

## Clinical Policy: Baricitinib (Olumiant)

Reference Number: IL.ERX.SPA.291

Effective Date: 06.01.21

Last Review Date: 05.21

Lines of Business: Illinois Medicaid

[Revision Log](#)

See **Important Reminder** at the end of this policy for important regulatory and legal information.

### Description

Baricitinib (Olumiant<sup>®</sup>) is Janus kinase (JAK) inhibitor.

### FDA Approved Indication(s)

Olumiant is indicated for 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) antagonist therapies.

Limitation(s) of use: Use of Olumiant in combination with other JAK inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

### Emergency Use Authorization

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of baricitinib for treatment of suspected or laboratory confirmed coronavirus disease 2019 (COVID-19) in hospitalized adults and pediatric patients 2 years of age or older requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

Baricitinib has been authorized by FDA for the emergency uses described above. Baricitinib is not FDA-approved for these uses.

Baricitinib is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of baricitinib under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

### Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

*Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.*

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Olumiant is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Coronavirus-19 Infection (FDA Emergency Use Authorization):

1. Initiation of outpatient treatment will not be authorized as Olumiant is authorized for emergency use only in the hospital setting (*see Appendix H*).

**Approval duration: Not Applicable**

##### B. Rheumatoid Arthritis (must meet all):

1. Diagnosis of RA per American College of Rheumatology (ACR) criteria (*see Appendix E*);
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years;

4. Member meets one of the following (a or b):
  - a. Failure of a  $\geq 3$  consecutive month trial of methotrexate (MTX) at up to maximally indicated doses;
  - b. Member has intolerance or contraindication to MTX (see *Appendix D*), and failure of a  $\geq 3$  consecutive month trial of at least ONE conventional DMARD (e.g., sulfasalazine, leflunomide, hydroxychloroquine) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
5. Failure of at least TWO of the following, each used for  $\geq 3$  consecutive months, unless contraindicated or clinically significant adverse effects are experienced: Enbrel®, Humira®, Cimzia®, Xeljanz®/Xeljanz XR®;  
*\*Prior authorization may be required for Enbrel, Humira, Cimzia, and Xeljanz/Xeljanz XR*
6. Documentation of one of the following baseline assessment scores (a or b):
  - a. Clinical disease activity index (CDAI) score (see *Appendix F*);
  - b. Routine assessment of patient index data 3 (RAPID) score (see *Appendix G*);
7. Dose does not exceed 2 mg (1 tablet) per day.

**Approval duration: 6 months**

**C. Other diagnoses/indications**

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**II. Continued Therapy**

**A. Coronavirus-19 Infection (FDA Emergency Use Authorization):**

1. Continuation of therapy in the outpatient setting will not be authorized as Olumiant is authorized for emergency use only in the hospitalized setting for 14 days or until the discharge from the hospital, whichever comes first (see *Appendix H*).

**Approval duration: Not Applicable**

**B. Rheumatoid Arthritis (must meet all):**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy as evidenced by one of the following (a or b):
  - a. A decrease in CDAI (see *Appendix F*) or RAPID3 (see *Appendix G*) score from baseline;
  - b. Medical justification stating ability to conduct CDAI re-assessment, and submission of RAPID3 score associated with disease severity that is similar to initial CDAI assessment or improved;
3. If request is for a dose increase, new dose does not exceed 2 mg (1 tablet) per day.

**Approval duration: 12 months**

**C. Other diagnoses/indications (must meet 1 or 2):**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.

**Approval duration: Duration of request or 6 months (whichever is less); or**

2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents;
- B. Combination use of biological disease-modifying antirheumatic drugs (bDMARDs), including any tumor necrosis factor (TNF) antagonists [Cimzia®, Enbrel®, Simponi®, Avsola™, Inflectra™, Remicade®, Renflexis™], interleukin agents [Aralyst® (IL-1 blocker), Ilaris® (IL-1 blocker), Kineret® (IL-1RA), Actemra® (IL-6RA), Kevzara® (IL-6RA), Stelara® (IL-12/23 inhibitor), Cosentyx® (IL-17A inhibitor), Taltz® (IL-17A inhibitor), Siliq™ (IL-17RA), Ilumya™ (IL-23 inhibitor), Skyrizi™ (IL-23 inhibitor), Tremfya® (IL-23 inhibitor)], janus kinase inhibitors (JAKi) [Xeljanz®/Xeljanz XR,

Rinvoq™], anti-CD20 monoclonal antibodies [Rituxan®, Riabni™, Ruxience™, Truxima®, and Rituxan Hycela®], selective co-stimulation modulators [Orencia®], or integrin receptor antagonists [Entyvio®] because of the possibility of increased immunosuppression, neutropenia and increased risk of infection.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

CDAI: clinical disease activity index

DMARD: disease-modifying antirheumatic drug

EUA: emergency use authorization

FDA: Food and Drug Administration

JAK: Janus kinase

MTX: methotrexate

RA: rheumatoid arthritis

RAPID3: routine assessment of patient index data 3

TNF: tumor necrosis factor

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria.*

*The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
azathioprine (Azasan®, Imuran®)	<b>RA</b> 1 mg/kg/day PO QD or divided BID	2.5 mg/kg/day
Cuprimine® (d-penicillamine)	<b>RA*</b> <u>Initial dose:</u> 125 or 250 mg PO QD <u>Maintenance dose:</u> 500 – 750 mg/day PO QD	1,500 mg/day
cyclosporine (Sandimmune®, Neoral®)	<b>RA</b> 2.5 – 4 mg/kg/day PO divided BID	4 mg/kg/day
hydroxychloroquine (Plaquenil®)	<b>RA*</b> <u>Initial dose:</u> 400 – 600 mg/day PO QD <u>Maintenance dose:</u> 200 – 400 mg/day PO QD	600 mg/day
leflunomide (Arava®)	<b>RA</b> 100 mg PO QD for 3 days, then 20 mg PO QD	20 mg/day
methotrexate (Rheumatrex®)	<b>RA</b> 7.5 mg/week PO, SC, or IM or 2.5 mg PO Q12 hr for 3 doses/week	30 mg/week
Ridaura® (auranofin)	<b>RA</b> 6 mg PO QD or 3 mg PO BID	9 mg/day (3 mg TID)
sulfasalazine (Azulfidine®)	<b>RA</b> 2 g/day PO in divided doses	3 g/day
Enbrel® (etanercept)	<b>RA</b> 25 mg SC twice weekly or 50 mg SC once weekly	50 mg/week
Humira® (adalimumab)	<b>RA</b> 40 mg SC every other week (may increase to once weekly)	40 mg/week
Cimzia® (certolizumab)	<b>RA</b> <u>Initial dose:</u> 400 mg SC at 0, 2, and 4 weeks <u>Maintenance dose:</u> 200 mg SC every other week (or 400 mg SC every 4 weeks)	400 mg every 4 weeks
Xeljanz® (tofacitinib immediate-release)	<b>RA</b> 5 mg PO BID	10 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Xeljanz XR® (tofacitinib extended-release)	<b>RA</b> 11 mg PO QD	11 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

\*Off-label

**Appendix C: Contraindication/Boxed Warnings**

- Contraindication(s): none reported
- Boxed Warning(s): serious infection, malignancy and thrombosis

**Appendix D: General Information**

- Definition of MTX or DMARD failure:
  - Child-bearing age is not considered a contraindication for use of MTX. Each drug has risks in pregnancy. An educated patient and family planning would allow use of MTX in patients who have no intention of immediate pregnancy.
  - Social use of alcohol is not considered a contraindication for use of MTX. MTX may only be contraindicated if patients choose to drink over 14 units of alcohol per week. However, excessive alcohol drinking can lead to worsening of the condition, so patients who are serious about clinical response to therapy should refrain from excessive alcohol consumption.
- Examples of positive response to therapy may include, but are not limited to:
  - Reduction in joint pain/swelling/tenderness
  - Improvement in ESR/CRP levels
  - Improvements in activities of daily living

**Appendix E: The 2010 ACR Classification Criteria for RA**

- Add score of categories A through D; a score of ≥ 6 out of 10 is needed for classification of a patient as having definite RA.

A	Joint involvement	Score
	1 large joint	0
	2-10 large joints	1
	1-3 small joints (with or without involvement of large joints)	2
	4-10 small joints (with or without involvement of large joints)	3
	> 10 joints (at least one small joint)	5
B	Serology (at least one test result is needed for classification)	
	Negative rheumatoid factor (RF) and negative anti-citrullinated protein antibody (ACPA)	0
	Low positive RF or low positive ACPA * Low: < 3 x upper limit of normal	2
	High positive RF or high positive ACPA * High: ≥ 3 x upper limit of normal	3
C	Acute phase reactants (at least one test result is needed for classification)	
	Normal C-reactive protein (CRP) and normal erythrocyte sedimentation rate (ESR)	0
	Abnormal CRP or abnormal ESR	1
D	Duration of symptoms	
	< 6 weeks	0
	≥ 6 weeks	1

**Appendix F: Clinical Disease Activity Index (CDAI) Score**

- The Clinical Disease Activity Index (CDAI) is a composite index for assessing disease activity in RA. CDAI is based on the simple summation of the count of swollen/tender joint count of 28 joints along with patient and physician global assessment on VAS (0–10 cm) Scale for estimating disease activity. The CDAI score ranges from 0 to 76.

CDAI Score	Disease state interpretation
≤ 2.8	Remission
> 2.8 to ≤ 10	Low disease activity
> 10 to ≤ 22	Moderate disease activity
> 22	High disease activity

*Appendix G: Routine Assessment of Patient Index Data 3 (RAPID3) Score*

The Routine Assessment of Patient Index Data 3 (RAPID3) is a pooled index of the three patient-reported ACR core data set measures: function, pain, and patient global estimate of status. Each of the individual measures is scored 0 – 10, and the maximum achievable score is 30.

RAPID3 Score	Disease state interpretation
≤ 3	Remission
3.1 to 6	Low disease activity
6.1 to 12	Moderate disease activity
> 12	High disease activity

*Appendix H: Coronavirus-19 Infection (FDA Emergency Use Authorization):*

- The United States FDA has made baricitinib available under an emergency access mechanism called an EUA as a treatment of baricitinib to treat suspected or laboratory-confirmed COVID-19 in hospitalized adults and pediatric patients 2 years or older requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). This is not an FDA-approved use of baricitinib. The EUA is supported by a Secretary of Health and Human Service (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.
- Baricitinib, as a treatment for COVID-19, has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that it is reasonable to believe that the product meets certain criteria for safety, performance, and labeling and may be effective in treatment of patients during the COVID-19 pandemic. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.
- The EUA for baricitinib as a treatment for certain patients with COVID-19 is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).
- To request baricitinib under Emergency Use Authorization (EUA): In-patient pharmacies may order directly from an Authorized Distributor of Record. A current list of Lilly’s Authorized Distributors of Record is available at [www.lillytrade.com](http://www.lillytrade.com) or visit [www.baricitinibemergencyuse.com](http://www.baricitinibemergencyuse.com) for additional access information.

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
RA	2 mg PO QD	2 mg/day
COVID-19 (EUA)	<ul style="list-style-type: none"> <li>• Age 2 to &lt; 9 years: 2 mg PO QD for 14 days or until discharged from the hospital (whichever comes first)</li> <li>• Age ≥ 9 years: 4 mg PO QD for 14 days or until discharged from the hospital (whichever comes first)</li> </ul>	4 mg/day

**VI. Product Availability**

Tablets: 1 mg, 2 mg

**VII. References**

1. Olumiant Prescribing Information. Indianapolis, IN: Eli Lilly and Company; July 2020. Available at: <http://uspl.lilly.com/olumiant/olumiant.html#pi>. Accessed January 6, 2021.

2. Singh JA, Furst DE, Bharat A, et al. 2012 update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. *Arthritis Care Res.* 2012; 64(5): 625-639.
3. Singh JA, Saag KG, Bridges SL, et al. 2015 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Care and Research.* 2015; 1-25. DOI 10.1002/acr.22783.
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2021. Available at: <http://www.clinicalpharmacology-ip.com/>.
5. Food and Drug Administration. Fact Sheet for Patients, Parents and Caregivers: Emergency Use Authorization (EUA) of Baricitinib. Issued July 28, 2021. <http://pi.lilly.com/eua/baricitinib-eua-factsheet-patient.pdf>. Accessed August 4, 2021.
6. Food and Drug Administration. Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of Baricitinib. Issued July 28, 2021. <https://www.fda.gov/media/143825/download>. Accessed August 4, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	04.20.21	05.21
RT4: EUA no longer requires baricitinib be used in combination with remdesivir.	08.04.21	

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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