Department of Origin: Pharmacy	**Effective Date:** 12/06/2023
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)

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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:

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Revised Date: 5/1/2022

Nondiscrimination & Language Access Policy

Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, sex, sexual orientation, or gender identity. *We* do not exclude people or treat them differently because of race, color, national origin, age, disability, sex, sexual orientation, or gender identity.

We will:
Provide free aids and services to people with disabilities to communicate effectively with us, such as:
- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provide free language services to people whose primary language is not English, such as:
- Qualified interpreters
- Information written in other languages

If *you* need these services, contact *us* at the phone number shown on the inside cover of this *contract*, *your* id card, or aspirushealthplan.com.

If *you* believe that *we* have failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, sex, sexual orientation, or gender identity, *you* can file a grievance with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1062
Minneapolis, MN 55440
Phone: 1.866.631.5404 (TTY: 711)
Fax: 763.847.4010
Email: customerservice@aspirushealthplan.com

You can file a grievance in person or by mail, fax, or email. If *you* need help filing a grievance, the Nondiscrimination Grievance Coordinator is available to help you.

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)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë.Telefononi në 1.866.631.5404 (TTY: 711).

Arabic تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً . اتصل بن اعلى رقم الهاتف 1.866.631.5404(رقم هاتف الصم والبك : 711)

French: ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelezle 1.866.631.5404 (ATS : 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zurVerfügung. Rufnummer: 1.866.631.5404 (TTY: 711).

Hindi: _यान द_: य_द आप ि◌हंदी बोलते ह_ तो आपके ि◌लए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_। 1.866.631.5404 (TTY: 711) पर कॉल कर_।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.866.631.5404 (TTY: 711).

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Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.866.631.5404 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1.866.631.5404 (TTY: 711)

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Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.866.631.5404 (TTY: 711).

Pennsylvania Dutch: Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1.866.631.5404 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ,ໂດຍບໍ່ເສັ້ງຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1.866.631.5404 (TTY:711).

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