Geisinger

POLICIES AND PROCEDURE MANUAL

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
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. 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 all lines of business for the treatment of insured individuals when ALL of the following criteria are met:

For active, autoantibody positive, Systemic Lupus Erythematosus (SLE)

- Medical record documentation of age greater than or equal to 5 years **AND**
- Physician provided documentation of a diagnosis of systemic lupus erythematosus **AND**
- Medical record documentation that patient has active disease OR recurrent flares OR inability to wean steroids in systemic lupus erythematosus **AND**
- Positive ANA/anti-dsDNA antibody **AND**
- Medical record documentation that Benlysta is being used in combination with, or patient has a contraindication or intolerance to, standard therapy (e.g. corticosteroid, NSAID, anti-malarial or immunosuppressant) **AND**
- No severe active CNS involvement **AND**
- Must be prescribed by a Rheumatologist **AND**
- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

AUTHORIZATION DURATION:
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

AND

- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

For active Lupus Nephritis

- Medical record documentation of age greater than or equal to 5 years **AND**
- Physician provided documentation of a diagnosis of active lupus nephritis, Class III, IV, V alone or in combination, confirmed by a kidney biopsy **AND**
- Benlysta will be prescribed in combination with standard therapy (e.g. mycophenolate mofetil (MMF), corticosteroids, cyclophosphamide, azathioprine) **AND**
- Prescription written by or in consultation with a rheumatologist or nephrologist **AND**
- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

AUTHORIZATION DURATION:
Initial approval will be for 12 months. Subsequent approvals will be for 12 months. Re-authorization will require the following:

- Medical record documentation of a positive clinical response to Benlysta (e.g. improvement/stabilization in UPCR, eGFR, renal-related events) **AND**
- Medical record documentation that Benlysta will be prescribed in combination with standard therapy (e.g. mycophenolate mofetil (MMF), corticosteroids, cyclophosphamide, azathioprine)

AND

- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

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.

REFERENCES:

1. Benlysta [prescribing information]. Philadelphia, PA: GlaxoSmithKline LLC; February 2023.
2. Fanouriakis A, Kostopoulou M, Alunno A, et al. 2019 update of the EULAR recommendations for the management of systemic lupus erythematosus [Internet]. Annals of the Rheumatic Diseases. 2019 March; 78:736-745 [cited 2022 Nov 17]. Available from: https://ard.bmj.com/content/78/6/736

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

Devised: 6/8/11

Revised: 2/2012 (limitation), 3/2013 (re-auth criteria) 3/24/15 (auth duration), 1/21/20 (age), 1/25/21 (nephritis), 7/20/21 (formatting, added Lupus Nephritis indication), 6/21/22 (dosing requirement, Medicaid PARP statement), 11/15/22 (standard therapy verbiage, LOB carve out), 12/23/22 (SLE Dx clarification, Lupus Nephritis age, Medicaid business segment), 1/26/24 (severe active SLE clarification, references)

Reviewed: 1/2014, 1/20/15, 3/2016, 3/30/17, 3/29/18, 1/30/19, 11/1/19, 1/1/21, 12/19/23