

Origination Date: 4/06	Revision Date(s): 4/07, 4/08, 4/09
Developed By: Medical Criteria Committee	

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**Description:**

Rheumatoid arthritis (RA) is a chronic, inflammatory, autoimmune disease that affects approximately 1% of the U.S. population. It is characterized by inflammation of the lining of the joints. Typically, RA is a progressive illness that can lead to joint destruction and functional disability. Early diagnosis and treatment of RA is important in order to limit joint damage, preserve physical function, and prevent long-term disability.

Abatacept (Orencia) is the first drug in a new class of biological therapies to treat RA. This class of biologic agents is called selective costimulation modulators. Orencia is a novel fusion protein that inhibits T-cell activation and interrupts the process leading to inflammation in RA. On December 23, 2005, the U.S. Food and Drug Administration approved Orencia for reducing the signs and symptoms of RA, inducing major clinical response, slowing the progression of structural damage, and improving physical function in adult patients with moderately to severely active RA who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDS), such as methotrexate or a tumor necrosis factor (TNF) antagonist.

**Criteria:**

- I. Orencia will be covered to plan limitations for the treatment of rheumatoid arthritis when **all** of the following criteria are met:
  - A. Member is an adult 18 years of age or older; and
  - B. Member has moderately to severely active rheumatoid arthritis; and
  - C. Member has had an inadequate response, contraindication or intolerance to one DMARD for at least 3 consecutive months within the past 12 months; and
  - D. Member has had an inadequate response, contraindication or intolerance to one tumor necrosis factor (TNF) antagonist (i.e. adalimumab (Humira), etanercept (Enbrel), infliximab (Remicade); and
  - E. Member does not have an active infection or a history of recurring infections; and
  - F. Member is not currently on Enbrel, Humira, Remicade, or Kineret; and
  - G. Treatment with Orencia has been prescribed by or is being supervised by a rheumatologist
  
- II. Orencia will be covered to plan limitations for the treatment of juvenile idiopathic arthritis when **all** of the following criteria are met:
  - A. The member is 6-17 years of age or older; and
  - B. The member has moderately to severely active polyarticular juvenile idiopathic arthritis; and
  - C. The member has had an inadequate response to one or more DMARD, such as methotrexate or TNF antagonist.

**Note:** According to FDA approval labeling Orencia may be used as monotherapy or concomitantly with DMARDS other than TNF antagonists (Enbrel, Humira, Remicade). It is also not recommended for use concomitantly with Kineret.

- III. If approved, Orencia should be administered as a 30 minute IV infusion at 0, 2, and 4 weeks. Then every 4 weeks thereafter. For continued authorization, patients must experience 20% or greater improvement in tender joint count and swollen joint count.

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- IV. ODS considers Orencia experimental and investigational for any other non FDA-approved indications, including but not limited to the following:
- A. Multiple sclerosis
  - B. Systemic lupus erythematosus
- Effectiveness for these conditions has not been established.

The following are examples of DMARDS:

1. methotrexate
2. leflunomide
3. azathioprine
4. cyclosporine
5. hydroxychloroquine
6. minocycline
7. penicillamine
8. sulfasalazine
9. gold sodium thiomalate
10. aurothioglucose
11. auranofin

**Information to be Submitted with Pre-Authorization Request:**

- Chart notes from ordering rheumatologist
- X-ray or other diagnostic study results
- Response to previous drug therapies that the patient has tried
- Current medications patient is taking for RA

**Applicable CPT/HCPC:**

**Note: this list may not be all inclusive**

<b>J0129</b>   Injection, abatacept, 10 mg.
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**References:**

- Bristol-Myers Squibb Co. U.S. Food and Drug Administration approves Orencia® (abatacept) for the treatment of rheumatoid arthritis. Press release. Princeton, NJ: Bristol-Myers Squibb; December 23, 2005. Available at [www.bms.com/new/press/data/fg\\_press\\_release\\_6097.html](http://www.bms.com/new/press/data/fg_press_release_6097.html). Accessed April 10, 2006.
- Bristol-Myers Squibb Co. Orencia® (abatacept). Prescribing information. December 2005. Available at [www.orencia.com](http://www.orencia.com). Accessed April 10, 2006.
- Genovese MC, Becker JC, Schiff M, et al. Abatacept for rheumatoid arthritis refractory to tumor necrosis factor alpha inhibition. N Eng J Med. Sept 2005; 353(11):1114-1123.
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- Hervey PS, Keam SJ. Abatacept. Bio Drugs. 2006; 20(1):53-60.
- [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Abatacept and Infliximab in combination with methotrexate in subjects with rheumatoid arthritis. NCT00095147. Sponsored by Bristol-Myers Squibb.
- Emery P, Kosinski M, Li T, et al. Treatment of rheumatoid arthritis patients with abatacept and methotrexate significantly improved health-related quality of life. J Rheumatology. 2006; 33:681-9.
- Nogid A, Pham DQ. Role of abatacept in the management of rheumatoid arthritis. Clin Ther. 2006 Nov;28(11):1764-78.
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