## RX.PA.050.CCH BENLYSTA® (BELIMUMAB)

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

Benlysta® (belimumab) is indicated for:

- the treatment of patients aged 5 years and older with active, autoantibody-positive, systemic lupus erythematosus (SLE) who are receiving standard therapy
- Adult patients with active lupus nephritis who are receiving standard therapy

The efficacy of Benlysta® (belimumab) has not been evaluated in patients with severe active central nervous system lupus. Benlysta® (belimumab) has not been studied in combination with other biologics. Use of Benlysta® (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 Medical Policy Committee.

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

## PROCEDURE

**Initial Authorization Criteria:**

*Must meet all the criteria listed below:*

### 1. Systemic Lupus erythematosus

- Must be prescribed by, or in consultation with, a rheumatologist
- Must have a diagnosis of systemic lupus erythematosus (SLE)
- Must be at least age:
  - 5 years or older (intravenous formulation)
  - 18 years or older (subcutaneous formulation)
- Must NOT have 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) titer ≥ 1:80
  - Anti-double stranded DNA (dsDNA) ≥ 30 IU/mL
- Must have an adequate trial (of at least 3 months) of the following with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies:
  - Hydroxychloroquine **AND**
  - Azathioprine **OR** Methotrexate **OR** Mycophenolate
- 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
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling

### 2. Lupus Nephritis

- Must be prescribed by, or in consultation with, a rheumatologist or nephrologist
- Must have a diagnosis of active lupus nephritis confirmed by biopsy
- Must be at least age:
  - 5 years or older (intravenous formulation)
  - 18 years or older (subcutaneous formulation)
- Must NOT have 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) titer ≥ 1:80

  - Anti-double stranded DNA (dsDNA) ≥ 30 IU/mL
- Must be receiving one of the following combinations for standard therapy:
  - Corticosteroids with mycophenolate for induction and maintenance
  - Corticosteroids with cyclophosphamide for induction and azathioprine for maintenance
- Must not have evidence of active infection
- Must not be on concomitant therapy with biologic therapies, including B-cell targeted therapies
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling

## 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 1 year |
| Reauthorization | Same as initial |
| **Quantity Level Limit** | |
| Syringe/Auto-injector | 4 syringes/auto-injectors per 28 days |

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

## Codes:

| CPT Codes / HCPCS Codes / ICD-10 Codes | | |
|---|---|---|
| Code | Brand | Description |
| J0490 | Benlysta | INJECTION BELIMUMAB 10 MG |

### REFERENCES

1. Benlysta [package insert]. Rockville, MD: Human Genome Sciences, Inc.; December 2020.
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.

**REVIEW HISTORY**

| DESCRIPTION OF REVIEW / REVISION | DATE APPROVED |
|---|---|
| Initial Review | 3/22 |
| Revision of prerequisite trials for Systemic Lupus erythematosus and added requirement to be prescribed per FDA-approved labeling | 2/23 |

## 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.

## Disclaimer

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