UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number | 2016 P 3026-6
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Program | Step Therapy
Medications | Xeljanz®/ Xeljanz® XR (tofacitinib)
P&T Approval Date | 2/2013, 7/2013, 10/2014, 10/2015, 8/2016
Effective Date | 11/1/2016; Oxford only: N/A

1. **Background:**

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to try two preferred self-administered injectable products before providing coverage for Xeljanz® or Xeljanz® XR (tofacitinib). Infused medications approved for the treatment of rheumatoid arthritis are not part of the criteria.

Xeljanz/Xeljanz XR is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate. It may be used as monotherapy or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs). Examples of nonbiologic DMARDs commonly used in the treatment of rheumatoid arthritis include methotrexate, leflunomide, and sulfasalazine.

Humira® (adalimumab) is indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. Ćimzia® (certolizumab) and Simponi® (golimumab) are indicated for the treatment of adults with moderately to severely active rheumatoid arthritis. Ćimzia and Humira may be used alone or in combination with a disease-modifying anti-rheumatic drugs (DMARDs). Simponi is FDA approved for use with methotrexate in patients with moderately to severely active rheumatoid arthritis.

Members currently on Xeljanz or Xeljanz XR therapy as documented in claims history will be allowed to continue on their current therapy. Members new to therapy will be required to meet the coverage criteria below.

2. **Coverage Criteria a,b,c:**

A. **Rheumatoid Arthritis (RA)**

1. **Xeljanz or Xeljanz XR** will be approved based on **one** of the following criteria:

   a. History of failure, contraindication, or intolerance to **two** of the following preferred products:

      (1) Ćimzia (certolizumab)
      (2) Humira (adalimumab)
      (3) Simponi (golimumab)

   -OR-

   b. Patient has a documented needle-phobia to the degree that the patient has previously
refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria7).

-OR-

c. Both of the following:

(1) Patient is currently on Xeljanz or Xeljanz XR therapy

-AND-

(2) One of the following:

(a) Patient has not received a manufacturer supplied sample at no cost from a prescriber office or a 30 day free trial from a pharmacy as a means to establish as a current user of Xeljanz or Xeljanz XR

-OR-

(b) Both of the following:

i. Patient has received a manufacturer supplied sample at no cost from a prescriber office or a 30 day free trial from a pharmacy as a means to establish as a current user of Xeljanz or Xeljanz XR

-AND-

ii. One of the following:

• History of failure, contraindication, or intolerance to two of the following preferred products:
  • Cimzia (certolizumab)
  • Humira (adalimumab)
  • Simponi (golimumab)

-OR-

• Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-5-TR 300.29 for specific phobia diagnostic criteria7).

B. Other Diagnoses

1. Xeljanz or Xeljanz XR will be approved

Authorization will be issued for 60 months.

a For Maryland, requests for continuation of therapy may also be approved if the provider confirms the patient has been on the medication in the past 180 days and that the
medication is effective in treating the patient’s condition. Please see Maryland Continuation of Care guideline.

b For Indiana (effective 7/1/16) and West Virginia (effective 1/1/17), step therapy requirements may be approved if the patient has previously received either a documented step one prescription drug or another prescription drug that has the same mechanism of action as a preceding prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event. For West Virginia (effective 1/1/17) members only, coverage may also be provided for continuation of therapy if the member is currently stabilized on the requested medication for the same medical condition.

c For California, requests for continuation of therapy may also be approved if the provider confirms the patient has been on the medication, it is appropriately prescribed, and that the medication is considered safe and effective in treating the patient’s condition.

3. **Additional Clinical Rules:**
Supply limits and/or Notification may be in place.

4. **References:**


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<td><strong>Change Control</strong></td>
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<tr>
<td>10/2014</td>
<td>Revised step 1 agents to remove Enbrel and replace with Humira. Updated references.</td>
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<tr>
<td>10/2015</td>
<td>Annual review. Updated references and added additional sample pack language. Added Maryland Continuation of Care.</td>
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<tr>
<td>7/2016</td>
<td>Added Indiana and West Virginia coverage information.</td>
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<td>8/2016</td>
<td>Annual review. Added Xeljanz XR to the criteria. Updated references.</td>
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<tr>
<td>11/2016</td>
<td>Administrative change. Added California coverage information.</td>
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