Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Rinvoq® (upadacitinib)**

Effective: January 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Rinvoq (upadacitinib) is a Janus kinase inhibitor indicated for:

Disease State	
Ankylosing Spondylitis	X
Atopic Dermatitis	X
Crohn's Disease	X
Giant Cell Arteritis	X
Non-radiographic Axial Spondyloarthritis	X
Polyarticular Juvenile Idiopathic Arthritis	X
Psoriatic Arthritis	X
Rheumatoid Arthritis	X
Ulcerative Colitis	X

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Rinvoq for Members when **ALL** of the following criteria are met:

Ankylosing Spondylitis

Initial Authorization Criteria

1. Documented diagnosis of active ankylosing spondylitis

AND

2. Patient is at least 18 years of age or older

AND

3. Prescribed by a rheumatologist

AND

4. Documentation of history of failure to **one (1)** prescription strength non-steroidal anti-inflammatory drug (e.g., celecoxib, diclofenac, ibuprofen, naproxen, meloxicam), unless contraindicated or clinically significant adverse effects are experienced *(Note: document drug, date and duration of trial)*

AND

5. Documentation the patient has had a trial and inadequate response or intolerance to one or more tumor necrosis factor inhibitor

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a

targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of active ankylosing spondylitis

AND

3. Patient is at least 18 years of age or older

AND

4. Prescribed by a rheumatologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Atopic Dermatitis

Initial Authorization Criteria

1. Documented diagnosis of moderate to severe atopic dermatitis

AND

2. Documentation the patient's condition meets **one (1)** of the following:
    a. Body Surface Area (BSA) of at least 10%
    b. Eczema Area and Severity Index EASI score of at least 16
    c. Investigator's Global Assessment/Physician Global Assessment (IGA/PGA) score of at least 3

AND

3. Patient is at least 12 years of age or older

AND

4. Prescribed by a dermatologist, allergist, or immunologist

AND

5. Documentation of history of failure to a minimum 30-day supply (14-day supply for topical corticosteroids) to **one (1)** of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced: medium or high potency topical corticosteroids, calcineurin inhibitor, crisaborole, ruxolitinib *(Note: document drug, date and duration of trial)*

AND

6. Documentation of history of failure to a minimum of 12-week supply to **one (1)** systemic drug product for the treatment of atopic dermatitis (e.g., Adbry, Dupixent), unless contraindicated or clinically significant adverse effects are experienced

AND

7. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been receiving the requested medication for at least six (6) months

AND

2. Documented diagnosis of moderate to severe atopic dermatitis

AND

3. Patient is at least 12 years of age or older

AND

4. Prescribed by a dermatologist, allergist, or immunologist

AND

5. Documentation the patient has experienced a beneficial clinical response, defined as improvement from baseline in at least **one (1)** of the following:
    a. Estimated body surface area affected by atopic dermatitis, erythema, induration/thickness, and/or scale of areas affected by atopic dermatitis
    b. Reduction in the use of other topical or systemic therapies

AND

6. Documentation that compared to baseline, the patient has experienced an improvement in at least one symptom of atopic dermatitis such as pruritus, xerosis, crusting, or lichenification

AND

7. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Crohn's Disease

Initial Authorization Criteria

1. Documented diagnosis of moderately to severely active Crohn's disease

AND

2. Patient is at least 18 years of age or older

AND

3. Prescribed by a gastroenterologist

AND

4. Documentation of history of failure to **one (1)** of the following, unless contraindicated or clinically significant adverse effects are experienced *(Note: document drug, date, and duration of trial):*
    a. Corticosteroid
    b. 5-aminosalycylate
    c. 6-mercaptopurine
    d. Methotrexate

AND

5. Documentation of **one (1)** of the following:
    a. The patient has had a trial and inadequate response or intolerance to one or more tumor necrosis factor (TNF) inhibitor
    b. If treatment is inadvisable (i.e., contraindicated) with a TNF inhibitor, patient has had a trial of a systemic therapy approved for the requested indication

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic dug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of moderately to severely active Crohn's disease

AND

3. Patient is at least 18 years of age or older

AND

4. Prescribed by a gastroenterologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Giant Cell Arteritis

Initial Authorization Criteria

1. Documented diagnosis of giant cell arteritis

AND

2. Patient is at least 18 years of age or older

AND

3. Prescribed by a rheumatologist or neurologist

AND

4. Documentation of history of failure to a systemic corticosteroid, unless contraindicated (*Note: document drug, date and duration of trial)*

AND

5. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the Member has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of giant cell arteritis

AND

3. Patient is at least 18 years of age or older

AND

4. Prescribed by a rheumatologist or neurologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Non-radiographic Axial Spondyloarthritis

Initial Authorization Criteria

1. Documented diagnosis of active non-radiographic axial spondyloarthritis with objective signs of inflammation

AND

2. Patient is at least 18 years of age or older

AND

3. Prescribed by rheumatologist

AND

4. Documentation of history of failure to **one (1)** prescription strength non-steroidal anti-inflammatory drug (e.g., celecoxib, diclofenac, ibuprofen, naproxen, meloxicam), unless contraindicated or clinically significant adverse effects are experienced *(Note: document drug, date and duration of trial)*

AND

5. Documentation the patient has had a trial and inadequate response or intolerance to one or more tumor necrosis factor inhibitor

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been receiving the requested medication for at least twelve months

AND

2. Documented diagnosis of active non-radiographic axial spondyloarthritis with objective signs of inflammation

AND

3. Patient is at least 18 years of age or older

AND

4. Prescribed by a rheumatologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Polyarticular Juvenile Idiopathic Arthritis

Initial Authorization Criteria

1. Documented diagnosis of active polyarticular juvenile idiopathic arthritis

AND

2. Patient is at least 2 years of age or older

AND

3. Prescribed by a rheumatologist

AND

4. Documentation of history of failure to **one (1)** traditional disease modifying antirheumatic drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine), unless contraindicated or clinically significant adverse effects are experienced *(Note: document drug, date, and duration of trial)*

AND

5. Documentation the patient has had a trial and inadequate response or intolerance to one or more tumor necrosis factor inhibitor

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of active polyarticular juvenile idiopathic arthritis

AND

3. Patient is at least 2 years of age or older

AND

4. Prescribed by a rheumatologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Psoriatic Arthritis

Initial Authorization Criteria

1. Documented diagnosis of active apsoriatic arthritis

AND

2. Documentation of **one (1)** of the following:
    a. Actively inflamed joints
    b. Dactylitis
    c. Enthesitis
    d. Axial disease
    e. Active skin and/or nail involvement

AND

3. Patient is at least 2 years of age or older

AND

4. Prescribed by a rheumatologist or dermatologist

AND

5. Documentation the patient has had a trial and inadequate response or intolerance to one or more tumor necrosis factor inhibitor

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been receiving the requested medication for at least six (6) months

AND

2. Documented diagnosis of active psoriatic arthritis

AND

3. Patient is at least 2 years of age or older

AND

4. Prescribed by a rheumatologist or dermatologist

AND

5. Submission of medical charts documenting the patient experienced a beneficial clinical response defined improvement from baseline in at least **one (1)** of the following:
    a. Body surface area affected by psoriatic arthritis
    b. Total active (swollen and tender) joint count

AND

6. Submission of medical charts documenting that compared to baseline, the patient has experienced an improvement in at least one symptom of psoriatic arthritis such as joint pain, morning stiffness, fatigue, joint or tendon sheath swelling

AND

7. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Rheumatoid Arthritis

Initial Authorization Criteria

1. Documented diagnosis of moderately to severely active rheumatoid arthritis

AND

2. Patient is at least 18 years of age or older

AND

3. Prescribed by a rheumatologist

AND

4. Documentation of history of failure to **one (1)** traditional disease modifying antirheumatic drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine), unless contraindicated or clinically significant adverse effects are experienced *(Note: document drug, date, and duration of trial)*

AND

5. Documentation the patient has had a trial and inadequate response or intolerance to one or more tumor necrosis factor inhibitor

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the Member has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of moderately to severely active rheumatoid arthritis

AND

3. Patient is at least 18 years of age or older

AND

4. Prescribed by a rheumatologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Ulcerative Colitis

Initial Authorization Criteria

1. Documented diagnosis of moderately to severely active ulcerative colitis

AND

2. Patient is at least 18 years of age or older

AND

3. Prescribed by a gastroenterologist

AND

4. Documentation of history of failure to **one (1)** of the following, unless contraindicated or clinically significant adverse effects are experienced *(Note: document drug, date, and duration of trial)*
    a. Corticosteroid
    b. *5*-aminosalycyclate
    c. 6-mercaptopurine
    d. Methotrexate

AND

5. Documentation of **one (1)** of the following:
    a. The patient has had a trial and inadequate response or intolerance to one or more tumor necrosis factor (TNF)

inhibitor

b. If treatment is inadvisable (i.e., contraindication) with a TNF inhibitor, patient has had a trial of a systemic therapy approved for the requested indication

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of moderately to severely active ulcerative colitis

AND

3. Patient is at least 18 years of age or older

AND

4. Prescribed by a gastroenterologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Limitations

1. Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response and will not be considered for prior authorization.
2. Documentation of a Member being a social drinker does not qualify as a medically acceptable contraindication or clinical inappropriateness to methotrexate therapy.
3. For ankylosing spondylitis, non-radiographic axial spondyloarthritis, Crohn's disease, giant cell arteritis, polyarticular juvenile idiopathic arthritis, rheumatoid arthritis and ulcerative colitis, authorizations will be provided in 12-month intervals. A patient who has received less than 12 months of therapy or who is restarting therapy with the requested drug is reviewed under Initial Authorization Criteria.
4. For atopic dermatitis and psoriatic arthritis, initial approval will be authorized for six (6) months. Reauthorization will be provided in 12-month intervals. A Member who has received less than six (6) months of therapy or who is restarting therapy with the requested drug is reviewed under Initial Authorization Criteria.
5. Members new the plan stable on the requested medication should be reviewed against Initial Authorization Criteria.

Codes

None

References

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5. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of Crohn's disease in adults. Am J Gastroenterol. 2018;113:481-517.
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8. Singh S, Loftus EV, Jr, Limketkai BN, et al. AGA Living Clinical Practice Guideline on Pharmacological Management of Moderate-to-Severe Ulcerative Colitis. Gastroenterology. 2024 Dec;167(7):1307-1343.

Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

- February 14, 2023: Added criteria for supplemental indication for non-radiographic axial spondyloarthritis (effective February 17, 2023).
- July 11, 2023: Added criteria for supplemental indication for Crohn's Disease (effective August 1, 2023)
- June 11, 2024: Added criteria for supplemental indication for Polyarticular Juvenile Idiopathic Arthritis. Updated age requirements for PsA based on expanded indication (eff 7/1/24).
- June 10, 2025: No changes (eff 6/10/25)
- September 9, 2025: Added coverage criteria for supplemental indication for Giant Cell Arteritis (eff 9/9/25).
- October 14, 2025: Provider requirements no longer allow with in consultation with the specialist. Added a step through TNF inhibitors for shared indications. Added coverage criteria to prevent duplicative targeted immunomodulator therapy. For psoriatic arthritis, initial approvals limited to 6 months with annual reauthorization coverage criteria added, added disease severity requirements, updated Initial Authorization Criteria prerequisite language (no change in prerequisites) and removed previous treatment with a biologic agent indicated for the requested use and Rinvoq stability language. For ankylosing spondylitis, non-radiographic axial spondyloarthritis, Crohn's disease, giant cell arteritis, polyarticular juvenile idiopathic arthritis, rheumatoid arthritis and ulcerative colitis, approvals limited to 12 months with reauthorization coverage criteria added, updated Initial Authorization Criteria prerequisite language (no change in prerequisites), and removed previous treatment with a biologic agent indicated for the requested use and Rinvoq stability language (eff 1/1/26)
- December 9, 2025: Updated prerequisite TNF inhibitor language for Crohn's disease and ulcerative colitis based on updated package labeling (eff 1/1/26).

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.