UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Xeljanz/Xeljanz XR - OHIO

Program	Prior Authorization
Medication	Xeljanz and Xeljanz XR (tofacitinib)
Markets In Scope	Ohio

1. Background:

XELJANZ/XELJANZ XR (tofacitinib) 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 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.

2. Coverage Criteria:

A. Rheumatoid Arthritis (RA)

1. **Initial Authorization**

a. Diagnosis of moderately to severely active RA (e.g., swollen, tender joints with limited range of motion)

-AND-

b. Prescribed or recommended by a rheumatologist

-AND-

c. History of failure, contraindication, or intolerance to methotrexate

-AND-

d. **One** of the following:

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

- Cimzia (certolizumab)
- Humira (adalimumab)

- Enbrel (etanercept)

-OR-

(2) For continuation of prior Xeljanz/Xeljanz XR therapy

-AND-

e. Patient is not receiving Xeljanz/Xeljanz XR in combination with a biologic DMARD [e.g. Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]

-AND-

f. Patient is not receiving Xeljanz/Xeljanz XR in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine)

Authorization will be issued for 12 months.

2. **Reauthorization**

a. Documentation of positive clinical response to Xeljanz/Xeljanz XR therapy

-AND-

b. Patient is not receiving Xeljanz/Xeljanz XR in combination with a biologic DMARD [e.g. Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]

-AND-

c. Patient is not receiving Xeljanz/Xeljanz XR in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine)

Authorization will be issued for 12 months.

B. Psoriatic Arthritis (PsA)

1. **Initial Authorization**

a. Diagnosis of active psoriatic arthritis

-AND-

b. Prescribed or recommended by a rheumatologist or dermatologist

-AND-

c. History of failure, contraindication, or intolerance to one non-biologic disease modifying anti-rheumatic drug (DMARD) [eg, methotrexate, leflunomide, sulfasalazine, hydroxychloroquine]

-AND-

d. **One** of the following:

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

- Cimzia (certolizumab)
- Humira (adalimumab)
- Enbrel (etanercept)

-OR-

(2) For continuation of prior Xeljanz/Xeljanz XR therapy

-AND-

e. Patient is not receiving Xeljanz/Xeljanz XR in combination with a biologic DMARD [e.g. Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]

-AND-

f. Patient is not receiving Xeljanz/Xeljanz XR in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine)

Authorization will be issued for 12 months.

2. **Reauthorization**

a. Documentation of positive clinical response to Xeljanz/Xeljanz XR therapy

-AND-

b. Patient is not receiving Xeljanz/Xeljanz XR in combination with a biologic DMARD [e.g. Enbrel (etanercept), Humira (adalimumab), Cimzia

(certolizumab), Simponi (golimumab)]

-AND-

c. Patient is not receiving Xeljanz/Xeljanz XR in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine)

Authorization will be issued for 12 months.

3. References:

1. Xeljanz/Xeljanz XR Prescribing Information. Pfizer, Inc. December 2017.
2. van Vollenhoven RF, Fleischmann R, Cohen S, Lee EB, García Meijide JA, Wagner S, Forejtova S, Zwillich SH, Gruben D, Koncz T, Wallenstein GV, Krishnaswami S, Bradley JD, Wilkinson B; ORAL Standard Investigators. Tofacitinib or adalimumab versus placebo in rheumatoid arthritis. N Engl J Med. 2012;367(6):508-519.
3. Fleischmann R, Kremer J, Cush J, Schulze-Koops H, Connell CA, Bradley JD, Gruben D, Wallenstein GV, Zwillich SH, Kanik KS; ORAL Solo Investigators. Placebo-controlled trial of tofacitinib monotherapy in rheumatoid arthritis. N Engl J Med. 2012;367(6):495-507.
4. Singh JA, Furst DE, Bharat A, et al. 2012 update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. Arthritis Care Res. 2012;64(5):625-39.
5. American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Review. Washington, DC, American Psychiatric Association, 2000.

Program	Program type – Prior Authorization
Change Control	
Date	Change
2/2018	Ohio specific policy created for 4/1/18 since Ohio will be moving to a Single PDL later in 2018.