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
- Polyarticular 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)
  - lefunomidesulfasalazine (Azulfidine)
- Inadequate response to 3 or more months of one or more tumor necrosis factor (TNF) antagonists:
  - e.g. adalimumab (Humira), etanercept (Enbrel), infliximab (Remicade)
- 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)
  - lefunomidesulfasalazine (Azulfidine)
- Inadequate response to 3 or more months of one or more tumor necrosis factor (TNF) antagonists:
  - e.g. adalimumab (Humira), etanercept (Enbrel), infliximab (Remicade)
- 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.

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