

**Xeljanz® (tofacitinib)  
Xeljanz XR® (tofacitinib)  
Effective 11/01/2022**

<b>Plan</b>	<input type="checkbox"/> MassHealth <input checked="" type="checkbox"/> MassHealth (PUF) <input type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
<b>Specialty Limitations</b>	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	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
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>	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. Active ankylosing spondylitis (AS)
4. Moderately to severely active ulcerative colitis (UC)
5. Moderate to severe polyarticular juvenile idiopathic arthritis (pJIA) – Xeljanz/Xeljanz solution only

**Coverage Guidelines**

Authorization may be reviewed on a case-by-case basis for members new to the plan 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, and documentation is provided:

**Moderate to Severe Rheumatoid Arthritis (RA)**

Prescriber provides documentation of ALL of the following:



1. Appropriate diagnosis
2. **ONE** of the following:
  - a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** or contraindication to **ALL** traditional DMARDs
  - b. Paid claims or physician documented inadequate response or adverse reaction to **ONE** or contraindication to **ALL** anti-TNF agents that are FDA-approved for requested indication
3. **ONE** of the following:
  - a. If the request is for Xeljanz<sup>®</sup>, quantity requested is  $\leq 2$  tablets/day
  - b. If the request is for Xeljanz XR<sup>®</sup>, quantity requested is  $\leq 1$  tablet/day

*Note: Xeljanz solution is only FDA approved for P/JIA.*

### **Psoriatic Arthritis (PsA)**

Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Paid claims or physician documented inadequate response or adverse reaction to **ONE** or contraindication to **ALL** traditional DMARDs
3. Paid claims or physician documented inadequate response or adverse reaction to **ONE** or contraindication to **ALL** anti-TNF agents that are FDA-approved for requested indication
4. Appropriate dosing
5. **ONE** of the following:
  - a. If the request is for Xeljanz<sup>®</sup>, quantity requested is  $\leq 2$  tablets/day
  - b. If the request is for Xeljanz XR<sup>®</sup>, quantity requested is  $\leq 1$  tablet/day

### **Moderate to Severe Ulcerative Colitis (UC)**

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of moderate to severe ulcerative colitis
2. Paid claims or physician documented inadequate response or adverse reaction to **ONE** or contraindication to **ALL** anti-TNF agents that are FDA-approved for requested indication
3. Appropriate dosing
4. **ONE** of the following:
  - a. If the request is for Xeljanz<sup>®</sup>, quantity requested is  $\leq 2$  tablets/day
  - b. If the request is for Xeljanz XR<sup>®</sup>, quantity requested is  $\leq 1$  tablet/day

### **Ankylosing Spondylitis**

Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Paid claims or physician documented inadequate response or adverse reaction to **TWO** or contraindication to **ALL** NSAIDs
3. Paid claims or physician documented inadequate response or adverse reaction to **ONE** or contraindication to **ALL** anti-TNF agents that is FDA-approved for ankylosing spondylitis
4. Appropriate dosing
5. **ONE** of the following:
  - a. If the request is for Xeljanz<sup>®</sup>, quantity requested is  $\leq 2$  tablets/day
  - b. If the request is for Xeljanz XR<sup>®</sup>, quantity requested is  $\leq 1$  tablet/day

### **Moderate to Severe Plaque Psoriasis**

Prescriber provides documentation of **ALL** of the following:



1. Appropriate diagnosis
2. **ONE** of the following:
  - a. Paid claims or physician documented inadequate response or adverse reaction to **ONE conventional therapy** (see appendix):
    - i. topical agent
    - ii. phototherapy
    - iii. systemic agent
  - b. Contraindication to **ALL conventional therapies**
    - i. topical agents
    - ii. phototherapy
    - iii. systemic agent
  - c. Paid claims or physician documented inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for plaque psoriasis
3. Appropriate dosing

**Moderate to Severe Polyarticular Juvenile Idiopathic Arthritis (pJIA)**

Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. **ONE** of the following:
  - a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** traditional DMARD or contraindication to **ALL** traditional DMARDs
  - b. Paid claims or physician documented inadequate response or adverse reaction to **ONE** anti-TNF agent or contraindication to **ALL** anti-TNF agents
3. Appropriate dosing
4. **ONE** of the following:
  - a. If the request is for Xeljanz®, quantity requested is  $\leq 2$  tablets/day
  - b. If the request is for Xeljanz® solution, quantity requested is  $\leq 10$  mL/day

**Continuation of Therapy**

Resubmission by prescriber for any of the following FDA-approved diagnoses will infer a positive response to therapy and request can be recertified if dosing is appropriate.

**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® 5mg and 10mg	60 tablets per 30 days
Xeljanz® XR 22mg	30 tablets per 30 days

**Appendices**

**Appendix A: Traditional DMARDS**

<b>Traditional DMARDS*</b>	
azathioprine	methotrexate*
cyclosporine	sulfasalazine*
hydroxychloroquine*	thalidomide
leflunomide	

If a member has a contraindication to **ALL** of the most commonly used traditional DMARDs\* (methotrexate, sulfasalazine, and hydroxychloroquine), a trial with a traditional DMARD may be bypassed.

### Appendix B: More frequent/Higher doses

Requests more frequent or higher doses of injectable biologics, may be approved if **ALL** of the following is provided:

1. Documentation of severe disease
2. **ONE** of the following:
  - a. Inadequate response or adverse reaction to **ONE** other injectable biologic which is FDA-approved for the requested indication
  - b. Contraindication to **ALL** other injectable biologics which are FDA-approved for the requested indication
3. Documented partial response to FDA-approved dosing of current biologic therapy
4. Documentation of specialist consult for the requested indication

### Appendix C: Xeljanz<sup>®</sup> and Xeljanz XR<sup>®</sup> in Alopecia Areata

Requests for Xeljanz<sup>®</sup> (tofacitinib) or Xeljanz XR<sup>®</sup> (tofacitinib extended-release) in alopecia areata should be reviewed using the criteria below:

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of alopecia areata
2. Prescriber is a dermatologist or consult notes from a dermatologist are provided
3. **ONE** of the following:
  - a. **BOTH** of the following:
    - i. Physician documentation of inadequate response or adverse reaction to **ONE** or contraindication **ALL** to topical corticosteroids\*
    - ii. Physician documentation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** intralesional corticosteroids\*
  - b. Physician documentation that member has a large area of hair loss (such as  $\geq 25\%$  scalp hair)
4. **ONE** of the following
  - a. For Xeljanz<sup>®</sup>, requested quantity is  $\leq 2$  tablets/day
  - b. For Xeljanz XR<sup>®</sup>, requested quantity is  $\leq 1$  tablet/day
  - c. For Xeljanz<sup>®</sup> solution, requested quantity is  $\leq 10$  mL/day
5. For **Xeljanz<sup>®</sup> solution**, medical necessity for the use of a solution formulation as noted by **ONE** of the following:
  - a. Member utilizes tube feeding (G-tube/J-tube)
  - b. Member has a swallowing disorder or condition affecting ability to swallow
  - c. Member is  $< 13$  years of age
  - d. Requested dose is  $< 5$  mg

### References

1. Xeljanz/Xeljanz XR (tofacitinib) [prescribing information]. New York, NY: Pfizer; December 2021.
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.

10/21/2020 – Reviewed and Updated; separated out Comm/Exch vs. MassHealth. Matched MassHealth Preferred Unified Formulary for implementation 1/1/2021

03/17/2021 – Reviewed and Updated; added moderate to severe polyarticular juvenile idiopathic arthritis (pJIA). Effective 06/01/2021

11/17/2021 –Reviewed and Updated for Nov P&T; matched MH UPPL for 1/1/2022 implementation; added appendix with higher dose/more frequent dosing and off label indication. Effective 01/01/2022.

05/18/2022 – Reviewed and Updated for May P&T; the guideline was updated to reflect the preferred drug status of Xeljanz® (tofacitinib oral solution) which was recently added to the supplemental rebate contract; added indication for PJIA and criteria for moderate to severe plaque psoriasis. Matched MH UPPL effective 7/1/2022

06/22/2022 – Reviewed and Updated for June P&T; matched MH UPPL. Added criteria for newly FDA-approved indications: ankylosing spondylitis. Updated RA, PsA, UC, and pJIA criteria to require a step through at least one anti-TNF agent. Continuation of therapy language was updated. Updated Appendices and References. Effective 08/01/2022.

11/16/2022 – Reviewed and updated for Nov P&T; matched MH. Added “Appendix C: Xeljanz® and Xeljanz XR® in Alopecia Areata” to reflect off-label use in alopecia areata. Separated RA, PsA, UC criteria with different step through requirement. Effective 11/01/2022

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