

PHARMACY POLICY STATEMENT

Indiana 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 NOT MEDICALLY NECESSARY	Click Here

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.

PSORIATIC ARTHRITIS (PsA)

For **initial** authorization:

1. Member must be 18 years of age or older; 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 or dermatologist; AND
4. Member has tried and failed treatment with **both** Enbrel and Humira; AND
5. Member has predominately non-axial disease and has tried and failed to respond to treatment with at least 8-week trial of methotrexate and NSAID.
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.

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.

ULCERATIVE COLITIS

For **initial** authorization:

1. Member is 18 years of age or older with moderate to severe active UC (e.g., total Mayo score of 6 to 12, with an endoscopy subscore of at least 2, and rectal bleeding subscore of at least 1); AND
2. Member had failed or were intolerant to at least 1 of the following treatments: oral or intravenous corticosteroids, azathioprine, 6-MP or TNF blocker; AND
3. 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
4. Member does not have presence of indeterminate colitis, microscopic colitis, ischemic colitis, infectious colitis, or clinical findings suggestive of Crohn's disease; AND
5. Medication must be prescribed by a gastroenterologist; AND
6. Member has documented trial and failure of or contraindication to Humira. Treatment failure requires at least 12 weeks of therapy without an adequate response.
7. **Dosage allowed:** 10 mg twice daily for at least 8 weeks; followed by 5 or 10 mg twice daily, depending on therapeutic response. Lowest effective dose must be used to maintain response. See package insert for details on dose adjustments. Discontinue Xeljanz after 16 weeks of treatment with 10 mg twice daily, if adequate therapeutic benefit is not achieved.

If member meets all the requirements listed above, the medication will be approved for 16 weeks.

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
- Prevention of organ transplant rejection

- Plaque psoriasis

DATE	ACTION/DESCRIPTION
05/10/2017	New policy for Xeljanz/Xeljanz XR created. Policy SRx-0042 archived. For diagnosis of RA: trial of Humira and Enbrel required. List of diagnoses considered not medically necessary was added.
02/05/2018	New indication of Psoriatic Arthritis (PsA) was added.
09/14/2018	New indication of Ulcerative Colitis was added. Requirements on axial disease type removed from PsA.

References:

1. Xeljanz [package insert]. New York, NY: Pfizer; May, 2018.
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.
5. Kornbluth A, Sachar DB, Janowitz HD, et al. Ulcerative Colitis in Adults: American College of Gastroenterology. *Am J Gastroenterol* 2010; 105:501–523; doi:10.1038/ajg.2009.727.
6. ClinicalTrials.gov. Identifier: NCT01458951. A Study To Evaluate Both The Efficacy and Safety Profile of CP-690,550 In Patients With Moderately to Severely Active Ulcerative Colitis (OCTAVE). Available at: <https://clinicaltrials.gov/ct2/show/NCT01458951?term=xeljanz&draw=2&rank=55>.
7. Pascart T et al. Comparative efficacy of tocilizumab, abatacept and rituximab after non-TNF inhibitor failure: results from a multicentre study. *Int J Rheum Dis*. 2016 Nov;19(11):1093-1102.
8. Emery P. Optimizing outcomes in patients with rheumatoid arthritis and an inadequate response to anti-TNF treatment. *Rheumatology (Oxford)*. 2012 Jul;51 Suppl 5:v22-30.
9. Remy A, et al. Clinical relevance of switching to a second tumour necrosis factor-alpha inhibitor after discontinuation of a first tumour necrosis factor-alpha inhibitor in rheumatoid arthritis: a systematic literature review and meta-analysis. *Clin Exp Rheumatol*. 2011 Jan-Feb;29(1):96-103.

Effective date: 01/01/2019

Revised date: 09/14/2018