Abatacept, IV (Orencia®)	Place of Service Office Administration Home Infusion Infusion Center Administration Outpatient Facility Infusion Administration HCPCS: **J0129** per 10 mg

Conditions listed in policy (*see criteria for details*)

- Graft versus host disease (GVHD)
- Polyarticular juvenile idiopathic arthritis
- Psoriatic arthritis
- Rheumatoid arthritis

AHFS therapeutic class: Disease-Modifying Antirheumatic Agent

Mechanism of action: Abatacept is a selective co-stimulation modulator that inhibits T cell (T lymphocyte) activation by binding to CD80 and CD86, thereby blocking interaction with CD28

(1) Special Instructions and Pertinent Information

Orencia, given by intravenous (IV) injection is managed under the Medical Benefit. Please submit clinical information for prior authorization review.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Orencia® (abatacept) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Graft versus host disease (GVHD)

1. Either 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, and
        ii. Being used in combination with a calcineurin inhibitor and methotrexate

    OR

    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

Intravenous:

- 2 to > 6 years: Up to 15 mg/kg IV on the day before transplantation, followed by a 12 mg/kg dose on Day 5, 14, and 28 after transplant
- 6 years and older: Up to 1000 mg IV on the day before transplantation, followed by up to 1000 mg on Day 5, 14, and 28 after transplant

Treatment of GVHD

Intravenous: Up to 10 mg/kg IV for up to 8 doses over a year

Coverage Period

Prophylaxis of acute GVHD: 1 month

Treatment of GVHD: Indefinite

ICD-10:

D89.810, D89.12, D89.813, T86.09

Polyarticular juvenile idiopathic arthritis

1. Prescribed by or in consultation with a rheumatologist, **AND**
2. Inadequate response or intolerance to a disease modifying anti-rheumatic drugs (DMARD) or documented medical justification why methotrexate cannot be used, **AND**
3. Inadequate response, intolerable side effect or contraindication with at least two of the following: anti-TNFs or JAK inhibitor, **AND**
4. Not used in combination with a targeted immunomodulator

Covered Doses

Intravenous: Dose is given at weeks 0, 2, and 4; then 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

Cover yearly

ICD-10:

M08.00-M08.40

Psoriatic arthritis

1. Prescribed by or in consultation with a rheumatologist, **AND**
2. Inadequate response, intolerance, or contraindication to one or more disease modifying anti-rheumatic drugs (DMARDs) or has a medical reason why methotrexate, sulfasalazine, and leflunomide cannot be used, **AND**
3. Not used in combination with Otezla or another targeted immunomodulator, **AND**
4. Patient has had an inadequate response or intolerable side effect with preferred infliximab (Avsola, Inflectra, or Renflexis), or contraindication to all infliximab products

Covered Doses

Intravenous: Dose is given at weeks 0, 2, and 4; then 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

Cover yearly, based upon continued response.

ICD-10:

L40.50-L40.59

Rheumatoid arthritis

1. Prescribed by or in consultation with a rheumatologist**, AND**
2. Not used in combination with another targeted immunomodulator, **AND**
3. Inadequate response, intolerable side effect, or contraindication to methotrexate, **AND**
4. Patient has had an inadequate response or intolerable side effect with preferred infliximab (Avsola, Inflectra, or Renflexis) or contraindication to all preferred infliximab products

Covered Doses

Intravenous: Dose is given at weeks 0, 2, and 4; then 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

Cover yearly

ICD-10: (X=0-9)

M05.XXX, M06.0XX, M06.2XX, M06.3XX, M06.8XX, M06.9

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Orencia® (abatacept) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21):

- Combination use with other targeted immunomodulators
- Ulcerative Colitis
- Crohn's disease
- Psoriasis

- Irritable Bowel Disease

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How Supplied:
Intravenous: 250 mg lyophilized powder (single-dose vial)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- American Academy of Allergy Asthma and Immunology. Guidelines for the Site of Care for Administration of IGIV Therapy. December 2011.
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- 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.
- Ringold, S, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroilitis, and Enthesitis. Arthritis Care & Research 2019; 71: 717-734. Available at https://www.rheumatology.org
- MCG™ Care Guidelines, 19th edition, 2015, Home Infusion Therapy, CMT: CMT-0009(SR)
- National Comprehensive Cancer Network. Hematopoietic transplantation (Version 2.2023). Available by subscription at www.nccn.org.
- Orencia (abatacept) [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company. 12/2021.
- 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.

(7) Policy Update

Date of last review: 4Q2022
Date of next review: 4Q2023
Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee