UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Xeljanz/Xeljanz XR/Xeljanz Oral Solution

Program	Prior Authorization
Medication	Xeljanz, Xeljanz XR and Xeljanz Oral Solution (tofacitinib)
Markets in Scope	Colorado, California, Hawaii, Maryland, Nevada, New Jersey, New York, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	3/2013
Pharmacy and Therapeutics Approval Date	12/2020
Effective Date	1/1/2021

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 non-biologic disease-modifying anti-rheumatic 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/Xeljanz XR is also indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response or who are intolerant to TNF blockers.

Xeljanz/Xeljanz Oral Solution is indicated for the treatment of active polyarticular course juvenile idiopathic arthritis in patients 2 years of age and older.

Xeljanz/Xeljanz XR/Xeljanz Oral Solution in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

2. Coverage Criteria:

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

1. **<u>Initial Authorization</u>**

<u>One</u> of the following:

(1) **<u>All</u>** of the following:

a. Diagnosis of moderately to severely active RA

-AND-

b. History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)

-AND-

c. **Both** of the following:

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

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

-AND-

(b) History of failure, contraindication, or intolerance to Olumiant (baricitinib)

-AND-

d. Patient is not receiving Xeljanz/Xeljanz XR in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Potent immunosuppressant (e.g., azathioprine or cyclosporine)
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]
(4) Janus kinase inhibitor [e.g., Olumiant (baricitinib)]

-AND-

e. Prescribed by or in consultation with a rheumatologist

-OR-

(2) **All** of the following:

a. Diagnosis of moderately to severely active RA

-AND-

b. Patient is not receiving Xeljanz/Xeljanz XR in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Potent immunosuppressant (e.g., azathioprine or cyclosporine)
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]
(4) Janus kinase inhibitor [e.g., Olumiant (baricitinib)]

-AND-

c. Patient is currently on Xeljanz/Xeljanz XR therapy and the provider attests that switching therapy would be clinically inappropriate

-AND-

d. Prescribed by or in consultation with a rheumatologist

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 **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Potent immunosuppressant (e.g., azathioprine or cyclosporine)
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]
(4) Janus kinase inhibitor [e.g., Olumiant (baricitinib)]

-AND-

c. Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

B. Psoriatic Arthritis (PsA)

1. **Initial Authorization**

One of the following:

(1) **All** of the following:

a. Diagnosis of active psoriatic arthritis

-AND-

b. History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)

-AND-

c. **Both** of the following:

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

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

-AND-

(b) History of failure, contraindication, or intolerance to Cosentyx (secukinumab)

-AND-

d. Patient is not receiving Xeljanz/Xeljanz XR in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Potent immunosuppressant (e.g., azathioprine or cyclosporine)
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]
(4) Janus kinase inhibitor [e.g., Olumiant (baricitinib)]

-AND-

e. Prescribed by or in consultation with **one** of the following:

(1) Rheumatologist
(2) Dermatologist

-OR-

(2) **All** of the following:

a. Patient is currently on Xeljanz/Xeljanz XR therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

-AND-

b. Diagnosis of active psoriatic arthritis

-AND-

c. Patient is not receiving Xeljanz/Xeljanz XR in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Potent immunosuppressant (e.g., azathioprine or cyclosporine)
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]
(4) Janus kinase inhibitor [e.g., Olumiant (baricitinib)]

-AND-

d. Prescribed by or in consultation with **one** of the following:

(1) Rheumatologist
(2) Dermatologist

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 **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Potent immunosuppressant (e.g., azathioprine or cyclosporine)
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]
(4) Janus kinase inhibitor [e.g., Olumiant (baricitinib)]

-AND-

c. Prescribed by or in consultation with **one** of the following:

(1) Rheumatologist
(2) Dermatologist

Authorization will be issued for 12 months.

C. Ulcerative Colitis (UC)

1. **Initial Authorization**

One of the following:

(1) **All** of the following:

a. Diagnosis of moderately to severely active UC

-AND-

b. History of failure to **one** of the following conventional therapies at maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):

(1) Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
(2) 6-mercaptopurine (Purinethol)
(3) Azathioprine (Imuran)
(4) Aminosalicylates (e.g., mesalamine, sulfasalazine)

-AND-

c. History of failure, contraindication, or intolerance to Humira (adalimumab)

-AND-

d. Patient is not receiving Xeljanz/Xeljanz XR in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Potent immunosuppressant (e.g., azathioprine or cyclosporine)
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]
(4) Janus kinase inhibitor [e.g., Olumiant (baricitinib)]

-AND-

e. Prescribed by or in consultation with a gastroenterologist

-OR-

(2) **All** of the following:

a. Patient is currently on Xeljanz/Xeljanz XR therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

-AND-

b. Diagnosis of moderately to severely active UC

-AND-

c. Patient is not receiving Xeljanz/Xeljanz XR in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Potent immunosuppressant (e.g., azathioprine or cyclosporine)
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]
(4) Janus kinase inhibitor [e.g., Olumiant (baricitinib)]

-AND-

d. Prescribed by or in consultation with a gastroenterologist

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 **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Potent immunosuppressant (e.g., azathioprine or cyclosporine)
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]
(4) Janus kinase inhibitor [e.g., Olumiant (baricitinib)]

-AND-

c. Prescribed by or in consultation with a gastroenterologist

Authorization will be issued for 12 months.

D. Polyarticular Juvenile Idiopathic Arthritis

1. Initial Authorization

One of the following:

(1) **All** of the following:

a. Diagnosis of active polyarticular juvenile idiopathic arthritis

-AND-

b. History of failure, contraindication, or intolerance to **both** of the following:
- Humira (adalimumab)
- Enbrel (etanercept)

-AND-

c. Patient is not receiving Xeljanz or Xeljanz Oral Solution in combination with **any** of the following:

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(b) Potent immunosuppressant (e.g., azathioprine or cyclosporine)
(c) Janus kinase inhibitor [e.g., Olumiant (baricitinib)]

-AND-

d. Prescribed by or in consultation with a rheumatologist

-OR-

(2) **All** of the following:

a. Patient is currently on Xeljanz/Xeljanz Oral Solution as documented by claims history or medical records (document drug, date, and duration of therapy)

-AND-

b. Diagnosis of active polyarticular juvenile idiopathic arthritis

-AND-

c. Patient is not receiving Xeljanz or Xeljanz Oral Solution in combination with **any** of the following:

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(b) Potent immunosuppressant (e.g., azathioprine or cyclosporine)
(c) Janus kinase inhibitor [e.g., Olumiant (baricitinib)]

-AND-

d. Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

2. Reauthorization

a. Xeljanz or Xeljanz Oral Solution will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Xeljanz or Xeljanz Oral Solution therapy

-AND-

(2) Patient is not receiving Xeljanz or Xeljanz Oral Solution in combination with **any** of the following:

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(b) Potent immunosuppressant (e.g., azathioprine or cyclosporine)
(c) Janus kinase inhibitor [e.g., Olumiant (baricitinib)]

-AND-

(3) Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4. References:

1. Xeljanz/Xeljanz XR/Xeljanz Oral Solution [package insert]. New York, NY: Pfizer, Inc. September 2020.
2. 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.
3. Singh, JA, Guyatt, G, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis & Rheumatology. 2019; 71(1): 5-32.

Program	Program type – Prior Authorization
Change Control	
Date	Change
3/2013	New Guideline
2/2015	Template updated Removed age requirement for all indications. Changed requirement that there is a trial of two of the following: Cimzia, Enbrel, Humira, Simponi to new requirement of trial of

	both Humira and Cimzia or continuation of existing Xeljanz therapy. Added requirement to the reauthorization criteria that the patient is not using Xeljanz in combination with a biologic DMARD
3/2016	Added Enbrel to prerequisite therapy list Updated policy template
10/2016	Annual Review – no change
1/2017	Added "Xeljanz XR" where only Xeljanz was listed previously – criteria applies to both Xeljanz and Xeljanz XR Updated policy template
3/2017	Minor updates to policy template
2/2018	Updated step therapy medications in the rheumatoid arthritis section to a trial of two TNF inhibitors and Kevzara due to PDL changes effective 4/1/18. Added review criteria for psoriatic arthritis. Updated background and references.
7/2018	Updated background and criteria to include new indication of ulcerative colitis. Added Olumiant to list of medications not to be used with Xeljanz/Xeljanz XR. Updated references.
3/2019	Removed prescriber check. Revised step therapy medications for RA section.
11/2019	Revised PsA and UC step therapy medications. Updated background and references.
12/2019	Revised additional prerequisite therapies and added documentation of drug, date, and duration of trials. Separated continuation of therapy requirements for current users.
1/2020	Revised RA biologic step therapy medications due to PDL changes. Added prescriber attestation to the continuation of therapy allowance due to PDL strategy.
2/2020	Added Xeljanz XR to the ulcerative colitis section due to expanded indication for use. Updated background and references.
5/2020	Added prescriber requirement. Minor updates to prerequisite therapy requirements.

1/2021	Added Xeljanz Oral Solution to the program. Added ST thru preferred medications and COT language. Updated background and criteria due to new indication for polyarticular juvenile idiopathic arthritis. Added Additional Clinical Rules section.