UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 3026-10
Program	Step Therapy
Medications	Xeljanz®/ Xeljanz® XR (tofacitinib)
P&T Approval Date	2/2013, 7/2013, 10/2014, 10/2015, 8/2016, 8/2017, 2/2018, 9/2018
Effective Date	11/1/2018; Oxford only: 12/1/2018

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). Xeljanz/Xeljanz XR is also indicated for the treatment of adult patients with active psoriatic arthritis who have had an inadequate response or intolerance to methotrexate or other DMARDs. Xeljanz, but not Xeljanz XR, is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis.[1]

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.[2] Humira is also indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis. Cimzia® (certolizumab) and Simponi® (golimumab) are indicated for the treatment of adults with moderately to severely active rheumatoid arthritis and for the treatment of adult patients with active psoriatic arthritis.[3,4] Cimzia and Humira may be used alone or in combination with a disease-modifying anti-rheumatic drugs (DMARDs). Simponi is indicated for use with methotrexate in patients with moderately to severely active rheumatoid arthritis. Stelara® (ustekinumab) is indicated for the treatment of adult patients with active psoriatic arthritis and can be used alone or in combination with methotrexate (MTX).

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]:

A. <u>Rheumatoid Arthritis (RA)</u>

1. Xeljanz or Xeljanz XR will be approved based on **<u>both</u>** of the following criteria:

a. Diagnosis of rheumatoid arthritis

-AND-

b. **One** of the following:

(1) History of failure, contraindication, or intolerance to **two** of the following preferred products:

(a) Cimzia (certolizumab)
(b) Humira (adalimumab)
(c) Simponi (golimumab)

-OR-

(2) 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 criteria[5]).

-OR-

(3) **Both** of the following:

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

-AND-

(b) Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Pfizer sponsored XELSOURCE program (e.g. sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Xeljanz or Xeljanz XR*

*Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Pfizer sponsored XELSOURCE program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

B. Psoriatic Arthritis

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

a. Diagnosis of active psoriatic arthritis

-AND-

b. **One** of the following:

(1) History of failure, contraindication, or intolerance to **two** of the following preferred products:

(a) Humira (adalimumab)
(b) Stelara (ustekinumab)
(c) Cimzia (certolizumab)
(d) Simponi (golimumab)

-OR-

(2) 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 criteria[5]).

-OR-

(3) **Both** of the following:

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

-AND-

(b) Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Pfizer sponsored XELSOURCE program (e.g. sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Xeljanz or Xeljanz XR*

*Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Pfizer sponsored XELSOURCE program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

B. Ulcerative Colitis (UC) (Xeljanz only)

1. **Xeljanz** will be approved based on **both** of the following criteria:

c. Diagnosis of moderately to severely active UC

-AND-

d. **One** of the following:

(1) History of failure, contraindication, or intolerance to **both** of the following preferred products:

(a) Humira (adalimumab)
(b) Simponi (golimumab)

-OR-

(2) 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 criteria[5]).

-OR-

(3) **Both** of the following:

(a) Patient is currently on Xeljanz therapy

-AND-

(b) Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Pfizer sponsored XELSOURCE program (e.g. sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Xeljanz*

*Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Pfizer sponsored XELSOURCE program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

D. Other Diagnoses

1. **Xeljanz or Xeljanz XR** will be approved

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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

4. References:

1. Xeljanz/Xeljanz XR [package insert]. New York, NY: Pfizer Labs; June 2018.
2. Humira [package insert]. North Chicago, IL: AbbVie Inc..; December 2017.
3. Cimzia [package insert]. Smyrna, GA: UCB, Inc.; January 2017.
4. Simponi [package insert]. Horsham, PA: Janssen Biotech, Inc. ; June 2017.
5. American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Arlington, VA: American Psychiatric Publishing. 2013.
6. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc. October 2017.
7. Coates LC, Kavanaugh A, Mease PJ, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis 2015 Treatment Recommendations for Psoriatic Arthritis. Arthritis Rheumatol. 2016 May;68(5):1060-71.

Program	Step Therapy – Xeljanz/Xeljanz XR (tofacitinib)
Change Control	
10/2014	Revised step 1 agents to remove Enbrel and replace with Humira. Updated references.
10/2015	Annual review. Updated references and added additional sample pack language. Added Maryland Continuation of Care.
7/2016	Added Indiana and West Virginia coverage information.
8/2016	Annual review. Added Xeljanz XR to the criteria. Updated references.
11/2016	Administrative change. Added California coverage information.
8/2017	Annual Review. Updated sample language, added diagnosis requirement, and changed duration of approval. References updated. State mandate reference language updates.
3/2018	Administrative change to adjust Oxford effective date.
2/2018	Added step therapy criteria for psoriatic arthritis. Updated references.
9/2018	Added step therapy criteria for ulcerative colitis. Updated references.