Orencia

Description

Orencia (abatacept)

Background
Orencia is a prescription medication that reduces signs and symptoms in adults with moderate to severe rheumatoid arthritis (RA), including those who have experienced an inadequate response to other medications for RA. Orencia may prevent further damage to bones and joints and may help the patient’s ability to perform daily activities. In adults, Orencia may be used alone or with other RA treatments other than tumor necrosis factor (TNF) antagonists (1).

Orencia is indicated to reduce the signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in pediatric patients 2 years of age and older. Patients may receive Orencia alone (monotherapy) or in combination with methotrexate (1).

Regulatory Status
FDA-approved indication: Orencia is a selective T cell costimulation modulator indicated for: (1)

1. Adult Rheumatoid Arthritis (RA) – Moderately to severely active RA in adults. Orencia may be used as monotherapy or concomitantly with DMARDs other than TNF antagonists
2. Juvenile Idiopathic Arthritis – Moderately to severely active polyarticular juvenile idiopathic arthritis in pediatric patients 2 years of age and older. Orencia may be used as monotherapy or concomitantly with methotrexate
3. Adult Psoriatic Arthritis (PsA) – active PsA in adults

Limitations of Use:
Orencia should not be given concomitantly with TNF antagonists as it can increase the risk of infections and serious infections (1).

Physicians should exercise caution when considering the use of Orencia in patients with a history of recurrent infections, underlying conditions which may predispose them to infections, or chronic, latent, or localized infections. Patients who develop a new infection while undergoing treatment with Orencia should be monitored closely. Administration of Orencia should be discontinued if a patient develops a serious infection. A higher rate of serious infections has been observed in adult RA patients treated with concurrent TNF antagonists and Orencia (1).

Prior to initiating immunomodulatory therapies, including Orencia, patients should be screened for latent tuberculosis infection with a tuberculin skin test. Orencia has not been studied in patients with a positive tuberculosis screen, and the safety of Orencia in individuals with latent tuberculosis infection is unknown. Patients testing positive in tuberculosis screening should be treated by standard medical practice prior to therapy with Orencia (1).

Antirheumatic therapies have been associated with hepatitis B reactivation. Therefore, screening for viral hepatitis should be performed in accordance with published guidelines before starting therapy with Orencia. In clinical studies with Orencia, patients who screened positive for hepatitis were excluded from study (1).

The safety and effectiveness of Orencia in pediatric patients below 2 years of age have not been established (1).

Related policies
Actemra, Cimzia, Cosentyx, Enbrel, Humira, Kineret, Remicade, Simponi, Stelara, Xeljanz

Policy
This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Orencia may be considered medically necessary for patients age 2 or older for the treatment of juvenile rheumatoid arthritis (JRA)/ active polyarticular juvenile idiopathic arthritis (pJIA) and if the conditions below are met.
Orencia may be considered **medically necessary** for patients age 18 or older for the treatment of rheumatoid arthritis (RA), or active psoriatic arthritis (PsA) and if the conditions below are met.

Orencia may be considered **investigational** for all other ages and indications.

**Prior-Approval Requirements**

**Diagnoses**

Patient must have **ONE** of the following:

1. Moderately to severely active rheumatoid arthritis (RA)
   a. 18 years of age or older
   b. Inadequate treatment response, intolerance, or contraindication to at least a 3-month trial of methotrexate
   c. Prescriber will be dosing the patient within the FDA labeled dose of **ONE** of the following:
      i. IV infusion: Less than 60 kg – 500 mg every 4 weeks
      ii. IV infusion: 60 kg to 100kg – 750 mg every 4 weeks
      iii. IV infusion: More than 100 kg – 1000 mg every 4 weeks
      iv. Subcutaneous administration: 125 mg every week

2. Active Juvenile Rheumatoid Arthritis (JRA)/ Polyarticular Juvenile Idiopathic Arthritis (pJIA)
   a. 2 years of age or older
   b. Inadequate treatment response, intolerance, or contraindication to at least a 3-month trial of a TNF inhibitor
   c. Prescriber will be dosing the patient within the FDA labeled dose of **ONE** of the following:
      i. IV infusion: Less than 75kg – 10mg/kg every 4 weeks
      ii. Subcutaneous administration: 10 to less than 25 kg – 50 mg every week
      iii. Subcutaneous administration: 25 to less than 50 kg – 87.5 mg every week
      iv. Subcutaneous administration: More than 50 kg – 125 mg every week
3. Active Psoriatic Arthritis (PsA)
   a. 18 years of age or older
   b. Inadequate treatment response, intolerance, or contraindication to at least a 3-month trial of a TNF inhibitor
   c. Prescriber will be dosing the patient within the FDA labeled dose of **ONE** of the following:
      i. IV infusion: Less than 60 kg – 500 mg every 4 weeks
      ii. IV infusion: 60 kg to 100 kg – 750 mg every 4 weeks
      iii. IV infusion: More than 100 kg – 1000 mg every 4 weeks
      iv. Subcutaneous administration: 125 mg every week

   **AND ALL** of the following:
   1. Tuberculin skin test conducted to rule out TB
      a. Patients testing positive in tuberculosis screening must be treated by standard medical practice currently or completed prior to therapy.
   2. Hepatitis B virus (HBV) has been ruled out or treatment initiated.
   3. **NO** active infection
   4. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD
   5. **NOT** given concurrently with live vaccines

Prior – Approval *Renewal* Requirements

**Diagnoses**

Patient must have **ONE** of the following:

1. Rheumatoid Arthritis (RA) in adults
   a. 18 years of age or older
   b. Prescriber will be dosing the patient within the FDA labeled dose of **ONE** of the following:
      i. IV infusion: Less than 60 kg – 500 mg every 4 weeks
      ii. IV infusion: 60 kg to 100 kg – 750 mg every 4 weeks
      iii. IV infusion: More than 100 kg – 1000 mg every 4 weeks
      iv. Subcutaneous administration: 125 mg every week
2. Juvenile Rheumatoid Arthritis (JRA)/Polyarticular Juvenile Idiopathic Arthritis (pJIA)
   a. 2 years of age or older
   b. Prescriber will be dosing the patient within the FDA labeled dose of **ONE** of the following:
      i. IV infusion: Less than 75kg – 10mg/kg every 4 weeks
      ii. Subcutaneous administration: 10 to less than 25 kg – 50 mg every week
      iii. Subcutaneous administration: 25 to less than 50 kg – 87.5 mg every week
      iv. Subcutaneous administration: More than 50 kg – 125 mg every week

3. Psoriatic Arthritis (PsA)
   a. 18 years of age or older
   b. Prescriber will be dosing the patient within the FDA labeled dose of **ONE** of the following:
      i. IV infusion: Less than 60 kg – 500 mg every 4 weeks
      ii. IV infusion: 60 kg to 100kg – 750 mg every 4 weeks
      iii. IV infusion: More than 100 kg – 1000 mg every 4 weeks
      iv. Subcutaneous administration: 125 mg every week

**AND ALL** of the following:
1. Condition has improved or stabilized
2. Absence of active infection (including tuberculosis and hepatitis B virus (HBV))
3. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD
4. **NOT** given concurrently with live vaccines

### Policy Guidelines

**Pre - PA Allowance**
None

**Prior - Approval Limits**

Duration 12 months
Prior – Approval Renewal Limits

Duration 18 months

Rationale

Summary
Orencia is indicated for the treatment of moderately to severely active RA and PsA in adults, may be used as monotherapy or concomitantly with DMARDs other than TNF antagonists. Orencia is also indicated for pediatric patients 2 years of age or older with moderately to severely active polyarticular juvenile idiopathic arthritis, may be used as monotherapy or concomitantly with methotrexate. Prior to initiating immunomodulatory therapies, including Orencia, patients should be screened for latent tuberculosis infection with a tuberculin skin test. Antirheumatic therapies have been associated with hepatitis B reactivation (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Orencia while maintaining optimal therapeutic outcomes.

References

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>April 2008</td>
<td>FDA approved Abatacept (Orencia) for reducing signs and symptoms in pediatric patients six years and older with moderately to severely active polyarticular juvenile idiopathic arthritis (JIA).</td>
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<tr>
<td>September 2012</td>
<td>Annual editorial review and reference update</td>
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<tr>
<td>March 2013</td>
<td>Annual editorial review and reference update; updated contraindicated concomitant therapies and any live vaccine.</td>
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<tr>
<td>September 2013</td>
<td>Annual editorial review and reference update. Addition of TB testing, no hepatitis B virus, and no active infection requirements to the criteria.</td>
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<tr>
<td>September 2014</td>
<td>Annual editorial review and reference update and renewal limit to 18 months</td>
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<tr>
<td>March 2016</td>
<td>Annual editorial review and reference update. Policy number changed from 5.02.18 to 5.70.18</td>
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<tr>
<td>September 2016</td>
<td>Annual editorial review. Addition of not given concurrently with live vaccines per SME</td>
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December 2016  Annual editorial review and reference update
Additional criteria added to initiation for treatment of RA: Contraindication, intolerance, or inadequate treatment response to at least a 3-month trial of methotrexate despite adequate dosing
Additional criteria added to initiation for treatment of JRA/pJIA: Contraindication, intolerance, or inadequate treatment response to at least a 3-month trial of a TNF inhibitor

April 2017  Addition of FDA approval for ages two years and older for JRA/pJIA

June 2017  Annual review

July 2017  Addition of Psoriatic Arthritis (PsA) and dosing requirements for each indication

September 2017  Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 15, 2017 and is effective on October 1, 2017.