information](#) for SKYRIZI on page 19. Please see full [Prescribing Information](#) for SKYRIZI or visit https://www.rxabbvie.com/pdf/skyrizi_pi.pdf





SUBMITTING AN APPEAL LETTER

While going through the prescription fulfillment process to get your patient on RINVOQ and SKYRIZI, 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. 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.

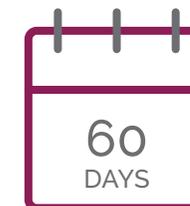
The adjudication time frame typically begins when the request is received by the plan sponsor. However, if the request involves an exception request, the adjudication time frame begins when the plan sponsor receives the physician's supporting statement. These are standard time frames, but timing varies by plan and may differ from the information presented here.



for urgent care



for non-urgent care



for services already provided

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

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SUBMITTING A LETTER OF MEDICAL NECESSITY

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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 LMN:

- 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 Disease (ICD) code(s)
- Clinical support for your recommendation
- Your office contact information

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SAMPLE LETTER OF MEDICAL NECESSITY

Date: _____

[Payer Name] _____

[Payer Address] _____

[Appeals Department] _____

Re: [Patient Name] _____

[Policy ID/Group Number] _____

Date of Service: _____

To whom it may concern:

My name is [Name] _____ and [Board-certified medical specialty] [NPI] _____ writing on behalf of my patient, [Patient name] _____, to request coverage for [product, dosage, and frequency] _____.

[Patient name] _____ has been under my care for 0 months for the treatment of [disease or symptoms] _____.

I am writing this letter for medical necessity because, after working with [Patient name] _____, [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 (000) 000-0000 _____ 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 NPI] _____

[Physician's practice name] _____

Phone (000) 000-0000 _____

Fax (000) 000-0000 _____

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Helpful tip:

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

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WRITING A FORMULARY EXCEPTION REQUEST LETTER FOR COMMERCIAL INSURANCE

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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.

Important compliance tips

- 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 RINVOQ and SKYRIZI; 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] 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]. 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 [condition], [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, diagnosis, condition, and symptoms*:
 Duration of illness _____
 ___ Abdominal pain/cramping ___ Bowel urgency ___ Fatigue
 ___ Frequent stools ___ Nausea/vomiting ___ Weight loss
 ___ Corticosteroid use ___ Biologic use
 Duration of use _____ Specify biologic _____
 Duration of use _____

Past Treatment(s)†	Start/Stop Dates	Reason(s) for Discontinuing
[Drug name]	[MM/YY] - [MM/YY]	[Please list side effects, lack of efficacy, etc]
[Drug name]	[MM/YY] - [MM/YY]	[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, [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]
 [Physician's medical specialty] [NPI]
 [Physician's practice name]
 [Phone #] [Fax #]
 Encl: [Medical records, clinical trial information, photo(s), Letter of Medical Necessity]

*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

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

Digital templates for all RINVOQ and SKYRIZI indications are available at [CompletePro.com](https://www.completepro.com) and [RINVOQHCP.com](https://www.rinvoqhcp.com) and [SkyriziHCP.com](https://www.skyrizihcp.com)

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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 11; otherwise, your request 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

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WRITING A TIERING EXCEPTION REQUEST LETTER FOR MEDICAID & TRICARE

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WHAT IS A TIERING EXCEPTION REQUEST LETTER?

A tiering exception request letter can help make medication more affordable for patients covered through Medicaid or TRICARE who may not be eligible to participate in savings programs but need assistance covering costs. A tiering exception request letter can help a patient gain access by outlining the reasons why a treatment is necessary to meet the medical needs of the patient.

Tiering exception request letter submission process

A tiering exception is a type of coverage determination used when a medication is on a plan's formulary, but is placed in a nonpreferred tier that has a higher copay or coinsurance. Plans may make a tiering exception when the drug is demonstrated to be medically necessary.

1. The tiering 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.

Important compliance tips

- 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 RINVOQ and SKYRIZI; 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-grievances/prescription-drug/exceptions>.

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SAMPLE TIERING EXCEPTION REQUEST LETTER

This is an example of a letter you can use for patients when the prescribed product is on a health plan's formulary, but is placed in a nonpreferred tier that has a higher copay or coinsurance. This step may require you to submit an LMN with the tiering exception request letter.

[Date]
[Formulary director]
[Name of health plan]
[Mailing address]

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

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 tiering 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 [condition], [ICD code(s)].
I am requesting that [product] be made available to my patient as a preferred medication.
In the past, [patient's name] has attempted other treatments for [condition], but those trials have failed due to either inadequate efficacy or lack of tolerability.

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

The patient's present treatment(s) are as follows:

Current Treatment(s) [†]	Start Date	Dosage
[Drug name]	[MM/YY]	[XX]
[Drug name]	[MM/YY]	[XX]

Currently, [patient's name] has the following unresolved symptoms:
•[Symptom 1] •[Symptom 2]

Along with this letter, I have enclosed a copy of my patient's medical records and a Letter of Medical Necessity. The letter describes why [product] is medically necessary for my patient's care over the preferred drugs listed in the plan's formulary.
[Explain why lower-tiered formulary drugs would not be as effective as product].
The reason I am requesting a tiering exception is because the cost associated with [product] assigned tier would present a financial burden to [patient's name]. Furthermore, it prevents my patient from utilizing a medication that will help treat the [condition].
To summarize, I consider [product] to be the best option in successfully treating my patient's [condition]. Please contact me, [name], at [telephone number] to answer any pending questions.

Sincerely,

[Physician's name and signature]
[Physician's medical specialty] [Physician's NPI]
[Physician's practice name]
[Phone #] [Fax #]
Enc: [Medical records, photo(s), Letter of Medical Necessity, statement of financial hardship, case number, written response to denial]

NPI, National Provider Identifier
*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.

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Help for denied appeals

If this appeal has previously been denied, consider explaining:

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

Remember to attach:

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

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LMN=Letter of medical necessity

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WRITING A TIERING EXCEPTION REQUEST LETTER AND WHAT TO INCLUDE

Make sure you include all of the information highlighted in red on the sample letter shown on page 15; otherwise, your request 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

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

INDICATIONS

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. If TNF blockers are clinically inadvisable, patients should have received at least one approved systemic therapy prior to use of RINVOQ.
- **Moderately to severely active Crohn's disease (CD)** in adults who have had an inadequate response or intolerance to one or more TNF blockers. If TNF blockers are clinically inadvisable, patients should have received at least one approved systemic therapy prior to use of RINVOQ.

Limitations of Use: RINVOQ is not recommended for use in combination with other JAK inhibitors, biological therapies for UC or CD, 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)

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.

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.

(Continued on next page)

Please see additional [Important Safety Information](#) for RINVOQ, including **BOXED WARNING** on Serious Infections, Mortality, Malignancies, Major Adverse Cardiovascular Events, and Thrombosis, on page 18. Please see full [Prescribing Information](#) for RINVOQ, including **BOXED WARNING**, or visit https://www.rxabbvie.com/pdf/rinvoq_pi.pdf





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

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 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.

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

Please see [Indications](#) and additional [Important Safety Information](#) for RINVOQ, including **BOXED WARNING on Serious Infections, Mortality, Malignancies, Major Adverse Cardiovascular Events, and Thrombosis, on page 17**. Please see full [Prescribing Information](#) for RINVOQ, including **BOXED WARNING**, or visit https://www.rxabbvie.com/pdf/rinvoq_pi.pdf





INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR SKYRIZI (risankizumab-rzaa)

INDICATIONS

Plaque Psoriasis: SKYRIZI is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

Psoriatic Arthritis: SKYRIZI is indicated for the treatment of active psoriatic arthritis in adults.

Crohn's Disease: SKYRIZI is indicated for the treatment of moderately to severely active Crohn's disease in adults.

Ulcerative Colitis: SKYRIZI is indicated for the treatment of moderately to severely active ulcerative colitis in adults.

IMPORTANT SAFETY INFORMATION

Hypersensitivity Reactions

SKYRIZI[®] (risankizumab-rzaa) is contraindicated in patients with a history of serious hypersensitivity reaction to risankizumab-rzaa or any of the excipients. Serious hypersensitivity reactions, including anaphylaxis, have been reported with the use of SKYRIZI. If a serious hypersensitivity reaction occurs, discontinue SKYRIZI and initiate appropriate therapy immediately.

Infection

SKYRIZI may increase the risk of infection. Do not initiate treatment with SKYRIZI in patients with a clinically important active infection until it resolves or is adequately treated.

In patients with a chronic infection or a history of recurrent infection, consider the risks and benefits prior to prescribing SKYRIZI. Instruct patients to seek medical advice if signs or symptoms of clinically important infection occur. If a patient develops such an infection or is not responding to standard therapy, closely monitor and discontinue SKYRIZI until the infection resolves.

Tuberculosis (TB)

Prior to initiating treatment with SKYRIZI, evaluate for TB infection and consider treatment in patients with latent or active TB for whom an adequate course of treatment cannot be confirmed. Monitor patients for signs and symptoms of active TB during and after SKYRIZI treatment. Do not administer SKYRIZI to patients with active TB.

Hepatotoxicity in Treatment of Inflammatory Bowel Disease

Drug-induced liver injury was reported in a patient with Crohn's disease who was hospitalized for a rash during induction dosing of SKYRIZI. For the treatment of Crohn's disease and ulcerative colitis, evaluate liver enzymes and bilirubin at baseline and during induction (12 weeks); monitor thereafter according to routine patient management. Consider an alternate treatment for patients with evidence of liver cirrhosis. Interrupt treatment if drug-induced liver injury is suspected, until this diagnosis is excluded. Instruct your patient to seek immediate medical attention if they experience symptoms suggestive of hepatic dysfunction.

Administration of Vaccines

Avoid use of live vaccines in patients treated with SKYRIZI. Medications that interact with the immune system may increase the risk of infection following administration of live vaccines. Prior to initiating SKYRIZI, complete all age-appropriate vaccinations according to current immunization guidelines.

Adverse Reactions

Most common ($\geq 1\%$) adverse reactions associated with SKYRIZI in plaque psoriasis and psoriatic arthritis include upper respiratory infections, headache, fatigue, injection site reactions, and tinea infections.

In psoriatic arthritis phase 3 trials, the incidence of hepatic events was higher with SKYRIZI compared to placebo.

Most common ($>3\%$) adverse reactions associated with SKYRIZI in Crohn's disease are upper respiratory infections, headache, and arthralgia in induction, and arthralgia, abdominal pain, injection site reactions, anemia, pyrexia, back pain, arthropathy, and urinary tract infection in maintenance.

Most common ($\geq 3\%$) adverse reactions associated with SKYRIZI in ulcerative colitis are arthralgia in induction, and arthralgia, pyrexia, injection site reactions, and rash in maintenance.

Lipid Elevations: Increases from baseline and increases relative to placebo were observed at Week 4 and remained stable to Week 12 in patients treated with SKYRIZI in Crohn's disease. Lipid elevations observed in patients with ulcerative colitis were similar to those in Crohn's disease.

Dosage Forms and Strengths: SKYRIZI (risankizumab-rzaa) is available in a 150 mg/mL prefilled syringe and pen, a 600 mg/10 mL single-dose vial for intravenous infusion, and a 180 mg/1.2 mL or 360 mg/2.4 mL single-dose prefilled cartridge with on-body injector.

Please see [Indications](#) and [Important Safety Information](#) for RINVOQ, including **BOXED WARNING** on Serious Infections, Mortality, Malignancies, Major Adverse Cardiovascular Events, and Thrombosis, on pages 17–18. Please see full [Prescribing Information](#) for RINVOQ, including **BOXED WARNING**, or visit https://www.rxabbvie.com/pdf/rinvoq_pi.pdf

Please see full [Prescribing Information](#) for SKYRIZI or visit https://www.rxabbvie.com/pdf/skyrizi_pi.pdf

