AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Xeljanz-Xeljanz XR	Page:	1 of 5
Effective Date:	2/1/2024	Last Review Date:	12/2023

Applies to:	☐Illinois	☐Florida	☒Florida Kids
	☐New Jersey	☐Maryland	☐Michigan
	☒Pennsylvania Kids	☐Virginia	☐Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Xeljanz/Xeljanz XR under the patient's prescription drug benefit.

Description:

A. FDA-Approved Indications
   1. Xeljanz/Xeljanz XR is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers.
   2. Xeljanz/Xeljanz XR is indicated for the treatment of adult patients with active psoriatic arthritis (PsA) who have had an inadequate response or intolerance to one or more TNF blockers.
   3. Xeljanz/Xeljanz XR is indicated for the treatment of adult patients with active ankylosing spondylitis (AS) who have had an inadequate response or intolerance to one or more TNF blockers.
   4. Xeljanz/Xeljanz XR is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response or intolerance to one or more TNF blockers.
   5. Xeljanz/Xeljanz Oral Solution is indicated for the treatment of active polyarticular course juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older who have had an inadequate response or intolerance to one or more TNF blockers.

B. Compendial Uses
   1. Non-radiographic axial spondyloarthritis
   2. Oligoarticular juvenile idiopathic arthritis
   3. Immune checkpoint inhibitor related toxicity

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Non-Preferred:
Xeljanz
Xeljanz XR
Xeljanz Oral Solution

Policy/Guideline:

Documentation for all indications:
The patient is unable to take Rinvoq and TWO additional preferred products (a preferred adalimumab product, Enbrel), where indicated, for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.

Documentation:

A. **Articular juvenile idiopathic arthritis (JIA)**
   1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.
   2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

Prescriber Specialty:
This medication must be prescribed by or in consultation with one of the following:

A. Articular juvenile idiopathic arthritis: rheumatologist

Criteria for Initial Approval:

A. Articular juvenile idiopathic arthritis (JIA)
   1. Authorization of 12 months may be granted for members 2 years of age or older for treatment of active articular juvenile idiopathic arthritis when the member has experienced an inadequate response or intolerance to at least one TNF inhibitor.

   2. Authorization of 12 months may be granted for members 2 years of age or older who have previously received a biologic (other than a TNF inhibitor) or targeted synthetic drug indicated for active articular juvenile idiopathic arthritis.

Continuation of Therapy:

A. Articular juvenile idiopathic arthritis (JIA)
   Authorization of 12 months may be granted for all members 2 years of age and older (including new members) who are using the requested medication for active articular juvenile idiopathic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

1. Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
2. Number of joints with limitation of movement
3. Functional ability

Other Criteria:
Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [PPD], an interferon-release assay [IGRA], or a chest x-ray)* within 6 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

*If the screening testing for TB is positive, there must be further testing to confirm there is no active disease. Do not administer the requested drug to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested drug.

Member cannot use the requested medication concomitantly with any other biologic drugs, targeted synthetic drugs, or potent immunosuppressants such as azathioprine or cyclosporine.

Approval Duration and Quantity Restrictions:
Approval:
Initial Approval: 12 months
Renewal Approval: 12 months

Quantity Level Limit:
Xeljanz 5 mg tablet: 60 tablets per 30 days
Xeljanz 10 mg tablet: 60 tablets per 30 days
Xeljanz XR 11 mg tablet: 30 tablets per 30 days
Xeljanz XR 22 mg tablet: 30 tablets per 30 days
Xeljanz oral solution 1 mg/mL: 240 mL (1 bottle) per 24 days

Xeljanz FDA-Recommended Dosing:
RA/PsA/pcJIA/AS:
- 5 mg twice daily (for pcJIA, if body weight ≥ 40 kg)
- Dose adjustment: reduce to 5 mg once daily for patients:
  - Receiving strong CYP3A4 inhibitors
  - Receiving a moderate CYP3A4 inhibitor with a strong CYP2C19 inhibitor (coadministration with strong CYP3A4 inducer is not recommended)

- With moderate or severe renal impairment
- With moderate hepatic impairment
  (not recommended for patients with severe hepatic impairment)

Xeljanz oral solution 1 mg/mL FDA-Recommended Dosing for pcJIA:

- 10 kg ≤ body weight < 20 kg: 3.2 mg (3.2 mL oral solution) twice daily
- 20 kg ≤ body weight < 40 kg: 4 mg (4 mL oral solution) twice daily
- Body weight ≥ 40 kg: 5 mg (5 mL oral solution) twice daily
- Dose adjustment: reduce to once daily dosing for patients:
  - Receiving strong CYP3A4 inhibitors
  - Receiving a moderate CYP3A4 inhibitor with a strong CYP2C19 inhibitor (coadministration with strong CYP3A4 inducer is not recommended)
  - With moderate or severe renal impairment
  - With moderate hepatic impairment (not recommended for patients with severe hepatic impairment)

References:

1. Xeljanz/Xeljanz XR [package insert]. New York, NY: Pfizer, Inc.; January 2022.
2. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol.* 2016;68(1)1-26.
3. Smolen JS, Landewé R, Bijlsma J, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update. *Ann Rheum Dis*. 2020;79:685-699.
4. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol*. 2011;65(1):137-174.
5. 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.* 2016;75(3):499-510.
6. Talley NJ, Abreu MT, Achkar J, et al. An evidence-based systematic review on medical therapies for inflammatory bowel disease. *Am J Gastroenterol.* 2011;106(Suppl 1):S2-S25.
7. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Arthritis Rheum*. 2018;71:5-32.
8. Rubin DT, Ananthakrishnan AN, et al. 2019 ACG Clinical Guideline: Ulcerative Colitis in Adults. *Am J Gastroenterol*. 2019;114:384-413.
9. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on June 14, 2023 from: https://www.cdc.gov/tb/topic/testing/tbtesttypes.htm.
10. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. *Gastroenterology* 2020; 158:1450.
11. Ringold S, Angeles-Han S, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. *Arthritis Care Res (Hoboken).* 2019; 71(6):717-734.

12. Aletaha D, Neogi T, Silman, et al. 2010 Rheumatoid arthritis classification criteria: an American College of Rheumatology/European League Against Rheumatism collaborative initiative. *Arthritis Rheum*. 2010;62(9):2569-81.
13. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthrit Care Res*. 2021.
14. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed June 14, 2023.
15. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. *Arthritis Rheumatol.* 2019;71(10):1599-1613. doi:10.1002/art.41042.
16. Gossec L, Baraliakos X, Kerschbaumer A. EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2019 update. *Ann Rheum Dis*. 2020;79(6):700-712.
17. van der Heijde D, Ramiro S, Landewe R, et al. 2016 Update of the international ASAS-EULAR management recommendations for axial spondyloarthritis. *Ann Rheum Dis.* 2017;0:1-14.
18. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for oligoarthritis, temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis. *Arthritis Rheumatol*. 2022;74(4):553-569.
19. Coates LC, Soriano ER, Corp N, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. *Nat Rev Rheumatol.* 2022;18(8):465-479.