Clinical Policy Title:	baricitinib
Policy Number:	RxA.740
Drug(s) Applied:	Olumiant®
Original Policy Date:	04/18/2022
Last Review Date:	04/18/2022
Line of Business Policy Applies to:	All lines of business

Background

Baricitinib (Olumiant®) is a Janus kinase (JAK) inhibitor. It 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 blockers.

Limitation of Use: Olumiant® is not recommended for use in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
baricitinib (Olumiant®)	RA	2 mg orally once daily Moderate Renal Impairment: Reduce dose to 1 mg once daily.	2 mg/day

Dosage Forms

- Tablets: 2 mg, 1 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Rheumatoid Arthritis (must meet all):

1. Diagnosis of Rheumatoid Arthritis (RA);
2. Prescribed by or in consultation with a rheumatologist;
3. Member is ≥ 18 years;
4. Trial and failure of a ≥ 3 months of at least one conventional systemic therapy (methotrexate [MTX], sulfasalazine, leflunomide, hydroxychloroquine) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;

*Exception: If one biologic DMARD that is FDA-approved for rheumatoid arthritis has been previously tried, then trial of a conventional systemic agent is not required;

5. Member meets both (a and b):
   a. Trial and failure of at least two (2) of the following agents: Humira®, Cimzia®, Rinvoq®, Simponi®/ Simponi Aria®, or Xeljanz®/ XR unless contraindicated or clinically significant adverse effects are experienced;
      Exception: If a total of two TNF inhibitors (Humira®, Cimzia®, Simponi®/ Simponi Aria®, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required;
   b. Trial and failure of both Actemra® and Orencia® unless contraindicated or clinically significant adverse effects are experienced;
6. Dose does not exceed 2 mg per day.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

A. Rheumatoid Arthritis (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 2 mg per day.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
DMARDs: Disease-Modifying Antirheumatic Drugs
FDA: Food and Drug Administration
JAK: Janus kinase
TNF: Tumor necrosis factor
MTX: Methotrexate
RA: Rheumatoid Arthritis

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
azathioprine (Azasan®, Imuran®)	**RA:** 1 mg/kg/day orally once daily or divided twice daily	2.5 mg/kg/day
d-penicillamine (Cuprimine®)	**RA (off-label)** Initial dose: 125 or 250 mg orally once daily Maintenance dose: 500 – 750 mg/day orally once daily	1,500 mg/day
cyclosporine (Sandimmune®, Neoral®)	**RA:** 2.5 – 4 mg/kg/day orally divided twice daily	RA: 4 mg/kg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
hydroxychloroquine (Plaquenil®)	**RA (off-label)** Initial dose: 400 – 600 mg/day orally once daily Maintenance dose: 200 – 400 mg/day orally once daily	600 mg/day
leflunomide (Arava®)	**RA:** 100 mg orally once daily for 3 days, then 20 mg orally once daily	**RA**: 20 mg/day
methotrexate	**RA:** 7.5 mg/week orally, subcutaneous, or intramuscular or 2.5 mg orally every 12 hr for 3 doses/week	30 mg/week
Ridaura®	**RA:** 6 mg orally once daily or 3 mg orally twice daily	9 mg/day (3 mg three times daily)
sulfasalazine (Azulfidine®)	**RA:** 2 g/day orally in divided doses	RA: 3 g/day
Biologic DMARDs		
Humira®	**RA**: 40 mg subcutaneously every other week Some patients with RA not receiving concomitant methotrexate may benefit from increasing the frequency to 40 mg every Week or 80 mg every other week	**RA**: 40 mg/week
infliximab (Remicade®) Renflexis®, Inflectra®, Avsola®	**RA:** In conjunction with MTX Initial dose: 3 mg/kg intravenous at weeks 0, 2 and 6 Maintenance dose: 3 mg/kg intravenous every 8 weeks Some patients may benefit from increasing the dose up to 10 mg/kg or treating as often as every 4 weeks	**RA:** 10 mg/kg every 4 weeks
Simponi Aria®	**RA:** Initial dose: 2 mg/kg IV at weeks 0 and 4 Maintenance dose: 2 mg/kg intravenous every 8 weeks	**RA**: 2 mg/kg every 8 weeks
Xeljanz® / Xeljanz® oral Solution, Xeljanz® XR	Xeljanz®: **RA**: 5 mg orally twice daily RA: monotherapy or use in combination with nonbiologic disease-modifying antirheumatic drugs Xeljanz® XR: **RA**: 11 mg orally once daily	Xeljanz®: **RA:** 10 mg/day Xeljanz® XR: 11 mg/day
Kevzara®	**RA:** 200 mg subcutaneous once every two weeks	200 mg/2 Weeks
Kineret®	**RA:** 100 mg subcutaneous once daily	100 mg/day
Olumiant®	**RA:** 2 mg orally once daily	2 mg/day
Cimzia®	**RA:** Initial dose: 400 mg subcutaneous at 0, 2, and 4 weeks. Maintenance dose: 200 mg subcutaneous every other week (or 400 mg subcutaneous every 4 weeks)	**RA:** 400 mg every 4 weeks

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Simponi®	**RA:** 50 mg subcutaneous once monthly	50 mg/month
Actemra®	**RA:** Intravenous: 4 mg/kg every 4 weeks followed by an increase to 8 mg/kg every 4 weeks based on clinical response. Subcutaneous: Weight < 100 kg: 162 mg every other week, followed by an increase to every week based on clinical response. Weight ≥ 100 kg: 162 mg every week.	**RA**: Intravenous: 800 mg every 4 weeks Subcutaneous: 162 mg every week
Rinvoq®	**RA:** 15 mg orally once daily Can be used as monotherapy or in combination with methotrexate or other non biologic DMARDs. *For use in adults who have had an inadequate response or intolerance to one or more TNF blockers	15 mg/day
Enbrel®	**RA:** 25 mg subcutaneous twice weekly or 50 mg subcutaneous once Weekly	50 mg/week

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

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None reported.

- Boxed Warning(s):
  - Serious infections, mortality, malignancies, major adverse cardiovascular events (MACE), thrombosis.

APPENDIX D: General Information

- Safety:
  - These agents are immunosuppressives and have the potential to increase the risk of infection and reactivate latent, chronic infections. They should not be administered to patients with a clinically important infection. Caution should be used in patients with chronic infections or history of recurrent infection. If patient develops a serious infection these agents should be discontinued.
  - Olumiant® is not recommended for members with severe hepatic and renal impairment.
- MTX is a pregnancy category X and is absolutely contraindicated in pregnancy and is not recommended for female patients attempting to conceive.

References

1. Olumiant® Prescribing Information. Indianapolis, IN: Eli Lilly and Company; December 2021. Available at: https://uspl.lilly.com/olumiant/olumiant.html#pi. February 11, 2022.
2. Aletaha D, Neogi T, Silman AJ, et al. 2010 Rheumatoid Arthritis Classification Criteria : an american college of rheumatology/european league against rheumatism collaborative initiative. Arthritis and Rheumatism September 2010;62(9):2569-2581. Available at: https://pubmed.ncbi.nlm.nih.gov/20872595/. Accessed February 11, 2022.
3. Lexi-Drug. Lexicomp. Wolters Kluwer. Hudson, OH. Available at: http://online.lexi.com. Accessed February 11, 2022.
4. Clinical Pharmacology [database online] powered by ClinicalKey. Tampa, FL: Elsevier, 2022. Available at: http://www.clinicalpharmacology-ip.com/. Accessed February 11, 2022.

Review/Revision History	Review/Revision Date	P&T Approval Date
RxA.592.Biologic_DMARDs was last reviewed and updated on 01/05/2022 and archived on 04/18/2022. For details, please refer to RxA.592.Biologic_DMARDs.	01/05/2022	04/18/2022
Drug specific policy for Olumiant was created based on RxA.592.Biologic_DMARDs 1. Dosing Information, Dosing Regimen: Updated to include renal impairment dosing information for indication RA. 2. Initial Approval Criteria I.A.5: Updated to remove prior trial and failure criteria "Failure of two (2) of the following, each used for ≥ 3 months, unless contraindicated or clinically significant adverse effects are experienced: Humira®, Cimzia®, Inflectra®, Rinvoq™, Renflexis™, Simponi®, Simponi Aria®, or Xeljanz®/ Xeljanz XR®." 3. Initial Approval Criteria I.A.5: Updated to include new trial and failure criteria "Member meets both (a and b): • Trial and failure of at least two (2) of the following agents: Humira®, Cimzia®, Rinvoq®, Simponi®/ Simponi Aria®, or Xeljanz®/ XR unless contraindicated or clinically significant adverse effects are experienced; Exception: If a total of two TNF inhibitors (Humira®, Cimzia®, Simponi®/ Simponi Aria®, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required; • Trial and failure of both Actemra® and Orencia® unless contraindicated or clinically significant adverse effects are experienced"	02/11/2022	04/18/2022

4. Appendix B, Drug Name: Updated to include brand-name therapeutic alternative of other biological DMARDs. 5. Appendix C, Boxed Warnings: Updated to include new boxed warning mortality and major adverse cardiovascular events (MACE). 6. Appendix D, General Information: Updated to remove information regarding: (a, b, c and d) a. Safety information regarding Olumiant use. b. Rheumatoid Arthritis; c. Definition of failure of MTX or DMARDs; d. Examples of positive response to therapy References were reviewed and updated. 7. References were reviewed and updated.		