

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.

Approved Off-Label Compendial Use(s)

None

Coverage Guidelines

For all approved indications, the individual must meet **all** of the following criteria for approval:

- Does not have an active infection including localized infection
- Orencia (abatacept) will not be used in combination with another biologic agent (e.g., IL-inhibitor, rituximab, TNF-inhibitor)
- For an initial authorization request, an individual has been screened for latent tuberculosis (TB). For positive latent TB, an individual has started/completed or will be treated for TB prior to starting Orencia (abatacept)
- For a re-authorization request, an individual's condition has improved or stabilized with Orencia (abatacept) therapy

For rheumatoid arthritis:

- Had an inadequate response or intolerance to prior biologic agent or targeted synthetic DMARD (i.e., tofacitinib) OR
- Has moderately to severely active disease AND
- Had an inadequate response to at least 3 months of methotrexate therapy unless contraindicated or intolerant to methotrexate OR
- Had an inadequate response to at least 3 months of leflunomide or sulfasalazine unless contraindicated or intolerant to leflunomide or sulfasalazine

For psoriatic arthritis:

- Had an inadequate response or intolerance to prior biologic agent or targeted synthetic DMARD (i.e., tofacitinib) OR
- Had an inadequate response to methotrexate unless contraindicated or intolerant to methotrexate

For polyarticular juvenile idiopathic arthritis:

- Had an inadequate response to at least one TNF-inhibitor (e.g., adalimumab, etanercept)

Approval duration (initial and renewal): 12 months

Dosing Recommendations

Orencia may be administered as an intravenous infusion or as a subcutaneous injection.

Rheumatoid arthritis and psoriatic arthritis:Intravenous dosing regimen

- 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

- The recommended dose is 125 mg administered by subcutaneous injection once weekly

Polyarticular 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, must follow 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)

- For patients weighing 10 to less than 25 kg, the recommended dose is 50 mg administered by subcutaneous injection once weekly

- For patients weighing 25 to less than 50 kg, the recommended dose is 87.5 mg administered by subcutaneous injection once weekly
- For patients weighing 50 kg or more, the recommended dose is 125 mg administered by subcutaneous injection once weekly

References

1. Orenzia prescribing information. Princeton, NJ; Bristol-Myers Squibb Company. June 2017.
2. Singh JA, Saag KG, Bridges JR SL, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care & Research*. 2015.
3. Smolen JS, Landewe R, Bijlsma J, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2016 update. *Ann Rheum Dis* Published Online First: [March 6, 2017] doi:10.1136/annrheumdis-2016-210715
4. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 2. Psoriatic arthritis: Overview and guidelines of care for treatment with an emphasis on the biologics. *J Am Acad Dermatol* 2008;58:851-864.
5. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: Case-based presentations and evidence-based conclusions. *J Am Acad Dermatol* 2011;65:137-174.
6. Ringold S, Weiss PF, Beukelman T, et al. 2-013 Update of the 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis. *Arthritis & Rheumatism*. 2013;65:2499-2512.