DRUG DETERMINATION POLICY

Title: DDP-09 Orencia

Effective Date: 8/23/23

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 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 several 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:

I. General Considerations.

A. Orencia subcutaneous (abatacept SQ) is an excluded product.

1. Trials of all preferred biologic products are required unless all are contraindicated. Trials must result in an inadequate response after four consecutive months of use per medication or severe adverse reactions.

B. Medication administration [must meet both listed below]:

1. At required site-of-care as determined by the Health Plan (see DDP-08 Site of Care for Parenteral Specialty Drugs)

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

C. Pharmaceutical sample use: The Plan does not recognize samples as a medication trial or for continuation of therapy.

D. Dose Rounding: Medication requests may be automatically rounded up or down by 10% of the requested dose in order to fit the nearest manufacturer strength of the requested medication for patients weighing above 10 Kg (see DDP-21 Dose Rounding and Wastage).

E. Appropriate medication use [must meet one listed below]:

1. The Food and Drug Administration (FDA) approval status [must meet one listed below]:

a. FDA approved: product, indication, and/or dosage regimen.

b. Non-FDA approved: Compendium support (Lexicomp™) for use of a drug for a non-FDA approved indication or dosage regimen

2. Place in therapy: sequence of therapy supported by national or international accepted guidelines and/or studies (e.g., oncologic, infectious conditions).

F. Approval:

1. Initial: six months.

2. Re-approval: one year [must meet both listed below]:

a. Adherence: consistent utilization (at least 80% of days covered) based on medical claims history or chart notes.

b. Decreased or sustained reduction in disease activity.

II. Juvenile Idiopathic Arthritis [must meet all listed below]:

A. Age: at least six years.

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

C. Other therapies: Trials of one disease-modifying anti-rheumatic drug (DMARD) and one biological drug below are required unless all are contraindicated. Trials must result in an inadequate response after four consecutive months of use per medication or severe adverse reactions.

1. Chronic traditional DMARD: sulfasalazine, methotrexate.

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

D. 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			

III. Rheumatoid Arthritis [must meet all listed below]:

A. Age: at least 18 years.

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

C. Other therapies: Trials of two disease-modifying anti-rheumatic drugs (DMARDs) and one biological drug below are required unless all are contraindicated. Trial must result in an inadequate response after four consecutive months of use per medication or a severe adverse reaction.

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

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

D. 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			

IV. Psoriatic Arthritis [must meet all listed below]:

A. Age: at least 18 years.

B. Diagnosis and severity: Active psoriatic arthritis

C. Other therapies: Trials of one traditional therapy from the appropriate category and one biologic below are required unless all are contraindicated. Trial must result in an inadequate response after four consecutive months of use per medication or a severe adverse reaction.

1. Traditional therapy:

a. Peripheral disease: disease-modifying anti-rheumatic drug - methotrexate, leflunomide, sulfasalazine.

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

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

D. 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			

4.0 Coding:

COVERED CODES				
HCPCS Code	**Brand Name**	**Generic Name**	**Billing Units (1 unit)**	**Prior Approval**
J0129	Orencia	abatacept	10 mg	Y

5.0 References, Citations & Resources:

1. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Orencia, accessed July 2022.
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 spondylarthritis and psoriatic arthritis. Madrid, (Spain): Spanish Society of Rheumatology (SER);2015.
7. Treatment of Psoriatic arthritishttps://www.uptodate.com/contents/treatment-of-psoriatic-arthritis?search=psoriatic%20arthritis%20treatment&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1 UpToDate accessed June 2021.
8. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Care Res (Hoboken)*. 2021;73(7):924-939. doi:10.1002/acr.24596[PubMed 34101387]

6.0 Appendices:

See page 5.

7.0 Revision History:

Original Effective Date: March 18, 2010

Next Review Date: 09/01/2024

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.
6/21	Annual review: formatting, clarified criteria instructions, replaced abbreviations, added reference #7, added appropriate use and reformatted
11/21	Off-cycle review; identified typo and corrected it
7/22	Annual review: no change other than added reference and mentioned site of care policy
6/23	Annual review; clarified other therapies language, added adherence to re-approval criteria, added no pharmaceutical sample use, added dose rounding language.

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