HELDRUG DETERMINATION POLICY

Title: DDP-41 Xeljanz

Effective Date: 03/17/2020

Physicians Health Plan
PHP Insurance Company
PHP Service Company

Important Information - Please Read Before Using This Policy

The following policy applies to health benefit plans administered by PHP and may not be covered by all PHP plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Benefit determinations for individual requests require consideration of:

1. The terms of the applicable benefit document in effect on the date of service.
2. Any applicable laws and regulations.
3. Any relevant collateral source materials including coverage policies.
4. The specific facts of the particular situation.

Contact PHP Customer Service to discuss plan benefits more specifically.

1.0 Policy:

This policy describes the determination process for coverage of specific drugs that require prior approval.

This policy does not guarantee or approve benefits. Coverage depends on the specific benefit plan. Drug Determination Policies are not recommendations for treatment and should not be used as treatment guidelines.

2.0 Background or Purpose:

Xeljanz (tofacitinib) is a specialty drug indicated for a number of diagnoses and is associated with adverse effects. These criteria were developed and implemented to ensure appropriate use for the intended diagnoses and mitigation of adverse effects, if possible.

3.0 Clinical Determination Guidelines:

Document the following with chart notes:

A. Rheumatoid Arthritis (RA).

   1. Age: at least 18 years.

   2. Prescriber: rheumatologist.

   3. Diagnosis and severity: moderate to severe active RA.

   4. Other therapies (must try for four months' duration each drug): contraindicated, failed or had significant adverse effects with two of the drugs below:

      a. Methotrexate (MTX): one must be MTX (unless contraindicated).

      b. Other: leflunomide (Arava), sulfasalazine, cyclosporine, azathioprine.

   5. Dosage regimen: refer to Appendix I for adjustments.

a. Xeljanz IR oral (tofacitinib): 5mg two times daily; or

b. Xeljanz XR oral (tofacitinib XR): 11mg daily.

6. Approval.

a. Initial: six months.

b. Re-approval: one year (reduced or sustained decrease in disease activity).

7. Exclusions.

a. Non-Food and Drug Administration (FDA) approved indications.

b. Combo use with biological disease-modifying anti-rheumatic drugs (DMARDs), tumor necrosis factor (TNF) antagonists, IL-1R antagonist, IL-6R antagonist, anti-CD20 monoclonal antibodies or co-stimulant modulators.

B. Psoriatic Arthritis (PA).

1. Age: at least 18 years.

2. Prescriber: rheumatologist.

3. Diagnosis and severity: active PA with at least five swollen and tender joints.

4. Other therapies (must try for four months): contraindicated, failed or significant adverse effects from two agents below (peripheral or axial disease):

a. Peripheral disease: DMARD therapy - methotrexate, leflunomide, sulfasalazine.

b. Axial disease, enthesitis, dactylitis and uveitis: non-steroidal anti-inflammatory drugs (NSAID)s.

5. Dosage regimen: refer to Appendix I for adjustments.

a. Xeljanz IR oral (tofacitinib): 5 mg two times daily; or

b. Xeljanz XR oral (tofacitinib XR): 11mg daily.

6. Approval.

a. Initial: six months.

b. Re-approval: one year (decrease or sustained decrease in disease activity).

C. Inflammatory bowel disease: ulcerative colitis (UC).

1. Age: at least 18 years.

2. Prescriber: gastroenterologist.

3. Diagnosis and severity: moderate to severe UC.

4. Other therapies: failed or significant adverse effects (must meet one below): inadequate response to therapy requires minimum trial duration of four months.

    a. Conventional therapies: mesalamine.

    b. DMARD: sulfasalazine.

5. Dosage regimen: refer to Appendix I for adjustments.

    a. Xeljanz IR (tofacitinib oral): 10 mg twice daily for eight weeks, then 5mg to 10mg twice daily depending on response.

6. Approval.

    a. Initial: six months.

    b. Re-approval: one year (reduced or sustained decrease in disease activity).

4.0 Coding:

None.

5.0 References, Citations & Resources:

1. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Xeljanz, accessed Dec. 2019.

6.0 Appendices:

Appendix I: Dosage Adjustment

State	Value	Recommendation
Anemia	Hemoglobin (Hgb) at least 9g/dL and decreased less than 2gm/dL	Maintain dose
	Hgb less than 8g/dL or decreased more than 2gm/dL	Stop dosing until Hgb normalizes
Lymphopenia	Lymphocytes at least 500 cells/mm^3	Maintain dose
	Lymphocytes less than 500 cells/mm^3	Discontinue
Neutropenia	Absolute Neutrophil Count (ANC) more than 1,000 cells/mm^3	Maintain dose
	ANC 500 to 1,000 cells/mm^3	Persistent decrease: stop dosing until ANC more than 1,000 cells/mm^3 when ANC more than 1,000 cells/mm^3 resume normal dose
	ANC less than 500 cells/mm^3*	Discontinue
Concurrent CYP450	Potent P450 3A4 Inducer (rifampin)	Not recommended
	Potent Inhibitor (ketoconazole) or more than one moderate CYP3A inhibitor positive Potent CYP2C19 inhibitor (fluconazole)	5mg once daily
Renal function	Mild impairment	No adjustment

State	Value	Recommendation
	Moderate to severe impairment	Decrease 5mg once daily
	Dialysis	Not recommended
Hepatic function	Mild impairment	No adjustment
	Moderate impairment	Decrease 5mg once daily
	Severe Impairment	Not recommended

Appendix II: Monitoring & Patient Safety

Drug	Adverse Reactions	Monitoring & Contraindications	REMS
Xeljanz tofacitinib	• Respiratory: nasopharyangitis (3-14%), upper respiratory infection (URI) • Miscellaneous: infection (20-22%) • Pregnancy: Class C	• Labs: lymphocytes (pre and every 3 months); neutrophil, platelets, Hgb, /lipids (pre, 6 weeks, then every 6 months); liver function tests • Infections: viral hepatitis (pre), signs and symptoms of infection	• Purpose: warn re risk of serious/fatal infections; malignancies • Prescriber: review med guide prescribing/safety info • Web site: www.xeljanzrems.com

7.0 Revision History:

Original Effective Date: 01/01/2019

Next Review Date: 03/17/2021

Revision Date	Reason for Revision
12/19	New format, replaced abbreviations, clarified dosage adjustments and UC dose