MEDICATION POLICY:
Janus Kinase (JAK) Inhibitors

Generic Name: N/A
Therapeutic Class or Brand Name: JAK Inhibitors

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

GPI Code: 66603072007520, 66603065100330,
66603065102020, 66603010000320,
66603010000310

Preferred: Rinvoq®, Xeljanz®/XeljanzXR®
Non-preferred: Olumiant®

Date of Origin: 9/10/2019
Date Last Reviewed / Revised: 2/22/2021

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. History of treatment failure, intolerance, or contraindication to methotrexate.
   2. History of treatment failure intolerance, or contraindication to one or more tumor necrosis factor (TNF) antagonist therapies. (Criteria applied to Olumiant®)
   3. Minimum age requirement: 18 years old.
   4. Treatment must be prescribed by a rheumatologist.

B. Active Psoriatic Arthritis and the following criteria are met:
   1. Have inadequate response, treatment failure, intolerance, or contraindication to Methotrexate or other disease-modifying antirheumatic drugs (DMARDs).
   2. Patient has severe PsA and severe psoriasis or has predominantly axial disease. See Table 1 under Appendix.
   3. Minimum age requirement: 18 years old.
   4. Treatment must be prescribed by a rheumatologist or dermatologist.
   5. Request is for Xeljanz®/XeljanzXR®.

C. Moderately to severe active Ulcerative Colitis and the following criteria are met:
   1. History of treatment failure, intolerance, or contraindication to conventional therapy (i.e. 5-aminosalicylates, antibiotics, methotrexate, 6-mercaptopurine, azathioprine, corticosteroids, budesonide, etc.).
   2. History of treatment failure, intolerance or contraindication to one or more tumor necrosis factor (TNF) antagonist therapies.
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3. Minimum age requirement: 18 years old.
4. Treatment must be prescribed by a gastroenterologist.
5. Request is for Xeljanz® immediate release only.

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 a rheumatologist.
   3. Minimum age requirement: 2 years old

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/mm³, absolute neutrophil count (ANC) < 1000 cells/mm³ or hemoglobin < 9 g/dL - Xeljanz®/XeljanzXR®.

- Absolute lymphocyte count < 500 cells/mm³, absolute neutrophil count (ANC) < 1000 cells/mm³ 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)
  - Cosentyx® (secukinumab)
  - Entyvio® (vedolizumab)
  - Kevzara® (sarilumab)
  - Kineret® (anakinra)
  - Orencia® (abatacept)
  - Rituxan® (rituximab)
  - Siliq® (brodalumab)
  - Stelara® (ustekinumab)
  - Taltz® (Ixekizumab)
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- 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**

- The FDA is alerting the public that preliminary results from a safety clinical trial show an increased risk of serious heart-related problems and cancer with Xeljanz, Xeljanz XR (tofacitinib) compared with tumor necrosis factor inhibitors. The safety trial also investigated other potential risks, including blood clots in the lungs and death, but those results are not yet available. Health care providers should consider the benefits and risks when deciding whether to prescribe or continue patients on tofacitinib.

**Quantity / Days Supply Restrictions**

- 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.
- Rinvoq®: Quantities of up to 30 tablets per 30 days.
- Olumiant®: Quantities of up to 30 tablets 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:
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## Medication Policy:

### Severe Psoriatic Arthritis
- 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

### Severe Psoriasis
- 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

2. Rinvoq package insert. [https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/211675s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/211675s000lbl.pdf)
3. Olumiant package insert. [https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/207924s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/207924s000lbl.pdf)
4. Medispan®
5. UpToDate

## Disclaimer:
Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.