Xeljanz® (tofacitinib)
Xeljanz XR® (tofacitinib)
Xeljanz ® (tofacitinib) solution
Effective 03/01/2023

Plan	☐ MassHealth ☒ MassHealth (PUF) ☐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. Active ankylosing spondylitis (AS)
4. Moderately to severely active ulcerative colitis (UC)
5. Moderate to severe polyarticular juvenile idiopathic arthritis (pJIA) – Xeljanz tablet, 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 requested medication 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

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

1. Diagnosis of moderate-to-severe rheumatoid arthritis
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®, quantity requested is ≤2 tablets/day
    b. If the request is for Xeljanz XR®, quantity requested is ≤1 tablet/day

Note: Xeljanz solution is only FDA approved for PJIA.

Psoriatic arthritis (PsA)

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

1. Diagnosis of psoriatic arthritis
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®, quantity requested is ≤2 tablets/day
    b. If the request is for Xeljanz XR®, quantity requested is ≤1 tablet/day

Moderate to severe ulcerative colitis

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®, quantity requested is ≤2 tablets/day
    b. If the request is for Xeljanz XR®, quantity requested is ≤1 tablet/day

Ankylosing spondylitis

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

1. Diagnosis of ankylosing spondylitis
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®, quantity requested is ≤2 tablets/day
    b. If the request is for Xeljanz XR®, quantity requested is ≤1 tablet/day

Moderate-to-severe polyarticular juvenile idiopathic arthritis

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

1. Diagnosis of moderate-to-severe polyarticular juvenile idiopathic arthritis

2. Paid claims or physician documented inadequate response or adverse reaction to **ONE** 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 ≤2 tablets/day
    b. If the request is for Xeljanz® solution, quantity requested is ≤20 mL/day

Off-Label Indications

For Xeljanz® solution

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

1. PA criteria for Xeljanz® or Xeljanz XR® must be met, depending on indication
2. 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
3. Requested quantity is ≤ 20 mL/day

For Xeljanz®, Xeljanz® XR, Xeljanz® solution

Alopecia areata

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 showing that member has a large area of hair loss (such as ≥ 25% scalp hair)
4. **ONE** of the following
    a. For Xeljanz® tablet, requested quantity is ≤ 2 tablets/day
    b. For Xeljanz XR®, requested quantity is ≤ 1 tablet/day
    c. For Xeljanz® solution, requested quantity is ≤ 20 mL/day
5. For Xeljanz® 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

Hidradenitis suppurativa

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

1. Diagnosis of hidradenitis suppurativa
2. Paid claims or physician documentation of inadequate response, adverse reaction or contraindication to Humira®

3. For Xeljanz® oral 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
4. **ONE** of the following:
    a. For Xeljanz XR®, requested quantity is ≤ 1 tablet/day
    b. For Xeljanz® tablet, requested quantity is ≤ 2 tablets/day
    c. For Xeljanz® solution, requested quantity is ≤ 20 mL/day

Moderate to severe plaque psoriasis
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of moderate to severe plaque psoriasis
2. **ONE** of the following:
    a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** or contraindication to **ALL** conventional therapies (see appendix):
        i. topical agent
        ii. phototherapy
        iii. systemic agent
    b. Paid claims or physician documented inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for plaque psoriasis
3. For Xeljanz® oral 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
4. **ONE** of the following:
    a. For Xeljanz XR®, requested quantity is ≤ 1 tablet/day
    b. For Xeljanz® tablet, requested quantity is ≤ 2 tablets/day
    c. For Xeljanz® solution, requested quantity is ≤ 20 mL/day

New members currently stable on Xeljanz®/Xeljanz XR® can be approved without documentation of failed trials with the conventional therapies for that diagnosis.

Continuation of Therapy
Reauthorization requires physician documentation of a positive response to therapy.

Limitations
1. Initial approvals will be granted for:
    a. Plaque psoriasis and off-label indications: 3 months
    b. FDA-approved indications: 6 months.
2. Reauthorizations will be granted for 12 months
3. The following quantity limits apply:

Xeljanz® 5mg, 10mg	60 tablets per 30 days
Xeljanz® XR 11mg, 22mg	30 tablets per 30 days
Xeljanz® solution 1mg/mL	600 mL per 30 days

Appendix A: Traditional DMARDS

Traditional DMARDS*	
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.	

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
01/11/2023 – Reviewed and updated for Jan P&T. Update included removal of the option for a low cost alternative trial with traditional DMARDs for Xeljanz requests in PJIA and RA and to specifically require an anti-TNF agent trial. QL for Xeljanz oral solution was increased from 10 mL/day to 20 mL/day. New off-label indications added including: alopecia areata, HS, plaque psoriasis. Clarified initial approval durations: PsA and off-label for 3 months and FDA-approved indications for 6 months. Added strengths 11mg and 1mg/mL solution. Removed appendix for higher doses as it only pertains to injectable biologics. Appropriate diagnosis was replaced with a specific indication throughout. Added language regarding stability of requested medication for new members. Effective 3/1/23.

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