

PRIOR AUTHORIZATION POLICY

POLICY: Inflammatory Conditions – Rinvoq/Rinvoq LQ Prior Authorization Policy

- Rinvoq® (upadacitinib extended-release tablets – AbbVie)
- Rinvoq® LQ (upadacitinib oral solution – AbbVie)

REVIEW DATE: 02/07/2024; selected revision 05/15/2024

OVERVIEW

Rinvoq, a Janus kinase inhibitor (JAKi), is indicated for the following uses:¹

- **Ankylosing spondylitis**, for treatment of active disease in adults who have had an inadequate response or intolerance to one or more tumor necrosis factor inhibitors (TNFis).
- **Atopic dermatitis**, for treatment of refractory, moderate to severe atopic dermatitis in patients \geq 12 years of age, whose disease is not adequately controlled with other systemic drug products (including biologics) or when those therapies are not advisable.
- **Crohn's disease**, for treatment of moderately to severely active disease in adults who have had an inadequate response or intolerance to one or more TNFis.
- **Non-radiographic axial spondyloarthritis**, in adults with objective signs of inflammation who have had an inadequate response or intolerance to one or more TNFis.
- **Polyarticular juvenile idiopathic arthritis (JIA)**, in patients \geq 2 years of age with active disease who have had an inadequate response or intolerance to one or more TNFis.
- **Psoriatic arthritis**, for treatment of active disease in patients \geq 2 years of age who have had an inadequate response or intolerance to one or more TNFis.
- **Rheumatoid arthritis**, for treatment of moderately to severely active disease in adults who have had an inadequate response or intolerance to one or more TNFis.
- **Ulcerative colitis**, for treatment of moderately to severely active disease in adults who have had an inadequate response or intolerance to one or more TNFis.

Rinvoq LQ oral solution is only indicated for use in **polyarticular JIA** and **psoriatic arthritis in patients 2 to < 18 years of age**.¹ Rinvoq LQ oral solution is not substitutable with Rinvoq extended-release tablets.

For all indications, Rinvoq/Rinvoq LQ is not recommended for use in combination with other JAKis, biologics, or potent immunosuppressants such as azathioprine or cyclosporine.¹

Guidelines

Guidelines are available for treatment of inflammatory conditions:

- **Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis:** Current guidelines do not address Rinvoq. Guidelines from the American College of Rheumatology (ACR)/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network (2019) recommend a TNFi as the initial biologic.² In those who are secondary non-responders to a TNFi, a second TNFi is recommended over switching out of the class. Both TNFis and interleukin (IL)-17 blockers are recommended over Xeljanz®/Xeljanz® XR (tofacitinib tablets/tofacitinib extended release tablets).
- **Atopic Dermatitis:** Guidelines for the care and management of atopic dermatitis from the American Academy of Dermatology (2023) and the American Academy of Allergy, Asthma and Immunology (2023) have been updated to address Rinvoq.^{3,4} Systemic therapies are recommended in patients with moderate to severe or widespread disease, in those with impaired quality of life, and those whose atopic dermatitis is refractory to topical therapies. Biologic agents, such as

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Dupixent® (dupilumab subcutaneous injection) or Adbry® (tralokinumab-ldrm subcutaneous injection), are recommended as initial systemic treatment due to their favorable efficacy and safety profiles compared to traditional systemic therapies (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate mofetil). Rinvoq may be considered in adults refractory or intolerant to Dupixent or Adbry.

- **Crohn’s Disease:** Current guidelines do not address Rinvoq. The American College of Gastroenterology (ACG) has guidelines for Crohn’s disease (2018).⁵ TNFi are listed as an option for disease that is resistant to corticosteroids, severely active disease, perianal fistulizing disease, and maintenance of remission. In post-operative Crohn’s disease, a TNFi should be started within 4 weeks of surgery to prevent recurrence. Guidelines from the American Gastroenterological Association (AGA) [2021] include TNFi among the therapies for moderate to severe Crohn’s disease, for induction and maintenance of remission.⁶
- **JIA:** Rinvoq is not addressed in ACR/Arthritis Foundation guidelines for the treatment of JIA (2019) specific to juvenile non-systemic polyarthritis, sacroiliitis, and enthesitis.¹¹ TNFi are the biologics recommended for polyarthritis, sacroiliitis, and enthesitis. Actemra® (tocilizumab intravenous infusion, tocilizumab subcutaneous injection) and Orencia® (abatacept intravenous infusion, abatacept subcutaneous injection) are also among the biologics recommended for polyarthritis. Biologics are recommended following other therapies (e.g., following DMARDs for active polyarthritis or following a nonsteroidal anti-inflammatory drug for active JIA with sacroiliitis or enthesitis). However, there are situations where initial therapy with a biologic may be preferred over other conventional therapies (e.g., if there is involvement of high-risk joints such as the cervical spine, wrist, or hip; high disease activity; and/or those judged to be at high risk of disabling joint damage).
- **Psoriatic Arthritis:** Current guidelines do not address Rinvoq. Guidelines from ACR (2018) recommend TNFi over other biologics and Xeljanz for use in treatment-naïve patients with psoriatic arthritis and in those who were previously treated with an oral therapy.⁷
- **Rheumatoid Arthritis:** Guidelines from ACR (2021) recommend addition of a biologic or a targeted synthetic disease-modifying antirheumatic drug (DMARD) for a patient taking the maximum tolerated dose of methotrexate who is not at target.⁸
- **Ulcerative Colitis:** Rinvoq has not yet been addressed in guidelines. Guidelines from the American College of Gastroenterology for ulcerative colitis (2019) note that the following agents can be used for induction of remission in moderately to severely active disease: budesonide extended-release tablets, oral or intravenous systemic corticosteroids, Entyvio® (vedolizumab intravenous infusion), Xeljanz/Xeljanz XR, or TNFi.⁹ Guidelines from the American Gastroenterological Association (2020) recommend Xeljanz only after failure of or intolerance to a TNFi.¹⁰

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Rinvoq/Rinvoq LQ. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Rinvoq/Rinvoq LQ as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Rinvoq/Rinvoq LQ to be prescribed by or in consultation with a physician who specializes in the condition being treated.

All reviews for use of Rinvoq for COVID-19 and/or cytokine release syndrome associated with COVID-19 will be forwarded to the Medical Director.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Rinvoq/Rinvoq LQ is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. Ankylosing Spondylitis. Approve Rinvoq extended-release tablets (not Rinvoq LQ oral solution) for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, and iii):

i. Patient is ≥ 18 years of age; AND

ii. Patient meets ONE of the following (a or b):

a) Patient has had a 3-month trial of at least ONE tumor necrosis factor inhibitor; OR

b) Patient has tried at least one tumor necrosis factor inhibitor but was unable to tolerate a 3-month trial; AND

Note: Refer to [Appendix](#) for examples of tumor necrosis factor inhibitors used for rheumatoid arthritis. Conventional synthetic disease-modifying antirheumatic drugs (DMARDs) such as methotrexate, leflunomide, hydroxychloroquine, and sulfasalazine do not count.

iii. The medication is prescribed by or in consultation with a rheumatologist.

B) Patient is Currently Receiving Rinvoq extended-release tablets. Approve for 1 year if the patient meets BOTH of the following (i and ii):

i. Patient has been established on therapy for at least 6 months; AND

Note: A patient who has received < 6 months of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy).

ii. Patient meets at least ONE of the following (a or b):

a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Rinvoq); OR

Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Global Score (BAS-G), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), Health Assessment Questionnaire for the Spondylarthropathies (HAQ-S), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).

b) Compared with baseline (prior to initiating Rinvoq), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.

2. Atopic Dermatitis. Approve Rinvoq extended-release tablets (not Rinvoq LQ oral solution) for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 3 months if the patient meets ALL of the following (i, ii, and iii):

i. Patient is ≥ 12 years of age; AND

ii. Patient meets ONE of the following (a or b):

a) Patient has had a 4-month trial of at least ONE systemic therapy; OR

b) Patient has tried at least ONE systemic therapy but was unable to tolerate a 4-month trial; AND

Note: Examples of systemic therapies include Dupixent (dupilumab subcutaneous injection) and Adbry (tralokinumab-ldrm subcutaneous injection). Methotrexate, azathioprine, cyclosporine, or mycophenolate mofetil also count towards trial of a systemic therapy.

- iii. The medication is prescribed by or in consultation with an allergist, immunologist, or dermatologist.
 - B) Patient is Currently Receiving Rinvoq extended-release tablets. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
 - i. Patient has been established on therapy for at least at least 90 days; AND
Note: A patient who has received < 90 days of therapy or who is restarting therapy with Rinvoq is reviewed under criterion A (Initial Therapy).
 - ii. Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating Rinvoq) in at least one of the following: estimated body surface area affected, erythema, induration/papulation/edema, excoriations, lichenification, and/or a decreased requirement for other topical or systemic therapies for atopic dermatitis; AND
 - iii. Compared with baseline (prior to receiving Rinvoq), patient experienced an improvement in at least one symptom, such as decreased itching.
3. **Crohn's Disease.** Approve Rinvoq extended-release tablets (not Rinvoq LQ oral solution) for the duration noted if the patient meets ONE of the following (A or B):
- A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, and iii):
 - i. Patient is \geq 18 years of age; AND
 - ii. Patient meets ONE of the following (a or b):
 - a) Patient has had a 3-month trial of at least ONE tumor necrosis factor inhibitor; OR
 - b) Patient has tried at least one tumor necrosis factor inhibitor but was unable to tolerate a 3-month trial; AND
Note: Refer to [Appendix](#) for examples of tumor necrosis factor inhibitors used for Crohn's disease.
 - iii. The medication is prescribed by or in consultation with a gastroenterologist.
 - B) Patient is Currently Receiving Rinvoq extended-release tablets. Approve for 1 year if the patient meets BOTH of the following (i and ii):
 - i. Patient has been established on therapy for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with Rinvoq is reviewed under criterion A (Initial Therapy).
 - ii. Patient meets at least ONE of the following (a or b):
 - a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Rinvoq); OR
Note: Examples of objective measures include fecal markers (e.g., fecal lactoferrin, fecal calprotectin), serum markers (e.g., C-reactive protein), imaging studies (magnetic resonance enterography [MRE], computed tomography enterography [CTE]), endoscopic assessment, and/or reduced dose of corticosteroids.
 - b) Compared with baseline (prior to initiating Rinvoq), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or blood in stool.

Juvenile Idiopathic Arthritis (JIA). Approve Rinvoq extended-release tablets or Rinvoq LQ oral solution for the duration noted if the patient meets ONE of the following (A or B):

Note: This includes JIA regardless of type of onset and a patient with juvenile spondyloarthritis/active sacroiliac arthritis. JIA is also referred to as Juvenile Rheumatoid Arthritis.

A) Initial Therapy. Approve for 6 months if the patient meets the following (i and ii):

i. Patient meets ONE of the following (a or b):

a) Patient has had a 3-month trial of at least one tumor necrosis factor inhibitor; OR

b) Patient has tried at least one tumor necrosis factor inhibitor but was unable to tolerate a 3-month trial; AND

Note: Refer to [Appendix](#) for examples of tumor necrosis factor inhibitors. Conventional synthetic disease-modifying antirheumatic drugs (DMARDs) such as methotrexate, leflunomide, hydroxychloroquine, and sulfasalazine do not count.

ii. The medication is prescribed by or in consultation with a rheumatologist.

B) Patient is Currently Receiving Rinvoq/Rinvoq LQ. Approve for 1 year if the patient meets BOTH of the following (i and ii):

i. Patient has been established on therapy for at least 6 months; AND

Note: A patient who has received < 6 months of therapy or who is restarting therapy with Rinvoq/Rinvoq LQ is reviewed under criterion A (Initial Therapy).

ii. Patient meets at least ONE of the following (a or b):

a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Rinvoq/Rinvoq LQ); OR

Note: Examples of objective measures include Physician Global Assessment (MD global), Parent/Patient Global Assessment of Overall Well-Being (PGA), Parent/Patient Global Assessment of Disease Activity (PDA), Juvenile Arthritis Disease Activity Score (JDAS), Clinical Juvenile Arthritis Disease Activity Score (cJDAS), Juvenile Spondyloarthritis Disease Activity Index (JSpADA), serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids.

b) Compared with baseline (prior to initiating Rinvoq/Rinvoq LQ), patient experienced an improvement in at least one symptom, such as improvement in limitation of motion, less joint pain or tenderness, decreased duration of morning stiffness or fatigue, improved function or activities of daily living.

5. Non-Radiographic Axial Spondyloarthritis. Approve Rinvoq extended-release tablets (not Rinvoq LQ oral solution) for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, and iii):

i. Patient has objective signs of inflammation, defined as at least one of the following (a or b):

a) C-reactive protein (CRP) elevated beyond the upper limit of normal for the reporting laboratory; OR

b) Sacroiliitis reported on magnetic resonance imaging (MRI); AND

ii. Patient meets ONE of the following (a or b):

a) Patient has had a 3-month trial of at least ONE tumor necrosis factor inhibitor; OR

b) Patient has tried at least one tumor necrosis factor inhibitor but was unable to tolerate a 3-month trial; AND

Note: Cimzia (certolizumab pegol subcutaneous injection) is an example of a tumor necrosis factor inhibitor used for non-radiographic axial spondyloarthritis. Conventional synthetic disease-modifying antirheumatic drugs (DMARDs) such as methotrexate, leflunomide, hydroxychloroquine, and sulfasalazine do not count.

iii. The medication is prescribed by or in consultation with a rheumatologist.

B) Patient is Currently Receiving Rinvoq extended-release tablets. Approve for 1 year if the patient meets BOTH of the following (i and ii):

i. Patient has been established on the requested drug for at least 6 months; AND

Note: A patient who has received < 6 months of therapy or who is restarting therapy with the requested drug is reviewed under criterion A (Initial Therapy).

- ii. Patient meets at least one of the following (a or b):
 - a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug); OR
Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Global Score (BAS-G), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), Health Assessment Questionnaire for the Spondylarthropathies (HAQ-S), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
 - b) Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.

6. **Psoriatic Arthritis.** Approve Rinvoq extended-release tablets or Rinvoq LQ oral solution for the duration noted if the patient meets ONE of the following (A or B):
 - A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, and iii):
 - i. Patient is ≥ 2 years of age; AND
 - ii. Patient meets ONE of the following (a or b):
 - a) Patient has had a 3-month trial of at least ONE tumor necrosis factor inhibitor; OR
 - b) Patient has tried at least one tumor necrosis factor inhibitor but was unable to tolerate a 3-month trial; AND
Note: Refer to [Appendix](#) for examples of tumor necrosis factor inhibitors used for psoriatic arthritis. Conventional synthetic disease-modifying antirheumatic drugs (DMARDs) such as methotrexate, leflunomide, hydroxychloroquine, and sulfasalazine do not count.
 - iii. The medication is prescribed by or in consultation with a rheumatologist or a dermatologist.
 - B) Patient is Currently Receiving Rinvoq/Rinvoq LQ. Approve for 1 year if the patient meets BOTH of the following (i and ii):
 - i. Patient has been established on therapy for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with Rinvoq/Rinvoq LQ is reviewed under criterion A (Initial Therapy).
 - ii. Patient meets at least one of the following (a or b):
 - a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Rinvoq/Rinvoq LQ); OR
Note: Examples of objective measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PsA DAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
 - b) Compared with baseline (prior to initiating Rinvoq/Rinvoq LQ), patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

7. **Rheumatoid Arthritis.** Approve Rinvoq extended-release tablets (not Rinvoq LQ oral solution) for the duration noted if the patient meets ONE of the following (A or B):
 - A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, and iii):

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Rinvoq/Rinvoq LQ is not recommended in the following situations:

- 1. Concurrent Use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drug (DMARD).** Rinvoq should not be administered in combination with a biologic used for an inflammatory condition (see [Appendix](#) for examples).¹ Combination therapy is generally not recommended due to a potential for a higher rate of adverse effects with combination therapies and lack of evidence supporting additive efficacy. There are no data evaluating combination of Rinvoq with other targeted synthetic DMARDs (e.g., Otezla [apremilast tablets], Xeljanz/ Xeljanz XR [tofacitinib tablets/extended-release tablets], Olumiant [baricitinib tablets]); therefore, safety and efficacy of this combination therapy is unknown.
- 2. Concurrent Use with a Biologic Immunomodulator.** Rinvoq is not recommended in combination with biologic immunomodulators.¹
Note: Examples include Adbry (tralokinumab-ldrm subcutaneous injection), Cinqair (reslizumab intravenous), Dupixent (dupilumab subcutaneous injection), Fasenra (benralizumab subcutaneous injection), Nucala (mepolizumab subcutaneous injection), Tezspire (tezepelumab-ekko subcutaneous injection), and Xolair (omalizumab subcutaneous injection).
- 3. Concurrent Use with Other Janus Kinase Inhibitors (JAKis).** Rinvoq is not recommended in combination with other JAKis, such as Cibinqo, Xeljanz/ Xeljanz XR, Olumiant.¹
- 4. Concurrent Use with Other Potent Immunosuppressants** (e.g., azathioprine, cyclosporine).¹ Co-administration with other potent immunosuppressive drugs has the risk of added immunosuppression and has not been evaluated in rheumatoid arthritis. Note: This does NOT exclude use of Rinvoq with methotrexate. In rheumatoid arthritis, Rinvoq has been evaluated with background methotrexate and other conventional synthetic disease-modifying antirheumatic drugs (DMARDs).
- 5. COVID-19 (Coronavirus Disease 2019).** Forward all requests to the Medical Director.
Note: This includes requests for cytokine release syndrome associated with COVID-19.
- 6.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

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APPENDIX

* Not an all-inclusive list of indications (e.g., oncology indications and rare inflammatory conditions are not listed). Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn’s disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous, PJIA – Polyarticular juvenile idiopathic arthritis; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; ^ Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis; DMARD – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis; TYK2 – Tyrosine kinase 2.