CareSource

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) QUANTITY LIMIT— see **Dosage allowed** below
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Xeljanz/Xeljanz XR (tofacitinib) is a **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)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist or dermatologist; AND
4. Member has predominately non-axial disease (e.g., peripheral synovitis or dactylitis or nail involvement) and has tried and failed to respond to treatment with at least 8-week trial of methotrexate and NSAID taken at the maximum recommended dosages (if unable to tolerate or has contraindication to methotrexate than 8-week trial of sulfasalazine or azathioprine or cyclosporine).
5. **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)) within 12 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.
5. **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 (UC)

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 have had a documented history of an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker (e.g., Remicade, Humira, Simponi, etc.); AND
3. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 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.
6. **Dosage allowed:** Induction: 10 mg twice daily for 8 weeks. If needed, continue 10 mg twice daily for a maximum of 16 weeks. Maintenance: 5 mg twice daily. 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 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
- Crohn’s 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.
02/26/2019	Humira and Enbrel removed from trials requirement. Initial authorization length increased to 12 months for UC. TB test allowed to be done within 12 months prior to initiation of therapy; chest x-ray option removed. References updated. Other drugs options allowed for PsA if there is an intolerance or contraindication to methotrexate.
08/06/2019	For diagnosis of UC, treatment options of immunomodulators, corticosteroids and salicylates were removed.

References:

1. Xeljanz [package insert]. New York, NY: Pfizer; July, 2019.
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: 09/26/2019
Revised date: 08/06/2019