Clinical Policy: Abatacept (Orencia)

Reference Number: ERX.SPMN.171
Effective Date: 10/16
Last Review Date: 09/16

See Important Reminder at the end of this policy for important regulatory and legal information.

Policy/Criteria
It is the policy of health plans affiliated with Envolve Pharmacy Solutions® that abatacept (Orencia®) is medically necessary for members meeting the following criteria:

I. Initial Approval Criteria
   A. Rheumatoid Arthritis (must meet all):
      1. Prescribed by or in consultation with a rheumatologist;
      2. Age ≥ 18 years;
      3. Diagnosis of rheumatoid arthritis (RA) and one or more of the following:
         a. Presence of at least five inflamed joints;
         b. Elevation in the erythrocyte sedimentation rate (ESR) and/or serum C-reactive protein (CRP) concentration;
         c. Positive rheumatoid factor and/or anticyclic citrullinated peptide antibodies;
         d. Evidence of inflammation on plain radiography of the hands, wrists, or feet, such as osteopenia and/or periarticular swelling;
      4. Member has failed one of the following therapies, unless contraindicated:
         a. A biologic for RA other than Orencia;
         b. Methotrexate for ≥ 3 consecutive months;
         c. If methotrexate is contraindicated, failure of leflunomide, sulfasalazine, or hydroxychloroquine for ≥ 3 consecutive months;
      5. Member has failed Enbrel AND Humira, each trialed for ≥ 3 consecutive months, unless contraindicated;
      6. Prescribed dose of Orencia does not exceed the following:
         a. Intravenous (IV):
            i. < 60 kg: 500 mg every 2 weeks for 3 doses (i.e., a dose at weeks 0, 2, and 4), and then every 4 weeks thereafter;
            ii. 60-100 kg: 750 mg every 2 weeks for 3 doses (i.e., a dose at weeks 0, 2, and 4), and then every 4 weeks thereafter;
            iii. > 100 kg: 1000 mg every 2 weeks for 3 doses (i.e., a dose at weeks 0, 2, and 4), and then every 4 weeks thereafter;
         b. Subcutaneous (SC): 125 mg once weekly.
Approval duration: 6 months

B. **Polyarticular Juvenile Idiopathic Arthritis** (must meet all):
   1. Prescribed by or in consultation with a rheumatologist;
   2. Age ≥ 6 years and < 18 years;
   3. Diagnosis of polyarticular juvenile idiopathic arthritis (PJIA);
   4. Member has failed one of the following therapies, unless contraindicated:
      a. A biologic for PJIA other than Orencia;
      b. Methotrexate for ≥ 3 consecutive months;
      c. If methotrexate is contraindicated, failure of leflunomide, sulfasalazine, or hydroxychloroquine for ≥ 3 consecutive months;
   5. Member has failed Enbrel AND Humira, each trialed for ≥ 3 consecutive months, unless contraindicated;
   6. Prescribed route of administration is IV infusion;
   7. Prescribed dose of Orencia does not exceed the following:
      a. ≤ 100 kg: 750 mg every 2 weeks for 3 doses (i.e., a dose at weeks 0, 2, and 4), and then every 4 weeks thereafter;
      b. > 100 kg: 1000 mg every 2 weeks for 3 doses (i.e., a dose at weeks 0, 2, and 4), and then every 4 weeks thereafter.

Approval duration: 6 months

C. **Other diagnoses/indications:** Refer to ERX.SPMN.16 - Global Biopharm Policy.

II. **Continued Approval**
   A. **All Indications** (must meet all):
      1. Currently receiving medication via health plan benefit or member has previously met all initial approval criteria;
      2. Member is responding positively to therapy;
      3. Prescribed regimen does not exceed the following:
         a. For RA (IV):
            i. ≤ 60 kg: 500 mg every 4 weeks;
            ii. 60-100 kg: 750 mg every 4 weeks;
            iii. > 100 kg: 1000 mg every 4 weeks;
         c. For RA (SC): 125 mg once weekly;
         d. For PJIA (IV):
            i. ≤ 100 kg: 750 mg every 4 weeks;
            ii. > 100 kg: 1000 mg every 4 weeks.

Approval duration: 12 months

B. **Other diagnoses/indications** (must meet 1 or 2):
1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy; or
2. Refer to ERX.SPMN.16 - Global Biopharm Policy.

**Background**

**Description/Mechanism of Action:**
Abatacept, a selective co-stimulation modulator, 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 RA and are found in the synovium of patients with RA. In vitro, abatacept decreases T cell proliferation and inhibits the production of the cytokines TNF alpha (TNFα), interferon-γ, and interleukin-2. The relationship of these biological response markers to the mechanisms by which Orenica exerts its effects in RA is unknown.

**Formulations:**
Orencia is available as follows:
- Intravenous infusion:
  - Injection: 250 mg lyophilized powder in a single-use vial
- Subcutaneous injection:
  - Injection: 125 mg/mL of a clear, colorless to pale-yellow solution in a single-dose prefilled glass syringe
  - Injection: 125 mg/mL of a clear, colorless to pale-yellow solution in a single-dose prefilled Clickject autoinjector

**FDA Approved Indications:**
Orencia is a selective T cell co-stimulation modulator/injection for intravenous or subcutaneous use indicated for:
- Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. Orencia may be used as monotherapy or concomitantly with disease-modifying antirheumatic drugs (DMARDs) other than tumor necrosis factor (TNF) antagonists.
- Reducing signs and symptoms in pediatric patients 6 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis. Orencia may be used as monotherapy or concomitantly with methotrexate (MTX).

**Limitations of use:**
- Orencia should not be administered concomitantly with TNF antagonists. Orencia is not recommended for use concomitantly with other biologic rheumatoid arthritis (RA) therapy, such as anakinra.

**Appendices**

**Appendix A: Abbreviation Key**
- CRP: C-reactive protein
- DMARDs: disease-modifying antirheumatic drugs
- ESR: erythrocyte sedimentation rate
- IV: intravenous
- MTX: methotrexate
Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

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<th>HCPCS Codes</th>
<th>Description</th>
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<tr>
<td>J0129</td>
<td>Injection, abatacept, 10 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)</td>
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Reviews, Revisions, and Approvals
Policy split from USS.SPMN.44 Rheumatoid Arthritis and Ankylosing Spondylitis Treatments and converted to new template. Removed all safety criteria. Added weight range-based dosing for each indication per PI. Modified criteria to require trial of other biologic for the indication or methotrexate, unless contraindicated; added sulfasalazine as an alternative to methotrexate if methotrexate is contraindicated; added preferencing for Enbrel & Humira. RA: added age requirement per PI. PJIA: removed question related to number of affected joints as development of arthritis in > 4 joints is required for the diagnosis.

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<td>08/16</td>
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References


**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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