Pharmacy Benefit Determination Policy

Policy Subject:	Xeljanz (tofacitinib)	**Dates:**	
Policy Number:	SHS PBD40	**Effective Date:**	January 2019
Category:	Rheumatology	**Revision Date:**	
Policy Type:	☐ **Medical** ☒ **Pharmacy**	**Approval Date:**	December 5, 2018
Department:	Pharmacy	**Next Review Date:**	August 2019

Product (check all that apply):	**Clinical Approval By:**
☒ Group HMO/POS	**Medical Directors**
☒ Individual HMO/POS	PHP: Peter Graham, MD
☒ PPO	**Pharmacy and Therapeutics Committee**
☒ ASO	PHP: Peter Graham, MD

Policy Statement:

Physicians Health Plan, PHP Insurance & Service Company, and Sparrow PHP will cover Xeljanz (tofacitinib) through the Pharmacy Benefit based on approval by the Clinical Pharmacist or Medical Director using the following determination guidelines.

Drugs and Applicable Coding:

Clinical Determination Guidelines:

Document the following with chart notes

A. Rheumatoid Arthritis (RA)
   1. Age: ≥ 18 years
   2. Prescriber: Rheumatologist
   3. Diagnosis and severity: Moderate to severe active RA
   4. Other therapies: Failed or had significant adverse effects with 2 of the below:
      a. Methotrexate (MTX): One must be MTX (unless contraindicated)
      b. Other: Leflunomide (Arava), sulfasalazine, cyclosporin, azathioprine
   4. Dosage regimen: Refer to Appendix I for adjustments
      a. Xeljanz IR (tofacitinib oral): 5 mg 2x daily or
      b. Xeljanz XR (tofacitinib XR oral): 11mg daily
   5. Approval
      a. Initial: 6 months.
      b. Re-approval: 1 year (↓ or sustained ↓ in disease activity)
   6. Exclusions
      a. Non-FDA approved indications
      b. Combo use with biological DMARDS (TNF antagonists, IL-1R antagonist, IL-6R antagonist, anti-CD20 monoclonal antibodies, co-stim. modulators)

C. Psoriatic Arthritis (PA)
1. Age: ≥ 18 years
2. Prescriber: Rheumatologist
3. Diagnosis & severity: Active PA w ≥ 5 swollen and ≥ 5 tender joints
4. Other therapies: Failed or significant adverse effects from 2 below (dependent on location):
   a. Peripheral disease: DMARD therapy (4 months) - Methotrexate, leflunomide, sulfasalazine
   b. Axial disease, enthesitis, dactylitis and uveitis: NSAIDs (4 months)
5. Dosage regimen: Refer to Appendix I for adjustments
   c. Xeljanz IR (tofacitinib oral): 5 mg 2x daily or
   d. Xeljanz XR (tofacitinib XR oral): 11mg daily
6. Approval
   a. Initial: 6 months.
   b. Re-approval: 1 year (↓ or sustained ↓ in disease activity)

D. Ulcerative Colitis (UC)
1. Age > 18 years
2. Prescriber: Gastroenterologist
3. Diagnosis and severity: Moderate to severe UC
4. Other therapies: Failed or significant adverse effects (1 of both below)
   a. Conventional therapies (4 months.): Mesalamine, metronidazole
   b. DMARD (4 months.): CD - Azathioprine, MTX; UC - Sulfasalazine
5. Dosage regimen: Refer to Appendix I for adjustments
   a. Xeljanz IR (tofacitinib oral): 5 mg 2x daily or
   b. Xeljanz XR (tofacitinib XR oral): 11mg daily
6. Approval
   a. Initial: 6 months.
   b. Re-approval: 1 year (↓ or sustained ↓ in disease activity)

Appendix I: Dosage Adjustment

State	Value	Recommendation
Anemia	Hgb ↓ <2g/dL & > 9g/dL	Maintain dose
	Hgb ↓ <2g/dL* or < 8g/dL*	Stop dosing until Hgb normalizes
Lymphopenia	Lymphocytes ≥ 500 cells/mm^3	Maintain dose
	Lymphocytes < 500 cells/mm^3*	Discontinue
Neutropenia	ANC >1,000 cells/mm^3	Maintain dose
	ANC 500-1,000 cells/mm^3	Persistent↓: stop dosing until ANC >1,000 cells/mm^3 When ANC >1,000 cells/mm^3 resume normal dose
	ANC <500 cells/mm^3*	D/C
Concurrent CYP450	Potent P450 3A4 Inducer (rifampin)	Not recommended
	Potent Inhibitor (ketoconazole) or >1 Mod. CYP3A inhibitor + potent CYP2C19 inhib (fluconazole)	5mg 1x/day
Renal function	Mild impairment	No adjustment
	Mod-severe impairment	↓ 5mg 1x/day
	Dialysis	Not recommended
Hepatic function	Mild impairment	No adjustment
	Mod impairment	↓ 5mg 1x/day
	Severe Impairment	Not recommended

**Confirm by retesting*

Appendix II: Monitoring & Patient Safety

Drug	Adverse Reactions	Monitoring & Contraindications	REMS
Xeljanz tofacitinib	• CNS: HA • CV: HTN • GI: Diarrhea • Resp: Nasopharyangitis, URI • Misc: Serious infection, malignancy (Black box) • Pregnancy: Class C	• Labs: Lymphocytes (pre & q 3 mons); Neutrophil/plt count/Hgb/lipids (pre, 6 wks, then q 6 mons); LFT • Infections: Viral hepatitis (pre), S & S of infection	• Purpose: warn re risk of serious/fatal infections; malignancies • Prescriber: review med guide prescribing/safety info • Web site: www.xeljanzrems.com

References and Resources:

1. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Xeljanz, accessed November 2018

Approved By:	
	12/5/18
Peter Graham, MD – PHP Executive Medical Director	Date
	12/5/18
Human Resources – Kurt Batteen	Date