Xeljanz® (tofacitinib)
Xeljanz XR® (tofacitinib)
Effective 06/22/20

Plan	☒ MassHealth ☐ 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)

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

Coverage Guidelines

Rheumatoid Arthritis (RA) and Psoriatic Arthritis (PsA)

Authorization may be granted for members who are currently receiving treatment 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 members when all the following criteria are met:

1. Member has a diagnosis of RA **OR** PsA
2. Member is at least 18 years of age
3. Prescriber has provided documentation of an inadequate response, adverse reaction, or contraindication to at least ONE of the following:
    a. An aminosalicylate
    b. A corticosteroid

c. An immunomodulator (hydroxychloroquine, methotrexate, 6-mercaptopurine) *

4. Inadequate response or adverse reaction to either Humira OR Enbrel

**DMARD trial is not required in members with active psoriatic arthritis with axial (spine) involvement (including sacroiliitis) whose condition is not sufficiently controlled with NSAIDs*

Ulcerative Colitis (UC)

Authorization may be granted for members who are currently receiving treatment 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 members when all the following criteria are met:

1. Member has a diagnosis of moderate to severely active ulcerative colitis
2. Member is at least 18 years of age
3. Prescriber has provided documentation of an inadequate response, adverse reaction, or contraindication to ALL of the following:
   a. An aminosalicylate
   b. A corticosteroid
   c. An immunomodulator (hydroxychloroquine, methotrexate, 6-mercaptopurine) *
4. Inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for ulcerative colitis

Continuation of Therapy

Reauthorization will be granted if documentation is submitted indicating a positive response to therapy

Limitations

1. Initial approvals will be granted for 6 months
2. Reauthorizations will be granted for 12 months
3. The following quantity limits apply:

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

References

1. Xeljanz/Xeljanz XR (tofacitinib) [prescribing information]. New York, NY: Pfizer; October 2018
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. Sandborn WJ, Su C, Sands BE, et al. Tofacitinib as Induction and Maintenance Therapy for Ulcerative Colitis. N Engl J Med 2017; 376:1723.

Review History

06/24/2013: Reviewed
02/24/2014: Reviewed
02/23/2015: Reviewed
02/22/2016: Reviewed
02/27/2017: Adopted SGM & Step
03/01/2018: Adopted MH RS
02/20/2019: Reviewed P&T Mtg
03/18/2020: Updated (Included Ulcerative colitis indication to coverage guidelines); removed dosing
4/15/2020: MH unified drug list to prefer Xeljanz and Xeljanz XR ; change previous use of ONE biologic DMARD to inadequate response to Enbrel OR Humira. Change effective 6/22/20.

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