UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2022 P 1292-5
Program	Prior Authorization/Notification
Medication	Rinvoq™ (upadacitinib) extended-release tablets
P&T Approval Date	9/2019, 9/2020, 9/2021, 2/2022, 3/2022
Effective Date	5/1/2022; Oxford only: N/A

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 one or more tumor necrosis factor (TNF) blockers.

Limitation of Use:
The use of Rinvoq in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

- Adults with active psoriatic arthritis who have an inadequate response or intolerance to one or more TNF blockers.

Limitation of Use:
The use of Rinvoq in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

- Adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable.

  Limitation of Use:
  Rinvoq is not recommended in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.

2. Coverage Criteria:

A. <u>Rheumatoid Arthritis (RA)</u>

1. **<u>Initial Authorization</u>**

   a. **Rinvoq** will be approved based on **<u>all</u>** of the following criteria:

      (1) Diagnosis of moderately to severely active RA

-AND-

(2) History of failure, contraindication, or intolerance to at least **one** TNF inhibitor [e.g., Cimzia (certolizumab), Humira (adalimumab), Simponi (golimumab)].

-AND-

(3) Patient is not receiving Rinvoq in combination with **any** of the following:

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab),Cimzia (certolizumab), Simponi (golimumab)]
(b) Potent immunosuppressant (e.g., azathioprine or cyclosporine)
(c) Janus kinase inhibitor [e.g., Xeljanz/XR (tofacitinib), Olumiant (baricitinib)]

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Rinvoq** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to Rinvoq therapy

-AND-

(2) Patient is not receiving Rinvoq in combination with **any** of the following:

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(b) Potent immunosuppressant (e.g., azathioprine or cyclosporine)
(c) Janus kinase inhibitor [e.g., Xeljanz/XR (tofacitinib), Olumiant (baricitinib)]

Authorization will be issued for 12 months.

B. Psoriatic Arthritis (PsA)

1. **Initial Authorization**

a. **Rinvoq** will be approved based on **all** of the following criteria:

(1) Diagnosis of active psoriatic arthritis

-AND-

(2) History of failure, contraindication, or intolerance to at least **one** TNF inhibitor [e.g., Cimzia (certolizumab), Humira (adalimumab), Simponi (golimumab)].

-AND-

(3) Patient is not receiving Rinvoq in combination with **any** of the following:

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(b) Potent immunosuppressant (e.g., azathioprine or cyclosporine)
(c) Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]
(d) Janus kinase inhibitor [e.g., Xeljanz/XR (tofacitinib), Olumiant (baricitinib)]

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Rinvoq** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to Rinvoq therapy

-AND-

(2) Patient is not receiving Rinvoq in combination with **any** of the following:

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(b) Potent immunosuppressant (e.g., azathioprine or cyclosporine)
(c) Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]
(d) Janus kinase inhibitor [e.g., Xeljanz/XR (tofacitinib), Olumiant (baricitinib)]

Authorization will be issued for 12 months.

C. Atopic Dermatitis

1. **Initial Authorization**

a. **Rinvoq** will be approved based on **all** of the following criteria:

(1) Diagnosis of moderate-to-severe chronic atopic dermatitis

-AND-

(2) Patient is 12 years of age or older

-AND-

(3) History of failure, contraindication, or intolerance to at least **one** systemic drug product for the treatment of atopic dermatitis

-AND-

(4) Patient is not receiving Rinvoq in combination with **any** of the following:

(a) Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm), Dupixent (dupilumab)]
(b) Janus kinase inhibitor [e.g., Cibinqo (abrocitinib), Xeljanz/XR (tofacitinib), Olumiant (baricitinib), Opzelura (topical ruxolitinib)]
(c) Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Rinvoq** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to Rinvoq therapy

-AND-

(2) Patient is not receiving Rinvoq in combination with **any** of the following:

(a) Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm), Dupixent (dupilumab)]
(b) Janus kinase inhibitor [e.g., Cibinqo (abrocitinib), Xeljanz/XR (tofacitinib), Olumiant (baricitinib), Opzelura (topical ruxolitinib)]
(c) Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

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, Medical Necessity, and/or Step Therapy may be in place.

4. References:

1. Rinvoq [package insert]. North Chicago, IL: AbbVie Inc.; January 2022.

Program	Prior Authorization/Notification – Rinvoq (upadacitinib)
Change Control	
9/2019	New program
9/2020	Annual review. Minor update to background. Changed reauthorization duration to 12 months. Updated reference.
9/2021	Annual review with no changes to coverage criteria.
2/2022	Added step through a TNF inhibitor for RA and coverage criteria for PsA per updated label. Updated background and references.
3/2022	Updated background and added coverage criteria for new indication for atopic dermatitis. Updated references.