CareSource

PHARMACY POLICY STATEMENT **Indiana Medicaid**	
DRUG NAME	Rinvoq (upadacitinib)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— 30 tablets per 30 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Rinvoq (upadacitinib) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

RHEUMATOID ARTHRITIS (RA)

For **initial** authorization:

1. Member must be 18 years of age or older with moderately to severely active RA; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by or in consultation with a rheumatologist; 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 must have a trial and failure of, or intolerance to methotrexate and **one** other non-biologic DMARD (i.e., hydroxychloroquine, sulfasalazine, and leflunomide) for 3 months per trial, either together or separately; AND
   Note: only one non-biologic DMARD is required if member has a poor prognostic factor such as high swollen joint count, presence of early joint erosions, presence of autoantibodies (RF and/or ACPA).
6. **Dosage allowed:** 15 mg (1 tablet) once daily.

If member meets all the requirements listed above, the medication will be approved for 12 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 member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Rinvoq (upadacitinib) not medically necessary for the treatment of the diseases that are not listed in this document.

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.

References:

1. Rinvoq [prescribing information]. North Chicago, IL: AbbVie Inc.; July 2020.
2. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol.* 2016;68(1):1-26.
3. Smolen JS, Landewé RBM, Bijlsma JWJ, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update. *Ann Rheum Dis*. 2020;79(6):685-699.
4. ClinicalTrials.gov. Identifier: NCT02706873. A Study to Compare ABT-494 Monotherapy to Methotrexate Monotherapy in Subjects With Rheumatoid Arthritis (RA) Who Have Not Previously Taken Methotrexate (SELECT-EARLY). Available at: https://clinicaltrials.gov/ct2/show/NCT02706873?term=NCT02706873&rank=1.
5. ClinicalTrials.gov. Identifier: NCT02706951. A Study Comparing Upadacitinib (ABT-494) Monotherapy to Methotrexate (MTX) Monotherapy in Subjects With Rheumatoid Arthritis (RA) Who Have an Inadequate Response to MTX (SELECT-MONOTHERAPY). Available at: https://clinicaltrials.gov/ct2/show/NCT02706951?term=NCT02706951&rank=1.
6. ClinicalTrials.gov. Identifier: NCT02675426. A Study Comparing Upadacitinib (ABT-494) to Placebo in Subjects With Rheumatoid Arthritis on a Stable Dose of Conventional Synthetic Disease-Modifying Antirheumatic Drugs (csDMARDs) Who Have an Inadequate Response to csDMARDs Alone (SELECT-NEXT). Available at: https://clinicaltrials.gov/ct2/show/NCT02675426?term=NCT02675426&rank=1.
7. ClinicalTrials.gov. Identifier: NCT02629159. A Study Comparing ABT-494 to Placebo and to Adalimumab in Subjects With Rheumatoid Arthritis Who Are on a Stable Dose of Methotrexate and Who Have an Inadequate Response to Methotrexate (SELECT-COMPARE). Available at: https://clinicaltrials.gov/ct2/show/NCT02629159?term=NCT02629159&rank=1.
8. ClinicalTrials.gov. Identifier: NCT02706847. A Study to Compare Upadacitinib (ABT-494) to Placebo in Subjects With Rheumatoid Arthritis on Stable Dose of Conventional Synthetic Disease-Modifying Antirheumatic Drugs (csDMARDs) Who Have an Inadequate Response or Intolerance to Biologic DMARDs (SELECT-BEYOND). Available at: https://clinicaltrials.gov/ct2/show/NCT02706847?term=NCT02706847&rank=1.

Effective date: 04/01/2021
Revised date: 11/19/2020