Approval Criteria Department of Pharmacy Services

Generic Name: abatacept

Brand Name: Orencia®

Medication Class: Immumodulator

FDA Approved Uses

- Adult Rheumatoid Arthritis: for reducing signs and symptoms, including major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis (RA). Abatacept may be used as monotherapy or concomitantly with disease-modifying antirheumatic drugs (DMARDs) other than tumor necrosis factor (TNF) antagonists.
- Juvenile idiopathic arthritis: for reducing signs and symptoms in children 6 years of age and older with moderately to severely active polyarticular juvenile arthritis. Abatacept may be used as monotherapy or concomitantly with methotrexate.

Criteria for use (bullet points are all inclusive unless stated otherwise)

- The indicated diagnosis (including appropriate labs and tests) and medication utilization must be supported by documentation in the patient’s medical record.
- Prescribed by a rheumatologist
- Must have a documented negative tuberculosis test or received treatment if tested positive.
- Must have clinically diagnosed adult RA or juvenile RA Criteria

  for adult RA:
  - Trial, failure, or intolerance to at least 90 days of therapy with methotrexate
  - Trial, failure, or intolerance to at least 90 days of therapy with etanercept (Enbrel) or adalimumab (Humira)

  for juvenile RA:
  - Trial, failure, or intolerance to at least 90 days of therapy with methotrexate
  - Trial, failure, or intolerance to at least 90 days of therapy with etanercept (Enbrel) or adalimumab (Humira)

Not Approved For

- If concurrently used with TNF antagonist or anakinra
- Does not meet above criteria
- Has any contraindication to Orencia or any component of the formulation
- Positive tuberculosis test and not being treated

Required Medical Information

- Medical record documentation of diagnosis, laboratory and radiological tests, previous medication treatment with dates and documented outcome.

Contraindications

- None known
Dosing
- Adult Rheumatoid Arthritis:
  - Dosage is based on weight. Following initial administration, abatacept should be given at 2 and 4 weeks after the first infusion, then every 4 weeks thereafter.

<table>
<thead>
<tr>
<th>Abatacept dosing in Adults with RA</th>
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</thead>
<tbody>
<tr>
<td><strong>Body weight</strong></td>
</tr>
<tr>
<td>&lt; 60 kg</td>
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<tr>
<td>60 to 100 kg</td>
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<tr>
<td>&gt;100 kg</td>
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</tbody>
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- Subcutaneous:
  - Following a single intravenous (IV) loading dose, the first 125 mg subcutaneous injection of abatacept should be given within a day, followed by 125 mg subcutaneously once weekly

- Juvenile Rheumatoid Arthritis
  - Dosage is based on weight. Following initial administration, abatacept should be given at 2 and 4 weeks after the first infusion, then every 4 weeks thereafter.

<table>
<thead>
<tr>
<th>Abatacept dosing in children with RA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Body weight</strong></td>
</tr>
<tr>
<td>&lt; 75 kg</td>
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<tr>
<td>&gt;75 kg</td>
</tr>
</tbody>
</table>

Authorization
- One year

Approved by P&T: 09/16/2013 Reviewed:3/18/2014

References
14. Furst DE, Keystone EC, Fleischmann R, et al. Updated consensus statement on biological agents for the...