

Commercial PA Criteria Effective: November 7th, 2018

<u>Prior Authorization:</u> Olumiant (baricitinib)

Products Affected: Olumiant (baricitinib)

<u>Medication Description</u>: Baricitinib is a Janus kinase (JAK) inhibitor which blocks the phosphorylation and activation of Signal Transducers and Activators of Transcription (STATs) via modulation of the signaling pathway

Covered Uses:

- Moderate-to-severe active rheumatoid arthritis (RA) in adult patients for whom one or more tumor necrosis factor (TNF) inhibitor therapies have been ineffective.
- Alopecia Areata, in adults with severe disease.
- Coronavirus Disease 2019 (COVID-19), for hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO)

Exclusion Criteria:

- 1. Concurrent use with a biologic or DMARD
- 2. Concurrent use with a biologic immunomodulator
- 3. Concurrent use with a topical JAKis
- 4. Concurrent use with Other Potent Immunosuppressant
- 5. COVID-19 NON-Hospitalized Patient

Required Medical Information:

- 1. Diagnosis
- 2. Previous medications tried/failed
- 3. Current medication regimen

Age Restrictions: 18 years and older

Prescriber Restrictions:

- Rheumatoid Arthritis Prescribed by or in consultation with a rheumatologist.
- Alopecia Areata Prescribed by or in consultation with a dermatologist

Coverage Duration:

Alopecia Areata & Rheumatoid Arthritis - Initial: 6 months, Continuation: 1 year COVID 19 – 14 days

Other Criteria:

1. Rheumatoid Arthritis:

A. Patient has had at least a 3 month trial and failed previous therapy with 1 oral disease modifying antirheumatic agent (DMARD), such as methotrexate, azathioprine, auranofin, hydroxychloroquine, penicillamine, sulfasalazine, or leflunomide; **AND**

December 2023





- B. Patient has had a 3-month trial and failure or was unable to tolerate of at least **ONE** tumor necrosis factor **AND**
- C. Used as single agent or in combination with methotrexate or other non-biologic DMARD, such as leflunomide, hydroxychloroquine, sulfasalazine; **AND**
- D. Patient has had a documented failure of, or intolerance to, **TWO** of the following, as follows:

Rheumatoid Arthritis (TWO of the following)
Enbrel
Adalimumab Product
Actemra SC
Xeljanz/XR
Rinvoq

2. Alopecia Areata

- A. Patient has a current episode of alopecia areata lasting for ≥ 6 months; AND
- B. Patient has ≥ 50% scalp hair loss; **AND**
- C. Patient has tried at least one of the following for alopecia areata (i, or ii):
 - Conventional systemic therapy; OR
 NOTE: Examples of systemic therapies include corticosteroids, methotrexate, and cyclosporine.
 An exception to the requirement for a trial of one conventional systemic agent can be made if the patient has already tried Litfulo (ritlecitinib capsules).
 - ii. Topical corticosteroids;

3. COVID-19 (Coronavirus Disease 2019) - Hospitalized Patient.

For a patient who is hospitalized, forward all requests to the Medical Director. For a non-hospitalized patient, do not approve. Olumiant is indicated for COVID-19 only in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). For COVID-19, the dose is 4 mg once daily for 14 days or until hospital discharge, whichever comes first.

1. Note: This includes requests for cytokine release syndrome in a patient hospitalized with COVID-19.3,4

References:

1. Olumiant [package insert]. Indianapolis, IN: Eli Lilly and Company; August 2022

Policy Revision history

Rev#	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	11/7/2018
2	Policy Update	Added Continuation approval for 3 years	Coverage Duration	7/1/2019
3	Policy Update	Added Rinvoq as a preferred product for RA	Other Criteria	10/18/2019

December 2023



4	Policy Update	Added new FDA approved indication – Alopecia Areata	Prescriber Restrictions Other Criteria	8/23/22
5	Policy Update	Added trial and failure of one TNFi to RA indication per FDA label	Other Criteria	8/23/22
6	Policy Update	Other Criteria: Changed "Humira" to "adalimumab"	Other Criteria	05/11/2023
7	Policy Update	Exlcusion Criteria: Removed: Patients with latent tuberculosis (TB) infection, viral hepatitis or active infections (including important localized infections) prior to initiating treatment, Patients with viral hepatitis prior to initiating treatment, Concurrent administration with live vaccines, Patients with severe hepatic impairment, Patients with renal impairment, defined as an estimated glomerular filtration rate (GFR) < 60 mL/min. Addition of Concurrent use with biologix immunomodulator, JAK Inhibitot, COVID-19 NON hospitalized patient. Updated coverage duration - Alopecia Areata & Rheumatoid Arthritis - Initial: 6 months, Continuation: 1 year. COVID 19 – 14 days Removal from Alopecia Areata - Patient does not have hair loss due to androgenetic alopecia, chemotherapy-induced hair loss, or other causes of hair loss other than alopecia areata Addition of COVID 19 Criteria	Covered uses Exclusion criteria Coverage duration Other Criteria	12/20/2023