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

1. Xeljanz/Xeljanz XR is 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.
2. Xeljanz/Xeljanz XR is indicated for the treatment of adult patients with active psoriatic arthritis (PsA) who have had an inadequate response or intolerance to one or more TNF blockers.
3. Xeljanz/Xeljanz XR is indicated for the treatment of adult patients with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers.
4. Xeljanz/Xeljanz XR is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response or intolerance to one or more TNF blockers.

5. Xeljanz/Xeljanz Oral Solution is 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 Uses
Oligoarticular juvenile idiopathic arthritis

POLICY

Required Documentation
Submission of the following information is necessary to initiate the prior authorization review:

A) **Rheumatoid arthritis (RA)**
   1. For initial requests:
      1. Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy (if applicable).
      2. Laboratory results, chart notes, or medical record documentation of biomarker testing (i.e., rheumatoid factor [RF], anti-cyclic citrullinated peptide [anti-CCP], and C-reactive protein [CRP] and/or erythrocyte sedimentation rate [ESR]) (if applicable).
   2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

B) **Psoriatic arthritis (PsA):**
   1. For initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.
   2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

C) **Active ankylosing spondylosis (AS)**
   1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy (if applicable).
   2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

D) **Ulcerative colitis (UC)**
   1. Initial requests
      1. 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. Chart notes or medical record documentation of hospitalization due to acute, severe ulcerative colitis (if applicable).
   2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

E) **Articular juvenile idiopathic arthritis:**
   1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy (if applicable).
   2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

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., Rinvoq, 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 all of the following criteria are met:
    1. Member meets either of the following criteria:
        1. Member has been tested for either of the following biomarkers and the test was positive:
            a. Rheumatoid factor (RF)
            b. Anti-cyclic citrullinated peptide (anti-CCP)
        2. Member has been tested for ALL of the following biomarkers:
            a. RF
            b. Anti-CCP
            c. C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
    2. Member has had an inadequate response or intolerance to one or more TNF blockers.

B) **Active psoriatic arthritis (PsA)**
1. Authorization of 12 months may be granted for treatment of active PsA when all of the following criteria are met:
    1. Member has had an inadequate response or intolerance to one or more TNF blockers.
    2. The requested drug is used in combination with a conventional synthetic DMARD (e.g., methotrexate, leflunomide, sulfasalazine, etc.)

C) **Active ankylosing spondylitis (AS)**
1. Authorization of 12 months may be granted for members who have previously received a biologic indicated for treatment of active ankylosing spondylitis.
2. Authorization of 12 months may be granted for treatment of active ankylosing spondylitis when member has had an inadequate response or intolerance to one or more TNF blockers.

D) **Moderately to severely active ulcerative colitis (UC)**
1. Authorization of 12 months may be granted for members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq) indicated for moderately to severely active ulcerative colitis.
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 the treatment of moderately to severely active ulcerative colitis when the following criteria is met:
    1. The member has had an inadequate response, intolerance or contraindication to at least one tumor necrosis factor inhibitor (TNF-i)
    2. 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

E) **Active articular juvenile idiopathic arthritis**
1. Authorization of 12 months may be granted for members who have previously received a biologic or targeted synthetic DMARD indicated for active articular juvenile idiopathic arthritis.
2. Authorization of 12 months may be granted for the treatment of active articular juvenile idiopathic arthritis when member has had an inadequate response or intolerance to one or more TNF blockers

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).

Continuation of Therapy

A. **Moderately to severely active rheumatoid arthritis (RA)**
Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active rheumatoid arthritis 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.

B. **Active psoriatic arthritis (PsA)**
Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for active psoriatic arthritis 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:
    1. Number of swollen joints
    2. Number of tender joints
    3. Dactylitis
    4. Enthesitis
    5. Skin and/or nail involvement

C. **Active ankylosing spondylitis (AS)**
Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for active ankylosing spondylitis and who achieve or maintain 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:

    1. Functional status
    2. Total spinal pain
    3. Inflammation (e.g., morning stiffness)

D. **Moderately to severely active 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 ulcerative colitis 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 ulcerative colitis 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:

        1. Stool frequency
        2. Rectal bleeding
        3. Urgency of defecation
        4. C-reactive protein (CRP)
        5. Fecal calprotectin (FC)
        6. Endoscopic appearance of the mucosa

7. Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

E. **Active articular juvenile idiopathic arthritis**

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for active articular juvenile idiopathic arthritis 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:

1. Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
2. Number of joints with limitation of movement
3. Functional ability

Other

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 or targeted synthetic DMARDs 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. Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

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.

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
Xeljanz 1mg/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, 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 Xeljanz XR 22 mg will be limited to induction with the shortest 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

REFERENCES

- Xeljanz/Xeljanz XR [package insert]. New York, NY: Pfizer, Inc.; December 2021.
- Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol*. 2016;68(1)1-26.
- Smolen JS, Landewé R, Bijlsma J, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update. *Ann Rheum Dis*. 2020;79:685-699.
- Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011;65(1):137-174.
- Gossec L, Smolen JS, Ramiro S, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update. *Ann Rheum Dis*. 2016;75(3):499-510.
- Talley NJ, Abreu MT, Achkar J, et al. An evidence-based systematic review on medical therapies for inflammatory bowel disease. Am J Gastroenterol. 2011;106(Suppl 1):S2-S25.
- Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheum. 2018;71:5-32.
- Rubin DT, Ananthakrishnan AN, et al. 2019 ACG Clinical Guideline: Ulcerative Colitis in Adults. Am J Gastroentrol. 2019;114:384-413.
- Tuberculosis (TB). TB risk factors. Centers for Disease Control and Prevention. Retrieved on 21 June 2019 from: https://www.cdc.gov/tb/topic/basics/risk.htm.
- Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology 2020; 158:1450.
- Ringold S, Angeles-Han S, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. American College of Rheumatology. 2019;1-18.
- Aletaha D, Neogi T, Silman, et al. 2010 Rheumatoid arthritis classification criteria: an American College of Rheumatology/European League Against Rheumatism collaborative initiative. Arthritis Rheum. 2010;62(9):2569-81.
- Smolen JS, Aletaha D. Assessment of rheumatoid arthritis activity in clinical trials and clinical practice. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Available with subscription. URL: www.uptodate.com. Accessed March 19, 2021.
- Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. Arthrit Care Res. 2021.
- The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed June 6, 2021.
- Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. *Arthritis Rheumatol.* 2019;71(10):1599-1613. doi:10.1002/art.41042.

*Some content reprinted from CVSHealth

POLICY HISTORY

Policy #: 05.02.16
Reviewed: April 2022
Revised: April 2022
Current Effective Date: 7/21/2022