Commercial PA Criteria

Effective: February 2013

Prior Authorization: Xeljanz/Xeljanz XR

Products Affected: Xeljanz/Xeljanz XR (tofacitinib) oral tablets/Xeljanz oral solution

Medication Description: Tofacitinib inhibits Janus kinases (JAK), which are intracellular enzymes, and modulates a signaling pathway that influences the cellular processes of hematopoiesis and immune cell function. Signals in this pathway arise from cytokine or growth factor-receptor interactions on the cellular membrane. Inhibition of JAK prevents the phosphorylation and activation of Signal Transducers and Activators of Transcription (STATs), which modulate gene expression and other intracellular activity

Covered Uses:

Xeljanz/Xeljanz XR (tofacitinib) oral tablets

1. Treatment of moderate to severe rheumatoid arthritis. It may be used as monotherapy or in combination with methotrexate or other nonbiologic disease modifying antirheumatic drugs (DMARDs).
2. Treatment of psoriatic arthritis in combination with a conventional synthetic DMARD
3. Treatment of moderate to severe ulcerative colitis
4. Treatment of Ankylosing Spondylitis

Xeljanz/Xeljanz oral solution

1. Treatment of Polyarticular Course Juvenile Idiopathic Arthritis

Exclusion Criteria:

1. Concomitant use with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine.

2. Renal Transplantation

Required Medical Information:

1. Diagnosis
2. Previous medications tried/failed

Age Restrictions:

Rheumatoid Arthritis: 18 years of age or older
Psoriatic Arthritis: 18 years of age or older
Ulcerative Colitis: 18 years of age or older
Juvenile Idiopathic Arthritis: 2 years of age or older
Ankylosing Spondylitis: 18 years of age or older

Prescriber Restrictions:

1. Rheumatoid arthritis and Juvenile Idiopathic Arthritis: prescribed by, or in consultation, with a rheumatologist
2. Psoriatic arthritis: prescribed by, or in consultation, with a rheumatologist or a dermatologist

3. Ulcerative Colitis: prescribed by, or in consultation, with a gastroenterologist
4. Ankylosing Spondylitis: prescribed by, or in consultation with a rheumatologist

Coverage Duration:
Initial: 6 months
Continuation: 1 year

Other Criteria:

Initiation

1. **Ankylosing Spondylitis**
   Initial Therapy Approve if the patient meets ALL of the following criteria
   A. Patient meets ONE of the following (i **OR** ii):
      i. Patient has had a 3-month trial of at least ONE tumor necrosis factor inhibitor; **OR**
      ii. Patient has tried at least one tumor necrosis factor inhibitor but was unable to tolerate a 3-month trial; **AND**
   B. Patient has a documented failure of, or intolerance to ONE of an adalimumab product OR Enbrel
      Note: A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.

2. **Juvenile Idiopathic Arthritis (JIA)**
   Initial Therapy Approve if the patient meets ALL of the following criteria
   A. Patient has had a 3-month trial of at least one tumor necrosis factor inhibitor; **OR**
   B. Patient has tried at least one tumor necrosis factor inhibitor but was unable to tolerate a 3-month trial; **AND**
   C. Patient has a documented failure of, or intolerance to ONE of an adalimumab product OR Enbrel
      Note: A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.

3. **Psoriatic Arthritis.**
   Initial Therapy Approve if the patient meets ALL of the following criteria
   A. Patient has had a 3-month trial of at least one tumor necrosis factor inhibitor; **OR**
   B. Patient has tried at least one tumor necrosis factor inhibitor but was unable to tolerate a 3-month trial; **AND**
   C. The medication will be used in combination with methotrexate or another conventional synthetic disease-modifying antirheumatic drug (DMARD), unless contraindicated; **AND**
      Note: Examples of other conventional synthetic DMARDs include leflunomide and sulfasalazine.
   D. Patient has a documented failure of, or intolerance to ONE of an adalimumab product OR Enbrel
      Note: A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.

4. **Rheumatoid Arthritis**

Initial Therapy Approve if the patient meets ALL of the following criteria

A. Patient has had a 3-month trial of at least one tumor necrosis factor inhibitor; **OR**
B. Patient has tried at least one tumor necrosis factor inhibitor but was unable to tolerate a 3-month trial; **AND**
C. Patient has a documented failure of, or intolerance to ONE of an adalimumab product OR Enbrel
Note: A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.

5. **Ulcerative Colitis**

Initial Therapy Approve if the patient meets ALL of the following criteria

A. Patient has had a 3-month trial of at least one tumor necrosis factor inhibitor; **OR**
B. Patient has tried at least one tumor necrosis factor inhibitor but was unable to tolerate a 3-month trial; **AND**
C. Patient has a documented failure of, or intolerance to an adalimumab product
Note: A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.

Continuation

1. Patient meets all initial authorization criteria, AND
2. Patient achieves or maintains a positive clinical response after at least 6 months of therapy with Xeljanz/Xeljanz XR/Xeljanz oral solution as evidenced by low disease activity or improvement in signs and symptoms of the condition.

References:

1. Xeljanz®/Xeljanz XR [prescribing information]. New York, NY: Pfizer; December 2021.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	2/2013
2	Policy Update	CCI adopted EH Policy Template, changed continuation duration from 1 to 3 years CCI P&T Review History: 2/13, 10/13, 10/14, 11/15, 11/16, 11/17, 7/18, 11/18 CCI Revision History: 12/13, 9/14, 2/16, 4/16, 11/16, 1/18, 7/18, 8/18, 12/18, 1/19	All	6/28/2019
3	Policy Update	For Ulcerative Colitis: Added Xeljanz XR, moved from preferred to non-preferred behind Humira	Other Criteria	12/20/2019

4	Policy Update	Added Treatment of Polyarticular Course Juvenile Idiopathic Arthritis to covered uses, Added age restrictions: 2 years of age or older Added prescriber restriction: prescribed by, or in consultation, with a rheumatologist Added other criteria: Patient has documented failure or intolerance to an adequate trial of NSAID/COX-2 or steroid therapy; AND Patient has documented failure or intolerance to an adequate trial (at least 3 months) of ONE DMARD (e.g., methotrexate [oral or injectable], leflunomide, and sulfasalazine); AND Patient has a documented failure of, or intolerance to, two of the following: Enbrel, Humira, and Actemra SC	Covered Uses Age Restrictions Prescriber Restrictions Other Criteria	11/4/2020
5	Update	Added Xeljanz oral solution to products affected Clarified covered use for Xeljanz/Xeljanz XR/Xeljanz oral solution to include "Treatment of Polyarticular Course Juvenile Idiopathic Arthritis" Clarified criteria for Juvenile Idiopathic Arthritis – Removed "Patient has a documented failure of, or intolerance to two of the following: Enbrel, Humira, and Actemra SC."	Products Affected Covered Uses	2/21/2021

6	Policy Update	Clarified covered use for Psoriatic Arthritis to match FDA label added “in combination with a conventional synthetic DMARD” Added criteria to match FDA label for Rheumatoid Arthritis and Psoriatic Arthritis “Patient has a documented inadequate response or intolerance to ONE or more of the following TNF inhibitors: Enbrel or Humira” Clarified criteria for Juvenile Idiopathic Arthritis – added “Patient has a documented inadequate response or intolerance to ONE or more of the following TNF inhibitors: Enbrel or Humira” Added new indication “Ankylosing Spondylitis” to match FDA label under covered uses Added age restriction under indication Ankylosing Spondylitis “Ankylosing Spondylitis: 18 years of age or older” Added prescriber restriction for indication Ankylosing Spondylitis “Ankylosing Spondylitis: prescribed by, or in consultation with a rheumatologist” Added criteria to Ankylosing Spondylitis “1.Patient has a diagnosis of active Ankylosing Spondylitis and has had an inadequate response or intolerance to one or more of the following TNF blockers (A OR B):2. Patient has documented failure or intolerance to an adequate trial of NSAID/COX-2 or steroid therapy; AND 3. Patient has documented failure or intolerance to an adequate trial (at least 3 months) of ONE DMARD (e.g., methotrexate [oral or injectable], leflunomide, and sulfasalazine); Clarified continuation criteria to include Xeljanz Oral Solution Removed “patient meets all initial authorization criteria” from continuation criteria	Covered Uses Age Restriction Prescriber Restriction Other Criteria Continuation Criteria	2/11/22
7	Update	Added notes to criteria based on indication: Note: Members who have had a previous trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) do not need to step thru Enbrel or Humira Note: Note: Members who have had a previous trial of an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) do not need to step thru Humira	Other Criteria	4/1/2022

8	Update	In Other Criteria changed “Humira” “Adalimumab”	Other Criteria	05/11/2023
9	Update	Addition of Renal transplantation for exclusion Coverage duration updated Initial from 3 months to 6 months. Continuation from 3 years to 1 year Removed current criteria for AS/JIA/PA/RA/UC and replaced with Select criteria for implementation to label Removal of -ConnectiCare does not consider alcohol use to be a clinical reason to use Xeljanz over methotrexate. ConnectiCare does not consider needlephobia to be a clinical reason to use Xeljanz Oral Solution over injectable medications	Exclusion Coverage Duration Other Criteria	12/18/2023