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
  - Member has tried therapy with methotrexate or another DMARD with either treatment failure after 12 weeks or intolerable side effects (unless DMARDs are contraindicated) AND
  - Medication will be used in combination with a non-biologic DMARD AND
  - Medication will not be used in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine.

- 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 methotrexate or another DMARD with either treatment failure after 12 weeks or intolerable side effects (unless DMARDs are contraindicated) AND
  - Medication will not be used in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine.
• Ulcerative colitis (moderate to severe disease):
  o Member is at least 18 years of age AND
  o Medication is prescribed by a gastroenterologist AND
  o When requesting coverage of a brand medication for which a plan-preferred 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
  o Member has had an inadequate response or intolerance to medications from ONE of the
    following plan-preferred categories:
    ▪ Aminosalicylates (e.g. sulfasalazine, 5-ASA)
    ▪ Immune modulators (e.g. azathioprine, 6-MP)
    ▪ Oral or intravenous (IV) steroids (steroid refractory) AND
  o The member has tried therapy with the plan-preferred TNF inhibitor, Humira AND
  o Step therapy criteria for plan-preferred categories/medications listed above apply unless 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 AND
  o Medication will not be used in combination with biological therapies for UC or with potent
    immunosuppressants such as azathioprine and cyclosporine.

IV. Quantity Limitations

• For the treatment of Psoriatic Arthritis or Rheumatoid Arthritis:
  o Xeljanz 5 mg tablets: up to 60 tablets per 30 days
  o Xeljanz XR 11mg tablets: up to 30 tablets per 30 days
• For the treatment of Ulcerative Colitis only:
  o Xeljanz:
    ▪ 5 mg tablets: up to 60 tablets per 30 days
    ▪ 10 mg tablets: up to 60 tablets per 30 days for maximum of 16 weeks at this induction dose (see coverage duration and renewal criteria)
  o Xeljanz XR:
    ▪ 11 mg tablets: up to 30 tablets per 30 days
    ▪ 22 mg tablets: up to 30 tablets per 30 days for maximum of 16 weeks at this induction dose (see coverage duration and renewal criteria)

V. Coverage Duration

• For the treatment of Psoriatic Arthritis and Rheumatoid Arthritis:
  o Xeljanz: Initial coverage is available for 12 months and may be renewed
  o Xeljanz XR: Initial coverage is available for 12 months and may be renewed

• For treatment of Ulcerative Colitis only:
  o Induction dosing:
    ▪ Xeljanz 10 mg twice daily: Initial coverage is available for 16 weeks
    ▪ Xeljanz XR 22 mg once daily: Initial coverage is available for 16 weeks
  o Maintenance dosing:
    ▪ Xeljanz 5 mg twice daily: coverage is available for 12 months and may be renewed
    ▪ Xeljanz XR 11 mg daily: coverage is available for 12 months and may be renewed

VI. Coverage Renewal Criteria

• For the treatment of Psoriatic Arthritis and Rheumatoid Arthritis:
  o Coverage of Xeljanz or Xeljanz XR may be renewed in 12-month increments based upon the following criteria:
    ▪ Clinical response and remission of disease is maintained with continued use AND
    ▪ Absence of unacceptable toxicity from the drug.

• For the treatment of Ulcerative Colitis:
  o Xeljanz:
    ▪ 5 mg tablets: coverage may be renewed in 12-month increments upon the following criteria:
      • Clinical response and remission of disease is maintained with continued use AND
      • Absence of unacceptable toxicity from the drug
    ▪ 10 mg tablets: renewal and duration of coverage will be reviewed on a case-by-case basis according to the following:
If use of 10 mg twice daily is warranted beyond the 16-week induction period, documentation has been provided that the member will be continuing this dose for the shortest necessary duration (anticipated duration needs to be specified), with careful consideration of the benefits and risks for the individual member AND

Provider documents rationale for not transitioning to recommended maintenance dose (Xeljanz 5 mg twice daily or Xeljanz 11 mg daily) AND

Provider attests this is the lowest effective dose needed to maintain response

Xeljanz XR:
- 11 mg tablets: coverage may be renewed in 12-month increments upon the following criteria:
  - Clinical response and remission of disease is maintained with continued use AND
  - Absence of unacceptable toxicity from the drug
- 22 mg tablet: renewal and duration of coverage will be reviewed on a case-by-case basis according to the following:
  - If use of 22 mg daily is warranted beyond the 16-week induction period, documentation has been provided that the member will be continuing this dose for the shortest necessary duration (anticipated duration needs to be specified), with careful consideration of the benefits and risks for the individual member AND
  - Provider documents rationale for not transitioning to recommended maintenance dose (Xeljanz 5 mg twice daily or Xeljanz XR 11 mg daily) AND
  - Provider attests this is the lowest effective dose needed to maintain response.

VII. Billing/Coding Information

- Xeljanz is available as 5mg and 10mg tablets.
- Xeljanx XR is available as 11mg and 22mg extended-release tablets.

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
- 2/15/19: updated coverage criteria for UC; removed step therapy criteria for UC and PsA (Xeljanz now a preferred product); updated initial coverage duration for UC
- 5/15/19: added DMARD trial to coverage criteria for PsA; added explanation of DMARD therapy
• 8/15/19: changed and added STEP language to UC criteria
• 11/15/19: added Humira as a plan-preferred product for the diagnosis of UC
• 1/30/20: updated criteria, quantity limitations, available products, step, and renewal criteria in accordance with FDA black box warning and most recent prescribing information

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.