Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Benlysta (belimumab)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***March 2011 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Benlysta (belimumab).

Benlysta (belimumab) is indicated for the treatment of adult patients with active, autoantibody-positive, systemic lupus erythematosus (SLE) who are receiving standard therapy.

The efficacy of belimumab has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus. Belimumab has not been studied in combination with other biologics or intravenous cyclophosphamide. Use of belimumab is not recommended in these situations.

DEFINITIONS

Systemic Lupus Erythematosus (SLE) – a chronic inflammatory autoimmune condition that can cause disease of the skin, heart, lungs, kidneys, joints, and/or nervous system.

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Benlysta (belimumab), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by a rheumatologist
- Must have a diagnosis of systemic lupus erythematosus (SLE)
- Must not have either severe active lupus nephritis or severe active central nervous system lupus
- Must be auto-antibody positive, as evidenced through documentation of having one of the following laboratory markers:
    - Positive antinuclear antibodies (ANAs) titre ≥ 1:80
    - Anti-double stranded DNA (dsDNA) ≥ 30 IU/mL
- Must have an adequate trial of at least 3 months of hydroxychloroquine, azathioprine, methotrexate, or mycophenolate with an inadequate response, significant side effect/toxicity, or have a contraindication to these therapies
- Must be on concomitant therapy with an SLE regimen comprised of any of the following (alone or in combination): corticosteroids, antimalarials, non-steroidal anti-inflammatory drugs (NSAIDs), and immunosuppressives
- Must not have evidence of active infection
- Must not be on concomitant therapy with biologic therapies, including B-cell targeted therapies, or IV cyclophosphamide

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 6 months
Reauthorization	Up to 1 year

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Benlysta [package insert]. Rockville, MD: Human Genome Sciences, Inc.; March 2011
2. Navarra SV, Guzman 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;377:721-31
3. 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;61(9):1668-1178
4. American College of Rheumatology Ad Hoc Committee on Systemic Lupus Erythematosus Guidelines. Guidelines for the referral and management of systemic lupus erythematosus in adults. *Arthritis Rheum* 1999;42(9):1785-1796
5. Kurien BT, Scofield RH. Autoantibody determination in the diagnosis of systemic lupus erythematosus. *Scandinavian Journal of Immunology* 2006;64:227-235

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/17, 02/18*