

Clinical Policy: Baricitinib (Olmiant)

Reference Number: CP.PHAR.135

Effective Date: 07.24.18

Last Review Date: 05.20

Line of Business: Medicaid

[Revision Log](#)

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

Description

Baricitinib (Olmiant[®]) is Janus kinase (JAK) inhibitor.

FDA Approved Indication(s)

Olmiant 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 Olmiant 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 Olmiant is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria**A. 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[®], Kevzara[®], Xeljanz[®]/Xeljanz XR[®];

**Prior authorization is required for Enbrel, Kevzara, and Xeljanz/Xeljanz XR*

6. Documentation of baseline clinical disease activity index (CDAI) score (*see Appendix F*);
7. Dose does not exceed 2 mg per day (1 tablet per day).

Approval duration: 6 months

B. 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. Rheumatoid Arthritis (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
 - a. Member is responding positively to therapy as evidenced by a decrease in CDAI score since baseline (*see Appendix F*);
2. 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

| | |
|---|----------------------------|
| DMARD: disease-modifying antirheumatic drug | MTX: methotrexate |
| FDA: Food and Drug Administration | RA: rheumatoid arthritis |
| JAK: Janus kinase | 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 |
| Cuprimine [®] (d-penicillamine) | RA* <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 |
| cyclosporine (Sandimmune [®] , Neoral [®]) | RA 2.5 to 4 mg/kg/day PO divided BID | 4 mg/kg/day |
| hydroxychloroquine (Plaquenil [®]) | RA* <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 [®]) | RA 100 mg PO QD for 3 days, then 20 mg PO QD | 20 mg/day |
| methotrexate (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 2 g/day PO in divided doses | 3 g/day |
| 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 |
| 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 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.
- 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) <i>and</i> negative anti-citrullinated protein antibody (ACPA) | 0 |
| | Low positive RF <i>or</i> low positive ACPA <i>* Low: < 3 x upper limit of normal</i> | 2 |
| | High positive RF <i>or</i> high positive ACPA <i>* High: ≥ 3 x upper limit of normal</i> | 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 normal 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 |

V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|------------|----------------|--------------|
| RA | 2 mg PO QD | 2 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.

| 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 |

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.

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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.

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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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