Pharmacy Medical Necessity Guidelines: Orencia® (abatacept)

Effective: June 19, 2017

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

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 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* MM: 888.415.9055

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

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

1. The Member has a documented diagnosis of 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

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

OR

6. The Member is new to the plan and has been stable on Orencia prior to enrollment

Orencia intravenous

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

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. Orecnia (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. 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

1. 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.
2. 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

1. Agency for Healthcare Research and Quality. Choosing Medications for Rheumatoid Arthritis. Available at effectivehealthcare.ahrq.gov/ehc/products/14/85/RheumArthritisClinicianGuide.pdf. Accessed 2012 August 23.
2. Athanasakis K, Petrakis I, Kyriopoulos J. Investigating the value of abatacept in the treatment of rheumatoid arthritis: a systematic review of cost-effectiveness studies. *ISRN Rheumatol*. 2013 May 30;2013:256871.
3. Atzeni F, Puttini PS, Mutti A, et al. Long-term safety of abatacept in patients with rheumatoid arthritis. *Autoimmun Rev.* 2013 Jun 22. pii: S1568-9972(13)00115-8.
4. Enbrel (etanercept) [prescribing information]. Thousand Oaks, CA: Amgen Inc. and Pfizer Inc.; 2015 March.
5. Genovese MC, Becker JC, Schiff M, et al. Abatacept for rheumatoid arthritis refractory to tumor necrosis factor alpha inhibition. *N Engl J Med*. 2005;353(11):1114-23.

6. Humira (adalimumab) [prescribing information]. North Chicago, IL: AbbVie Inc.; 2016 June.
7. Kaine J, Gladstein G, Strusberg I et al. Evaluation of abatacept administered subcutaneously in adults with active rheumatoid arthritis: impact of withdrawal and reintroduction on immunogenicity, efficacy and safety (phase Iiib ALLOW study). *Ann Rheum Dis*. 2012 Jan; 71(1):38-44.
8. Kremer JM, Genant HK, Moreland LW et al. Effects of abatacept in patients with methotrexate-resistant active rheumatoid arthritis: a randomized trial. *Ann Intern Med*. 2006 Jun 20;144(12):865-76.
9. Kremer JM, Russell AS, Emery P et al. Long-term safety, efficacy and inhibition of radiographic progression with abatacept treatment in patients with rheumatoid arthritis and an inadequate response to methotrexate: 3-year results from the AIM trial. *Ann Rheum Dis*. 2011 Oct; 70(10):1826-30.
10. McEvoy GK, ed. AHFS 2013 Drug Information. Bethesda, MD: American Society of Health-Systems Pharmacists, Inc. 2013.
11. Orencia (abatacept) [package insert]. Princeton, NJ: Bristol-Myers Squibb; March 2017.
12. Remicade (infliximab) [prescribing information]. Malvern, PA: Centocor Ortho Biotech, Inc.; 2015 January.
13. Ruperto N, Lovell DJ, Quartier P et al. Abatacept in children with juvenile idiopathic arthritis: a randomised, double-blind, placebo-controlled withdrawal trial. *Lancet*. 2008 Aug 2;372(9636):383-91.
14. Saag KG, Teng GG, Patkar NM, et al. American College of Rheumatology 2008 Recommendations for the Use of Nonbiologic and Biologic Disease-Modifying Antirheumatic Drugs in Rheumatoid Arthritis. *Arthritis Rheum* 2008 Jun 15; 59(6):762-84.
15. Schiff M, Pritchard C, Huffstutter JE et al. The 6-month safety and efficacy of abatacept in patients with rheumatoid arthritis who underwent a washout after anti-tumour necrosis factor therapy or were directly switched to abatacept: the ARRIVE trial. *Ann Rheum Dis*. 2009 Nov;68(11):1708-14.
16. Simponi (golimumab) [prescribing information]. Horsham, PA: Janssen Biotech Inc.; 2016 January.
17. Simponi Aria (golimumab) [prescribing information]. Horsham, PA: Janssen Biotech Inc.; 2016 August.
18. Singh JA, Furst DE, Bharat A et al. Update of the 2008 American College of Rheumatology Recommendations for the Use of Disease-Modifying Antirheumatic Drugs and Biologic Agents in the Treatment of Rheumatoid Arthritis. *Arthritis Care & Research*. Vol. 64, No. 5, May 2012, pp 625–639.
19. 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.
20. Smolen JS, Landewé R, Breedveld FC, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs. *Ann Rheum Dis* 2010; 69: 964 – 75.
21. Wells AF, Westhovens R, Reed DM et al. Abatacept plus methotrexate provides incremental clinical benefits versus methotrexate alone in methotrexate-naive patients with early rheumatoid arthritis who achieve radiographic nonprogression. *J Rheumatol*. 2011 Nov;38(11):2362-8.

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.
- June 13, 2017: Updated criteria for expanded indication and dosing of subcutaneous Orencia (abatacept) in pediatric patients with juvenile idiopathic arthritis.

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^{SM} 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.

Provider Services