Generic name: abatacept

Brand name: Orencia

Medication class: Immunomodulator

FDA-approved uses: Reducing signs and symptoms, including major clinical response, slowing the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis.

Reducing signs and symptoms in pediatric patients 6 years of age and older with moderately to severely active polyarticular idiopathic arthritis.

Available dosage forms: 250 mg vial for injection; 125 mg/ml single-dose prefilled glass syringe

Usual dose:

Intravenous administration:
- Intravenously infused over 30 minutes at 0, 2 and 4 weeks, then every 4 weeks.
  - Adult rheumatoid arthritis:
    - < 60 kg: 500 mg
    - 60-100 kg: 750 mg
    - >100 kg: 1000 mg
  - Juvenile idiopathic arthritis:
    - < 75 kg: 10 mg/kg
    - > 75 kg-100 kg: 750 mg
    - > 100 kg: 1000 mg

Subcutaneous administration
- Adult rheumatoid arthritis:
  - After a single intravenous infusion as a loading dose, 125 mg administered by subcutaneous injection should be given within a day, followed by 125 mg subcutaneously once a week.
  - Weekly SC injections may be initiated if the patient is unable to receive an infusion.

Duration of therapy: Indefinite

Approximate monthly cost (based on AWP 2011):
- 250 mg vial for injection is $670/vial. Cost is based on use of 2-4 vials per month after the initial loading dose: $1,340.00 to $2,680.00.

- 125 mg/ml single-dose prefilled glass syringe: $600/syringe. Cost per month is about $2400.
Criteria for use: *(bullet points below are all inclusive unless otherwise noted)*
- The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records.
- Prescribed by a rheumatologist
- Must have a negative tuberculosis test or received treatment if tested positive.
- Must have clinically diagnosed adult RA or juvenile RA.

**Criteria for adult RA:**
- Intolerant or inadequate response after 3 months of treatment to methotrexate
- Intolerant or inadequate response after 3 months of treatment to etanercept (Enbrel) and adalimumab (Humira)
- Intolerant or inadequate response after 3 months of treatment to Remicade

**Criteria for juvenile RA:**
- Intolerant or inadequate response after 3 months of treatment to methotrexate
- Intolerant or inadequate response after 3 months of treatment to etanercept (Enbrel) and adalimumab (Humira)

**Criteria for continuation of therapy:**
- Documentation that there is disease stability or improvement.

**Cautions:**
- Patients should not receive live vaccines while they are being treated or for 3 months afterwards.
- Patients with COPD had more respiratory adverse effects compared to placebo.
- Higher incidence of infections

**Contraindications:**
- History of hypersensitivity to any of the product ingredients.

**Not approved if:**
- Being used concurrently with TNF antagonists or anakinra.
- Does not meet the above stated criteria
- Has any contraindications to the use of Orencia
- Positive tuberculosis test and not being treated.

**Special considerations:**
- For adult RA, may be used as monotherapy or concomitantly with DMARDs other than TNF antagonists.
- For juvenile RA, may be used as monotherapy or concomitantly with methotrexate.
- Linked to a spike in serious infections—particularly when used in combination with other biologics TNF antagonists.
- It appears effective in patients failing to respond to MTX, Enbrel, or Remicade when used in combination with MTX or other nonbiological DMARD therapy.
- Additional clinical efficacy and adverse effect information is necessary to identify the best place for abatacept in the treatment of RA.