

Corporate Medical Policy

Abatacept (Orencia®)

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| File Name: | abatacept_orencia |
| Origination: | 4/2008 |
| Last CAP Review: | 2/2011 |
| Next CAP Review: | 2/2012 |
| Last Review: | 6/2011 |

Description of Procedure or Service

Orencia® (abatacept) is a biologic drug used to reduce the signs and symptoms of rheumatoid arthritis. It is a fusion protein that blocks T-cell activation. This inhibits the progression of structural damage, which occurs over time with rheumatoid arthritis. T-cell activation is key in rheumatoid arthritis immunopathology.

Rheumatoid arthritis is a chronic condition where the person's own immune system causes inflammation of the joints and the tissue around the joints. The body is equipped with a defense mechanism called the immune system which protects you from disease and infection. When a person has an autoimmune condition, the immune system creates antibodies that attack its own tissues. Rheumatoid arthritis usually starts between the age of 25 and 55 and the cause is unknown. Symptoms of rheumatoid arthritis (RA) are described as painful inflammation of the synovial tissue lining the joints. These patients have elevated levels of tumor necrosis factor-alpha (TNF-a) in their joints. Chronic joint inflammation leads to tissue break down, cell damage to the bone, edema, warmth, redness, joint stiffness, and pain. These patients are also fatigued, weak, have a low-grade fever, and loss of appetite.

Arthritis occurring in children is referred to as juvenile idiopathic arthritis (JIA) (juvenile rheumatoid arthritis (JRA).) Children with JIA have similar symptoms to those which adults with RA exhibit. Additional medical conditions are experienced in children with JIA, such as inflammation of the inner part of the eye (uveitis). If untreated, uveitis can lead to glaucoma, cataracts, and permanent vision damage. These patients must see an ophthalmologist regularly.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for Orencia® (abatacept) for the treatment of rheumatoid arthritis when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

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When Abatacept is covered

Orencia® (abatacept) may be medically necessary for the treatment of rheumatoid arthritis in the following conditions:

1. Adults with moderate to severe rheumatoid arthritis.
2. Moderate to severe juvenile idiopathic arthritis (JIA) in patients six years and older.

When Abatacept is not covered

1. When the criteria stated above are not met.
2. Orencia® (abatacept) should not be used in combination with Tumor Necrosis Factor (TNF) inhibiting drugs or other rheumatoid arthritis biologics including Rituxan (rituximab) or Kineret (anakinra), an interleukin-1 receptor antagonist.
3. Orencia® (abatacept) is not covered when used for the treatment of multiple sclerosis, systemic lupus erythematosus, graft versus host disease (GVHD) and other non FDA-approved indications. These indications are considered investigational.

Policy Guidelines

Abatacept may be subject to prior review requirements.

Orencia® (abatacept) may be used alone or in combination with methotrexate.

Orencia® (abatacept) is administered as a 30 minute IV infusion based on weight. It should be given at 2 and 4 weeks after the first infusion, then every 4 weeks. Authorization may be renewed if the biologic has improved the patient's condition as determined by clinical assessment or various Rheumatoid Arthritis disease assessment tools.

According to the Food and Drug Administration (FDA) approved labeling for Abatacept, the dose should not exceed 1000 mg every 28 days (maintenance); allow 1000 mg at 2 weeks and 4 weeks after the initial infusion only.

The approved labeling does not describe circumstances in which dosages above this maximum would be considered safe and effective.

Subcutaneous Administration for Adult RA

- After a single intravenous infusion as a loading dose (as per body weight indications), 125 mg administered by a subcutaneous injection should be given within a day, followed by 125 mg subcutaneously once a week.
- Patients who are unable to receive an infusion may initiate weekly injections of subcutaneous Orencia without an intravenous loading dose.
- Patients transitioning from Orencia intravenous therapy to subcutaneous administration should administer the first subcutaneous dose instead of the next scheduled intravenous dose.

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Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: J0129

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Bristol-Myers Squibb Co. Orencia® (abatacept) product information. Retrieved 3/14/08 from http://www.orencia.com/orencia/home/index.jsp?BV_UseBVCookie=Yes.

Senior Medical Director review, 3/20/2008.

Schiff M, Keiserman M, Codding C, et.al. Efficacy and safety of abatacept or infliximab versus placebo in ATTEST: a phase III, multicenter, randomized, double-blind, placebo-controlled study in patients with rheumatoid arthritis and an inadequate response to methotrexate. *Ann Rheum Dis*. published online 29 Nov 2007; doi 10.1136/ard.2007.080002.

Bristol-Myers Squibb Co. U.S. Food and Drug Administration Approves ORENCIA® (abatacept) for the Treatment of Moderate-to-Severe Polyarticular Juvenile Idiopathic Arthritis (JIA) in Patients Six Years and Older. Retrieved 10/7/08 from http://newsroom.bms.com/article_display.cfm?article_id=5249

FDA Website. Approval History: sBLA 125057/114. Retrieved 10/7/08 from <http://www.fda.gov/cder/foi/appletter/2008/125057s114ltr.pdf>

Bristol-Myers Squibb Co. Orencia® (abatacept) full prescribing information. Retrieved 10/29/09 from http://packageinserts.bms.com/pi/pi_orencia.pdf

Specialty Matched Consultant Advisory Panel – 1/2010

Specialty Matched Consultant Advisory Panel- 2/2011

FDA website, Retrieved 6/23/11 from <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/PediatricAdvisoryCommittee/UCM192052.pdf>

Bristol-Myers Squibb Co. Orencia® (abatacept) full prescribing information. Retrieved 8/10/11 from http://packageinserts.bms.com/pi/pi_orencia.pdf

Policy Implementation/Update Information

4/1/08 New policy developed. Under the "When Covered" section;"Orencia® (abatacept) may be

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medically necessary for the treatment of rheumatoid arthritis when the medical criteria and guidelines shown below are met: 1. The patient has moderate to severe rheumatoid arthritis; and 2. The patient has failed to respond adequately to at least one Tumor Necrosis Factor (TNF) inhibiting drug or is intolerant to all TNF-inhibiting drugs (i.e., Remicade (infliximab), Enbrel (etanercept), Humira (adalimumab)); and 3. Orencia® (abatacept) may be used alone or in combination with methotrexate. Under the "When Not Covered" section; "1. When the criteria stated above are not met. 2. Orencia® (abatacept) should not be used in combination with Tumor Necrosis Factor (TNF) inhibiting drugs or other rheumatoid arthritis biologics including Rituxan (rituximab) or Kineret (anakinra), an interleukin-1 receptor antagonist. 3. Orencia® (abatacept) is not covered when used for the treatment of juvenile rheumatoid arthritis, juvenile idiopathic arthritis (JIA), multiple sclerosis, systemic lupus erythematosus, graft versus host disease (GVHD) and other non FDA-approved indications is considered investigational." Senior Medical Director review, 3/20/2008. References added. Notification given April 1, 2008. Policy effective July 1, 2008.

- 7/01/08 Added additional FDA indication to the "When Covered" section to include #4. "Orencia® (abatacept) may be covered when used for the treatment of moderate to severe juvenile idiopathic arthritis (JIA) in patients six years and older." Removed reference to JIA from #3 under the "When Not Covered" section.
- 11/3/08 Removed criteria from the "When Covered" section requiring "The patient has failed to respond adequately to at least one Tumor Necrosis Factor (TNF) inhibiting drug or is intolerant to all TNF-inhibiting drugs (i.e., Remicade (infliximab), Enbrel (etanercept), Humira (adalimumab))." Revised "Policy Guidelines" section. References added (btw)
- 2/2/10 Specialty Matched Consultant Advisory Panel review 1/5/2010. Updated "Description" section. No change to policy statement. References added. (btw)
- 4/30/10 Policy number(s) removed. (btw)
- 3/15/11 Specialty Matched Consultant Advisory Panel review 2/2011. Medical definitions removed. Moved the following statement from the "When not Covered" section to "Policy Guidelines" section: "Orencia® (abatacept) may be used alone or in combination with methotrexate." (lpr)
- 7/1/11 Added quantity limitations to Policy Guidelines. Medical director review 6/2011. Notification date 7/1/11 for effective date of 10/1/11. Also added indications for subcutaneous use to Policy Guidelines since Orencia was recently approved for subcutaneous use by the FDA. (lpr)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.