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

Rinvoq (upadacitinib) tablets

Initial requests for Rinvoq (upadacitinib) tablets 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. Individual has had an inadequate response to methotrexate titrated to maximally tolerated dose (ACR 2021);
   OR
   C. 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. 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. Polyarticular Juvenile Idiopathic Arthritis (PJIA) when each of the following criteria are met:
   A. Individual is 2 years of age or older with moderate to severe PJIA; **AND**
   B. Individual has had an inadequate response to, or is intolerant of conventional therapy [nonbiologic DMARDS (such as methotrexate)]; **OR**
   C. Individual has a contraindication to methotrexate;

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

OR

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

A. Individual is 2 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
IV. Atopic Dermatitis when each of the following criteria are met:
A. Individual is 12 years of age or older with refractory, moderate to severe atopic dermatitis;
AND
B. Documentation is provided that a non-corticosteroid systemic immunosuppressant (such as cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil) has failed to achieve and maintain remission of low or mild disease activity state or contraindications to all non-corticosteroid systemic immunosuppressants for atopic dermatitis;
OR
C. Documentation is provided that a biologic therapy for atopic dermatitis failed to achieve and maintain remission of low or mild disease activity state or contraindications to all biologics for atopic dermatitis;

OR
V. 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 a trial and inadequate response or intolerance to one or more tumor necrosis factor (TNF) antagonist agents;
OR
C. If TNF antagonists are inadvisable, individual has had a trial and inadequate response to at least one other approved systemic therapy for UC;

OR
VI. 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 a trial and inadequate response or intolerance to one or more tumor necrosis factor (TNF) antagonist agents;
OR
C. If TNF antagonists are inadvisable, individual has had a trial and inadequate response to at least one other approved systemic therapy for CD;

OR

VII. 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

VIII. 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)]; **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;

OR

IX. Giant cell arteritis (GCA) when each of the following criteria are met:
   A. Individual is 18 years of age or older with GCA;
   AND
   B. Upadacitinib is used in combination with a tapering course of corticosteroids (such as prednisone); **OR**
   C. Upadacitinib is used as a single agent following discontinuation of corticosteroids.

<u>Rinvoq LQ (upadacitinib) oral solution</u>

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

I. Polyarticular Juvenile Idiopathic Arthritis (PJIA) when each of the following criteria are met:
   A. Individual is 2 years of age or older with moderate to severe PJIA; **AND**
   B. Individual has had an inadequate response to, or is intolerant of conventional therapy [nonbiologic DMARDS (such as methotrexate)]; **OR**
   C. Individual has a contraindication to methotrexate;

   AND
   D. 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 2 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;

Continuation requests for Rinvoq (upadacitinib) tablets or Rinvoq LQ (upadacitinib) oral solution may be approved if the following criterion is met:

I. Individual has been receiving and is maintained on a stable dose of Rinvoq (upadacitinib). 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.

Rinvoq (upadacitinib) tablets or Rinvoq LQ (upadacitinib) oral solution 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, lerikizumab-lbkz, nemolizumab-ilto, tralokinumab or natalizumab **OR**
II. If initiating therapy, individual has an absolute neutrophil count (ANC) less than 1000 cells/mm^3, lymphocyte count less than 500 cells/mm^3, 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 [eGFR less than 15 mL/min/1.73 m^2]; **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.

Key References:

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2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
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4. Centers for Disease Control and Prevention (CDC). Tuberculosis (TB). Available at: https://www.cdc.gov/tb/risk-factors/?CDC_AAref_Val=https://www.cdc.gov/tb/topic/basics/risk.htm.
5. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res (Hoboken). 2021;73(7):924-939.
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8. Lichtenstein GR, Loftus EV, Afzali, A et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. The American Journal of Gastroenterology 120(6):p 1225-1264, June 2025.
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10. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2019; 80: 1029-72.
11. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheum. 2019; 71(1): 5-32.
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13. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. *Arthritis Care & Research*, 2019; 21(6): 717-34.
14. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis Rheum. 2022; 74(4):553-569.
15. Ward MM. Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/ Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Rheumatol. 2019; 71(10):1599-1613.
16. Davis DMR, Drucker AM, Alikhan A, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. J Am Acad Dermatol. 2024;90(2):e43-e56. doi:10.1016/j.jaad.2023.08.102
17. AAAAI/ACAAI JTF Atopic Dermatitis Guideline Panel; Chu DK, Schneider L, Asiniwasis RN, Boguniewicz M, et al. Atopic dermatitis (eczema) guidelines: 2023 American Academy of Allergy, Asthma and Immunology/American College of Allergy, Asthma and Immunology Joint Task Force on Practice Parameters GRADE- and Institute of Medicine-based recommendations. Ann Allergy Asthma Immunol. 2023 Dec 18:S1081-1206(23)01455-2.

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.