Reference number(s)
2210-A

STANDARD MEDICARE PART B MANAGEMENT

ORENCIA (abatacept)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
1. Treatment of moderately to severely active rheumatoid arthritis in adults
2. Treatment of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older
3. Treatment of active psoriatic arthritis in adults
4. 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

Limitation 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.

B. Compendial Uses
1. Methotrexate-naive, early rheumatoid arthritis patients with poor prognostic factors
2. Giant cell arteritis
3. Chronic graft versus host disease
4. Immune checkpoint inhibitor-related toxicity
5. Oligoarticular juvenile idiopathic arthritis

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

II. CRITERIA FOR INITIAL APPROVAL

A. Rheumatoid arthritis (RA)
Authorization of 12 months may be granted for treatment of rheumatoid arthritis.

B. Articular juvenile idiopathic arthritis (JIA)
Authorization of 12 months may be granted for treatment of articular juvenile idiopathic arthritis.

C. Psoriatic arthritis (PsA)
Authorization of 12 months may be granted for treatment of psoriatic arthritis.

D. Prophylaxis of acute graft versus host disease

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

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

E. Giant cell arteritis

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

F. Chronic graft versus host disease

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

1. Member has experienced an inadequate response to systemic corticosteroids.
2. Member has an intolerance or contraindication to corticosteroids.

G. Immune checkpoint inhibitor-related toxicity

Authorization of 1 month may be granted for treatment of immune checkpoint inhibitor-related toxicity when the member has cardiac toxicity.

III. CONTINUATION OF THERAPY

A. 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 initial authorization criteria.

B. All other indications

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

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

1. The member is currently receiving therapy with Orencia.
2. Orencia is being used to treat an indication enumerated in Section II.
3. The member is receiving benefit from therapy.

IV. REFERENCES

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9. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthrit Care Res*. 2021;0:1-16.
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12. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Arthritis Rheum*. 2018;71:5-32.
13. Gossec L, Baraliakos X, Kerschbaumer A. EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2019 update. *Ann Rheum Dis*. 2020;79(6):700-712.