

# UnitedHealthcare Pharmacy Clinical Pharmacy Programs

| Program Number    | 2023 1249-8  |
|-------------------|--|
| Program           | Prior Authorization/Notification                                 |
| Medication        | Olumiant® (baricitinib)  |
| P&T Approval Date | 7/1/2108, 7/2019, 7/2020, 7/2021, 2/2022, 8/2022, 7/2023, 9/2023 |
| Effective Date    | 12/1/2023  |

# 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 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.<sup>1</sup>

# 2. Coverage Criteria<sup>a</sup>:

# A. Rheumatoid Arthritis (RA)

# 1. Initial Authorization

- a. **Olumiant** will be approved based on <u>all</u> of the following criteria:
  - (1) Diagnosis of moderately to severely active RA

### -AND-

(2) History of failure, contraindication, or intolerance to at least <u>one</u> TNF antagonist therapy

#### -AND-

- (3) Patient is not receiving Olumiant in combination with <u>either</u> of the following:
  - (a) Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib)]
  - (b) Potent immunosuppressant (e.g., azathioprine or cyclosporine)

Authorization will be issued for 12 months.

## 2. Reauthorization

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



(1) Documentation of positive clinical response to Olumiant therapy

#### -AND-

- (2) Patient is not receiving Olumiant in combination with <u>either</u> of the following:
  - (a) Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib)]
  - (b) Potent immunosuppressant (e.g., azathioprine or cyclosporine)

### Authorization will be issued for 12 months.

### B. Alopecia Areata

### 1. Initial Authorization

- a. **Olumiant** will be approved based on **both** of the following criteria:
  - (1) Diagnosis of severe alopecia areata

### -AND-

- (2) Patient is not receiving Olumiant in combination with <u>either</u> of the following:
  - (a) Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib)]
  - (b) Potent immunosuppressant (e.g., azathioprine or cyclosporine)

# Authorization will be issued for 12 months.

### 2. Reauthorization

- a. **Olumiant** will be approved based on **both** of the following criteria:
  - (1) Documentation of positive clinical response to Olumiant therapy

# -AND-

- (2) Patient is not receiving Olumiant in combination with <u>either</u> of the following:
  - (a) Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib)]
  - (b) Potent immunosuppressant (e.g., azathioprine or cyclosporine)

### Authorization will be issued for 12 months.

<sup>&</sup>lt;sup>a</sup> 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, Step Therapy, and/or Medical Necessity may be in place.

### 4. References:

- 1. Olumiant [package insert]. Indianapolis, IN: Lilly USA, LLC; June 2022.
- 2. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. Arthritis Rheum. 2021;73(7):924-939.

| Program        | Prior Authorization/Notification – Olumiant (baricitinib)           |
|----------------|---|
| Change Control |   |
| 7/2018         | New program.  |
| 7/2019         | Annual review. No changes to the program.                           |
| 7/2020         | Annual review. Updated reauthorization issue duration.              |
| 7/2021         | Annual review. No changes to coverage criteria.                     |
| 2/2022         | Added Rinvoq as an example of JAKi. Updated references.             |
| 8/2022         | Added coverage criteria for alopecia areata. Updated background and |
|                | reference. Added state mandate footnote.                            |
| 7/2023         | Updated not receiving in combination language to targeted           |
|                | immunomodulator and updated examples.                               |
| 9/2023         | Updated examples. No change to coverage criteria.                   |