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Approved by: Pharmacy and Therapeutics Quality Management Subcommittee	Date Approved: 12/06/2023
Pharmacy Clinical Policy Document: Orencia Infusion Prior Authorization	Replaces Effective Clinical Policy Dated: 5/24/2023
Reference #: PC/O003	Page: 1 of 4

PURPOSE:
The intent of this Orencia Infusion Prior Authorization Pharmacy Clinical Policy is to ensure services are medically necessary

Please refer to the member's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the terms of the member's benefit plan document will govern.

POLICY:
Benefits must be available for health care services. Health care services must be ordered by a provider. Health care services must be medically necessary, applicable conservative treatments must have been tried, and the most cost-effective alternative must be requested for coverage consideration.

Self-administered formulations are taken into consideration as the most cost-effective alternative for any provider-administered medication request and may result in a requirement to use the self-administered formulation for that particular medication when applicable.

Note: Confirm if the treatment plan is for ongoing intravenous administration. If the request is for an intravenous test/loading dose, follow PBM guidelines for medical necessity

GUIDELINES:
Medical Necessity Criteria – Must satisfy any of the following: I - II

Table 1: Orencia (abatacept) Infusion

Biologic	Molecule	Route of Administration	Biosimilar?	Drug Class
Orencia	abatacept	intravenous infusion	No	T-lymphocyte inhibitor

I. Initial request for Orencia (abatacept) infusion – must satisfy all of the following: A – C or D.

   A. Must satisfy one of the following: 1 - 3
      1. Diagnosis of active psoriatic arthritis in a member equal to or greater than 18 years of age; or
      2. Diagnosis of moderate to severe active rheumatoid arthritis in a member equal to or greater than 18 years of age; or
      3. Diagnosis of moderate to severe active polyarticular juvenile idiopathic arthritis (PJIA) in a member equal to or greater than 2 years of age
   B. Prescribed by or in consultation with a rheumatologist; and

   C. The member has not responded to, is intolerant to, responds to but cannot taper off without recurrent symptoms, or is a poor candidate for two self-administered biologic drugs with different mechanisms of action (ie, from different drug classes) (Tables 2, 3 and 4).

   D. When used for prophylaxis of acute graft versus host disease (aGVHD): must satisfy 1 and 2
      1. The member is equal to or greater than 2 years of age undergoing hematopoietic stem cell transplantation (HSCT); and
      2. Is being used in combination with a calcineurin inhibitor and methotrexate.

II. Continuation request – allow up to 12 months.

Table 2: Self-Administered Biologic Drugs for PJIA*

Drug	Generic/ Molecule Name	Is this a Biosimilar?	FYI ONLY			Drug Class
			Generic available	Route of Administration	Recommended Age	
Actemra	tocilizumab	N	N	subcutaneous injection	age 2 and older	IL-6 receptor inhibitor
Enbrel	etanercept	N	N	subcutaneous injection	age 2 and older	TNFα blocker
Humira	adalimumab	N	N	subcutaneous injection	age 2 and older	TNFα blocker
Ilaris	canakinumab	N	N	subcutaneous injection	age 2 and older	IL-1α receptor antagonist
Orencia	abatacept	N	N	subcutaneous injection	age 2 and older	T lymphocyte inhibitor
Xeljanz/XR	tofacitinib	N	N	oral	age 2 and older	JAK inhibitor

* Listing of drugs in table above does not ensure coverage. Please check member's prescription benefit.

Table 3: Self-Administered Biologic Drugs for Rheumatoid Arthritis*

Drug	Generic/ Molecule Name	Is this a Biosimilar?	Generic available	Route of Administration	Recommended Age	Drug Class
Actemra	tocilizumab	N	N	subcutaneous injection	adult	IL-6 antagonist
Cimzia	certolizumab	N	N	subcutaneous injection	adult	TNFα blocker
Enbrel	etanercept	N	N	subcutaneous injection	not age specific	TNFα blocker
Humira	adalimumab	N	N	subcutaneous injection	adult	TNFα blocker
Kevzara	sarilumab	N	N	subcutaneous injection	adult	IL-6 antagonist
Kineret	anakinra	N	N	subcutaneous injection	adult	IL-1 antagonist
Olumiant	baricitinib	N	N	oral	adult	JAK inhibitor
Orencia	abatacept	N	N	subcutaneous injection	adult	T lymphocyte inhibitor
Rinvoq	upadacitinib	N	N	oral	adult	JAK inhibitor
Simponi	golimumab	N	N	subcutaneous injection	adult	TNFα blocker
Xeljanz/XR	tofacitinib	N	N	oral	adult	JAK inhibitor

* Listing of drugs in table above does not ensure coverage. Please check member's prescription benefit.

Table 4: Self-administered Biologic Drugs for Psoriatic arthritis*

Drug	Generic/ Molecule Name	Is this a Biosimilar ?	Generic available	Route of Administration	Recommended Age	Drug Class
Cimzia	certolizumab	N	N	subcutaneous injection	adult	TNFα blocker
Cosentyx	secukinumab	N	N	subcutaneous injection	adult	IL-17A antagonist
Enbrel	etanercept	N	N	subcutaneous injection	not age specific	TNFα blocker
Humira	adalimumab	N	N	subcutaneous injection	adult	TNFα blocker
Orencia	abatacept	N	N	subcutaneous injection	adult	T lymphocyte inhibitor
Simponi	golimumab	N	N	subcutaneous injection	adult	TNFα blocker
Skyrizi	risankizumab	N	N	subcutaneous injection	adult	IL-23 antagonist
Stelara	ustekinumab	N	N	subcutaneous injection	adult	IL-12 and IL23 antagonist
Taltz	ixekizumab	N	N	subcutaneous injection	adult	IL-17A antagonist
Tremfya	guselkumab	N	N	subcutaneous injection	adult	IL-23 antagonist
Xeljanz/XR	tofacitinib	N	N	oral	adult	JAK inhibitor

* Listing of drugs in table above does not ensure coverage. Please check member's prescription benefit.

DEFINITIONS:
Biologic/biological: Biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins.

BACKGROUND:
This clinical policy is based on U.S. Food and Drug Administration (FDA) approved indications and dosing, expert consensus opinion and/or available reliable evidence.

Prior Authorization: Yes, per network provider agreement - up to 12 months. This is subject to the member's contract benefits.

CODING: HCPCS – 2023
J0129 Injection, abatacept, 10mg (Orencia)

REFERENCES:

1. Fraenkel L, Bathon J, England B, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Retrieved from https://rheumatology.org/rheumatoid-arthritis-guideline. Accessed 10-2-23.
2. Orencia [package insert]. Princeton, NJ: Bristol Myers Squibb Company; 2021.
3. Integrated Healthcare Services Process Manual: UR015 Use of Medical Policy and Criteria
4. Medical Policy: MP/C009 Coverage Determination Guidelines
5. Pharmacy Clinical Policy: PP/O001 Off-label Drug Use
6. Pharmacy Clinical Policy: PP/O002 Off-label Drug Use for Business Process Outsourced Clients
7. Pharmacy Clinical Policy: PP/T002 Therapeutic Equivalence

DOCUMENT HISTORY:

Created Date: 04/16/21
Reviewed Date: 4/7/2022, 2/27/2023, 10/2/2023
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PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

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You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

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Fax: 763.847.4010
customerservice@preferredone.com

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You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

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