Pharmacy Medical Necessity Guidelines: Orencia® (abatacept)

Effective: July 11, 2017

<table>
<thead>
<tr>
<th>Prior Authorization Required</th>
<th>√</th>
<th>Type of Review – Care Management</th>
<th>Type of Review – Clinical Review</th>
<th>√</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Covered</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacy (RX) or Medical (MED) Benefit</td>
<td>SQ: RX / IV: MED</td>
<td>Department to Review</td>
<td>RXUM/ PRECERT /MM</td>
<td></td>
</tr>
</tbody>
</table>

This Pharmacy Medical Necessity Guideline applies to the following:

**Tufts Health Plan Commercial Plans**
- Tufts Health Plan Commercial Plans – large group plans
- Tufts Health Plan Commercial Plans – small group and individual plans

**Tufts Health Public Plans**
- Tufts Health Direct – Health Connector
- Tufts Health Together – A MassHealth Plan
- Tufts Health RITogether – A RIte Care + Rhody Health Partners Plan

**Tufts Health Freedom Plan products**
- Tufts Health Freedom Plan - large group plans
- Tufts Health Freedom Plan - small group plans

Fax Numbers:
- **Subcutaneous Formulation**
  - RXUM: 617.673.0988
- **Intravenous Formulation**
  - All plans except Tufts Health Direct –Health Connector
  - PRECERT:617.972.9409
  - Tufts Health Direct – Health Connector Only
  - MM: 888.415.9055

Note: For Tufts Health Plan Medicare Preferred Members, please refer to the Tufts Health Plan Medicare Preferred Prior Authorization Criteria. Background, applicable product and disclaimer information can be found on the last page.

**OVERVIEW**

**FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS**

Orencia (abatacept) is a selective T cell costimulation modulator indicated for:

- **Adult Rheumatoid Arthritis (RA)**
  - Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. Orencia may be used as monotherapy or concomitantly with disease-modifying antirheumatic drugs other than tumor necrosis factor (TNF) antagonists.

- **Juvenile Idiopathic Arthritis**
  - Reducing signs and symptoms in pediatric patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis. Orencia may be used as monotherapy or concomitantly with methotrexate.

Orencia (abatacept) should not be administered concomitantly with TNF antagonists. Orencia (abatacept) is not recommended for use concomitantly with other biologic RA therapy, such as anakinra.

**COVERAGE GUIDELINES**

**Orencia (abatacept) injection for subcutaneous use**

The plan may authorize coverage of Orencia (abatacept) injection for subcutaneous use for Members, when all the following criteria are met:

**Rheumatoid Arthritis**

1. The Member has a documented diagnosis of rheumatoid arthritis
   **AND**

2. The prescription is written by a rheumatologist
   **AND**

3. The Member has tried and failed treatment with, has a contraindication to or the provider has indicated clinical inappropriateness of treatment with at least two of the following agents:
   - Humira® (adalimumab)
   - Enbrel® (etanercept)
   - Simponi® (golimumab)
4. The Member is new to the plan and has been stable on Orencia (abatacept) prior to enrollment

**Juvenile Idiopathic Arthritis**
1. The Member has a documented diagnosis of juvenile idiopathic arthritis
   AND
2. The prescription is written by a rheumatologist
   OR
3. The Member has tried and failed treatment with, has a contraindication to or the provider has indicated clinical inappropriateness of treatment with tolerate Enbrel® (etanercept) or Humira® (adalimumab)
   OR
4. The Member is new to the plan and has been stable on Orencia (abatacept) prior to enrollment

**Orencia (abatacept) injection for intravenous use**
The plan may authorize coverage of Orencia (abatacept) injection for intravenous use for Members, when all the following criteria are met:

**Rheumatoid Arthritis**
1. The Member has a documented diagnosis of rheumatoid arthritis
   AND
2. The prescription is written by a rheumatologist
   AND
3. The Member has tried and failed treatment with, has a contraindication to or the provider has indicated clinical inappropriateness of treatment with Remicade® (infliximab) or Simponi Aria® (golimumab)
   OR
4. The Member is new to the plan and has been stable on Orencia (abatacept) prior to enrollment

**For Juvenile Idiopathic Arthritis**
1. The Member has a documented diagnosis of juvenile idiopathic arthritis
   AND
2. The prescription is written by a rheumatologist
   OR
3. The Member has tried and failed treatment with, has a contraindication to or the provider has indicated clinical inappropriateness of treatment with tolerate Enbrel® (etanercept) or Humira® (adalimumab)
   OR
4. The Member is new to the plan and has been stable on Orencia (abatacept) prior to enrollment

**Intravenous Dosing Guidelines**
1. Dosage is based on weight. Following the initial administration, Orencia (abatacept) should be given at 2 and 4 weeks after the first infusion, then every 4 weeks thereafter.
2. Orencia (abatacept) dosing in adults with rheumatoid arthritis:
   - Body weight <60 kg: 500 mg
   - Body weight 60 to 100 kg: 750 mg
   - Body weight >100 kg: 1000 mg
3. Orencia (abatacept) dosing in patients 6 to 17 years of age for juvenile idiopathic arthritis:
   - Body weight <75 kg: 10 mg/kg
   - Body weight ≥75 kg: Administer Orencia (abatacept) following the adult IV dosing regimen, not to exceed a maximum dose of 1,000 mg.

**Subcutaneous Dosing Guidelines**
1. Orencia (abatacept) should be administered by subcutaneous injection once weekly.
2. Orencia (abatacept) subcutaneous injection for rheumatoid arthritis may be initiated with or without an intravenous loading dose. For Members initiating therapy with an intravenous loading dose, Orencia (abatacept) should be initiated with a single intravenous infusion, followed by the first 125 mg subcutaneous injection administered within a day of the intravenous infusion.
• Patients transitioning from Orencia (abatacept) intravenous therapy to subcutaneous administration should administer the first subcutaneous dose instead of the next scheduled intravenous dose.

3. Orencia (abatacept) subcutaneous injection for juvenile idiopathic arthritis should be initiated without an intravenous loading dose. Orencia (abatacept) dosing in patients 2 to 17 years of age for juvenile idiopathic arthritis:
   • Body weight 10 to <25 kg: 10 mg
   • Body weight 25 to <50 kg: 87.5 mg
   • Body weight ≥50 kg: 125 mg

LIMITATIONS
1. Samples, free goods or similar offerings of Orencia (abatacept) do not qualify for an established clinical response and will not be considered for prior authorization.
2. Orencia will not be approved if administered concomitantly with another tumor necrosis factor antagonist or Kineret (anakinra).
3. Coverage of Orencia prefilled syringe is limited as follows:
   • 50 mg/0.4 mL prefilled syringe – 4 syringes per 28 days
   • 87.5 mg/mL prefilled syringe – 4 syringes per 28 days
   • 125 mg/mL prefilled syringe – 4 syringes per 28 days

CODES
The following HCPCS/CPT code(s) are:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J0129</td>
<td>Injection, abatacept, per 10 mg</td>
</tr>
</tbody>
</table>

Note: Medical billing codes may not be used for Orencia prefilled syringe. This formulation must be obtained via the Member’s pharmacy benefit.

REFERENCES

**APPROVAL HISTORY**

May 9, 2006: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
- March 13, 2007: No changes
- March 4, 2008: No changes
- July 8, 2008: Added new indication of juvenile idiopathic arthritis to criteria #1 and #3. Criteria within #3 are specific with respect to diagnosis of rheumatoid arthritis or juvenile idiopathic arthritis.
- July 14, 2009: No changes
- January 1, 2010: Removal of Tufts Health Plan Medicare Preferred language (separate criteria have been created specifically for Tufts Health Plan Medicare Preferred)
- July 13, 2010: Added Cimzia (certolizumab) and Simponi (golimumab) to prerequisite options for rheumatoid arthritis. Added Enbrel (etanercept) to prerequisite options for juvenile idiopathic arthritis.
- July 12, 2011: No changes
- November 15, 2011: Added note that medical billing codes may not be used for Orencia prefilled syringe. This formulation must be obtained via the Member’s pharmacy benefit. Added dosing guidelines for intravenous and subcutaneous administration. Added quantity limitation for Orencia prefilled syringe.
- September 11, 2012: No changes
- September 10, 2013: No changes
- October 7, 2014: Updated dosing guidelines for subcutaneous Orencia (abatacept) based on supplemental FDA approval removing initial intravenous loading dose requirement for subcutaneous utilization.
- October 6, 2015: No changes
- January 1, 2016: Administrative change to rebranded template.
- September 13, 2016: Effective 1/1/2017: Changed prerequisite coverage of Orencia (abatacept) injection, for subcutaneous use: requires trial and failure of treatment with, contraindication to or clinical inappropriateness of treatment with at least two of the following agents where indicated: Humira, Enbrel, Simponi. Changed prerequisite coverage of Orencia (abatacept) injection, for intravenous use for the diagnosis of rheumatoid arthritis: requires trial and failure of treatment with, contraindication to or clinical inappropriateness of treatment with Remicade or Simponi Aria. Added exception language for Members new to the plan and stable on Orencia (abatacept) prior to enrollment.
- April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
- June 13, 2017: Updated criteria for expanded indication and dosing of subcutaneous Orencia (abatacept) in pediatric patients with juvenile idiopathic arthritis.
July 11, 2017: Administrative update to add the following Limitation: Samples, free goods or similar offerings of Orencia (abatacept) do not qualify for an established clinical response and will not be considered for prior authorization.

**BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION**

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a Member's benefit document and in coordination with the Member's physician(s). The plan makes coverage decisions on a case-by-case basis considering the individual Member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member's benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink℠ Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence. For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to Member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.