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, 66603010000320; 66603010000310

Preferred: Rinvoq®, Xeljanz®/XeljanzXR®

Non-preferred: Olumiant®

Date of Origin: 9/10/2019

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I - V 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 or intolerance to methotrexate.
      2. History of treatment failure or intolerance to one or more tumor necrosis factor (TNF) antagonist therapies. (Criteria applied to Olumiant®)
      3. 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. Treatment must be prescribed by a rheumatologist or dermatologist.
      3. 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 or intolerance to one or more tumor necrosis factor (TNF) antagonist therapies.
      3. Treatment must be prescribed by a gastroenterologist.
      4. Request is for Xeljanz® immediate release only.

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. Minimum age requirement: 18 years old.

V. 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)
    - Cosentyx® (secukinumab)
    - 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

- N/A

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

APPROVAL LENGTH

- **Authorization:** 1 Year.

  Re-Authorization: An updated letter of medical necessity or progress notes showing improvement or maintenance with medication.

REFERENCES

1. Xeljanz package insert. https://labeling.pfizer.com/ShowLabeling.aspx?id=959#section-7
2. Rinvoq package insert. 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
4. Medispan®
5. UpToDate

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
9/10/2019	1. New Policy