UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1292-13
Program	Prior Authorization/Notification
Medication	Rinvoq® (upadacitinib) extended-release tablets/ Rinvoq® LQ (upadacitinib) oral solution
P&T Approval Date	9/2019, 9/2020, 9/2021, 2/2022, 3/2022, 5/2022, 6/2022, 12/2022, 7/2023, 9/2023, 6/2024, 6/2025, 11/2025
Effective Date	2/1/2026

1. Background:

Rinvoq is a Janus kinase (JAK) inhibitor. Rinvoq and/or Rinvoq LQ is 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 and pediatric patients 2 years of age and older with active psoriatic arthritis who have an inadequate response or intolerance to one or more TNF blockers.

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

- 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.

- Adults with moderately to severely active ulcerative colitis 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 ulcerative colitis, or with other potent immunosuppressants such as azathioprine and cyclosporine.

  Rinvoq should be discontinued if adequate therapeutic response is not achieved with the 30 mg dosage. Use the lowest effective dosage needed to maintain response.

- Adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers.

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

- Adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy.

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

- Adults with moderately to severely active Crohn's disease 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 Crohn's disease, or with potent immunosuppressants such as azathioprine and cyclosporine

- Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis who have an inadequate response or intolerance to one or more TNF blockers.

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

- Adults with giant cell arteritis.

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

2. Coverage Criteria[a]:

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 **<u>one</u>** TNF inhibitor

-AND-

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

(a) Systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Orencia (abatacept), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication.
(b) Potent immunosuppressant (e.g., azathioprine or cyclosporine)

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 **either** of the following:

(a) Systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Orencia (abatacept), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication.
(b) Potent immunosuppressant (e.g., azathioprine or cyclosporine)

Authorization will be issued for 12 months.

B. Psoriatic Arthritis (PsA)

1. **Initial Authorization**

a. **Rinvoq or Rinvoq LQ** 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

-AND-

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

(a) Systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Simponi (golimumab), Skyrizi (risankizumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab] for treatment of the same indication.

(b) Potent immunosuppressant (e.g., azathioprine or cyclosporine)

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Documentation of positive clinical response to Rinvoq or Rinvoq LQ therapy

-AND-

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

(a) Systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab] for treatment of the same indication.

(b) Potent immunosuppressant (e.g., azathioprine or cyclosporine)

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 **either** of the following:

(a) Systemic targeted immunomodulator [e.g., Adbry (tralokinumab-ldrm), Dupixent (dupilumab), Cibinqo (abrocitinib), Xeljanz/XR (tofacitinib), Olumiant

(baricitinib), Opzelura (topical ruxolitinib)] for treatment of the same indication.
(b) 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 **either** of the following:

(a) Systemic targeted immunomodulator [e.g., Adbry (tralokinumab-ldrm), Dupixent (dupilumab), Cibinqo (abrocitinib), Xeljanz/XR (tofacitinib), Olumiant (baricitinib), Opzelura (topical ruxolitinib)] for treatment of the same indication.
(b) Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

Authorization will be issued for 12 months.

D. Ulcerative Colitis (UC)

1. **Initial Authorization**

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

(1) Diagnosis of moderately to severely active UC

-AND-

(2) History of an inadequate response or intolerance to at least one TNF inhibitor or if TNF inhibitors are clinically inadvisable, patient received at least one approved systemic therapy.

-AND-

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

(a) Systemic targeted immunomodulator [e.g., adalimumab, Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Simponi (golimumab), Skyrizi (risankizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab, Zeposia (ozanimod)] for treatment of the same indication.

(b) 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 **either** of the following:

(a) Systemic targeted immunomodulator [e.g., adalimumab, Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Simponi (golimumab), Skyrizi (risankizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab, Zeposia (ozanimod)] for treatment of the same indication.

(b) Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

Authorization will be issued for 12 months.

E. Ankylosing Spondylitis and Non-radiographic Axial Spondyloarthritis

1. **Initial Authorization**

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

(1) Diagnosis of active ankylosing spondylitis or non-radiographic axial spondyloarthritis

-AND-

(2) History of failure, contraindication, or intolerance to at least **one** TNF inhibitor

-AND-

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

(a) Systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Simponi (golimumab), Taltz (ixekizumab), Xeljanz (tofacitinib)] for treatment of the same indication.

(b) 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 **either** of the following:

(a) Systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Simponi (golimumab), Taltz (ixekizumab), Xeljanz (tofacitinib)] for treatment of the same indication.

(b) Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

Authorization will be issued for 12 months.

F. Crohn's Disease (CD)

1. **Initial Authorization**

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

(1) Diagnosis of moderately to severely active Crohn's disease

-AND-

(2) History of an inadequate response or intolerance to at least one TNF inhibitor or if TNF inhibitors are clinically inadvisable, patient received at least one approved systemic therapy.

-AND-

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

(a) Systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Skyrizi (risankizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication.

(b) 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 either of the following:

(a) Systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Skyrizi (risankizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication.

(b) Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

Authorization will be issued for 12 months.

G. Polyarticular Juvenile Idiopathic Arthritis (pJIA)

1. **Initial Authorization**

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

(1) Diagnosis of active polyarticular juvenile idiopathic arthritis

-AND-

(2) History of failure, contraindication, or intolerance to at least **one** TNF inhibitor

-AND-

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

(a) Systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication.

(b) Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Documentation of positive clinical response to Rinvoq or Rinvoq LQ therapy

-AND-

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

(a) Systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication.

(b) Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

Authorization will be issued for 12 months.

H. Giant Cell Arteritis (GCA)

1. **Initial Authorization**

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

(1) Diagnosis of giant cell arteritis

-AND-

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

(a) Systemic targeted immunomodulator for treatment of the same indication.
(b) 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 **either** of the following:

(a) Systemic targeted immunomodulator for treatment of the same indication.
(b) Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific

benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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.; October 2025.

Program	Prior Authorization/Notification – Rinvoq (upadacitinib)/ / Rinvoq LQ
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.
5/2022	Updated background and added coverage criteria for new indication for ulcerative colitis. Updated reference.
6/2022	Updated background and added coverage criteria for new indication for ankylosing spondylitis. Updated reference.
12/2022	Updated background and added coverage criteria for new indication for non-radiographic axial spondyloarthritis. Added state mandate footnote. Updated reference.
7/2023	Updated not receiving in combination language to targeted immunomodulator and updated examples. Updated background and added coverage criteria for crohn's disease. Updated reference.
9/2023	Updated examples. No change to coverage criteria.
6/2024	Added Rinvoq LQ to the program. Updated criteria with pediatric indication for PsA. Added criteria for new indication for pJIA. Updated background and reference.
6/2025	Updated background and added coverage criteria for new indication for Giant Cell Arteritis (GCA). Updated reference.
11/2025	Updated criteria to reflect updated UC and CD indication regarding TNF blockers. Updated background and reference. Updated combination examples and language with no change to clinical intent.