

## PHARMACY POLICY STATEMENT

### Ohio Medicaid

DRUG NAME	Xeljanz/Xeljanz XR (tofacitinib)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include Enbrel & Humira QUANTITY LIMIT — 5 mg tablet—60 per 30 days 11 mg XR tablet—30 per 30 days
LIST OF DIAGNOSES CONSIDERED <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

Xeljanz/Xeljanz XR (tofacitinib) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

### RHEUMATOID ARTHRITIS (RA)

For **initial** authorization:

1. Member must be 18 years of age or older with moderate to severe active RA; AND
2. Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist; AND
4. Member must have tried and failed treatment with at least **two** non-biologic DMARDS (i.e. methotrexate, hydroxychloroquine, sulfasalazine, azathioprine, cyclosporine and leflunomide) or must have documented contraindication to all non-biologic DMARDS. Treatment trial duration with each non-biologic DMARD agent must have been at least 12 weeks; AND
5. Member must have tried and failed treatment with **both** Enbrel and Humira.
6. **Dosage allowed:** Xeljanz is 5 mg twice daily; Xeljanz XR is 11 mg once daily.

***If member meets all the requirements listed above, the medication will be approved for 12 months.***

For **reauthorization**:

1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***

CareSource considers Xeljanz/Xeljanz XR (tofacitinib) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Alopecia

- Dry eye disease
- Inflammatory bowel diseases (Crohn's disease and ulcerative colitis)
- Prevention of organ transplant rejection
- Psoriasis
- Psoriatic arthritis

DATE	ACTION/DESCRIPTION
05/10/2017	New policy for Xeljanz/Xeljanz XR created. Policy SRx-0042 archived. For diagnosis of RA: trial of Humira required. List of diagnoses considered not medically necessary was added.

References:

1. Xeljanz [package insert]. New York, NY: Pfizer; February, 2016.
2. American College of Rheumatology. Guidelines for the management of rheumatoid arthritis: American College of Rheumatology Ad Hoc Committee on Clinical Guidelines. Arthritis Rheuma. 1996;39(5):713-723.
3. Fleischmann R, Kremer J, Cush J, et al. Placebo-controlled trial of tofacitinib monotherapy in rheumatoid arthritis. N Engl J Med. 2012b;367(6):495-507.
4. Singh JA, Furst DE, Beharat A, et al. 2012 Update the 2008 American College of Rheumatology Recommendations for the Use of Disease-Modifying Antirheumatic Drugs and Biologic Agents in the Treatment of Rheumatoid Arthritis. Arthritis Care Res (Hoboken). 2012;64(5):625-639.

Effective date: 05/10/2017

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