CareSource Rxinnovations

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. It works by inhibiting the activity of one or more of the Janus kinase family of enzymes, thereby interfering with the JAK-STAT signaling pathway.

Rinvoq (upadacitinib) will be considered for coverage when the following criteria are met:

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;
   Note: If methotrexate is contraindicated, one of the following conventional DMARDs must be trialed instead: leflunomide, sulfasalazine, or hydroxychloroquine; AND
5. Member has documentation of an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies; AND
6. Member does not have any laboratory abnormalities indicating neutropenia (ANC <1000 cells/mm^3), lymphopenia (ALC <500 cells/mm^3), or anemia (hemoglobin < 8 g/dL); AND
7. Member has had a negative tuberculosis test within the past 12 months.
8. **Dosage allowed/Quantity limit:** 15 mg once daily. (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 demonstrate improvement of RA signs and symptoms (e.g. fewer number of painful and swollen joints, achievement of remission, slowed progression of joint damage, etc.).

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

Psoriatic Arthritis (PsA)

For **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. Member has met a 4-week trial of an NSAID taken at maximally tolerated dose AND a 3-month trial of a non-biologic DMARD agent (e.g., methotrexate, sulfasalazine, cyclosporine, etc.) unless one of the following situations is met:
   a) Non-biologic DMARD is not required for:
      i) Concomitant axial disease (i.e., involving sacroiliac joint and spine) or enthesitis; OR
   b) NSAID and non-biologic DMARD are not required for:
      i) Severe PsA (defined as having at least one of the following: erosive disease, active PsA at many sites including dactylitis or enthesitis, elevated levels of ESR or CRP, joint deformities, or major impairment in quality of life); AND
5. Member must have a documented history of inadequate response or intolerance to a tumor necrosis factor (TNF) blocker (e.g., Remicade, Humira, Enbrel); AND
6. Member has had a negative tuberculosis test within the past 12 months.
7. Member does not have any laboratory abnormalities indicating neutropenia (ANC <1000 cells/mm^3), lymphopenia (ALC <500 cells/mm^3), or anemia (hemoglobin < 8 g/dL);
8. **Dosage allowed/Quantity limit:** 15 mg once daily. (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 of signs and symptoms of disease.

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

Atopic Dermatitis (AD)

For **initial** authorization:
1. Member must be 12 years of age or older; AND
2. Medication must be prescribed by a dermatologist, allergist, or immunologist; AND
3. Member has a documented diagnosis of moderate-to-severe atopic dermatitis; AND
4. Member's atopic dermatitis involves 10% or more of the body surface area (BSA) OR involves highly visible or functional areas (e.g., neck, face, genitals, palms) and is significantly impairing quality of life; AND
5. Member has a documented trial and failure of, intolerance, or contraindication to at least one of the following:
   a) Medium to high potency topical corticosteroid for at least 4 weeks;
   b) Topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus) or Eucrisa for at least 4 weeks; AND
6. Member has documented trial and failure of, intolerance, or contraindication to one of the following:
   a) At least 8 weeks of phototherapy treatment (i.e., UV-A, UV-B, a combination of both, psoralen plus UV-A (PUVA), or UV-B1 (narrow-band UV-B));
   b) At least 12 weeks of one oral immunomodulatory agent (e.g., cyclosporine, methotrexate, azathioprine).
7. Member does not have any laboratory abnormalities indicating neutropenia (ANC <1000 cells/mm^3), lymphopenia (ALC <500 cells/mm^3), or anemia (hemoglobin < 8 g/dL);
8. **Dosage allowed/Quantity limit:** Initiate treatment with 15 mg orally once daily. If an adequate response is not achieved, the dosage may be increased to 30 mg orally once daily. (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 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: 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 UC (defined as clinical remission, decrease in rectal bleeding, decreased improved Mayo score, improved endoscopic healing, etc.).

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

Ankylosing Spondylitis (AS) or Non-radiographic Axial Spondyloarthritis (nr-AxSpA)

Note: Diagnosis of axial spondyloarthritis (axSpA) is also accepted. AxSpA consists of 2 subtypes - ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA).

For **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; AND
3. Member has a documented diagnosis of active AS, nr-axSpA or axSpA; AND
4. Member shows at least one of the following signs or symptoms of inflammation:
   a) Elevated serum C-reactive protein (CRP);
   b) Sacroiliitis on magnetic resonance imaging (MRI); AND
5. Member has tried and failed to respond to treatment with at least two NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy with each NSAID without an adequate response; AND
6. Member has tried and failed one preferred TNF inhibitor for at least 3 months.
7. Member has had or will have completed a tuberculosis test within the past 12 months; AND
8. 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).
9. **Dosage allowed/Quantity limit:** 15 mg once daily. (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 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.

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Effective date: 01/01/2024
Revised date: 06/15/2023

Appendix: Preferred Biologic Products	
Approved for Rheumatoid Arthritis	• Actemra *(requires step through adalimumab)* • Enbrel • Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira
Approved for Juvenile Idiopathic Arthritis	• Actemra *(requires step through Humira)* • Enbrel • Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira
Approved for Ankylosing Spondylitis	• Cosentyx • Enbrel • Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira • Rinvoq
Approved for Non-radiographic Axial	• Cimzia • Cosentyx
Approved for Atopic Dermatitis	• Rinvoq
Approved for Psoriatic Arthritis	• Cosentyx • Enbrel • Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira • Otezla • Skyrizi • Stelara • Tremfya
Approved for Psoriasis	• Cosentyx • Enbrel • Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira • Otezla • Skyrizi • Stelara • Tremfya
Approved for Crohn's Disease	• Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira • Stelara
Approved for Ulcerative Colitis	• Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira • Stelara • Rinvoq