Clinical Policy Title:	tofacitinib
Policy Number:	RxA.749
Drug(s) Applied:	Xeljanz®, Xeljanz® XR, Xeljanz® oral solution
Original Policy Date:	04/18/2022
Last Review Date:	03/15/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

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 (RA) (must meet all)**:**

1. Diagnosis of RA;
2. Prescribed by or in consultation with a rheumatologist;
3. Trial and failure of a ≥ 3 months of at least one conventional systemic therapy (methotrexate [MTX], sulfasalazine, leflunomide, hydroxychloroquine), unless contraindicated or clinically significant adverse effects are experienced;
4. Inadequate response or intolerance to one preferred TNF inhibitor: adalimumab (adalimumab-adaz, Amjevita™, Hadlima, Humira, Yusimry), Cimzia, Enbrel, Simponi/Simponi Aria;

Approval Duration
All Lines of Business (except Medicare): 12 months

B. Psoriatic Arthritis (PsA) (must meet all)**:**

1. Diagnosis of PsA;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Inadequate response or intolerance to one preferred TNF inhibitor: adalimumab (adalimumab-adaz, Amjevita™, Hadlima, Humira, Yusimry), Cimzia, Enbrel, Simponi/Simponi Aria;

Approval Duration
All Lines of Business (except Medicare): 12 months

C. Ankylosing Spondylitis (AS) (must meet all):

1. Diagnosis of active ankylosing spondylitis (AS);
2. Prescribed by or in consultation with a rheumatologist;
3. Trial and failure of at least two (2) non-steroidal anti-inflammatory drugs (NSAIDs), each used for at ≥ 4 weeks unless contraindicated or clinically significant adverse effects are experienced;
4. Inadequate response or intolerance to one preferred TNF inhibitor: (adalimumab-adaz, Amjevita™, Hadlima, Humira, Yusimry), Cimzia, Enbrel, Simponi/Simponi Aria;

Approval Duration
All Lines of Business (except Medicare): 12 months

D. Ulcerative Colitis (UC) (must meet all)**:**

1. Diagnosis of UC;
2. Prescribed by or in consultation with a gastroenterologist;
3. Member meets one of the following (a or b):
   a. Trial and failure of ≥ 3 months of at least one (1) conventional agent (azathioprine, 6-mercaptopurine, aminosalicylate) unless contraindicated or clinically significant adverse effects are experienced;
   b. Trial and failure of corticosteroids (e.g., prednisone, methylprednisolone, budesonide) unless contraindicated or significant adverse effects are experienced;
4. Inadequate response or intolerance to one preferred TNF inhibitor: adalimumab (adalimumab-adaz, Amjevita™, Hadlima, Humira, Yusimry), Simponi (*Simponi Aria not approved for UC)

Approval Duration

All Lines of Business (except Medicare): 12 months

E. Polyarticular Course Juvenile Idiopathic Arthritis (pcJIA) (must meet all):

1. Diagnosis of pcJIA;
2. Request is for Xeljanz® tablets or Xeljanz® oral solution;
3. Prescribed by or in consultation with a rheumatologist;
4. Trial and failure of a ≥ 3 months of at least one (1) conventional systemic therapy (methotrexate [MTX] or leflunomide [Arava®]), unless contraindicated or clinically significant adverse effects are experienced;
5. Inadequate response or intolerance to one preferred TNF inhibitor: adalimumab (adalimumab-adaz, Amjevita™, Hadlima, Humira, Yusimry), Enbrel, Simponi Aria;

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all):

1. Member is currently receiving or has been treated with this medication within the past 90 days, excluding manufacturer samples;

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. Boulos P, Dougados M, MacLeod SM, et al. Pharmacological Treatment of Ankylosing Spondylitis. Drugs. 2005; 65: 2111-2127. Available at: https://pubmed.ncbi.nlm.nih.gov/16225367/. Accessed January 06, 2023.
2. Braun J, Davis J, Dougados M, et al. First update of the international ASAS consensus statement for the use of anti-TNF agents in patients with ankylosing spondylitis. Ann Rheum Dis. 2006; 65:316-320. Available at: https://pubmed.ncbi.nlm.nih.gov/16096329/. Accessed January 06, 2023.
3. Braun J, van den Berg R, Baraliako X, et al. 2010 Update of the ASAS/EULAR recommendations for the management of ankylosing spondylitis. Ann Rheum Dis 2011; 70:896-904. Available at: https://pubmed.ncbi.nlm.nih.gov/21540199/. Accessed January 06, 2023.
4. Ward M, Deodhar A, Akl E, et al. American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network 2015 Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Available at: http://www.rheumatology.org. Accessed January 06, 2023.
5. Menter A, Gottlieb A, Feldman SR, et al. American Academy of Dermatology. Guidelines of care for the management

of psoriasis and psoriatic arthritis. Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol. 2008; 58:826-850. Available at: https://www.jaad.org/article/S0190-9622(08)00273-9/fulltext. Accessed January 06, 2023.
6. Menter A, Gottlieb A, Feldman, SR, et al. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 2. Psoriatic arthritis: overview and guidelines of care for treatment with an emphasis on the biologics. J Am Acad Dermatol May 2008; 58(5): 826-50. Available at: https://pubmed.ncbi.nlm.nih.gov/18423260/. Accessed January 06, 2023.
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8. Menter A, Korman, NJ, Elmets CA, et al. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies. J Am Acad Dermatol. 2009; 60:643-659. Available at: https://pubmed.ncbi.nlm.nih.gov/19217694/. Accessed January 06, 2023.
9. Zochling J, van der Heijde D, Burgos-Vargas, R, et al. ASAS/EULAR recommendations for the management of ankylosing spondylitis. Ann Rheum Dis. 2006; 65:442-452. Available at: https://pubmed.ncbi.nlm.nih.gov/16126791/. Accessed January 06, 2023.
10. Gossec L, Smolen JS, Ramiro S, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update. Ann Rheum Dis 2015; 0:1-12. doi:10.1136/annrheumdis-2015-208337. Available at: https://pubmed.ncbi.nlm.nih.gov/26644232/. Accessed January 06, 2023
11. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. American College of Rheumatology. 2019; 71(1):5-32. doi: 10.1002/art.40726. Available at: https://pubmed.ncbi.nlm.nih.gov/30499246/. Accessed January 06, 2023.

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 Xeljanz_Xeljanz XR was created based on RxA.592.Biologic_DMARDs 1. Dosing Information, Dosing Regimen, Xelianz®: Updated to include renal and hepatic impairment dosing information for indication UC, PsA, RA, AS. 2. Dosing Information, Dosing Regimen, Xelianz® XR: Updated to include renal and hepatic impairment dosing information for indication UC, PsA, RA, AS. 3. Dosing Information, Dosing Regimen, Xelianz® oral solution: Updated to include renal and hepatic impairment dosing information for indication pcJIA. 4. Initial Approval Criteria, I.A.6 and I.B.5: Updated to include new trial and failure	2/16/2022	04/18/2022

criteria Trial and failure of a ≥ 3 months of at least one (1) TNF inhibitor (Cimzia®, Humira®, Simponi®/ Simponi Aria, Enbrel®) , unless contraindicated or clinically significant affects are experienced. 5. Initial Approval Criteria I.C.6: Updated to include new trial and failure criteria Trial and failure of at least two (2) of the following agents: Humira®, Simponi®/ Simponi Aria®, Cimzia®, 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. 6. Initial Approval Criteria I.D.6: Updated to include new trial and failure criteria Trial and failure of at least two (2) of the following agents: Humira®, Simponi®/ Simponi Aria®, Cimzia®, unless contraindicated or clinically significant adverse effects are experienced. 7. Initial Approval Criteria, I.E.5: Updated to remove prior trial and failure criteria "Failure of a trial of ≥ 3 months of MTX at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced". 8. Initial Approval Criteria, I.E.5: Updated to include new trial and failure criteria Trial and failure of a ≥ 3 months of at least one (1) conventional systemic therapy (methotrexate [MTX] or leflunomide [Arava®]) 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. 9. Initial Approval Criteria, I.E.6: Updated to include new trial and failure criteria "Trial and failure of Humira® unless contraindicated or clinically significant adverse effects are experienced; *Exception: If a total of two TNF inhibitors		

(Humira, Simponi Aria, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required". 10. Appendix B, Drug Name: Updated to include brand-name therapeutic alternative of other biological DMARDs. 11. Appendix D, General Information: Updated to remove information regarding: (a, b, c and d) a. Rheumatoid Arthritis b. Ulcerative Colitis; c. Definition of failure of MTX or DMARDs; d. Examples of positive response to therapy 12. Reference were reviewed and updated.		
Policy was reviewed: 1. Initial Approval Criteria, 1.C.6: Updated trial and failure criteria from Trial and failure of at least two (2) of the following agents: Humira®, Simponi®/ Simponi Aria®, Cimzia®, 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 to Trial and failure of at least one (1) of the following agents: Humira®, Enbrel®, Simponi®/ Simponi Aria®, Cimzia®, unless contraindicated or clinically significant adverse effects are experienced. 2. Initial Approval Criteria, 1.D.6: Updated trial and failure criteria from Trial and failure of at least two (2) of the following agents: Humira®, Simponi® or Stelara® ,unless contraindicated or clinically significant adverse effects are experienced; to Trial and failure of at least one (1) of the following agents: Humira®, Simponi® ,unless contraindicated or clinically significant adverse effects are experienced. 3. Initial Approval Criteria, I.E.6: Updated trial and failure criteria to include drug Enbrel®.	10/03/2022	10/19/2022

4. Reference were reviewed and updated.		
Policy was reviewed: 1. Initial Approval Criteria, I.A.6 and I.B.5: Updated trial and failure criteria from Trial and failure of a ≥ 3 months of at least one (1) TNF inhibitor (Cimzia®, Humira®, Simponi®/ Simponi Aria, Enbrel®), unless contraindicated or clinically significant affects are experienced to Member should have inadequate response or intolerance to one or more TNF inhibitors. 2. Initial Approval Criteria, I.C.6: Updated trial and failure criteria from Trial and failure of at least one (1) of the following agents: Humira®, Enbrel®, Simponi®/ Simponi Aria®, Cimzia®, unless contraindicated or clinically significant adverse effects are experienced to Member should have inadequate response or intolerance to one or more TNF inhibitors. 3. Initial Approval Criteria, I.D.6: Updated trial and failure criteria from Trial and failure of at least one (1) of the following agents: Humira®, Simponi®, unless contraindicated or clinically significant adverse effects are experienced to Member should have inadequate response or intolerance to one or more TNF inhibitors. 4. Initial Approval Criteria, I.E.6: Updated trial and failure criteria from Trial and failure of Humira® and Enbrel® unless contraindicated or clinically significant adverse effects are experienced to Member should have inadequate response or intolerance to one or more TNF inhibitors. 5. Reference were reviewed and updated.	01/06/2023	01/17/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy Reviewed <u>Removed</u>: 1. 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;	03/15/2024	10/19/2023

2. at up to maximally indicated doses <u>Added the following:</u> 1. T/F TNF of preferred agents per indication.		
Policy was reviewed.	02/28/2024	02/28/2024