UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 3026-14
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, 9/2019, 2/2020, 11/2020, 11/2021
Effective Date	2/1/2022; 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 self-administered injectable products before providing coverage for Xeljanz® or Xeljanz® XR (tofacitinib) for psoriatic arthritis or ulcerative colitis. Infused medications are not part of the criteria.

Xeljanz/Xeljanz XR is a Janus kinase (JAK) inhibitor indicated for the treatment of adult patients with active psoriatic arthritis who have had an inadequate response or intolerance to methotrexate or other disease modifying antirheumatic drugs (DMARDs). Xeljanz/Xeljanz XR is also indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have an inadequate response or who are intolerant to tumor necrosis factor (TNF) blockers.[1]

Humira® (adalimumab) is a TNF blocker indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis and can be used alone or in combination with non-biologic DMARDs.[2] Cimiza® (certolizumab) is a TNF blocker indicated for the treatment of adult patients with active psoriatic arthritis.[3] Simponi® (golimumab) is a TNF blocker indicated for the treatment of adult patients with active psoriatic arthritis alone, or in combination with methotrexate.[4] Stelara® (ustekinumab) is a interleukin-12 and -23 antagonist indicated for the treatment of adult patients with active psoriatic arthritis alone, or in combination with methotrexate.[5] Tremfya® (guselkumab) is an interleukin-23 blocker indicated for the treatment of adult patients with active psoriatic arthritis.[6]

Humira is indicated for inducing and sustaining clinical remission in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to immunosuppressants such as corticosteroids, azathioprine, or 6-mercaptopurine (6-MP).[2] Simponi is indicated in adult patients with moderate to severe ulcerative colitis who have demonstrated corticosteroid dependence or who have had an inadequate response or intolerance to oral aminosalicylates, oral corticosteroids, azathioprine, or 6-MP for inducing and maintaining clinical response, improving endoscopic appearance of the mucosa during induction, inducing clinical remission, and achieving and sustaining clinical remission in induction responders.[4] Stelara is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis. [6]

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. 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)
(e) Tremfya (guselkumab)

-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)

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

   a. Diagnosis of moderately to severely active UC

   -AND-

   b. **One** of the following:

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

         (a) Humira (adalimumab)
         (b) Simponi (golimumab)
         (c) Stelara (ustekinumab)

      -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.

C. 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/Xeljanz Oral Soultion [package insert]. New York, NY: Pfizer Labs; October 2020.
2. Humira [package insert]. North Chicago, IL: AbbVie Inc..; February 2021.
3. Cimzia [package insert]. Smyrna, GA: UCB, Inc.; September 2019.
4. Simponi [package insert]. Horsham, PA: Janssen Biotech, Inc.; September 2019.
5. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; December 2020.
6. Tremfya [package insert]. Horsham, PA: Janssen Biotech, Inc.; July 2020.
7. Singh JA, Guyatt G, Ogdie A, et al. Special Article: 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Arthritis Care Res (Hoboken)*. 2019;71(1):2-29. doi:10.1002/acr.23789
8. Rubin DT, Ananthakrishnan AN, Siegel CA, Sauer BG, Long MD. ACG Clinical Guideline: Ulcerative Colitis in Adults. *Am J Gastroenterol*. 2019;114(3):384-413. doi:10.14309/ajg.0000000000000152

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.
9/2019	Removed step therapy requirement for rheumatoid arthritis. Updated background and references.
2/2020	Added Stelara as a step therapy medication for ulcerative colitis due to new indication. Added Xeljanz XR to ulcerative colitis section due to expanded indication. Updated background and references.
11/2020	Added Tremfya as a step therapy medication for psoriatic arthritis. Updated background and references.
11/2021	Annual review with no changes to clinical coverage criteria. Updated background and references.