

baricitinib (Olumiant®)

Policy # 00637

Original Effective Date: 09/19/2018

Current Effective Date: 03/01/2026

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member’s contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Rheumatoid Arthritis

Based on review of available data, the Company may consider baricitinib (Olumiant®)† for the treatment of moderately to severely active rheumatoid arthritis to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for baricitinib (Olumiant) will be considered when the following criteria are met:

Initial

- Patient has a diagnosis of moderately to severely active rheumatoid arthritis; AND
- Patient is 18 years of age or older; AND
- Patient has failed treatment with one or more traditional disease-modifying anti-rheumatic drugs (DMARDs), such as methotrexate, unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND

*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

- Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: etanercept (Enbrel®)‡, adalimumab (Simlandi®, adalimumab-adaz, adalimumab-adbm [manufactured by Quallent Pharmaceuticals], adalimumab-ryvk [manufactured by Quallent Pharmaceuticals])‡, tofacitinib (Xeljanz/XR®)‡, upadacitinib (Rinvoq™)‡, or subcutaneous tocilizumab (Actemra®, Tyenne®)‡ unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND

*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

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- The requested drug is NOT used in combination with other biologic DMARDs, such as adalimumab (Humira, biosimilars) or etanercept (Enbrel) OR other drugs such as tofacitinib (Xeljanz/XR) or apremilast (Otezla/XR®)[†]; AND
- The requested drug is NOT used in combination with potent immunosuppressants such as azathioprine and cyclosporine; AND
- Patient has a negative tuberculosis (TB) test (e.g., purified protein derivative [PPD], blood test) prior to treatment.

Continuation

- Patient has received an initial authorization; AND
- Patient has experienced a beneficial clinical response from baseline (prior to therapy with Olumiant) as evidenced by improvement in clinical signs and symptoms 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.

*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

Alopecia Areata

Based on review of available data, the Company may consider baricitinib (Olumiant) for the treatment of severe alopecia areata to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for baricitinib (Olumiant) will be considered when the following criteria are met:

- Patient has a diagnosis of severe alopecia areata; AND
- Patient is 18 years of age or older; AND
- The requested drug is NOT used in combination with potent immunosuppressants such as azathioprine and cyclosporine; AND
- Patient has a negative TB test (e.g., PPD, blood test) prior to treatment; AND
- Patient's current alopecia areata episode has lasted at least 6 months; AND

*(Note: This specific patient selection criterion is an additional Company requirement, based on clinical trials, for coverage eligibility and will be denied as not medically necessary** if not met.)*

- Patient's current alopecia areata episode encompasses at least 50% of the scalp; AND
*(Note: This specific patient selection criterion is an additional Company requirement, based on clinical trials, for coverage eligibility and will be denied as not medically necessary** if not met.)*
- There has NOT been spontaneous improvement in the patient's alopecia areata over the past 6 months.
*(Note: This specific patient selection criterion is an additional Company requirement, based on clinical trials, for coverage eligibility and will be denied as not medically necessary** if not met.)*

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When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of baricitinib (Olumiant) when any of the following criteria for their respective disease listed below (and denoted in the patient selection criteria above) are not met to be **not medically necessary****:

- Rheumatoid arthritis
 - Patient has failed treatment with one or more traditional DMARDs
 - Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: etanercept (Enbrel), adalimumab (Simlandi, adalimumab-adaz, adalimumab-adbm [manufactured by Quallent Pharmaceuticals], adalimumab-ryvk [manufactured by Quallent Pharmaceuticals]), tofacitinib (Xeljanz/XR), upadacitinib (Rinvoq), or subcutaneous tocilizumab (Actemra, Tyenne)
 - For continuation requests: Patient has experienced a beneficial clinical response from baseline (prior to therapy with Olumiant) as evidenced by improvement in clinical signs and symptoms 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
- Alopecia areata
 - Patient's current alopecia areata episode has lasted at least 6 months
 - Patient's current alopecia areata episode encompasses at least 50% of the scalp
 - There has NOT been spontaneous improvement in the patient's alopecia areata over the past 6 months.

Based on review of available data, the Company considers the outpatient dispensing of baricitinib (Olumiant) for the treatment of COVID-19 in hospitalized patients to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of baricitinib (Olumiant) when the patient selection criteria are not met for rheumatoid arthritis or alopecia areata (with the exception of those denoted as **not medically necessary****) to be **investigational.***

Based on review of available data, the Company considers the use of baricitinib (Olumiant) for the treatment of COVID-19 in non-hospitalized patients to be **investigational.***

Background/Overview

Olumiant is a janus kinase (JAK) inhibitor indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF (tumor necrosis factor) antagonist therapies, for the treatment of COVID-19 in hospitalized patients, and for the treatment of adult patients with severe alopecia areata. Olumiant is available as 4 mg tablets, 2 mg tablets, and 1 mg tablets. It is dosed at 2 mg once daily with

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adjustments in renal impairment for rheumatoid arthritis. The dosing for COVID-19 in hospitalized patients is 4 mg once daily for up to 14 days. The dosing for alopecia areata is 2 mg once daily with increases to 4 mg once daily if the response to the 2 mg once daily dosage is not adequate. A reduction to 2 mg once daily for alopecia areata can be used when an adequate response has been achieved.

Rheumatoid Arthritis

Rheumatoid Arthritis is a chronic (long-term) disease that causes inflammation of the joints and surrounding tissues. It can also affect other organs. It is considered an autoimmune disease. In an autoimmune disease, the immune system confuses healthy tissue for foreign substances. Typically, first line treatments such as traditional DMARDs are used to treat this condition. An example of a traditional DMARD would include methotrexate.

Traditional Disease-Modifying Anti-Rheumatic Drugs (DMARDs)

Traditional DMARDs are typically used for the treatment of rheumatoid arthritis. These drugs slow the disease process by modifying the immune system. Examples include:

- methotrexate
- cyclosporine
- sulfasalazine
- mercaptopurine
- gold compounds

COVID-19

Note that the use of Olumiant for COVID-19 is limited to the inpatient setting and is beyond the scope of this medical policy. It will not be addressed beyond this point.

Alopecia Areata

Alopecia Areata is a chronic, relapsing, immune mediated condition that results in non-scarring hair loss. Management of the condition includes management of psychologic needs and offering treatment for those who would like intervention. There are a few off label strategies employed, but Olumiant is the first drug FDA approved for the treatment of alopecia areata.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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 TNF antagonist therapies, for the treatment of COVID-19 in hospitalized patients, and for the treatment of adult patients with severe alopecia areata.

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Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

Rheumatoid Arthritis

The efficacy and safety of Olumiant 2 mg once daily was assessed in two confirmatory phase 3, randomized, double-blind, multicenter studies in patients with moderately to severely active rheumatoid arthritis. All patients were over 18 years of age. Both studies were 24 weeks in length and contained over 500 subjects each. The first study (Study 1) was in patients who had an intolerance to conventional DMARDs, while the second trial (Study 2) was in patients who had an intolerance to 1 or more TNF antagonists. Both studies' primary endpoints were the proportion of patients who achieved an ACR20 (American College of Rheumatology) response at week 12. The proportion of patients to achieve ACR20 at week 12 in study 1 was 39% in the placebo plus conventional DMARDs group vs. 66% in the Olumiant plus conventional DMARDs group. The proportion of patients to achieve ACR20 at week 12 in study 2 was 27% in the placebo plus conventional DMARDs group vs. 49% in the Olumiant plus conventional DMARDs group.

Alopecia Areata

Two randomized, double-blind, placebo-controlled trials (Trials AA-1 and AA-2) enrolled a total of 1,200 patients, with alopecia areata (AA), who had at least 50% scalp hair loss as measured by the Severity of Alopecia Tool (SALT) for more than 6 months. At baseline, 53% of patients had at least 95% scalp hair loss, 34% had their current episode lasting at least 4 years, 69% had significant gaps in eyebrow hair or no notable eyebrow hair, and 58% had significant gaps in eyelashes or no notable eyelashes. In the Phase 3 portion of Trial AA-1 and in Trial AA-2, patients received Olumiant 2 mg, Olumiant 4 mg, or placebo once daily.

Both trials assessed the proportion of patients who achieved at least 80% scalp hair coverage (SALT score of ≤ 20) at week 36 as the primary endpoint. In trial AA-1, 22% of subjects in the Olumiant 2 mg group met the primary endpoint vs. 35% in the Olumiant 4 mg group vs. 5% in the placebo group. In trial AA-2, 17% of subjects in the Olumiant 2 mg group met the primary endpoint vs. 32% in the Olumiant 4 mg group vs. 3% in the placebo group.

COVID-19

Note that the use of Olumiant for COVID-19 is limited to the inpatient setting, therefore use in the outpatient setting is not warranted nor applicable to this medical policy.

References

1. Olumiant [package insert]. Eli Lilly and Company. Indianapolis, Indiana. Updated June 2022.

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Policy History

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09/06/2018	Medical Policy Committee review
09/19/2018	Medical Policy Implementation Committee approval. New policy,
09/05/2019	Medical Policy Committee review
09/11/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/05/2019	Medical Policy Committee review
12/11/2019	Medical Policy Implementation Committee approval. Added Rinvoq as a preferred option for rheumatoid arthritis.
11/05/2020	Medical Policy Committee review
11/11/2020	Medical Policy Implementation Committee approval. Removed Actemra SubQ as an option prior to use of Olumiant in rheumatoid arthritis. Updated relevant background information.
11/04/2021	Medical Policy Committee review
11/10/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/06/2022	Medical Policy Committee review
01/12/2022	Medical Policy Implementation Committee approval. Added subcutaneous Actemra to the list of products than can be tried and failed prior to use of Olumiant.
02/02/2023	Medical Policy Committee review
02/08/2023	Medical Policy Implementation Committee approval. Added a new indication, alopecia areata. Added not medically necessary and investigational statements for the treatment of COVID-19.
02/01/2024	Medical Policy Committee review
02/14/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/06/2025	Medical Policy Committee review
02/12/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/05/2026	Medical Policy Committee review
02/11/2026	Medical Policy Implementation Committee approval. Added criteria for continuation requests for rheumatoid arthritis.

Next Scheduled Review Date: 02/2027

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

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- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

****Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

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NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan's pharmacy benefit.