Clinical Policy: Baricitinib (Olumiant)

Reference Number: MDN.CP.PHAR.135
Effective Date: 04.01.22
Last Review Date: 5.14.24
Line of Business: Meridian IL 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
- Coronavirus disease 2019 (COVID-19) in hospitalized adult patients requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO)
- Adult patients with severe alopecia areata

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.

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 :

1. Initiation of outpatient treatment will not be authorized as Olumiant is FDA-approved for use only in the hospitalized setting.

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 ≥ 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 ≥ 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. 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)*;
6. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
7. Dose does not exceed 2 mg (1 tablet) per day.

Approval duration: 6 months

C. Alopecia Areata:

1. Use of Olumiant for the treatment of alopecia areata is a benefit exclusion and will not be authorized because it is considered cosmetic in nature.

Approval duration: Not applicable

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs in the formulary PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT in the formulary PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Coronavirus-19 Infection:

1. Continuation of therapy in the outpatient setting will not be authorized as Olumiant is FDA-approved for use only in the hospitalized setting for 14 days or until discharged from the hospital, whichever comes first.

Approval duration: Not Applicable

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

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*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. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
4. If request is for a dose increase, new dose does not exceed 2 mg (1 tablet) per day.

Approval duration: 12 months

C. . Alopecia Areata:

1. Use of Olumiant for the treatment of alopecia areata is a benefit exclusion and will not be authorized because it is considered cosmetic in nature.

Approval duration: Not applicable

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs in the formulary PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT in the formulary PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: 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;
B. Combination use with biological disease-modifying antirheumatic drugs (bDMARDs) or potent immunosuppressants, including but not limited to any tumor necrosis factor (TNF) antagonists [e.g., Cimzia®, Enbrel®, Humira® and its biosimilars, Remicade® and its biosimilars (Avsola™, Inflectra™, Renflexis™, Zymfentra®), Simponi®], interleukin agents [e.g., Actemra® (IL-6RA), Arcalyst® (IL-1 blocker), Bimzelx® (IL-17A and F antagonist), Cosentyx® (IL-17A inhibitor), Ilaris® (IL-1 blocker), Ilumya™ (IL-23 inhibitor), Kevzara® (IL-6RA), Kineret® (IL-1RA), Omvoh™ (IL-23 antagonist), Siliq™ (IL-17RA), Skyrizi™ (IL-23 inhibitor), Stelara® (IL-12/23 inhibitor), Taltz® (IL-17A inhibitor), Tofidence™ (IL-6), Tremfya® (IL-23 inhibitor), Wezlana™ (IL-12/23 inhibitor)], Janus kinase inhibitors (JAKi) [e.g., Cibinqo™, Olumiant™, Rinvoq™, Xeljanz®/Xeljanz® XR,], anti-CD20 monoclonal antibodies [Rituxan® and its biosimilars (Riabni™, Ruxience™, Truxima®), Rituxan Hycela®], selective co-stimulation modulators [Orencia®], integrin receptor antagonists [Entyvio®], tyrosine kinase 2 inhibitors [Sotyktu™], and sphingosine 1-phosphate receptor modulator [Velsipity™] because of the additive immunosuppression, increased risk of neutropenia, as well as increased risk of serious infections
C. Treatment of alopecia areata because it is considered cosmetic in nature.

IV. Appendices/General Information *Appendix A: Abbreviation/Acronym Key*

CDAI: clinical disease activity index
COVID-19: coronavirus disease 2019
DMARD: disease-modifying antirheumatic drug
ECMO: extracorporeal membrane oxygenation
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®)	**RA** 1 mg/kg/day PO QD or divided BID	2.5 mg/kg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Cuprimine® (d-penicillamine)	**RA*** Initial dose: 125 or 250 mg PO QD Maintenance dose: 500 to 750 mg/day PO QD	1,500 mg/day
cyclosporine (Sandimmune®, Neoral®)	**RA** 2.5 to 4 mg/kg/day PO divided BID	4 mg/kg/day
hydroxychloroquine (Plaquenil®)	**RA*** Initial dose: 400 to 600 mg/day PO QD Maintenance dose: 200 to 400 mg/day PO QD	600 mg/day
leflunomide (Arava®)	**RA** Initial dose (for low risk hepatotoxicity or myelosuppression): 100 mg PO QD for 3 days Maintenance dose: 20 mg PO QD	20 mg/day
methotrexate (Trexall®, Otrexup™, Rasuvo®, RediTrex®, Xatmep™, Rheumatrex®)	**RA** 7.5 mg/week PO, SC, or IM or 2.5 mg PO Q12 hr for 3 doses/week	30 mg/week
Ridaura® (auranofin)	**RA** 6 mg PO QD or 3 mg PO BID	9 mg/day (3 mg TID)
sulfasalazine (Azulfidine®)	**RA** Initial dose: 500 mg to 1,000 mg PO QD for the first week. Increase the daily dose by 500 mg each week up to a maintenance dose of 2 g/day. Maintenance dose: 2 g/day PO in divided doses	3 g/day

Actemra® (tocilizumab)	**RA** IV: 4 mg/kg every 4 weeks followed by an increase to 8 mg/kg every 4 weeks based on clinical response SC: Weight < 100 kg: 162 mg SC every other week, followed by an increase to every week based on clinical response Weight ≥ 100 kg: 162 mg SC every week	IV: 800 mg every 4 weeks SC: 162 mg every week
Enbrel® (etanercept)	**RA** 25 mg SC twice weekly or 50 mg SC once weekly	50 mg/week
Kevzara® (sarilumab)	**RA** 200 mg SC once every two weeks	200 mg/2 weeks
Xeljanz® (tofacitinib)	**RA** 5 mg PO BID	10 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Xeljanz XR® (tofacitinib extended-release)	**RA** 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, thrombosis, higher rate of major adverse cardiovascular events (cardiovascular death, myocardial infarction and stroke), and higher rates of all-causes mortality

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 ≥ 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
	Duration of symptoms	

D	< 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

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
RA	2 mg PO QD	2 mg/day

VI. Product Availability

Tablet: 1 mg, 2 mg, 4mg

VII. References

1. Olumiant Prescribing Information. Indianapolis, IN: Eli Lilly and Company; June 2022. Available at: http://uspl.lilly.com/olumiant/olumiant.html#pi. Accessed February 10. 2024.
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/. Accessed June 27, 2022.
5. Food and Drug Adminsitration. 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, adapted from CP.PHAR.135	04.01.22	04.22
Changes: RT4: revised FDA approved indications to include treatment of alopecia and hospitalized COVID-19; removed EUA criteria for COVID-19 (Appendix H); reiterated that Olumiant is not covered for COVID-19 since it is FDA-approved for use only in the hospital setting; added alopecia areata to the list of indications for which coverage is NOT authorized, since its use is cosmetic in nature and thus a benefit exclusion; Updated logo; Template changes applied to other diagnoses/indications and continued therapy section; references reviewed and updated.		
2Q 2023 annual review: no significant changes; updated off-label dosing in Appendix B; references reviewed.	5.15.23	

2Q 2024 annual review: added Bimzelx, Zymfentra, Omvoh, Wezlana, Sotyktu, Tofidence, and Velsipity to section III.B; references reviewed and updated.	5.14.24	

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.