MEDICATION POLICY

Generic Name: Tofacitinib

Therapeutic Class or Brand Name: Xeljanz®/ XR

Applicable Drugs (if Therapeutic Class)**:** N/A

Date of Origin: 2/1/13 **Date Last Reviewed/Revised:** 8/25/16

GPI Code: 6660306510

Prior Authorization Criteria (may be considered medically necessary when criteria I through VII are met):

I. Documented diagnosis of Moderately to Severely Active Rheumatoid Arthritis.

II. History of treatment failure, intolerance, or contraindication to Methotrexate.

III. Documented failure, intolerance, or contraindication to two preferred biologic products (refer to plan document for the list of preferred products).

IV. Diagnosis must be established by a rheumatologist.

V. Minimum age requirement: 18 years old.

VI. Absence of active serious infection or sepsis.

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

Exclusion Criteria:

- Coadministration of Xeljanz®/ XR with potent inducers of CYP3A4 (i.e. rifampin).
- Coadministration of Xeljanz®/ XR with biologic DMARDs, Otezla® (apremilast), or potent immunosuppressants such as azathioprine and cyclosporine. Examples of biologic DMARDs include the following:
  - Actemra® (tocilizumab)
  - Cosentyx® (secukinumab)
  - Entyvio® (vedolizumab)
  - Kineret® (anakinra)
  - Orencia® (abatacept)
  - Rituxan® (rituximab)
  - Stelara® (ustekinumab)
  - Taltz® (Ixekizumab)

- TNF inhibitors [Cimzia® (certolizumab pegol), Enbrel® (etanercept), Humira® (adalimumab), Remicade® (infliximab), Simponi®/Simponi® Aria® (golimumab)]
- Tysabri® (natalizumab)

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.

Approval Length:

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

Appendix:

N/A

References:

1. http://www.bcbsnc.com/assets/services/public/pdfs/medicalpolicy/xeljanz_um_criteria.pdf.
2. http://blue.regence.com/trgmedpol/drugs/dru289.pdf.
3. Medi-Span.
4. http://labeling.pfizer.com/ShowLabeling.aspx?id=959.

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Historical Tracking Of Changes Made To Policy	
8/25/2016	1. **Changed "Therapeutic Class or Brand Name" from** "Xeljanz®" **to** "Xeljanz®/ XR". 2. **Reordered criteria under Prior Authorization Criteria**. 3. **Changed** "III. Documented failure, intolerance, or contraindication to ALL preferred TNF inhibitors (refer to plan document for the list of preferred products)" **to** "III. Documented failure, intolerance, or contraindication to two preferred biologic products (refer to plan document for the list of preferred products)" **under Prior Authorization Criteria**. 4. **Added** "Coadministration of Xeljanz®/ XR with potent inducers of CYP3A4 (i.e. rifampin)" **under Exclusion Criteria**. 5. **Changed** "Xeljanz® should not be used in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine…" **to** "Coadministration of Xeljanz®/ XR with biologic DMARDs, Otezla® (apremilast), or potent immunosuppressants such as azathioprine and cyclosporine" **under Exclusion Criteria**. 6. **Changed** "Cosentyx™" **to** "Cosentyx®" **under Exclusion Criteria**. 7. **Added** "Taltz® (Ixekizumab)" **to list under Exclusion Criteria**. 8. **Changed** "Quantities of up to 60 tablets per 30 days" **to** "Xeljanz®: Quantities of up to 60 tablets per 30 days; Xeljanz® XR: Quantities of up to 30 tablets per 30 days" **under Quantity/Days Supply Restrictions**.
3/2/2015	1. **Added** "Cosentyx™ (secukinumab)" **to list under Exclusion Criteria.**
2/26/2015	1. **Reworded** "Documented diagnosis of Moderately to Severely Active Rheumatoid Arthritis; Diagnosis must be established by a rheumatologist" **to** "Documented diagnosis of Moderately to Severely Active Rheumatoid Arthritis and criterion A is met: A. Diagnosis must be established by a rheumatologist" **under Prior Authorization Criteria**. 2. **Changed** "Absence of active bacterial or viral infection, malignancy, or immunosuppressive condition" **to** "Absence of active serious infection or sepsis" **under Prior Authorization Criteria**. 3. **Changed** "Xeljanz® should not be used in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine. Some biologic DMARDs include TNF inhibitors (etanercept, adalimumab, infliximab, certolizumab, golimumab), anakinra, abatacept, rituximab, and tocilizumab." **to** "Xeljanz® should not be used in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine. Examples of biologic DMARDs include the following: Actemra® (tocilizumab); Entyvio® (vedolizumab); Kineret® (anakinra); Orencia® (abatacept); Rituxan® (rituximab); Stelara® (ustekinumab); TNF inhibitors [Cimzia® (certolizumab pegol), Enbrel® (etanercept), Humira® (adalimumab), Remicade® (infliximab), Simponi®/Simponi® Aria® (golimumab)]; Tysabri® (natalizumab)" **under Exclusion Criteria**. 4. **Removed** "http://www.fdhc.state.fl.us/medicaid/prescribed_drug/drug_creteria_pdf/Xeljanz_Criteria(1).pdf" **from under References** because link was no longer valid.
11/7/2013	1. **Adapted policy to new format**. 2. **Added GPI Code**. 3. **Changed** "Rheumatology consultation within the last 60 days" **to** "Diagnosis must be established by a rheumatologist 4. **Changed** "Must have trial and failure of methotrexate in combination with two separate preferred TNF inhibitors (i.e. Cimzia® and Humira®)" **to** "History of treatment failure, intolerance, or contraindication to Methotrexate" AND "Documented failure, intolerance, or contraindication to ALL preferred TNF inhibitors (refer to plan document for the list of preferred products)".

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Historical Tracking Of Changes Made To Policy	
	5. **Updated references** to include Medi-Span and Regence policy.