

PRIOR AUTHORIZATION POLICY

POLICY: Inflammatory Conditions – Rinvoq Prior Authorization Policy

- Rinvoq® (upadacitinib extended-release tablets – AbbVie)

REVIEW DATE: 08/26/2020

OVERVIEW

Rinvoq is a Janus kinase inhibitor (JAKi).¹ It is indicated for the treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate, either as monotherapy or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs). Rinvoq is not recommended for use in combination with other JAKis, biologics, or potent immunosuppressants such as azathioprine or cyclosporine.

Across the pivotal studies, response to Rinvoq was assessed at Week 12.

Guidelines

Guidelines from the American College of Rheumatology (ACR) [2015], updated prior to the approval of Rinvoq, have tumor necrosis factor (TNF) inhibitors and non-TNF biologics, administered with or without methotrexate, equally positioned as a recommended therapy following a trial of a conventional synthetic DMARD (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine).² Although Rinvoq and Olumiant (baricitinib tablets) [another approved JAKi] are not yet addressed, another JAKi (Xeljanz/Xeljanz XR [tofacitinib tablets, tofacitinib extended release tablets]) is not recommended for early rheumatoid arthritis in established RA, Xeljanz/XR is most frequently recommended for patients with moderate or high disease activity despite use of multiple biologics.

POLICY STATEMENT

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

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 is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Rheumatoid Arthritis.** Approve Rinvoq for the duration noted if the patient meets ONE of the following criteria (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 \geq 18 years of age; AND
 - ii. Patient has tried ONE conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months; AND
Note: Examples include methotrexate [oral or injectable], leflunomide, hydroxychloroquine, and sulfasalazine. An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the patient has already had a 3-month trial of at least one biologic. Refer to [Appendix](#) for examples of biologics used for rheumatoid arthritis. These patients who have already tried a biologic for RA are not required to “step back” and try a conventional synthetic DMARD.
 - iii. The medication is prescribed by or in consultation with a rheumatologist.
 - B) **Patient is Currently Receiving Rinvoq.** Approve for 3 years if the patient has had a response, as determined by the prescriber.
Note: Examples of a response to therapy include less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths; improved laboratory values; reduced dosage of corticosteroids. The patient may not have a full response, but there should have been a recent or past response to Rinvoq.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Rinvoq 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 combinations and lack of evidence supporting additive efficacy. There are no data evaluating combination of Rinvoq with other targeted synthetic DMARD (e.g., Otezla [apremilast tablets], Xeljanz/XR [tofacitinib tablets/extended-release tablets], Olumiant [baricitinib tablets]); therefore, safety and efficacy of this combination is unknown.
2. **Concurrent use with Other Potent Immunosuppressants** (e.g., azathioprine, cyclosporine).¹ Coadministration 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. Rinvoq has been evaluated with background methotrexate and other conventional synthetic DMARDs.
3. **COVID-19 (Coronavirus Disease 2019).** Forward all requests to the Medical Director.
Note: This includes requests for cytokine release syndrome associated with COVID-19.
4. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Rinvoq [prescribing information]. North Chicago, IL: AbbVie; July 2020.

- Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the treatment of rheumatoid arthritis. *Arthritis Rheumatol.* 2016;68(1):1-26.

APPENDIX

Biologic	Mechanism of Action	Examples of Inflammatory Indications for Products*
Biologics		
Adalimumab SC Products (Humira [®] , biosimilars)	Inhibition of TNF	AS, CD, JIA, PsO, PsA, RA, UC
Cimzia[®] (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, nr-axSpA, PsO, PsA, RA
Etanercept SC Products (Enbrel [®] , biosimilars)	Inhibition of TNF	AS, JIA, PsO, PsA
Infliximab IV Products (Remicade [®] , biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, UC
Simponi[®], Simponi[®] Aria[™] (golimumab SC injection, golimumab IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC
		IV formulation: AS, PsA, RA
Actemra[®] (tocilizumab IV infusion, tocilizumab SC injection)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA
		IV formulation: PJIA, RA, SJIA
Kevzara[®] (sarilumab SC injection)	Inhibition of IL-6	RA
Orencia[®] (abatacept IV infusion, abatacept SC injection)	T-cell costimulation modulator	SC formulation: JIA, PSA, RA
		IV formulation: JIA, PsA, RA
Rituximab IV Products (Rituxan [®] , biosimilars)	CD20-directed cytolytic antibody	RA
Kineret[®] (anakinra SC injection)	Inhibition of IL-1	JIA [^] , RA
Stelara[®] (ustekinumab SC injection, ustekinumab IV infusion)	Inhibition of IL-12/23	SC formulation: CD, PsO, PsA, UC
		IV formulation: CD, UC
Siliq[™] (brodalumab SC injection)	Inhibition of IL-17	PsO
Cosentyx[™] (secukinumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
Taltz[®] (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
Ilumya[™] (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
Skyrizi[™] (risankizumab-rzza SC injection)	Inhibition of IL-23	PsO
Tremfya[™] (guselkumab SC injection)	Inhibition of IL-23	PsO
Entyvio[™] (vedolizumab IV infusion)	Integrin receptor antagonist	CD, UC
Targeted Synthetic Disease-Modifying Antirheumatic Drugs		
Otezla[®] (apremilast tablets)	Inhibition of PDE4	PsO, PsA
Olumiant[®] (baricitinib tablets)	Inhibition of the JAK pathways	RA
Rinvoq[®] (upadacitinib extended-release tablets)	Inhibition of the JAK pathways	RA
Xeljanz[®], Xeljanz XR (tofacitinib tablets, tofacitinib extended-release tablets)	Inhibition of the JAK pathways	RA, PsA, UC

* Not an all-inclusive list of indication (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; SJIA – Systemic juvenile idiopathic arthritis; [^] Off-label use of Kineret in JIA supported in guidelines; JAK – Janus kinase.