Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Xeljanz (tofacitinib)**

Effective: October 13, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Xeljanz (tofacitinib) is a Janus Kinase inhibitor indicated for:

Disease State	
Ankylosing Spondylitis	X
Polyarticular Course Juvenile Idiopathic Arthritis	X
Psoriatic Arthritis	X
Rheumatoid Arthritis	X
Ulcerative Colitis	X

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Xeljanz (tofacitinib) for Members when **ALL** of the following criteria are met:

Ankylosing Spondylitis

Initial Authorization Criteria

1. Documented diagnosis of active ankylosing spondylitis

AND

2. Patient is at least 18 years of age or older

AND

3. Prescribed by a rheumatologist

AND

4. Documentation of history of failure to **one (1)** prescription strength non-steroidal anti-inflammatory drug (e.g., celecoxib, diclofenac, ibuprofen, naproxen, meloxicam), unless contraindicated or clinically significant adverse effects are experienced *(Note: document drug, date and duration of trial)*

AND

5. Documentation the patient has had a trial and inadequate response or intolerance to one or more tumor necrosis factor inhibitor

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of active ankylosing spondylitis

AND

3. Patient is at least 18 years of age or older

AND

4. Prescribed by a rheumatologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Polyarticular Course Juvenile Idiopathic Arthritis

Initial Authorization Criteria

1. Documented diagnosis of active polyarticular course juvenile idiopathic arthritis

AND

2. Patient is at least 2 years of age or older

AND

3. Prescribed by a rheumatologist

AND

4. Documentation of history of failure to **one (1)** traditional disease modifying antirheumatic drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine), unless contraindicated or clinically significant adverse effects are experienced *(Note: document drug, date, and duration of trial)*

AND

5. Documentation the patient has had a trial and inadequate response or intolerance to one or more tumor necrosis factor inhibitor

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of active polyarticular course juvenile idiopathic arthritis

AND

3. Patient is at least 2 years of age or older

AND

4. Prescribed by a rheumatologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Psoriatic Arthritis

Initial Authorization Criteria

1. Documented diagnosis of active psoriatic arthritis

AND

2. Documentation of **one (1)** of the following:
    a. Actively inflamed joints
    b. Dactylitis
    c. Enthesitis
    d. Axial disease
    e. Active skin and/or nail involvement

AND

3. Patient is at least 2 years of age or older

AND

4. Prescribed by a dermatologist or rheumatologist

AND

5. Documentation the patient has had a trial and inadequate response or intolerance to one or more tumor necrosis factor inhibitor

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been receiving the requested medication for at least six (6) months

AND

2. Documented diagnosis of active psoriatic arthritis

AND

3. Patient is at least 2 years of age or older

AND

4. Prescribed by a rheumatologist or dermatologist

AND

5. Submission of medical charts documenting the patient experienced a beneficial clinical response defined improvement from baseline in at least **one (1)** of the following:
    a. Body surface area affected by psoriatic arthritis
    b. Total active (swollen and tender) joint count

AND

6. Submission of medical charts documenting that compared to baseline, the patient has experienced an improvement in at least one symptom of psoriatic arthritis such as joint pain, morning stiffness, fatigue, joint or tendon sheath swelling

AND

7. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Rheumatoid Arthritis

Initial Authorization Criteria

1. Documented diagnosis of moderately to severely active rheumatoid arthritis

AND

2. Patient is at least 18 years of age or older

AND

3. Prescribed by a rheumatologist

AND

4. Documentation of history of failure to **one (1)** traditional disease modifying antirheumatic drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine), unless contraindicated or clinically significant adverse effects are experienced *(Note: document drug, date, and duration of trial)*

AND

5. Documentation the patient has had a trial and inadequate response or intolerance to one or more tumor necrosis factor inhibitor

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the Member has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of moderately to severely active rheumatoid arthritis

AND

3. Patient is at least 18 years of age or older

AND

4. Prescribed by a rheumatologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined

by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Ulcerative Colitis

Initial Authorization Criteria

1. Documented diagnosis of moderately to severely active ulcerative colitis

AND

2. Patient is at least 18 years of age or older

AND

3. Prescribed by a gastroenterologist

AND

4. Documentation of history of failure to **one (1)** of the following, unless contraindicated or clinically significant adverse effects are experienced *(Note: document drug, date, and duration of trial)*
    a. Corticosteroid
    b. 5-aminosalycyclate
    c. 6-mercaptopurine
    d. Methotrexate

AND

5. Documentation the patient has had a trial and inadequate response or intolerance to one or more tumor necrosis factor inhibitor

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of moderately to severely active ulcerative colitis

AND

3. Patient is at least 18 years of age or older

AND

4. Prescribed by a gastroenterologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Limitations

1. Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response and will not be considered for prior authorization.
2. Documentation of a patient being a social drinker does not qualify as a medically acceptable contraindication or clinical inappropriateness to methotrexate therapy.
3. Documentation of a patient having a needle phobia does not qualify as a medically acceptable contraindication or clinical inappropriateness to injectable products.
4. For ankylosing spondylitis, polyarticular course juvenile idiopathic arthritis, rheumatoid arthritis, and ulcerative colitis, authorizations will be provided in 12-month intervals. A patient who has received less than 12 months of therapy or who is restarting therapy with the requested drug is reviewed under Initial Authorization Criteria.
5. For psoriatic arthritis, initial approval will be authorized for six (6) months. Reauthorization will be provided in 12-month intervals. A patient who has received less than six (6) months of therapy or who is restarting therapy with the requested drug is reviewed under Initial Authorization Criteria.
6. Members new the plan stable on the requested medication should be reviewed against Initial Authorization Criteria.

Codes

None

References

1. Braun J, van den Berg R, Baraliakos X, et al. 2010 update of the ASAS/EULAR recommendations for the management of Ankylosing spondylitis. Ann Rheum Dis. 2011;70:896-904.
2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.
3. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.
4. Singh S, Loftus EV, Jr, Limketkai BN, et al. AGA Living Clinical Practice Guideline on Pharmacological Management of Moderate-to-Severe Ulcerative Colitis. Gastroenterology. 2024 Dec;167(7):1307-1343.
5. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res. 2021;73(7):924-939.
6. Ringold S, Angeles-Han ST, 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. Arthritis Rheumatol. 2019;71(6):846-863.
7. Xeljanz (tofacitinib) [prescribing information]. Pfizer, Labs; New York, NY: June 2026.

Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- September 2022 e-vote: Effective January 1, 2023, Enbrel added as a preferred agent.
- December 12, 2023: No changes
- June 11, 2024: Updated coverage criteria for pJIA to make Xeljanz a first line biologic treatment (eff 7/1/24).
- June 10, 2025: No changes (eff 6/10/25)
- October 14, 2025: Provider requirements no longer allow with in consultation with the specialist. Added coverage criteria to prevent duplicative targeted immunomodulator therapy. Added a step through a TNF inhibitor. For psoriatic arthritis, initial approvals limited to 6 months with annual reauthorization coverage criteria added, added disease severity requirements, removed previous treatment with a biologic agent indicated for the requested use and Xejlanz stability language. For ankylosing spondylitis, polyarticular course juvenile idiopathic arthritis, rheumatoid arthritis, ulcerative colitis, approvals limited to 12 months with reauthorization criteria added, updated Initial Authorization Criteria prerequisite language (no change in prerequisites) and removed previous treatment with a biologic agent indicated for the requested use and Xeljanz stability language (eff 1/1/26).
- December 9, 2025: Updated age requirements for psoriatic arthritis to patients at least 2 years of age based on expanded FDA-approved indication (eff 1/1/26).
- October 13, 2026: Administrative update to remove Carelink from Medical Necessity Guideline template.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.