Overview
Tofacitinib inhibits Janus kinase (JAK) enzymes, which are intracellular enzymes involved in stimulating hematopoiesis and immune cell function through a signaling pathway. Inhibition of JAKs interrupts this pathway and proinflammatory cytokines.

FDA-Approved Indications
1. Moderately to severely active rheumatoid arthritis
2. Active psoriatic arthritis
3. Moderately to severely active ulcerative colitis (UC)

All other indications are considered experimental/investigational and are not a covered benefit.

Coverage Guidelines

Moderately to severely active rheumatoid arthritis (RA)
1. Authorization may be granted for members who are currently receiving treatment with Xeljanz or Xeljanz XR, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

OR
2. Authorization may be granted for treatment of moderately to severely active RA when one of the following criteria is met:
   a. Member has experienced an inadequate response or intolerance to ALL preferred products (Enbrel, Humira and Rinvoq).
b. Member has a contraindication to Enbrel, Humira and Rinvoq and meets one of the following:
   • Member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to 20 mg/week).
   • Member has an intolerance or contraindication to methotrexate (see Appendix A).

Active psoriatic arthritis (PsA)
1. Authorization may be granted for members who are currently receiving treatment with Xeljanz or Xeljanz XR, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.
OR
2. Authorization may be granted for treatment of active psoriatic arthritis (PsA) if any of the following criteria is met:
   a. Member has had a documented inadequate response or intolerable adverse event with ALL of the preferred products (Cosentyx, Enbrel, Humira, Otezla and Stelara).
   b. Member has a contraindication to ALL of the preferred agents and meets one of the following:
      • Patient has had an intolerance to or inadequate response (after at least 3 months of treatment) with methotrexate OR leflunomide
      • Patient has a contraindication to BOTH methotrexate and leflunomide AND has experienced an inadequate response, intolerance, or contraindication to sulfasalazine.

Moderately to severely active ulcerative colitis (UC)
1. Authorization may be granted for members who are currently receiving treatment with Xeljanz for UC, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.
OR
2. Authorization may be granted for treatment of moderately to severely active UC if any of the following criteria is met:
   a. Member has experienced an inadequate response or intolerance to Humira
   b. Member has a contraindication to Humira AND has had an inadequate response, intolerance or contraindication to at least one conventional therapy option for moderate to severe UC (see Appendix B).

Continuation of Therapy
Reauthorization of may be granted for all members (including new members) who meet all initial authorization criteria and achieve or maintain positive clinical response after at least 3 months of therapy for RA and PsA or after 4 months for UC with Xeljanz/Xeljanz XR as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Limitations
1. Approvals will be granted for 24 months, except initial authorization for moderately to severely active UC.
   a. Initial approvals for moderately to severely active UC will be granted for 4 months.
2. For all indications: Member has a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB).
a. Note: Members who have received Cimzia or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) are exempt from requirements related to TB screening in this Policy.

Appendices

Appendix A
Examples of Contraindications to Methotrexate
1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia
9. Pregnancy or planning pregnancy (male or female)
10. Renal impairment
11. Significant drug interaction

Appendix B
Examples of Conventional Therapy Options for UC
1. Mild to moderate disease – induction of remission:
   a. Oral mesalamine (e.g., Asacol, Asacol HD, Lialda, Pentasa)
   b. Rectal mesalamine (e.g., Canasa, Rowasa)
   c. Alternatives: azathioprine, mercaptopurine, sulfasalazine
2. Mild to moderate disease – maintenance of remission:
   a. Oral mesalamine, rectal mesalamine
   b. Alternatives: azathioprine, mercaptopurine, sulfasalazine
3. Severe disease – induction of remission:
   a. Sulfasalazine
4. Severe disease – maintenance of remission:
   a. Azathioprine, mercaptopurine
   b. Alternative: sulfasalazine
5. Pouchitis: rectal mesalamine

References
1. Xeljanz/Xeljanz XR (tofacitinib) [prescribing information]. New York, NY: Pfizer; July 2019


**Review History**

06/24/13 – Reviewed  
02/24/14 – Reviewed  
02/23/15 – Reviewed  
02/22/16 – Reviewed  
02/27/17 – Adopted SGM & PDS  
02/26/18 – Updated  
06/25/18 – Updated  
11/20/19 – Added Rinvoq as a trial for RA

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