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Policy Number: C22209-A

Xeljanz/Xeljanz XR (tofacitinib) IL Medicaid Only

PRODUCTS AFFECTED

XELJANZ (tofacitinib) tablets, XELJANZ XR (tofacitinib) extended-release tablets, XELJANZ (tofacitinib) Oral Solution

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.

FOR ALL INDICATIONS:

1. (a) Prescriber attests member has had a negative TB screening or TB test result within the last 12 months for initial and continuation of therapy requests
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

Drug and Biologic Coverage Criteria

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 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
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- XELJANZ/XELJANZ XR ONLY

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
AND
3. (a) Member is concurrently receiving methotrexate
OR
(b) Member tried, failed, or has an FDA labeled contraindication or intolerance 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)

B. PSORIATIC ARTHRITIS (PsA)- XELJANZ/XELJANZ XR ONLY

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
AND
3. (a) Documented treatment failure with or FDA labeled 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 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),

Drug and Biologic Coverage Criteria

impairment of physical or mental functioning with lower amount of surface area of skin involved]

C. ANKYLOSING SPONDYLITIS- XELJANZ/XELJANZ XR ONLY

1. Documentation of active ankylosing spondylitis diagnosis
AND
2. Documentation of a trial and failure to conventional therapy and at least ONE TNF blocker
Note: Conventional treatment includes non-steroidal anti-inflammatory agents 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

D. POLYARTICULAR COURSE JUVENILE IDIOPATHIC ARTHRITIS- XELJANZ/XELJANZ Oral Solution ONLY

1. Member must have a diagnosis of active polyarticular course juvenile idiopathic arthritis (pcJIA) in children 2 years of age or older
AND
2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal
AND
3. Documentation of a trial and failure to conventional therapy (e.g. NSAIDs, methotrexate) and at least ONE TNF blocker

E. ULCERATIVE COLITIS- XELJANZ/XELJANZ XR ONLY

1. Member must have a diagnosis of moderate to severely active ulcerative colitis (UC)
AND
2. Documentation of a trial and failure to at least ONE TNF blocker
AND
3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal

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

DURATION OF APPROVAL:

12 months

PRESCRIBER REQUIREMENTS:

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Drug and Biologic Coverage Criteria

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 are required initially and at least once annually.

AGE RESTRICTIONS:

Xeljanz/Xeljanz Oral Solution FDA approved for ages 2 and older only for pcJIA

Xeljanz/Xeljanz XR FDA approved for ages 18 and older for RA, PsA, AS, and UC

QUANTITY:

See Illinois Medicaid Drug Formulary or use maximum quantity per FDA label

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) Inhibitor

FDA-APPROVED USES:

XELJANZ/XELJANZ XR indicated for the treatment of adult patients:

with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more TNF blockers; with active psoriatic arthritis (PsA) who have had an inadequate response or intolerance to one or more TNF blockers; with active ankylosing spondylitis (AS) who have had an inadequate response or intolerance to one or more TNF blockers; with moderately to severely active ulcerative colitis (UC), who have an inadequate response or intolerance to one or more TNF blockers

XELJANZ/XELJANZ Oral Solution: indicated for the 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

COMPENDIAL APPROVED OFF-LABELED USES:

None

APPENDIX

None

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.,

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Drug and Biologic Coverage Criteria

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.

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. The following contraindications or exclusions to Xeljanz therapy: Hypersensitivity to Xeljanz or any ingredient in the formulation, Severe hepatic impairment (Child- Pugh Class C), Active infection, including localized infections.

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:

NoneBlack Box Warning for serious infections, mortality, malignancy, major adverse cardiovascular events (mace), and thrombosis.

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:

Drug and Biologic Coverage Criteria

Xeljanz tablets 5MG
Xeljanz tablets 10MG
Xeljanz XR tablet 11MG
Xeljanz XR tablet 22MG
Xeljanz Oral Solution 1 mg/mL tofacitinib oral solution (240ml)

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Drug and Biologic Coverage Criteria

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SUMMARY OF REVIEW/REVISIONS	DATE
Q2 2023 Established tracking in new format	Historical changes on file