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Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Analgesics and Anesthetics	**Original Policy Date:**	June 22, 2018
Subject:	Olumiant	**Page:**	1 of 10

Last Review Date: September 6, 2024

Olumiant

Description

Olumiant (baricitinib)

Background
Olumiant (baricitinib) is a Janus kinase (JAK) inhibitor. JAKs are intracellular enzymes which transmit signals arising from cytokine or growth factor-receptor interactions on the cellular membrane to influence cellular processes or hematopoiesis and immune cell function. Janus kinase inhibitors inhibit one or more Janus family of enzymes (JAK1, JAK2, JAK3, TYK2), interfering with the JAK-STAT signaling pathway. Within the signaling pathway, JAKs phosphorylate and activate Signal Transducers and Activators of Transcription (STATs) which modulate intracellular activity including gene expression. Olumiant modulates the signaling pathway at the point of JAKs, preventing the phosphorylation and activation of STATs (1).

The use of Olumiant for the treatment of COVID-19 should be billed under the medical benefit.

The use of Olumiant for the treatment of alopecia areata is excluded from coverage.

Regulatory Status
FDA-approved indications: Olumiant is a Janus kinase (JAK) inhibitor indicated for: (1)

- the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more tumor necrosis factor (TNF) blockers.
    - Limitations of Use: Olumiant should not be used in combination with other JAK inhibitors, biological DMARDs or potent immunosuppressants such as azathioprine and cyclosporine.

- the treatment of COVID-19 in hospitalized adult patients requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO.
- the treatment of adult patients with severe alopecia areata.
    - Limitations of Use: Olumiant should not be used in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine, or other potent immunosuppressants.

In addition, the FDA has approved the emergency use of Olumiant for the treatment of COVID-19 in hospitalized pediatric patients (2).

Olumiant carries several boxed warnings: (1)

1. Serious infections
    a. Increased risk for serious infections, including tuberculosis and bacterial, invasive fungi, viral and other opportunistic infections that may lead to hospitalization. If a serious infection develops, interrupt Olumiant until the infection is controlled. Prior to the initiation of Olumiant, a test for latent tuberculosis must be conducted. If the test is positive, start treatment for tuberculosis prior to starting Olumiant. Monitor all patients for active tuberculosis during treatment, even if the initial latent tuberculosis test is negative.
2. Mortality
    a. RA patients 50 years of age and older with at least one cardiovascular risk factor showed a higher rate of all-cause mortality, including sudden cardiovascular death, in patients treated with JAK inhibitors compared to TNF blockers.
3. Malignancies
    a. Lymphoma and other malignancies have been observed in patients treated with Olumiant.
    b. In RA patients treated with a JAK inhibitor, a higher rate of malignancies was observed when compared with TNF blockers.
4. Major adverse cardiovascular events (MACE)
    a. RA patients 50 years of age and older with at least one cardiovascular risk factor treated with a JAK inhibitor showed a higher rate of MACE (defined as cardiovascular death, myocardial infarction, and stroke) when compared to TNF blockers. Patients who are current or past smokers are at increased risk. Olumiant should be discontinued in patients that have experienced a myocardial infarction or stroke.
5. Thrombosis

a. Thrombosis, including deep vein thrombosis, pulmonary embolism, and arterial thrombosis, have occurred in patients treated with Olumiant. Many of these adverse events were serious and some resulted in death.
b. In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with a JAK inhibitor, a higher rate of thrombosis was observed when compared with TNF blockers.

The safety and effectiveness of Olumiant in pediatric patients have not been established (1).

Related policies
Rinvoq, Xeljanz/XR

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Olumiant may be considered **medically necessary** if the conditions indicated below are met.

Olumiant may be considered **investigational** for all other indications.

Prior-Approval Requirements

The use of Olumiant for the treatment of COVID-19 should be billed under the medical benefit.

Age 18 years of age or older

Diagnosis

Patient must have the following:

Moderately to severely active rheumatoid arthritis (RA)

AND ALL of the following:

1. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional disease-modifying antirheumatic drug (DMARD) (see Appendix 1)
2. Inadequate treatment response, intolerance, or contraindication to at least **ONE** TNF blocker (e.g., Cimzia, Enbrel, Humira, Remicade, Simponi/Simponi Aria)
3. Prescriber has considered the risks for malignancy and major adverse cardiovascular events (MACE) (e.g., advanced age, smoking history, cardiovascular risk factors etc.) and determined that Olumiant therapy is appropriate
4. Result for latent TB infection is negative OR result was positive for latent TB and patient completed treatment (or is receiving treatment) for latent TB
5. Patient **MUST** have tried the preferred product(s) (see Appendix 2) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

AND NONE of the following:

1. Active bacterial, invasive fungal, viral, and other opportunistic infections
2. Severe hepatic impairment
3. A lymphocyte count less than 500 cells/mm3
4. An absolute neutrophil count less than 1000 cells/mm3
5. A hemoglobin less than 8 g/dL
6. History of thrombotic events including deep vein thrombosis (DVT) or pulmonary embolism (PE)
7. Used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)
8. Used in combination with potent immunosuppressants azathioprine or cyclosporine
9. Given concurrently with live vaccines

Prior–Approval *Renewal* Requirements

The use of Olumiant for the treatment of COVID-19 should be billed under the medical benefit.

Age 18 years of age or older

Diagnosis

Patient must have the following:

Rheumatoid arthritis (RA)

AND ALL of the following:

1. Condition has improved or stabilized
2. Prescriber has considered the risks for malignancy and major adverse cardiovascular events (MACE) (e.g., advanced age, smoking history, cardiovascular risk factors etc.) and determined that continuation of Olumiant therapy is appropriate
3. Patient **MUST** have tried the preferred product(s) (see Appendix 2) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

AND NONE of the following:

1. Active bacterial, invasive fungal, viral, and other opportunistic infections
2. Used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)
3. Used in combination with potent immunosuppressants azathioprine or cyclosporine
4. Development of thrombotic events (including DVTs or PEs)
5. Given concurrently with live vaccines

Policy Guidelines

Pre–PA Allowance

None

Prior–Approval Limits

Quantity

Strength	Quantity
1 mg tablet	90 tablets per 90 days
2 mg tablet	

4 mg tablet	Reserved for the treatment of COVID-19 under the medical benefit **OR** For the treatment of alopecia areata which is excluded from coverage

Duration 12 months

Prior–Approval *Renewal* Limits

Quantity

Strength	Quantity
1 mg tablet	90 tablets per 90 days
2 mg tablet	
4 mg tablet	Reserved for the treatment of COVID-19 under the medical benefit **OR** For the treatment of alopecia areata which is excluded from coverage

Duration 18 months

Rationale

Summary

Olumiant (baricitinib) is indicated for the treatment of adult patients with rheumatoid arthritis (RA), for the treatment of COVID-19 in hospitalized patients, and for the treatment of adults with severe alopecia areata. Olumiant has several boxed warnings including increased risk for: serious infections, mortality, malignancies, MACE, and thrombosis. The safety and effectiveness of Olumiant in pediatric patients have not been established (1).

The use of Olumiant for the treatment of COVID-19 should be billed under the medical benefit.

The use of Olumiant for the treatment of alopecia areata is excluded from coverage.

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Olumiant while maintaining optimal therapeutic outcomes.

References

1. Olumiant [package insert]. Indianapolis, IN: Lilly USA, LLC; June 2022.
2. Baricitinib EUA Letter of Authorization. May 2022. Available at: https://www.fda.gov/media/143822/download?utm_medium=email&utm_source=govdelivery

Policy History

Date	Action
June 2018	Addition to PA
September 2018	Annual editorial review Addition of requirement of inadequate response, intolerance, or contraindication to a 3-month trial of at least one biological disease-modifying antirheumatic drug (DMARD) per SME
March 2019	Annual review
October 2019	Revised quantity limit to 90 tablets per 90 days with the addition of 1 mg tablet availability
December 2019	Annual review. Addition of requirement to trial preferred product
March 2020	Annual review and reference update
December 2020	Annual review and reference update. Added Appendix 2 with a list of preferred medications based on diagnosis and plan
June 2021	Annual review
January 2022	Added t/f requirement to t/f at least one TNF blocker and added requirement for prescriber to assess risks with malignancy and MACE, per latest PI update
March 2022	Annual review
May 2022	COVID-19 added as a new indication per latest PI update. Added statement indicating that the use of Olumiant for COVID-19 must be billed under the medical benefit. Added quantity limit chart statement that the 4 mg tablet is reserved for the treatment of COVID-19 under the medical benefit
July 2022	Per PI update – addition of alopecia areata to criteria noting that it is excluded from coverage
September 2022	Annual review
September 2023	Annual review
December 2023	Annual review
March 2024	Annual review
September 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.

Appendix 1 - List of DMARDS

Conventional disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
azathioprine	Azasan, Imuran
cyclophosphamide	Cytoxan
cyclosporine	Neoral, Gengraf, Sandimmune
hydroxychloroquine	Plaquenil
leflunomide	Arava
methotrexate	Rheumatrex, Trexall
mycophenolate	Cellcept
sulfasalazine	Azulfidine, Sulfazine

Biological disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
abatacept	Orencia
adalimumab	Humira
anakinra	Kineret
brodalumab	Siliq
certolizumab	Cimzia
etanercept	Enbrel
golimumab	Simponi/Simponi Aria
guselkumab	Tremfya
infliximab	Remicade/Avsola/Inflectra/Renflexis
ixekizumab	Taltz
risankizumab-rzaa	Skyrizi
rituximab	Rituxan/Riabni/Ruxience/Truxima
sarilumab	Kevzara
secukinumab	Cosentyx
spesolimab-sbzo	Spevigo
tildrakizumab-asmn	Ilumya
tocilizumab	Actemra
ustekinumab	Stelara
vedolizumab	Entyvio

Targeted synthetic disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
apremilast	Otezla
baricitinib	Olumiant
deucravacitinib	Sotyktu

tofacitinib	Xeljanz/XR
upadactinib	Rinvoq

Appendix 2 - List of Preferred Products

Diagnosis	Standard Option/Basic Option Preferred Products	Blue Focus Preferred Products
Rheumatoid Arthritis (RA)	*must try **TWO** preferred products: Actemra SC Enbrel Humira** Rinvoq Xeljanz/XR	*must try **ONE** preferred product: Enbrel Humira**

**Including all preferred biosimilars (see reference product criteria)