

**Clinical Policy: Baricitinib (Olumiant)**

Reference Number: CP.PHAR.135

Effective Date: 07.24.18

Last Review Date: 02.21

Line of Business: Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

**Description**

Baricitinib (Olumiant®) 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, in combination with remdesivir, 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.*

It is the policy of health plans affiliated with Centene Corporation® 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 hospitalized 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  $\geq$  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, unless contraindicated or clinically significant adverse effects are experienced;
  - b. If intolerance or contraindication to MTX (*see Appendix D*), 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 contraindicated or clinically significant adverse effects are experienced;
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<sup>®</sup>, Kevzara<sup>®</sup>, Xeljanz<sup>®</sup>/Xeljanz XR<sup>®</sup>;  
*\*Prior authorization may be required for Enbrel, Kevzara, 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 (RAPID3) score (*see Appendix G*);
7. Dose does not exceed 2 mg per day (1 tablet per day).

**Approval duration: 6 months**

**C. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

**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 discharged from the hospital, whichever comes first (*see Appendix H*).

**Approval duration: Not Applicable**

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

1. Currently receiving medication via Centene benefit 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 inability 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 per day (1 tablet per day).

**Approval duration: 12 months**

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.  
**Approval duration: Duration of request or 6 months (whichever is less); or**
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

**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 – CP.PMN.53 for Medicaid or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

CDAI: clinical disease activity index  
DMARD: disease-modifying antirheumatic drug  
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 <sup>®</sup> , Imuran <sup>®</sup> )	<b>RA</b> 1 mg/kg/day PO QD or divided BID	2.5 mg/kg/day
Cuprimine <sup>®</sup> (d-penicillamine)	<b>RA*</b> <u>Initial dose:</u> 125 or 250 mg PO QD <u>Maintenance dose:</u> 500 to 750 mg/day PO QD	1,500 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
cyclosporine (Sandimmune <sup>®</sup> , Neoral <sup>®</sup> )	<b>RA</b> 2.5 to 4 mg/kg/day PO divided BID	4 mg/kg/day
hydroxychloroquine (Plaquenil <sup>®</sup> )	<b>RA*</b> <u>Initial dose:</u> 400 to 600 mg/day PO QD <u>Maintenance dose:</u> 200 to 400 mg/day PO QD	600 mg/day
leflunomide (Arava <sup>®</sup> )	<b>RA</b> 100 mg PO QD for 3 days, then 20 mg PO QD	20 mg/day
methotrexate (Rheumatrex <sup>®</sup> )	<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 <sup>®</sup> (auranofin)	<b>RA</b> 6 mg PO QD or 3 mg PO BID	9 mg/day (3 mg TID)
sulfasalazine (Azulfidine <sup>®</sup> )	<b>RA</b> 2 g/day PO in divided doses	3 g/day
Enbrel <sup>®</sup> (etanercept)	<b>RA</b> 25 mg SC twice weekly or 50 mg SC once weekly	50 mg/week
Kevzara <sup>®</sup> (sarilumab)	<b>RA</b> 200 mg SC once every two weeks	200 mg/2 weeks
Xeljanz <sup>®</sup> (tofacitinib)	<b>RA</b> 5 mg PO BID	10 mg/day
Xeljanz XR <sup>®</sup> (tofacitinib extended-release)	<b>RA</b> 11 mg PO QD	11 mg/day

*Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) 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 failure of MTX or DMARDs:
  - 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.

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

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

<b>A</b>	<b>Joint involvement</b>	<b>Score</b>
	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>B</b>	<b>Serology (at least one test result is needed for classification)</b>	
	Negative rheumatoid factor (RF) <i>and</i> negative anti-citrullinated protein antibody (ACPA)	0
	Low positive RF <i>or</i> low positive ACPA <i>* Low: <math>&lt; 3 \times</math> upper limit of normal</i>	2
	High positive RF <i>or</i> high positive ACPA <i>* High: <math>\geq 3 \times</math> upper limit of normal</i>	3
<b>C</b>	<b>Acute phase reactants (at least one test result is needed for classification)</b>	
	Normal C-reactive protein (CRP) and normal erythrocyte sedimentation rate (ESR)	0
	Abnormal CRP or abnormal ESR	1
<b>D</b>	<b>Duration of symptoms</b>	
	< 6 weeks	0
	$\geq 6$ 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.

<b>CDAI Score</b>	<b>Disease state interpretation</b>
$\leq 2.8$	Remission
2.8 to $\leq 10$	Low disease activity
10 to $\leq 22$	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, in combination with remdesivir, 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 in combination with remdesivir for 14 days or until discharged from the hospital (whichever comes first)</li> <li>• Age ≥ 9 years: 4 mg PO QD in combination with remdesivir for 14 days or until discharged from the hospital (whichever comes first)</li> </ul>	4 mg/day

**VI. Product Availability**

Tablet: 2 mg

## VII. References

1. Olumiant Prescribing Information. Indianapolis, IN: Eli Lilly and Company; October 2019. Available at: <http://uspl.lilly.com/olumiant/olumiant.html#pi>. Accessed February 28, 2020.
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.; 2019. Available at: <http://www.clinicalpharmacology-ip.com/>. Accessed February 26, 2019.
5. Food and Drug Administration. Fact Sheet for Patients, Parents and Caregivers: Emergency Use Authorization (EUA) of Baricitinib. Issued November 19, 2020. <https://www.fda.gov/media/143824/download>. Accessed November 19, 2020.
6. Food and Drug Administration. Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of Baricitinib. Issued November 19, 2020. <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-drug-combination-treatment-covid-19>. Accessed November 19, 2020

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	07.24.18	11.18
2Q 2019 annual review: no significant changes; references reviewed and updated.	02.26.19	05.19
Removed HIM-Medical Benefit line of business; updated preferred redirections based on SDC recommendation and prior clinical guidance: for RA, removed redirection to adalimumab and added redirection to 2 of 3 agents (Enbrel, Kevzara, Xeljanz/Xeljanz XR).	12.13.19	
2Q 2020 annual review: for RA, added specific diagnostic criteria for definite RA, baseline CDAI score requirement, and decrease in CDAI score as positive response to therapy; references reviewed and updated.	04.23.20	05.20
Revised typo in Appendix E from “normal ESR” to “abnormal ESR” for a point gained for ACR Classification Criteria.	11.22.20	
Added criteria for Coronavirus-19 Infection (FDA Emergency Use Authorization); Added criteria for RAPID3 assessment for RA given limited in-person visits during COVID-19 pandemic, updated appendices.	11.24.20	02.21

## **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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.



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