PRIOR AUTHORIZATION POLICY

POLICY: Inflammatory Conditions – Olumiant Prior Authorization Policy
- Olumiant® (baricitinib tablets – Lilly)

REVIEW DATE: 07/24/2024; selected revision 08/21/2024, 09/11/2024

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CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Olumiant, an inhibitor of the Janus kinases (JAK) pathways, is indicated for the following uses:[1]

- **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). 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 high- or super-high

potency topical corticosteroids 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 Diseases Society of America (IDSA) and the National Institutes of Health (NIH) have developed treatment guidelines for the management of COVID-19; both guidelines address the use of Olumiant.[3,4] 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.[2]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Olumiant. 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. 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 requests for use of Olumiant in a hospitalized patient with COVID-19 will be forwarded to the Medical Director. Of note, this includes requests for cytokine release syndrome associated with COVID-19.

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is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

1. **Alopecia Areata.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   Note: Alopecia universalis and alopecia totalis are subtypes of alopecia areata.
   A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv, and v):
      i. Patient is ≥ 18 years of age; AND
      ii. Patient has a current episode of alopecia areata lasting for ≥ 6 months; AND
      iii. Patient has ≥ 50% scalp hair loss; AND
      iv. Patient has tried at least ONE of the following for alopecia areata (a or b):
         a) Conventional systemic therapy; OR

Note: Examples of conventional 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 Leqselvi (deuruxolitinib tablets) or Litfulo (ritlecitinib capsules).

b) High- or super-high potency topical corticosteroid; AND

v. 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 ≥ 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 Covered– 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).[1] 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.[3,4]

3.Rheumatoid Arthritis. 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, and iii):

i. Patient is ≥ 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 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.

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is(are) considered experimental, investigational or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

CONDITIONS NOT COVERED

1. **Concurrent Use with a Biologic or with a Targeted Synthetic Oral Small Molecule Drug.** This medication should not be administered in combination with another biologic or with a targeted synthetic oral small molecule drug used for an inflammatory condition (see Appendix for examples). Combination therapy is generally not recommended due to a potentially higher rate of adverse events and lack of controlled clinical data supporting additive efficacy.
   Note: This does NOT exclude the use of conventional synthetic DMARDs (e.g., methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine) in combination with this medication.

2. **Concurrent Use with a Biologic Immunomodulator.** Olumiant is not recommended in combination with biologic immunomodulators.[1]
   Note: Examples include Adbry (tralokinumab-ldrm subcutaneous injection), Cinqair (reslizumab intravenous), Dupixent (dupilumab subcutaneous injection), Fasenra (benralizumab subcutaneous injection), Nucala (mepolizumab

subcutaneous injection), Tezspire (tezepelumab-ekko subcutaneous injection), and Xolair (omalizumab subcutaneous injection).

3. **Concurrent Use with Topical Janus Kinase Inhibitors (JAKis).** Olumiant should not be administered in combination with a topical JAKi [e.g. Opzelura (ruxolitinib) cream)] used for Atopic Dermatitis. Combination therapy is generally not recommended due to a potential for a higher rate of adverse effects and lack of evidence for additive efficacy.

4. **Concurrent use with Other Potent Immunosuppressants** (e.g., azathioprine, cyclosporine).[1] 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 in combinations with conventional synthetic DMARDs containing methotrexate.

5. **COVID-19 (Coronavirus Disease 2019) – Non-Hospitalized Patient.** Olumiant is only indicated in hospitalized adults with COVID-19 requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).[1] For COVID-19, the dose is 4 mg once daily for 14 days or until hospital discharge, whichever comes first.

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. Updated February 29, 2024. Available at: https://www.covid19treatmentguidelines.nih.gov/. Accessed on July 22, 2024.
4. Bhimraj A, Morgan RL, Shumaker AH, et al. Infectious Diseases Society of America Guidelines on the treatment and management of patients with COVID-19. Updated June 26, 2023. Available at: https://www.idsociety.org/COVID19guidelines. Accessed July 22, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Alopecia Areata:** Removed examples of other types of alopecia from criteria. **Conditions Not Covered** : Updated to state not recommended for concurrent use with biologic immunomodulators or topical JAKis.	06/28/2023
Selected Revision	**Alopecia Areata**: Listed alopecia universalis and alopecia totalis as subtypes of alopecia areata. Updated criteria for trial of systemic therapy to more specifically state conventional systemic therapy while allowing an exception if the patient has already tried Litfulo.	07/26/2023
Annual Revision	No criteria changes.	07/24/2024
Selected Revision	**Alopecia Areata**: Updated the exception to the requirement of a trial of one conventional systemic agent to include a previous trial of	08/21/2024

	Leqselvi. Previously, only Litfulo was listed in the exception. Additionally, for the option previous trial of a topical corticosteroid, specified trial to consist of a high- or super-high potency topical corticosteroid.	
Selected Revision	**Conditions Not Covered** **:** Concurrent use with a Biologic or with a Targeted Synthetic Oral Small Molecule Drug was changed to as listed (previously oral small molecule drug was listed as Disease-Modifying Antirheumatic Drug).	09/11/2024

APPENDIX

	Mechanism of Action	Examples of Indications*
Biologics		
Adalimumab SC Products (Humira®, biosimilars)	Inhibition of TNF	AS, CD, JIA, PsO, PsA, RA, UC
Cimzia® (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, nr-axSpA, PsO, PsA, RA
Etanercept SC Products (Enbrel®, biosimilars)	Inhibition of TNF	AS, JIA, PsO, PsA, RA
Infliximab IV Products (Remicade®, biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, UC
Zymfentra® (infliximab-dyyb SC injection)	Inhibition of TNF	CD, UC
Simponi®, Simponi Aria® (golimumab SC injection, golimumab IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC
		IV formulation: AS, PJIA, PsA, RA
Tocilizumab Products (Actemra® IV, biosimilar; Actemra SC, biosimilar)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA
		IV formulation: PJIA, RA, SJIA
Kevzara® (sarilumab SC injection)	Inhibition of IL-6	RA
Orencia® (abatacept IV infusion, abatacept SC injection)	T-cell costimulation modulator	SC formulation: JIA, PSA, RA
		IV formulation: JIA, PsA, RA
Rituximab IV Products (Rituxan®, biosimilars)	CD20-directed cytolytic antibody	RA
Kineret® (anakinra SC injection)	Inhibition of IL-1	JIA^, RA
Omvoh® (mirikizumab IV infusion, SC injection)	Inhibition of IL-23	UC
Stelara® (ustekinumab SC injection, ustekinumab IV infusion)	Inhibition of IL-12/23	SC formulation: CD, PsO, PsA, UC
		IV formulation: CD, UC
Siliq® (brodalumab SC injection)	Inhibition of IL-17	PsO
Cosentyx® (secukinumab SC injection; secukinumab IV infusion)	Inhibition of IL-17A	SC formulation: AS, ERA, nr-axSpA, PsO, PsA
		IV formulation: AS, nr-axSpA, PsA
Taltz® (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
Bimzelx® (bimekizumab-bkzx SC injection)	Inhibition of IL-17A/17F	PsO
Ilumya® (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
Skyrizi® (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)	Inhibition of IL-23	SC formulation: CD, PSA, PsO, UC
		IV formulation: CD, UC
Tremfya® (guselkumab SC injection, guselkumab IV infusion)	Inhibition of IL-23	SC formulation: PsA, PsO, UC
		IV formulation: UC
Entyvio® (vedolizumab IV infusion, vedolizumab SC injection)	Integrin receptor antagonist	CD, UC
Oral Therapies/Targeted Synthetic Oral Small Molecule Drugs		
Otezla® (apremilast tablets)	Inhibition of PDE4	PsO, PsA
Cibinqo™ (abrocitinib tablets)	Inhibition of JAK pathways	AD
Olumiant® (baricitinib tablets)	Inhibition of JAK pathways	RA, AA
Litfulo® (ritlecitinib capsules)	Inhibition of JAK pathways	AA

Leqselvi® (deuruxolitinib tablets)	Inhibition of JAK pathways	AA
Rinvoq® (upadacitinib extended-release tablets)	Inhibition of JAK pathways	AD, AS, nr-axSpA, RA, PsA, UC
Rinvoq® LQ (upadacitinib oral solution)	Inhibition of JAK pathways	PsA, PJIA
Sotyktu® (deucravacitinib tablets)	Inhibition of TYK2	PsO
Xeljanz® (tofacitinib tablets/oral solution)	Inhibition of JAK pathways	RA, PJIA, PsA, UC
Xeljanz® XR (tofacitinib extended-release tablets)	Inhibition of JAK pathways	RA, PsA, UC
Zeposia® (ozanimod tablets)	Sphingosine 1 phosphate receptor modulator	UC
Velsipity® (etrasimod tablets)	Sphingosine 1 phosphate receptor modulator	UC

* Not an all-inclusive list of indications. 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; ^ 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; AA – Alopecia areata; TYK2 – Tyrosine kinase 2.