

## PRIOR AUTHORIZATION POLICY

**POLICY:** Inflammatory Conditions – Olumiant Prior Authorization Policy

- Olumiant® (baricitinib tablets – Lilly)

**REVIEW DATE:** 05/18/2022; selected revision 06/22/2022

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### OVERVIEW

Olumiant, an inhibitor of the Janus kinases (JAK) pathways, is indicated for the following indications:<sup>1</sup>

- **Alopecia Areata**, in adults with severe disease.
- **Coronavirus Disease 2019 (COVID-19)**, for adults hospitalized 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.
- **Rheumatoid Arthritis**, in adults with moderate to severe active disease who have had an inadequate response to one or more tumor necrosis factor inhibitors. Olumiant is not recommended for use in combination with other JAK inhibitors, or in combination with biologics or potent immunosuppressants such as azathioprine or cyclosporine.

### Guidelines

Olumiant is addressed in the following guidelines:

- **Alopecia Areata:** An international expert opinion on treatments for alopecia areata (2020) lists JAK inhibitors among the therapies for treatment of extensive hair loss. First-line treatments for adults include topical and/or systemic corticosteroids. Steroid-sparing therapies to mitigate the risk associated with prolonged use of corticosteroids include cyclosporine, methotrexate, and azathioprine.
- **COVID-19:** The Infectious Disease Society of America (IDSA) and the National Institutes of Health (NIH) have developed treatment guidelines for the management of COVID-19 and each address the use of Olumiant.<sup>3,4</sup> Both the IDSA and NIH guidelines recommend Olumiant for hospitalized patients with COVID-19 for a duration of 14 days or until discharge from the hospital.
- **Rheumatoid Arthritis:** Guidelines from the American College of Rheumatology (2021) recommend addition of a biologic or a targeted synthetic disease-modifying antirheumatic drug (DMARD) for a patient taking the maximum tolerated dose of methotrexate who is not at target.<sup>2</sup>

### POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Olumiant. Because of the specialized skills required for evaluation and diagnosis of patients treated with Olumiant as well as the monitoring required for adverse events and long-term efficacy, initial approval for certain indications requires Olumiant to be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

All requests for use of Olumiant in a hospitalized patient with COVID-19 will be forwarded to Medical Director. Of note, this includes requests for cytokine release syndrome associated with COVID-19.

**Automation:** None.

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## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Olumiant is recommended in those who meet one of the following criteria:

### FDA-Approved Indications

1. **Alopecia Areata.** Approve for the duration noted if the patient meets one of the following (A or B):
  - A) **Initial Therapy.** Approve for 6 months if the patient meets all of the following (i, ii, iii, iv, and v):
    - i. Patient is  $\geq$  18 years of age; AND
    - ii. Patient has a current episode of alopecia areata lasting for  $\geq$  6 months; AND
    - iii. Patient has  $\geq$  50% scalp hair loss; AND
    - iv. Patient has tried at least one of the following for alopecia areata (a or b):
      - a) Systemic therapy; OR  
Note: Examples of systemic therapies include corticosteroids, methotrexate, and cyclosporine.
      - b) Topical corticosteroids; AND
    - v. Patient does not have hair loss due to androgenetic alopecia, chemotherapy-induced hair loss, or other causes of hair loss other than alopecia areata; AND  
Note: Androgenetic alopecia includes male and female pattern hair loss. Other causes of hair loss include trichotillomania, telogen effluvium, and systemic lupus erythematosus.
    - vi. The medication is prescribed by or in consultation with a dermatologist.
  - B) **Patient is Currently Receiving Olumiant.** Approve for 1 year if the patient meets all of the following (i, ii, iii, and iv):
    - i. Patient is  $\geq$  18 years of age; AND
    - ii. Patient has been established on the requested drug for at least 6 months; AND  
Note: A patient who has received  $<$  6 months of therapy or who is restarting therapy with the requested drug is reviewed under criterion A (Initial Therapy).
    - iii. Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating Olumiant) in extent and density of scalp hair loss; AND
    - iv. According to the prescriber, the patient continues to require systemic therapy for treatment of alopecia areata.  
Note: International consensus states that systemic treatment is best discontinued once complete regrowth has been achieved and maintained for 6 months or when regrowth is sufficient to be managed topically.
2. **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 (refer to Conditions Not Recommended for Approval – COVID-19 – Non-Hospitalized Patient). Olumiant is indicated for COVID-19 only in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).<sup>1</sup> For COVID-19, the dose is 4 mg once daily for 14 days or until hospital discharge, whichever comes first.  
Note: This includes requests for cytokine release syndrome in a patient hospitalized with COVID-19.<sup>3,4</sup>
3. **Rheumatoid Arthritis.** Approve for the duration noted if the patient meets ONE of the following criteria (A or B):
  - A) **Initial Therapy.** Approve for 6 months if the patient meets all of the following (i, ii, and iii):
    - i. Patient is  $\geq$  18 years of age; AND
    - ii. Patient meets ONE of the following (a or b):
      - a) Patient has had a 3-month trial of at least ONE tumor necrosis factor inhibitor; OR

- b) Patient has tried at least one tumor necrosis factor inhibitor but was unable to tolerate a 3-month trial; AND  
Note: Refer to [Appendix](#) for examples of tumor necrosis factor inhibitors used for rheumatoid arthritis. Conventional synthetic disease-modifying antirheumatic drugs (DMARDs) such as methotrexate, leflunomide, hydroxychloroquine, and sulfasalazine do not count.
- iii. The medication is prescribed by or in consultation with a rheumatologist.
- B) Patient is Currently Receiving Olumiant. Approve for 1 year if the patient meets BOTH of the following (i and ii):
  - i. Patient has been established on the requested drug for at least 6 months; AND  
Note: A patient who has received < 6 months of therapy or who is restarting therapy with the requested drug is reviewed under criterion A (Initial Therapy).
  - ii. Patient meets at least one of the following (a or b):
    - a) Patient experienced a beneficial clinical response when assessed by at least one objective measure; OR  
Note: Examples of standardized and validated objective measures of disease activity include Clinical Disease Activity Index (CDAI), Disease Activity Score (DAS) 28 using erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP), Patient Activity Scale (PAS)-II, Rapid Assessment of Patient Index Data 3 (RAPID-3), and/or Simplified Disease Activity Index (SDAI).
    - b) Patient experienced an improvement in at least one symptom, such as decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

#### CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Olumiant is not recommended in the following situations:

1. **Concurrent Use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drug (DMARD).** Olumiant should not be administered in combination with another biologic or with a targeted synthetic DMARD used for an inflammatory condition (see [Appendix](#) for examples).<sup>1</sup> Combination therapy is generally not recommended due to a potential for a higher rate of adverse effects with combinations and lack of evidence for additive efficacy.  
Note: This does NOT exclude the use of conventional synthetic DMARDs (e.g., methotrexate, leflunomide, hydroxychloroquine, and sulfasalazine) in combination with Olumiant.
  2. **Concurrent use with Other Potent Immunosuppressants** (e.g., azathioprine, cyclosporine).<sup>1</sup> Co-administration with other potent immunosuppressive drugs has the risk of added immunosuppression and has not been evaluated in rheumatoid arthritis. Note: This does NOT exclude use of Olumiant with methotrexate; Olumiant has been evaluated with background methotrexate or combinations of conventional synthetic DMARDs containing methotrexate.
  3. **COVID-19 (Coronavirus Disease 2019) – Non-Hospitalized Patient.** Olumiant is only indicated in hospitalized adults with COVID requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).<sup>1</sup> For COVID-19, the dose is 4 mg once daily for 14 days or until hospital discharge, whichever comes first.
  4. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.
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## REFERENCES

1. Olumiant® tablets [prescribing information]. Indianapolis, IN: Lilly; June 2022.
  2. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Rheumatol*. 2021;73(7):1108-1123.
  3. COVID-19 Treatment Guidelines Panel. Coronavirus disease 2019 (COVID-19) treatment guidelines. National Institutes of Health. Available at: <https://www.covid19treatmentguidelines.nih.gov/>. Accessed on May 12, 2022.
  4. Bhimraj A, Morgan RL, Shumaker AH, et al. Infectious Disease Society of America Guidelines on the treatment and management of patients with COVID-19. May 10, 2022. Available at: <https://www.idsociety.org/COVID19guidelines>. Accessed May 12, 2022.
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**APPENDIX**

	<b>Mechanism of Action</b>	<b>Examples of Inflammatory Indications*</b>
<b>Biologics</b>		
<b>Adalimumab SC Products</b> (Humira <sup>®</sup> , biosimilars)	Inhibition of TNF	AS, CD, JIA, PsO, PsA, RA, UC
<b>Cimzia<sup>®</sup></b> (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, nr-axSpA, PsO, PsA, RA
<b>Etanercept SC Products</b> (Enbrel <sup>®</sup> , biosimilars)	Inhibition of TNF	AS, JIA, PsO, PsA
<b>Infliximab IV Products</b> (Remicade <sup>®</sup> , biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, UC
<b>Simponi<sup>®</sup>, Simponi<sup>®</sup> Aria<sup>™</sup></b> (golimumab SC injection, golimumab IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC
		IV formulation: AS, PJIA, PsA, RA
<b>Actemra<sup>®</sup></b> (tocilizumab IV infusion, tocilizumab SC injection)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA
		IV formulation: PJIA, RA, SJIA
<b>Kevzara<sup>®</sup></b> (sarilumab SC injection)	Inhibition of IL-6	RA
<b>Orencia<sup>®</sup></b> (abatacept IV infusion, abatacept SC injection)	T-cell costimulation modulator	SC formulation: JIA, PsA, RA
		IV formulation: JIA, PsA, RA
<b>Rituximab IV Products</b> (Rituxan <sup>®</sup> , biosimilars)	CD20-directed cytolytic antibody	RA
<b>Kineret<sup>®</sup></b> (anakinra SC injection)	Inhibition of IL-1	JIA <sup>^</sup> , RA
<b>Stelara<sup>®</sup></b> (ustekinumab SC injection, ustekinumab IV infusion)	Inhibition of IL-12/23	SC formulation: CD, PsO, PsA, UC
		IV formulation: CD, UC
<b>Siliq<sup>™</sup></b> (brodalumab SC injection)	Inhibition of IL-17	PsO
<b>Cosentyx<sup>®</sup></b> (secukinumab SC injection)	Inhibition of IL-17A	AS, ERA, nr-axSpA, PsO, PsA
<b>Taltz<sup>®</sup></b> (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
<b>Ilumya<sup>™</sup></b> (tildrakizumab-asnm SC injection)	Inhibition of IL-23	PsO
<b>Skyrizi<sup>®</sup></b> (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)	Inhibition of IL-23	SC formulation: CD, PsA, PsO
		IV formulation: CD
<b>Tremfya<sup>™</sup></b> (guselkumab SC injection)	Inhibition of IL-23	PsO
<b>Entyvio<sup>™</sup></b> (vedolizumab IV infusion)	Integrin receptor antagonist	CD, UC
<b>Oral Therapies/Targeted Synthetic DMARDs</b>		
<b>Otezla<sup>®</sup></b> (apremilast tablets)	Inhibition of PDE4	PsO, PsA
<b>Cibinqo<sup>™</sup></b> (abrocitinib tablets)	Inhibition of JAK pathways	AD
<b>Olumiant<sup>®</sup></b> (baricitinib tablets)	Inhibition of JAK pathways	RA
<b>Rinvoq<sup>®</sup></b> (upadacitinib extended-release tablets)	Inhibition of JAK pathways	AD, AS, RA, PsA, UC
<b>Xeljanz<sup>®</sup></b> (tofacitinib tablets)	Inhibition of JAK pathways	RA, PJIA, PsA, UC
<b>Xeljanz<sup>®</sup> XR</b> (tofacitinib extended-release tablets)	Inhibition of JAK pathways	RA, PsA, UC

\* Not an all-inclusive list of indications (e.g., oncology indications and rare inflammatory conditions are not listed). Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn’s disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous, PJIA – Polyarticular juvenile idiopathic arthritis; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; <sup>^</sup> Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis; DMARD – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis.