UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1116-18
Program	Prior Authorization/Notification
Medication	Xeljanz®/Xeljanz® XR/Xeljanz® Oral Solution (tofacitinib)
P&T Approval Date	11/2012, 2/2013, 2/2014, 2/2015, 3/2016, 3/2017, 2/2018, 7/2018, 7/2019, 9/2019, 2/2020, 11/2020, 11/2021, 2/2022, 2/2023, 7/2023, 9/2023
Effective Date	12/1/2023

1. Background:

Xeljanz/Xeljanz XR (tofacitinib) is a Janus kinase (JAK) inhibitor indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis, active psoriatic arthritis, ankylosing spondylitis and moderately to severely active ulcerative colitis, who have had an inadequate response or intolerance to one or more 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 who have had an inadequate response or intolerance to one or more TNF blockers.

Limitations of Use:
The use of Xeljanz/Xeljanz XR/Xeljanz Oral Solution in combination with biologic DMARDs, biologic therapies for UC or potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

2. Coverage Criteria[a]:

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

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

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

(1) Diagnosis of moderately to severely active RA

-AND-

(2) History of failure, contraindication, or intolerance to at least **<u>one</u>** TNF inhibitor

-AND-

(3) Patient is not receiving Xeljanz or Xeljanz XR in combination with **<u>either</u>** of the following:

(a) Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Rinvoq (upadacitinib), Olumiant (baricitinib)]
(b) Potent immunosuppressant (e.g., azathioprine or cyclosporine)

Authorization will be issued for 12 months.

2. **Reauthorization**

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

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

-AND-

(2) Patient is not receiving Xeljanz or Xeljanz XR in combination with **either** of the following:

(a) Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Rinvoq (upadacitinib), Olumiant (baricitinib)]
(b) Potent immunosuppressant (e.g., azathioprine or cyclosporine)

Authorization will be issued for 12 months.

B. Psoriatic Arthritis (PsA)

1. **Initial Authorization**

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

(1) Diagnosis of active PsA

-AND-

(2) History of failure, contraindication, or intolerance to at least **one** TNF inhibitor

-AND-

(3) Patient is not receiving Xeljanz or Xeljanz XR in combination with **either** of the following:

(a) Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Rinvoq (upadacitinib), Olumiant (baricitinib), Otezla (apremilast)]
(b) Potent immunosuppressant (e.g., azathioprine or cyclosporine)

Authorization will be issued for 12 months.

2. **Reauthorization**

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

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

-AND-

(2) Patient is not receiving Xeljanz or Xeljanz XR in combination with **either** of the following:

(a) Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Rinvoq (upadacitinib), Olumiant (baricitinib), Otezla (apremilast)]
(b) Potent immunosuppressant (e.g., azathioprine or cyclosporine)

Authorization will be issued for 12 months.

C. Ulcerative Colitis (UC)

1. **Initial Authorization**

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

(1) Diagnosis of moderately to severely active UC

-AND-

(2) History of failure, contraindication, or intolerance to at least **one** TNF inhibitor

-AND-

(3) Patient is not receiving Xeljanz or Xeljanz XR in combination with **either** of the following:

(a) Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Rinvoq (upadacitinib), Olumiant (baricitinib), Stelara (ustekinumab), Skyrizi (risankizumab)]
(b) Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

Authorization will be issued for 12 months.

2. **Reauthorization**

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

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

-AND-

(2) Patient is not receiving Xeljanz or Xeljanz XR in combination with **either** of the following:

(a) Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Rinvoq (upadacitinib), Olumiant (baricitinib), Stelara (ustekinumab), Skyrizi (risankizumab)]
(b) Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

Authorization will be issued for 12 months.

D. Ankylosing Spondylitis

1. **Initial Authorization**

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

(1) Diagnosis of active ankylosing spondylitis

-AND-

(2) History of failure, contraindication, or intolerance to at least **one** TNF inhibitor

-AND-

(3) Patient is not receiving Xeljanz or Xeljanz XR in combination with **either** of the following:

(a) Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Rinvoq (upadacitinib), Olumiant (baricitinib)]
(b) Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

Authorization will be issued for 12 months.

2. **Reauthorization**

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

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

-AND-

(2) Patient is not receiving Xeljanz or Xeljanz XR in combination with **either** of

the following:

(a) Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Rinvoq (upadacitinib), Olumiant (baricitinib)]
(b) Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

Authorization will be issued for 12 months.

E. Polyarticular Course Juvenile Idiopathic Arthritis (pcJIA)

1. **Initial Authorization**

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

(1) Diagnosis of active polyarticular course juvenile idiopathic arthritis

-AND-

(2) History of failure, contraindication, or intolerance to at least **one** TNF inhibitor

-AND-

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

(a) Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Olumiant (baricitinib), Rinvoq (upadacitinib)]
(b) Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(a) Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Olumiant (baricitinib), Rinvoq (upadacitinib)]
(b) Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

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:

- 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 and/or Step Therapy may be in place.

4. References:

1. Xeljanz/Xeljanz XR/Xeljanz Oral Solution [package insert]. New York, NY: Pfizer Labs; January 2022.

Program	Prior Authorization/Notification – Xeljanz/Xeljanz XR/Xeljanz Oral Solution (tofacitinib)
Change Control	
2/2014	Changed methotrexate failure criterion to standard verbiage. Reauthorization criteria revised to include concomitant therapy criteria. Extended reauthorization duration to 24 months.
9/2014	Administrative change - Tried/Failed exemption for State of New Jersey removed.
2/2015	Annual review with no change to coverage criteria. Minor reformatting. Updated clinical rules, background and references.
3/2016	Annual review with minor formatting changes to the coverage criteria with no changes to the clinical intent. Added Xeljanz XR to criteria. Updated reference.
3/2017	Annual review with no change to coverage criteria. Updated references.
3/2018	Administrative change to adjust Oxford effective date.
2/2018	Added psoriatic arthritis to the coverage rationale. Updated references.
7/2018	Added ulcerative colitis to the coverage rationale. Updated references.
7/2019	Annual review with no changes to the coverage criteria. Updated background.
9/2019	Updated coverage rationale for ulcerative colitis to align with prescribing information. Updated background and references.
2/2020	Added Xeljanz XR to the ulcerative colitis section due to expanded indication for use. Updated background and references.
11/2020	Updated background and criteria due to new indication for polyarticular juvenile idiopathic arthritis. Changed all reauthorization durations to 12

	months and removed concomitant use with PDE4 inhibitor in UC section to align with related programs. Updated references.
11/2021	Annual review. Added Rinvoq as example of JAK inhibitor in RA section. Updated background and reference.
2/2022	Added step through a TNF inhibitor for RA, PsA and pcJIA per updated label. Updated language in step through TNF inhibitor for UC. Added coverage criteria for new indication, ankylosing spondylitis. Updated background and references.
2/2023	Annual review. Updated listed examples from Humira to adalimumab. Updated reference. Added state mandate footnote.
7/2023	Updated not receiving in combination language to targeted immunomodulator and updated examples.
9/2023	Updated examples. No change to coverage criteria.