

(UnitedHealthcare Pharmacy
Clinical Pharmacy Programs)

Program Number	2024 P 2202-13
Program	Prior Authorization/Medical Necessity
Medication	Rinvoq® (upadacitinib) extended-release tablets/ Rinvoq® LQ (upadacitinib) oral solution
P&T Approval Date	5/2020, 5/2021, 6/2021, 12/2021, 2/2022, 3/2022, 5/2022, 6/2022, 7/2022, 12/2022, 7/2023, 9/2023, 6/2024
Effective Date	8/1/2024

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 TNF 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.

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.

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.

2. Coverage Criteria^a:

A. Rheumatoid Arthritis (RA)

1. Initial Authorization

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

(1) Diagnosis of moderately to severely active RA

-AND-

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

(a) **Both** of the following

i. **One** of the following:

- 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, unless contraindicated or clinically significant adverse effects are experienced (document drug, date and duration of trial)^b

-OR-

- Patient has been previously treated with targeted immunomodulator FDA-approved for the treatment of rheumatoid arthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Enbrel (etanercept), Cimzia (certolizumab), adalimumab, Simponi (golimumab), Orenzia (abatacept), Olumiant (baricitinib), Xeljanz/Xeljanz XR (tofacitinib)]

-AND-

ii. **One** of the following:

- History of failure, contraindication, or intolerance to at least **one** TNF inhibitor[^]

-OR-

- Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria⁶).

-OR-

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

- i. Patient is currently on Rinvoq therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

- ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Abbvie sponsored Rinvoq Complete program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Rinvoq*

-AND-

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

- (a) Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orenzia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib)]
- (b) Potent immunosuppressant (e.g., azathioprine or cyclosporine)

-AND-

(4) Prescribed by or in consultation with a rheumatologist

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Abbvie sponsored Rinvoq Complete program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Rinvoq** will be approved based on **all** 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) Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orenia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib)]
- (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) **One** of the following:

(a) **Both** of the following

i. **One** of the following:

- History of failure to a 3 month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)^b

-OR-

- Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as documented by claims history or submission of medical records (Document drug, date,

and duration of therapy) [e.g., Enbrel (etanercept), Cimzia (certolizumab), adalimumab, Simponi (golimumab), Orencia (abatacept), Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Olumiant (baricitinib), Otezla (apremilast)Xeljanz/Xeljanz XR (tofacitinib)]

-AND-

ii. **One** of the following:

- History of failure, contraindication, or intolerance to at least **one** TNF inhibitor ^

-OR-

- Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria⁶).

-OR-

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

i. Patient is currently on Rinvoq or Rinvoq LQ therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Abbvie sponsored Rinvoq Complete program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Rinvoq or Rinvoq LQ*

-AND-

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

- (a) Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Otezla (apremilast)]
- (b) Potent immunosuppressant (e.g., azathioprine or cyclosporine)

-AND-

(4) Prescribed by or in consultation with **one** of the following:

- (a) Rheumatologist
- (b) Dermatologist

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Abbvie sponsored Rinvoq Complete program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Rinvoq or Rinvoq LQ** will be approved based on **all** 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) Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Otezla (apremilast)]
- (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) **One** of the following:

- (a) **Both** of the following:

- i. History of failure, contraindication, or intolerance to **two** of the following therapeutic classes of topical therapies (document drug, date of trial, and/ or contraindication to medication):
 - a. Medium to very-high potency topical corticosteroid [e.g., Elocon (mometasone furoate), Synalar (fluocinolone acetonide), Lidex (fluocinonide)]

- b. Topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)].[‡]
- c. Eucrisa (crisaborole)[‡]

-AND-

ii. **One** of the following:

a. **Both** of the following[^]:

- Submission of medical records (e.g., chart notes, laboratory values) documenting a 3 month trial^b of a systemic drug product for the treatment of atopic dermatitis [examples include, but are not limited to, Adbry (tralokinumab-ldrm), Dupixent (dupilumab), etc.^Ω] (prescription claims history may be used in conjunction as documentation of medication use, dose, and duration)

-AND-

- Physician attests that the patient was not adequately controlled with the documented systemic drug product

-OR-

b. Physician attests that systemic treatment with **both** of the following, FDA-approved chronic atopic dermatitis therapies is inadvisable. (Document drug and contraindication rationale)[^]

- Adbry (tralokinumab-ldrm)
- Dupixent (dupilumab)

-OR-

c. Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria⁶).

-OR-

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

i. Patient is currently on Rinvoq therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Abbvie sponsored Rinvoq Complete program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Rinvoq*

-AND-

- (3) Patient is not receiving Rinvoq in combination with **either** of the following:
- (a) Targeted immunomodulator [e.g., Adbry (tralokinumab-ldrm), Dupixent (dupilumab), Cibinqo (abrocitinib), Xeljanz/XR (tofacitinib), Olumiant (baricitinib), Opzelura (topical ruxolitinib)]
 - (b) Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

-AND-

- (4) Prescribed by **one** of the following:
- (a) Dermatologist
 - (b) Allergist
 - (c) Immunologist

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Abbvie sponsored Rinvoq Complete program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

2. **Reauthorization**

- a. **Rinvoq** will be approved based on **all** 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) Targeted immunomodulator [e.g., Adbry (tralokinumab-ldrm), Dupixent (dupilumab), Cibinqo (abrocitinib), Xeljanz/XR (tofacitinib), Olumiant (baricitinib), Opzelura (topical ruxolitinib)]
 - (b) Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

-AND-

- (3) Prescribed by or in consultation with **one** of the following:
- (a) Dermatologist
 - (b) Allergist
 - (c) Immunologist

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) **One** of the following:

(a) **Both** of the following:

i. **One** of the following:

- Patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, 6-mercaptopurine)

-OR-

- Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ulcerative colitis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Simponi (golimumab), Stelara (ustekinumab), Xeljanz/XR (tofacitinib)]

-AND-

ii. **One** of the following:

- History of failure, contraindication, or intolerance to at least **one** TNF inhibitor[^]

-OR-

- Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria⁵).

-OR-

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

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

-AND-

- ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Abbvie sponsored Rinvoq Complete program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Rinvoq*

-AND-

- (3) Patient is not receiving Rinvoq in combination with **either** of the following:
 - (a) Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orenzia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Stelara (ustekinumab), Skyrizi (risankizumab)]
 - (b) Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

-AND-

- (4) Prescribed by or in consultation with a gastroenterologist

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Abbvie sponsored Rinvoq Complete program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

2. **Reauthorization**

- a. **Rinvoq** will be approved based on **all** 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) Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orenzia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Stelara (ustekinumab), Skyrizi (risankizumab)]
 - (b) Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

Authorization will be issued for 12 months.

E. **Ankylosing Spondylitis and non-radiographic Axial Spondyloarthritis (nr-axSpA)**

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) **One** of the following:

(a) **Both** of the following:

i. **One** of the following:

- History of failure to **two** NSAIDs (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)

-OR-

- Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ankylosing spondylitis or non-radiographic axial spondyloarthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Enbrel (etanercept), Cimzia (certolizumab), adalimumab, Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)]

-AND-

ii. **One** of the following:

- History of failure, contraindication, or intolerance to at least **one** TNF inhibitor[^]

-OR-

- Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria⁵).

-OR-

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

i. Patient is currently on Rinvoq therapy as documented by claims history or submission of medical records (Document drug, date, and duration of therapy):

-AND-

- ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Abbvie sponsored Rinvoq Complete program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Rinvoq*

-AND-

- (3) Patient is not receiving Rinvoq in combination with **either** of the following:
 - (a) Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Oencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib)]
 - (b) Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

-AND-

- (4) Prescribed by or in consultation with a rheumatologist

*Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Abbvie sponsored Rinvoq Complete program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

2. **Reauthorization**

- a. **Rinvoq** will be approved based on **all** 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) Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Oencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib)]
- (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) **One** of the following:

(a) **Both** of the following:

i. **One** of the following:

- History of failure to **one** of the following conventional therapies at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):
 - Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
 - 6-mercaptopurine (Purinethol)
 - Azathioprine (Imuran)
 - Methotrexate (Rheumatrex, Trexall)

-OR-

- Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of Crohn's disease as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Cimzia (certolizumab), Stelara (ustekinumab), Skyrizi (isankizumab)]

-AND-

ii. **One** of the following:

- History of failure, contraindication, or intolerance to at least one TNF inhibitor^

-OR-

- Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria⁵).

-OR-

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

- i. Patient is currently on Rinvoq therapy as documented by claims history or submission of medical records (Document drug, date, and duration of therapy):

-AND-

- ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Abbvie sponsored Rinvoq Complete program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Rinvoq*

-AND-

- (3) Patient is not receiving Rinvoq in combination with either of the following:
 - (a) Targeted immunomodulator [e.g., adalimumab, Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Stelara (ustekinumab), Skyrizi (risankizumab)]
 - (b) Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

-AND-

- (4) Prescribed by or in consultation with a gastroenterologist

*Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Abbvie sponsored Rinvoq Complete program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

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) Targeted immunomodulator [e.g., adalimumab, Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Stelara (ustekinumab), Skyrizi (risankizumab)]
 - (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) **One** of the following:

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

-OR-

(b) Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria⁵).

-OR-

(c) **Both** of the following:

i. Patient is currently on Rinvoq or Rinvoq LQ therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Abbvie sponsored Rinvoq Complete program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Rinvoq or Rinvoq LQ*

-AND-

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

(a) Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Olumiant (baricitinib), Xeljanz (tofacitinib)]

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

-AND-

(4) Prescribed by or in consultation with a rheumatologist

* Patients requesting initial authorization who were established on therapy via the receipt of a

manufacturer supplied sample at no cost in the prescriber’s office or any form of assistance from the Abbvie sponsored Rinvoq Complete program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

2. Reauthorization

a. **Rinvoq or Rinvoq LQ** will be approved based on **all** 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) Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Olumiant (baricitinib), Xeljanz (tofacitinib)]
- (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.

^b For Connecticut, Kentucky and Mississippi business only a 30-day trial will be required.

[^] Tried/failed alternative(s) are supported by FDA labeling

[¥] Elidel, Protopic/tacrolimus ointment, and Eucrisa require prior authorization.

Table 1: Relative potencies of topical corticosteroids⁸

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1

	Triamcinolone acetonide	Cream, ointment	0.5
	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
Medium potency	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

Table 2: Systemic immunomodulatory agents recommended by the 2014 American Academy of Dermatology guidelines for the treatment of refractory atopic dermatitis ^{Ω,9}

Cyclosporine

Azathioprine

Methotrexate

Mycophenolate mofetil

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.; April 202.
2. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care & Research. Arthritis Rheum.* 2021;73(7):924-939.
3. Cohen S, Mikuls TR. Initial treatment of rheumatoid arthritis in adults. In: Post TW, ed. UpToDate. UpToDate; 2021. Accessed on December 17th, 2021.
4. Sing JA, Guyatt G, Ogie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis.
5. Gladman DD, Ritchlin C. Treatment of psoriatic arthritis. In: Post TW, ed. UpToDate. UpToDate; 2021. Accessed on December 17th, 2021.

6. American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Arlington, VA: American Psychiatric Publishing. 2013.
7. Eichenfield LF, Tom WL, Chamlin SL et al. Guidelines of care for the management of atopic dermatitis: section 1. Diagnosis and assessment of atopic dermatitis. J Am Acad Dermatol. 2014; 70(1):338-51.
8. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol. 2014; 71(1):116-32.
9. Sidbury R, Davis DM, Cohen DE, et al. Guidelines of care for the management of atopic dermatitis: Section 3. Management and treatment with phototherapy and systemic agents. J Am Acad Dermatol. 2014 Aug;71(2):327-49.

Program	Prior Authorization/Medical Necessity – Rinvoq (upadacitinib)/Rinvoq LQ
Change Control	
5/2020	New program
5/2021	Annual review. Removed preceding month requirement from failure criteria. Removed prescriber requirement from reauthorization criteria. Reference updated.
6/2021	Added coverage criteria for patients previously treated with a biologic DMARD. Added clarification that submission of medical records is required documenting previous or current therapy with a biologic DMARD in order to bypass step through non-biologic therapies if claim history not available.
12/2021	Updated conventional DMARD bypass language for rheumatoid arthritis with no change to clinical intent. Updated CT/KY footnote.
2/2022	Added step through a TNF inhibitor for RA and coverage criteria for PsA per updated label. Updated background and references. Added footnote to support FDA labeled first line requirements.
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 state mandate to include Mississippi. Updated reference.
6/2022	Updated background and added coverage criteria for new indication for ankylosing spondylitis. Updated reference.
7/2022	Removed age requirement from initial authorization criteria for atopic dermatitis.
12/2022	Updated background and added coverage criteria for new indication for non-radiographic axial spondyloarthritis. 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, reference and state mandate footnote.