Xeljanz (tofacitinib immediate-release), Xeljanz XR (tofacitinib extended-release), Xeljanz Oral Solution (tofacitinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Xeljanz (tofacitinib immediate-release) tablets Xeljanz XR (tofacitinib extended-release) tablets Xeljanz Oral Solution (tofacitinib)	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Xeljanz (tofacitinib immediate-release) tablets or Xeljanz XR (tofacitinib extended-release) tablets may be approved for the following:

I. Rheumatoid arthritis (RA) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe RA; **AND**
   B. Documentation is provided that individual has had an inadequate response to methotrexate titrated to maximally tolerated dose (ACR 2021); **OR**
   C. Documentation is provided that if methotrexate is not tolerated , individual has had an inadequate response to or is intolerant of other conventional therapy (sulfasalazine, leflunomide, or hydroxychloroquine); **OR**
   D. Documentation is provided that individual has a contraindication to methotrexate, sulfasalazine, leflunomide, and hydroxychloroquine;
   AND
   E. Documentation is provided that individual has had a trial and inadequate response or intolerance to one or more tumor necrosis factor (TNF) antagonist agents;
   AND
   F. Individual has had a trial and inadequate response or intolerance to ONE (1) preferred agent [Current preferred agent includes – Rinvoq (upadacitinib). Medication samples/coupons/discount cards are excluded from consideration as a trial.;
      AND
      1. Documentation is provided describing the nature of the inadequate response or intolerance for each product tried;
         OR
      2. Documentation is provided that a completed FDA MedWatch Adverse Event Reporting Form has been submitted to the FDA for each product tried;
   OR
   G. Documentation is provided that individual has been receiving and is maintained on a stable dose of Xeljanz (tofacitinib immediate-release) or Xeljanz XR (tofacitinib extended-release). Medication samples/coupons/discount cards are excluded from

consideration as a trial.;

OR

II. Psoriatic arthritis (PsA) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe PsA; **AND**
   B. Documentation is provided that individual has had an inadequate response to or is intolerant of conventional therapy [nonbiologic disease modifying anti-rheumatic drugs (DMARDs) (such as methotrexate, sulfasalazine, cyclosporine, leflunomide)]; **OR**
   C. Individual has a contraindication to methotrexate, sulfasalazine, cyclosporine and leflunomide;

   AND

   D. Individual has had a trial and inadequate response or intolerance to one or more tumor necrosis factor (TNF) antagonist agents;

   AND

   E. Documentation is provided that individual has had a trial and inadequate response or intolerance to ONE (1) preferred agent [Current preferred agent includes – Rinvoq (upadacitinib). Medication samples/coupons/discount cards are excluded from consideration as a trial.;

      AND

      1. Documentation is provided describing the nature of the inadequate response or intolerance for each product tried;

         OR

      2. Documentation is provided that a completed FDA MedWatch Adverse Event Reporting Form has been submitted to the FDA for each product tried;

   OR

   F. Documentation is provided that individual has been receiving and is maintained on a stable dose of Xeljanz (tofacitinib immediate-release) or Xeljanz XR (tofacitinib extended-release). Medication samples/coupons/discount cards are excluded from consideration as a trial;

OR

III. Ulcerative colitis (UC) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe UC; **AND**
   B. Documentation is provided that individual has had an inadequate response to or is intolerant of conventional therapy (such as 5-aminosalicylic acid products, systemic corticosteroids, or immunosuppressants [such as thiopurines]); **OR**
   C. Individual has a contraindication to 5-ASA products or systemic corticosteroids or thiopurines;

      AND

   D. Individual has had a trial and inadequate response or intolerance to one or more tumor necrosis (TNF) antagonist agents; **AND**
   E. Documentation is provided that individual has had a trial and inadequate response or intolerance to ONE (1) preferred agent [Current preferred agent includes – Rinvoq (upadacitinib). Medication samples/coupons/discount cards are excluded from consideration as a trial.;

      AND

      1. Documentation is provided describing the nature of the inadequate response or intolerance for each product tried;

OR

2. Documentation is provided that a completed FDA MedWatch Adverse Event Reporting Form has been submitted to the FDA for each product tried;

OR

F. Documentation is provided that individual has been receiving and is maintained on a stable dose of Xeljanz (tofacitinib immediate-release) or Xeljanz XR (tofacitinib extended-release). Medication samples/coupons/discount cards are excluded from consideration as a trial;

OR

IV. Ankylosing spondylitis (AS) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe AS; **AND**
   B. Documentation is provided that individual has had an inadequate response to or is intolerant of conventional therapy [such as NSAIDs or nonbiologic DMARDs (such as sulfasalazine)]; **OR**
   C. Individual has a contraindication to NSAIDs or sulfasalazine; **AND**
   D. Individual has had a trial and inadequate response or intolerance to one or more tumor necrosis factor (TNF) antagonist agents; **AND**
   E. Documentation is provided that individual has had a trial and inadequate response or intolerance to ONE (1) preferred agent [Current preferred agent includes – Rinvoq (upadacitinib). Medication samples/coupons/discount cards are excluded from consideration as a trial.;

      AND

      1. Documentation is provided describing the nature of the inadequate response or intolerance for each product tried;

      OR

      2. Documentation is provided that a completed FDA MedWatch Adverse Event Reporting Form has been submitted to the FDA for each product tried;

   OR

   F. Documentation is provided that individual has been receiving and is maintained on a stable dose of Xeljanz (tofacitinib immediate-release) or Xeljanz XR (tofacitinib extended-release). Medication samples/coupons/discount cards are excluded from consideration as a trial.

OR

V. Immunotherapy-related toxicities when each of the following criteria are met (NCCN 2A):
   A. Individual is undergoing immune checkpoint inhibitor therapy for a cancer diagnosis; **AND**
   B. Individual is experiencing moderate to severe diarrhea or colitis as a result of immune checkpoint inhibitor treatment; **AND**
   C. Symptoms persist despite treatment with steroids and biologics (infliximab and/or vedolizumab).

Initial requests for Xeljanz (tofacitinib) tablets or Xeljanz (tofacitinib) Oral Solution may be approved for the following:

I. Polyarticular Juvenile Idiopathic Arthritis (PJIA) when each of the following criteria are met:

A. Individual is 2 years of age or older with moderate to severe PJIA; **AND**
B. Individual has had an inadequate response to or is intolerant of conventional therapy [nonbiologic DMARDS (such as methotrexate)]; **OR**
C. Individual has a contraindication to methotrexate;

AND

C. Individual has had a trial and inadequate response to one or more tumor necrosis factor (TNF) antagonist agents;

Continuation requests for Xeljanz (tofacitinib immediate-release) tablets, Xeljanz (tofacitinib) Oral Solution or Xeljanz XR (tofacitinib extended-release) may be approved if the following criterion is met:

I. Documentation is provided that individual has been receiving and is maintained on a stable dose of Xeljanz/Xeljanz XR. Medication samples/coupons/discount cards are excluded from consideration as a trial.; **AND**
II. There is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease.

Xeljanz (tofacitinib immediate-release) tablets, Xeljanz (tofacitinib) Oral Solution or Xeljanz XR (tofacitinib extended-release) may not be approved for the following:

I. In combination with topical or oral JAK inhibitors, ozanimod, etrasimod, apremilast, deucravacitinib, potent immunosuppressants (such as azathioprine and cyclosporine), or any of the following biologic immunomodulators: TNF antagonists, IL-23 inhibitors, other IL-17 inhibitors, vedolizumab, ustekinumab, abatacept, IL-1 inhibitors, IL-6 inhibitors, rituximab, dupilumab, tralokinumab, or natalizumab; **OR**
II. If initiating therapy, individual has an absolute neutrophil count (ANC) less than 1000 cells/mm3, lymphocyte count less than 500 cells/mm3, or hemoglobin less than 9 g/dL; **OR**
III. Tuberculosis or other active serious infections or a history of recurrent infections [repeat testing not required for ongoing authorization]; **OR**
IV. If initiating therapy, individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention -recommended equivalent to evaluate for latent tuberculosis (unless switching therapy from another targeted immune modulator and no new risk factors); **OR**
V. Individual has severe hepatic impairment (Child Pugh class C); **OR**
VI. Individual has had a myocardial infarction or stroke while on JAK inhibitor therapy; **OR**
VII. Individual is at an increased risk of thrombosis; **OR**
VIII. Individual is using for treatment of alopecia areata.

Note: Rinvoq is the preferred Janus Kinase (JAK) inhibitor. JAK inhibitor clinical criteria require a trial and inadequate response or intolerance to one or more tumor necrosis factor (TNF) antagonist agents**.**

Note:
Xeljanz (tofacitinib) has black box warnings for serious infections, mortality, malignancy, major adverse cardiovascular events (MACE), and thrombosis. Increased risk of serious bacterial, fungal, viral, and opportunistic infections leading to hospitalization or death, including tuberculosis (TB). Interrupt treatment with Rinvoq if serious infection occurs until the infection is controlled.

Test for latent TB before and during therapy; treat latent TB prior to use. Monitor all patients for active TB during treatment, even patients with initial negative, latent TB test. Higher rate of all-cause mortality, including sudden cardiovascular death with another Janus kinase (JAK) inhibitor vs. tumor necrosis factor (TNF) blockers in rheumatoid arthritis (RA) patients. Malignancies have occurred in patients treated with Xeljanz. Higher rate of lymphomas and lung cancers with another JAK inhibitor vs. TNF blockers in RA patients. Higher rate of MACE (defined as cardiovascular death, myocardial infarction, and stroke) with another JAK inhibitor vs. TNF blockers in RA patients. Thrombosis has occurred in patients treated with Xeljanz. Increased incidence of pulmonary embolism, venous and arterial thrombosis with another JAK inhibitor vs. TNF blockers.

Key References:

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Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.