Mass General Brigham
Health Plan

Tofacitinib
Tofacitinib extended-release
Effective 01/01/2027

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview
Tofacitinib tablets and tofacitinib extended-releaseare Janus kinase (JAK) inhibitors indicated for treatment of adult patients with:

1. Moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more TNF blockers
2. Active psoriatic arthritis (PsA) who have had an inadequate response or intolerance to one or more TNF blockers
3. Active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers
4. Moderately to severely active ulcerative colitis (UC) who have had an inadequate response or intolerance to one or more TNF blockers

Tofacitinib tablets and oral solution are indicated for the treatment of pediatric patients 2 years of age or older with:

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

Coverage Guidelines
If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with the requested drug, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization may be granted when all the following diagnosis-specific criteria are met:

Moderately to severely active rheumatoid arthritis (RA) – Tofacitinib tablet/Tofacitinib XR

1. Diagnosis of moderately to severely active rheumatoid arthritis (RA)

2. Minimum duration of 3-month trial and failure, contraindication, or intolerance to ONE of the following conventional therapies at maximally tolerated doses:
    a. Methotrexate
    b. Leflunomide
    c. Sulfasalazine
3. Inadequate response or intolerance to ONE or more TNF inhibitors (e.g., adalimumab, certolizumab pegol, etanercept, golimumab)

Active psoriatic arthritis (PsA) – Tofacitinib tablet, oral solution/Tofacitinib XR

1. Diagnosis of active psoriatic arthritis (PsA)
2. ONE of the following:
    a. Actively inflamed joints
    b. Dactylitis
    c. Enthesitis
    d. Axial disease
    e. Active skin and/or nail involvement
3. Inadequate response or intolerance to ONE or more TNF inhibitors (e.g., adalimumab, certolizumab pegol, etanercept, golimumab)

Moderately to severely active ulcerative colitis (UC) – Tofacibinib tablet/Tofacitinib XR

1. Diagnosis of moderately to severely active ulcerative colitis
2. ONE of the following:
    a. Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies:
        i. 6-mercaptopurine
        ii. Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
        iii. Azathioprine
        iv. Corticosteroids (e.g., prednisone)
    b. Disease severity warrants systemic biologic or targeted synthetic therapy as first-line therapy
3. Inadequate response or intolerance to ONE or more TNF inhibitors (e.g., adalimumab, golimumab)

Active polyarticular-course juvenile idiopathic arthritis (pcJIA) – Tofacitinib tablet, oral solution

1. Diagnosis of active polyarticular-course juvenile idiopathic arthritis (pcJIA)
2. Inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., adalimumab, etanercept)
3. Minimum duration of 6-week trial and failure, contraindication, or intolerance to ONE of the following conventional therapies at maximally tolerated doses:
    a. Leflunomide
    b. Methotrexate

Ankylosing spondylitis (AS) – Tofacitinib tablet/Tofacitinib XR

1. Diagnosis of active ankylosing spondylitis
2. Minimum duration of 1-month trial and failure, contraindication, or intolerance to TWO different non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) at maximally tolerated doses.
3. Inadequate response or intolerance to ONE or more TNF inhibitors (e.g., adalimumab, certolizumab pegol, etanercept, golimumab)

Continuation of Therapy

Requests for reauthorization will be approved when all of the following criteria are met:

1. Submission of medical records (e.g., chart notes) documenting an improvement in the member's condition, as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Limitations

1. Initial approvals and reauthorizations will be granted for 24 months
2. The following quantity limits apply:

Drug Name and Dosage Form	Quantity Limitation
Tofacitinib tablet	2 tablets per day
Tofacitinib XR tablet	1 tablet per day
Tofacitinib oral solution	10 mL per day

References

1. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterol. 2020;158:1450-1461.
2. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. 2021;73(7):924-939.
3. 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.
4. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG Clinical Guideline: Ulcerative Colitis in Adults. Am J Gastroenterol 2019;114:384–413.
5. 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.
6. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res. 2015;68(1):1-25.
7. 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.
8. Xeljanz, Xeljanz XR (tofacitinib) [prescribing Information]. Pfizer, Inc: New York, NY; February 2025.

Review History

06/24/2013 – Reviewed
02/24/2014 – Reviewed
02/23/2015 – Reviewed
02/22/2016 – Reviewed
02/27/2017 – Adopted SGM & PDS
02/26/2018 – Updated
06/25/2018 – Updated
11/20/2019 – Added Rinvoq as a trial for RA
03/18/2020 – Reviewed; Added Xeljanz XR to criteria (effective 6/1/20)
01/19/2022 – Reviewed and Updated; added new indication of active polyarticular-course juvenile idiopathic arthritis (pJIA); references updated.
03/16/2022 – Reviewed and updated for March P&T; Added Rinvoq and Skyrizi as preferred trial for PsA. Effective 05/01/2022

09/21/2022 – Reviewed and Updated for Sept P&T; Added criteria for active ankylosing spondylitis. Effective 11/1/22.
03/15/2023 – Reviewed and Updated for March P&T; updated Ulcerative Colitis contraindication criteria to add Rinvoq and Stelara to Humira. Effective 6/1/2023.
11/15/2023 – Reviewed and Updated for Nov P&T; updated criteria to be in line with FDA approved indication. Removed TB requirement. Added examples for each indication and updated conventional therapies. Effective 1/1/2024
10/09/2024 – Reviewed and updated at October P&T. Removed age requirements for ankylosing spondylitis and pcJIA. Specified approvable formulations for each indication. Updated reauthorization criteria to require documentation of clinical response to treatment. Effective 1/1/2025.
05/14/2025 – Reviewed and updated for May P&T. Updated criteria for ulcerative colitis to remove disease characteristic requirement and allow for approval if disease severity warrants systemic biologic as first-line therapy. Updated initial approval length for ulcerative colitis to 24 months. Effective 07/01/2025.
10/08/2025 – Reviewed and updated at October P&T. Minor verbiage updates to trial language for ankylosing spondylitis; intent remains the same. Effective 01/01/2026.
11/12/2025 – Reviewed and updated at November P&T. Updated policy to clarify which formulations are approved for which indications. Effective 01/01/2026.
03/11/2026 – Reviewed and updated for March P&T. Administrative update - changing verbiage in reauthorization criteria from “documentation is submitted” to “submission of medical records (e.g., chart notes…” and updating language for members who are new to the Plan. Effective 05/01/2026.
04/15/2026 – Reviewed and updated for April P&T. Updating previous trial language for ulcerative colitis to allow for bypassing conventional therapy if member has severe disease that warrants a biologic or targeted synthetic therapy as first-line therapy. Effective 08/16/2026.
09/09/2026 – Reviewed and updated at September P&T. Updating preferred tofacitinib products throughout policy. Updating title of policy from “Xeljanz/Xeljanz XR” to “Tofacitinib/Tofacitinib XR.” Effective 01/01/2027.