Drug Therapy Guidelines

<table>
<thead>
<tr>
<th></th>
<th>Orencia® (abatacept)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Applicable</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Medical Benefit</strong></td>
<td>x</td>
</tr>
<tr>
<td><strong>Pharmacy- Formulary 1</strong></td>
<td>x</td>
</tr>
<tr>
<td><strong>Pharmacy- Formulary 2</strong></td>
<td>x</td>
</tr>
<tr>
<td><strong>Pharmacy- Formulary 3/Exclusive</strong></td>
<td>x</td>
</tr>
<tr>
<td><strong>Pharmacy- Formulary 4/AON</strong></td>
<td>x</td>
</tr>
</tbody>
</table>

### I. Medication Description

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 Rheumatoid Arthritis (RA) and are found in the synovium of patients with RA. T-cell proliferation leads to increased production of the cytokines TNF-alpha, interferon-gamma, and interleukin which increases inflammation and joint destruction. Abatacept’s inhibitory action on these cytokines suppresses inflammation, decreases anti-collagen antibody production, and reduces antigen-specific production of interferon-gamma.

### II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

When administered subcutaneously, Orencia is considered a pharmacy benefit. When administered intravenously, Orencia is considered a medical benefit.

### III. Policy

**Medical Benefit: See Section A and C**  
**Formulary 1: See Section B and C**  
**Formulary 2: See Section B and C**  
**Formulary 3/Exclusive: See Section B and C**  
**Formulary 4/AON: See Section B and C**

**A.** Coverage of intravenous Orencia under the medical benefit is provided for the following conditions when the listed criteria are met:

- Juvenile idiopathic arthritis:
  - Prescribed by a rheumatologist **AND**
  - Member has tried therapy with at least one non-biologic DMARD with either treatment failure after 12 weeks or intolerable side effects (unless DMARDs are contraindicated) **AND**
  - Member has received at least a 3 month trial and failed on at least 1 plan-preferred self-injectable TNF-α inhibitor (Enbrel or Humira)

- Psoriatic arthritis (active disease):
  - Prescribed by a rheumatologist or dermatologist **AND**
o One of the following:
  ▪ Member has tried therapy with at least one non-biologic DMARD with either treatment failure after 12 weeks or intolerable side effects (unless DMARDs are contraindicated) OR
  ▪ If predominantly axial disease is documented, the member has experienced treatment failure with at least two oral NSAIDs (unless NSAIDs are contraindicated) AND
  o Member has first attempted therapy with a plan-preferred medication (Remicade or Simponi Aria)

• Rheumatoid arthritis (moderate to severe disease):
  o Prescribed by a rheumatologist AND
  o Member has tried therapy with at least one non-biologic DMARD with either treatment failure after 12 weeks or intolerable side effects (unless DMARDs are contraindicated)  AND
  o Member has tried at least TWO of the following plan-preferred products: Actemra SC, Enbrel or Humira.

• Psoriatic arthritis (active disease):
  o Prescribed by a rheumatologist or dermatologist AND
  o One of the following:
    ▪ Member has tried therapy with at least one non-biologic DMARD with either treatment failure after 12 weeks or intolerable side effects (unless DMARDs are contraindicated) OR
    ▪ If predominantly axial disease is documented, the member has experienced treatment failure with at least two oral NSAIDs (unless NSAIDs are contraindicated) AND
  o Member has first attempted therapy with TWO plan-preferred medications (Cosentyx, Enbrel, Humira, Stelara, or Xeljanz/Xeljanz XR)

• Rheumatoid arthritis (moderate to severe disease):
  o Prescribed by a rheumatologist AND
  o Member has tried therapy with at least one non-biologic DMARD with either treatment failure after 12 weeks or intolerable side effects (unless DMARDs are contraindicated) AND
  o Member has tried at least TWO of the following plan-preferred medications (Actemra, Humira, Enbrel, or Xeljanz/Xeljanz XR)

C. Step therapy criteria outlined in A and B apply unless the following criteria are met:
• When requesting coverage of a brand medication for which a plan-preferred A/B rated generic is available, there is sufficient evidence that the use of the A/B rated generic equivalent has resulted in inadequate results AND
• At least one of the following is met:
  o The plan-preferred medications are contraindicated or will likely cause an adverse reaction by or physical or mental harm to the member.
The plan-preferred medications are expected to be ineffective based on the known clinical history and conditions of the member and the member’s prescription drug regimen.

- The member has tried the plan-preferred medications or another prescription drug in the same pharmacologic class or with the same mechanism of action and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

- The member is stable on the medication selected by their healthcare professional for the medical condition under consideration (where “stable” is defined as receiving the medication for an adequate period of time, have achieved optimal response, and continued favorable outcomes are expected UNLESS the medication was initially selected solely due to the availability of a drug sample or a coupon card and the member does not otherwise meet the definition of “stable”).

- The plan-preferred medication is not in the best interest of the member because it will likely cause a significant barrier to the member’s adherence or to compliance with the member’s plan of care, will likely worsen a comorbid condition of the member, or will likely decrease the member’s ability to achieve or maintain reasonable functional ability in performing daily activities.

IV. **Quantity Limits**

- Coverage for intravenous dosing is available as follows:
  - For the treatment of juvenile idiopathic arthritis:
    - Members 6 years and older weighing more than 100 kg: 3000 mg in the first 28 days of therapy, then starting at week 8, 1000 mg every 28 days thereafter
    - Members 6 years and older weighing 75 kg to 100 kg: 2250 mg in the first 28 days of therapy, then starting at week 8, 750 mg every 28 days thereafter
    - Members 6 years and older weighing less than 75 kg: three 10 mg/kg doses in the first 28 days of therapy, then starting at week 8, 10 mg/kg every 28 days thereafter
  - For the treatment of psoriatic and rheumatoid arthritis:
    - Members 18 years and older weighing more than 100 kg: 3000 mg in the first 28 days of therapy, then starting at week 8, 1000 mg every 28 days thereafter
    - Members 18 years and older and weighing 60 kg to 100 kg: 2250 mg in the first 28 days of therapy, then starting at week 8, 750 mg every 28 days thereafter
    - Members 18 years of age and older weighing less than 60 kg: 1500 mg in the first 28 days of therapy, then starting at week 8, 500 mg every 28 days thereafter

- Coverage for subcutaneous dosing is available as follows:
  - For the treatment of juvenile idiopathic arthritis:
    - Members 2 years and older weighing 50 kg or more: four 125 mg syringes or autoinjectors per each 28 days
    - Members 2 years and older weighing 25 kg to less than 50 kg: four 87.5 mg syringes per each 28 days
    - Members 2 years and older weighing 10 kg to less than 25 kg: four 50 mg syringes per each 28 days
o For the treatment of psoriatic and rheumatoid arthritis:
  ▪ Members 18 years and older: four 125mg syringes or autoinjectors per each 28 days

V. Coverage Duration

Coverage is provided for 12 months and may be renewed.

VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Clinical response or remission of disease is maintained with continued use **AND**
- Absence of unacceptable toxicity from the drug

VII. Billing/Coding Information

- J0129 – 1 billable unit is 10mg
- Available as:
  - Orencia 250 mg lyophilized powder in a single use vial for reconstitution prior to intravenous infusion
  - Orencia single dose prefilled syringes for subcutaneous use (provided in a packs of 4 syringes):
    ▪ 50 mg/0.4 ml
    ▪ 87.5 mg/0.7 ml
    ▪ 125 mg/ml
  - Orencia (single dose prefilled ClickJect™ autoinjector)- 125 mg/ml syringe for subcutaneous use, provided in a pack of 4 autoinjectors
- Pertinent diagnoses:
  - Juvenile rheumatoid arthritis: M08.00, M08.3, M08.40
  - Psoriatic Arthritis: L40.50- L40.53, L40.59
  - Rheumatoid arthritis: M05.00, M05.30, M05.60, M06.1, M06.9

VIII. Summary of Policy Changes

- 1/2011:
  - Clarification of prior DMARD use requirements
  - Clarification of plan-preferred medications: Humira and Enbrel
- 6/15/12:
  - Addition of Orencia SC criteria for coverage;
  - Addition of Orencia SQ / prefilled syringe dosing and product information to guideline
  - Coverage duration extended to 12 months
- 3/15/13: no changes
- 7/1/13: Medical, Commercial Rx, and Medicaid/FHP Rx criteria differentiated
- 3/15/13: clarified need for latent Tb testing
• 8/1/14: Coverage for the treatment of RA under the medical benefit requires the use of either Remicade or Simponi Aria first
• 3/15/14: no policy changes
• 7/1/15: formulary distinctions made
• 3/15/16: no policy changes
• 1/1/17: step therapy rules updated on the pharmacy benefit
• 5/1/17: step therapy criteria added
• 10/20/17: coverage of Orencia for the treatment of psoriatic arthritis added; available products and quantity limits updated
• 1/1/18: no policy changes
• 12/13/18: added step criteria for JIA indication on the pharmacy benefit
• 2/15/19: added Xeljanz/Xeljanz XR as preferred products for PsA (under pharmacy benefit)

IX. References

1. Up-to-date Online, retrieved November 2018.
3. Facts and Comparisons Online, retrieved November 2010

*These guidelines are not applicable to benefits covered under Medicare Advantage. Medicare Advantage benefit coverage requests are reviewed in accordance with the guidance set forth in Chapter 15 Section 50 of the Centers for Medicare & Medicaid Services Medicare Benefit Policy Manual.

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.