CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Rinvoq (upadacitinib)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Rinvoq was initially approved by the FDA in 2019 for rheumatoid arthritis. Since then, it has also been granted approvals for the treatment of moderate to severe atopic dermatitis, psoriatic arthritis, ulcerative colitis and ankylosing spondylitis. 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. (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 has tried and failed at least two preferred biologic DMARDs for at least 3 months each, one of which must be another TNF inhibitor (same class as Humira); 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. (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.

Moderate-to-Severe 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 has documentation of a trial and failure of, intolerance, or contraindication to Dupixent or Adbry.
8. 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);
9. **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)

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 ankylosing spondylitis (AS); AND
4. Member has had a negative tuberculosis test within the past 12 months; AND
5. Member has had back pain for 3 months or more that began before the age of 50; AND
6. Current imaging results show an inflammation of one or both of the sacroiliac joints (sacroiliitis); AND
7. 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
8. Member has tried and failed at least two preferred biologic DMARDs for at least 3 months each, one of which must be a TNF inhibitor (same class as Humira).
9. **Dosage allowed/Quantity limit:** 15 mg once daily. (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. decreased morning stiffness, tenderness or inflammatory back pain, 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.

References:

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