Mass General Brigham
Health Plan

Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib extended-release tablets)
Effective 01/01/2024

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 and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview
Tofacitinib inhibits Janus kinase (JAK) enzymes, which are intracellular enzymes involved in stimulating hematopoiesis and immune cell function through a signaling pathway. Inhibition of JAKs interrupts this pathway and proinflammatory cytokines.

FDA-Approved Indications

1. Moderately to severely active rheumatoid arthritis (RA)
2. Active psoriatic arthritis (PsA)
3. Moderately to severely active ulcerative colitis (UC)
4. Active polyarticular-course juvenile idiopathic arthritis (pJIA)
5. Active Ankylosing Spondylitis

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

Coverage Guidelines
Moderately to severely active rheumatoid arthritis (RA)
Authorization may be granted for members new to the plan who are currently receiving treatment and is stable with Xeljanz or Xeljanz XR, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted the following criteria is met:

1. Diagnosis of moderately to severe active rheumatoid arthritis (RA)
2. Member has minimum duration of a 3-month trial and failure, intolerance, or contraindication to ONE of the following conventional therapies at maximally tolerated doses:
    a. Methotrexate
    b. Leflunomide
    c. sulfasalazine

3. Member has had an inadequate response or intolerance to ONE or more TNF inhibitors (e.g., adalimumab, certolizumab pegol, etanercept, golimumab)

Active psoriatic arthritis (PsA)
Authorization may be granted for members new to the plan who are currently receiving treatment and is stable with Xeljanz or Xeljanz XR, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted the following criteria is met:
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. Member has had an inadequate response or intolerance to ONE or more TNF inhibitors (e.g., adalimumab, certolizumab pegol, etanercept, golimumab)

Moderately to severely active ulcerative colitis (UC)
Authorization may be granted for members new to the plan who are currently receiving treatment and is stable with Xeljanz and Xeljanz XR for UC, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted ALL of the following criteria is met:
1. Diagnosis of moderately to severely active ulcerative colitis
2. ONE of the following:
    a. Greater than 6 stools per day
    b. Frequent blood in stools
    c. Frequent urgency
    d. Presence of ulcers
    e. Abnormal lab values (e.g., hemoglobin, ESR, CRP)
    f. Dependent on, or refractory to, corticosteroids
3. Trial and failure, intolerance, or contraindication to ONE of the following conventional therapies:
    a. 6-mercaptopurine
    b. Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
    c. Azathioprine
    d. Corticosteroids (e.g., prednisone)
4. Member has had an inadequate response or intolerance to ONE or more TNF inhibitors (e.g., adalimumab, golimumab)

Active polyarticular-course juvenile idiopathic arthritis (pJIA)
Authorization may be granted for members new to the plan who are currently receiving treatment and is stable with Xeljanz and Xeljanz XR for pJIA, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR

Authorization may be granted ALL of the following criteria is met:

1. Diagnosis of active polyarticular-course juvenile idiopathic arthritis (pJIA)
2. Member is at least 2 years of age
3. Member has had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., adalimumab, etanercept)
4. Minimum duration of a 6-week trial and failure, intolerance, or contraindication to ONE of the following conventional therapies at maximally tolerated doses
    a. Leflunomide
    b. methotrexate

Ankylosing spondylitis (AS)

Authorization may be granted for members new to the plan who are currently receiving treatment and is stable with Xeljanz and Xeljanz XR for AS, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted ALL of the following criteria is met:

1. Diagnosis of active ankylosing spondylitis
2. The member is at least 18 years of age
3. Member has minimal duration of 1-month trial and failure, contraindication, or intolerance to TWO different non-steroidal anti-inflammatory drugs (NSAIDs) at maximally tolerated doses.
4. Member has had an inadequate response or intolerance to ONE or more TNF inhibitors (e.g., adalimumab, certolizumab pegol, etanercept, golimumab)

Continuation of Therapy

Reauthorization of may be granted for members who achieve or maintain positive clinical response after at least 3 months of therapy for AS, RA, and PsA or after 4 months for UC with Xeljanz/Xeljanz XR as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Limitations

1. Approvals will be granted for 24 months, except initial authorization for moderately to severely active UC.
    a. Initial approvals for moderately to severely active UC will be granted for 4 months.
2. The following quantity limits apply:

Xeljanz®	60 tablets per 30 days
Xeljanz® XR	30 tablets per 30 days

References

1. Xeljanz, Xeljanz XR Prescribing Information. Pfizer, Inc. New York, NY. January 2022.
2. 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.
3. 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.
4. 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.
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. 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.
7. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG Clinical Guideline: Ulcerative Colitis in Adults. Am J Gastroenterol 2019;114:384–413.
8. 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.

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