Reference number(s)
2210-A

Standard Medicare Part B Management Orencia

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Orencia	abatacept

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, the member has no exclusions to the prescribed therapy, and the drug or biological is usually not self-administered. The criteria outlined in this policy is only applicable to drugs not usually self-administered and are furnished incident to a physician's service. Requests for drugs on a region's self-administered drug list are not covered. Members enrolled in Medicare Part D may seek coverage under their Medicare Part D plan.

FDA-approved Indications[1]

- Treatment of moderately to severely active rheumatoid arthritis (RA) in adults
- Treatment of moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older
- Treatment of active psoriatic arthritis (PsA) in patients 2 years of age and older
- 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

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Limitations of Use

Concomitant use of Orencia with other potent immunosuppressants [e.g., biologic disease-modifying antirheumatic drugs (bDMARDs), Janus kinase (JAK) inhibitors] is not recommended.

Compendial Uses[2,8,11]

- Methotrexate-naive, early rheumatoid arthritis patients with poor prognostic factors
- Giant cell arteritis
- Chronic graft versus host disease
- Immune checkpoint inhibitor-related toxicity
- Oligoarticular juvenile idiopathic arthritis

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Documentation

The following documentation must be available, upon request, for all submissions:

Rheumatoid arthritis (RA), articular juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA), and giant cell arteritis

Continuation requests

Chart notes or medical record documentation supporting benefit from therapy.

Chronic graft versus host disease

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation supporting benefit from therapy.

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Immune checkpoint inhibitor-related toxicity

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Coverage Criteria

Rheumatoid arthritis (RA)[1,2,9]

Authorization of 12 months may be granted for treatment of active rheumatoid arthritis.

Articular juvenile idiopathic arthritis (JIA)[1,10,11]

Authorization of 12 months may be granted for treatment of active articular juvenile idiopathic arthritis.

Psoriatic arthritis (PsA)[1,12,13]

Authorization of 12 months may be granted for treatment of active psoriatic arthritis.

Prophylaxis of acute graft versus host disease[1]

Authorization of 1 month may be granted for prophylaxis of acute graft versus host disease when both of the following criteria are met:

- Member is undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor.
- The requested medication will be used in combination with a calcineurin inhibitor (e.g., cyclosporine, tacrolimus) and methotrexate.

Giant cell arteritis[2]

Authorization of 12 months may be granted for treatment of giant cell arteritis.

Chronic graft versus host disease[8]

Authorization of 12 months may be granted for treatment of chronic graft versus host disease when either of the following criteria is met:

- Member has had an inadequate response to systemic corticosteroids.

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- Member has an intolerance or contraindication to corticosteroids.

Immune checkpoint inhibitor-related toxicity[8]

Authorization of 6 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when the member has myocarditis and meets any of the following:

- Member has had an inadequate response to systemic corticosteroids.
- Member has an intolerance or contraindication to corticosteroids.
- Member has concomitant myositis and the requested medication will be used in combination with ruxolitinib.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Prophylaxis of acute graft versus host disease and immune checkpoint inhibitor-related toxicity

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

All other indications

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with Orencia.
- Orencia is being used to treat an indication listed in the coverage criteria.
- The member is receiving benefit from therapy.

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Orencia.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs

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    - Clinical Pharmacology
- EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update.
- 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis.
- American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis.
- 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features.
- 2013 Update of the 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis.
- 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis.
- 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis.
- 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for oligoarthritis, temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis.
- 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis.
- EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2019 update.

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Orencia are covered in addition to the following:

- Methotrexate-naive, early rheumatoid arthritis patients with poor prognostic factors
- Giant cell arteritis
- Chronic graft versus host disease
- Immune checkpoint inhibitor-related toxicity
- Oligoarticular juvenile idiopathic arthritis

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Orencia to treat methotrexate-naïve, early rheumatoid arthritis patients with poor prognostic factors can be found in a study by Westhovens et al. Abatacept plus methotrexate compared with placebo plus methotrexate significantly improved the rate of remission at 1 year (41.4% vs 23.3%) and the extent of structural damage (mean change from baseline in Genant-modified Sharp scoring system total score [TS], 0.63 vs 1.06), in a randomized trial (N=509) of methotrexate-naïve patients with rheumatoid arthritis. Remission was defined as a disease activity score in 28 joints (DAS28; C-reactive protein [CRP]) of less than 2.6. At 1 year, abatacept plus methotrexate compared with methotrexate alone

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was associated with significant differences in mean change from baseline to 1 year in DAS28 (CRP)(-3.22 vs -2.49), American College of Rheumatology 50% improvement (ACR50; 57.4% vs 42.3%), ACR70 (42.6% vs 27.3%), ACR90 (16.4% vs 6.7%), and major clinical response (ACR70 for at least 6 months, 27.3% vs 11.9%). At 1 year, abatacept plus methotrexate was also associated with a significant difference in Genant-modified Sharp erosion score (mean change from baseline, 0.5 vs 0.89) but not joint-space narrowing score (mean change from baseline, 0.13 vs 0.17), and there was no significant difference in the proportion of patients with no radiographic progression (TS 0 or less; 61.2% vs 52.9%). A health assessment questionnaire disability index (HAQ-DI) change from baseline of 0.3 or more units was achieved by significantly more patients with abatacept and methotrexate (71.9% vs 62.1%). Adverse events were reported in 84.8% with abatacept plus methotrexate versus 83.4% with placebo plus methotrexate, with infections being the most common (51.6% vs 54.9%); serious adverse events were reported in 7.8% and 7.9%, respectively. Adults enrolled in the study had rheumatoid arthritis for 2 years or less, at least 12 tender and 10 swollen joints, CRP of 0.45 mg/dL or higher, rheumatoid factor of anti-cyclic citrullinated protein type 2 positivity, and radiographic evidence of bone erosion of hands/wrists/feet. Abatacept 10 mg/kg IV infusion was given on days 1, 15, and 29, then every 4 weeks. Methotrexate 7.5 mg/week was increased to 15 mg/week at week 4, then to 20 mg/week at week 8. Oral corticosteroids (10 mg prednisone equivalent or less daily) and up to 2 corticosteroid pulses (more than 10 mg prednisone or equivalent orally for at least 3 consecutive days or injectable corticosteroids) were permitted during any 6-month period. A non-biological disease modifying antirheumatic drug (DMARD) was allowed after 6 months.

Support for using Orencia to treat giant cell arteritis can be found in a study by Langford et al. During a randomized, double-blind trial (N=41), the relapse-free survival rate at 1 year was significant in patients who received abatacept (48%) compared with patients who received placebo (31%), and the median duration of remission was significantly longer (9.9 vs 3.9 months, respectively). Patients with newly diagnosed or relapsing giant cell arteritis were treated with abatacept 10 mg/kg (500 mg for body weight less 60 kg, 750 mg for 60 to 100 kg, and 1000 mg for greater than 100 kg) IV infusion on days 1, 15, 29 and week 8, in combination with oral prednisone 40 to 60 mg/day. Those who achieved remission after 12 weeks of treatment were randomized to continue abatacept every 4 weeks or switch to placebo, in combination with oral prednisone 20 mg/day, which was tapered after randomization so that all patients discontinued prednisone at week 28. Seven of the 41 randomized patients withdrew prior to week 64, and a subset analysis performed on the remaining 34 patients at week 64 demonstrated a significant relapse-free survival rate at 1 year for abatacept (52.9%) vs placebo (23.5%). There was no difference in the severity or frequency of adverse events between treatment groups.

Support for using Orencia to treat chronic graft versus host disease can be found in the National Comprehensive Cancer Network's guideline for hematopoietic cell transplantation. The NCCN Guideline supports the use of Orencia for chronic graft versus host disease as an additional therapy in conjunction with systemic corticosteroids following no response (steroid-refractory disease) to first-line therapy options.

Support for using Orencia to treat immune checkpoint inhibitor-related toxicity can be found in the National Comprehensive Cancer Network's guideline for the management of immunotherapy-related toxicities. The NCCN Guideline supports the use of Orencia as a further intervention for the management

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of myocarditis if no improvement within 24 to 48 hours of starting high-dose methylprednisolone. Orencia with ruxolitinib has also been used in concomitant myositis and myocarditis.

Support for using Orencia to treat oligoarticular juvenile idiopathic arthritis can be found in the 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for oligoarthritis, temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis. In children with oligoarticular JIA, give biologic disease-modifying antirheumatic drugs (DMARDs). This approach is preferred instead of combining or switching conventional synthetic DMARDs due to reported greater probability of achieving rapid and sustained response.

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