I. Medication Description

Tofacitinib is a Janus kinase (JAK) inhibitor. JAKs are intracellular enzymes which transmit signals arising from cytokine or growth factor-receptor interactions on the cellular membrane to influence cellular processes of hematopoiesis and immune cell function. Within the signaling pathway, JAKs phosphorylate and activate Signal Transducers and Activators of Transcription (STATs) which modulate intracellular activity including gene expression. Tofacitinib modulates the signaling pathway at the point of JAKs, preventing the phosphorylation and activation of STATs. JAK enzymes transmit cytokine signaling through pairing of JAKs (e.g., JAK1/JAK3, JAK1/JAK2, JAK1/TyK2, JAK2/JAK2). Tofacitinib inhibited the in vitro activities of JAK1/JAK2, JAK1/JAK3, and JAK2/JAK2 combinations with IC50 of 406, 56, and 1377 nM, respectively. However, the relevance of specific JAK combinations to therapeutic effectiveness is not known.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage of Xeljanz or Xeljanz XR is provided for the following conditions when the listed criteria are met:

- Psoriatic Arthritis (active disease):
  - Member is at least 18 years of age AND
  - Medication is prescribed by a rheumatologist or dermatologist AND
  - Medication is used in combination with a non-biologic DMARD AND
  - When requesting coverage of a brand medication for which an A/B rated generic is available, coverage will be provided when there is sufficient evidence that the use of the A/B rated generic equivalent has resulted in inadequate results AND
  - Coverage will be provided when the patient has experienced intolerance or therapeutic failure with TWO plan-preferred medications (Cosentyx, Enbrel, Humira, or Stelara SC) first OR when at least ONE of the following criteria have been met:
    - The plan-preferred medications are contraindicated or will likely cause an adverse reaction by or physical or mental harm to the member.
    - The plan-preferred medications are expected to be ineffective based on the known clinical history and conditions of the member and the member’s prescription drug regimen.
The member has tried the plan-preferred medications or another prescription drug in the same pharmacologic class or with the same mechanism of action and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

The member is stable on the medication selected by their healthcare professional for the medical condition under consideration (where “stable” is defined as receiving the medication for an adequate period of time, have achieved optimal response, and continued favorable outcomes are expected UNLESS the medication was initially selected solely due to the availability of a drug sample or a coupon card and the member does not otherwise meet the definition of “stable”).

The plan-preferred medication is not in the best interest of the member because it will likely cause a significant barrier to the member’s adherence or to compliance with the member’s plan of care, will likely worsen a comorbid condition of the member, or will likely decrease the member’s ability to achieve or maintain reasonable functional ability in performing daily activities.

- Rheumatoid Arthritis (moderate to severe disease):
  - Member is at least 18 years of age AND
  - Medication is prescribed by a rheumatologist AND
  - Member has tried therapy with at least one non-biologic DMARD with either treatment failure after 12 weeks or intolerable side effects (unless DMARDs are contraindicated).

Coverage of Xeljanz is provided for the following condition when the listed criteria are met:

- Ulcerative colitis (moderate to severe disease):
  - Member is at least 18 years of age AND
  - Medication is prescribed by a gastroenterologist AND
  - One of the following:
    - The member has experienced treatment failure or intolerable side effects with an immune modulator such as azathioprine, 6MP, methotrexate (unless contraindicated) OR
    - The severity of the condition requires rapid improvement not attainable with immune modulators AND
  - When requesting coverage of a brand medication for which an A/B rated generic is available, coverage will be provided when there is sufficient evidence that the use of the A/B rated generic equivalent has resulted in inadequate results AND
  - Coverage will be provided when the patient has experienced intolerance or therapeutic failure with the plan-preferred medication (Humira) first OR when at least ONE of the following criteria have been met:
    - The plan-preferred medications are contraindicated or will likely cause an adverse reaction by or physical or mental harm to the member.
    - The plan-preferred medications are expected to be ineffective based on the known clinical history and conditions of the member and the member’s prescription drug regimen.
    - The member has tried the plan-preferred medications or another prescription drug in the same pharmacologic class or with the same mechanism of action and such
prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

- The member is stable on the medication selected by their healthcare professional for the medical condition under consideration (where “stable” is defined as receiving the medication for an adequate period of time, have achieved optimal response, and continued favorable outcomes are expected UNLESS the medication was initially selected solely due to the availability of a drug sample or a coupon card and the member does not otherwise meet the definition of “stable”).

- The plan-preferred medication is not in the best interest of the member because it will likely cause a significant barrier to the member’s adherence or to compliance with the member’s plan of care, will likely worsen a comorbid condition of the member, or will likely decrease the member’s ability to achieve or maintain reasonable functional ability in performing daily activities.

IV. Quantity Limitations

- Xeljanz:
  - 5 mg tablets: 60 tablets per 30 days
  - 10 mg tablets (for the treatment of ulcerative colitis only): 60 tablets per 30 days

- Xeljanz XR 11mg tablets: 30 tablets per 30 days

V. Coverage Duration

- For the treatment of Ulcerative Colitis: Initial coverage is available for 6 months and may be renewed in 12-month increments.

- For all other indications: Initial coverage is available for 12 months and may be renewed in 12-month increments.

VI. Coverage Renewal Criteria

Coverage may be renewed based upon the following criteria:

- Clinical response and remission of disease is maintained with continued use **AND**
- Absence of unacceptable toxicity from the drug **AND**
- For the treatment of ulcerative colitis only (supporting documentation required): adequate clinical response has been documented after 16 weeks of treatment (e.g. improvement in stool frequency, rectal bleeding, findings on endoscopy, and/or physician global assessment).

VII. Billing/Coding Information

N/A
VIII. Summary of Policy Changes

- 6/15/13: New Policy
- 7/1/13: Commercial Rx and Medicaid/Family Health Plus Rx criteria differentiated
- 6/15/14: addition of use of oral DMARDs to Section A of policy (removal from Section B)
- 7/1/15: formulary distinctions made
- 3/15/16: no policy changes
- 4/2016: policy updated to include Xeljanz XR
- 1/1/17: Xeljanz/XR is a preferred medication for the treatment of RA
- 1/1/18: policy updated to include minimum age for treatment
- 5/1/18: policy updated to include new psoriatic arthritis indication
- 11/1/18: policy updated to include new ulcerative colitis indication

IX. References


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.