

### Clinical Pharmacy Program Guidelines for Olumiant

Program	Prior Authorization
Medication	Olumiant® (baricitinib)
Markets in Scope	California, Hawaii, Maryland, Nevada, New Jersey, New York, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	7/2018
Pharmacy and Therapeutics Approval Date	5/2020
Effective Date	7/2020

**1. Background:**

Olumiant (baricitinib) is a Janus kinase (JAK) inhibitor indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies.

**2. Coverage Criteria:**

<p><b>A. <u>Rheumatoid Arthritis (RA)</u></b></p> <p><b>1. <u>Initial Authorization</u></b></p> <p><b>a. Olumiant</b> will be approved based on <b><u>one</u></b> of the following:</p> <p>(1) <b><u>All</u></b> of the following:</p> <p>(a) Diagnosis of moderately to severely active RA</p> <p style="text-align: center;"><b>-AND-</b></p> <p>(b) History of failure to a 3 month trial of <b><u>one</u></b> non-biologic disease modifying anti-rheumatic drug (DMARD) at maximally indicated doses within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] (document drug, date, and duration of trial)</p> <p style="text-align: center;"><b>-AND-</b></p> <p>(c) Patient is not receiving Olumiant in combination with <b><u>any</u></b> of the</p>
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following:

- (1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- (2) Potent immunosuppressant (e.g., azathioprine or cyclosporine)
- (3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]
- (4) Janus kinase inhibitor [e.g., Xeljanz/Xeljanz XR (tofacitinib)]

**-AND-**

- (d) Prescribed by or in consultation with a rheumatologist

**-OR-**

(2) **All** of the following:

- (a) Patient is currently on Olumiant therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

**-AND-**

- (b) Diagnosis moderately to severely active RA

**-AND-**

- (c) Patient is not receiving Olumiant in combination with **any** of the following:

- (1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- (2) Potent immunosuppressant (e.g., azathioprine or cyclosporine)
- (3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]
- (4) Janus kinase inhibitor [e.g., Xeljanz/Xeljanz XR (tofacitinib)]

**-AND-**

- (d) Prescribed by or in consultation with a rheumatologist

**Authorization will be issued for 12 months.**

## **2. Reauthorization**

**a. Olumiant** will be approved based on **all** of the following criteria:

- (1) Documentation of positive clinical response to Olumiant therapy

**-AND-**

(2) Patient is not receiving Olumiant in combination with **any** of the following:

- (a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- (b) Potent immunosuppressant (e.g., azathioprine or cyclosporine)
- (c) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]
- (d) Janus kinase inhibitor [e.g., Xeljanz/Xeljanz XR (tofacitinib)]

**-AND-**

(3) Prescribed by or in consultation with a rheumatologist

**Authorization will be issued for 12 months.**

**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

**4. References:**

1. Olumiant [package insert]. Indianapolis, IN: Lilly USA, LLC; May 2018.
2. Singh JA, Saag KG, Bridges SL, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. Arthritis Rheum. 2016; 68(1):1-26.

Program	Prior Authorization
<b>Change Control</b>	
Date	Change
7/2018	New Program
1/2019	Removed step through Kevzara due to PDL changes.
3/2019	Removed prescriber check. Updated references.
11/2019	Annual review. No changes to criteria.
12/2019	Revised non-biologic DMARD requirement. Separated

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	continuation of therapy requirements for current users.
1/2020	Removed biologic step therapy medications due to PDL changes.
5/2020	Added prescriber requirement. Minor update to DMARD requirement.