Policy: MBP 90.0
Section: Medical Benefit Pharmaceutical Policy
Subject: Benlysta (belimumab)

I. Policy:
Benlysta (belimumab)

II. Purpose/Objective:
To provide a policy of coverage regarding Benlysta (belimumab)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.

(ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.

(iii) the service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.
DESCRIPTION:
Benlysta (belimumab) is a B-Lymphocyte stimulator-specific (BLyS) inhibitor that blocks the binding of soluble BLyS, a B-cell survival factor, to its receptors on B cells which inhibits the survival of B-cells, including autoreactive B cells, and reduces the differentiation of B cells into immunoglobulin-producing plasma cells.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Benlysta (belimumab) will be considered medically necessary for the treatment of insured individuals with active, autoantibody positive, systemic lupus erythematosus (SLE) when ALL of the following criteria are met:

- Medical record documentation of age greater than or equal to 5 years.
- Physician provided documentation of a diagnosis of active lupus; and
- Positive ANA/anti-dsDNA antibody; and
- Stable treatment regimen with prednisone, NSAID, anti-malarial or immunosuppressant; and
- No active severe nephritis or CNS involvement; and
- Must be prescribed by a Rheumatologist

Re-authorization Criteria:
Each authorization will be for a period of 12 months. Re-review is required with medical record documentation showing a clinical benefit of one of the following:

- Improvement in functional impairment
- Decrease in the number of exacerbations since the start of Benlysta
- Decrease in the daily required dose of oral corticosteroids such as Prednisone

LIMITATIONS
Benlysta has not been studied in combination with other biologics or intravenous cyclophosphamide. Use of Benlysta is not recommended in these situations.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 6/8/11

Revised: 2/12 (limitation), 3/13 (re-auth criteria) 3/24/15 (auth duration), 1/21/20 (age)

Reviewed: 1/14, 1/20/15, 3/16, 3/30/17, 3/29/18, 1/30/19, 11/1/19