baricitinib (Olumiant®)

Policy # 00637
Original Effective Date: 09/19/2018
Current Effective Date: 01/01/2021

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.

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.*

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:

- 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 disease-modifying anti-rheumatic drugs (DMARDs); AND
  *(Note: This specific patient 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 (Humira®)‡, tofacitinib (Xeljanz/XR®)‡, or upadacitinib (Rinvoq™)‡ 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 criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- The requested drug is NOT used in combination with other biologic DMARDs, such as adalimumab (Humira) or etanercept (Enbrel) OR other drugs such as tofacitinib (Xeljanz/XR) or apremilast (Otezla®)‡; 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.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of baricitinib (Olumiant) when the patient has NOT failed treatment with one or more DMARDs to be **not medically necessary.****

Based on review of available data, the Company considers the use of baricitinib (Olumiant) when the patient has NOT failed treatment with TWO of the following after at least TWO months of therapy with EACH product: etanercept (Enbrel), adalimumab (Humira), tofacitinib (Xeljanz/XR), or upadacitinib (Rinvoq) 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 (with the exception of those denoted as **not medically necessary****) 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. Olumiant is available as 2 mg tablets and 1 mg tablets and it is dosed at 2 mg once daily with adjustments in renal impairment. Olumiant carries a boxed warning for thrombosis, which is not shared by the other products to treat this condition.

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 DMARDs are used to treat this condition. An example of a DMARD would include methotrexate. After a DMARD is tried and failed, typically a biologic product is used.

Disease-Modifying Anti-Rheumatic Drugs (DMARDs)
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

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. Olumiant carries a boxed warning for thrombosis, which is not shared by the other products to treat this condition.

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, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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.

References

1. Olumiant [package insert]. Eli Lilly and Company. Indianapolis, Indiana. Updated May 2018.

Policy History

Original Effective Date: 09/19/2018
Current Effective Date: 01/01/2021

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.

Next Scheduled Review Date: 11/2021

*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:

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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
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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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.