

Title: abatacept (Orencia)

Origination: 05/27/09	Revised: 11/25/11	Annual Review: 12/15/11
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Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Background Information:

Reference Statement

- Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

Medication Summary

- Orencia (abatacept) is a selective costimulation modulator that inhibits T-cell interaction by binding to CD80 and CD86 thereby blocking interaction with CD28. This cascade of events blocks the activation of T lymphocytes. Activated T lymphocytes are responsible for the pathogenesis of Rheumatoid Arthritis (RA) and are found in the synovium of Members with RA.
- Orencia, alone or in combination with Methotrexate (MTX) or Disease Modifying Anti-Rheumatic Drugs (DMARDs) other than tumor necrosis factor (TNF) antagonists, is indicated for reducing sign and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in Members with moderately to severely active **Rheumatoid Arthritis (RA)**.
- Orencia, alone or in combination with Methotrexate (MTX), is indicated for reducing signs and symptoms in Members six (6) years of age and older with moderately to severely active **Polyarticular Juvenile Idiopathic Arthritis (JIA/JRA)**.
- Orencia is administered as an intravenous (IV) infusion over 30 minutes given initially then followed by a dose at week two (2) and week four (4), then maintenance infusions are given every four (4) weeks. Orencia comes as a 250mg vial.
- Orencia can be given subcutaneously (adults only) at a dose of 125 mg weekly with the first subcutaneous dose given within 24 hours of the IV loading dose (unless unable to receive IV infusion). Members who are unable to receive an infusion may initiate weekly injections without an intravenous loading dose. Members transitioning from intravenous therapy to subcutaneous administration should administer the first subcutaneous dose instead of the next scheduled intravenous dose.

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Background Information, continued:

Eligibility Criteria

- Member must be eligible and have applicable benefits.
- **Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.**

Exclusions

- Members less than six (6) years of age, as safety and efficacy have not been established.
- Concurrent administration of multiple biological response modifiers [including, but not limited to: Kineret (anakinra), Remicade (infliximab), Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Rituxan (rituximab)]. Only one (1) agent at a time will be covered for the treatment of Rheumatoid Arthritis.
- Members with a history of hypersensitivity to Orencia or any of its ingredients.
- Members experiencing clinically important, active infections including, but not limited to, sepsis, tuberculosis without treatment, aplastic anemia, or opportunistic infections.

Additional Information

- Requests received **for Medicare Members** will be reviewed using CMS “LCD for Abatacept (L29051)” – Refer to Attachment A or view on-line at:
http://www.cms.hhs.gov/mcd/results_index.asp?from=%27lmpcontractor%27&contractor=197&name=First+Coast+Service+Options%2C+Inc%2E+%2809102%2C+MAC+%2D+Part+B%29&letter_range=4&retired

Procedure:

- 1.0 Request for *initial therapy* with Orencia for **rheumatoid arthritis (RA)** requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following:
 - 1.1 Diagnosis of moderate to severe RA; **AND**
 - 1.2 Age 18 years of age or older; **AND**
 - 1.3 Member shows inadequate response to an adequate dose of Methotrexate; **OR**

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Procedure, continued:

- 1.0 Request for *initial therapy* with Orencia for **rheumatoid arthritis (RA)** requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following, continued:
- OR** 1.3 Member has contraindication to Methotrexate as evidenced by **at least one (1)** of the following:
- 1.3.1 Chronic liver disease;
 - 1.3.2 Leukopenia;
 - 1.3.3 Thrombocytopenia;
 - 1.3.4 Creatinine clearance less than 40mL/minute;
 - 1.3.5 Immunodeficiency; **AND**
- 1.4 Member shows inadequate response to an adequate dose of **OR** is not a candidate for at least (1) of the following DMARDs:
- 1.4.1 Oral or Injectable Gold;
 - 1.4.2 Leflunomide (Arava);
 - 1.4.3 Hydroxychloroquine (Plaquenil);
 - 1.4.4 Sulfasalazine;
 - 1.4.5 Azathioprine (Imuran);
 - 1.4.6 D-Penicillamine;
 - 1.4.7 Cyclosporine; **AND**
- 1.5 **For Commercial Members only (excludes Medicare or Miami Dade County):** Member shows inadequate response, or intolerance to, an adequate dose of both Humira (adalimumab) **AND** Enbrel (etanercept); **AND**
- 1.6 If Member meets the above criteria, initial therapy for Orencia may be approved for up to six (6) months at the following dosing:

Member’s Body Weight (in kg)	Dose/Route	Number of Vials (250mg/vial)
Less than 60kg	500mg IV	2
60-100kg	750mg IV	3
Over 100kg	1000mg IV	4
Subcutaneous Dose	150mg SC	0

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Procedure, continued:

- 2.0 Request for *continuation of therapy* beyond initial authorization period for **RA** requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the criteria required for initial therapy (as listed under section 1.0):
 - 2.1 If criteria are met, Orencia may be approved for up to six (6) months at the appropriate dosing (as listed in section 1.6).

- 3.0 Request for *initial therapy* with Orencia for **Polyarticular Juvenile Idiopathic Arthritis (JIA/JRA)** requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following:
 - 3.1 Diagnosis of moderate to severe JIA/JRA; **AND**
 - 3.2 Member at least six (6) years of age; **AND**
 - 3.3 Member shows inadequate response to an adequate dose of Methotrexate; **OR**
 - 3.3 Member has a contraindication to Methotrexate (as listed in section 1.3); **AND**
 - 3.4 Member shows inadequate response to an adequate dose of **OR** is not a candidate for at least one (1) of the DMARDs (as listed in section 1.4); **AND**
 - 3.5 **For Commercial Members only (excludes Medicare or Miami Dade County):** Member shows inadequate response to **OR** is not a candidate for both of the following medications:
 - 3.5.1 Humira (adalimumab); **AND**
 - 3.5.1 Enbrel (etanercept);
 - 3.6 If all criteria are met, initial therapy for Orencia may be approved for up to six (6) months at the following dosing:

Member’s Body Weight (in kg)	Dose/Route	Number of Vials (250mg/vial)
Less than 75kg	10mg/kg IV	Up to 3
75-100kg	750mg IV	3
Over 100kg	1000mg IV	4

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Procedure, continued:

- 4.0 Request for *continuation of therapy* beyond the initial authorization period for **JIA/JRA** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying the criteria required for initial therapy (section 3.0):
- 4.1. If criteria are met, Orencia may be approved for up to six (6) months at the appropriate dosing (as listed in section 3.6).

References:

1. Orencia (abatacept) Prescribing Information. Bristol-Myers Squibb. Princeton, NJ. April 2008.
2. Saag, KG. et al. American College of Rheumatology 2008 Recommendations for the Use of Nonbiologic and Biologic Disease-Modifying Antirheumatic Drugs in Rheumatoid Arthritis. *Arthritis & Rheumatism (Arthritis Care & Research)*. 2008; 59, 762–784.
3. Kremer, JM, et al. Treatment of Rheumatoid Arthritis with the Selective Costimulation Modulator Abatacept. *Arthritis Rheum* 2005; 52:2263.
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2008. Available at: <http://cp.gsm.com>.
5. Centers for Medicare & Medicaid Services, US Department of Health and Human Services. Local Coverage Determination (LCD) for Abatacept (L29051). 1st Quarter 2009 update. Revision 1, effective 02/02/2009.
6. Facts and Comparisons 4.0, St. Louis, MO. Walters Kluwer Health URL: www.factsandcomparisons.com Updated 2010.
7. Chowdhury, Badrul A. "SUPPLEMENT BLA APPROVAL." Letter to Ashley Pereira, Pharm.D. 29 July 2011. MS. Accessed online 30 September 2011. <http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/125118s0122ltr.pdf>

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Disclaimer Information:

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.