UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2200-12
Program	Prior Authorization/Medical Necessity
Medication	Olumiant® (baricitinib)
P&T Approval Date	5/2020, 5/2021, 6/2021, 12/2021, 2/2022, 8/2022, 7/2023, 9/2023, 11/2023, 2/2024, 10/2024, 4/2025
Effective Date	6/1/2025

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.[1]

2. Coverage Criteria[a]:

A. Rheumatoid Arthritis (RA)

1. **Initial Authorization**

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

(1) Diagnosis of moderately to severely active RA

-AND-

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

(a) History of failure to a 3 month trial of one non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)[b]

-OR-

(b) Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of rheumatoid arthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib)]

-AND-

(3) **One** of the following:

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

i. One of the preferred adalimumab products[c]
ii. Cimzia (certolizumab)
iii. Enbrel (etanercept)
iv. Rinvoq (upadacitinib)
v. Simponi (golimumab)
vi. Xeljanz/Xeljanz XR (tofacitinib)

-OR-

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

i. Patient is currently on Olumiant therapy as documented by claims history or submission of medical records (Document drug, date, and duration of therapy):

-AND-

ii. 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*

-AND-

(4) Patient is not receiving Olumiant in combination with **either** 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)

-AND-

(5) Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

* 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.

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 **either** 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 **all** of the following criteria:

(1) Diagnosis of severe alopecia areata

-AND-

(2) Other causes of hair loss have been ruled out (e.g., androgenetic alopecia, cicatricial alopecias, secondary syphilis, tinea capitis, triangular alopecia, and trichotillomania)

-AND-

(3) Patient has a current episode of alopecia areata with at least 50% scalp hair loss

-AND-

(4) Patient is not receiving Olumiant in combination with **either** of the following:

(a) Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib), Litfulo (ritlecitinib)]
(b) Potent immunosuppressant (e.g., azathioprine or cyclosporine)

-AND-

(5) Prescribed by or in consultation with a dermatologist

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 **either** of the following:

(a) Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib), Litfulo (ritlecitinib)]
(b) Potent immunosuppressant (e.g., azathioprine or cyclosporine)

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.
[b] For Connecticut, Kentucky and Mississippi business only a 30-day trial will be required.
[c] For a list of preferred products please reference drug coverage tools.

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; June 2022.
2. Fraenkel L, Bathon JM, England BR, et al. 2021American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. Arthritis Rheum. 2021;73(7):924-939.
3. American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Arlington, VA: American Psychiatric Publishing. 2013.
4. Messenger AG, McKillop J, Farrant P, et al. British Association of Dermatologists' guidelines for the management of alopecia areata 2012. *Br J Dermatol*. 2012;166(5):916-926.
5. King B, Ohyama M, Kwon O, et al. BRAVE-AA Investigators. Two Phase 3 Trials of Baricitinib for Alopecia Areata. N Engl J Med. 2022 May 5;386(18):1687-1699.
6. King BA, Mesinkovska NA, Craiglow B, et al. Development of the alopecia areata scale for clinical use: results of an academic-industry collaborative effort. J Am Acad Dermatol. 2022;86(2):359-364.

7. Meah N, Wall D, York K, et al. The Alopecia Areata Consensus of Experts (ACE) study: Results of an international expert opinion on treatments for alopecia areata. *J Am Acad Dermatol*. 2020;83(1):123-130.

Program	Prior Authorization/Medical Necessity- Olumiant (baricitinib)
Change Control	
5/2020	New program.
5/2021	Annual review. Removed prescriber requirement from reauthorization criteria. References updated.
6/2021	Updated coverage criteria to allow coverage for patients previously treated with a TNF inhibitor. Added clarification that submission of medical records is required documenting current therapy with Olumiant in order to bypass step if claim history not available.
12/2021	Updated conventional DMARD bypass language for rheumatoid arthritis with no change to clinical intent. Updated CT/KY footnote.
2/2022	Updated formatting to clarify intent of the bypass of conventional therapy requirement for patients previously treated with bDMARD or tsDMARD. Added bypass of TNFi requirement for patients with needle phobia. Added Rinvoq as example of JAK inhibitor. Updated references. Added footnote to support FDA labeled first line requirements.
8/2022	Added coverage criteria for alopecia areata. Updated background and references.
7/2023	Updated not receiving in combination language to targeted immunomodulator and updated examples.
9/2023	Updated examples. Added Mississippi to state mandate footnote. No change to coverage criteria.
11/2023	Removed criteria that current AA episode lasting more than 6 months. Added Litfulo as an example not to be used in combination. Removed prescriber requirement for reauthorization. Updated state mandate footnote.
2/2024	Updated criteria to require a failure, contraindication or intolerance to two preferred products for RA removing failure of TNF or needle-phobia. Added adalimumab preferred product footnote.
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.
4/2025	Removed examples for adalimumab step therapy. Added the footnote "For a list of preferred products please reference drug coverage tools."