Date Effective: 9/2018
Revised: 10/2019 Reviewed: 9/2018, 10/2019, 8/2020, 12/2020, 5/2021, 6/2021 Scope: Medicaid

XELJANZ (tofacitinib)
XELJANZ XR (tofacitinib extended-release tablets)
XELJANZ SOLUTION (tofacitinib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

A. Moderately to severely active rheumatoid arthritis
B. Active psoriatic arthritis
C. Moderately to severely active ulcerative colitis

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INTIAL AND RENEWAL CRITERIA

For all indications:

- Prior Authorization Request is submitted by the Provider's office; AND
- Prior Authorization Request is not submitted by a pharmacy or another third party; AND
- Submission of the member's chart or medical record is required, documenting medical necessity based on the criteria corresponding to the applicable indication

III. CRITERIA FOR INITIAL APPROVAL

For all indications:

- Member has a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB). *[Note: Members who have received tofacitinib or any other biologic DMARD are exempt from requirements related to TB screening in this Policy.]*
- Prior Authorization Request is submitted by the Provider's office; AND
- Prior Authorization Request is not submitted by a pharmacy or another third party; AND
- Submission of the member's chart or medical record is required, documenting medical necessity based on the criteria corresponding to the applicable indication

A. Moderately to severely active rheumatoid arthritis (RA)

Authorization of 6 months may be granted for treatment of moderately to severely active RA when any of the following criteria is met:

i. Member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to 20 mg/week).
ii. Member has an intolerance or contraindication to methotrexate (see Appendix).

B. Active psoriatic arthritis (PsA)

Authorization of 6 months may be granted for treatment of active PsA when all of the following criteria are met:

i. Member has experienced an inadequate response to at least a 3-month trial of methotrexate (MTX) or other nonbiologic disease-modifying antirheumatic drugs (DMARDs) (e.g., leflunomide, sulfasalazine, etc.)
ii. Tofacitinib is used in combination with a nonbiologic DMARD (e.g., methotrexate, leflunomide, sulfasalazine, etc.)

C. Moderately to severely active ulcerative colitis (UC)
Authorization of 6 months may be granted for treatment of moderately to severely active UC if the member has had an inadequate response or intolerance to at least one tumor necrosis factor (TNF) inhibitor.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for all members (including new members) who achieve or maintain positive clinical response after at least 3 months of therapy with tofacitinib as evidenced by low disease activity or improvement in signs and symptoms of the condition.

V. QUANTITY LIMIT

Xeljanz has a quantity limit of 2 tablets per day.
Xeljanz XR has a quantity limit of 1 tablet per day.
Xeljanz solution has a quantity limit of 10ml per day.

VI. APPENDIX

Examples of Contraindications to Methotrexate

1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia
9. Pregnancy or planning pregnancy
10. Renal impairment
11. Significant drug interaction

VII. REFERENCES

1. Xeljanz/Xeljanz XR [package insert]. New York, NY: Pfizer, Inc.; July 2021.
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, Billsma J, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2016 update. *Ann Rheum Dis.* 2017*;0*:1-18.

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.