PHARMACY POLICY STATEMENT
Ohio Medicaid

<table>
<thead>
<tr>
<th>DRUG NAME</th>
<th>Xeljanz/Xeljanz XR (tofacitinib)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BILLING CODE</td>
<td>Must use valid NDC code</td>
</tr>
<tr>
<td>BENEFIT TYPE</td>
<td>Pharmacy</td>
</tr>
<tr>
<td>SITE OF SERVICE ALLOWED</td>
<td>Home</td>
</tr>
<tr>
<td>COVERAGE REQUIREMENTS</td>
<td>Prior Authorization Required (Non-Preferred Product) Alternative preferred products include Enbrel &amp; Humira QUANTITY LIMIT—5 mg tablet—60 per 30 days 11 mg XR tablet—30 per 30 days</td>
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</tbody>
</table>

| 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 meets at least one of the following scenarios:
   a) Member has predominantly axial disease (i.e., sacroiliitis or spondylitis) as indicated by radiographic evidence;
   b) Member has shown symptoms of predominantly axial disease (i.e., sacroiliitis or spondylitis) for more than 3 months (i.e., limited spinal range of motion, spinal morning stiffness for more than 30 minutes) AND has tried and failed to respond to treatment with at least 2 prescription NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy without an adequate response;
   c) 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.**

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
- Plaque psoriasis

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
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<tbody>
<tr>
<td>05/10/2017</td>
<td>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.</td>
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<tr>
<td>02/05/2018</td>
<td>New indication of Psoriatic Arthritis (PsA) was added.</td>
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References:

Effective date: 04/04/2018
Revised date: 02/28/2018