

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

Orencia is indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis.

Orencia is indicated for reducing signs and symptoms in patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis.

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

Coverage Guidelines

Rheumatoid arthritis (RA)

For an initial authorization, the individual must meet all of the following criteria:

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

Psoriatic arthritis (PsA)

For an initial authorization, the individual must meet the following criteria:

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

Juvenile idiopathic arthritis (JIA)

For an initial authorization, the individual must meet all of the following criteria:

- Has tried at least one other agent for JIA (e.g., methotrexate, leflunomide, etanercept, adalimumab); OR
- Orencia will be started concurrently with methotrexate, leflunomide, or sulfasalazine; OR
- Has an absolute contraindication to methotrexate, leflunomide, or sulfasalazine (e.g., pregnancy, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias); OR
- Has aggressive disease; AND

- Orenzia is prescribed by or in consultation with a rheumatologist.

For re-authorization (for all indications), the individual must meet the following criteria:

- Has had a response to Orenzia therapy (e.g., less joint pain, less morning stiffness, or less fatigue, improved function or activities of daily living).

Approval duration (initial): 3 months

Approval duration (renewal): 12 months

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 transitioning from Orenzia intravenous therapy to subcutaneous administration should administer the first subcutaneous dose instead of the next scheduled intravenous dose.

Subcutaneous dosing regimen for PsA

- 125 mg once weekly without the need of an intravenous loading 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 to less than 25 kg	50 mg
25 to less than 50 kg	87.5 mg
50 kg or more	125 mg

References

1. Orencia® for injection [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; June 2020.
2. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the treatment of rheumatoid arthritis. *Arthritis Rheumatol*. 2016;68(1):1-26.
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. Furst DE, Keystone EC, Braun J, et al. Updated consensus statement on biological agents for the treatment of rheumatic diseases, 2011. *Ann Rheum Dis*. 2012;71 Suppl 2:i2-i45.
7. Xeljanz® tablets [prescribing information]. New York, NY: Pfizer Inc; December 2017.
8. Sandborn WJ, Colombel JF, Sands BE, et al. Abatacept for Crohn's disease and ulcerative colitis. *Gastroenterology*. 2012;143(1):62-69.e4.
9. Abrams JR, Lebowitz MG, Guzzo CA, et al. CTLA4Ig-mediated blockade of T-cell costimulation in patients with psoriasis vulgaris. *J Clin Invest*. 1999;103:1243-1252.