Pharmacy Benefit Determination Policy

Policy Subject: Orencia	**Dates:**
Policy Number: SHS PBD27	**Effective Date:** March 18, 2010
Category: Rheumatology	**Revision Date** July 31, 2018
Policy Type: ☒ **Medical** ☒ **Pharmacy**	**Approval Date:** February 27, 2019
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 Orencia IV through the Medical or Pharmacy benefit based on approval by the Clinical Pharmacist or Medical Director using the following determination guidelines

Drugs and Applicable Coding:

J-code: J0129 (1u=10mg)

Clinical Determination Guidelines:

Document the following with chart notes

A. Juvenile Idiopathic Arthritis (JIA):
   1. Age: ≥2 yrs.
   2. Prescriber: Rheumatologist
   3. Diagnosis & severity: Mod-severe active polyarticular JIA
   4. Other therapies: Failed or had significant adverse effects with 1 of a and b
      a. DMARD (4 mons): sulfasalazine, MTX
      b. Biological Step therapy (4 months): Rx (self-injected) - Humira, Enbrel; Medical (infused) - Inflectra, Remicade
      c. May be used as monotherapy or concomitantly with MTX.
   5. Exclude: Orencia SC (abatacept)
      a. All preferred products are contraindicated, failed or resulted in significant adverse effects
      b. Required site of care determined by the health plan
   6. Dosage Regimen
      d. Orencia IV (abatacept):

Weight	Dose	# of vials	Initial	Maintenance	Route
< 75Kg	10mg/Kg	NA	0, 2 ,4 weeks	Every 4 weeks	IV Infusion
>75Kg	750mg	3	0, 2, 4 weeks	Every 4 weeks	IV Infusion
>100Kg	1,000mg	4	0, 2, 4 weeks	Every 4 weeks	IV Infusion

   7. Approval
      a. Initial: 6 months
      b. Re-approval: 1 year (decreased or sustained reduction in disease activity)

B. Rheumatoid Arthritis (RA)
1. Age: ≥ 18 years.
2. Prescriber: Rheumatologist
3. Disease severity: Mod-severe active RA
4. Other therapies: Failed or had significant adverse effects of 2 in category a and 1 in b
   a. DMARD (4 mons): MTX, leuflonomide, hydrochloroquine, sulfasalazine
   b. Biological step therapy (4 mons): Rx (self-injected) Pharmacy - Humira, Enbrel; Medical (infused) - Inflectra, Remicade, Simponi Aria
3. Exclude: Orencia SC (abatacept)
   a. All preferred products are contraindicated, failed or resulted in significant adverse effects
   b. Required site of care determined by the health plan
4. Dosage regimen: Orencia IV (abatacept):

Weight	Dose	# of vials	Initial	Maintenance	Route
< 60Kg	500mg	2	0, 2 ,4 weeks	Every 4 weeks	IV Infusion
60-100Kg	750mg	3	0, 2, 4 weeks	Every 4 weeks	IV Infusion
>100Kg	1,000mg	4	0, 2, 4 weeks	Every 4 weeks	IV Infusion

5. Approval
   a. Initial: 6 months
   b. Re-approval: 1 year. (decreased or sustained reduction in disease activity)

C. Psoriatic Arthritis (PA)
1. Age: ≥18 yrs.
2. Prescriber: Rheumatologist
3. Diagnosis & severity: Active PA w ≥ 5 swollen and ≥ 5 tender joints
4. Other therapies: Failed or to significant adverse effects from1 from both below:
   a. Per location
      - Peripheral disease: DMARD therapy (4 months) - Methotrexate, leflunomide, sulfasalazine
      - Axial disease, enthesitis, dactylitis and uveitis: NSAIDs (4 months)
   b. Biological Step Therapy (4 months): Rx (self-injected) - Enbrel, Humira, Otezla; Medical (infused) - Inflectra, Remicade, Simponi Aria,
4. Exclude: Orencia SC (abatacept)
   a. All preferred products are contraindicated, failed or resulted in significant adverse effects
   b. Required site of care determined by the health plan
5. Dosage regimen: Orencia IV (abatacept)

Weight	Dose	# of vials	Initial	Maintenance	Route
< 60Kg	500mg	2	0, 2 ,4 weeks	Every 4 weeks	IV Infusion
60-100Kg	750mg	3	0, 2, 4 weeks	Every 4 weeks	IV Infusion
>100Kg	1,000mg	4	0, 2, 4 weeks	Every 4 weeks	IV Infusion

5. Approval
   a. Initial: 6 months
   b. Re-approval: 1 year (decreased or sustained reduction in disease activity)

Appendix I: Monitoring & Patient Safety

Drug	Adverse Reactions	Monitoring	REMS
Orencia (abatacept)	• CNS: HA (≤18%) • GI: Nausea (10%), • Resp: Nasopharyngitis (12%), URI • Misc: Infection (36-54%), antibodies (2-41%) • Pregnancy category: C	• Infection: monitor signs & symptoms (S & S) • TB skin test pre • Viral Hep B test pre	None needed

References and Resources:

1. Lexicomp Online®, Lexi-Drugs® , Hudson, Ohio: Lexi-Comp, Inc.; Orencia, accessed July, 2018
2. Juvenile Idiopathic Arthritis. Pediatric Clinics of North America.2005:52(2).
3. 2015 college of Rheumatology Guideline for the treatment of Rheumatoid Arthritis. Arthritis & Rheumatology. 2016;68(1):1-26.
4. 2013 Update of the 2011 American College of Rheumatology recommendations for the treatment of juvenile Idiopathic arthritis. Arthritis & Rheumatology. 2013;65(10):2499-2512
5. British Association of Dermatologists guidelines for the biological therapy for psoriasis 2017;177(3):628-36.
6. Clinical Practice Guidelines for the treatment of patients with axial spondyloarthritis and psoriatic arthritis. Madrid, (Spain): Spanish Society of Rheumatology (SER);2015.

Approved By:

2/27/19

Peter Graham, MD – PHP Executive Medical Director — Date

2/27/19

Kurt Batteen - Human Resources — Date