

## SPECIALTY GUIDELINE 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.

###### FDA-Approved Indications

1. Moderately to severely active rheumatoid arthritis in adults
2. Moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age or older
3. Active psoriatic arthritis in adults

All other indications are considered experimental/investigational and are not a covered benefit.

##### II. CRITERIA FOR INITIAL APPROVAL

###### **A. Moderately to severely active rheumatoid arthritis (RA)**

1. Authorization of 24 months may be granted for members who have received Orenzia or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) indicated for the treatment of moderately to severely active rheumatoid arthritis in a paid claim through a pharmacy or medical benefit within the previous 120 days of the initial request for Orenzia.
2. Authorization of 24 months may be granted for treatment of moderately to severely active RA when any of the following criteria is met:
  - a. Member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to 20 mg/week).
  - b. Member has an intolerance or contraindication to methotrexate (see Appendix).

###### **B. Moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA)**

1. Authorization of 24 months may be granted for members who have received Orenzia or Actemra in a paid claim through a pharmacy or medical benefit within the previous 120 days of the initial request for Orenzia.
2. Authorization of 24 months may be granted for treatment of active pJIA when any of the following criteria is met:
  - a. Member has experienced an inadequate response to at least a 3-month trial of a TNF inhibitor.
  - b. Member has intolerance or contraindication to a TNF inhibitor.

###### **C. Active psoriatic arthritis (PsA)**

Authorization of 24 months may be granted for treatment of active psoriatic arthritis (PsA).

##### III. CONTINUATION OF THERAPY

Authorization of 24 months may be granted for all members (including new members) who meet all initial authorization criteria and achieve or maintain positive clinical response after at least 3 months of therapy with Orenzia as evidenced by low disease activity or improvement in signs and symptoms of the condition.

#### IV. OTHER

For all indications: Member has a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB).

Note: Members who have received Orenzia or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) in a paid claim through a pharmacy or medical benefit within the previous 120 days of the continuation request are exempt from requirements related to TB screening in this Policy.

#### V. APPENDIX: Examples of Contraindications to Methotrexate

1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia
9. Pregnancy or planning pregnancy (male or female)
10. Renal impairment
11. Significant drug interaction

#### VI. REFERENCES

1. Orenzia [package insert]. Princeton, NJ: Bristol-Myers Squibb; June 2017.
2. Smolen JS, Landewé R, Breedveld FC, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2013 update. *Ann Rheum Dis*. 2014;73:492-509.
3. 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.
4. 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.
5. 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.

#### DOCUMENT HISTORY

Created: Specialty Clinical Development (HY) 09/2014 (separated from RA SGM)  
Revised: IP 09/2015, 03/2016 (ACR RA Guidelines); KF 08/2016 (annual), 01/2017 (MTX dose), 02/2017 (exclusion), 04/2017 (removed SC formulation restriction for pJIA), 07/2017 (PsA label update)  
Reviewed: CDPR/SES 10/2014; MM 09/2015, 10/2015; MES 04/2016; ME 09/2016; LMS 01/2017; LCB 02/2017; ME 04/2017, ME 07/2017  
External Review: 11/2014, 10/2015, 05/2016