BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

MEDICAL COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 07/09/14
LAST REVIEW DATE:
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

ORENCIA® (abatacept)

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

Orencia is a selective co-simulation modulator which inhibits T cell (T lymphocyte) activation by binding to CD80 and CD86, thereby blocking interaction with CD28. This interaction provides a co-stimulatory signal necessary for full activation of T lymphocytes. Activated T lymphocytes are implicated in the pathogenesis of rheumatoid arthritis (RA) and are found in the synovium (smooth lining of the joint) of individuals with RA.

Definitions:

Adult: Age 18 years and older

Preferred Tumor Necrosis Factor (TNF) Medications:
- Enbrel®
- Humira®
- Remicade®

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Definitions: (cont.)

Significant Adverse Drug Event:
A significant adverse drug event is when an individual's outcome is death, life-threatening, hospitalization (initial or prolonged), disability resulting in a significant, persistent, or permanent change, impairment, damage or disruption in the individuals' body function/structure, physical activities or quality of life, or requires intervention to prevent permanent impairment or damage.

Criteria:

See Resources section for FDA-approved dosage.

- FDA-approved dosage of Orencia is considered ***medically necessary*** for adults with moderately to severely active rheumatoid arthritis as monotherapy or concomitantly with DMARDs other than tumor necrosis factor (TNF) antagonists with documentation of **ALL** of the following:

  1. Failed response to the preferred TNF medications Enbrel **AND** Humira **AND** Remicade (unless otherwise contraindicated) with documentation of **ANY** of the following: [1]

     - Individual's condition has not improved or has worsened
     - Individual experienced a significant adverse drug event to the preferred TNF medications
     - Individual is intolerant to the preferred TNF medications
     - Individual is non-adherent to the preferred TNF medications

  2. No evidence of active serious infections including clinically important localized infections or sepsis when initiating or continuing therapy
  3. Evidence of testing for latent tuberculosis before Orencia use and during therapy and any treatment for latent infection has been initiated prior to Orencia therapy
  4. Evidence of ongoing monitoring in individuals who are known hepatitis B carriers for reactivation of this viral infection during Orencia therapy
  5. Evidence of close monitoring in individuals who have a history of or develop chronic obstructive pulmonary disease (COPD) while on Orencia therapy
  6. Orencia is not being used concurrently with anakinra (e.g. Kineret®), live vaccines or TNF antagonists
  7. Dosage is not greater that the FDA approved dosing for the labeled indication (refer to dosing table)

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Criteria: (cont.)

- FDA-approved dosage of Orencia is considered ***medically necessary*** for individuals 6 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis as monotherapy or concomitantly with methotrexate with documentation of **ALL** of the following:

  1. Failed response to the preferred TNF medications Enbrel **AND** Humira **AND** Remicade (unless otherwise contraindicated) with documentation of **ANY** of the following: [1]

     - Individual's condition has not improved or has worsened
     - Individual experienced a significant adverse drug event to the preferred TNF medications
     - Individual is intolerant to the preferred TNF medications
     - Individual is non-adherent to the preferred TNF medications

  2. No evidence of active serious infections including clinically important localized infections or sepsis when initiating or continuing therapy
  3. Evidence of testing for latent tuberculosis before Orencia use and during therapy and any treatment for latent infection has been initiated prior to Orencia therapy
  4. Evidence of ongoing monitoring in individuals who are known hepatitis B carriers for reactivation of this viral infection during Orencia therapy
  5. Evidence of close monitoring in individuals who have a history of or develop chronic obstructive pulmonary disease (COPD) while on Orencia therapy
  6. Orencia is not being used concurrently with anakinra (e.g. Kineret), live vaccines or TNF antagonists
  7. Immunizations are up to date prior to Orencia therapy
  8. Dosage is not greater that the FDA approved dosing for the labeled indication (refer to dosing table)

- Orencia for all other indications not previously listed or if above criteria not met is considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

[1] Not applicable for current members on Orencia prior to 07/09/14 or new members who are actively being treated with Orencia prior to their effective date with BCBSAZ. (Excludes any changes in route of administration, such as changing intravenous delivery to subcutaneous delivery.)

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Resources:

Orencia Package Insert:

- FDA-approved indication and dosage:

Indication	Recommended Dose
Adult moderately to severely active rheumatoid arthritis	Intravenous: Following the initial dose, give at 2 and 4 weeks, then every 4 weeks Body weight less than 60kg: 500mg Body weight 60 to 100 kg: 750mg More than 100kg: 1000mg Subcutaneous: Orencia 125 mg should be administered by subcutaneous injection once weekly and may be initiated with or without an intravenous loading dose. For patients initiating therapy with an intravenous loading dose, Orencia should be initiated with a single intravenous infusion (as per body weight categories listed above) followed by the first 125 mg subcutaneous injection administered within a day of the intravenous infusion.
Pediatric moderately to severely active polyarticular juvenile idiopathic arthritis	Pediatric patients weighing less than 75 kg receive 10mg/kg intravenously based on the patient's body weight. Pediatric patients weighing 75 kg or more should be administered Orencia following the adult intravenous dosing regimen, not to exceed a maximum dose of 1000mg.