Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib extended release tablets)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Xeljanz and Xeljanz XR drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies.

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate.
2. Adult patients with active psoriatic arthritis who have had an inadequate response or intolerance to methotrexate or other DMARDs.
3. Adult patients with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to TNF blockers.

POLICY

Criteria for Initial Approval

A) **Moderately to severely active rheumatoid arthritis (RA)**
   1. Authorization of 12 months may be granted to members who have previously received a biologic or targeted synthetic DMARD (e.g., Rinvvoq, Olumiant) indicated for the treatment of moderately to severely active rheumatoid arthritis.

2. Authorization of 12 months may be granted for treatment of moderately to severely active RA when any of the following criteria is met:
    a. Member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to 20 mg/week).
    b. Member has an intolerance or contraindication to methotrexate (see Appendix A).

B) **Active psoriatic arthritis (PsA)**
1. Authorization of 12 months may be granted to members who have previously received Otezla or any biologic indicated for the treatment of active psoriatic arthritis when used in combination with a nonbiologic DMARD (e.g., methotrexate, leflunomide, sulfasalazine, etc.).
2. Authorization of 12 months may be granted for treatment of active PsA when all of the following criteria are met:
    a. Member has experienced an inadequate response to at least a 3-month trial of methotrexate (MTX) or other nonbiologic disease-modifying antirheumatic drugs (DMARDs) (e.g., leflunomide, sulfasalazine, etc.)
    b. Xeljanz/Xeljanz XR is used in combination with a nonbiologic DMARD (e.g., methotrexate, leflunomide, sulfasalazine, etc.)

C) **Moderately to severely active ulcerative colitis (UC)**
1. Authorization of 12 months may be granted for members who have previously received a biologic indicated for the treatment of moderately to severely active ulcerative colitis.
2. Authorization of 12 months may be granted for members who have been hospitalized for fulminant UC (e.g., continuous bleeding, severe toxic symptoms including, fever and anorexia).
3. Authorization of 4 months may be granted for the treatment of moderately to severely active ulcerative colitis when the following criteria is met:
    a) The member has had an inadequate response, intolerance or contraindication to at least one tumor necrosis factor inhibitor (TNF-i)
    b) The lowest effective dose will be utilized with the higher induction dose (i.e.,10 mg twice-daily or 22 mg once daily) being limited to the shortest duration needed

Note: Submission of chart notes detailing the outcomes of treatment, intolerable adverse event(s) experienced, contraindication(s), or exclusion(s) to treatment(s) is required (where applicable).

<u>Continuation of Therapy</u>

A) Authorization of 24 months may be granted for all members (including new members) who meet the following:
1. The member meets all initial authorization criteria
2. The member has achieved or maintained a positive clinical response after at least 3 months of therapy with Xeljanz/Xeljanz XR as evidenced by low disease activity or improvement in signs and symptoms of the condition
3. The maintenance dose being used is 5 mg twice daily or 11 mg once daily

B) Authorization of 6 months may be granted for all members (including new members) who meet the following:
1. The member meets all initial authorization criteria
2. The member has achieved or maintained a positive clinical response after at least 3 months of therapy with Xeljanz/Xeljanz XR as evidenced by low disease activity or improvement in signs and symptoms of the condition
3. The member has a diagnosis of moderately to severely active ulcerative colitis
4. The maintenance dose being used is 10 mg twice daily or 22 mg once daily and documentation demonstrates that the member developed a loss of response with lower dose and the treatment plan is to use the higher dose for the shortest duration, with careful consideration of the benefits and risks for the individual patient

<u>Other</u>

For all indications: Member has had a documented negative TB test (which can include a tuberculosis skin test [PPD], an interferon-release assay [IGRA], or a chest x-ray)* within 6 months of initiating therapy for

persons who are naïve to biologic DMARDs and repeated yearly for members with risk factors** for TB that are continuing therapy with biologics.

* If the screening testing for TB is positive, there must be documentation of further testing to confirm there is no active disease. Do not administer tofacitinib to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of tofacitinib.

** Risk factors for TB include: Persons with close contact to people with infectious TB disease; persons who have recently immigrated from areas of the world with high rates of TB (e.g., Africa, Asia, Eastern Europe, Latin America, Russia); children less than 5 years of age who have a positive TB test; groups with high rates of TB transmission (e.g., homeless persons, injection drug users, persons with HIV infection); persons who work or reside with people who are at an increased risk for active TB (e.g., hospitals, long-term care facilities, correctional facilities, homeless shelters).

For all indications: Member cannot use Xeljanz, Xeljanz XR concomitantly with biologic DMARDs (e.g., adalimumab, infliximab), targeted synthetic DMARDS, or potent immunosuppressants (i.e., azathioprine, cyclosporine).

Xeljanz and Xeljanz XR are considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

Trade Name	Generic Name	Quantity Limit
Xeljanz 5mg	tofacitinib	60 tablets per 30 days
Xeljanz 10mg*	tofacitinib	60 tablets per 30 days
Xeljanz XR 11mg	tofacitinib	30 tablets per 30 days
Xeljanz XR 22mg*	tofacitinib	30 tablets per 30 days

*For use in members with a diagnosis of UC. Xeljanz has been given a black box warning for a higher rate of all-cause mortality, including sudden CV death, with the 10mg twice daily dosing of tofacitinib. Coverage will be limited to 60 tablets/30 days for Xeljanz 5 mg and 30 tablets /30 days for Xeljanz XR 11 mg. Coverage of Xeljanz 10 mg and Xeljax XR 22 mg will be limited to induction with the shortest duration.

Appendix

Appendix A: Examples of Contraindications to Methotrexate

1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia
9. Pregnancy or planning pregnancy

10. Renal impairment
11. Significant drug interaction

Appendix B: Examples of Conventional Therapy Options for UC

1. Mild to moderate disease – induction of remission:
   a. Oral mesalamine (e.g., Asacol, Asacol HD, Lialda, Pentasa), balsalazide, olsalazine
   b. Rectal mesalamine (e.g., Canasa, Rowasa)
   c. Rectal hydrocortisone (e.g., Colocort, Cortifoam)
   d. Alternatives: prednisone, azathioprine, mercaptopurine, sulfasalazine
2. Mild to moderate disease – maintenance of remission:
   a. Oral mesalamine, balsalazide, olsalazine, rectal mesalamine
   b. Alternatives: azathioprine, mercaptopurine, sulfasalazine
3. Severe disease – induction of remission:
   a. Prednisone, hydrocortisone IV, methylprednisolone IV
   b. Alternatives: cyclosporine IV, tacrolimus, sulfasalazine
4. Severe disease – maintenance of remission:
   a. Azathioprine, mercaptopurine
   b. Alternative: sulfasalazine
5. Pouchitis: Metronidazole, ciprofloxacin
   a. Alternative: rectal mesalamine

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- N/A

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*Some content reprinted from CVSHealth

POLICY HISTORY

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