

### Clinical Pharmacy Program Guidelines for Rinvoq

Program	Prior Authorization
Medication	Rinvoq™ (upadacitinib) extended-release tablets
Markets in Scope	California, Hawaii, Maryland, Nevada, New Jersey, New York, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	11/2019
Pharmacy and Therapeutics Approval Date	5/2020
Effective Date	7/2020

**1. Background:**

Rinvoq is a Janus kinase (JAK) inhibitor indicated for the treatment of adults with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate.

**2. Coverage Criteria:**

<p><b>A. <u>Rheumatoid Arthritis</u></b></p> <p>1. <b><u>Initial Authorization</u></b></p> <p><b><u>One</u></b> of the following:</p> <p>(1) <b><u>All</u></b> of the following:</p> <p>a. Diagnosis of moderately to severely active RA</p> <p style="text-align: center;"><b>-AND-</b></p> <p>b. History of failure to a 3 month trial of one non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)</p> <p style="text-align: center;"><b>-AND-</b></p> <p>c. Patient is not receiving Rinvoq in combination with <b><u>any</u></b> of the following:</p> <p>(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]</p>
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- (2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- (3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

**-AND-**

d. **Both** of the following:

- (1) History of failure, contraindication, or intolerance to **three** of the following:

- Cimzia (certolizumab)
- Enbrel (etanercept)
- Humira (adalimumab)
- Kevzara (sarilumab)

**-AND-**

- (2) History of failure, contraindication, or intolerance to Olumiant (baricitinib)

**-AND-**

e. Prescribed by or in consultation with a rheumatologist

**-OR-**

(2) **All** of the following:

- a. Patient is currently on Rinvoq therapy as documented by claims history or medical records (document drug, date, and duration of trial)

**-AND-**

- b. Diagnosis of moderately to severely active RA

**-AND-**

c. Patient is not receiving Rinvoq in combination with **any** of the following:

- (1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- (2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- (3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

**-AND-**

d. Prescribed by or in consultation with a rheumatologist

**Authorization will be issued for 12 months.**

2. **Reauthorization**

a. Documentation of positive clinical response to Rinvoq therapy

**-AND-**

b. Patient is not receiving Rinvoq in combination with **any** of the following:

- (1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- (2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- (3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

**-AND-**

c. Prescribed by or in consultation with a rheumatologist

**Authorization will be issued for 12 months.**

3. **Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. **References:**

1. Rinvoq [package insert]. North Chicago, IL: AbbVie Inc.; August 2019.
2. Pavy S, Constantin A, Pham T, et al. Methotrexate therapy for rheumatoid arthritis: clinical practice guidelines based on published evidence and expert opinions. *Joint Bone Spine* 2006;73(4):388-95.
3. Singh JA, Saag KG, Bridges SL, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care & Research. Arthritis Rheum.* 2016;68(1):1-26.

Program	Prior Authorization –Rinvoq <sup>™</sup> (upadacitinib)
<b>Change Control</b>	

Date	Change
11/2019	New program
12/2019	Added documentation of drug, date, and duration to non-biologic DMARD trial. Separated continuation of therapy requirements for current users.
1/2020	Revised step therapy medications due to PDL changes.
5/2020	Added prescriber requirement. Minor update to DMARD requirement. Updated references.