Abatacept (Orencia®)	**Place of Service** **Office Administration** **Home Infusion** **Infusion Center Administration** **Outpatient Facility Infusion Administration*** [***Prior authorization required – see section (1)] **Self-Administration** (subcutaneous injection) – *May be covered under the pharmacy benefit* **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

Subcutaneous (SC) Orencia is managed under the outpatient Pharmacy Benefit for self-administration. Please contact the member's Pharmacy Benefit for information on how to obtain this drug.

To submit a request for SC Orencia under the Medical Benefit, please submit clinical information for prior authorization review and include medical rationale why the patient cannot self-administer this drug in the home.

For plans with self-injectables only covered under the Medical Benefit, please submit clinical information for prior authorization review.

Intravenous (IV) Orencia is managed under the Medical Benefit, please submit clinical information for prior authorization review.

**** CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION****

AAAAI Guidelines 2011, MCG™ Care Guidelines, 19th edition, 2015

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

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

1. **Patient is receiving the 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.**

(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

Subcutaneous: 125 mg SC injection once weekly

Subcutaneous Orencia is managed under the Outpatient Pharmacy Benefit unless medical rationale is provided why the patient cannot self-administer this medication in the home. Please contact the member's Pharmacy Benefit for information on how to obtain this drug.

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 intolerable side effect with one disease modifying anti-rheumatic drug (DMARD– *see section 5*) or has a medical justification why methotrexate cannot be used, **AND**
3. Not being used in combination with other targeted immunomodulators (i.e., anti-TNFs, interleukin inhibitors), **AND**
4. Inadequate response or intolerable side effect with two of the following BSC-preferred agents, Enbrel, Humira, Xeljanz/Xeljanz XR, or contraindication to all preferred agents

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

Subcutaneous:

Dose is given once weekly according to body weight:

Body Weight	Dose
10 to < 25 kg	50 mg
25 to < 50 kg	87.5 mg
≥ 50 kg	125 mg

Subcutaneous Orencia is managed under the Outpatient Pharmacy Benefit unless medical rationale is provided why the patient cannot self-administer this medication in the home. Please contact the member's Pharmacy Benefit for information on how to obtain this drug.

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, intolerable side effect with one disease modifying anti-rheumatic drug (DMARD – *see section 5*) or has medical reason why methotrexate, sulfasalazine, and leflunomide cannot be used, **AND**
3. Not being used in combination with other targeted immunomodulators (i.e., anti-TNFs, interleukin inhibitors), **AND**
4. Inadequate response or intolerable side effect with two of the following BSC-preferred agents, Enbrel, Humira, preferred infliximab (*through 3/31/22*: Inflectra or Remicade, or *effective 4/1/2022*: Inflectra or Avsola), Otezla, Rinvoq, Skyrizi, Stelara, Taltz, Tremfya, and Xeljanz/Xeljanz XR, or contraindication to all preferred agents

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

Subcutaneous: 125 mg SC injection once weekly

Subcutaneous Orencia is managed under the Outpatient Pharmacy Benefit unless medical rationale is provided why the patient cannot self-administer this medication in the home. Please contact the member's Pharmacy Benefit for information on how to obtain this drug.

Coverage Period
Cover yearly, based upon continued response

ICD-10:
L40.50-L40.59

Rheumatoid arthritis

1. Disease is moderate to severe, **AND**
2. Diagnosed by or in consultation with a rheumatologist, **AND**
3. Inadequate response, intolerable side effect, or contraindication to methotrexate**, AND**
4. Not used in combination with another targeted immunomodulator (e.g., TNF inhibitors, IL-6 inhibitors, JAK inhibitors), **AND**

5. Inadequate response, intolerable side effect, with two BSC-preferred agents, Enbrel, Humira, preferred infliximab (*through 3/31/22*: Inflectra or Remicade, or *effective 4/1/2022*: Inflectra or Avsola), Rinvoq ER, and Xeljanz/Xeljanz XR, or contraindication to all preferred agents

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

Subcutaneous: 125 mg SC injection given within one day of an intravenous loading dose (based on the above chart), then 125 mg SC injection once weekly thereafter

Subcutaneous (SC) Orencia is managed under the Outpatient Pharmacy Benefit unless medical rationale is provided why the patient cannot self-administer this medication in the home. Please contact Blue Shield Pharmacy services to obtain a prior authorization.

Patients who are unable to receive an infusion may initiate weekly injections of subcutaneous abatacept without an intravenous loading dose OR Patients transitioning from abatacept intravenous therapy to subcutaneous administration should administer the first subcutaneous dose instead of the next scheduled intravenous dose.

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)

Subcutaneous:

- 50 mg/0.4 mL, 87.5 mg/0.7ml, 125 mg/ml solution (single-dose prefilled syringes)
- 125 mg/ml solution (single-dose prefilled ClickJet autoinjector)

(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
- MCG™ Care Guidelines, 19th edition, 2015, Home Infusion Therapy, CMT: CMT-0009(SR)
- National Comprehensive Cancer Network. Hematopoietic transplantation (Version 1.2021). Available by subscription at www.nccn.org.
- Orencia (abatacept) [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company. March 2019.
- Saag KG, Teng GG, Patkar NM, et al. America College of Rheumatology 2008 Recommendations for the Use of Nonbiologic and Biologic Disease-Modifying Antirheumatic Drugs in Rheumatoid Arthritis. Arthritis Rheum. 2008 ;59 :762-84.
- Singh JA, Furst DE, Bharat A, et al. 2012 Update of the 2008 American College of Rheumatology Recommendations for the Use of Disease Modifying Antirheumatic Drugs and Biologic Agents in the Treatment of Rheumatoid Arthritis. Arthritis Care and Res 2012 64(5):625-639
- 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.
- Singh JA, Saag KG, Bridges SL et al. 2015 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. Arthritis Rheum 2016;68: 1-26.
- Ringold S, Weiss PF, Beukelman T, et al. 2013 update of the 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: recommendations for the medical therapy of children with systemic juvenile idiopathic arthritis and tuberculosis screening among children receiving biologic medications. Arthritis Rheum 2013;65:2499-512.

(7) Policy Update

Date of last revision: 1Q2022
Date of next review: 4Q2022
Changes from previous policy version:

- Section (2): Graft versus Host Disease – Expanded coverage to include prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor and methotrexate, in patients undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor

  Rationale: In December 2021, the FDA approved Orencia (IV) for the prophylaxis of aGVHD, in combination with a calcineurin inhibitor and methotrexate, in adults and pediatric patients 2 years of age and older undergoing HSCT from a matched or 1 allele-mismatched unrelated donor
- Section (2): Psoriatic arthritis – Added Rinvoq and Skyrizi as preferred agents. Effective 4/1/2022, preferred infliximab drugs will be Inflectra and Avsola.

  Rationale: Selection of preferred drugs is supported by similar safety and efficacy and are guideline supported agents