

# RINVOQ/ RINVOQ LQ (upadacitinib)

### **Pre - PA Allowance**

None

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### **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
  - 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)
  - d. Blue Focus **only:** Patient **MUST** have tried **ONE** of the preferred products (Enbrel or Humira) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
- 2. Active psoriatic arthritis (PsA)
  - a. 2 years of age or older
  - 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)
  - d. Blue Focus **only:** Patient **MUST** have tried **ONE** of the preferred products (Enbrel or Humira) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
- 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)



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- d. Blue Focus **only:** Patient **MUST** have tried the preferred product (Humira) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
- 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)
  - d. Blue Focus **only:** Patient **MUST** have tried the preferred product (Humira) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
- 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)
  - d. Blue Focus only: Patient MUST have tried ONE of the preferred products (Enbrel or Humira) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
- 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
  - 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)
  - d. Blue Focus **only:** Patient **MUST** have tried **ONE** of the preferred products (Enbrel or Humira) unless the patient has a valid medical



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exception (e.g., inadequate treatment response, intolerance, contraindication)

- 8. Giant cell arteritis
  - a. 18 years of age or older
  - Inadequate treatment response to at least a 3 month trial of corticosteroids
  - Used in combination with a tapering course of corticosteroids or as monotherapy following discontinuation of corticosteroids

#### AND ALL of the following:

- 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
- 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:



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- 1. Inadequate treatment response, intolerance, or contraindication to at least **TWO** systemic atopic dermatitis medications, including biologics (e.g., oral corticosteroids, hydroxyzine, Adbry, Cibingo, Dupixent, etc.)
- 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
- 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)
- 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)
- Used in combination with potent immunosuppressants azathioprine or cyclosporine
- 10. Given concurrently with live vaccines

# **Prior - Approval Limits Quantity**

Indication	Strength/Dosage Form	Quantity
Ankylosing spondylitis (AS)	15 mg tablet	90 tablets per 90 days <b>OR</b>
Atopic dermatitis	15 mg tablet	90 tablets per 90 days <b>OR</b>
Atopic definations	30 mg tablet	90 tablets per 90 days OK
	15 mg tablet	
Crohn's Disease (CD)	30 mg tablet	90 tablets per 90 days <b>OR</b>
	45 mg tablet	
Giant cell arteritis	15 mg tablet	90 tablets per 90 days OR



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Non-radiographic axial spondyloarthritis (nr-axSpA)	15 mg tablet	90 tablets per 90 days <b>OR</b>
Delverticular invenile	15 mg tablet	90 tablets per 90 days OR
Polyarticular juvenile idiopathic arthritis (pJIA)	1 mg/mL oral solution	6 bottles per 90 days <b>OR</b>
Psoriatic arthritis (PsA)	15 mg tablet	90 tablets per 90 days <b>OR</b>
	1 mg/mL oral solution	6 bottles per 90 days <b>OR</b>
Rheumatoid arthritis (RA)	15 mg tablet	90 tablets per 90 days <b>OR</b>
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 Requirements

### **Diagnoses**

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

- 1. Rheumatoid arthritis (RA)
  - a. 18 years of age or older
  - Blue Focus only: Patient MUST have tried ONE of the preferred products (Enbrel or Humira) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
- 2. Psoriatic arthritis (PsA)
  - a. 2 years of age or older
  - Blue Focus only: Patient MUST have tried ONE of the preferred products (Enbrel or Humira) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
- 3. Ulcerative colitis (UC)
  - a. 18 years of age or older
  - b. Blue Focus **only:** Patient **MUST** have tried the preferred product (Humira) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)



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- 4. Crohn's disease (CD)
  - a. 18 years of age or older
  - b. Blue Focus **only:** Patient **MUST** have tried the preferred product (Humira) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
- 5. Ankylosing spondylitis (AS)
  - a. 18 years of age or older
  - Blue Focus only: Patient MUST have tried ONE of the preferred products (Enbrel or Humira) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
- 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
  - **b.** Blue Focus **only:** Patient **MUST** have tried **ONE** of the preferred products (Enbrel or Humira) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
- 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

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### **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 Rinvog 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)
- Used in combination with potent immunosuppressants azathioprine or cyclosporine
- 5. Development of thrombotic events (including DVTs or PEs)
- 6. Given concurrently with live vaccines

## Prior - Approval Renewal Limits

### Quantity

Indication	Strength/Dosage Form	Quantity
Ankylosing spondylitis (AS)	15 mg tablet	90 tablets per 90 days <b>OR</b>
Atopic dermatitis	15 mg tablet	90 tablets per 90 days <b>OR</b>
	30 mg tablet	, , , , , , , , , , , , , , , , , , , ,
Crohn's Disease (CD)	15 mg tablet	90 tablets per 90 days <b>OR</b>
Cremine Bleedee (CB)	30 mg tablet	oo tabloto por oo dayo <b>o</b> rt
Giant cell arteritis	15 mg tablet	90 tablets per 90 days <b>OR</b>
Non-radiographic axial		
spondyloarthritis (nr-	15 mg tablet	90 tablets per 90 days <b>OR</b>
axSpA)		
Polyarticular juvenile	15 mg tablet	90 tablets per 90 days <b>OR</b>
idiopathic arthritis (pJIA)	1 mg/mL oral	6 bottles per 90 days <b>OR</b>



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	solution	
	15 mg tablet	90 tablets per 90 days <b>OR</b>
Psoriatic arthritis (PsA)	1 mg/mL oral solution	6 bottles per 90 days <b>OR</b>
Rheumatoid arthritis (RA)	15 mg tablet	90 tablets per 90 days <b>OR</b>
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

**Appendix 1 - List of DMARDs** 

Conventional disease-modifying antirheumatic drugs (DMARDs)

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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
brodalumab	Siliq
certolizumab	Cimzia
etanercept	Enbrel
golimumab	Simponi/Simponi Aria
guselkumab	Tremfya
infliximab	Remicade/Avsola/Inflectra/Renflexis
ixekizumab	Taltz
risankizumab-rzaa	Skyrizi
rituximab	Rituxan/Riabni/Ruxience/Truxima
sarilumab	Kevzara
secukinumab	Cosentyx
spesolimab-sbzo	Spevigo



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tildrakizumab-asmn	Ilumya
tocilizumab	Actemra
ustekinumab	Stelara
vedolizumab	Entyvio

Targeted synthetic disease-modifying antirheumatic drugs (DMARDs)

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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:



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- 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
tralokinumab-ldrm	Adbry
upadactinib	Rinvoq