Xeljanz (tofacitinib), Xeljanz XR (tofacitinib extended-release tablets), and Xeljanz Oral Solution (tofacitinib oral solution)

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, Xeljanz XR, and Xeljanz Oral Solution 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

Xeljanz/Xeljanz XR are 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 tumor necrosis factor (TNF) blockers.
- Active psoriatic arthritis (PsA), who have had an inadequate response or intolerance to one or more TNF blockers.
- Active ankylosing spondylitis (AS), who have had an inadequate response or intolerance to one or more TNF blockers.
- Moderately to severely active ulcerative colitis (UC), who have had an inadequate response or intolerance to one or more TNF blockers.

Xeljanz/Xeljanz Oral Solution are indicated for the treatment of pediatric patients 2 years of age and older with:

- Active PsA, who have had an inadequate response or intolerance to one or more TNF blockers.
- Active polyarticular course juvenile idiopathic arthritis (pcJIA), who have had an inadequate response or intolerance to one or more TNF blockers.

Compendial Uses
- Non-radiographic axial spondyloarthritis
- Oligoarticular juvenile idiopathic arthritis
- Immune checkpoint inhibitor-related toxicity

POLICY

Required Documentation
Submission of the following information is necessary to initiate the prior authorization review:
Rheumatoid Arthritis (RA), Psoriatic Arthritis (PsA), Ankylosing Spondylitis (AS), Non-Radiographic Axial Spondyloarthritis (nr-axSpA), and Articular Juvenile Idiopathic Arthritis (JIA)
1. For initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.
2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

Ulcerative Colitis (UC)
1. For initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

Immune Checkpoint Inhibitor-Related Toxicity
1. For initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Prescriber Specialties (initial approvals only)
This medication must be prescribed by or in consultation with one of the following:
1. Rheumatoid arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, and articular juvenile idiopathic arthritis: rheumatologist
2. Psoriatic arthritis: rheumatologist or dermatologist
3. Ulcerative colitis: gastroenterologist
4. Immune checkpoint inhibitor-related toxicity: gastroenterologist, hematologist, or oncologist

Criteria for Initial Approval
Rheumatoid Arthritis (RA)
1. Authorization of 12 months may be granted for adult members for treatment of moderately to severely active RA when the member has experienced an inadequate response, intolerance, or has a contraindication to one or more TNF inhibitors.
2. Authorization of 12 months may be granted for adult members who have previously received a biologic (other than a TNF inhibitor) or targeted synthetic drug (e.g., Rinvoq, Olumiant) indicated for moderately to severely active RA.

Psoriatic Arthritis (PsA)

1. Authorization of 12 months may be granted for members 2 years of age or older for treatment of active PsA when the requested drug will be used in combination with a conventional synthetic drug (e.g., methotrexate, leflunomide, sulfasalazine, etc.) and one of the following:
    A. Member has had an inadequate response or intolerance to one or more TNF blockers.
    B. Member has previously received a biologic (other than a TNF inhibitor) or targeted synthetic drug (e.g., Rinvoq, Otezla) indicated for active PsA.

Ankylosing Spondylitis (AS) and Non-Radiographic Axial Spondyloarthritis (nr-axSpA)

1. Authorization of 12 months may be granted for adult members for treatment of active AS or nr-axSpA when the member has had an inadequate response or intolerance to one or more TNF inhibitors.
2. Authorization of 12 months may be granted for adult members who have previously received a biologic (other than a TNF inhibitor) or targeted synthetic drug (e.g., Rinvoq) indicated for treatment of active AS or nr-axSpA.

Ulcerative Colitis (UC)

1. Authorization of 12 months may be granted for members who have previously received a biologic (other than a TNF inhibitor) or targeted synthetic drug (e.g., Rinvoq) indicated for moderately to severely active UC.
2. Authorization of 12 months may be granted for members who have been hospitalized for acute, severe UC (e.g., continuous bleeding, severe toxic symptoms including fever and anorexia).
3. Authorization of 4 months may be granted for members for the treatment of moderately to severely active UC when the following criteria are met:
    A. The member has had an inadequate response, intolerance or contraindication to at least one TNF inhibitor.
    B. The lowest effective dose will be utilized with the higher induction dose (i.e.,10 mg twice-daily or 22 mg once daily) limited to the shortest necessary duration.

Articular Juvenile Idiopathic Arthritis (JIA)

1. Authorization of 12 months may be granted for members 2 years of age or older for the treatment of active JIA when the member has experienced an inadequate response or intolerance to one or more TNF inhibitors.
2. Authorization of 12 months may be granted for members 2 years of age or older members who have previously received a biologic (other than a TNF inhibitor) or targeted synthetic drug indicated for active JIA.

Immune Checkpoint Inhibitor-Related Toxicity

1. Authorization of 6 months may be granted for treatment of immune checkpoint inhibitor-related diarrhea or colitis when the member has had an inadequate response, intolerance, or contraindication to infliximab or vedolizumab.

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>

Rheumatoid Arthritis (RA)

1. Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderately to severely active RA and who achieve or maintain a positive clinical response as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

Psoriatic Arthritis (PsA)

1. Authorization of 12 months may be granted for all members 2 years of age or older (including new members) who are using the requested medication for PsA and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:
    A. Number of swollen joints
    B. Number of tender joints
    C. Dactylitis
    D. Enthesitis
    E. Axial disease
    F. Skin and/or nail involvement
    G. Functional status
    H. C-reactive protein (CRP)

Ankylosing Spondylitis (AS) and Non-Radiographic Axial Spondyloarthritis (nr-axSpA)

1. Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for active AS or nr-axSpA and who achieve or maintain a positive clinical response with the requested medication as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:
    A. Functional status
    B. Total spinal pain
    C. Inflammation (e.g., morning stiffness)
    D. Swollen joints
    E. Tender joints
    F. C-reactive protein (CRP)

Ulcerative Colitis (UC)

1. Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active UC and who achieve or maintain remission.
2. Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active UC and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:
    A. Stool frequency
    B. Rectal bleeding
    C. Urgency of defecation
    D. C-reactive protein (CRP)
    E. Fecal calprotectin (FC)
    F. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
    G. Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

Articular Juvenile Idiopathic Arthritis (JIA)

1. Authorization of 12 months may be granted for all members 2 years of age or older (including new members) who are using the requested medication for active JIA and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:
    A. Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
    B. Number of joints with limitation of movement
    C. Functional ability

Immune Checkpoint Inhibitor-Related Toxicity

1. All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

Other

For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA])* within 12 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

*If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., a chest x-ray). Do not administer the requested drug to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested drug.

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug, targeted synthetic drugs, or potent immunosuppressants such as azathioprine or cyclosporine.

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

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

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 5 mg	tofacitinib	60 tablets per 30 days
Xeljanz 10 mg*	tofacitinib	60 tablets per 30 days
Xeljanz XR 11 mg	tofacitinib	30 tablets per 30 days
Xeljanz XR 22 mg*	tofacitinib	30 tablets per 30 days
Xeljanz 1 mg/mL Oral Solution	Tofacitinib	10 mL per day

*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, at the 10 mg twice daily dose. 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 Xeljanz XR 22 mg will be limited to induction for the shortest necessary duration.

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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POLICY HISTORY

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