UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 2207-11
Program	Prior Authorization/Medical Necessity
Medication	Xeljanz®/Xeljanz® XR/Xeljanz® Oral Solution (tofacitinib)
P&T Approval Date	5/2020, 11/2020, 6/2021, 12/2021, 2/2022, 5/2022, 6/2022, 9/2022, 7/2023, 9/2023
Effective Date	12/1/2023

1. Background:

Xeljanz/Xeljanz XR (tofacitinib) is an inhibitor of Janus kinase (JAK) indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers. It may be used as monotherapy or in combination with methotrexate or other non-biologic disease-modifying antirheumatic drugs (DMARDs).[1] Examples of non-biologic DMARDs commonly used in the treatment of rheumatoid arthritis include methotrexate, leflunomide, and sulfasalazine.[2,3] Xeljanz/Xeljanz XR is also indicated for the treatment of adult patients with active psoriatic arthritis, active ankylosing spondylitis, and moderately to severely active ulcerative colitis, who have an inadequate response or intolerance to one or more TNF blockers. Xeljanz/Xeljanz Oral Solution is indicated for the treatment of active polyarticular 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 or with 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) **<u>One</u>** of the following:

(a) **<u>Both</u>** of the following:

i. **<u>One</u>** of the following:

- History of failure to a 3 month trial of **<u>one</u>** non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses, unless contraindicated or clinically significant

adverse effects are experienced (document drug, date, and duration of trial)[b]

-OR-

- Patient has been previously treated with targeted immunomodulator FDA-approved for the treatment of rheumatoid arthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Enbrel (etanercept), Cimzia (certolizumab), adalimumab, Simponi (golimumab), Orencia (abatacept), Olumiant (baricitinib), Rinvoq (upadacitinib)]

-AND-

ii. **One** of the following:

- History of failure, contraindication, or intolerance to at least **one** TNF inhibitor^

-OR-

- 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-

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

i. Patient is currently on Xeljanz or Xeljanz XR therapy as documented by claims history or submission of medical records (Document drug, date, and duration of therapy):

-AND-

ii. 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*

-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 or cyclosporine)

-AND-

(4) Prescribed by or in consultation with a rheumatologist

*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.

2. **Reauthorization**

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

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

i. **One** of the following:

- History of failure to a 3 month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant

adverse effects are experienced (document date and duration of trial)[b]

-OR-

- Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Enbrel (etanercept), Cimzia (certolizumab), adalimumab, Simponi (golimumab), Orencia (abatacept), Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

-AND-

ii. **One** of the following:

- History of failure, contraindication, or intolerance to at least one TNF inhibitor^

-OR-

- 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-

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

i. Patient is currently on Xeljanz or Xeljanz XR therapy as documented by claims history or submission of medical records (Document drug, date, and duration of therapy):

-AND-

ii. 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*

-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)

-AND-

(4) Prescribed by or in consultation with **one** of the following:

(a) Rheumatologist
(b) Dermatologist

*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.

2. **Reauthorization**

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

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

i. **One** of the following:

- Patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, 6-mercaptopurine)

-OR-

- Patient has been previously treated with targeted immunomodulator FDA-approved for the treatment of ulcerative colitis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Simponi (golimumab), Stelara (ustekinumab), Rinvoq (upadacitinib)]

-AND-

ii. **One** of the following:

- History of failure, contraindication, or intolerance to at least **one** TNF inhibitor^

-OR-

- 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-

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

i. Patient is currently on Xeljanz or Xeljanz XR therapy as documented by claims history or submission of medical records (Document drug, date, and duration of therapy):

-AND-

ii. 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*

-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)

-AND-

(4) Prescribed by or in consultation with a gastroenterologist

*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.

2. **Reauthorization**

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

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

i. **One** of the following:

- History of failure to **two** NSAIDs (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)

-OR-

- Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ankylosing spondylitis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Enbrel (etanercept), Cimzia (certolizumab), adalimumab, Simponi (golimumab), Rinvoq (upadacitinib)]

-AND-

ii. **One** of the following:

- History of failure, contraindication, or intolerance to at least **one** TNF inhibitor^

-OR-

- 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-

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

i. Patient is currently on Xeljanz or Xeljanz XR therapy as documented by claims history or submission of medical records (Document drug, date, and duration of therapy):

-AND-

ii. 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*

-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)

-AND-

(4) Prescribed by or in consultation with a rheumatologist

*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.

2. **Reauthorization**

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

(1) Diagnosis of active polyarticular course juvenile idiopathic arthritis

-AND-

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

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

-OR-

(b) 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-

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

i. Patient is currently on Xeljanz or Xeljanz XR therapy as documented by claims history or submission of medical records (Document drug, date, and duration of therapy):

-AND-

ii. 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*

-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)

-AND-

(4) Prescribed by or in consultation with a rheumatologist

*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.

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 **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.
[b] For Connecticut business, only a 60-day trial will be required. For Kentucky and Mississippi business only a 30-day trial will be required.
^Tried/Failed alternatives(s) are supported by FDA labeling.

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 Labs; January 2022.
2. Pavy S. Constantin A, Pham T, et al. Methotrexate therapy for rheumatoid arthritis: clinical practice guidelines based on published evidence and expert opinions. Joint Bone Spine 2006;73(4):388-95.
3. Singh JA, Saag KG, Bridges SL, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. Arthritis Rheum. 2016;68(1):1-26.

4. 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.
5. American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Arlington, VA: American Psychiatric Publishing. 2013.
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10. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. J Am Acad Dermatol 2009;61(3):451-85.
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12. Gossec L, et al; European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update, Ann Rheum Dis 2016;75:499-510.
13. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterology. 2020; 158(5):1450-61.
14. Ward MM, Deodhar, A, Gensler, LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis & Rheumatology. 2019; 71(10): 1599-1613.
15. Yu, DT, van Tubergen A. Treatment of axial spondyloarthritis (ankylosing spondylitis and nonradiographic axial spondyloarthritis) in adults. In: Post TW, ed. UpToDate. UpToDate; 2021. Accessed on December 17th, 2021.

Program	Prior Authorization/Medical Necessity – Xeljanz or Xeljanz XR or Xeljanz Oral Solution (tofacitinib)
Change Control	
5/2020	New program.
11/2020	Added Xeljanz Oral Solution to the program. Added Tremfya as a step therapy medication for psoriatic arthritis. Updated background and criteria due to new indication for polyarticular juvenile idiopathic arthritis.
12/2020	Administrative change to correct misspelling.
6/2021	Removed preceding month requirement from failure criteria. Removed prescriber requirement from reauthorization criteria. Added coverage criteria for patients previously treated with a biologic DMARD. Added

	clarification that submission of medical records is required documenting current therapy with Xeljanz in order to bypass step if claim history not available. Updated coverage criteria for ulcerative colitis requiring trial of oral corticosteroids and/or immunosuppressants.
12/2021	Updated conventional DMARD bypass language for rheumatoid arthritis and psoriatic arthritis with no change to clinical intent. Updated CT/KY footnote.
2/2022	Added step through a TNF inhibitor for RA and pcJIA per updated label. Updated step criteria for PsA. Updated formatting for UC without changes to clinical intent. Added coverage criteria for new indication, ankylosing spondylitis. Updated background and references. Added footnote to support FDA labeled first line requirements.
5/2022	For Ulcerative Colitis criteria, added targeted synthetic DMARD to bypass language and removed step through two preferred agents and replaced with failure, contraindication, or intolerance to at least one TNF inhibitor. Updated state mandate to include Mississippi.
6/2022	For ankylosing spondylitis removed step through two preferred agents and replaced with failure, contraindication, or intolerance to at least one TNF inhibitor.
9/2022	Added criteria for continuation of care for polyarticular course juvenile idiopathic arthritis. Updated reference.
7/2023	Updated not receiving in combination language to targeted immunomodulator and updated examples.
9/2023	Updated examples. No change to coverage criteria.