UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3177-2
Program	Step Therapy
Medications	Olumiant® (baricitinib)
P&T Approval Date	2/2024, 10/2024
Effective Date	1/1/2025

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).

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 and for the treatment of adult patients with severe alopecia areata. Use of Olumiant in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended. Olumiant is also indicated for the treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO.

Adalimumab, tumor necrosis factor (TNF) blocker is indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. Cimzia® (certolizumab), Enbrel® (etanercept), and Simponi® (golimumab), all TNF blockers, are indicated for the treatment of adults with rheumatoid arthritis. Simponi is FDA approved for use with methotrexate (MTX) in these patients. Actemra® (tocilizumab), an interleukin-6 (IL-6) receptor antagonist is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). Rinvoq™ (upadacitinib) and Xeljanz®/Xeljanz® XR (tofacitinib) are JAK inhibitors indicated for the treatment of adults with moderately to severely active rheumatoid arthritis who have had an adequate response or intolerance to one or more TNF antagonist therapies. Orencia® (abatacept) is indicated for moderately to severely active rheumatoid arthritis in adults. Orencia may be used as monotherapy or concomitantly with DMARDs other than JAK inhibitors or biologic DMARDs (e.g., TNF antagonists).

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

2. Coverage Criteria[a]:

A. <u>Rheumatoid Arthritis (RA)</u>

1. **Olumiant** will be approved based on **<u>one</u>** of the following criteria:

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

(a) One of the preferred adalimumab products (i.e. Adalimumab-adaz (unbranded Hyrimoz), Amjevita for Nuvaila, Humira)
(b) Cimzia (certolizumab)
(c) Enbrel (etanercept)
(d) Rinvoq (upadacitinib)
(e) Simponi (golimumab)
(f) Xeljanz/Xeljanz XR (tofacitinib)

-OR-

b. **Both** of the following:

(1) Patient is currently on Olumiant therapy

-AND-

(2) Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Eli Lilly sponsored Olumiant Together 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 Together 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 may be in place
- Notification may be in place

4. References:

1. Olumiant [package insert]. Indianapolis, IN: Lilly USA, LLC; June 2022.
2. Humira [package insert]. North Chicago, IL: AbbVie Inc.; February 2021.
3. Cimzia [package insert]. Smyrna, GA: UCB, Inc.; September 2019.
4. Simponi [package insert]. Horsham, PA: Janssen Biotech, Inc.; September 2019.
5. Xeljanz/Xeljanz XR/Xeljanz Oral Solution [package insert]. New York, NY: Pfizer Labs; January 2022.
6. Rinvoq [package insert]. North Chicago, IL: AbbVie Inc.; April 2022.
7. Enbrel [package insert]. Thousand Oaks, CA: Immunex Corp.; June 2022.

Program	Step Therapy - Olumiant (baricitinib)
Change Control	
2/2024	New program.
10/2024	Updated RA step requirement noting Adalimumab-adaz (unbranded Hyrimoz), Amjevita for Nuvaila, and Humira as preferred adalimumab products with no change to clinical intent. Removed preferred adalimumab footnote.