BlueCross BlueShield
Federal Employee Program

XELJANZ (tofacitinib tablets; oral solution)
XELJANZ XR (tofacitinib extended-release tablets)

Pre - PA Allowance

None

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Moderately to severely active rheumatoid arthritis (RA)
    a. 18 years of age or older
    b. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional disease-modifying antirheumatic drug (DMARD) (see Appendix 1)
    c. Inadequate treatment response, intolerance, or contraindication to at least **ONE** TNF blocker (e.g., Cimzia, Enbrel, Humira, Remicade, Simponi/Simponi Aria)
    d. Blue Focus **only:** Patient **MUST** have tried **ONE** of the preferred products (Enbrel or Humira) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

2. Active psoriatic arthritis (PsA)
    a. 18 years of age or older
    b. Used in combination with a nonbiologic disease-modifying antirheumatic drug (DMARD) such as methotrexate, leflunomide, sulfasalazine, etc.
    c. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional disease-modifying antirheumatic drug (DMARD) (see Appendix 1)
    d. Inadequate treatment response, intolerance, or contraindication to at least **ONE** TNF blocker (e.g., Cimzia, Enbrel, Humira, Remicade, Simponi/Simponi Aria)
    e. Blue Focus **only:** Patient **MUST** have tried **ONE** of the preferred products (Enbrel or Humira) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

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3. Active ankylosing spondylitis (AS)
    a. 18 years of age or older
    b. Inadequate treatment response, intolerance, or contraindication to at least **TWO** non-steroidal anti-inflammatory drugs (NSAIDs)
    c. Inadequate treatment response, intolerance, or contraindication to at least **ONE** TNF blocker (e.g., Cimzia, Enbrel, Humira, Remicade, Simponi/Simponi Aria)
    d. Patient **MUST** have tried the preferred product(s) (see Appendix 3) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

4. Moderate to severely active Ulcerative Colitis (UC)
    a. 18 years of age or older
    b. Inadequate treatment response, intolerance, or contraindication to at least **ONE** conventional therapy option (see Appendix 2)
    c. Inadequate treatment response, intolerance, or contraindication to at least **ONE** TNF blocker (e.g., Humira, Remicade, Simponi)
    d. Patient **MUST** have tried Humira unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

5. Active Polyarticular Course Juvenile Idiopathic Arthritis (pcJIA)
    a. 2 years of age or older
    b. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional disease-modifying antirheumatic drugs (DMARDs) (see Appendix 1)
    c. Inadequate treatment response, intolerance, or contraindication to at least **ONE** TNF blocker (e.g., Enbrel, Humira, Remicade, Simponi Aria)
    d. Blue Focus **only:** Patient **MUST** have tried **ONE** of the preferred products (Enbrel or Humira) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

AND ALL of the following for **ALL** indications:
    a. Prescriber has considered the risks for malignancy and major adverse cardiovascular events (MACE) (e.g., advanced age, smoking history, cardiovascular risk factors etc.) and determined that Xeljanz therapy is appropriate

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b. Result for latent TB infection is negative **OR** result was positive for latent TB and patient completed treatment (or is receiving treatment) for latent TB
c. **NO** active bacterial, invasive fungal, viral, and other opportunistic infections
d. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)
e. **NOT** used in combination with potent immunosuppressants azathioprine or cyclosporine
f. **NOT** given concurrently with live vaccines

AND NONE of the following for **ALL** indications:
a. Severe hepatic impairment
b. A lymphocyte count less than 500 cells/mm3
c. An absolute neutrophil count less than 1000 cells/mm3
d. A hemoglobin less than 9 g/dL

Prior - Approval Limits

Quantity

Drug	Diagnosis	Quantity
Xeljanz Oral Solution 1mg/mL	pcJIA	960 mL per 90 days **OR**
Xeljanz 5mg	AS pcJIA PsA RA UC	180 tablets per 90 days **OR**
Xeljanz 10mg	UC	180 tablets per 90 days **OR**
Xeljanz XR 11mg	AS PsA RA UC	90 tablets per 90 days **OR**
Xeljanz XR 22mg	UC	90 tablets per 90 days

Duration 12 months

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Prior – Approval *Renewal* Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Rheumatoid arthritis (RA)
    a. 18 years of age or older
    b. Blue Focus **only:** Patient **MUST** have tried **ONE** of the preferred products (Enbrel or Humira) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

2. Psoriatic arthritis (PsA)
    a. 18 years of age or older
    b. Used in combination with a nonbiologic disease-modifying antirheumatic drug (DMARD) such as methotrexate, leflunomide, sulfasalazine, etc.
    c. Blue Focus **only:** Patient **MUST** have tried **ONE** of the preferred products (Enbrel or Humira) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

3. Ankylosing spondylitis (AS)
    a. 18 years of age or older
    b. Patient **MUST** have tried the preferred product(s) (see Appendix 3) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

4. Ulcerative Colitis (UC)
    a. 18 years of age or older
    b. Patient **MUST** have tried Humira unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

5. Polyarticular Course Juvenile Idiopathic Arthritis (pcJIA)
    a. 2 years of age or older

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b. Blue Focus **only:** Patient **MUST** have tried **ONE** of the preferred products (Enbrel or Humira) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

AND ALL of the following for **ALL** indications:

a. Condition has improved or stabilized
b. Prescriber has considered the risks for malignancy and major adverse cardiovascular events (MACE) (e.g., advanced age, smoking history, cardiovascular risk factors etc.) and determined that continuation of Xeljanz therapy is appropriate
c. Absence of active bacterial, invasive fungal, viral, and other opportunistic infections
d. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)
e. **NOT** used in combination with potent immunosuppressants azathioprine or cyclosporine
f. **NOT** given concurrently with live vaccines

Prior - Approval *Renewal* Limits

Quantity

Drug	Diagnosis	Quantity
Xeljanz Oral Solution 1mg/mL	pcJIA	960 mL per 90 days **OR**
Xeljanz 5mg	AS pcJIA PsA RA UC	180 tablets per 90 days **OR**
Xeljanz 10mg	UC	180 tablets per 90 days **OR**
Xeljanz XR 11mg	AS PsA RA UC	90 tablets per 90 days **OR**
Xeljanz XR 22mg	UC	90 tablets per 90 days

Duration 18 months

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Appendix 1 - List of DMARDs

Conventional disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
azathioprine	Azasan, Imuran
cyclophosphamide	Cytoxan
cyclosporine	Neoral, Gengraf, Sandimmune
hydroxychloroquine	Plaquenil
leflunomide	Arava
methotrexate	Rheumatrex, Trexall
mycophenolate	Cellcept
sulfasalazine	Azulfidine, Sulfazine

Biological disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
abatacept	Orencia
adalimumab	Humira
anakinra	Kineret
brodalumab	Siliq
certolizumab	Cimzia
etanercept	Enbrel
golimumab	Simponi/Simponi Aria
guselkumab	Tremfya
infliximab	Remicade/Renflexis/Inflectra
ixekizumab	Taltz
risankizumab-rzaa	Skyrizi
rituximab	Rituxan
sarilumab	Kevzara
secukinumab	Cosentyx
spesolimab-sbzo	Spevigo
tildrakizumab-asmn	Ilumya
tocilizumab	Actemra
ustekinumab	Stelara
vedolizumab	Entyvio

Targeted synthetic disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
apremilast	Otezla
baricitinib	Olumiant
deucravacitinib	Sotyktu
tofacitinib	Xeljanz
upadactinib	Rinvoq

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Appendix 2 - List of Conventional Therapies

Conventional Therapy Options for UC
1. Mild to moderate disease – induction of remission: a. Oral mesalamine (e.g., Asacol, Lialda, Pentasa), balsalazide, olsalazine b. Rectal mesalamine (e.g., Canasa, Rowasa) c. Rectal hydrocortisone (e.g., Colocort, Cortifoam) d. Alternatives: prednisone, azathioprine, mercaptopurine, sulfasalazine
2. Mild to moderate disease – maintenance of remission: a. Oral mesalamine, balsalazide, olsalazine, rectal mesalamine b. Alternatives: azathioprine, mercaptopurine, sulfasalazine
3. Severe disease – induction of remission: a. Prednisone, hydrocortisone IV, methylprednisolone IV b. Alternatives: cyclosporine IV, tacrolimus, sulfasalazine
4. Severe disease – maintenance of remission: a. Azathioprine, mercaptopurine b. Alternative: sulfasalazine
5. Pouchitis: a. Metronidazole, ciprofloxacin b. Alternative: rectal mesalamine

Appendix 3 - List of Preferred Products

Diagnosis	Standard Option/Basic Option Preferred Products	Blue Focus Preferred Products
Ankylosing spondylitis (AS)	*must try **TWO** preferred products: Enbrel Humira** Rinvoq Taltz	*must try **ONE** preferred product: Enbrel Humira**
Ulcerative colitis (UC)	*must try **Humira** first: Humira** Rinvoq Skyrizi Stelara (SC)	Humira**

**Including all preferred biosimilars (see reference product chart)