**Orencia® (abatacept) subcutaneous [SC], intravenous [IV] injection**
**Prior Approval Criteria**

October 2015

**Definition:** Abatacept (Orencia®, Bristol-Myers Squibb Company, Princeton, NJ) is a soluble recombinant fusion protein, selective T cell costimulation modulator that inhibits T cell activation. The drug consists of human cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4) linked to a modified Fc portion of human immunoglobulin G1 (IgG1). Abatacept selectively inhibits T-cell activation and stimulation by binding to CD80 and CD86 on antigen-presenting cells (APC), thereby preventing the binding of CD80 or CD86 to CD28 on T cells.

**Preferred Specialty Management:**

**Orencia IV**

1. **Patient has been Established on Orencia (IV or SC):** Approve Orencia IV if the patient meets the *Recommended Authorization Criteria* for RA or JIA for patients established on Orencia (IV or SC). Patients not established on Orencia (IV or SC) should follow the criteria, below.

2. **Rheumatoid Arthritis (RA):**
   a) Approve Orencia IV if the patient meets the following conditions (i and ii):
      i. The patient meets the *Recommended Authorization Criteria* for RA; AND
      ii. The patient has tried ONE of the following: adalimumab [Humira®], anakinra [Kineret®], etanercept [Enbrel®], certolizumab pegol [Cimzia®], golimumab [Simponi® SC/Simponi Aria®], infliximab [Remicade®], tocilizumab [Actemra®].
   b) If criterion 2aii is not met and Orencia IV is not approved, offer to approve Enbrel or Humira if the patient has met criterion 2ai (the *Recommended Authorization Criteria* for RA).

3. **Juvenile Idiopathic Arthritis (JIA):**
   a) Approve Orencia IV if the patient meets the following conditions (i and ii):
      i. The patient meets the *Recommended Authorization Criteria* for JIA; AND
      ii. The patient has tried ONE of the following: Enbrel or Humira.
   b) If criterion 3aii is not met and Orencia IV is not approved, offer to approve Enbrel or Humira if the patient has met criterion 3ai (the *Recommended Authorization Criteria* for JIA).

**Orencia SC**

1. **Patient has been Established on Orencia (IV or SC):** Approve Orencia SC if the patient meets the *Recommended Authorization Criteria* for RA for patients established on Orencia (IV or SC). Patients not established on Orencia (IV or SC) should follow the criteria, below.

2. **Rheumatoid Arthritis (RA):**
   a) Approve Orencia SC if the patient meets the following conditions (i and ii):
      i. The patient meets the *Recommended Authorization Criteria* for RA; AND
      ii. The patient has tried ONE of the following: adalimumab [Humira®], anakinra [Kineret®], etanercept [Enbrel®], certolizumab pegol [Cimzia®], golimumab [Simponi® SC], tocilizumab [Actemra®]. **NOTE:** Trials of the infused products infliximab [Remicade®] and golimumab [Simponi Aria®] also count.
b) If criterion 2aii is not met and Orencia SC is not approved, offer to approve Enbrel or Humira if the patient has met criterion 2ai (the Recommended Authorization Criteria for RA).

Recommended Authorization Criteria

Coverage of Orencia is recommended in those who meet the following criteria:

Food and Drug Administration (FDA)-Approved Indications

I. Juvenile idiopathic arthritis: The Company considers abatacept medically necessary and eligible for reimbursement providing that all of the following medical criteria are met:

- Age ≥6 years; and
- Moderate to severe polyarticular juvenile idiopathic arthritis; and
- Failure of (trial of ≥3 months), intolerance to or unable to receive methotrexate/leflunomide; and
- Failure of (trial of ≥2 months), intolerance to or unable to receive at least one TNF-α inhibitor (e.g., adalimumab [Humira®], etanercept [Enbrel®], certolizumab pegol [Cimzia®], golimumab [Simponi SC/Simponi Aria], infliximab [Remicade]); and
- Abatacept will not be used in combination with another biologic agent (e.g., adalimumab [Humira®], anakinra [Kineret®], etanercept [Enbrel®], certolizumab pegol [Cimzia®], golimumab [Simponi® SC/Simponi Aria®], infliximab [Remicade®], tocilizumab [Actemra®]), apremilast [Otezla®] or tofacitinib citrate [Xeljanz®]; and
- Orencia IV is prescribed by or in consultation with a rheumatologist; and
- Dosage and administration are consistent with U.S. Food and Drug Administration approved label (i.e., intravenous: weight <75 kg: 10 mg/kg; weight 75-100 kg: 750 mg; weight >100 kg: 1,000 mg† at 0, two and four weeks, followed by a maintenance regimen of every four weeks);

OR

- History of beneficial response;

AND

At least one of the following clinical conditions is present:

- Polyarticular juvenile rheumatoid arthritis, chronic or unspecified
- Polyarticular juvenile rheumatoid arthritis

II. Rheumatoid arthritis: The Company considers abatacept medically necessary and eligible for reimbursement providing that all of the following medical criteria are met:

- Age ≥18 years; and
- Moderately to severe rheumatoid arthritis; and
- Failure of (trial of ≥3 months), intolerance to or unable to receive methotrexate or administration of >2 other nonbiologic disease modifying antirheumatic drugs (e.g., hydroxychloroquine, leflunomide, sulfasalazine, minocycline); and
- Failure of (trial of ≥3 months), intolerance to or unable to receive at least one TNF-α inhibitor (e.g., adalimumab [Humira®], anakinra [Kineret®], etanercept [Enbrel®], certolizumab pegol [Cimzia®], golimumab [Simponi® SC/Simponi Aria®], infliximab [Remicade®], tocilizumab [Actemra]) or Orencia IV/SC; and
- Abatacept will not be used in combination with another biologic agent (e.g., adalimumab [Humira®], anakinra [Kineret®], etanercept [Enbrel®], certolizumab pegol [Cimzia®], golimumab [Simponi® SC/Simponi Aria®], infliximab [Remicade®], tocilizumab [Actemra®]), apremilast [Otezla®] or tofacitinib citrate [Xeljanz®]; and
- Orencia IV or SC is prescribed by or in consultation with a rheumatologist; and
- Dosage and administration are consistent with U.S. Food and Drug Administration approved label (i.e., intravenous: weight <60 kg: 500 mg; weight 60-100 kg: 750 mg; weight >100 kg: 1,000 mg† at 0, two and four weeks, followed by a maintenance regimen of every four weeks; subcutaneous: 125 mg administered SC once weekly and may be initiate with or without an IV loading dose. Following a single intravenous loading dose [per body weight categories], the first 125 mg subcutaneous injection should be given within a day, followed by 125 mg subcutaneous injections once weekly);

**OR**

- History of beneficial response;

**AND**

*At least one* of the following clinical conditions is present:

- Rheumatoid arthritis
- Felty’s syndrome
- Other rheumatoid arthritis with visceral or systemic involvement

†Each vial provides 250 mg of abatacept for administration.
Sources of Information:


- Centers for Medicare & Medicaid Services: Abatacept (Orencia). No national or local coverage determination found in the coverage database. Current date.


