MEDICAL POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
6/10/2011	2/10/2015	2/10/2014
Policy Name		**Policy Number**
Abatacept (Orencia) Injection		**SRx-0011**

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

For Medicare plans please reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

A. SUBJECT

Abatacept (Orencia) Injection

B. BACKGROUND

The CareSource Medication Policies are therapy class policies that are used as a guide when determining health care coverage for our members with benefit plans covering prescription drugs. Medication Policies are written on selected prescription drugs requiring prior authorization or Step-Therapy. The Medication Policy is used as a tool to be interpreted in conjunction with the member's specific benefit plan.

The intent of the abatacept (Orencia) PA program is to encourage appropriate selection of therapy for patients according to product labeling and/or clinical guidelines and/or clinical studies, and also to encourage use of preferred agents.

C. DEFINITIONS

N/A

D. POLICY

Abatacept functions as an immunologic agent to block costimulation of T cells, reducing their role in the inflammatory response.

CareSource will approve the use of abatacept (Orencia), and considers its use as medically necessary when the following criteria have been met for:

- Rheumatoid arthritis
- Polyarticlar juvenile idiopathic arthritis

Rheumatoid Arthritis

Prior Authorization Criteria:

- Documented diagnosis of moderate to severe active rheumatoid arthritis (at least 6 swollen and 9 tender joints).
- Age 18 years or older
- Prescribed by a rheumatologist or under the recommendation of a rheumatologist.
- Inadequate response to 3 or more months of treatment with a DMARD (disease-modifying anti-rheumatic drug), including **1 or more** of the following:
  - methotrexate (e.g., Rheumatrex)
  - leflunomidesulfasalazine (Azulfidine)
- Inadequate response to3 or more months of one or more tumor necrosis factor (TNF) antagonists:
  - e.g. adalimumab (Humira), etanercept (Enbrel), infliximab (Remicade)

  OR
- Unable to tolerate or has a medical contraindication of conventional therapies

NOTE: Abatacept (Orencia) is proven as monotherapy or concomitantly with DMARDs *other than* anakinra or TNF antagonists.

Juvenile Idiopathic Arthritis

Prior Authorization Criteria as indicated by 1 or more of the following:

Initial course, as indicated by **ALL** of the following:

- Documented diagnosis of moderate to severe juvenile idiopathic arthritis..
- Prescribed by a rheumatologist or under the recommendation of a rheumatologist.
- Age 6 years or older
- Joint involvement of 5 joints or more
- Inadequate response to 3 or more months of treatment with a DMARD (disease-modifying anti-rheumatic drug), including **1 or more** of the following:
  - methotrexate (e.g., Rheumatrex)
  - leflunomidesulfasalazine (Azulfidine)
- Inadequate response to3 or more months of one or more tumor necrosis factor (TNF) antagonists:
  - e.g. adalimumab (Humira), etanercept (Enbrel), infliximab (Remicade)

  OR
- Unable to tolerate or has a medical contraindication of conventional therapies

NOTE: Abatacept (Orencia) is proven as monotherapy or concomitantly with DMARDs *other than* anakinra or TNF antagonists.

NOTE: It is recommended that JIA patients be brought up to date with all immunizations in agreement with current immunization guidelines prior to initiating therapy with abatacept (Orencia).

Note: Documented diagnosis must be confirmed by contemporaneous portions of the individual's medical record which will confirm the presence of disease and will need to be supplied with prior authorization request. These medical records may include, but not limited to test reports, chart notes from provider's office or hospital admission notes.

For Medicare Plan members, refer to the CareSource policy or Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD).

If there is no NCD or LCD present, reference the CareSource Policy for coverage.

CONDITIONS OF COVERAGE

HCPCS J0129
CPT

PLACE OF SERVICE
Office, Outpatient, Home
*****Preferred place of service is in the home*.**
Note: CareSource supports administering injectable medications in various settings, as long as those services are furnished in the most appropriate and cost effective setting that are supportive of the patient's medical condition and unique needs and condition. The decision on the most appropriate setting for administration is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of the specific medication.

AUTHORIZATION PERIOD
Approved initial authorizations are valid for 3 months. Continued treatment may be considered when the member has shown biological response to treatment.

ALL authorizations are subject to continued eligibility.

E. REVIEW/REVISION HISTORY

Date Issued:	06/10/2011
Date Reviewed:	06/10/2011, 01/10/2013, 02/10/2014, 02/10/2015
Date Revised:	01/10/2013 – Changes in APJIA criteria 02/10/2015 – recommended age added to RA, change in trial requirements for JIA and RA

F. REFERENCES

1. Orencia (abatacept) [prescribing information]. Princeton, NJ; Bristol-Myers Squibb Company: Revised April 2015.
2. Pollard L, Choy E. Rheumatoid Arthritis: Non-tumor necrosis factor targets. Curr Opin Rheumatol. 2005;17(3):242-46. Ruderman EM, Pope RM. The evolving clinical profile of abatacept (CTLA4Ig): A novel co-stimulatory modulator for the treatment of rheumatoid arthritis. Arthritis Res Ther. 2005;7 Suppl 2:S21-S25.
3. Orencia (abatacept) For Rheumatoid Arthritis. Available at: :http://arthritis.about.com/od/abatacept/a/orencia_(2/10/2011).
4. Voll RE, Kalden JR. Do we need new treatment that goes beyond tumor necrosis factor blockers for rheumatoid arthritis? Ann N Y Acad Sci. 2005;1051:799-810.
5. FDA Website. Approval History: BLA 125118/0045. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2008/125118s045ltr.pdf. (February 25, 2011)
6. Saag KG, Teng GG, Patkar NM, et al. American College of Rheumatology 2008 Recommendations for the Use of Non- biologic and Biologic Disease-Modifying Antirheumatic Drugs in Rheumatoid Arthritis. Arthritis Care & Research. Arthritis Rheum 2008;59(6):762-84.
7. Ruperto N, Lovell DJ, Quartier P, et al. Paediatric Rheumatology International Trials Organization; Pediatric Rheumatology Collaborative Study Group. Abatacept in children with juvenile idiopathic arthritis: A randomized, double-blind, placebo- controlled withdrawal trial. Lancet. 2008;372(9636):383-391.

8. Milliman Clinical Guidelines, 19th edition, 2015.

The medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.

Independent medical review – 5/2011