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. Rheumatoid Arthritis
   Treatment of moderately to severely active rheumatoid arthritis in adults.
2. Juvenile Idiopathic Arthritis
   Treatment of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older.
3. Psoriatic arthritis
   Treatment of active psoriatic arthritis in adults

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. Rheumatoid arthritis in methotrexate naïve patients
2. Giant cell arteritis
3. Chronic graft versus host disease
4. Immune checkpoint inhibitor-related toxicity

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
Authorization of 24 months may be granted for treatment of rheumatoid arthritis.

B. Polyarticular juvenile idiopathic arthritis
Authorization of 24 months may be granted for treatment of polyarticular juvenile idiopathic arthritis.

C. Psoriatic arthritis
Authorization of 24 months may be granted for treatment of psoriatic arthritis.

D. Giant cell arteritis
Authorization of 24 months may be granted for treatment of giant cell arteritis.

E. Chronic graft versus host disease
Authorization of 24 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.

F. 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. 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 of 24 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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2. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed June 03, 2020.
3. Smolen JS, Landewé R, Bijlsma J, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update. *Ann Rheum Dis.* 2020*;79*:685-699.
4. 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.
5. Saag KG, Teng GG, Patkar NM, et al. American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. *Arthritis Rheum.* 2008;59(6):762-784.
6. Beukelman T, Patkar NM, Saag KG, et al. 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. *Arthritis Care Res*. 2011;63(4):465-482.
7. Ringold S, Weiss PF, Beukelman, et al. 2013 Update of the 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis. *Arthritis & Rheumatism.* 2013;64(10):2499-2512.
8. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed June 09, 2020.