Mass General Brigham
Health Plan

Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib extended-release tablets)
Effective 06/01/2023

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
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 for treatment of moderately to severely active RA when one of the following criteria is met:

1. Member has experienced an inadequate response or intolerance to ALL preferred products (Enbrel, Humira and Rinvoq).
2. Member has a contraindication to Enbrel, Humira and Rinvoq and meets one of the following:
    a. Member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to 20 mg/week).
    b. Member has an intolerance or contraindication to methotrexate (see Appendix A).

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 for treatment of active psoriatic arthritis (PsA) if any of the following criteria is met:
1. Member has had a documented inadequate response or intolerable adverse event with ALL of the preferred products (Cosentyx, Enbrel, Humira, Otezla, Stelara, Rinvoq, and Skyrizi).
2. Member has a contraindication to ALL of the preferred agents and meets one of the following:
    a. Patient has had an intolerance to or inadequate response (after at least 3 months of treatment) with methotrexate OR leflunomide
    b. Patient has a contraindication to BOTH methotrexate and leflunomide AND has experienced an inadequate response, intolerance, or contraindication to sulfasalazine.

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 for treatment of moderately to severely active UC if any of the following criteria is met:
1. Member meets ONE of the following:
    a. Member has experienced an inadequate response or intolerance to Humira, Rinvoq and Stelara
    b. Member meets BOTH of the following:
        i. Member has a contraindication to Humira, Rinvoq and Stelara
        ii. Member has had an inadequate response, intolerance or contraindication to at least one conventional therapy option for moderate to severe UC (see Appendix B).

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 for treatment of moderately to severely active pJIA when ALL of the following criteria is met:
1. Member is at least 2 years of age
2. Member has had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers.

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 for treatment of active AS when ALL of the following criteria is met:

1. The member is at least 18 years of age
2. The member has been diagnosed with active ankylosing spondylitis
3. ONE of the following:
    a. Member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs).
    b. Member has an intolerance or contraindication to two or more NSAIDs.
4. The member has intolerance, adverse effect, or contraindication to Cosentyx, Enbrel, Humira, and Rinvoq

Continuation of Therapy

Reauthorization of may be granted for all members (including new members) who meet all initial authorization criteria and 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. For all indications: Member has a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB).
    a. Note: Members who have received Cimzia or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) are exempt from requirements related to TB screening in this Policy.
3. The following quantity limits apply:

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

Appendices

Appendix A

Examples of Contraindications to Methotrexate

1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia
9. Pregnancy or planning pregnancy (male or female)
10. Renal impairment
11. Significant drug interaction

Appendix B

Examples of Conventional Therapy Options for UC

1. Mild to moderate disease – induction of remission:
    a. Oral mesalamine (e.g., Asacol, Asacol HD, Lialda, Pentasa)
    b. Rectal mesalamine (e.g., Canasa, Rowasa)
    c. Alternatives: azathioprine, mercaptopurine, sulfasalazine
2. Mild to moderate disease – maintenance of remission:
    a. Oral mesalamine, rectal mesalamine
    b. Alternatives: azathioprine, mercaptopurine, sulfasalazine
3. Severe disease – induction of remission:
    a. Sulfasalazine
4. Severe disease – maintenance of remission:
    a. Azathioprine, mercaptopurine
    b. Alternative: sulfasalazine
5. Pouchitis: rectal mesalamine

References

1. Xeljanz/Xeljanz XR (tofacitinib) [prescribing information]. New York, NY: Pfizer; July 2019
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. Dai C, Jiang M, Sun MJ. Tofacitinib as Induction and Maintenance Therapy for Ulcerative Colitis. N Engl J Med 2017; 377:496.
7. https://www.fda.gov/safety/medwatch-safety-alerts-human-medical-products/xeljanz-xeljanz-xr-tofacitinib-drug-safety-communication-due-increased-risk-blood-clots-and-death (Accessed on August 15, 2019

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.