UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2019 P 3121-1
Program	Step Therapy
Medications	Olumiant® (baricitinib)
P&T Approval Date	3/2019
Effective Date	6/1/2019; Oxford only: N/A

1. Background:

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to try preferred products before providing coverage for Olumiant (baricitinib). Infused medications for any of the conditions referenced in this document are not part of the criteria.

Cimzia (certolizumab) is indicated for the treatment of adults with moderately to severely active rheumatoid arthritis (RA). Humira (adalimumab) is indicated for reducing signs and symptoms, including major clinical response, inhibiting the progression of structural damage, and improving physical function, in adult patients with moderately and severely active RA. Simponi (golimumab) is indicated for the treatment of adult patients with moderately to severely active RA in combination with methotrexate. Actemra (tocilizumab) is indicated for the treatment of adult patients with moderately to severely active RA who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). Xeljanz/Xeljanz XR (tofacitinib) is indicated for the treatment of adult patients with moderately to severely active RA who have had an inadequate response or intolerance to methotrexate.

Members currently on Olumiant therapy as documented in claims history will be allowed to continue on their current therapy. Members new to therapy will be required to meet the coverage criteria below.

2. Coverage Criteria[a]:

A. <u>Rheumatoid Arthritis</u>

1. Olumiant will be approved based on of the following criteria:

a. **<u>One</u>** of the following:

(1) **<u>Both</u>** of the following:

(a) History of failure, contraindication, or intolerance to **<u>two</u>** of the following preferred products (Document drug, date, and duration of trial):

i. Cimzia (certolizumab)
ii. Humira (adalimumab)
iii. Simponi (golimumab)

-AND-

(b) History of failure, contraindication, or intolerance to **both** of the following preferred products (Document drug, date, and duration of trial):

i. Actemra (tocilizumab)
ii. Xeljanz/Xeljanz XR (tofacitinib)

-OR-

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

(a) Patient is currently on Olumiant therapy

-AND-

(b) Patient has not received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance form the Eli Lilly sponsored Olumiant Savings Card program (e.g. sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Olumiant.*

*Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Eli Lilly sponsored Olumiant Savings Card program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

B. Other Diagnoses

1. Olumiant will be approved.

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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 and/or Notification may be in place.

4. References:

1. Actemra [package insert]. South San Francisco, CA: Genentech, Inc.; December 2018.
2. Cimzia [package Insert]. Smyrna, GA: UCB, Inc.; June 2018.
3. Humira [package insert]. North Chicago, IL: AbbVie Inc.; January 2019.
4. Olumiant [package insert]. Indianapolis, IN: Lilly USA, LLC; May 2018.
5. Simponi [package Insert]. Horsham, PA: Janssen Biotech Inc.; May 2018.
6. Xeljanz/Xeljanz XR [package insert]. New York, NY: Pfizer Labs; October 2018.

Program	Step Therapy - Olumiant (baricitinib)
Change Control	
3/2019	New program