Drug Therapy Guidelines

Orencia® (abatacept)

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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
Formulary 1: See Section B
Formulary 2: See Section B
Formulary 3/Exclusive: See Section B
Formulary 4/AON: See Section B

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) OR the following criteria have been met:
       - When requesting coverage of a brand medication for which an 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:

- 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 due to the availability of a drug sample or a coupon card).
- 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.

- Rheumatoid arthritis (moderate to severe disease):
  - 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 first attempted therapy with plan-preferred medication (Remicade or Simponi Aria) OR the following criteria have been met:
    - When requesting coverage of a brand medication for which an 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:
      - 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 due to the availability of a drug sample or a coupon card).
      - 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.

B. Coverage of subcutaneous Orencia under the pharmacy benefit is provided for the treatment of moderate to severe active rheumatoid arthritis (RA) when the following criteria are met:
   - 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**
   - The member has tried at least two of the following plan-preferred medications first (or there is a contraindication to the use of these medications that does not apply to Orencia): Actemra, Humira, Enbrel, Xeljanz/Xeljanz XR, Cimzia, Remicade, or Simponi **OR** the following criteria have been met:
     - When requesting coverage of a brand medication for which an 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:
       - 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 due to the availability of a drug sample or a coupon card).
       - 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**

- Intravenous dosing:
  - First month of therapy (loading dose) – 3,000mg (300 billable units) **THEN**
  - 100 billable units (1,000mg) every 4 weeks thereafter

- Subcutaneous dosing: Coverage available for up to four 125mg syringes or autoinjectors per each 28 days in accordance with FDA-approved dosing.
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**

- Orencia (abatacept lyophilized powder for injection)
  - J0129 – 1 billable unit is 10mg
  - 250mg/vial
  - Pertinent Indications
    - RA – M06.9
    - JIA – M08.00, M08.3, M08.40
- Orencia (single dose prefilled syringe) – 125mg in each 1ml syringe, provided in a pack of 4 syringes.
- Orencia (single dose prefilled ClickJect™ autoinjector)- 125 mg in each 1 ml syringe, provided in a pack of 4 autoinjectors
- Pertinent diagnoses:
  - Rheumatoid arthritis: M05.00, M05.30, M05.60, M06.1, M06.9
  - Juvenile rheumatoid arthritis: M08.00, M08.3, M08.40

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
- 7/1/15: 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
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.