

# DRUG DETERMINATION POLICY

**Title:** DDP-09 Orencia

**Effective Date:** 06/12/2019



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 IV 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.

### 3.0 Clinical Determination Guidelines:

Document the following with chart notes

#### A. General Considerations

1. Subcutaneous Orencia (Orencia SQ) is an excluded product.
  - a. All preferred biologic products for diagnosis are contraindicated, failed, or resulted in significant adverse effects.
2. Medication administration at required site-of-care as determined by the Health Plan.

#### B. Juvenile Idiopathic Arthritis (JIA):.

1. Age:  $\geq 2$  years.
2. Prescriber: rheumatologist.
3. Diagnosis and severity: moderate to severe active polyarticular JIA.

4. Other therapies: contraindicated, failed or had significant adverse effects to one agent in category a and one agent in category b:
  - a. DMARD (four months): sulfasalazine, methotrexate.
  - b. Biological Step therapy (four months): Rx (self-injected) - Humira, Enbrel; Medical (infused) - Inflectra, Remicade.
  - c. May be used as monotherapy or concomitantly with methotrexate.
5. Dosage Regimen
  - a. Orenzia IV (abatacept):

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	0, 2, 4 weeks	Every 4 weeks	IV Infusion
>100 kg	1,000 mg	4	0, 2, 4 weeks	Every 4 weeks	IV Infusion

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

C. Rheumatoid Arthritis (RA)

1. Age:  $\geq 18$  years.
2. Prescriber: rheumatologist.
3. Disease severity: moderate to severe active RA.
4. Other therapies: failed or had significant adverse effects to two agents in category a and one in category b:
  - a. DMARD (four months): methotrexate, leflunomide, hydrochloroquine, sulfasalazine.
  - b. Biologic step therapy (four months): Rx (self-injected) pharmacy - Humira, Enbrel; Medical (infused) - Inflectra, Remicade, Simponi Aria.
5. Dosage regimen: Orenzia IV (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	0, 2, 4 weeks	Every 4 weeks	IV Infusion
>100 kg	1,000 mg	4	0, 2, 4 weeks	Every 4 weeks	IV Infusion

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

C. Psoriatic Arthritis (PA)

1. Age:  $\geq 18$  years.
2. Prescriber: rheumatologist.
3. Diagnosis and severity: active PA with  $\geq 5$  swollen and  $\geq 5$  tender joints.
4. Other therapies: contraindicated, failed or had significant adverse effects to one agent from category a and one agent from category b:
  - a. Per location
    - i. Peripheral disease: DMARD therapy (four months) - methotrexate, leflunomide, sulfasalazine.
    - ii. Axial disease, enthesitis, dactylitis and uveitis: NSAIDs (four months).
  - b. Biological Step Therapy (four months): Rx (self-injected) - Enbrel, Humira, Otezla; Medical (infused) - Inflectra, Remicade, Simponi Aria.
5. Dosage regimen: Orenzia IV (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	0, 2, 4 weeks	Every 4 weeks	IV Infusion
>100 kg	1,000 mg	4	0, 2, 4 weeks	Every 4 weeks	IV Infusion

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

**4.0 Coding:**

<b>AFFECTED CODES</b>				
<b>HCPSC Code</b>	<b>Brand Name</b>	<b>Generic Name</b>	<b>HCPSC units (per 1 unit)</b>	<b>Prior authorization required</b>
J0129	Orenzia IV	abatacept	10 mg	Yes

**5.0 References, Citations & Resources:**

1. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Orenzia, accessed June, 2019.
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:**

Appendix I: Monitoring & Patient Safety

Drug	Adverse Reactions	Monitoring	REMS
Orencia (abatacept)	<ul style="list-style-type: none"> <li>• CNS: HA (<math>\leq</math>18%)</li> <li>• GI: nausea (10%),</li> <li>• Resp: nasopharyngitis (12%), URI</li> <li>• Misc: infection (36-54%), antibodies (2-41%)</li> <li>• Pregnancy category: C</li> </ul>	<ul style="list-style-type: none"> <li>• Infection: monitor signs &amp; symptoms (S &amp; S)</li> <li>• TB skin test pre</li> <li>• Viral Hep B test pre</li> </ul>	None needed

**7.0 Revision History:**

Original Effective Date: March 18, 2010

Last Approval Date: 06/12/2019

Next Review Date: 06/12/2020

Revision Date	Reason for Revision
3/19	Moving to new format
4/29/19	Edition revised format