

Orencia® (abatacept)

When requesting Orencia® (abatacept), the individual requiring treatment must be diagnosed with an FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indications

Adult Rheumatoid Arthritis

Orencia is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis.

Polyarticular Juvenile Idiopathic Arthritis

Orencia is indicated for the treatment of patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis.

Adult Psoriatic Arthritis

Orencia is indicated for the treatment of adult patients with active psoriatic arthritis.

Prophylaxis for Acute Graft versus Host Disease

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

Coverage Guidelines

Rheumatoid arthritis (RA)

The individual must meet both of the following criteria for initial authorization:

- Must meet one of the following:
 - o Has had a 3-month trial of at least one biologic agent for RA; OR
 - o Has had a 3-month trial of at least one conventional synthetic disease-modifying antirheumatic drug (DMARD) (e.g., methotrexate, leflunomide, hydroxychloroquine, and sulfasalazine);
- Orencia is prescribed by or in consultation with a rheumatologist.

Psoriatic arthritis (PsA)

The individual must meet the following criteria for initial authorization:

- Orencia is prescribed by or in consultation with a dermatologist or a rheumatologist.

Juvenile Idiopathic Arthritis (JIA) or Juvenile Rheumatoid Arthritis

The individual must meet both of the following criteria for initial authorization:

- Orencia is prescribed by or in consultation with a rheumatologist;

- Must meet one of the following:
 - o Has tried at least one other agent for JIA (e.g., methotrexate, leflunomide, sulfasalazine, nonsteroidal anti-inflammatory drug [NSAID], etanercept, adalimumab); OR
 - o Orencia will be started concurrently with methotrexate, leflunomide, or sulfasalazine; OR
 - o Has an absolute contraindication to methotrexate, leflunomide, or sulfasalazine (e.g., pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias); OR
 - o Has aggressive disease.

Graft-versus-Host Disease (GVHD) prophylaxis

The individual must meet **all** of the following criteria for approval:

- Is 2 years of age or older;
- Orencia is being used for prevention of acute graft-versus-host disease;
- Will also receive a calcineurin inhibitor (e.g., cyclosporine and tacrolimus) for prevention of acute GVHD;
- Will also receive methotrexate for prevention of acute GVHD;
- Will undergo hematopoietic stem cell transplantation from one of the following donors:
 - o Matched unrelated donor; OR
 - o 1-allele-mismatched unrelated donor;
- Orencia is prescribed by or in consultation with an oncologist, hematologist, or a physician affiliated with a transplant center.

The individual must meet the following criteria for re-authorization (for all indications except GVHD):

- Has been established on Orencia therapy for at least 6 months (*Note: A patient who has received < 6 months of therapy, or who is restarting therapy with Orencia, is reviewed under initial authorization criteria.*);
- Meets one of the following:
 - o Has experienced an improvement in at least one objective measure compared to baseline (e.g., Clinical Disease Activity Index [CDAI], Minimal Disease Activity [MDA], improvement of serum markers such as C-reactive protein, Physician Global Assessment [MD global]); OR
 - o Has experienced an improvement in at least one symptom compared to baseline (e.g., less joint pain, less morning stiffness, less fatigue, improved function or activities of daily living).

Approval duration:

- **Initial authorization:** GVHD 30 days (4 doses), all other indications 12 months
- **Renewal authorization:** 12 months (all indications except GVHD)

Dosing Recommendations

Rheumatoid arthritis (RA) and psoriatic arthritis (PsA)

Intravenous dosing regimen for RA and PsA

- For patients weighing less than 60 kg, the recommended dose is 500 mg given as a 30-minute intravenous infusion at week 0, 2, and 4 weeks then every 4 weeks thereafter
- For patients weighing 60 kg to 100 kg, the recommended dose is 750 mg given as a 30-minute intravenous infusion at week 0, 2, and 4 weeks then every 4 weeks thereafter
- For patients weighing more than 100 kg, the recommended dose is 1000 mg given as a 30-minute intravenous infusion at week 0, 2, and 4 weeks then every 4 weeks thereafter

Subcutaneous dosing regimen for RA

- 125 mg once weekly with or without an intravenous loading dose. For patients initiating therapy with an intravenous loading dose, administer a single intravenous infusion (as per body weight categories above), followed by the first 125 mg subcutaneous injection given within a day of the intravenous infusion.
- Patients switching from intravenous use to subcutaneous use, administer first subcutaneous dose instead of next scheduled intravenous dose.

Subcutaneous dosing regimen for PsA

- 125 mg once weekly without an intravenous loading dose.
- Patients switching from intravenous use to subcutaneous use, administer first subcutaneous dose instead of next scheduled intravenous dose.

Juvenile idiopathic arthritis

Intravenous dosing regimen (for 6 years of age and older)

- For patients weighing less than 75 kg, the recommended dose is 10 mg/kg given as a 30-minute intravenous infusion at week 0, 2, and 4 weeks then every 4 weeks thereafter
- For patients weighing 75 kg or more, follow the adult intravenous dosing regimen, not to exceed a maximum dose of 1000 mg, given as a 30-minute intravenous infusion at week 0, 2, and 4 weeks then every 4 weeks thereafter

Subcutaneous dosing regimen (for 2 years of age and older)

Orencia for subcutaneous injection should be initiated without an intravenous loading dose.

Body weight of patient	Dose (once weekly)
10 kg to less than 25 kg	50 mg
25 kg to less than 50 kg	87.5 mg
50 kg or more	125 mg

Graft-versus-host disease prophylaxis

Intravenous dosing regimen for GVHD

- For patients 6 years of age and older: the recommended dose is 10 mg/kg (maximum dose 1,000 mg) administered as a 60-minute infusion on the day before transplantation, followed by a dose on Day 5, 14, and 28 after transplant.
- For patients 2 to less than 6 years of age: the recommended dose is 15 mg/kg administered as a 60-minute infusion on the day before transplantation, followed by a 12 mg/kg dose as a 60-minute infusion on Day 5, 14, and 28 after transplant.

References

1. Orencia® intravenous infusion [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; October 2023.
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3. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. *Arthritis Rheumatol*. 2019;71(6):717-734.
4. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. *Arthritis Care Res (Hoboken)*. 2019;71(1):2-29.
5. Song IH, Heldmann F, Rudwaleit M, et al. Treatment of active ankylosing spondylitis with abatacept: an open-label, 24-week pilot study. *Ann Rheum Dis*. 2011;70(6):1108-1110.
6. Sandborn WJ, Colombel JF, Sands BE, et al. Abatacept for Crohn's disease and ulcerative colitis. *Gastroenterology*. 2012;143(1):62-69.
7. Abrams JR, Lebwohl MG, Guzzo CA, et al. CTLA4Ig-mediated blockade of T-cell costimulation in patients with psoriasis vulgaris. *J Clin Invest*. 1999;103:1243-1252.
8. Mease PJ, Gottlieb AB, van der Heijde D, et al. Efficacy and safety of abatacept, a T-cell modulator, in a randomised, double-blind, placebo-controlled, phase III study in psoriatic arthritis. *Ann Rheum Dis*. 2017;76(9):1550-1558.
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