BlueCross BlueShield
Federal Employee Program.

Blue Cross Blue Shield Association
750 9th St NW, Suite 900
Washington, D.C. 20001
1-800-624-5060
Fax 1-877-378-4727

5.70.074

Section:	Prescription Drugs	**Effective Date:**	January 1, 2026
Subsection:	Analgesics and Anesthetics	**Original Policy Date:**	September 13, 2019
Subject:	Rinvoq	**Page:**	1 of 15

Last Review Date: December 12, 2025

Rinvoq

Description

Rinvoq/Rinvoq LQ (upadacitinib)

Background
Rinvoq/Rinvoq LQ (upadacitinib) is a Janus kinase (JAK) inhibitor. JAKs are intracellular enzymes which transmit signals arising from cytokine or growth factor-receptor interactions on the cellular membrane to influence cellular processes of hematopoiesis and immune cell function. Within the signaling pathway, JAKs phosphorylate and activate Signal Transducers and Activators of Transcription (STATs) which modulate intracellular activity including gene expression. Rinvoq/Rinvoq LQ modulates the signaling pathway at the point of JAKs, preventing the phosphorylation and activation of STATs (1).

Regulatory status
FDA-approved indications: Rinvoq is a Janus kinase (JAK) inhibitor indicated for the treatment of: (1)

- 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.
    - Limitations of Use: Rinvoq is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, 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.

  - Limitations of Use: Rinvoq is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.
- Adults with moderately to severely active ulcerative colitis (UC) 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.
- Adults with moderately to severely active Crohn's disease (CD) 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.
- Adults with active ankylosing spondylitis (AS) 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 (nr-axSpA) 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 giant cell arteritis.
  - 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.

Rinvoq/Rinvoq LQ is indicated for the treatment of (1):

- Adults and pediatric patients 2 years of age and older with active psoriatic arthritis (PsA) who have had an inadequate response or intolerance to one or more TNF blockers.
  - Limitations 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.
- Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis (pJIA) who have had an inadequate response or intolerance to one or more TNF blockers.

- Limitations 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.

Rinvoq/Rinvoq LQ carries several boxed warnings: (1)

1. Serious infections
    a. Serious infections, including tuberculosis and bacterial, invasive fungal, viral, and other opportunistic infection leading to hospitalization or death. If a serious infection develops, interrupt Rinvoq/Rinvoq LQ until the infection is controlled. Prior to starting Rinvoq/Rinvoq LQ, perform a test for latent tuberculosis; if it is positive, start treatment for tuberculosis prior to starting Rinvoq/Rinvoq LQ. Monitor all patients for active tuberculosis during treatment, even if the initial latent tuberculosis test is negative.
2. Mortality
    a. RA patients 50 years of age and older with at least one cardiovascular risk factor showed a higher rate of all-cause mortality, including sudden cardiovascular death, in patients treated with JAK inhibitors compared to TNF blockers.
3. Malignancies
    a. Lymphoma and other malignancies have been observed in patients treated with Rinvoq/Rinvoq LQ.
    b. In RA patients treated with a JAK inhibitor, a higher rate of malignancies was observed when compared with TNF blockers.
4. Major adverse cardiovascular events (MACE)
    a. RA patients 50 years of age and older with at least one cardiovascular risk factor treated with a JAK inhibitor showed a higher rate of MACE (defined as cardiovascular death, myocardial infarction, and stroke) when compared to TNF blockers. Patients who are current or past smokers are at increased risk. Rinvoq/Rinvoq LQ should be discontinued in patients that have experienced a myocardial infarction or stroke.
5. Thrombosis
    a. Thrombosis, including deep vein thrombosis, pulmonary embolism, and arterial thrombosis, have occurred in patients treated with JAK inhibitors used to treat inflammatory conditions. Many of these adverse events were serious and some resulted in death.
    b. In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with a JAK inhibitor, a higher rate of thrombosis was observed when compared with TNF blockers.

Rinvoq/Rinvoq LQ can cause fetal harm when administered to a pregnant woman. Pregnancy status of patients of reproductive potential should be verified prior to treatment with Rinvoq/Rinqvoq LQ. Advise females of reproductive potential of the potential risk to the fetus and to use effective contraception during treatment with Rinvoq/Rinvoq LQ and for 4 weeks following completion of therapy (1).

The safety and effectiveness of Rinvoq have not been established in pediatric patients less than 12 years of age with atopic dermatitis, less than 2 years of age with psoriatic arthritis or pJIA, or in patients less than 18 years of age for the other approved indications. The safety and effectiveness of Rinvoq LQ have not been established in pediatric patients less than 2 years of age with psoriatic arthritis or pJIA, or in patients less than 18 years of age for the other approved indications (1).

Related policies
Adbry, Cibinqo, Dupixent, Olumiant, Xeljanz/XR

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Rinvoq may be considered **medically necessary** if the conditions indicated below are met.

Rinvoq may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Moderately to severely active rheumatoid arthritis (RA)
    a. 18 years of age or older
    b. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional disease-modifying anti-rheumatic drug (DMARD) (see Appendix 1)

   c. Inadequate treatment response, intolerance, or contraindication to at least **ONE** TNF blocker (e.g., Cimzia, Enbrel, Humira, Remicade, Simponi/Simponi Aria)
2. Active psoriatic arthritis (PsA)
   a. 2 years of age or older
   b. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional disease-modifying anti-rheumatic drug (DMARD) (see Appendix 1)
   c. Inadequate treatment response, intolerance, or contraindication to at least **ONE** TNF blocker (e.g., Cimzia, Enbrel, Humira, Remicade, Simponi/Simponi Aria)
3. Moderately to severely active ulcerative colitis (UC)
   a. 18 years of age or older
   b. Inadequate treatment response, intolerance, or contraindication to at least **ONE** conventional therapy option (see Appendix 2)
   c. Inadequate treatment response, intolerance, or contraindication to at least **ONE** TNF blocker (e.g., Humira, Remicade, Simponi)
4. Moderately to severely active Crohn's disease (CD)
   a. 18 years of age or older
   b. Inadequate treatment response, intolerance, or contraindication to at least **ONE** conventional therapy option (see Appendix 2)
   c. Inadequate treatment response, intolerance, or contraindication to at least **ONE** TNF blocker (e.g., Cimzia, Humira, Remicade)
5. Active ankylosing spondylitis (AS)
   a. 18 years of age or older
   b. Inadequate treatment response, intolerance, or contraindication to at least **TWO** non-steroidal anti-inflammatory drugs (NSAIDs)
   c. Inadequate treatment response, intolerance, or contraindication to at least **ONE** TNF blocker (e.g., Cimzia, Enbrel, Humira, Remicade, Simponi/Simponi Aria)
6. Active non-radiographic axial spondyloarthritis (nr-axSpA)
   a. 18 years of age or older
   b. Patient has objective signs of inflammation
   c. Inadequate treatment response, intolerance, or contraindication to at least **TWO** non-steroidal anti-inflammatory drugs (NSAIDs)
   d. Inadequate treatment response, intolerance, or contraindication to at least **ONE** TNF blocker (e.g., Cimzia)

7. Active Polyarticular Juvenile Idiopathic Arthritis (pJIA)
    a. 2 years of age or older
    b. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional disease-modifying anti-rheumatic drug (DMARD) (see Appendix 1)
    c. Inadequate treatment response, intolerance, or contraindication to at least **ONE** TNF blocker (e.g., Enbrel, Humira, Remicade, Simponi Aria)
8. Giant cell arteritis
    a. 18 years of age or older
    b. Inadequate treatment response to at least a 3 month trial of corticosteroids
    c. Used in combination with a tapering course of corticosteroids or as monotherapy following discontinuation of corticosteroids

AND ALL of the following:

1. Prescriber has considered the risks for malignancy and major adverse cardiovascular events (MACE) (e.g., advanced age, smoking history, cardiovascular risk factors etc.) and determined that Rinvoq therapy is appropriate
2. Result for latent TB infection is negative **OR** result was positive for latent TB and patient completed treatment (or is receiving treatment) for latent TB

AND NONE of the following:

1. Active bacterial, invasive fungal, viral, and other opportunistic infections
2. Severe hepatic impairment (Child Pugh C)
3. A lymphocyte count less than 500 cells/mm3
4. An absolute neutrophil count less than 1000 cells/mm3
5. A hemoglobin less than 8 g/dL
6. History of thrombotic events including deep vein thrombosis (DVT) or pulmonary embolism (PE)
7. Used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)
8. Used in combination with potent immunosuppressants azathioprine or cyclosporine
9. Given concurrently with live vaccines

Age 12 years of age or older

Diagnosis

Patient must have the following:

1. Moderate to severe atopic dermatitis (eczema)

AND ALL of the following:

1. Inadequate treatment response, intolerance, or contraindication to at least **TWO** systemic atopic dermatitis medications, including biologics (e.g., oral corticosteroids, hydroxyzine, Adbry, Cibinqo, Dupixent, etc.)
2. Prescriber has considered the risks for malignancy and major adverse cardiovascular events (MACE) (e.g., advanced age, smoking history, cardiovascular risk factors etc.) and determined that Rinvoq therapy is appropriate
3. Result for latent TB infection is negative **OR** result was positive for latent TB and patient completed treatment (or is receiving treatment) for latent TB

AND NONE of the following:

1. Active bacterial, invasive fungal, viral, and other opportunistic infections
2. Severe hepatic impairment (Child Pugh C)
3. A lymphocyte count less than 500 cells/mm3
4. An absolute neutrophil count less than 1000 cells/mm3
5. A hemoglobin less than 8 g/dL
6. History of thrombotic events including deep vein thrombosis (DVT) or pulmonary embolism (PE)
7. Used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)
8. Used in combination with another non-topical Prior Authorization (PA) medication for atopic dermatitis (see Appendix 3)
9. Used in combination with potent immunosuppressants azathioprine or cyclosporine
10. Given concurrently with live vaccines

Prior-Approval Renewal Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Rheumatoid arthritis (RA)
    a. 18 years of age or older
2. Psoriatic arthritis (PsA)
    a. 2 years of age or older
3. Ulcerative colitis (UC)
    a. 18 years of age or older
4. Crohn's disease (CD)
    a. 18 years of age or older
5. Ankylosing spondylitis (AS)
    a. 18 years of age or older
6. Non-radiographic axial spondyloarthritis (nr-axSpa)
    a. 18 years of age or older
7. Polyarticular Juvenile Idiopathic Arthritis (pJIA)
    a. 2 years of age or older
8. Giant cell arteritis
    a. 18 years of age or older

AND ALL of the following:

1. Condition has improved or stabilized
2. Prescriber has considered the risks for malignancy and major adverse cardiovascular events (MACE) (e.g., advanced age, smoking history, cardiovascular risk factors etc.) and determined that continuation of Rinvoq therapy is appropriate

AND NONE of the following:

1. Active bacterial, invasive fungal, viral, and other opportunistic infections
2. Used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)
3. Used in combination with potent immunosuppressants azathioprine or cyclosporine
4. Development of thrombotic events (including DVTs or PEs)
5. Given concurrently with live vaccines

Age 12 years of age or older

Diagnosis

Patient must have the following:

1. Atopic dermatitis (eczema)

AND ALL of the following:

1. Condition has improved or stabilized
2. Prescriber has considered the risks for malignancy and major adverse cardiovascular events (MACE) (e.g., advanced age, smoking history, cardiovascular risk factors etc.) and determined that continuation of Rinvoq therapy is appropriate

AND NONE of the following:

1. Active bacterial, invasive fungal, viral, and other opportunistic infections
2. Used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)
3. Used in combination with another non-topical Prior Authorization (PA) medication for atopic dermatitis (see Appendix 3)
4. Used in combination with potent immunosuppressants azathioprine or cyclosporine
5. Development of thrombotic events (including DVTs or PEs)
6. Given concurrently with live vaccines

Policy Guidelines

Pre–PA Allowance

None

Prior–Approval Limits

Quantity

Indication	Strength/Dosage Form	Quantity
Ankylosing spondylitis (AS)	15 mg tablet	90 tablets per 90 days **OR**

Atopic dermatitis	15 mg tablet 30 mg tablet	90 tablets per 90 days **OR**
Crohn's Disease (CD)	15 mg tablet 30 mg tablet 45 mg tablet	90 tablets per 90 days **OR**
Giant cell arteritis	15 mg tablet	90 tablets per 90 days **OR**
Non-radiographic axial spondyloarthritis (nr-axSpA)	15 mg tablet	90 tablets per 90 days **OR**
Polyarticular juvenile idiopathic arthritis (pJIA)	15 mg tablet	90 tablets per 90 days **OR**
	1 mg/mL oral solution	6 bottles per 90 days **OR**
Psoriatic arthritis (PsA)	15 mg tablet	90 tablets per 90 days **OR**
	1 mg/mL oral solution	6 bottles per 90 days **OR**
Rheumatoid arthritis (RA)	15 mg tablet	90 tablets per 90 days **OR**
Ulcerative colitis (UC)	15 mg tablet 30 mg tablet 45 mg tablet	90 tablets per 90 days

Duration 4 months for atopic dermatitis
12 months for all other indications

Prior–Approval *Renewal* Limits

Quantity

Indication	Strength/Dosage Form	Quantity
Ankylosing spondylitis (AS)	15 mg tablet	90 tablets per 90 days **OR**
Atopic dermatitis	15 mg tablet 30 mg tablet	90 tablets per 90 days **OR**
Crohn's Disease (CD)	15 mg tablet 30 mg tablet	90 tablets per 90 days **OR**
Giant cell arteritis	15 mg tablet	90 tablets per 90 days **OR**
Non-radiographic axial spondyloarthritis (nr-axSpA)	15 mg tablet	90 tablets per 90 days **OR**
Polyarticular juvenile idiopathic arthritis (pJIA)	15 mg tablet	90 tablets per 90 days **OR**
	1 mg/mL oral solution	6 bottles per 90 days **OR**

Psoriatic arthritis (PsA)	15 mg tablet	90 tablets per 90 days **OR**
	1 mg/mL oral solution	6 bottles per 90 days **OR**
Rheumatoid arthritis (RA)	15 mg tablet	90 tablets per 90 days **OR**
Ulcerative colitis (UC)	15 mg tablet 30 mg tablet	90 tablets per 90 days

Duration 12 months for atopic dermatitis
18 months for all other indications

Rationale

Summary

Rinvoq (upadacitinib) is a Janus kinase (JAK) inhibitor indicated for patients with rheumatoid arthritis (RA), ulcerative colitis (UC), Crohn's disease (CD), ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), atopic dermatitis, and giant cell arteritis. Rinvoq/Rinvoq LQ is indicated for patients with psoriatic arthritis (PsA) and polyarticular juvenile idiopathic arthritis (pJIA). Rinvoq/Rinvoq LQ has several boxed warnings including risk of serious infections, mortality, malignancies, MACE, and thrombosis. The safety and effectiveness of Rinvoq have not been established in pediatric patients less than 12 years of age with atopic dermatitis, less than 2 years of age with psoriatic arthritis or pJIA, or in patients less than 18 years of age for the other approved indications. The safety and effectiveness of Rinvoq LQ have not been established in pediatric patients less than 2 years of age with psoriatic arthritis or pJIA, or in patients less than 18 years of age for the other approved indications (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Rinvoq while maintaining optimal therapeutic outcomes.

References

1. Rinvoq/Rinvoq LQ [package insert]. North Chicago, IL: AbbVie Inc.; April 2025.

Policy History

Date	Action
September 2019	Addition to PA
December 2019	Annual review. Addition of requirement to trial preferred product

March 2020	Annual review
December 2020	Annual review and reference update. Revised requirements to t/f preferred products to apply to Blue Focus patients only
June 2021	Annual review
December 2021	Annual review
January 2022	Added t/f requirement to t/f at least one TNF blocker per package insert update. Added indication: psoriatic arthritis (PsA). Added requirement for prescriber to assess risks with malignancy and MACE, per latest PI update
March 2022	Annual review and reference update
April 2022	Addition of indications per PI update: atopic dermatitis and ulcerative colitis. Addition of Appendix 2 and Appendix 3
May 2022	Addition of indication per PI update: ankylosing spondylitis
June 2022	Annual review. Per SME, added example names of biologics to the atopic dermatitis t/f requirement
September 2022	Annual review
November 2022	Per PI update, added indication of non-radiographic axial spondyloarthritis (nr-axSpA)
December 2022	Annual review
June 2023	Per PI update, added Crohn’s disease indication
September 2023	Annual review
March 2024	Annual review and reference update
May 2024	Per PI update, added indication of pJIA, reduced age for PsA to 2 and older, and added Rinvoq LQ oral solution to quantity chart
June 2024	Annual review
September 2024	Annual review. Per SME, differentiated Rinvoq/Rinvoq LQ indications and added embryo-fetal toxicity warning to the regulatory status section
March 2025	Annual review
May 2025	Per PI update, added indication of giant cell arteritis
June 2025	Annual review
December 2025	Annual review. Removed Blue Focus t/f requirements

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 12, 2025 and is effective on January 1, 2026.

Appendix 1 - List of DMARDs

Conventional disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
azathioprine	Azasan, Imuran
cyclophosphamide	Cytoxan
cyclosporine	Neoral, Gengraf, Sandimmune
hydroxychloroquine	Plaquenil
leflunomide	Arava
methotrexate	Rheumatrex, Trexall
mycophenolate	Cellcept
sulfasalazine	Azulfidine, Sulfazine

Biological disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
abatacept	Orencia
adalimumab	Humira
anakinra	Kineret
bimekizumab-bkzx	Bimzelx
brodalumab	Siliq
certolizumab	Cimzia
etanercept	Enbrel
golimumab	Simponi/Simponi Aria
guselkumab	Tremfya
infliximab	Remicade
infliximab-dyyb	Zymfentra
ixekizumab	Taltz
risankizumab-rzaa	Skyrizi
rituximab	Rituxan
sarilumab	Kevzara
secukinumab	Cosentyx
spesolimab-sbzo	Spevigo
tildrakizumab-asmn	Ilumya
tocilizumab	Actemra
ustekinumab	Stelara
vedolizumab	Entyvio

Targeted synthetic disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name

apremilast	Otezla
baricitinib	Olumiant
deucravacitinib	Sotyktu
tofacitinib	Xeljanz/XR
upadactinib	Rinvoq

Appendix 2 - List of Conventional Therapies

Conventional Therapy Options for CD
1. Mild to moderate disease – induction of remission: a. Oral budesonide, oral mesalamine b. Alternatives: metronidazole, ciprofloxacin
2. Mild to moderate disease – maintenance of remission: a. Azathioprine, mercaptopurine b. Alternatives: oral budesonide, methotrexate intramuscularly (IM)
3. Moderate to severe disease – induction of remission: a. Prednisone, methylprednisolone intravenously (IV) b. Alternatives: methotrexate IM
4. Moderate to severe disease – maintenance of remission: a. Azathioprine, mercaptopurine b. Alternative: methotrexate IM
5. Perianal and fistulizing disease – induction of remission c. Metronidazole ± ciprofloxacin
6. Perianal and fistulizing disease – maintenance of remission d. Azathioprine, mercaptopurine e. Alternative: methotrexate IM

Conventional Therapy Options for UC
1. Mild to moderate disease – induction of remission: a. Oral mesalamine (e.g., Asacol, Lialda, Pentasa), balsalazide, olsalazine b. Rectal mesalamine (e.g., Canasa, Rowasa) c. Rectal hydrocortisone (e.g., Colocort, Cortifoam) d. Alternatives: prednisone, azathioprine, mercaptopurine, sulfasalazine
2. Mild to moderate disease – maintenance of remission: a. Oral mesalamine, balsalazide, olsalazine, rectal mesalamine

b. Alternatives: azathioprine, mercaptopurine, sulfasalazine
3. Severe disease – induction of remission: a. Prednisone, hydrocortisone IV, methylprednisolone IV b. Alternatives: cyclosporine IV, tacrolimus, sulfasalazine
4. Severe disease – maintenance of remission: a. Azathioprine, mercaptopurine b. Alternative: sulfasalazine
5. Pouchitis: a. Metronidazole, ciprofloxacin b. Alternative: rectal mesalamine

Appendix 3 - List of Non-Topical PA Medications for Atopic Dermatitis

Generic Name	Brand Name
abrocitinib	Cibinqo
dupilumab	Dupixent
lebrikizumab-lbkz	Ebglyss
tralokinumab-ldrm	Adbry
upadactinib	Rinvoq