Clinical Policy: Tofacitinib (Xeljanz, Xeljanz XR)

Reference Number: CP.PHAR.267
Effective Date: 01.30.18
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Line of Business: Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Tofacitinib (Xeljanz®, Xeljanz® XR) is a Janus kinase (JAK) inhibitor.

FDA Approved Indication(s)

Xeljanz and Xeljanz XR are indicated for the treatment of adult patients with:

- Moderately to severely active rheumatoid arthritis (RA), who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers.
- Active psoriatic arthritis (PsA), who have had an inadequate response or intolerance to one or more TNF blockers.
- Moderately to severely active ulcerative colitis (UC), who have had an inadequate response or intolerance to one or more TNF blockers.
- Active ankylosing spondylitis, who have had an inadequate response or intolerance to one or more TNF blockers.

Xeljanz is additionally indicated for the treatment of pediatric patients 2 years of age and older with:

- Active polyarticular course juvenile idiopathic arthritis (pcJIA), who have had an inadequate response or intolerance to one or more TNF blockers.
- Active PsA, who have had an inadequate response or intolerance to one or more TNF blockers.

Limitation(s) of use: Use of Xeljanz/Xeljanz XR in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results, or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that tofacitinib, tofacitinib XR, Xeljanz, and Xeljanz XR are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Polyarticular Course Juvenile Idiopathic Arthritis (must meet all)**:**

1. Diagnosis of pcJIA as evidenced by ≥ 5 joints with active arthritis;
2. Request is for Xeljanz immediate-release tablets or oral solution;
3. Prescribed by or in consultation with a rheumatologist;
4. Age ≥ 2 years;

5. If request is for brand Xeljanz, member must use tofacitinib (generic Xeljanz), unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for tofacitinib*
6. Member meets one of the following, unless previously failed a biologic agent for pJIA (a, b, c, or d):
   a. Failure of a ≥ 3 consecutive month trial of methotrexate (MTX) at up to maximally indicated doses;
   b. Member has intolerance or contraindication to MTX (*see Appendix D*), and failure of a ≥ 3 consecutive month trial of leflunomide or sulfasalazine at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated;
   c. For sacroiliitis/axial spine involvement (i.e., spine, hip), failure of a ≥ 4 week trial of an NSAID at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   d. Documentation of high disease activity;
7. Member has not responded or is intolerant to one or more TNF blockers (e.g., *Hadlima™, Simlandi®, Yusimry™, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, and adalimumab-fkjp are preferred*), unless contraindicated;
   **Prior authorization may be required for TNF blockers*
8. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
9. Dose does not exceed both of the following (a and b):
   a. 10 mg per day;
   b. 2 tablets or 10 mL per day.

Approval duration: 12 months

B. Psoriatic Arthritis (must meet all)**:**

1. Diagnosis of PsA;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Member meets one of the following (a or b):
   a. For Xeljanz/tofacitinib: Age ≥ 2 years;
   b. For Xeljanz XR/tofacitinib XR: Age ≥ 18 years;
4. If request is for brand Xeljanz/Xeljanz XR, member must use tofacitinib/tofacitinib XR (generic Xeljanz/Xeljanz XR), unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for tofacitinib/tofacitinib XR*
5. Member has not responded or is intolerant to one or more TNF blockers (e.g., *Hadlima, Simlandi, Yusimry, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, and adalimumab-fkjp are preferred*), unless contraindicated;
   **Prior authorization may be required for TNF blockers*
6. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
7. Dose does not exceed one of the following (a or b):
   a. Xeljanz/tofacitinib (both i and ii):
      i. 10 mg per day;

ii. 2 tablets or 10 mL per day;
b. Xeljanz XR/tofacitinib XR (both i and ii):
i. 11 mg per day;
ii. 1 tablet per day.

Approval duration: 12 months

C. Rheumatoid Arthritis (must meet all)**:**
1. Diagnosis of RA per American College of Rheumatology (ACR) criteria (*see Appendix F*);
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years;
4. If request is for brand Xeljanz/Xeljanz XR, member must use tofacitinib/tofacitinib XR (generic Xeljanz/Xeljanz XR), unless contraindicated or clinically significant adverse effects are experienced;
**Prior authorization may be required for tofacitinib/tofacitinib XR*
5. Member meets one of the following, unless previously failed a biologic agent for RA (a or b):
a. Failure of a ≥ 3 consecutive month trial of MTX at up to maximally indicated doses;
b. Member has intolerance or contraindication to MTX (*see Appendix D*), and failure of a ≥ 3 consecutive month trial of at least ONE conventional DMARD,(e.g., sulfasalazine, leflunomide, hydroxychloroquine) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
6. Member has not responded or is intolerant to one or more TNF blockers (e.g., *Hadlima, Simlandi, Yusimry, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, and adalimumab-fkjp are preferred*), unless contraindicated;
**Prior authorization may be required for TNF blockers*
7. Documentation of one of the following baseline assessment scores (a or b):
a. Clinical disease activity index (CDAI) score (*see Appendix G*);
b. Routine assessment of patient index data 3 (RAPID3) score (*see Appendix H)*;
8. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
9. Dose does not exceed one of the following (a or b):
a. Xeljanz/tofacitinib (both i and ii):
i. 10 mg per day;
ii. 2 tablets per day;
b. Xeljanz XR/tofacitinib XR (both i and ii):
i. 11 mg per day;
ii. 1 tablet per day.

Approval duration: 12 months

D. Ulcerative Colitis (must meet all)**:**
1. Diagnosis of UC;
2. Prescribed by or in consultation with a gastroenterologist;
3. Age ≥ 18 years;

4. If request is for brand Xeljanz/Xeljanz XR, member must use tofacitinib/tofacitinib XR (generic Xeljanz/Xeljanz XR), unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for tofacitinib/tofacitinib XR*
5. Documentation of a Mayo Score ≥ 6, modified Mayo Score ≥ 5, or Mayo Endoscopic Score ≥ 2 (*see Appendix E*);
6. Failure of an 8-week trial of systemic corticosteroids, unless contraindicated, clinically significant adverse effects are experienced, or previously failed a biologic agent for UC;
7. Member has not responded or is intolerant to one or more TNF blockers, unless contraindicated;
   **Prior authorization may be required for TNF blockers*
8. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
9. Dose does not exceed one of the following (a or b):
   a. Xeljanz/tofacitinib (both i and ii):
      i. 20 mg per day;
      ii. 2 tablets per day;
   b. Xeljanz XR/tofacitinib XR (both i and ii):
      i. 22 mg per day;
      ii. 1 tablet per day.

Approval duration: 12 months

E. Ankylosing Spondylitis (must meet all)**:**
1. Diagnosis of AS;
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years;
4. If request is for brand Xeljanz/Xeljanz XR, member must use tofacitinib/tofacitinib XR (generic Xeljanz/Xeljanz XR), unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for tofacitinib/tofacitinib XR*
5. Failure of at least TWO non-steroidal anti-inflammatory drugs (NSAIDs) at up to maximally indicated doses, each used for ≥ 4 weeks unless contraindicated, clinically significant adverse events are experienced, or previously failed a biologic agent for AS;
6. Member has not responded or is intolerant to one or more TNF blockers (e.g., *Hadlima, Simlandi, Yusimry, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, and adalimumab-fkjp are preferred*), unless contraindicated;
   **Prior authorization may be required for TNF blockers*
7. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
8. Dose does not exceed one of the following (a or b):
   a. Xeljanz/tofacitinib (both i and ii):
      i. 10 mg per day;
      ii. 2 tablets per day;

b. Xeljanz XR/tofacitinib XR (both i and ii):
   i. 11 mg per day;
   ii. 1 tablet per day.

Approval duration: 12 months

F. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member meets one of the following (a or b):
   a. For RA: Member is responding positively to therapy as evidenced by one of the following (i or ii):
      i. A decrease in CDAI (*see Appendix G*) or RAPID3 (*see Appendix H*) score from baseline;
      ii. Medical justification stating inability to conduct CDAI re-assessment, and submission of RAPID3 score associated with disease severity that is similar to initial CDAI assessment or improved;
   b. For all other indications: Member is responding positively to therapy;
3. If request is for brand Xeljanz/Xeljanz XR, member must use tofacitinib/tofacitinib XR (generic Xeljanz/Xeljanz XR), unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for tofacitinib/tofacitinib XR*
4. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
5. If request is for a dose increase, new dose does not exceed one of the following (a or b):

a. Xeljanz/tofacitinib (i, ii, or iii):
   i. AS or RA(both 1 and 2):
      1) 10 mg per day;
      2) 2 tablets per day;
   ii. UC (both 1 and 2):
      1) 20 mg per day;
      2) 2 tablets per day;
   iii. pcJIA or PsA (both 1 and 2):
      1) 10 mg per day;
      2) 2 tablets or 10 mL per day;
b. Xeljanz XR/tofacitinib XR (i or ii):
   i. AS, RA, or PsA (both 1 and 2):
      1) 11 mg per day;
      2) 1 tablet per day;
   ii. UC (both 1 and 2):
      1) 22 mg per day;
      2) 1 tablet per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid or evidence of coverage documents;

B. Combination use with biological disease-modifying antirheumatic drugs (bDMARDs) or potent immunosuppressants, including but not limited to any tumor necrosis factor (TNF) antagonists [e.g., Cimzia®, Enbrel®, Humira® and its biosimilars, Remicade® and its biosimilars, Simponi®], interleukin agents [e.g., Actemra® (IL-6RA) and its biosimilars, Arcalyst® (IL-1 blocker), Bimzelx® (IL-17A and F antagonist), Cosentyx® (IL-17A inhibitor), Ilaris® (IL-1 blocker), Ilumya™ (IL-23 inhibitor), Kevzara® (IL-6RA), Kineret® (IL-1RA), Omvoh™ (IL-23 antagonist), Siliq™ (IL-17RA), Skyrizi™ (IL-23 inhibitor), Spevigo® (IL-36 antagonist), Stelara® (IL-12/23 inhibitor) and its biosimilars,

Taltz® (IL-17A inhibitor), Tremfya® (IL-23 inhibitor)], Janus kinase inhibitors (JAKi) [e.g., Cibinqo™, Olumiant™, Rinvoq™, Xeljanz®/Xeljanz® XR,], anti-CD20 monoclonal antibodies [Rituxan® and its biosimilars], selective co-stimulation modulators [Orencia®], integrin receptor antagonists [Entyvio®], tyrosine kinase 2 inhibitors [Sotyktu™], and sphingosine 1-phosphate receptor modulator [Velsipity™] because of the additive immunosuppression, increased risk of neutropenia, as well as increased risk of serious infections;

C. Alopecia areata (ICD10: L63), also referred to as patchy hair loss.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AS: Ankylosing Spondylitis
CDAI: clinical disease activity index
cJADAS: clinica juvenile arthritis disease activity score
DMARDs: disease-modifying antirheumatic drugs
FDA: Food and Drug Administration
JAK: Janus kinase
MTX: methotrexate
pcJIA: polyarticular course juvenile idiopathic arthritis;
RA: rheumatoid arthritis
RAPID3: routine assessme of patient index data 3
PsA: psoriatic arthritis
UC: ulcerative colitis

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
azathioprine (Azasan®, Imuran®)	**RA** 1 mg/kg/day PO QD or divided BID	2.5 mg/kg/day
Cuprimine® (d-penicillamine)	**RA*** Initial dose: 125 or 250 mg PO QD Maintenance dose: 500 – 750 mg/day PO QD	1,500 mg/day
corticosteroids	**UC*** *Adult:* Prednisone 40 mg – 60 mg PO QD, then taper dose by 5 to 10 mg/week Budesonide (Uceris®) 9 mg PO QAM for up to 8 weeks	Various
cyclosporine (Sandimmune®, Neoral®)	**RA** 2.5 – 4 mg/kg/day PO divided BID	4 mg/kg/day
hydroxychloroquine (Plaquenil®)	**RA*** Initial dose: 400 – 600 mg/day PO QD	600 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Maintenance dose: 200 – 400 mg/day PO QD	
leflunomide (Arava®)	**RA** Initial dose (for low risk hepatotoxicity or myelosuppression): 100 mg PO QD for 3 days Maintenance dose: 20 mg PO QD **PJIA*** Weight < 20 kg: 10 mg every other day Weight 20 - 40 kg: 10 mg/day Weight > 40 kg: 20 mg/day	20 mg/day
methotrexate (Trexall®, Otrexup™, Rasuvo®, RediTrex®, Xatmep™, Rheumatrex®)	**RA** 7.5 mg/week PO, SC, or IM or 2.5 mg PO Q12 hr for 3 doses/week **PJIA*** 10 – 20 mg/m^2/week PO, SC, or IM	30 mg/week
NSAIDs (e.g., indomethacin, ibuprofen, naproxen, celecoxib)	**AS** Varies	Varies
Ridaura® (auranofin)	**RA** 6 mg PO QD or 3 mg PO BID	9 mg/day (3 mg TID)
sulfasalazine (Azulfidine®)	**RA** Initial dose: 500 mg to 1,000 mg PO QD for the first week. Increase the daily dose by 500 mg each week up to a maintenance dose of 2 g/day. Maintenance dose: 2 g/day PO in divided doses **PJIA*** 30-50 mg/kg/day PO divided BID	RA: 3 g/day PJIA: 2 g/day
NSAIDs (e.g., indomethacin, ibuprofen, naproxen, celecoxib)	**AS, PJIA*** Varies	Varies
Hadlima (adalimumab-	**RA, AS, PsA** 40 mg SC every other week	**RA** 40 mg every week

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
bwwd), Simlandi (adalimumab-ryvk), Yusimry (adalimumab-aqvh), adalimumab-aaty (Yuflyma®), adalimumab-adaz (Hyrimoz®), adalimumab-fkjp (Hulio®), adalimumab-adbm (Cyltezo®)	**pJIA** **Cyltezo, Hadlima, Hyrimoz:** Weight 10 kg (22 lbs) to < 15 kg (33 lbs): 10 mg SC every other week **Cyltezo, Hadlima, Hulio, Yuflyma:** Weight 15 kg (33 lbs) to < 30 kg (66 lbs): 20 mg SC every other week **Cyltezo, Hadlima, Hulio, Hyrimoz, Simlandi, Yuflyma, Yusimry:** Weight ≥ 30 kg (66 lbs): 40 mg SC every other week	**AS, PsA, pJIA** 40 mg every other week

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
**Off-label*

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none reported
- Boxed warning(s):
  - Serious infections: There is an increased risk of serious bacterial, fungal, viral, and opportunistic infections leading to hospitalization or death, including tuberculosis (TB). Mortality: RA patients 50 years and older with at least one cardiovascular risk factor treated with Xeljanz 10 twice daily had a higher rate of all-cause mortality, including sudden CF death, compared to those treated with Xeljanz 5 mg given twice daily or TNF blockers in a large, ongoing, post marketing study. Malignancies: Lymphoma and other malignancies, as well as Epstein Barr Virus-associated post-transplant lymphoproliferative disorder has been observed. Lymphomas and lung cancer, which are a subset of all malignancies in RA Safety Study 1, were observed at a higher rate in patients treated with Xeljanz 5 mg twice a day and Xeljanz 10 mg twice a day compared to those treated with TNF blockers.
  - Cardiovascular events: RA patients who were 50 years of age and older with at least one cardiovascular risk factor treated with Xeljanz 5 mg twice daily or Xeljanz 10 mg twice daily had a higher rate of major adverse cardiovascular events (MACE) defined as cardiovascular death, non-fatal myocardial infarction (MI), and non-fatal stroke, compared to those treated with TNF blockers.
  - Thrombosis: Thrombosis, including pulmonary embolism, deep venous thrombosis, and arterial thrombosis have occurred in patients treated with Xeljanz and other Janus kinase inhibitors used to treat inflammatory conditions.
    - A large, ongoing postmarketing safety study observed an increase in incidence of thrombosis events in RA patients who were 50 years of age and older with at least one CV risk factor treated with Xeljanz 10 mg twice daily compared to Xeljanz 5 mg twice daily or TNF blockers.

Appendix D: General Information

- Definition of failure of MTX or DMARDs
  - Child-bearing age is not considered a contraindication for use of MTX. Each drug has risks in pregnancy. An educated patient and family planning would allow use of MTX in patients who have no intention of immediate pregnancy.
  - Social use of alcohol is not considered a contraindication for use of MTX. MTX may only be contraindicated if patients choose to drink over 14 units of alcohol per week. However, excessive alcohol drinking can lead to worsening of the condition, so patients who are serious about clinical response to therapy should refrain from excessive alcohol consumption.
- Examples of positive response to therapy may include, but are not limited to:
  - Reduction in joint pain/swelling/tenderness
  - Improvement in erythrocyte sedimentation rates/C-reactive protein (ESR/CRP) levels
  - Improvements in activities of daily living
- TNF blockers:
  - Etanercept (Enbrel®), adalimumab (Humira®) and its biosimilars, infliximab (Remicade®) and its biosimilars (Avsola™, Renflexis™, Inflectra®), certolizumab pegol (Cimzia®), and golimumab (Simponi®, Simponi Aria®).

Appendix E: Mayo Score, Modified Mayo Score, or Mayo Endoscopic Score

- Mayo Score: evaluates ulcerative colitis stage, based on four parameters: stool frequency, rectal bleeding, endoscopic evaluation, and Physician's global assessment. Each parameter of the score ranges from zero (normal or inactive disease) to 3 (severe activity) with an overall score of 12.

Score	Decoding
0 – 2	Remission
3 – 5	Mild activity
6 – 10	Moderate activity
>10	Severe activity

- Modified Mayo Score: developed from the full Mayo score and evaluates ulcerative colitis stage, based on three parameters: stool frequency, rectal bleeding, and endoscopic evaluation. The modified Mayo Score gives a maximum overall score of 9. The FDA currently accepts the modified Mayo Score for the assessment of disease activity in pivotal UC clinical trials.
- Mayo Endoscopic Score: tool used to assess severity based on endoscopic findings during a colonoscopy and ranges from 0 to 3. A score of 2 or higher means there is moderate-to-severe inflammation.

Score	Decoding
0	Normal or inactive disease
1	Mild disease (erythema, decreased vascular pattern, mild friability)
2	Moderate disease (marked erythema, absent vascular pattern, moderate friability, erosions)
3	Severe disease (spontaneous bleeding, ulcerations)

Appendix F: The 2010 ACR Classification Criteria for RA
Add score of categories A through D; a score of ≥ 6 out of 10 is needed for classification of a patient as having definite RA.

A	**Joint involvement**	Score
	1 large joint	0
	2-10 large joints	1
	1-3 small joints (with or without involvement of large joints)	2
	4-10 small joints (with or without involvement of large joints)	3
	> 10 joints (at least one small joint)	5
B	**Serology (at least one test result is needed for classification)**	
	Negative rheumatoid factor (RF) *and* negative anti-citrullinated protein antibody (ACPA)	0
	Low positive RF *or* low positive ACPA * *Low: < 3 x upper limit of normal*	2
	High positive RF *or* high positive ACPA * *High: ≥ 3 x upper limit of normal*	3
C	**Acute phase reactants (at least one test result is needed for classification)**	
	Normal C-reactive protein (CRP) and normal erythrocyte sedimentation rate (ESR)	0
	Abnormal CRP or abnormal ESR	1
D	**Duration of symptoms**	
	< 6 weeks	0
	≥ 6 weeks	1

Appendix G: Clinical Disease Activity Index (CDAI) Score
The Clinical Disease Activity Index (CDAI) is a composite index for assessing disease activity in RA. CDAI is based on the simple summation of the count of swollen/tender joint count of 28 joints along with patient and physician global assessment on VAS (0–10 cm) Scale for estimating disease activity. The CDAI score ranges from 0 to 76.

CDAI Score	Disease state interpretation
≤ 2.8	Remission
> 2.8 to ≤ 10	Low disease activity
> 10 to ≤ 22	Moderate disease activity
> 22	High disease activity

Appendix H: Routine Assessment of Patient Index Data 3 (RAPID3) Score
The Routine Assessment of Patient Index Data 3 (RAPID3) is a pooled index of the three patient-reported ACR core data set measures: function, pain, and patient global estimate of status. Each of the individual measures is scored 0 – 10, and the maximum achievable score is 30.

RAPID3 Score	Disease state interpretation
≤ 3	Remission
3.1 to 6	Low disease activity
6.1 to 12	Moderate disease activity
> 12	High disease activity

Appendix I: Polyarticular Juvenile Idiopathic Arthritis Disease Activity
According to 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis, disease activity (moderate/high and low) as defined by the clinical Juvenile Disease Activity score based on 10 joints (cJADAS-10) is provided as a general parameter and should be interpreted within the clinical context.
The cJADAS10 is a continuous disease activity score specific to JIA and consisting of the following three parameters totaling a maximum of 30 points:

- Physician's global assessment of disease activity measured on a 0-10 visual analog scale (VAS), where 0 = no activity and 10 = maximum activity;
- Parent global assessment of well-being measured on a 0-10 VAS, where 0 = very well and 10 = very poor;
- Count of joints with active disease to a maximum count of 10 active joints*

**ACR definition of active joint: presence of swelling (not due to currently inactive synovitis or to bony enlargement) or, if swelling is not present, limitation of motion accompanied by pain, tenderness, or both*

cJADAS-10	Disease state interpretation
≤ 1	Inactive disease
1.1 to 2.5	Low disease activity
2.51 to 8.5	Moderate disease activity
> 8.5	High disease activity

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Tofacitinib immediate-release (Xeljanz)	pcJIA, PsA	• 10 kg ≤ body weight < 20 kg: 3.2 mg (3.2 mL oral solution) PO BID • 20 kg ≤ body weight < 40 kg: 4 mg (4 mL oral solution) PO BID • Body weight ≥ 40 kg: 5 mg (5 mL oral solution) PO BID	10 mg/day
	RA AS	5 mg PO BID	
	UC	Induction: 10 mg PO BID for 8 weeks, up to 16 weeks Maintenance: 5 mg PO BID	Induction: 20 mg/day Maintenance: 10 mg/day
Tofacitinib extended-release (Xeljanz XR)	PsA RA AS	11 mg PO QD	11 mg/day
	UC	Induction: 22 mg PO QD for 8 weeks, up to 16 weeks Maintenance: 11 mg PO QD	Induction: 22 mg/day Maintenance: 11 mg/day

VI. Product Availability

Drug Name	Availability
Tofacitinib immediate- release (Xeljanz)	Tablets: 5 mg, 10 mg

Drug Name	Availability
	Oral solution: 1 mg/mL
Tofacitinib extended-release (Xeljanz XR)	Tablets: 11 mg, 22 mg

VII. References

1. Xeljanz/Xeljanz XR Prescribing Information. New York, NY: Pfizer Labs; October 2025. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/203214s039,213082s011lbl.pdf. Accessed January 20, 2026.
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Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2022 annual review: RT4: added newly FDA-approved indication for AS; updated place in therapy after TNFi per FDA labeling; reiterated requirement against combination use with a bDMARD or JAKi from Section III to Sections I and II; references reviewed and updated.	02.21.22	05.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.13.22	
2Q 2023 annual review: no significant changes; updated off-label dosing in Appendix B; references reviewed and updated.	02.13.23	05.23
Per July SDC: updated criteria with examples of preferred TNF blockers: Humira biosimilars Yusimry, Hadlima, unbranded adalimumab-fkjp, and unbranded adalimumab-adaz; updated Appendix D with list of TNF blockers.	07.25.23	
Per December SDC, added adalimumab-adbm to listed examples of preferred adalimumab products.	12.06.23	02.24
2Q 2024 annual review: removed PsA supplemental guideline information from Appendix D; added Bimzelx, Zymfentra, Omvoh, Wezlana, Sotyktu, Tofidence, and Velsipity to section III.B; references reviewed and updated.	01.22.24	05.24
Per June SDC, added Simlandi to listed examples of preferred adalimumab products. Per SDC, added unbranded adalimumab-aaty to listed examples of preferred adalimumab products.	07.23.24	08.24
2Q 2025 annual review: for UC initial criteria, added option for documentation of modified Mayo Score ≥ 5; removed examples of preferred adalimumab products as adalimumab is not recommended due to low efficacy per 2024 AGA guidelines; for Appendix E, added supplemental information on modified Mayo Score; for pJIA:	01.23.25	05.25

Reviews, Revisions, and Approvals	Date	P&T Approval Date
removed criteria for minimum cJADAS-10 score ≥ 8.5 for documentation of high disease activity and "baseline 10-joint clinical juvenile arthritis disease activity score" in initial criteria to align with competitor analysis; removed criteria for "member is responding positively to therapy as evidence by decrease in cJADAS-10 from baseline" in continued therapy; for Appendix I, added pJIA disease activity information per 2019 ACR guidelines; updated section III.B with Spevigo and biosimilar verbiage; references reviewed and updated.		
For UC, added option for Mayo Endoscopic Score ≥ 2 to define moderate-to-severe UC; for pJIA, RA, UC, and AS, added bypass of conventional therapies if a member has failed a biologic agent to clarify intention of not stepping back from biologic agent to conventional therapy. Extended initial approval duration to 12 months for chronic condition indications. RT4: for Xeljanz, applied pediatric age extension for PsA per updated FDA labeling.	10.28.25	11.25
2Q 2026 annual review: no significant changes; references reviewed and updated.	01.20.26	05.26
Per SDC: added generic redirection to tofacitinib/tofacitinib XR for brand Xeljanz/Xeljanz XR requests.	07.20.26	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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