PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Rinvoq (upadacitinib)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Rinvoq was initially approved by the FDA in 2019 for rheumatoid arthritis. Since then, it has obtained approval for the treatment of moderate to severe atopic dermatitis, psoriatic arthritis, ulcerative colitis, Crohn's disease, ankylosing spondylitis and non-radiographic axial spondyloarthritis. Rinvoq is a Janus kinase (JAK) inhibitor

Rheumatoid Arthritis (RA)

For initial authorization:

1. Member is at least at least 18 years of age; AND
2. Rinvoq must be prescribed by or in consultation with a rheumatologist; AND
3. Member has a documented diagnosis of moderately to severely active RA; AND
4. Member must have a trial and failure of, or intolerance to methotrexate for at least 3 months;

initial authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a rheumatologist or a dermatologist; AND
3. Member has a documented diagnosis of active psoriatic arthritis (PsA); AND

4.

1. Chart notes demonstrate improvement of signs and symptoms such as fewer flares, less itching/erythema, improved quality of life, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Ulcerative Colitis (UC)

For initial authorization:

1. Member is 18 years of age or older with moderately to severely active UC; AND
2. Medication must be prescribed by or in consultation with a gastroenterologist; AND
3. Member has had a negative tuberculosis test within the past 12 months; AND
4. Member must have a documented history of inadequate response or intolerance to a tumor necrosis factor (TNF) blocker (e.g., Remicade, Humira, Simponi); AND
5. Member does not have any laboratory abnormalities indicating neutropenia (ANC <1000 cells/mm^3), lymphopenia (ALC <500 cells/mm^3), or anemia (Hg < 8 g/dL).
6. Dosage allowed/Quantity limit:
   a) Induction: 45 mg once daily for 8 weeks.
   b) Maintenance:

For reauthorization:
1. Chart notes have been provided showing improvement of signs and symptoms of disease (ie. improvement of back pain, function, morning stiffness, etc).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Crohn's Disease (CD)

For initial authorization:
1. Member is 18 years of age or older with moderately to severely active CD; AND
2. Medication must be prescribed by or in consultation with a gastroenterologist; AND
3. Member must have a documented history of inadequate response or intolerance to a tumor necrosis factor (TNF) blocker (e.g., Remicade or Humira); AND
4. Member does not have any laboratory abnormalities indicating neutropenia (ANC <1000 cells/mm^3), lymphopenia (ALC <500 cells/mm^3), or anemia (Hg < 8 g/dL); AND
5. Member has had or will have completed a tuberculosis test within the past 12 months.
6. Dosage allowed/Quantity limit:
   a. Induction: 45 mg once daily for 12 weeks.
   b. Maintenance: 15 mg once daily. A dosage of 30 mg once daily may be considered for patients with refractory, severe or extensive disease. (Quantity Limit: 30 tablets per 30 days).

If all the above requirements are met, the medication will be approved for 6 months.

For reauthorization:
1. Chart notes have been provided showing improvement in signs and symptoms of CD (defined as mucosal healing, fewer flare-ups of symptoms, improved quality of life, etc.).

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Rinvoq (upadacitinib) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
09/26/2019	New policy for Rinvoq created.
11/19/2020	Changed the trials to require methotrexate as one of the non-biologic DMARD trials; only one trial is needed if member has poor prognostic factors. Removed repeated TB test in reauth. Replaced the list of excluded diagnoses with the generic statement. Updated references.
12/30/2021	Transferred to new template. RA: Updated references. Changed initial approval duration to 6 months (was 12 months). Edited the terminology "non-biologic" DMARD to "conventional" DMARD. Changed from requiring 2 csDMARD to just 1. Added trial and failure of TNF blocker; now 2nd line per label change. Added criteria for new indication of PsA. Added criteria for new indication of AD.
05/24/2022	Added criteria for new indication of UC. Added criteria for new indication of AS.
02/23/2022	Updated references. Added criteria for new indication of nr-AxSpA. Added trial duration for biologics in AD. Simplified AD header to exclude moderate to severe.
06/15/2023	Added criteria for new indication of CD.

11/20/2023	Changed trials to two topicals, one topical and phototherapy or one immunomodulator and one topical; changed duration of steroid topicals to 2 weeks, added duration of 6

21. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology. 2021;160(7):2496-2508. doi:10.1053/j.gastro.2021.04.022.
22. ClinicalTrials.gov. Identifier: NCT03345823. A Maintenance and Long-Term Extension Study of the Efficacy and Safety of Upadacitinib (ABT-494) in Participants With Crohn's Disease Who Completed the Studies M14-431 or M14-433. Available at: https://clinicaltrials.gov/ct2/show/NCT03345823.

Effective date: 04/01/2024
Revised date: 11/20/2023

Appendix: Preferred Biologic Products	
Approved for Rheumatoid Arthritis	x Actemra (requires step through adalimumab) x Enbrel x Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira
Approved for Juvenile Idiopathic Arthritis	x Actemra (requires step through Humira) x Enbrel x Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira
Approved for Ankylosing Spondylitis	x Cosentyx x Enbrel x Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira x Rinvoq