MEDICAL POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
01/18/2013	02/14/2016	02/14/2015

Policy Name	Policy Number
Belimumab (Benlysta)	SRx-0005

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

Belimumab (Benlysta)

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 belimumab (Benlysta) 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

D. POLICY

CareSource will approve the use of belimumab (Benlysta) and consider its use as medically necessary when the following criteria have been met for:

Systemic Lupus Erythematosus (SLE)

Belimumab (Benlysta) is a B-lymphocyte stimulator (BLyS)-specific inhibitor indicated for the treatment of adult patients with active, autoantibody-positive, systemic lupus erythematosus who are receiving standard therapy.

Prior Authorization Criteria:

- Documented diagnosis of systemic lupus erythematosus
  AND
- 18 years of age or older
  AND
- Documented as autoantibody-positive (e.g., anti-nuclear antibody (ANA) titer ≥ 1:80 or anti-dsDNA level ≥ 30 IU/mL)
  AND
- Currently receiving at least one standard of care treatment for acute SLE with **ANY** of the following:
  - non-steroidal anti-inflammatory drugs (NSAIDS) (e.g. aspirin, ibuprofen, naproxen)
  - hydroxychloroquine
  - immunosuppressant agents(e.g.- azathioprine mycophenolate, methotrexate
  - cyclosporine)
  - corticosteroids (methylprednisolone, prednisone, etc.)
  - Unable to tolerate or has a medical contraindication to standard of care treatments as listed above.

ALL other uses of belimumab (Benlysta) are considered experimental/investigational and therefore, will follow CareSource's off-label policy.

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.

Refer to the product package insert for dosing, administration and safety guidelines.

For Medicare Plan members, refer to the CareSource policy and National and Local Coverage Determination

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

CONDITIONS OF COVERAGE

HCPCS J0490
CPT

PLACE OF SERVICE
Office, Outpatient
Note: CareSource supports administering inject able medications in various setting, 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
Coverage may be approved for up to 3 months. Coverage may be approved for re-treatment at 3 month intervals.

E. REVIEW/REVISION HISTORY

Date Issued: 01/18/2013
Date Reviewed: 01/18/2013, 02/14/2015
Date Revised: 02/14/2015 – Annual Review

F. REFERENCES

1. Benlysta® [prescribing information]. Rockville, MD: Human Genome Sciences, Inc.; Revised October 2014.
2. FDA Briefing Document for the Arthritis Advisory Committee Meeting: Benlysta/Belimumab. November 16, 2010. Available at: http://www.fda.gov/downloads/advisory committees/committees meeting materials/drugs/arthritis drugs advisory committee/ucm233579.pdf. Accessed March 12, 2012.
3. Furie R, Petri M, Zamani O, et al. A phase III, randomized, placebo-controlled study of belimumab, a monoclonal antibody that inhibits B lymphocyte stimulator, in patients with systemic lupus erythematosus. *Arthritis Rheum*. 2011 Dec;63(12):3918-30.
4. Navarra SV, Guzmán RM, Gallacher AE, et al. Efficacy and safety of belimumab in patients with active systemic lupus erythematosus: a randomized, placebo-controlled, phase 3 trial. *Lancet*. 2011 Feb 26;377(9767):721-31.
5. Wallace DJ, Stohl W, Furie RA, et al. A phase II, randomized, double-blind, placebo controlled, dose-ranging study of belimumab in patients with active systemic lupus erythematosus. *Arthritis Rheum*. 2009 Sep 15;61(9):1168-78.
6. American College of Rheumatology Ad Hoc Committee on Systemic Lupus Erythematosus Guidelines. Guidelines for referral and management of systemic lupus erythematosus in adults. *Arthritis Rheum*. 1999 Sep;42(9):785–96.
7. Gold Standard, Inc. Benlysta. Clinical Pharmacology [database online]. Available at: http://www.clinicalpharmacology.com. Accessed: March 12, 2012.
8. American College of Rheumatology. Belimumab for systemic lupus erythematosus. March 15, 2011.

"This guideline contains custom content that has been modified from the standard care guidelines and has not been reviewed or approved by MCG Health, LLC."

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

Independent medical review – 11/2012