I. Medication Description

Baricitinib is an oral 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. Baricitinib modulates the signaling pathway at the point of JAKs, preventing the phosphorylation and activation of STATs.

JAK enzymes transmit cytokine signaling through their pairing (e.g., JAK1/JAK2, JAK1/JAK3, JAK1/TYK2, JAK2/JAK2, JAK2/TYK2). In cell-free isolated enzyme assays, baricitinib had greater inhibitory potency at JAK1, JAK2 and TYK2 relative to JAK3. In human leukocytes, baricitinib inhibited cytokine induced STAT phosphorylation mediated by JAK1/JAK2, JAK1/JAK3, JAK1/TYK2, or JAK2/TYK2 with comparable potencies. However, the relevance of inhibition of specific JAK enzymes to therapeutic effectiveness is not currently known.

II. Position Statement

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

III. Policy

Coverage of Olumiant is provided for the treatment of Rheumatoid Arthritis (RA) when the following criteria are met:

- Member is at least 18 years of age AND
- Medication is prescribed by a rheumatologist AND
- Member has moderate to severe active disease AND
- Medication will be used as monotherapy or in combination with methotrexate or other DMARDs AND
- Medication will not be used in combination with other Janus kinase (JAK) inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine AND
- Member has had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies for the treatment of RA 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 (Actemra SC, Enbrel, Humira, Rinvoq, or Xeljanz/XR) first OR when at least ONE of the following criteria have been met:
  o The plan-preferred medications are contraindicated or will likely cause an adverse reaction by or physical or mental harm to the member.
  o 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.
  o 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.
  o 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”).
  o 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

Coverage is available for up to 30 tablets per each 30 days.

V. Coverage Duration

Initial coverage is available for 4 months and may be renewed.

VI. Coverage Renewal Criteria

Coverage can be renewed in 12-month increments based upon the following criteria (supporting documentation such as progress notes required):
  • Stabilization of disease or absence of disease progression have been documented (e.g., less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths; improved laboratory values; reduced dosage of corticosteroids) **AND**
  • Absence of unacceptable toxicity from the drug.

VII. Billing/Coding Information

Olumiant is available as 1 mg and 2 mg immediate-release tablets.
VIII. Summary of Policy Changes

- 12/13/18: new policy
- 1/15/19: no policy changes
- 10/15/19: Rinvoq became a plan-preferred agent for the treatment of RA
- 1/30/20: updated available products

IX. References

1. Olumiant® tablets [prescribing information]. Indianapolis, IN: Lilly; October 2019.

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