Olumiant (baricitinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Olumiant (baricitinib) tablets	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Olumiant (baricitinib) may be approved for the following:

I. Rheumatoid Arthritis (RA) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe RA; **AND**
   B. Individual has had an inadequate response to methotrexate titrated to maximally tolerated dose (ACR 2021); **OR**
   C. If methotrexate is not tolerated or contraindicated, individual has had an inadequate response to, is intolerant of, or has a contraindication to other conventional therapy (sulfasalazine, leflunomide or hydroxychloroquine); **AND**
   D. Individual has had an inadequate response to one or more tumor necrosis factor (TNF) antagonist agents; **AND**
   E. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to ONE (1) preferred agent [Current preferred agent includes – Rinvoq (upadacitinib) unless the following criteria is met:
      1. Individual has been receiving and is maintained on a stable dose of Olumiant (baricitinib).

OR

II. Coronavirus Disease 2019 (COVID-19) when each of the following criteria are met:
   A. Individual is 18 years of age or older; **AND**
   B. Individual is currently hospitalized with COVID-19; **AND**
   C. Individual requires supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO);

OR

III. Alopecia Areata (AA) when each of the following criteria are met:
   A. Individual is 18-70 years of age with severe AA; **AND**
   B. Individual has at least 50% scalp hair loss as measured by the Severity of Alopecia Tool (SALT); **AND**
   C. Hair loss has persisted for at least 6 months without spontaneous improvement.

Diagnosis is covered based on benefits.

Continuation requests for Olumiant (baricitinib) may be approved if the following criterion is met:

I. There is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease.

Requests for Olumiant (baricitinib) may **not** be approved for the following:

I. Individual is using for hair loss other than alopecia areata (such as androgenic alopecia [male pattern], etc.); **OR**
II. In combination with topical or oral JAK inhibitors, ozanimod, apremilast, deucravacitinib, potent immunosuppressants (such as azathioprine and cyclosporine), or any of the following biologic immunomodulators: TNF antagonists, IL-23 inhibitors, IL-17 inhibitors, vedolizumab, ustekinumab, abatacept, IL-1 inhibitors, IL-6 inhibitors, rituximab or natalizumab); **OR**
III. If initiating therapy for a diagnosis other than COVID-19, individual has an absolute neutrophil count (ANC) less than 1000 cells/mm^3, lymphocyte count less than 500 cells/mm^3, or hemoglobin less than 8 g/dL; **OR**
IV. Tuberculosis or other active serious infections or a history of recurrent infection; **OR**
V. If initiating therapy for a diagnosis other than COVID-19, individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention - recommended equivalent to evaluate for latent tuberculosis (unless switching therapy from another targeted immune modulator and no new risk factors); **OR**
VI. Individual has severe hepatic impairment (Child Pugh class C) [does not apply to COVID-19 use]; **OR**
VII. Individual has a diagnosis of moderate [30-59 mL/min/1.73 m^2 (KDIGO 2012)] or severe [less than 30 mL/min/1.73 m^2 (KDIGO 2012)] renal impairment [does not apply to COVID-19 use]; **OR**
VIII. Individual has a had a myocardial infarction or stroke while on JAK inhibitor therapy; **OR**
IX. Individual is at an increased risk of thrombosis.

Note: Olumiant (baricitinib) has black box warnings for serious infections, malignancy, and thrombosis. The increased risk of developing serious infections can result in hospitalization or death. Most individuals that developed serious infections were taking concomitant immunosuppressants. Individuals should be closely monitored for the development of an infection during and after treatment with discontinuation of therapy if the individual develops a serious infection. Reported infections include: Active tuberculosis (pulmonary or extrapulmonary disease), invasive fungal infections (including candidiasis and pneumocystosis), and infections (bacterial, viral, or other) due to opportunistic pathogens. Individuals should be tested for latent tuberculosis prior to administration of Olumiant. Latent tuberculosis should be treated prior to initiation of therapy. The risks and benefits of treatment with Olumiant should be considered prior to initiating in individuals with chronic or recurrent infection. Lymphoma and other malignancies have occurred with therapy. The risks and benefits of treatment with Olumiant should be considered prior to initiating in individuals with a known malignancy other than a successfully treated non-melanoma skin cancer. Thrombosis, including deep venous thrombosis and pulmonary embolism, has been observed at an

increased incidence in individuals treated with Olumiant. In addition, there were cases of arterial thrombosis. Many of these adverse events were serious and some resulted in death. Olumiant should be used with caution in individuals at an increased risk for thrombosis. Individuals with symptoms of thrombosis should be promptly evaluated.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: October 14, 2022.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
4. Centers for Disease Control and Prevention (CDC). Tuberculosis (TB). Available at: https://www.cdc.gov/tb/topic/basics/risk.htm. Last updated: March 18, 2016. Accessed October 14, 2022.
5. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res (Hoboken). 2021;73(7):924-939.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.