Policy Title:	Orencia (abatacept) Intravenous		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	09/18/2019, 12/20/2019, 1/29/20		
Revision Date:	09/18/2019, 12/20/2019, 1/29/20		

Purpose: To support safe, effective and appropriate use of Orencia (abatacept).

Scope: Medicaid, Exchange, Medicare-Medicaid Plan (MMP)

Policy Statement:

Orencia (abatacept) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Orencia (abatacept) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria:

- 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);
- Dose is within FDA guidelines;
- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements

Moderately to severely active rheumatoid arthritis (RA)

- Authorization of 6 months may be granted for members who have previously received Orencia or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) indicated for the treatment of moderately to severely active rheumatoid arthritis.
- Authorization of 6 months may be granted for treatment of moderately to severely active RA when any of the following criteria is met:
    - 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).
    - Member has an intolerance or contraindication to methotrexate (see Appendix).

Moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA)

- Authorization of 6 months may be granted for members who have previously received Orencia or Actemra.
- Authorization of 6 months may be granted for treatment of active pJIA when any of the following criteria is met:
    - Member has experienced an inadequate response to at least a 3-month trial of a TNF inhibitor.
    - Member has intolerance or contraindication to a TNF inhibitor.

Active Psoriatic Arthritis (PsA)

- Authorization of 6 months may be granted for treatment of active psoriatic arthritis (PsA).

Continuation of Therapy Criteria:

- Authorization of 6 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 Orencia as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Coverage durations:

- Initial coverage: 6 months
- Continuation of therapy coverage: 6 months

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable. ***

Dosage/Administration:

Indication	**Dose**	**Maximum dose (1 billable unit = *10* mg)**
Rheumatoid Arthritis and Psoriatic Arthritis in adults	Intravenous Dosing Weight < 60kg: 500 mg at weeks 0, 2, & 4, then every 4 weeks thereafter Weight 60 to 100 kg: 750 mg at weeks 0, 2, & 4, then every 4 weeks thereafter Weight > 100 kg: 1,000 mg at weeks 0, 2, & 4, then every 4 weeks thereafter	Loading: 100 billable units at weeks 0, 2, & 4 Maintenance: 100 billable units per 4 weeks
Polyarticular Juvenile Idiopathic Arthritis	Intravenous Dosing (patients aged 6 years or older ONLY) Weight < 75 kg:	Loading: 100 billable units at weeks 0, 2, & 4 Maintenance:

	10 mg/kg at weeks 0, 2, & 4, then every 4 weeks thereafter Weight 75 to 100 kg: 750 mg at weeks 0, 2, & 4, then every 4 weeks thereafter Weight > 100 kg: 1,000 mg at weeks 0, 2, & 4, then every 4 weeks thereafter	100 billable units per 4 weeks

Appendix:

Examples of Contraindications to Methotrexate

- Alcoholism, alcoholic liver disease or other chronic liver disease
- Breastfeeding
- Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
- Elevated liver transaminases
- History of intolerance or adverse event
- Hypersensitivity
- Interstitial pneumonitis or clinically significant pulmonary fibrosis
- Myelodysplasia
- Pregnancy or planning pregnancy (male or female)
- Renal impairment
- Significant drug interaction

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:
Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT code is:

HCPCS/CPT Code	Description
J0129	Injection, abatacept, 10 mg

References:

1. Orencia [package insert]. Princeton, NJ: Bristol-Myers Squibb; June 2017.
2. Smolen JS, Landewé R, Billsma J, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2016 update. *Ann Rheum Dis.* 2017*;0*:1-18.
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.