

Rinvoq (upadacitinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Rinvoq (upadacitinib)	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Rinvoq (upadacitinib) may be approved for the following:

I. Rheumatoid Arthritis (RA) when each of the following criteria are met:

A. Individual is 18 years of age or older with moderate to severe RA;

AND

B. Documentation is provided that individual has had an inadequate response to methotrexate titrated to maximally tolerated dose (ACR 2021);

OR

C. Documentation is provided that if methotrexate is not tolerated, individual has had an inadequate response to or is intolerant of other conventional therapy (sulfasalazine, leflunomide, or hydroxychloroquine); **OR**

D. Documentation is provided that individual has a contraindication to methotrexate, sulfasalazine, leflunomide, and hydroxychloroquine;

AND

E. Individual has had a trial and inadequate response or intolerance to one or more tumor necrosis factor (TNF) antagonist agents;

OR

II. Psoriatic Arthritis (PsA) when each of the following criteria are met:

A. Individual is 18 years of age or older with moderate to severe PsA; **AND**

B. Individual has had an inadequate response to or is intolerant of conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine, cyclosporine, or leflunomide)]; **OR**

C. Individual has a contraindication to methotrexate, sulfasalazine, cyclosporine, and leflunomide;

AND

D. Individual has had a trial and inadequate response or intolerance to one or more tumor necrosis factor (TNF) antagonist agents;

OR

III. Atopic Dermatitis when each of the following criteria are met:

A. Individual is age 12 years of age or older with refractory, moderate to severe atopic dermatitis;

AND

- B. Documentation is provided that a non-corticosteroid systemic immunosuppressants (such as cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil) has failed to achieve and maintain remission of low or mild disease activity state or are contraindicated;

OR

- C. Documentation is provided that a biologic therapy (such as dupilumab or tralokinumab) has failed to achieve and maintain remission of low or mild disease activity state or are contraindicated;

OR

- IV. Ulcerative Colitis (UC) when each of the following criteria are met:

- A. Individual is 18 years of age or older with moderate to severe UC; **AND**
B. Individual has had an inadequate response to or is intolerant of conventional therapy (such as 5-Aminosalicylic acid products, systemic corticosteroids, or immunosuppressants [such as thiopurines]); **OR**
C. Individual has a contraindication to 5-ASA products or systemic corticosteroids or thiopurines;

AND

- D. Individual has had a trial and inadequate response or intolerance to one or more tumor necrosis factor (TNF) antagonist agents;

OR

- V. Crohn's Disease (CD) when each of the following criteria are met:

- A. Individual is 18 years of age or older with moderate to severe CD; **AND**
B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as systemic corticosteroids or immunosuppressants [such as thiopurines or methotrexate]); **AND**
C. Individual has had a trial and inadequate response or intolerance to one or more tumor necrosis factor (TNF) antagonist agents;

OR

- VI. Ankylosing spondylitis (AS) when each of the following criteria are met:

- A. Individual is 18 years of age or older with moderate to severe AS; **AND**
B. Individual has had an inadequate response to or is intolerant of conventional therapy [such as NSAIDs or nonbiologic DMARDs (such as sulfasalazine)]; **OR**
C. Individual has a contraindication to NSAIDs or sulfasalazine;

AND

- D. Individual has had a trial and inadequate response or intolerance to one or more tumor necrosis factor (TNF) antagonist agents;

OR

- VII. Non-radiographic axial spondyloarthritis (nr-axSpA) when each of the following criteria are met:

- A. Individual is 18 years of age or older with moderate to severe nr-axSpA; **AND**
B. Individual has had an inadequate response to or is intolerant of conventional therapy [such as NSAIDs or nonbiologic DMARDs (such as sulfasalazine)] (ACR 2019); **OR**

C. Individual has a contraindication to NSAIDs or sulfasalazine;

AND

D. Individual has had a trial and inadequate response or intolerance to tumor necrosis factor (TNF) antagonist therapy.

Continuation requests for Rinvoq (upadacitinib) may be approved if the following criterion is met:

- I. Individual has been receiving and is maintained on a stable dose of Rinvoq. Medication samples/coupons/discount cards are excluded from consideration as a trial.; **AND**
- II. There is clinically significant improvement or stabilization in clinical signs and symptoms of disease.

Requests for Rinvoq (upadacitinib) may not be approved for the following:

- I. In combination with topical or oral JAK inhibitors, ozanimod, etrasimod, apremilast, deucravacitinib, potent immunosuppressants (such as azathioprine and cyclosporine), or any of the following biologic immunomodulators: TNF antagonists, IL-23 inhibitors, IL-17 inhibitors, vedolizumab, ustekinumab, abatacept, IL-1 inhibitors, IL-6 inhibitors, rituximab dupilumab, tralokinumab or natalizumab **OR**
- II. If initiating therapy, individual has an absolute neutrophil count (ANC) less than 1000 cells/mm³, lymphocyte count less than 500 cells/mm³, or hemoglobin less than 8 g/dL; **OR**
- III. Tuberculosis or other active serious infections or a history of recurrent infection [repeat testing not required for ongoing authorization]; **OR**
- IV. If initiating therapy, individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention -recommended equivalent to evaluate for latent tuberculosis (unless switching therapy from another targeted immune modulator and no new risk factors); **OR**
- V. Individual has severe hepatic impairment (Child Pugh class C); **OR**
- VI. Individual has end stage renal disease [less than 15 mL/min/1.73 m² (KDIGO 2012)]; **OR**
- VII. Individual has had a myocardial infarction or stroke, while on JAK inhibitor therapy; **OR**
- VIII. Individual is at an increased risk of thrombosis; **OR**
- IX. Individual is using for treatment of alopecia areata.

Note:

Rinvoq (upadacitinib) has black box warnings for serious infections, mortality, malignancy, major adverse cardiovascular events (MACE), and thrombosis. Increased risk of serious bacterial, fungal, viral, and opportunistic infections leading to hospitalization or death, including tuberculosis (TB). Interrupt treatment with Rinvoq if serious infection occurs until the infection is controlled. Test for latent TB before and during therapy; treat latent TB prior to use. Monitor all patients for active TB during treatment, even patients with initial negative, latent TB test. Higher rate of all-cause mortality, including sudden cardiovascular death with another Janus kinase (JAK) inhibitor vs. tumor necrosis factor (TNF) blockers in rheumatoid arthritis (RA) patients. Malignancies have occurred in patients treated with Rinvoq. Higher rate of lymphomas and lung cancers with another JAK inhibitor vs. TNF blockers in RA patients. Higher rate of MACE (defined as cardiovascular

death, myocardial infarction, and stroke) with another JAK inhibitor vs. TNF blockers in RA patients. Thrombosis has occurred in patients treated with Rinvoq. Increased incidence of pulmonary embolism, venous and arterial thrombosis with another JAK inhibitor vs. TNF blockers.

Key References:

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Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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