Clinical Policy Title:	baricitinib
Policy Number:	RxA.740
Drug(s) Applied:	Olumiant®
Original Policy Date:	04/18/2022
Last Review Date:	01/01/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

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. Minimum duration of a 3-month trial and failure to one conventional systemic therapy (methotrexate [MTX], sulfasalazine, leflunomide, hydroxychloroquine) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. Member meets both (a and b):
   a. Trial and failure of at least two (2) of the following agents: adalimumab (adalimumab-adaz, Amjevita™, Hadlima, Humira, Yusimry), Cimzia®, Enbrel®, Rinvoq®*, Simponi®/ Simponi Aria®, or Xeljanz®/ XR* unless contraindicated or clinically significant adverse effects are experienced;
   b. Trial and failure of both Actemra® and Orencia® unless contraindicated or clinically significant adverse effects are experienced;

Approval Duration

All Lines of Business (except Medicare): 12 months

B. Coronavirus-19 Infection:

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

Approval duration: Not applicable

II. Continued Therapy Approval

A. Rheumatoid Arthritis (must meet all):

1. Member is currently receiving medication, excluding manufacturer samples

Approval Duration

All Lines of Business (except Medicare): 12 months

B. Coronavirus-19 Infection:

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

Approval duration: Not applicable

References

1. 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 January 01, 2024.
2. Singh H, Kumar H, Handa R, Talapatra P, Ray S, Gupta V. Use of clinical disease activity index score for assessment of disease activity in rheumatoid arthritis patients: an indian experience. Arthritis. 2011;2011:146398. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3254008/. Accessed January 01, 2024.
3. El-Haddad C, Castrejon I, Gibson KA, Yazici Y, Bergman MJ, Pincus T. MDHAQ/RAPID3 scores in patients with osteoarthritis are similar to or higher than in patients with rheumatoid arthritis: a cross-sectional study from current routine rheumatology care at four sites. RMD Open. 2017;3(1):e000391. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5708309/#:~:text=RAPID3%20is%20a%20composite%20index,comprising%20a%200%E2%80%9330%20score.&text=Higher%20scores%20indicate%20poorer%20status,near%20remission%20(%E2%89%A43). Accessed January 01, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
1. 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. 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®." 2. Initial Approval Criteria I.A.5: Updated to include new trial and failure criteria "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" 3. References were reviewed and updated.	02/11/2022	04/18/2022

Policy was reviewed: 1. Initial Approval Criteria, I.A.5.a: Updated trial and failure criteria to include drug Enbrel®. 2. Approval Criteria, I.A.5.a: Updated to remove exception about trial and failure criteria "*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." 3. Initial Approval Criteria, I.A.6: Updated to include new documentation criteria a. Clinical disease activity index (CDAI) score (see Appendix D). b. Routine assessment of patient index data 3 (RAPID3) score (see Appendix D). 4. Initial Approval Criteria, I.B: Updated to include approval criteria for indication, Coronavirus-19 Infection. 5. Initial Approval Criteria, I.C.: Updated to include approval criteria for indication, Alopecia Areata. 6. Continued Therapy Approval Criteria II.B: Updated to include approval criteria for indication, Coronavirus-19 Infection. 7. Continued Therapy Approval Criteria II.C: Updated to include approval criteria for indication, Alopecia Areata. 8. References were reviewed and updated.	10/03/2022	10/19/2022
Policy was reviewed: 1. Initial Approval Criteria I.A.5.a: Updated to add *Trial of Xeljanz/XR®, Rinvoq® requires inadequate response to one or more TNF inhibitors 2. Initial Approval Criteria I.C.7: Updated to remove Member has tried at least one of the following for alopecia areata (a or b): a. Systemic therapies (e.g., corticosteroids, methotrexate, cyclosporine) b. Topical corticosteroids 3. References were reviewed and updated.	01/05/2023	01/17/2023
Policy was reviewed: 1. Initial Approval Criteria, I.A.5.a: Updated trial and failure criteria to include new drug Amjevita™. 2. References were reviewed and updated.	04/05/2023	04/13/2023
Policy was reviewed: 1. Removed prior age criteria. 2. Removed Exception criteria from trial and failure for RA.	01/01/2024	01/01/2024

3. Updated trial and failure criteria to include Humira biosimilar. 4. Removed requirement for documentation of CDAI and RAPID3 score criteria. 5. Removed prior dosing criteria. 6. Updated approval duration. 7. Removed Alopecia Areata indication. 8. Removed reauthorization requirement for positive response to therapy. 9. References were reviewed and updated.		