CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Xeljanz/Xeljanz XR (tofacitinib)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
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. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
5. Member has had an adequate trial and failure of a non-biologic DMARD (e.g., methotrexate, leflunomide, etc.) for 8 weeks, unless not tolerated or contraindicated; 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).
7. **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. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided showing improvement of signs and symptoms of disease.

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. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
5. Member has met a 4-week trial of an NSAID taken at maximally tolerated doses AND a 3-month trial of a non-biologic DMARD agent (e.g., methotrexate, sulfasalazine, cyclosporine, etc.) unless **one** of the following situations is met:
   a) Non-biologic DMARD is not required for:
      i) Concomitant axial disease (i.e., involving sacroiliac joint and spine) or enthesitis; OR
   b) NSAID and non-biologic 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
6. Member has tried and failed at least two preferred biologic DMARDs for at least 3 months each, one of which must be another TNF inhibitor (same class as Humira); 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).
8. **Dosage allowed/Quantity limit:** Xeljanz is 5 mg twice daily; Xeljanz XR is 11 mg once 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 (ie. decreased joint swelling and pain, improved skin appearance, improved quality of life, etc).

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 at least 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 (60 tablets per 30 days)
   Xeljanz XR: 11 mg once daily (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 RA signs and symptoms (e.g. fewer number of painful and swollen joints, achievement of remission, slowed progression of joint damage, etc.).

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 with moderately to severely active UC; AND
2. Medication must be prescribed by or in consultation with a gastroenterologist; AND
3. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; 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).
6. **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. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided showing improvement in signs and symptoms of UC (defined as clinical remission, decrease in rectal bleeding, decreased corticosteroid use, etc.).

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 ankylosing spondylitis (AS); AND
4. Member must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
5. Member has had back pain for 3 months or more that began before the age of 50; AND
6. Current imaging results show an inflammation of one or both of the sacroiliac joints (sacroiliitis); AND
7. Member has tried and failed to respond to treatment with at least two NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy with each NSAID without an adequate response; AND
8. Member has tried and failed at least two preferred biologic DMARDs for at least 3 months each, one of which must be another TNF inhibitor (same class as Humira).

9. **Dosage allowed/Quantity limit:**
   Xeljanz: 5 mg twice daily (60 tablets per 30 days)
   Xeljanz XR: 11 mg once daily (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 (ie. decreased morning stiffness, tenderness or inflammatory back pain, improved quality of life, etc).

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.

References:

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