

Pharmacy Medical Necessity Guidelines: Orencia® (abatacept)

Effective: January 1, 2018

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	SQ: RX / IV: MED	Department to Review	RXUM/ MM
<p>This Pharmacy Medical Necessity Guideline applies to the following:</p> <p>Tufts Health Plan Commercial Plans</p> <input type="checkbox"/> Tufts Health Plan Commercial Plans – large group plans <input type="checkbox"/> Tufts Health Plan Commercial Plans – small group and individual plans <p>Tufts Health Public Plans</p> <input type="checkbox"/> Tufts Health Direct – Health Connector <input checked="" type="checkbox"/> Tufts Health Together – A MassHealth Plan <input type="checkbox"/> Tufts Health RITogether – A RItE Care + Rhody Health Partners Plan <p>Tufts Health Freedom Plan products</p> <input type="checkbox"/> Tufts Health Freedom Plan - large group plans <input type="checkbox"/> Tufts Health Freedom Plan - small group plans		<p>Fax Numbers:</p> <p><i>Subcutaneous Formulation</i> RXUM: 617.673.0988</p> <p><i>Intravenous Formulation</i> MM: 888.415.9055</p>	

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

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

Adult Psoriatic Arthritis

- Treatment of adult patients with active psoriatic arthritis.

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

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

Orencia Subcutaneous

1. The Member has a documented diagnosis of psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis or juvenile idiopathic arthritis

AND

2. The Member is over 2 years of age

AND

3. The Member has been evaluated by a rheumatologist

AND

4. The Member has previously tried and failed treatment with, is intolerant to, or has a contraindication to, at least **one** of the oral, non-biologic Disease Modifying Anti-rheumatic Drugs (DMARDs), such as azathioprine, gold therapy, hydroxychloroquine, methotrexate, penicillamine, sulfasalazine, cyclosporine or leflunomide

AND

- The Member has tried and failed treatment with, or the provider has indicated clinical inappropriateness of Humira and Enbrel

Orencia Intravenous

- The Member has tried and failed, or the provider has indicated inappropriateness to, the subcutaneous dosage form of Orencia (abatacept)

Intravenous Dosing Guidelines

- 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.
- Orencia (abatacept) dosing in adults with psoriatic arthritis or rheumatoid arthritis:
 - Body weight <60 kg: 500 mg
 - Body weight 60 to 100 kg: 750 mg
 - Body weight >100 kg: 1000 mg
- 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

- Orencia (abatacept) should be administered by subcutaneous injection once weekly.
- There is no need for an intravenous loading dose of Orencia (abatacept) for the treatment of psoriatic arthritis. Patients transitioning from Ocrencia (abatacept) intravenous therapy to subcutaneous administration should administer the first subcutaneous dose instead of the next scheduled intravenous dose.
- 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.
- Orencia (abatacept) subcutaneous injection for juvenile idiopathic arthritis should be initiated without an intravenous loading dose. Orecenia (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

- 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.
- Members new to the plan and stable on Orencia (abatacept) are not required to provide documentation of prerequisite trials with conventional (i.e., non-biologic) therapies (e.g., hydroxychloroquine, methotrexate, sulfasalazine).
- Initial authorization will be for 6 months, unless the Member is already stable on the medication, in which case the initial authorization will be for 1 year. Subsequent authorization may be given in 12-month intervals based on submission of current progress notes from the physician documenting efficacy.
- 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:

Code	Description
J0129	Injection, abatacept, per 10 mg

REFERENCES

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16. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Rheumatol*. 2016 Jan;68(1):1-26.
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APPROVAL HISTORY

March 10, 2015: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- October 6, 2015: No changes
- January 1, 2016: Administrative change to rebranded template.
- September 13, 2016: No changes
- April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
- June 13, 2017: Updated criteria for expanded indication and dosing of subcutaneous Orenzia (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 Orenzia (abatacept) do not qualify for an established clinical response and will not be considered for prior authorization.
- October 17, 2017: Added criteria for the supplemental indication of psoriatic arthritis to the Medical Necessity Guideline.
- December 12, 2017: Effective January 1, 2018, removed criteria allowing members new to the plan stable on Orenzia (abatacept) to be authorized due to new state requirements. Added the following limitation: Members new to the plan and stable on Orenzia (abatacept) are not required to provide documentation of prerequisite trials with conventional (i.e., non-biologic) therapies (e.g., hydroxychloroquine, methotrexate, sulfasalazine).

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 CareLinkSM 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.