PHARMACY POLICY STATEMENT

Original Effective Date	Next Annual Review	Last Revision
01/18/2013	01/18/2018	11/21/2016
Policy Name		**Policy Number**
Benlysta (belimumab)		SRx-0060-KY-MCD
Policy Type		
Medical	Administrative	**PHARMACY** Reimbursement

Pharmacy 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, Pharmacy Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Pharmacy 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 Pharmacy Policy Statement. If there is a conflict between the Pharmacy 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

Contents of Policy

A. INTRODUCTION

Benlysta (belimumab) is a monoclonal antibody that is administered intravenously, and used in the treatment of adult patients with active, auto-antibody positive systemic lupus erythematosus (SLE) who are receiving standard therapy. It works to reduce the activity of B-cell mediated immunity and the autoimmune response.

Benlysta has only been studied for the treatment of active SLE. It was shown to be ineffective in seronegative patients and is therefore only indicated in patients with active SLE who are auto-antibody positive (seropositive). Benlysta has not been studied as first-line treatment or monotherapy for SLE.

The intent of CareSource Pharmacy Policy Statements is to encourage appropriate selection of patients for therapy according to product labeling, clinical guidelines, and/or clinical studies as well as to encourage use of preferred agents. The CareSource Pharmacy Policy Statement is a guideline for determining health care coverage for our patients with benefit plans covering prescription drugs. Pharmacy Policy Statements are written on selected prescription drugs requiring prior authorization or step therapy. The Pharmacy Policy Statement is used as a tool to be interpreted in conjunction with the member's specific benefit plan.

NOTE: The Introduction section is for your general knowledge and is not to be construed as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals and is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider can also be a place where medical care is given, like a hospital, clinic or lab. This policy informs providers about when a service may be covered.

B. DEFINITIONS

1. SELENA-SLEDAI = Safety of Estrogens in Lupus Erythematosus National Assessment – Systemic Lupus Erythematosus Disease Activity Index

C. POLICY COVERAGE CRITERIA

1. Site of Service

Site of Service Administration	Coverage Criteria
Office, Outpatient	**Preferred place of service is in the practitioner's office or outpatient setting.** CareSource supports administering injectable medications in various settings, as long as those services are furnished in the most appropriate and cost effective settings that are supportive of the patient's medical condition(s) and unique needs and condition(s). The decision on the most appropriate setting for administration is based on the member's current medical condition(s) and any required monitoring or additional services that may coincide with the delivery of the specific medication.

2. Coverage Criteria

CareSource will approve the use of Benlysta (belimumab) and consider its use medically necessary when the criteria have been met for each condition listed below. Prior authorization request should be submitted with chart notes and documentation supporting medical necessity.

Condition	Benlysta Coverage criteria:
Systemic lupus erythematosus	1) Member is 18 years of age or older 2) Member has a diagnosis of active SLE 3) Has been prescribed by a rheumatologist 4) Prior to initiation of Benlysta therapy, member's disease is active as evidenced by SELENA-SLEDAI score of 6 or greater 5) Prior to initiating Benlysta therapy, member is autoantibody-positive as documented by anti-nuclear antibody (ANA) titer ≥1:80 and/or anti-double-stranded DNA (anti-dsDNA) ≥30 IU/mL. 6) Member meets all of the following: a. Member requires daily use of oral corticosteroids, unless contraindicated, or previously ineffective or not tolerated b. Previous treatment courses of at least 12 weeks each with 2 or more of the following have been ineffective: chloroquine, hydroxychloroquine, methotrexate, azathioprine, cyclophosphamide, or mycophenolate mofetil, unless all are contraindicated or not tolerated c. Member is not currently on intravenously administered cyclophosphamide or another biologic agent 7) Must only have involvement of the musculoskeletal and mucocutaneous system

All other uses of Benlysta are considered experimental/investigational; and therefore, will follow CareSource's off-label policy.

Please note that this policy is reviewed on an annual basis. New drugs and indications receiving FDA approval may not be reflected in this policy immediately.

Notes:

- Documented diagnosis must be confirmed by portions of the individual's medical record which need to be supplied with prior authorization request. These medical records may include, but are not limited to test reports, chart notes from provider's office, or hospital admission notes.
- Member is required to have completed the trial(s) listed in the above criteria unless the member is unable to tolerate or has a contraindication to trial medications. Documentation such as chart notes or pharmacy claims may be requested to verify trial(s), intolerance, or contraindication(s).
- Refer to the product package insert for dosing, administration and safety guidelines.

3. Dosage and Quantity Limits (listed if applicable)

Information for patients with renal or hepatic impairment is not included. See package insert for individual agents.

Condition	Dosage and Quantity Limit of Benlysta
Systemic lupus erythematosus	10 mg/kg at 2 week intervals for first 3 doses and at 4 week intervals thereafter

4. Authorization Period

Condition	Approval Period
Systemic lupus erythematosus	The initial authorization for Benlysta is valid for 3 months. Continued treatment may be considered when clinical benefit is achieved from Benlysta therapy (e.g., documentation of a reduction in SELENA-SLEDAI score) and member's disease state does not have involvement in the CNS or kidneys. All members must meet all initial authorization criteria for continuation of therapy. A reauthorization after successful initiation period will be placed for 3 months. **ALL** authorizations are subject to continued eligibility.

5. Coding

HCPCS	
J0490	Benlysta

D. RELATED POLICIES

AD-0004: Medical Necessity - Off-Label, Approved Orphan and Compassionate Use Drugs

E. REVIEW/REVISION HISTORY

DATE	ACTION/DESCRIPTION
01/18/2013	Issued, Reviewed
02/14/2015	Reviewed
01/14/2016	Reviewed, phenotypes, adding testing and lab values Updated references
11/21/2016	Updated format, added background information, prescribers, SELENA-SLEDAI score, duration of therapy for previous/current trials, limited disease involvement to musculoskeletal and mucocutaneous systems, and updated references

F. REFERENCES

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The Pharmacy Policy detailed above has received due consideration and is approved.

Independent medical review – 11/2012