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Section:	Prescription Drugs	**Effective Date:**	January 1, 2026
Subsection:	Analgesics and Anesthetics	**Original Policy Date:**	October 20, 2006
Subject:	Orencia	**Page:**	1 of 12

Last Review Date: December 12, 2025

Orencia

Description

Orencia (abatacept)

Background
Orencia (abatacept) is a selective costimulation modulator that inhibits T cell (T lymphocyte) activation by binding to CD80 and CD86, thereby blocking interaction with CD28. This interaction provides a costimulatory signal necessary for full activation of T lymphocytes. Activated T lymphocytes are implicated in the pathogenesis of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, and psoriatic arthritis (1).

Regulatory Status
FDA-approved indications: Orencia is a selective T cell costimulation modulator indicated for: (1)

1. Adult Rheumatoid Arthritis (RA)
    a. Orencia is indicated for the treatment of adult patients with moderately to severely active RA. Orencia may be used as monotherapy or concomitantly with DMARDs other than JAK inhibitors or biologic DMARDs.
2. Polyarticular Juvenile Idiopathic Arthritis (pJIA)
    a. Orencia is indicated for the treatment of patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis. Orencia may be used as monotherapy or concomitantly with methotrexate.
3. Psoriatic Arthritis (PsA)
    a. Orencia is indicated for the treatment of patients 2 years of age and older with active PsA.
4. Prophylaxis for Acute Graft versus Host Disease (aGVHD)

a. Orencia is indicated for the prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor and methotrexate, in adults and pediatric patients 2 years of age and older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor.

Limitations of Use:
The concomitant use of Orencia with other potent immunosuppressants [e.g., biologic disease-modifying antirheumatic drugs (bDMARDS), Janus kinase (JAK) inhibitors] is not recommended (1).

Physicians should exercise caution when considering the use of Orencia in patients with a history of recurrent infections, underlying conditions which may predispose them to infections, or chronic, latent, or localized infections. Patients who develop a new infection while undergoing treatment with Orencia should be monitored closely. Administration of Orencia should be discontinued if a patient develops a serious infection. A higher rate of serious infections has been observed in adult RA patients treated with concurrent TNF antagonists and Orencia (1).

Prior to initiating immunomodulatory therapies, including Orencia, patients should be screened for latent tuberculosis infection with a tuberculin skin test. Orencia has not been studied in patients with a positive tuberculosis screen, and the safety of Orencia in individuals with latent tuberculosis infection is unknown. Patients testing positive in tuberculosis screening should be treated by standard medical practice prior to therapy with Orencia (1).

Antirheumatic therapies have been associated with hepatitis B reactivation. Therefore, screening for viral hepatitis should be performed in accordance with published guidelines before starting therapy with Orencia. In clinical studies with Orencia, patients who screened positive for hepatitis were excluded from study (1).

The safety and effectiveness of Orencia in pediatric patients less than 2 years of age with pJIA, PsA, or prophylaxis of acute graft versus host disease (aGVHD) have not been established. The safety and effectiveness of Orencia in pediatric patients less than 18 years of age with RA have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Orencia may be considered **medically necessary** if the conditions indicated below are met.

Orencia may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following with provided documentation (e.g., medical records, laboratory reports):

1. Moderately to severely active rheumatoid arthritis (RA)
    a. 18 years of age or older
    b. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional disease-modifying antirheumatic drugs (DMARDs) (see Appendix 2)
    c. Prescriber will not exceed the FDA labeled maintenance dose of the following:
        i. IV infusion: 1000 mg every 4 weeks
        ii. Subcutaneous administration: 125 mg every week
    d. Patient **MUST** have tried the preferred product(s) (see Appendix 3) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

2. Active Juvenile Rheumatoid Arthritis (JRA)/ Polyarticular Juvenile Idiopathic Arthritis (pJIA)
    a. 2 years of age or older
    b. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional disease-modifying antirheumatic drugs (DMARDs) (see Appendix 2)
    c. Prescriber will not exceed the FDA labeled maintenance dose of the following:
        i. IV infusion: 1000 mg every 4 weeks
        ii. Subcutaneous administration: 125 mg every week
    d. Patient **MUST** have tried the preferred product(s) (see Appendix 3) if adjudicated through the pharmacy benefit unless the patient has a valid

medical exception (e.g., inadequate treatment response, intolerance, contraindication)

3. Active Psoriatic Arthritis (PsA)
    a. 2 years of age or older
    b. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional DMARD (see Appendix 2)
    c. Prescriber will not exceed the FDA labeled maintenance dose of the following:
        i. IV infusion: 1000 mg every 4 weeks
        ii. Subcutaneous administration: 125 mg every week
    d. Patient **MUST** have tried the preferred product(s) (see Appendix 3) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

4. Prophylaxis of acute graft versus host disease (aGVHD)
    a. 2 years of age or older
    b. Used in combination with a calcineurin inhibitor and methotrexate
    c. Patient is undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor
    d. Prescriber will not exceed the FDA labeled maintenance dose of the following:
        i. IV infusion: Age 6 and older – 10 mg/kg (maximum dose 1,000 mg) on the day before transplantation (Day -1), then Days 5, 14, and 28 after transplantation
        ii. IV infusion: Ages 2 to 5 – 15 mg/kg on the day before transplantation (Day -1), then 12 mg/kg on Days 5, 14, and 28 after transplantation

AND ALL of the following:

1. Tuberculin skin test conducted to rule out tuberculosis
    a. Patients testing positive in tuberculosis screening must be treated by standard medical practice currently or completed prior to therapy
2. Hepatitis B virus (HBV) has been ruled out or treatment initiated
3. **NO** active infection
4. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 2)
5. **NOT** given concurrently with live vaccines

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Prior – Approval *Renewal* Requirements

Diagnoses

Patient must have **ONE** of the following with provided documentation (e.g., medical records, laboratory reports):

1. Rheumatoid Arthritis (RA) in adults
    a. 18 years of age or older
    b. Prescriber will not exceed the FDA labeled maintenance dose of the following:
        i. IV infusion: 1000 mg every 4 weeks
        ii. Subcutaneous administration: 125 mg every week
    c. Patient **MUST** have tried the preferred product(s) (see Appendix 3) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

2. Juvenile Rheumatoid Arthritis (JRA)/Polyarticular Juvenile Idiopathic Arthritis (pJIA)
    a. 2 years of age or older
    b. Prescriber will not exceed the FDA labeled maintenance dose of the following:
        i. IV infusion: 1000 mg every 4 weeks
        ii. Subcutaneous administration: 125 mg every week
    c. Patient **MUST** have tried the preferred product(s) (see Appendix 3) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

3. Psoriatic Arthritis (PsA)
    a. 2 years of age or older
    b. Prescriber will not exceed the FDA labeled maintenance dose of the following:

i. IV infusion: 1000 mg every 4 weeks
ii. Subcutaneous administration: 125 mg every week

c. Patient **MUST** have tried the preferred product(s) (see Appendix 3) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

AND ALL of the following:

1. Condition has improved or stabilized
2. Absence of active infection [including tuberculosis and hepatitis B virus (HBV)]
3. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 2)
4. **NOT** given concurrently with live vaccines

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Medication	Diagnosis	Strength	Quantity
Orencia SC	Polyarticular Juvenile Idiopathic Arthritis	50 mg 87.5 mg 125 mg	12 units per 84 days
	Psoriatic Arthritis (**Age 2-17 only**)		
	Psoriatic Arthritis (**Age 18+ only**)	125 mg	12 units per 84 days
	Rheumatoid Arthritis		
Orencia IV	Prophylaxis of acute graft versus host disease	250 mg	16 vials
	Polyarticular Juvenile Idiopathic Arthritis	250 mg	56 vials every 365 days

	Psoriatic Arthritis (**Age 18+ only**)		(1000 mg at Week 0, 2, 4 then every 4 weeks)
	Rheumatoid Arthritis		

Duration 3 months for Prophylaxis of acute graft versus host disease
12 months for all other diagnoses

Prior – Approval *Renewal* Limits

Quantity

Medication	Diagnosis	Strength	Quantity
Orencia SC	Polyarticular Juvenile Idiopathic Arthritis	50 mg 87.5 mg 125 mg	12 units per 84 days
	Psoriatic Arthritis (**Age 2-17 only**)		
	Psoriatic Arthritis (**Age 18+ only**)	125 mg	12 units per 84 days
	Rheumatoid Arthritis		
Orencia IV	Prophylaxis of acute graft versus host disease	**NO** renewal	**NO** renewal
	Polyarticular Juvenile Idiopathic Arthritis	250 mg	12 vials every 84 days
	Psoriatic Arthritis (**Age 18+ only**)		
	Rheumatoid Arthritis		

Duration 18 months

Rationale

Summary

Orencia (abatacept) is indicated for the treatment of rheumatoid arthritis (RA) in adults; and for polyarticular juvenile idiopathic arthritis (pJIA), psoriatic arthritis (PsA), and prophylaxis of acute graft versus host disease (aGVHD) in pediatric patients 2 years of age and older. Prior to initiating immunomodulatory therapies, including Orencia, patients should be screened for latent tuberculosis infection with a tuberculin skin test. Antirheumatic therapies have been associated with hepatitis B reactivation (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Orencia while maintaining optimal therapeutic outcomes.

References

1. Orencia [package insert]. Princeton, NJ: Bristol-Myers Squibb; May 2024.

Policy History

Date	Action
April 2008	FDA approved Abatacept (Orencia) for reducing signs and symptoms in pediatric patients six years and older with moderately to severely active polyarticular juvenile idiopathic arthritis (JIA).
September 2012	Annual editorial review and reference update
March 2013	Annual editorial review and reference update; updated contraindicated concomitant therapies and any live vaccine.
September 2013	Annual editorial review and reference update. Addition of TB testing, no hepatitis B virus, and no active infection requirements to the criteria.
September 2014	Annual editorial review and reference update and renewal limit to 18 months
March 2016	Annual editorial review and reference update Policy number changed from 5.02.18 to 5.70.18
September 2016	Annual editorial review Addition of not given concurrently with live vaccines per SME
December 2016	Annual editorial review and reference update Additional criteria added to initiation for treatment of RA: Contraindication, intolerance, or inadequate treatment response to at least a 3-month trial of methotrexate despite adequate dosing Additional criteria added to initiation for treatment of JRA/pJIA: Contraindication, intolerance, or inadequate treatment response to at least a 3-month trial of a TNF inhibitor
April 2017	Addition of FDA approval for ages two years and older for JRA/pJIA
June 2017	Annual review
July 2017	Addition of Psoriatic Arthritis (PsA) and dosing requirements for each indication
September 2017	Annual review
December 2017	Annual review
March 2018	Annual editorial review Addition of Appendix - List of DMARDs
June 2018	Addition of Appendix - Examples of Contraindications to Methotrexate Change of requirement for JRA from t/f of TNF to contraindication to a 3-month trial of at least one conventional DMARD therapy

	Change of requirement for PsA from t/f of TNF to inadequate response, intolerance, or contraindication to a 3-month trial of at least ONE conventional DMARD
September 2018	Annual editorial review
March 2019	Annual review
December 2019	Annual review and reference update. Addition of requirement to trial preferred product
March 2020	Annual review
August 2020	Clarifying language added to pharmacy benefit
December 2020	Annual review. Added Appendix 3 with a list of preferred medications based on diagnosis and plan. Added PA quantity limits. Added initiation requirement for Orencia IV to t/f a biologic or targeted synthetic DMARD per FEP
April 2021	Clarification added to the t/f, intolerance, C/I to preferred products requirement indicating that it only applies to claims adjudicated through the pharmacy benefit. Appendix 2 updated.
September 2021	Annual review
January 2022	Addition of indication: prophylaxis of acute graft versus host disease (aGVHD). Added Rinvoq as a preferred PsA product to chart (Appendix 3)
March 2022	Annual review. Added Skyrizi as a preferred PsA product to chart (Appendix 3)
September 2022	Annual review
December 2022	Annual review
September 2023	Annual review
November 2023	Per PI update, reduced age requirement for PsA to 2 and older. Revised FDA dosing language and quantity limit chart
March 2024	Annual review
September 2024	Annual review and reference update
March 2025	Annual review
December 2025	Annual review. Added documentation requirement. Revised Appendix 3. Removed Orencia IV requirement to t/f DMARD

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 12, 2025 and is effective on January 1, 2026.

Appendix 1 – Examples of Contraindications to Methotrexate

Contraindications to Methotrexate
1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia
9. Pregnancy or planning pregnancy (male or female)
10. Renal impairment
11. Significant drug interaction

Appendix 2 - List of DMARDs

Conventional disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
azathioprine	Azasan, Imuran
cyclophosphamide	Cytoxan
cyclosporine	Neoral, Gengraf, Sandimmune
hydroxychloroquine	Plaquenil
leflunomide	Arava
methotrexate	Rheumatrex, Trexall
mycophenolate	Cellcept
sulfasalazine	Azulfidine, Sulfazine

Biological disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
abatacept	Orencia
adalimumab	Humira
anakinra	Kineret
bimekizumab-bkzx	Bimzelx
brodalumab	Siliq
certolizumab	Cimzia
etanercept	Enbrel
golimumab	Simponi/Simponi Aria
guselkumab	Tremfya
infliximab	Remicade
infliximab-dyyb	Zymfentra
ixekizumab	Taltz
risankizumab-rzaa	Skyrizi
rituximab	Rituxan
sarilumab	Kevzara
secukinumab	Cosentyx
spesolimab-sbzo	Spevigo
tildrakizumab-asmn	Ilumya
tocilizumab	Actemra
ustekinumab	Stelara
vedolizumab	Entyvio

Targeted synthetic disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name

apremilast	Otezla
baricitinib	Olumiant
deucravacitinib	Sotyktu
tofacitinib	Xeljanz/XR
upadactinib	Rinvoq

Appendix 3 - List of Preferred Products

List of preferred products:
https://info.caremark.com/content/dam/enterprise/caremark/microsites/dig/pdfs/pa-fep/fep-misc/FEP_IndicationMedChx.pdf

Refer to formulary documents for confirmation of coverage:
https://www.fepblue.org/pharmacy/prescriptions#drug-lists