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 tabs 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 moderate to severe active RA; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist; AND
4. Chart notes with all of the following submitted with prior authorization request: absolute lymphocyte count is > 500 cells/mm^3, absolute neutrophil count is > 1000 cells/mm^3, and hemoglobin level is > 8 g/dL; AND
5. Member must have tried and failed treatment with at least **one** non-biologic DMARDS (i.e., methotrexate, hydroxychloroquine, sulfasalazine, azathioprine, cyclosporine and leflunomide) or must have documented contraindication to all non-biologic DMARDS. Treatment trial duration with non-biologic DMARD agent must have been at least 12 weeks.
6. **Dosage allowed:** 15 mg once daily.

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

For **reauthorization**:

1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

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 following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Alopecia
- Dry eye disease
- Crohn's disease
- Prevention of organ transplant rejection
- Plaque psoriasis
- Psoriatic arthritis
- Ulcerative colitis

DATE	ACTION/DESCRIPTION
09/26/2019	New policy for Rinvoq created.

References:

1. Rinvoq [prescribing information]. North Chicago, IL: AbbVie Inc.; August 2019.
2. American College of Rheumatology. Guidelines for the management of rheumatoid arthritis: American College of Rheumatology Ad Hoc Committee on Clinical Guidelines. Arthritis Rheuma. 1996;39(5):713-723.
3. Singh JA, Furst DE, Beharat A, et al. 2012 Update the 2008 American College of Rheumatology Recommendations for the Use of Disease-Modifying Antirheumatic Drugs and Biologic Agents in the Treatment of Rheumatoid Arthritis. Arthritis Care Res (Hoboken). 2012;64(5):625-639.
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.
9. Singh JA, Saag KG, Bridges Jr SL, Akl EA, Bannuru RR, Sullivan MC, Vaysbrot E, McNaughton C, Osani M, Shmerling RH, Curtis JR. 2015 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. Arthritis & rheumatology. 2016 Jan;68(1):1-26.

Effective date: 04/01/2020
Revised date: 09/29/2019