



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Olumiant

Page: 1 of 4

Effective Date: 9/28/2023

Last Review Date: 7/25/2023

Applies to:	<input checked="" type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input type="checkbox"/> Florida Kids
	<input type="checkbox"/> New Jersey	<input type="checkbox"/> Maryland	<input type="checkbox"/> Michigan
	<input type="checkbox"/> Pennsylvania Kids	<input type="checkbox"/> Virginia	<input type="checkbox"/> Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Olumiant under the patient's prescription drug benefit.

Description:

FDA-Approved Indications

- A. Olumiant 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 tumor necrosis factor (TNF) blockers.
- B. Olumiant is indicated for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).
- C. Olumiant is indicated for the treatment of adult patients with severe alopecia areata.

Note: The criteria outlined in this policy is only applicable to coverage in the outpatient setting. Hospitalized members receiving Olumiant for the treatment of COVID-19 will be managed according to the member's inpatient benefit.

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Olumiant

Policy/Guideline:

Documentation for all indications:

The patient is unable to take THREE preferred products, where indicated, for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.

Documentation:

A. Rheumatoid arthritis (RA)

1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy (if applicable).
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

B. Alopecia areata:



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Page: 2 of 4

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1. Initial requests: Chart notes or medical record documentation supporting more than 50% scalp hair loss (e.g., Severity of Alopecia Tool [SALT] score of 50 or higher).
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response (e.g., increased scalp hair coverage, 80% total scalp hair coverage [SALT score of 20 or less]).

Prescriber Specialty:

This medication must be prescribed by or in consultation with one of the following:

- A. Rheumatoid arthritis: rheumatologist
- B. Alopecia areata: dermatologist

Criteria for Initial Approval:

A. Rheumatoid arthritis (RA)

1. Authorization of 12 months may be granted for adult members for treatment of moderately to severely active rheumatoid arthritis (RA) when the member has experienced an inadequate response or intolerance to at least one tumor necrosis factor (TNF) inhibitor.
2. Authorization of 12 months may be granted for adult members who have previously received a biologic (other than a TNF inhibitor) or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for moderately to severely active rheumatoid arthritis.

B. Alopecia areata

Authorization of 12 months may be granted for adult members for treatment of severe alopecia areata when both of the following criteria are met:

1. Member has more than 50% scalp hair loss (e.g., Severity of Alopecia Tool [SALT] score of 50 or higher).
2. Other forms of alopecia have been ruled out (e.g., androgenetic alopecia, trichotillomania, telogen effluvium, chemotherapy-induced hair loss, tinea capitis).

Continuation of Therapy:

A. Rheumatoid arthritis (RA)

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderately to severely active RA and who achieve or maintain a positive clinical response as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

B. Alopecia areata



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Olumiant

Page: 3 of 4

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Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for severe alopecia areata and who achieve or maintain a positive clinical response as evidenced by an improvement in signs and symptoms of the condition from baseline (e.g., increased scalp hair coverage, 80% total scalp hair coverage [SALT score of 20 or less]).

Other Criteria:

Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [PPD], an interferon-release assay [IGRA], or a chest x-ray)* within 6 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

* If the screening testing for TB is positive, there must be further testing to confirm there is no active disease. Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

Member cannot use the requested medication concomitantly with any other biologic drug, targeted synthetic drug, or potent immunosuppressant such as azathioprine or cyclosporine.

Approval Duration and Quantity Restrictions:

Approval:

Initial Approval: 12 months

Renewal Approval: 12 months

Quantity Level Limit: 30 tablets per 30 days

References:

1. Olumiant [package insert]. Indianapolis, IN: Lilly USA, LLC; June 2022.
2. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on November 17, 2022 from: <https://www.cdc.gov/tb/topic/basics/risk.htm>.
3. Smolen JS, Landewé R, Bijlsma J, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update. *Ann Rheum Dis.* 2020;79:685-699.
4. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthrit Care Res.* 2021;0:1-16.



AETNA BETTER HEALTH®
Coverage Policy/Guideline

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Page: 4 of 4

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5. King B, Ohyama M, Kwon O, et al. Two phase 3 trials of baricitinib for alopecia areata. *NEJM*. 2022;386(18):1687-1699.
6. King B, Ohyama M, Kwon O, et al. Two phase 3 trials of baricitinib for alopecia areata. *NEJM*. 2022;386(18)(suppl):1-77.