MEDICATION POLICY:

Janus Kinase (JAK) Inhibitors

Generic Name: N/A

Therapeutic Class or Brand Name: JAK Inhibitors

Applicable Drugs (if Therapeutic Class): Baricitinib (Olumiant®), Cibinqo (abrocitinib), Tofacitinib (Xeljanz®, XeljanzXR®), Upadacitinib (Rinvoq®)

Preferred: Rinvoq®, Xeljanz®/XeljanzXR®

Non-preferred: Olumiant®, Cibinqo

Date of Origin: 9/10/2019

Date Last Reviewed / Revised: 2/28/2022

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I - IV are met)

I. Documented diagnosis of one of the following conditions and must meet ALL criteria under each applicable diagnosis:

A. Moderate to Severely active rheumatoid arthritis and the following criteria are met:

1. Request is for Olumiant, Rinvoq, Xeljanz/XeljanzXR.
2. Documented treatment failure, intolerance, or contraindication to methotrexate.
3. Documented treatment failure, intolerance, or contraindication to a tumor necrosis factor (TNF) inhibitor.
4. Minimum age requirement: 18 years old.
5. Treatment must be prescribed by or in consultation with a rheumatologist.

B. Active Psoriatic Arthritis (PsA) and criteria 1 through 6 are met:

1. Request is for Rinvoq or Xeljanz®/XeljanzXR®.
2. Documented treatment failure, intolerance, or contraindication to Methotrexate or a second-line disease-modifying antirheumatic drug (DMARD).
3. Patient has severe PsA and severe psoriasis OR has predominantly axial disease. See Table 1 under Appendix.
4. Documented treatment failure, intolerance, or contraindication to a tumor necrosis factor (TNF) inhibitor.
5. Minimum age requirement: 18 years old.
6. Treatment must be prescribed by or in consultation with a rheumatologist or dermatologist.

C. Moderately to severe active Ulcerative Colitis and the following criteria are met:

1. Request is for Xeljanz/XeljanzXR
2. Patient meets at least one of the treatment criteria a through c:
    a) Documented clinically significant treatment failure or contraindication with an appropriate course of corticosteroids (e.g., oral prednisone 40 – 60 mg daily, oral budesonide 9 mg daily, or budesonide rectally with a course duration of at least 7 days.
    b) Documentation the patient is unable to taper an appropriate course of corticosteroids without disease worsening.
    c) Documentation patient is stabilized for at least 8 weeks on conventional therapy (e.g., azathioprine, balsalazide, cyclosporin, mercaptopurine, mesalamine, and sulfasalazine) and is experiencing active disease fares.
3. Documented treatment failure, intolerance, or contraindication to a tumor necrosis factor (TNF) inhibitor.
4. Minimum age requirement: 18 years old.
5. Treatment must be prescribed by or in consultation with a gastroenterologist.

D. Polyarticular Course Juvenile Idiopathic Arthritis and the following criteria are met:
1. Request is for Xeljanz® Oral Solution
2. Treatment must be prescribed by or in consultation with a rheumatologist.
3. Documented treatment failure, intolerance, or contraindication to a tumor necrosis factor (TNF) inhibitor.
4. Minimum age requirement: 2 years old

E. Moderate-to-severe atopic dermatitis and the following criteria 1 through 6 are met:
1. Request is for Rinvoq or Cibinqo.
2. Documented trial and failure of, intolerance, or contraindication to two high to very high potency topical corticosteroids (e.g., betamethasone dipropionate augmented cream or ointment 0.05%, triamcinolone acetonide cream or ointment 0.5%, etc.).
3. Documented trial and failure of, intolerance, or contraindication to one topical calcineurin inhibitor (e.g., tacrolimus, etc.).
4. Documented trial and failure of, intolerance, or contraindication to one systemic immunosuppressive drug (e.g., cyclosporine, azathioprine, and methotrexate).
5. Documentation that the patient has Body Surface Area (BSA) involvement of at least 10% OR that the atopic dermatitis is impairing the patient's activities of daily living (ADLs).
6. Minimum age requirement
    a) Cibinqo: 18 years of age and older
    b) Rinvoq: 12 years of age and older

7. Treatment must be prescribed by or in consultation with a dermatologist, allergist, or immunologist.

II. Negative TB skin test within the previous 12 months or history of treatment of latent TB infection.

III. Absence of active serious infection.

IV. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

EXCLUSION CRITERIA

- Absolute lymphocyte count < 500 cells/mm^3, absolute neutrophil count (ANC) <1000 cells/mm^3 or hemoglobin < 9 g/dL- Xeljanz®/XeljanzXR®.
- Absolute lymphocyte count < 500 cells/mm^3, absolute neutrophil count (ANC) <1000 cells/mm^3 or hemoglobin < 8 g/dL- Rinvoq™, Olumiant®.
- Co-administration with biologic DMARDs, other JAK inhibitors, and potent immunosuppressants such as azathioprine, cyclosporine, and tacrolimus. Examples of biologic DMARDs include the following:
    - Actemra® (tocilizumab)
    - Adbry™ (tralokinumab)
    - Cosentyx® (secukinumab)
    - Dupixent® (dupilumab)
    - Entyvio® (vedolizumab)
    - Kevzara® (sarilumab)
    - Kineret® (anakinra)
    - Orencia® (abatacept)
    - Rituxan® (rituximab)
    - Siliq® (brodalumab)
    - Stelara® (ustekinumab)
    - Taltz® (Ixekizumab))
    - TNF inhibitors [Cimzia® (certolizumab pegol), Enbrel® (etanercept), Simponi®/Simponi® Aria® (golimumab), Inflectra® (infliximab-dyyb), Remicade® (infliximab), Renflexis® (infliximab-abda)]
    - Tremfya® (guselkumab)
    - Tysabri® (natalizumab)

- Skyrizi® (Risankizumab)

- Co-administration with strong CYP3A4 inducers such as rifampin- Xeljanz®, Rinvoq®.
- Co-administration with strong Organic Anion Transport 3 (OAT3) inhibitors such as probenecid- Olumiant.

OTHER CRITERIA

- Click or tap here to enter text.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Cibinqo Quantities of up to 30 tablets per 30 days.
- Olumiant®: Quantities of up to 30 tablets per 30 days.
- Rinvoq®: Quantities of up to 30 tablets per 30 days.
- Xeljanz®: Quantities of up to 60 tablets per 30 days.
- Xeljanz® XR: Quantities of up to 30 tablets per 30 days.
- Xeljanz® Solution: Quantities of up to 300 ml per 30 days

APPROVAL LENGTH

- **Authorization:** 4 months.

  Re-Authorization: 1 year, with an updated letter of medical necessity or progress notes showing improvement or maintenance with medication.

APPENDIX

- Table 1 - Examples of severe psoriatic arthritis and severe psoriasis:

Severe Psoriatic Arthritis	Severe Psoriasis
• Erosive disease • Elevated markers of inflammation (ESR, CRP) attributable to PsA • Long-term damage that interferes with function (i.e., joint deformities) • Highly active disease that causes a major impairment in quality of life • Active PsA at many sites including dactylitis, enthesitis • Function-limiting PsA at a few sites • Rapidly progressive disease	• PASI of 12 or more • BSA of 5-10% or more • Significant involvement in specific areas • (e.g., face, hands or feet, nails, intertriginous areas, scalp) where the burden of the disease causes significant disability • Impairment of physical or mental functioning can warrant a designation of moderate-to-severe disease despite the lower amount of surface area of skin involved

REFERENCES

1. Olumiant [Package Insert]. Indianpolis, IN: Lilly USA. December 2021. Available at: https://uspl.lilly.com/olumiant/olumiant.html#pi. Accessed December 31, 2022.
2. Rinvoq [Package Insert]. North Chicago, IL: AbbVie. January 2022. Available at: https://www.rxabbvie.com/pdf/rinvoq_pi.pdf. Accessed December 31, 2022.
3. Xeljjanz/XR [Package Insert]. Cranbury, NJ: Sun Pharma. December 2021. Available at: https://labeling.pfizer.com/ShowLabeling.aspx?id=959#section-7. Accessed December 31, 2022.
4. Medispan®
5. UpToDate