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Tofacitinib (Xeljanz, Xeljanz XR, Xeljanz Solution)

POLICY

I. INDICATIONS

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. Moderately to severely active rheumatoid arthritis (RA) in adults who have had an inadequate response or intolerance to one or more TNF blockers
2. Active psoriatic arthritis (PsA) in adults and pediatric patients 2 years of age and older who have had an inadequate response or intolerance to one or more TNF blockers
3. Active ankylosing spondylitis (AS) in adults who have had an inadequate response or intolerance to one or more TNF blockers
4. Moderately to severely active ulcerative colitis (UC) in adults who have had an inadequate response or intolerance to one or more TNF blockers
5. Active polyarticular course juvenile idiopathic arthritis (pcJIA) in pediatric patients 2 years of age and older who have had an inadequate response or intolerance to one or more TNF blockers

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

For all indications:

- Submission of the member's chart or medical record is required, documenting medical necessity based on the criteria corresponding to the applicable indication; AND
- Physician has assessed baseline disease severity utilizing an objective measure/tool; AND
- Tofacitinib will not be used concomitantly with an injectable biologic response modifier including TNF-inhibitors (e.g., adalimumab (e.g., Hadlima), Enbrel (etanercept), infliximab (e.g., Inflectra), Simponi (golimumab), etc.) and IL-inhibitors (e.g., Cosentyx (secukinumab), ustekinumab (e.g., Stelara, Otulfi, Selarsdi, Steqeyma, and Yesintek, etc.), Tremfya (guselkumab), Ilumya (tildrakizumab), Skyrizi (risankizumab), Bimzelx (bimekizumab), Omvoh (mirikizumab), etc.) or other oral non-biologic agent (e.g., Otezla (apremilast), Olumiant (baricitinib), Rinvoq (upadacitinib), Velsipity (etrasimod), etc.); AND
- Member is free of any clinically important active infection, including clinically important localized infections; AND
- Member will not receive live vaccines during therapy; AND

- Member has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for the presence of TB during treatment.

A. Moderately to severely active rheumatoid arthritis (RA)

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 is 18 years of age or older; AND
2. Prescribed by, or in consultation with, a specialist in rheumatology; AND
3. Documentation has been submitted of one of the following criteria:
    i. 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); OR
    ii. 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); AND
4. Documentation has been submitted that the member has experienced an inadequate response, intolerance or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses.

B. Active psoriatic arthritis (PsA)

Authorization of 12 months may be granted for treatment of active psoriatic arthritis when all of the following criteria are met:

1. Member is 2 years of age or older; AND
2. Prescribed by, or in consultation with, a specialist in dermatology or rheumatology; AND
3. Tofacitinib will be used in combination with a nonbiologic DMARD (e.g., methotrexate, leflunomide, sulfasalazine, etc.); AND
4. Member has documented active disease; AND
5. If member is 18 years of age or older, documentation has been submitted that the member has had an inadequate response, intolerance or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses AND a 6-month trial of ustekinumab biosimilar at maximum tolerated doses.
6. If member is 6 years of age or older but under 18, documentation has been submitted that the member has had an inadequate response, intolerance or contraindication to at least a 6-month trial of ustekinumab biosimilar at maximum tolerated doses.

C. Active ankylosing spondylitis (AS)

Authorization of 12 months may be granted for treatment of active ankylosing spondylitis when all of the following criteria are met:

1. Member is 18 years of age or older; AND
2. Prescribed by, or in consultation with, a specialist in rheumatology; AND
3. Member has documented active disease; AND

4. Documentation has been submitted that the member has experienced an inadequate response, intolerance or contraindication to at two (2) NSAIDs; AND
5. Documentation has been submitted that the member has experienced an inadequate response, intolerance or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses.

D. Moderately to severely active ulcerative colitis (UC)

Authorization of 12 months may be granted for treatment of moderately to severely active UC when all the following criteria are met:

1. Member is 18 years of age or older; AND
2. Prescribed by, or in consultation with, a gastroenterologist; AND
3. Member has a documented diagnosis of moderately to severely active UC; AND
4. Documentation has been submitted that the member has had an inadequate response, intolerance or contraindication to at least a 3-month trial of infliximab IV or adalimumab at maximum tolerated doses; AND
5. Documentation has been submitted that the member has had an inadequate response, intolerance or contraindication to at least a 6-month trial of ustekinumab biosimilar at maximum tolerated doses.

E. Active polyarticular course juvenile idiopathic arthritis (pcJIA)

Authorization of 12 months may be granted for treatment of active articular juvenile idiopathic arthritis when all of the following criteria are met:

1. Member is 2 years of age or older; AND
2. Prescribed by, or in consultation with, a specialist in rheumatology; AND
3. Documentation has been submitted that the member has had an inadequate response, intolerance or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses.

III. CONTINUATION OF THERAPY

A. Moderately to severely active rheumatoid arthritis (RA)

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 rheumatoid arthritis and documentation is submitted indicating a positive clinical response as evidenced by improvement of disease activity by 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 2 years of age or older (including new members) who are using the requested medication for active psoriatic arthritis and documentation is submitted indicating 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
6. Axial disease
7. Functional status
8. C-reactive protein (CRP)

C. Active ankylosing spondylitis (AS)

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for active ankylosing spondylitis and documentation is submitted indicating 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. Functional status
2. Total spinal pain
3. Inflammation (e.g., morning stiffness)
4. Swollen joints
5. Tender joints
6. C-reactive protein (CRP)

D. Moderately to severely active ulcerative colitis (UC)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for active ulcerative colitis and documentation is submitted indicating one of the following:

1. Member has achieved or maintained remission; OR
2. Member has achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition from baseline (e.g., stool frequency, rectal bleeding, urgency of defecation, C-reactive protein (CRP), fecal calprotectin (FC), endoscopic appearance of the mucosa (e.g., computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound), improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score).

F. Active polyarticular course juvenile idiopathic arthritis (pcJIA)

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 polyarticular course juvenile idiopathic arthritis and documentation is submitted indicating 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

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IV. QUANTITY LIMIT

Tofacitinib 5mg and 10mg tablets: 2 tablets per day
Tofacitinib XR 11mg and 22mg tablets: 1 tablet per day
Tofacitinib 1mg/1ml solution: 10ml per day

V. DOSING

Indication	Recommended FDA Dosing
Adult patients with RA, PsA or AS	Tofacitinib tablets 5 mg twice daily OR Tofacitinib XR (extended-release tablets) 11 mg once daily
Pediatric patients 2 years of age and older with PsA or pcJIA and weigh at least 10kg	Tofacitinib (tablets or oral solution) 5 mg twice daily for those ≥40 kg OR Weight-based equivalent twice daily for those < 40 kg • ≥ 10 kg to < 20 kg: 3.2 mg (3.2 mL oral solution twice daily) • ≥ 20 kg to < 40 kg: 4 mg (4 mL oral solution twice daily)
Adult patients with UC	**Induction:** Tofacitinib tablets 10 mg twice daily OR Tofacitinib XR 22 mg once daily for 8 weeks (maximum 16 weeks, dependent on response) **Maintenance*:** Tofacitinib tablets 5 mg twice daily OR Tofacitinib XR 11 mg once daily * For patients with loss of response during maintenance treatment, Tofacitinib tablets 10 mg twice daily OR Tofacitinib XR 22 mg once daily may be considered and limited to the shortest duration

Abbreviations: RA = rheumatoid arthritis; PsA = psoriatic arthritis; AS = ankylosing spondylitis; PcJIA = polyarticular course juvenile idiopathic arthritis; UC = ulcerative colitis

VI. REFERENCES

1. Xeljanz/Xeljanz XR [package insert]. New York, NY: Pfizer, Inc.; March 2026.
2. 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.

3. Smolen JS, Landewé R, Billsma J, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2016 update. *Ann Rheum Dis.* 2017*;0*:1-18.
4. 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.
5. 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.
6. 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.