CareSource Rxinnovations

# PHARMACY POLICY STATEMENT
## Marketplace

| DRUG NAME | Xeljanz/Xeljanz XR (tofacitinib) |
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| BENEFIT TYPE | Pharmacy |
| STATUS | Prior Authorization Required |

Xeljanz was initially approved by the FDA in 2019 for rheumatoid arthritis. Since then, it has also been granted approvals for the treatment of polyarticular course juvenile arthritis, psoriatic arthritis, ulcerative colitis and ankylosing spondylitis. Xeljanz is a Janus kinase (JAK) inhibitor. It works by inhibiting the activity of one or more of the Janus kinase family of enzymes, thereby interfering with the JAK-STAT signaling pathway.

Xeljanz/Xeljanz XR (tofacitinib) will be considered for coverage when the following criteria are met:

## Polyarticular Course Juvenile Idiopathic Arthritis (pcJIA)- Xeljanz immediate release ONLY

For **initial** authorization:
1. Member is at least 2 years of age; AND
2. Medication must be prescribed by or in consultation with a rheumatologist; AND
3. Member has a confirmed diagnosis of active pcJIA; AND
4. Member has had an 8-week trial and failure of a conventional DMARD (e.g., methotrexate, leflunomide, etc.); AND
5. Member must have a documented history of inadequate response or intolerance to a tumor necrosis factor (TNF) blocker (e.g., Remicade, Humira, Simponi); AND
6. Member does NOT have any laboratory abnormalities indicating neutropenia (ANC <1000 cells/$mm^3$), lymphopenia (ALC <500 cells/$mm^3$), or anemia (Hg < 9 g/dL); AND
7. Member has had a negative tuberculosis test within the past 12 months.
8. **Dosage allowed/Quantity limit:**
   a) 10 kg to 19 kg: 3.2 mg (3.2 mL oral solution) twice daily
   b) 20 kg to 39 kg: 4 mg (4 mL oral solution) twice daily
   c) 40 kg or higher: 5 mg (one 5 mg tablet or 5 mL oral solution) twice daily

***If all the above requirements are met, the medication will be approved for 12 months.***

For **reauthorization**:
1. Chart notes have been provided showing improvement of signs and symptoms of disease such as decreased joint swelling and pain and improved quality of life.

***If all the above requirements are met, the medication will be approved for an additional 12 months.***

## Psoriatic Arthritis (PsA)

For **initial** authorization:
1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a rheumatologist or dermatologist; AND

3. Member has a documented diagnosis of active psoriatic arthritis (PsA); AND
4. Member has met a 4-week trial of an NSAID taken at maximally tolerated doses AND a 3-month trial of a conventional DMARD agent (e.g., methotrexate, sulfasalazine, cyclosporine, etc.) unless **ONE** of the following situations is met:
   a) Conventional DMARD is **NOT** required for:
      i) Concomitant axial disease (i.e., involving sacroiliac joint and spine) or enthesitis; OR
   b) NSAID and conventional DMARD are **NOT** required for:
      i) Severe PsA (defined as having at least one of the following: erosive disease, active PsA at many sites including dactylitis or enthesitis, elevated levels of ESR or CRP, joint deformities, or major impairment in quality of life); AND
5. Member has tried and failed at least **TWO** preferred biologic DMARDs for at least 3 months each, one of which must be a TNF inhibitor; AND
6. Member does **NOT** have any laboratory abnormalities indicating neutropenia (ANC <1000 cells/$mm^3$), lymphopenia (ALC <500 cells/$mm^3$), or anemia (Hg < 9 g/dL); AND
7. Member has had a negative tuberculosis test within the past 12 months.
8. **Dosage allowed/Quantity limit:**
   a) Xeljanz: 5 mg twice daily (quantity limit: 60 tablets per 30 days)
   b) Xeljanz XR: 11 mg once daily (quantity limit: 30 tablets per 30 days)

***If all the above requirements are met, the medication will be approved for 12 months.***

For **reauthorization**:
1. Chart notes have been provided showing improvement of signs and symptoms of disease such as decreased joint swelling and pain, improved skin appearance and improved quality of life.

***If all the above requirements are met, 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; AND
2. Medication must be prescribed by or in consultation with a rheumatologist; AND
3. Member has a diagnosis of moderately to severely active RA; AND
4. Member must have a trial and failure of, or intolerance to methotrexate for 3 months;
   *Note*: If methotrexate is contraindicated, one of the following conventional DMARDs must be trialed instead: leflunomide, sulfasalazine, or hydroxychloroquine; AND
5. Member has documentation of an inadequate response to **ONE** or more tumor necrosis factor (TNF) antagonist therapies; AND
6. Member does **NOT** have any laboratory abnormalities indicating neutropenia (ANC <1000 cells/$mm^3$), lymphopenia (ALC <500 cells/$mm^3$), or anemia (Hg < 9 g/dL); AND
7. Member has had a negative tuberculosis test within the past 12 months.
8. **Dosage allowed/Quantity limit:**
   Xeljanz: 5 mg twice daily (quantity limit: 60 tablets per 30 days)
   Xeljanz XR: 11 mg once daily (quantity limit: 30 tablets per 30 days)

***If all the above requirements are met, the medication will be approved for 6 months.***

For **reauthorization**:
1. Chart notes demonstrate improvement of signs and symptoms such as fewer number of painful and swollen joints, achievement of remission and slowed progression of joint damage.

***If all the above requirements are met, 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; AND
2. Medication must be prescribed by or in consultation with a gastroenterologist; AND
3. Member has a diagnosis of moderately to severely active UC; AND
4. Member must have a documented history of inadequate response or intolerance to a tumor necrosis factor (TNF) blocker (e.g., Remicade, Humira, Simponi); AND
5. Member does **NOT** have any laboratory abnormalities indicating neutropenia (ANC <1000 cells/$mm^3$), lymphopenia (ALC <500 cells/$mm^3$), or anemia (Hg < 9 g/dL); AND
6. Member has had a negative tuberculosis test within the past 12 months.
7. **Dosage allowed/Quantity limit:**
   a) Xeljanz:
      i) Induction: 10 mg twice daily for at least 8 weeks or up to 16 weeks. Discontinue after 16 weeks if adequate therapeutic response is not achieved.
      ii) Maintenance: 5 mg twice daily.
   b) Xeljanz XR:
      i) Induction: 22 mg once daily for at least 8 weeks or up to 16 weeks. Discontinue after 16 weeks if adequate therapeutic response is not achieved.
      ii) Maintenance: 11 mg once daily.

***If all the above requirements are met, the medication will be approved for 6 months.***

For **reauthorization**:
1. Chart notes have been provided showing improvement in signs and symptoms such as clinical remission, decrease in rectal bleeding and decreased corticosteroid use.

***If all the above requirements are met, the medication will be approved for an additional 12 months.***

## Ankylosing Spondylitis (AS)

For **initial** authorization:
1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a rheumatologist; AND
3. Member has a documented diagnosis of active AS; AND
4. Member shows at least **ONE** of the following signs or symptoms of inflammation:
   a) Elevated serum C-reactive protein (CRP);
   b) Sacroiliitis on magnetic resonance imaging (MRI); AND
5. Member has had a trial and failure of **TWO** NSAIDs for 14 days each, taken at the maximum recommended dosages; AND
6. Member has tried and failed **TWO** preferred biologic DMARDs for 3 months each, one of which must be a TNF inhibitor; AND
7. Member does **NOT** have any laboratory abnormalities indicating neutropenia (ANC <1000 cells/$mm^3$), lymphopenia (ALC <500 cells/$mm^3$), or anemia (Hg < 9 g/dL); AND

8. Member has had a negative tuberculosis test within the past 12 months.
9. **Dosage allowed/Quantity limit:**
   Xeljanz: 5 mg twice daily (quantity limit: 60 tablets per 30 days)
   Xeljanz XR: 11 mg once daily (quantity limit: 30 tablets per 30 days)

***If all the above requirements are met, the medication will be approved for 6 months.***

For **reauthorization**:
1. Chart notes have been provided showing improvement of signs and symptoms of disease such as decreased morning stiffness, tenderness, or inflammatory back pain and improved quality of life.

***If all the above requirements are met, the medication will be approved for an additional 12 months.***

## CareSource considers Xeljanz/Xeljanz XR (tofacitinib) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

| 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. |
| **10/06/2020** | New diagnosis polyarticular course juvenile idiopathic arthritis (pcJIA) added. Replaced list of excluded diagnoses with the generic statement. Updated references. For all diagnoses: Removed repeat TB in reauth for all diagnoses. Added member does not have neutropenia, anemia, or lymphopenia. For PsA: Added requirement of diagnosis of PsA. Allowed coverage of axial disease with trial of NSAID. Changed length of trials to be 4 weeks of NSAID and 3 months of non-biologic DMARD. For RA: Changed the trials to require methotrexate as one of the non-biologic DMARD trials; only one trial is needed if member has poor prognostic factors. For UC: removed Mayo score in diagnosis. Removed requirement that exclude Crohn's disease symptoms. |
| **01/04/2022** | Transferred to new template. RA: Added new reference. Changed initial approval duration to 6 months (was 12 months). Edited the terminology "non-biologic" DMARD to "conventional" DMARD. Changed from requiring 2 csDMARD to just 1. Added trial and failure of TNF blocker. Added criteria for new indication of AS. Added a trial with at least one TNFi for PsA indication. |
| **06/11/2024** | Added references. PcJIA: removed that initial criteria must be met from reauthorization criteria and added examples of improvement; added trial of TNFi per label; edited the terminology "non-biologic" DMARD to "conventional" DMARD. PsA: added quantity limit; edited the terminology "non-biologic" DMARD to "conventional" DMARD. |

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| | UC: removed that initial criteria must be met from reauthorization<br>AS: changed trial of each NSAID from 4 weeks to 2 weeks for a total of 4 weeks of treatment per EULAR 22 guidelines; added that member does not have laboratory abnormalities; reduced initial authorization length from 12 months to 6 months; removed criteria requiring back pain for 3 or more months before the age of 50 and inflammation of one or both of the sacroiliac joints and added that member must have elevated CRP or sacroiliitis on MRI per EULAR 22 |

References:


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