DRUG DETERMINATION POLICY

Title: DDP-09 Orencia

Effective Date: 09/21/2020

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.

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:

Orencia is a specialty drug indicated for a number of diagnoses and is associated with significant toxicity. These criteria were developed and implemented to ensure appropriate use for the intended diagnoses and mitigation of toxicity, if possible.

Note that this policy applies only to the intravenous infusion formulation of Orencia, not the self-administered subcutaneous (SQ) formulation.

3.0 Clinical Determination Guidelines:

Document the following with chart notes:

A. General Considerations.

1. Subcutaneous Orencia subcutaneous (abatacept SQ) is an excluded product.

    a. Contraindication, inadequate response, or significant adverse effects to all preferred biologic products.

2. Medication administration (must meet both below):

    a. At required site-of-care as determined by the Health Plan.

    b. Concomitant immunosuppressives: Orencia is not to be used with other immunosuppressives (e.g., biological disease-modifying anti-rheumatic drugs and Janus Kinase inhibitors).

B. Juvenile Idiopathic Arthritis (JIA) (must meet 1-4 below):

1. Age: at least two years.

2. Diagnosis and severity: moderate to severe active polyarticular juvenile idiopathic arthritis.

3. Other therapies: contraindicated, inadequate response after four months with each agent or had significant adverse effects to one disease-modifying anti-rheumatic drug (DMARD) and one biological drug

   a. Chronic traditional DMARD: sulfasalazine, methotrexate.

   b. Biological: pharmacy self-injected agent - Humira, Enbrel; medical infused agent - Renflexis, Inflectra

4. Dosage Regimen: Orencia intravenous (abatacept IV).

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

5. Approval.

   a. Initial: six months.

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

D. Rheumatoid Arthritis (RA) (must meet 1-4 below):

1. Age: at least 18 years.

2. Disease severity: moderate to severe active rheumatoid arthritis.

3. Other therapies: contraindicated, inadequate response after four months with each agent or significant adverse effects to two DMARDs and one biological drug.

   a. Chronic traditional DMARD: methotrexate, leflunomide, hydroxychloroquine, sulfasalazine.

   b. Biologic: pharmacy self-injected agent: Humira, Enbrel; medical infused product – Renflexis, Inflectra, Simponi Aria.

4. Dosage regimen: Orencia (abatacept):

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

5. Approval.

   a. Initial: six months.

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

E. Psoriatic Arthritis (PA) (must meet 1-4 below):

1. Age: at least 18 years.

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

3. Other therapies: contraindicated, inadequate response after four months with each agent or significant adverse effects to one based on location and one biological drug.

   a. Per location.

      i. Peripheral disease: disease modifying anti-rheumatic drug - methotrexate, leflunomide, ulfasalazine.

      ii. Axial disease, enthesitis, dactylitis and uveitis: nonsteroidal anti-inflammatory drugs.

   b. Biological therapy: pharmacy self-injected agent - Enbrel, Humira, Otezla; medical infused agent - Renflexis, Inflectra, Simponi Aria.

4. Dosage regimen: Orencia intravenous (abatacept IV).

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

5. Approval.

   a. Initial: six months.

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

4.0 Coding:

AFFECTED CODES				
HCPCS Code	**Brand Name**	**Generic Name**	**HCPCS units (per 1 unit)**	**Prior authorization**
J0129	Orencia	abatacept	10 mg	Yes

5.0 References, Citations & Resources:

1. Lexicomp Online®, Lexi-Drugs® , Hudson, Ohio: Lexi-Comp, Inc.; Orencia, accessed July, 2020.
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.

6.0 Appendices:

See page 5.

7.0 Revision History:

Original Effective Date: March 18, 2010

Next Review Date: 07/22/2021

Revision Date	Reason for Revision
3/19	Moving to new format
4/29/19	Edition revised format
7/19	Annual review; clarifications added; replaced abbreviations
6/20	Annual review; replaced abbreviations, added no use with other biologicals, changed other therapies language, clarified criteria instructions, approved by P&T Committee 8/26/20.

Appendix I: Monitoring & Patient Safety

Drug	Adverse Reactions	Monitoring	REMS
Orencia (abatacept)	• Central nervous system: headache (≤18%) • Gastrointestinal: nausea (10%), • Respiratory: bronchitis (5-13%), nasopharyngitis (12%), upper respiratory infection (13%) • Miscellaneous: infection (36-54%), antibodies (2-41%) • Pregnancy category: C	• Infection: monitor signs and symptoms • TB skin test pretreatment • Viral Hepatitis B test pretreatment	None needed