Clinical Policy: Tofacitinib (Xeljanz/Xeljanz XR)

Reference Number: PA.CP.PHAR.267
Effective Date: 01/18
Last Review Date: 07/17 Revision Log
Line of Business: Medicaid

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

FDA approved indication
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 methotrexate (MTX). They may be used as monotherapy or in combination with MTX or other nonbiologic disease-modifying antirheumatic drugs (DMARDs).

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

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria)

It is the policy of Pennsylvania Health and Wellness® that Xeljanz and Xeljanz XR are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Rheumatoid Arthritis (must meet all):

1. Diagnosis of RA per American College of Rheumatology (ACR) criteria (refer to *Appendix B*);
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years;
4. Member meets one of the following (a or b):
   a. Failure of MTX for ≥ 3 consecutive months unless contraindicated or clinically significant adverse effects are experienced;
   b. If intolerance or contraindication to MTX, failure of sulfasalazine, leflunomide, or hydroxychloroquine for ≥ 3 consecutive months unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of etanercept *(Enbrel is preferred)* AND adalimumab *(Humira is preferred),* each trialed for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization is required for etanercept and adalimumab*
6. Tuberculosis (TB) test within the past 12 months is negative, or if positive, active TB has been ruled out and the patient has received treatment for latent TB infection;
7. Dose does not exceed (a or b):
   a. Xeljanz: 10 mg/day;
   b. Xeljanz XR: 11 mg/day.

Approval duration: 6 months

B. Other diagnoses/indications
1. Refer to PA.CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Approval

A. Rheumatoid Arthritis:
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy (e.g., reduction in joint pain/swelling/tenderness, improvement in erythrocyte sedimentation rate [ESR]/C-reactive protein [CRP] levels, activities of daily living, etc.);
3. If request is for a dose increase, new dose does not exceed:
   a. Xeljanz: 10 mg/day;
   b. Xeljanz XR: 11 mg/day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;.

Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to PA.CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – PA.CP.PHAR.57 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ACPA: anti-citrullinated protein antibody
ACR: American College of Rheumatology
CRP: C-reactive protein
DMARDs: disease modifying anti-rheumatic drugs
FDA: Food and Drug Administration
ESR: erythrocyte sedimentation rate
MTX: methotrexate
PO: by mouth
RA: rheumatoid arthritis
RF: rheumatoid factor
TB: tuberculosis
TNF: tumor necrosis factor

Appendix B: 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 CRP and normal ESR	0
	Abnormal CRP or normal ESR	1
D	**Duration of symptoms**	
	< 6 weeks	0
	≥ 6 weeks	1

Appendix C: Definition of MTX or DMARD Failure
In RA, failure of MTX or DMARD is defined as ≤ 50% decrease in swollen joint count, ≤ 50% decrease in tender joint count, and ≤ 50% decrease in ESR, or ≤ 50% decrease in CRP.

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Tofacitinib (Xeljanz)	5 mg PO twice daily	10 mg/day
Tofacitinib (Xeljanz XR)	11 mg PO four times daily	11 mg/day

VI. Product Availability

Drug	Availability
Tofacitinib (Xeljanz)	Tablets: 5 mg
Tofacitinib (Xeljanz XR)	Tablets: 11 mg

VII. References

1. Xeljanz [package insert]. New York, NY: Pfizer, Inc.; February 2016.
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):625-639.
3. Schur PH, Cohen S. Initial treatment of moderately to severely active rheumatoid arthritis in adults. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2016. Available at www.UpToDate.com. Accessed June 17, 2016.
4. Aletaha D, Neogi T, Silman AJ et al. 2010 Rheumatoid Arthritis Classification Criteria. Arthritis and Rheumatism September 2010;62(9):2569-2581.

Reviews, Revisions, and Approvals	Date	Approval Date