Kansas City

An Independent Licensee of the Blue Cross and Blue Shield Association

Olumiant (baricitinib)

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Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for Olumiant (baricitinib) when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered

Olumiant may be considered **medically necessary** for patients with a diagnosis of Rheumatoid Arthritis (RA) who meet the following criteria:

1. **Rheumatoid Arthritis (RA).** Approve for the duration noted if the patient meets ONE of the following criteria (A or B):

   A) Initial Therapy. Approve for three months if the patient meets BOTH of the following (i and ii):
   The patient has tried TWO of Actemra SC, Enbrel, Humira, and Xeljanz/XR. Note: A trial of Actemra IV, Cimzia, an infliximab product (e.g., Inflectra, Remicade, Renflexis), Kevzara, Orencia IV or SC, or Simponi Aria or SC also counts; AND
   i. Olumiant is prescribed by or in consultation with a rheumatologist.

   B) Patients Currently Receiving Olumiant. Approve for 1 year if the patient has had a response (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), as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Olumiant.

Guidelines from the American College of Rheumatology (ACR) [2015] recommend initial therapy with a conventional synthetic DMARD in patients with low, medium, and high disease activity.[4] For early and established RA, combination conventional synthetic DMARDs, TNFis ± MTX, or a non-TNF biologic (e.g., Actemra IV/SC, Orencia IV/SC, Rituxan) ± MTX are recommended for patients with moderate or high disease activity despite treatment with a conventional synthetic DMARD. Another JAK inhibitor

(Xeljanz/Xeljanz XR [tofacitinib tablets, tofacitinib extended release tablets]) is not recommended for early RA; in established RA, this JAK inhibitor is most frequently recommended for patients with moderate or high disease activity despite use of multiple biologics.

When Policy Topic is not covered

Olumiant has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions and may be considered **investigational**. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. **Concurrent Use with a Biologic or with a Targeted Synthetic DMARD.** Olumiant has not been evaluated and should not be administered in combination with a biologic used for an inflammatory condition (see APPENDIX for examples), another JAK inhibitor, or .[1] Combination therapy is generally recommended due to a potential for a higher rate of adverse effects with combinations and lack of evidence supporting additive efficacy. There are no data evaluating combination of Olumiant with a targeted synthetic DMARD (e.g., Otezla, Xeljanz/XR); therefore, safety and efficacy of this combination is unknown.

2. **Concurrent use with Other Potent Immunosuppressants** (e.g., azathioprine, cyclosporine).[1] Coadministration with other potent immunosuppressive drugs has the risk of added immunosuppression and has not been evaluated in RA. Note: This does NOT exclude use of Olumiant with MTX; Olumiant has been evaluated with background MTX or combinations of conventional synthetic DMARDs containing MTX.

3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Considerations

Olumiant requires prior authorization through the Clinical Pharmacy Department.

This Blue Cross and Blue Shield of Kansas City policy statement was developed using available resources such as, but not limited to: Food and Drug Administration (FDA) approvals, Facts and Comparisons, National specialty guidelines, local medical policies of other health plans, Medicare (CMS), local providers.

Description of Procedure or Service

Olumiant is an inhibitor of the Janus kinases (JAK) pathways approved for the treatment of adults with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more tumor necrosis factor

inhibitors.[1] It is a targeted synthetic disease-modifying antirheumatic drugs (DMARD) that may be used either as monotherapy or in combination with MTX or other conventional synthetic DMARDs for RA. Olumiant is not recommended for use in combination with other JAK inhibitors, or in combination with biologics or potent immunosuppressants such as azathioprine or cyclosporine.

Disease Overview

Inflammatory conditions are chronic, systemic, autoimmune, inflammatory disorders of unknown origin characterized by inflammation.[2] RA causes joint swelling, stiffness, and tenderness which may lead to cartilage damage, bone erosions, and joint destruction, and is often associated with significant activity limitations and disability. Compared with patients who do not have RA, mortality is increased in patients with established RA with approximately 40% of deaths in the RA population attributed to cardiovascular causes such as ischemic heart disease or stroke.[3] RA is associated with a decreased quality of life and can contribute to reduced employment rates and increased costs of care.[2] In RA, Olumiant inhibits JAK, an intracellular enzyme that transmits signals on the cellular membrane to influence cellular processes of hematopoiesis and immune cell function.[1] JAKs phosphorylate and activate Signal Transducers and Activators of Transcription (STAT) which then modulate intracellular activity such as gene expression. Inhibition of JAK enzymes block multiple cytokines resulting in modulation of the immune response involved in RA.

Safety

Olumiant has Boxed Warnings regarding increased risk of developing serious infections which may lead to hospitalization or death.[1] Patients who develop a serious infection should interrupt treatment with Olumiant until infection is controlled. Patients should be tested for tuberculosis (TB) prior to starting therapy and monitored during treatment with Olumiant. There is also a Boxed Warning for lymphoma and other lymphoproliferative disorders which have been observed in patients taking Olumiant. Viral reactivation, including cases of herpes virus reactivation, have been reported. Oluminat also has a Boxed Warning regarding thrombosis, including deep vein thrombosis and pulmonary embolism which occurred at a higher rate in patients taking Olumiant vs. placebo.

Rationale

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Olumiant (baricitinib) while maintaining optimal therapeutic outcomes.

References

1. Oluminat® tablets [prescribing information]. Indianapolis, IN: Lilly; June 2018.
2. Smolen JS, Aletaha D, Bijlsma JW, et al; T2T Expert Committee. Treating rheumatoid arthritis to target: recommendations of an international task force. *Ann Rheum Dis*. 2010;69:631-637.
3. Singh JA, Cameron DR. Summary of AHRQ's comparative effectiveness review of drug therapy for rheumatoid arthritis (RA) in adults--an update. *J Manag Care Pharm*. 2012;18(4 Supp C):S1-18.
4. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol*. 2016;68(1):1-26.

Billing Coding/Physician Documentation Information

N/A Olumiant is a pharmacy benefit

Additional Policy Key Words

N/A

Policy Implementation/Update Information

11/2018 New policy titled Olumiant (baricitinib)

APPENDIX

Biologic or Targeted Synthetic DMARD	Mechanism of Action
Cimzia® (certolizumab pegol for SC injection)	Inhibition of TNF
Enbrel® (etanercept for SC injection)	Inhibition of TNF
Erelzi™ (etanercept-szzs for SC injection)	Inhibition of TNF
Humira® (adalimumab for SC injection)	Inhibition of TNF
Amjevita™ (adalimumab-atto for SC injection)	Inhibition of TNF
Cyltezo® (adalimumab-adbm for SC injection)	Inhibition of TNF
Simponi® (golimumab for SC injection)	Inhibition of TNF

Simponi® Aria™ (golimumab for IV infusion)	Inhibition of TNF
Remicade® (infliximab for IV infusion)	Inhibition of TNF
Inflectra™ (infliximab-dyyb for IV infusion)	Inhibition of TNF
Renflexis® (infliximab-abda for IV infusion)	Inhibition of TNF
Actemra® (tocilizumab for IV infusion)	Inhibition of IL-6
Actemra® (tocilizumab for SC injection)	Inhibition of IL-6
Kevzara® (sarilumab for SC injection)	Inhibition of IL-6
Orencia® (abatacept for IV infusion)	T-cell costimulation modulator
Orencia® (abatacept for SC injection)	T-cell costimulation modulator
Rituxan® (rituximab for IV infusion)	CD20-directed cytolytic antibody
Kineret® (anakinra for subcutaneous SC injection)	Inhibition of IL-1
Stelara® (ustekinumab for SC injection)	Inhibition of IL-12/23
Stelara® (ustekinumab for IV infusion)	Inhibition of IL-12/23
Siliq™ (brodalumab SC injection)	Inhibition of IL-17
Cosentyx™ (secukinumab for SC injection)	Inhibition of IL-17A
Taltz® (ixekizumab for SC injection)	Inhibition of IL-17A
Ilumya™ (tildrakizumab-asmn for SC injection)	Inhibition of IL-23
Tremfya® (guselkumab for SC injection)	Inhibition of IL-23
Otezla® (apremilast tablets)	Inhibition of PDE4
Olumiant® (baricitinib tablets)	Inhibition of the JAK pathways
Xeljanz®, Xeljanz XR (tofacitinib tablets, tofacitinib extended-release tablets)	Inhibition of the JAK pathways

SC – Subcutaneous; TNF – Tumor necrosis factor; IL – Interleukin; IV – Intravenous; PDE4 – Phosphodiesterase 4; JAK – Janus kinase.