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. Moderate to severely active juvenile idiopathic arthritis (pJIA) – Xeljanz only

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members new to AllWays Health Partners 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), Psoriatic arthritis (PsA), Moderate to severe Ulcerative Colitis (UC) and 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 traditional DMARDs
   b. Paid claims or physician documented inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for the requested indication

3. **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 (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 traditional DMARDs
   b. Paid claims or physician documented inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for the requested indication
3. **ONE** of the following:
   a. If the request is for Xeljanz®, quantity requested is ≤2 tablets/day

**Continuation of Therapy**
Reauthorization requires physician documentation of continuation of therapy, positive response to therapy, FDA approved indication and appropriate dosing.

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

<table>
<thead>
<tr>
<th>Xeljanz® 5mg and 10mg</th>
<th>60 tablets per 30 days</th>
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<tbody>
<tr>
<td>Xeljanz® XR 22mg</td>
<td>30 tablets per 30 days</td>
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</table>

**Appendices**

**Appendix A: Traditional DMARDs**

<table>
<thead>
<tr>
<th>Traditional DMARDs*</th>
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<tbody>
<tr>
<td>azathioprine</td>
<td>methotrexate*</td>
</tr>
<tr>
<td>cyclosporine</td>
<td>sulfasalazine*</td>
</tr>
<tr>
<td>hydroxychloroquine*</td>
<td>thalidomide</td>
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<tr>
<td>leflunomide</td>
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</table>

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. Conventional Therapies for Plaque Psoriasis**

<table>
<thead>
<tr>
<th>Conventional Treatment Lines</th>
<th>Agents Used</th>
</tr>
</thead>
</table>
Topical Agents  |  emollients, keratolytics, corticosteroids, coal tar, anthralin, calcipotriene, tazarotene, calcitriol, calcineurin inhibitors
---|---
Systemic Agents  |  Traditional DMARDs: methotrexate, apremilast, acitretin,
Phototherapy  |  ultraviolet A and topical psoralens (topical PUVA), ultraviolet A and oral psoralens (systemic PUVA), narrow band UV-B (NUVB)

**Appendix C: Off-Label Indications**

**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

**Atopic Dermatitis (moderate-to-severe)**
Prescriber documents ALL of the following:

1. Paid claim or physician attestation of inadequate response, adverse reaction or contraindication to phototherapy
2. Paid claim or physician attestation of response, adverse reaction or contraindication to **TWO** traditional DMARDs (cyclosporine, methotrexate, mycophenolate, azathioprine) or a contraindication to all traditional DMARDs

**References**

1. Xeljanz/Xeljanz XR (tofacitinib) [prescribing information]. New York, NY: Pfizer; October 2018

**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
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.

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exclude people on the basis of race, color, national origin, age, disability, or sex.