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:

<table>
<thead>
<tr>
<th>Product</th>
<th>Quantity Limit</th>
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</thead>
<tbody>
<tr>
<td>Xeljanz®</td>
<td>60 tablets per 30 days</td>
</tr>
<tr>
<td>Xeljanz® XR</td>
<td>30 tablets per 30 days</td>
</tr>
</tbody>
</table>

**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

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