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Policy Number: C2721-A

Xeljanz/Xeljanz XR (tofacitinib)

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, Ulcerative colitis, Juvenile idiopathic arthritis, Ankylosing spondylitis

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. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

FOR ALL INDICATIONS:
1. Prescriber attests member does not have an active or latent untreated infection (e.g., Hepatitis B, tuberculosis, etc.), including clinically important localized infections, according to the FDA label

AND

2. Member is not on concurrent treatment or will not be used in combination with TNF- inhibitor, biologic response modifier or other biologic DMARDs, Janus kinase Inhibitors, or Phosphodiesterase 4 inhibitor (i.e., apremilast, tofacitinib, baricitinib) as verified by prescriber attestation, member medication fill history or submitted documentation
   AND
3. Prescriber attests that member does NOT have absolute lymphocyte count less than 500 cells/mm3, an absolute neutrophil count (ANC) less than 1000 cells/mm3 or hemoglobin levels less than 9 g/dL.
   AND
4. Documentation of treatment failure or serious side effects to a trial (> 3 months) of ONE FORMULARY OR PREFERRED TNF-inhibitor
   AND
5. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or serious side effects to a majority (not more than 2) of the preferred formulary/PDL alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s).
   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)

A. MODERATE TO SEVERE RHEUMATOID ARTHRITIS:

1. Documentation of moderate to severe rheumatoid arthritis 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 currently receiving maximally tolerated dose of methotrexate and is not at goal disease activity
   OR
   (a) 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 of at least one biologic. These members who have already tried a biologic for RA are not required to "step back" and try a conventional synthetic DMARD)

B. 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
   (a) 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 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
   (b) 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]

C. 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, or a corticosteroid such as prednisone, methylprednisolone) for ulcerative colitis or will continue to take concurrently.
NOTE: A previous trial of a biologic (e.g., an adalimumab product [e.g., Humira], Simponi SC [golimumab SC injection], or Entyvio [vedolizumab IV infusion]) also counts as a trial of one systemic agent for UC
OR
b) Documentation the Member has pouchitis AND 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]

D. JUVENILE IDIOPATHIC ARTHRITIS (ACTIVE SYSTEMIC AND POLYARTICULAR):
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. (a) FOR ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS:
   i. Documentation of treatment failure, serious side effects or clinical contraindication to an adequate trial (12 weeks) of one NSAID or glucocorticoid
   AND
   ii. Documentation of treatment failure, serious side effects or clinical contraindication to an adequate trial (12 weeks) of one of the following: methotrexate, leflunomide, anakinra (Kineret), canakinumab (Ilaris), or tocilizumab (Actemra)

   OR

   (b) FOR POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS: Documentation of treatment failure, serious side effects or clinical contraindication to an adequate trial (generally ≥12 weeks) of one or more of the following: Methotrexate, hydroxychloroquine, sulfasalazine, leflunomide

E. MODERATE TO SEVERE ANKYLOSING SPONDYLITIS:
1. Documented diagnosis of ankylosing spondylitis
AND
2. Documentation of treatment failure, serious side effects or clinical contraindication to TWO NSAIDs (e.g., ibuprofen, naproxen, etodolac, meloxicam, indomethacin) for ≥3 consecutive months at maximal recommended or tolerated anti- inflammatory doses
AND
3. FOR MEMBER WITH PROMINENT PERIPHERAL ARTHRITIS: Documentation of treatment failure, serious side effects or clinical contraindication to a trial (≥3 consecutive months) of methotrexate OR sulfasalazine
AND
4. 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

AND

2. Prescriber attests to or clinical reviewer has found no evidence ~~no~~ 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
4. Prescriber attests to ongoing monitoring for development of infection (e.g., tuberculosis, Hepatitis B reactivation, etc.) according to the FDA label

DURATION OF APPROVAL:
Initial authorization: 6 months, Continuation of therapy: 12 months

PRESCRIBER REQUIREMENTS:
ULCERATIVE COLITIS (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:
RHEUMATOID ARTHRITIS, PSORIATIC ARTHRITIS, ANKYLOSING SPONDYLITIS: Xeljanz 5 mg twice daily or Xeljanz XR 11 mg once daily

ULCERATIVE COLITIS:
Induction: Xeljanz 10 mg twice daily or Xeljanz XR 22 mg once daily for 8 weeks. This dose can be continued for a maximum of 16 weeks.
NOTE: If needed, continue Xeljanz 10 mg twice daily or Xeljanz XR 22 mg once daily for a maximum of 16 weeks. Discontinue Xeljanz 10 mg twice daily or Xeljanz XR 22 mg once daily after 16 weeks if adequate therapeutic response is not achieved.
Maintenance: Xeljanz 5 mg twice daily or Xeljanz XR 11 mg once daily
NOTE: For patients with loss of response during maintenance treatment, Xeljanz 10 mg twice daily or Xeljanz XR 22 mg once daily may be considered and limited to the shortest duration, with careful consideration of the benefits and risks for the individual patient. Use the lowest effective dose needed to maintain response.

The following is applicable to requests for UC for Xeljanz 10 mg twice daily or Xeljanz XR 22 mg once daily during the maintenance period (Sands, 2019):

When requests for off-label dosing, dose escalation, or dose intensification are received, requests will be reviewed for evidence that current or standard dosing is not adequate to produce a therapeutic level of drug (e.g., pharmacokinetic failure), clinical failure or significant loss of response is present, and the requested dosing is established as safe and effective for the condition. There are certain situations where no additional amount of drug is likely to produce or recapture clinical effect because the condition is no longer responsive to the drug (e.g., pharmacodynamic failure) or the drug cannot reach the site of activity at sufficient levels. Review the following items to determine if the requested dosing is medically necessary:

1. *FDA or compendium-supported dosing and therapeutic monitoring recommendations for the drug*
   AND
2. *Member claims/adherence history*
   AND
3. *Clinical documentation of the member's response to current or standard dosing regimens (disease activity indices if commonly used in clinical practice or documentation to approximate them may be*

necessary to demonstrate the response)
AND

4. *In conjunction with documented clinical failure or loss of response or wearing off of effect, test results that demonstrate failure of current or standard dosing to reach established treatment thresholds (e.g., established therapeutic monitoring recommendations)*
   AND
5. *If applicable, documentation showing the member does not have conditions which make achieving a therapeutic level of drug unlikely even with dose intensification (e.g., dose intensification may be futile due to the presence of anti-drug antibodies, protein losing enteropathy, nephrotic syndrome, severe drug excretion or malabsorption issues, etc.)*
   AND
6. *In certain situations, documentation, or peer-to-peer determination that re-induction cannot be tried to recapture response as an alternative to long term dose escalation or intensification*

POLYARTICULAR COURSE JUVENILE IDIOPATHIC ARTHRITIS: 5 mg twice daily or weight based equivalent twice daily
10 kg to <20 kg: 3.2 mg twice daily
20 kg to <40 kg: 4 mg twice daily
40 kg or more: 5 mg twice daily

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:
Antirheumatic - Janus Kinase (JAK) Inhibitors

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
- 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:

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 for SC 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 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.

Immunotherapy related diarrhea or colitis

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: avoid initiation in patients with hemoglobin less than 9 g/dL, avoid initiation in patients with absolute lymphocyte counts less than 500 cells/mm3, avoid initiation in patients with absolute neutrophil count (ANC) less than 1000 cells/mm3, avoid use during an active serious infection including localized infections, avoid concurrent use of live vaccines, avoid use in patients at increased risk of thrombosis.

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

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed*

HCPCS CODE	DESCRIPTION
N/A	

AVAILABLE DOSAGE FORMS:
Xeljanz TABS 5MG, 10MG
Xeljanz XR TB24 11MG, 22MG
Xeljanz SOLN 1 MG/ML

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Coding/Billing Information Template Update Required Medical Information Continuation of Therapy Contraindications/Exclusions/Discontinuation References	Q4 2024

REVISION- Notable revisions: Required Medical Information Continuation of Therapy Quantity Compendial Approved Off-Labeled Uses Available Dosage Forms References	Q4 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Prescriber Requirements Quantity FDA-Approved Uses Compendial Approved Off-Labeled Uses Background Contraindications/Exclusions/Discontinuation Other Special Considerations Available Dosage Forms References	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file