Effective Date 04/2024
Last Approval/Version: 04/2024
Next Review Due By: 04/2025
Policy Number: C22209-A

Xeljanz - IL Medicaid Only

PRODUCTS AFFECTED

Xeljanz, Xeljanz XR (tofacitinib)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Rheumatoid arthritis, Psoriatic arthritis, Ankylosing spondylitis, Ulcerative colitis, Juvenile idiopathic arthritis

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review.

A. FOR ALL INDICATIONS:
   1. (a) Prescriber attests, or clinical reviewer has found, member has had a negative TB screening* or TB test result (if indicated)** within the last 12 months for initial and continuation of therapy requests
      **MOLINA REVIEWER NOTE: TB SCREENING assesses patient for future or ongoing TB exposure or risk and includes reviewing if they have been exposed to tuberculosis, if they have resided or traveled to areas of endemic tuberculosis, if patient resides or works in a congregate setting (e.g., correctional*

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facilities, long-term care facilities, homeless shelters), etc.
***MOLINA REVIEWER NOTE: TB SKIN TEST (TST, PPD) AND TB BLOOD TEST (QuantiFERON TB Gold, T-Spot) are not required or recommended in those without risk factors for tuberculosis*
OR
(b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12 months) OR that member has been cleared by an infectious disease specialist to begin treatment
AND

2. Prescriber attests member has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment
   AND
3. Member is not on concurrent treatment or will not be using requested agent in combination with other TNF-inhibitors, biologic response modifiers or other biologic DMARDs, Janus kinase Inhibitors, or Phosphodiesterase 4 inhibitors (i.e., apremilast, baricitinib) as verified by prescriber attestation, member medication fill history, or submitted documentation
   AND
4. Prescriber attests member does not have an active infection, including clinically important localized infections
   AND
5. Prescriber attests that member does NOT have absolute lymphocyte countless than 500 cells/mm^3, an absolute neutrophil count (ANC) less than 1000 cells/mm^3 or hemoglobin levels less than 9 g/dL.
   AND
6. If the request is for **Xeljanz Oral Solution**: Documentation that this member has a diagnosis of juvenile idiopathic arthritis (see section D for diagnosis specific criteria)

B. MODERATE TO SEVERE RHEUMATOID ARTHRITIS (RA)
   1. Documentation of moderate to severe RA diagnosis
      AND
   2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
      AND
   3. (a) Member is concurrently receiving methotrexate maximally tolerated dose of methotrexate and is not at goal disease activity
      OR
      (b) Member has an FDA labeled contraindication or serious side effects to methotrexate, as determined by the prescribing physician AND Member has tried one additional disease-modifying antirheumatic drug (DMARD) (brand or generic; oral or injectable) for at least 3 months
      NOTE: An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the Member has already had a 3-month trial at least one biologic. These patients who have already tried a biologic for RA are not required to "step back" and try a conventional synthetic DMARD

C. PSORIATIC ARTHRITIS (PsA):
   1. Documentation of active psoriatic arthritis
      AND
   2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
      AND
   3. (a) Documented treatment failure, serious side effects or clinical contraindication to a minimum 3-month trial of ONE of the following: Leflunomide, Methotrexate, Sulfasalazine, Cyclosporine
      OR
      (b)Documentation member has severe psoriatic arthritis [erosive disease, elevated markers of inflammation, long term damage that interferes with function, highly active disease that causes a

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major impairment in quality of life, active PsA at many sites including dactylitis, enthesitis, function-limiting PsA at a few sites or rapidly progressive disease]
OR
(c) Documentation member has severe psoriasis [PASI >12, BSA of >5-10%, significant involvement in specific areas (e.g., face, hands or feet, nails, intertriginous areas, scalp), impairment of physical or mental functioning with lower amount of surface area of skin involved]

D. MODERATE TO SEVERE ANKYLOSING SPONDYLITIS (AS):
   1. Documentation of moderate to severe ankylosing spondylitis diagnosis
      AND
   2. Documentation of a trial (generally ≥3 consecutive months) and failure to conventional therapy
      Note: Conventional treatment includes NSAID agents at maximal recommended or tolerated anti-inflammatory doses and, for prominent peripheral arthritis, methotrexate or sulfasalazine.
      AND
   3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]

E. JUVENILE IDIOPATHIC ARTHRITIS (JIA), Xeljanz oral solution only:
   1. Documented diagnosis of systemic juvenile idiopathic arthritis (SJIA) or polyarticular juvenile idiopathic arthritis (PJIA) in a pediatric member
      AND
   2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
      AND
   3. Documentation of a trial (generally ≥12 weeks) and failure to conventional therapy (e.g. NSAIDs, glucocorticoid, methotrexate, etc.)

F. ULCERATIVE COLITIS (UC):
   1. Documentation of ulcerative colitis diagnosis with evidence of moderate to severe disease activity
      AND
   2. (a) Documentation of treatment failure, serious side effects or clinical contraindication to a 2-month trial of one systemic agent (e.g., 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, a corticosteroid such as prednisone) or a TNF blocker such as Humira
      OR
      (b) Documentation of pouchitis AND the member has tried therapy with an antibiotic (e.g., metronidazole, ciprofloxacin), probiotic, corticosteroid enema [for example, Cortenema® (hydrocortisone enema, generics)], or topical mesalamine
      AND
   3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]

CONTINUATION OF THERAPY:

A. ALL INDICATIONS:
   1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation (documentation required)
      AND
   2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
      AND
   3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms [DOCUMENTATION REQUIRED]
      AND

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4. (a) Prescriber attests, or clinical reviewer has found, member has had a negative TB screening* or TB test (if indicated)** result within the last 12 months for initial and continuation of therapy requests
   **MOLINA REVIEWER NOTE: TB SCREENING assesses patient for future or ongoing TB exposure or risk and includes reviewing if they have been exposed to tuberculosis, if they have resided or traveled to areas of endemic tuberculosis, if patient resides or works in a congregate setting (e.g., correctional facilities, long-term care facilities, homeless shelters), etc.*
   ***MOLINA REVIEWER NOTE: TB SKIN TEST (TST, PPD) AND TB BLOOD TEST (QuantiFERON TB Gold, TSpot) are not required or recommended in those without risk factors for tuberculosis*
   OR
   (b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12 months) OR that member has been cleared by an infectious disease specialist to begin treatment

DURATION OF APPROVAL:
Initial authorization and continuation of therapy: 12 months

PRESCRIBER REQUIREMENTS:
UC: Prescribed by or in consultation with a board-certified gastroenterologist.
All Other Indications: Prescribed by or in consultation with a board-certified rheumatologist or dermatologist
[If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
Rheumatoid Arthritis, Psoriatic Arthritis, Ulcerative Colitis, Ankylosing Spondylitis: 18 years of age and older
Polyarticular juvenile idiopathic arthritis: 2 years of age and older

QUANTITY:
See Illinois Medicaid Drug Formulary

MAXIMUM QUANTITY LIMITS:
Xeljanz 2 tablets per day
Xeljanz XR 1 tablet per day
Xeljanz Oral Solution 10 mL per day

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Janus Kinase (JAK) Inhibitor

FDA-APPROVED USES:
Indicated for:

- Treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers.

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- Treatment of adult patients with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers.
- Treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers.
- Treatment of active polyarticular course juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older who have had an inadequate response or intolerance to one or more TNF blockers.
- Treatment of adult patients with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers.

Limitations of Use: Use of XELJANZ/XELJANZ XR/ XELJANZ Oral Solution in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

COMPENDIAL APPROVED OFF-LABELED USES:
Plaque psoriasis

NOTE TO REVIEWER: Requests for the following indications should be reviewed for approval through Molina Off-Label policy (see Background for additional information): Immunotherapy related diarrhea or colitis

APPENDIX

APPENDIX:
American College of Rheumatology (ACR) Classification Criteria for Establishing the Diagnosis of Rheumatoid Arthritis (RA)
Diagnosis of RA requires the presence of at least 4 of 7 criteria below:
1. Morning stiffness in and around joints lasting more than 1 hour.
2. Arthritis in at least 1 area in a wrist or proximal interphalangeal (PIP) joint (hands or fingers) for > 6 weeks.
3. Simultaneous swelling or fluid accumulation in 3 or more joints for > 6 weeks.
4. Symmetric (bilateral joint) involvement for > 6 weeks.
5. Presence of rheumatoid nodules.
6. Positive serum rheumatoid factor.
7. Radiographic changes typical of RA (erosion or unequivocal bony decalcification in or adjacent to the involved joint) on hand and wrist are present.

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
(Xeljanz/ Xeljanz XR (tofacitinib) is an inhibitor of Janus kinases (JAKs) indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis and psoriatic arthritis who have had an inadequate response or intolerance to methotrexate. Xeljanz immediate release is also indicated for ulcerative colitis. It is a targeted synthetic disease-modifying antirheumatic drug (DMARD) that may be used either as monotherapy or in combination with MTX or other conventional synthetic DMARDs for RA. Xeljanz/Xeljanz XR should not be used in combination with other potent immunosuppressants (e.g., azathioprine and cyclosporine) or biologic DMARDs (e.g., Actemra® [tocilizumab intravenous {IV} infusion, tocilizumab for subcutaneous {SC} injection], Kineret® [anakinra for SC injection], Orencia® [abatacept forSC injection, abatacept for IV infusion] Rituxan® [rituximab for IV infusion], or a tumor necrosis factor [TNF] inhibitor [such as Cimzia® {certolizumab pegol for SC injection}, Enbrel® {etanercept for SC injection}, Humira® {adalimumab for SC injection}, Remicade® {infliximab for IV infusion}, Simponi™ {golimumab for SC injection}, Simponi® Aria™ {golimumab for IV infusion}]). Xeljanz/Xeljanz XR inhibits JAK, an intracellular enzyme that transmits signals on the cellular membrane to influence cellular processes of hematopoiesis and immune cell function. JAKs phosphorylate and activate Signal Transducers and Activators of Transcription (STAT) which then modulate intracellular activity such as gene

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expression. The efficacy of Xeljanz over placebo was established in seven pivotal studies that included a variety of clinical scenarios, including Xeljanz as monotherapy or in combination with MTX or other DMARDs and in patients who had failed a TNF inhibitor. Efficacy studies were not required for approval of Xeljanz XR because it was determined that Xeljanz XR (11 mg once daily) is pharmacokinetically equivalent to Xeljanz 5 mg administered twice daily.

AGA Guidelines Moderate to Severe Ulcerative Colitis
Recommendations from the recent 2020 guideline update include:

- In adult outpatients with moderate to severe UC who are naïve to biologic agents, the AGA suggests using infliximab or vedolizumab rather than adalimumab, for induction of remission.
- Updated FDA recommendations (July 26, 2019) on indications for use of tofacitinib in UC recommends its use only after failure of or intolerance to TNF-a antagonists.
- In adult outpatients with moderate to severe UC who have previously been exposed to infliximab, particularly those with primary nonresponse, the AGA suggests using ustekinumab or tofacitinib rather than vedolizumab or adalimumab for induction of remission.
- In adult outpatients with moderate to severe UC, the AGA suggests against using methotrexate monotherapy for induction or maintenance of remission
- In adult outpatients with active moderate to severe UC, the AGA suggests using biologic monotherapy (TNF-a antagonists, vedolizumab, or ustekinumab) or tofacitinib rather than thiopurine monotherapy for induction of remission.
- In adult outpatients with moderate to severe UC, the AGA suggests combining TNF-a antagonists, vedolizumab or ustekinumab with thiopurines or methotrexate rather than biologic monotherapy.
- In adult outpatients with moderate to severe UC who have achieved remission with biologic agents and/or immunomodulators or tofacitinib, the AGA suggests against continuing 5-ASA for induction and maintenance of remission.

<u>Immunotherapy related diarrhea or colitis</u>
Recent NCCN guidelines include use of tofacitinib for moderate and severe diarrhea and colitis (grade 2 and above) related to immune checkpoint inhibitor therapy. If no response to treatment with steroids, consider adding infliximab or vedolizumab. For infliximab and/or vedolizumab refractory colitis, consider tofacitinib or ustekinumab. Refer to NCCN guidelines for management of immunotherapy related toxicities.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Xeljanz/Xeljanz XR/Xeljanz Oral Solution (tofacitinib) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to Xeljanz/Xeljanz XR/Xeljanz Oral Solution (tofacitinib) include: patients with hemoglobin less than 9 g/dL, absolute lymphocyte counts less than 500 cells/mm3, absolute neutrophil count (ANC) less than 1000 cells/mm3, patients with active serious infection including localized infections, concurrent use of live vaccines, patients at increased risk of thrombosis.

OTHER SPECIAL CONSIDERATIONS:
Black Box Warning for serious infections, mortality, malignancy, major adverse cardiovascular events (mace), and thrombosis.

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CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:

Xeljanz tablets 5MG
Xeljanz tablets 10MG
Xeljanz XR tablet 11MG
Xeljanz XR tablet 22MG
Xeljanz Oral Solution 1 MG/ML

REFERENCES

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SUMMARY OF REVIEW/REVISIONS	DATE
ANNUAL REVIEW COMPLETED- Notable revisions: Products Affected Required Medical Information Continuation of Therapy Off-label Use Background Appendix References	04/2024
Established tracking in new format	Q2/2023

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