abatacept (Orencia IV)

Commercial Medical Benefit Drug Policy

Place of Service

Office Administration
Home Infusion
Infusion Center Administration
Outpatient Facility Infusion Administration

Drug Details

USP Category: IMMUNOLOGICAL AGENTS
Mechanism of Action: Selective co-stimulation modulator that inhibits T cell (T lymphocyte) activation by binding to CD80 and CD86, blocking interaction with CD28
HCPCS:
J0129:Injection, abatacept, 10 mg (code may be used for medicare when drug administered under the direct supervision of a physician, not for use when drug is self administered)
How Supplied:
250 mg lyophilized powder (single-dose vial)

Condition(s) listed in policy *(see coverage criteria for details)*

- Graft Versus Host Disease
- Polyarticular Juvenile Idiopathic Arthritis
- Psoriatic Arthritis
- Rheumatoid Arthritis

The following conditions do not meet the safety and efficacy criteria established by Blue Shield of California's Pharmacy & Therapeutics committee and are not covered:

- Combination use with other targeted immunomodulators

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Orencia given by intravenous (IV) injection is managed under the Medical Benefit policy. Orencia given by subcutaneous (SC) injection can be obtained through the patient's pharmacy benefit. Please refer to the "Self-Administered Drugs" medical benefit drug policy for more information.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct)** may be required to have their medication administered at a

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preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

MCG Care Guidelines, 19th edition, 2015

ADMINISTRATION OF THIS DRUG IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted)*

1. Patient is receiving their first dose of Orencia or is being re-initiated on Orencia after at least 6 months off therapy. *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

OR

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. Patient has experienced a previous severe adverse event on Orencia based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on Orencia based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
4. Patient is clinically unstable based on documentation submitted.
5. Patient is physically or cognitively unstable based on documentation submitted.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Graft Versus Host Disease

Meets medical necessity if all the following are met:

1. Meets ONE of the following:
   a. Prophylaxis of acute (GVHD) and meets the following:
      i. Patient is undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor
      ii. Being used in combination with a calcineurin inhibitor and methotrexate
   b. Treatment of GVHD and inadequate response to at least one prior drug for GVHD (i.e., systemic corticosteroids, immunosuppressants)

Covered Doses:

Prophylaxis of acute GVHD

- 2 to less than 6 years of age: Up to 15 mg/kg given intravenously on the day before transplantation, followed by a 12 mg/kg dose on Days 5, 14, and 28 after transplant
- 6 years and older: Up to 1000 mg given intravenously on the day before transplantation, followed by 1000 mg on Days 5, 14, and 28 after transplant

Treatment of GVHD
Up to 10 mg/kg given intravenously for up to 8 doses over a year

Coverage Period:
Prophylaxis of acute GVHD: 1 month
Treatment of GVHD: Indefinite

ICD-10:
D89.12, D89.810, D89.813, T86.09

Polyarticular Juvenile Idiopathic Arthritis
Meets medical necessity if all the following are met:

1. Prescribed by or in consultation with a rheumatologist
2. Inadequate response or intolerable side effect with one disease modifying anti-rheumatic drug (DMARD) or has a medical justification why methotrexate cannot be used
3. Not being used in combination with other targeted immunomodulators
4. Inadequate response or intolerable side effect with two of the following BSC-preferred agents (adalimumab-aacf, Enbrel, Rinvoq, and Xeljanz/Xeljanz XR), or contraindication to all preferred agents

Covered Doses:
A dose is given intravenously at weeks 0, 2, and 4, followed by every 4 weeks thereafter according to body weight.

Body Weight	Dose
< 75 kg	10 mg/kg
≥ 75 kg	Use adult dosing up to a maximum of 1000 mg

Coverage Period:
Yearly based on continued response

ICD-10:
M08.00-M08.40

Psoriatic Arthritis
Meets medical necessity if all the following are met:

1. Prescribed by or in consultation with a rheumatologist
2. Inadequate response, intolerable side effect with one disease modifying anti-rheumatic drug (DMARDs) or has medical reason why methotrexate, sulfasalazine, and leflunomide cannot be used
3. Not being used in combination with other targeted immunomodulators
4. Inadequate response or intolerable side effect with two of the following BSC-preferred agents (adalimumab-aacf, Cosentyx SC, Enbrel, infliximab (Avsola or Inflectra), Otezla, Rinvoq, Yesintek SC, Stelara SC, Tremfya SC, and Xeljanz/Xeljanz XR), or contraindication to all preferred agents

Covered Doses:

A dose is given intravenously at weeks 0, 2, and 4, followed by every 4 weeks thereafter according to body weight.

Body Weight	Dose	Number of Vials
< 60 kg	500 mg	2
60 to 100 kg	750 mg	3
> 100 kg	1000 mg	4

Coverage Period:
Yearly based upon continued response

ICD-10:
L40.50-L40.59

Rheumatoid Arthritis
Meets medical necessity if all the following are met:
1. Diagnosed by or in consultation with a rheumatologist
2. Inadequate response, intolerable side effect, or contraindication to methotrexate
3. Not used in combination with another targeted immunomodulator
4. Inadequate response, intolerable side effect, with two BSC-preferred agents (adalimumab-aacf, Enbrel, infliximab (Avsola or Inflectra), Rinvoq, and Xeljanz/Xeljanz XR), or contraindication to all preferred agents

Covered Doses:
A dose is given intravenously at weeks 0, 2, and 4, followd by every 4 weeks thereafter according to body weight.

Body Weight	Dose	Number of Vials
< 60 kg	500 mg	2
60 to 100 kg	750 mg	3
> 100 kg	1000 mg	4

Coverage Period:
Yearly based on continued response

ICD-10:
(X=0-9) M05.XXX, M06.0XX, M06.2XX, M06.3XX, M06.8XX, M06.9

References

1. AHFS. Available by subscription at http://www.lexi.com
2. American Academy of Allergy Asthma and Immunology. Guidelines for the Site of Care for Administration of IGIV Therapy. December 2011.
3. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
4. Fraenkel, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research 2021; 73: 924-939. Available at https://www.rheumatology.org.
5. MCG Care Guidelines, 19th edition, 2015, Home Infusion Therapy, CMT: CMT-0009(SR)
6. National Comprehensive Cancer Network. Hematopoietic transplantation (Version 1.2024). Available by subscription at www.nccn.org.

7. Onel K B, Horton D B, lovell D J, et al. 2021 American College of Rheumatology Guideline for the treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Idiopathic Arthritis. Arthritis & Rheum 2022;74:4 (553-569).
8. Orencia (abatacept) Prescribing Information. Bristol-Myers Squibb Company, Princeton, NJ. 12/2021.
9. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheum 2019; 71:5-32.

Review History

Date of Last Annual Review: 4Q2024
Changes from previous policy version:

- Psoriatic arthritis: Clarified preferred drugs

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee