belimumab (Benlysta®)

EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO112

Description

Belimumab (Benlysta) is a subcutaneously administered human IgG1 lambda monoclonal antibody that inhibits the binding of soluble human B lymphocyte stimulator protein (BLyS) to its receptors on the B cells.

Length of Authorization

- Initial: Six months
- Renewal: 12 months

Quantity limits

Product Name	Dosage Form	Indication	Quantity Limit
belimumab (Benlysta)	200 mg/mL syringe	Systemic Lupus Erythematosus (SLE)	4 syringes/28 days

Initial Evaluation

I. Belimumab (Benlysta) may be considered medically necessary when the following criteria below are met:
   A. Member is 18 years of age or older; **AND**
   B. Medication is prescribed by, or in consultation with, a rheumatologist; **AND**
   C. **Not** used in combination with other biologic(s) or intravenous cyclophosphamide; **AND**
   D. A diagnosis of **Systemic Lupus Erythematosus (SLE)** when the following are met:
      1. A confirmed positive autoantibody test [antinuclear (ANA) and/or anti-double-stranded DNA (anti-ds-DNA)]; **AND**
      2. A SLE Disease Activity Index (SELENA-SLEDAI) score of ≥ 8 supported by documentation in chart notes; **AND**
      3. Documentation of baseline Physician's Global Assessment (PGA) score; **AND**
      4. Treatment with **one** standard therapy agent from each category, has been ineffective, contraindicated, **or** ALL are not tolerated:
         i. Antimalarials (e.g., chlorquine, hydroxychloroquine)
         ii. NSAIDs (e.g., ibuprofen, naproxen)
         iii. Immunosuppressive (e.g., azathioprine, mycophenolate mofetil, methotrexate); **AND**
      5. Member will continue to receive standard therapy (e.g., antimalarials, NSAIDs, immunosuppressives, corticosteroids), unless all are contraindicated.

II. Belimumab (Benlysta) is considered investigational when used for all other conditions, including but not limited to:

A. Severe active lupus nephritis
B. Severe active central nervous system lupus

Renewal Evaluation

I. Member has received a previous prior authorization approval for this agent through this health plan; **AND**
II. Member is not continuing therapy based off being established on therapy through samples, manufacturer coupons, or otherwise. Initial policy criteria must be met for the member to qualify for renewal evaluation through this health plan; **AND**
III. Member has exhibited improvement or stability of disease symptoms (e.g., reduction in SELENA-SLEDAI score or PGA score); **AND**
IV. **Not** used in combination with other biologic(s) or intravenous cyclophosphamide; **AND**
V. Member will continue to receive standard therapy (e.g., antimalarials, NSAIDs, immunosuppressives, corticosteroids), unless all are contraindicated.

Supporting Evidence

I. The safety and efficacy of belimumab (Benlysta) in the setting of pediatric population was only studied with the intravenous formulation in an international, randomized, double blind, placebo-controlled, 52-week, trial involving 93 pediatric patients as young as five years of age. The primary efficacy endpoint was the SLE Responder Index (SRI-4) at Week 52, of the 53 randomized participants to the belimumab (Benlysta) arm, the SRI-4 was 53% while the placebo arm was 44% with an odds ratio of 1.49 and 95% CI (0.64, 3.46).
II. Belimumab (Benlysta) was shown to be ineffective in seronegative patients, and is therefore only indicated in patients with active SLE who are autoantibody positive (seropositive).
III. Per label, the use of belimumab (Benlysta) in combination with other biologics or intravenous cyclophosphamide has not been studied, and is not recommended.
IV. The safety and efficacy of belimumab (Benlysta) administered subcutaneously were evaluated in a randomized, double-blind, placebo-controlled trial involving 836 patients with SLE. Patients with severe active lupus nephritis and severe active CNS lupus were excluded. The primary efficacy endpoint was the SRI-4 at Week 52; in the belimumab (Benlysta) arm SRI-4 was 61% compared to placebo 48% with an odds ratio of 1.7 and 95% CI (1.3, 2.3).
    A. As reported in the trial baseline concomitant medications included corticosteroids (86%), antimalarials (69%), and immunosuppressives (46%, including azathioprine, methotrexate, and mycophenolate). Most patients (approximately 80%) were receiving 2 or more classes of SLE medications.

Investigational or Not Medically Necessary Uses

I. Severe active lupus nephritis and severe active central nervous system lupus
   A. Per label, the use of belimumab (Benlysta) in the setting of severe active lupus nephritis or severe active central nervous system lupus has not been evaluated, and efficacy has not been established; therefore, use is not recommended by the manufacturer in those instances.

References

1. Benlysta [Prescribing Information]. Rockville, MD: GlaxoSmithKline. September 2019.
2. Fanouriakis A, Kostopoulou M, Alunno A, et al. 2019 Update of the EULAR Recommendation for The Management of Systemic Lupus Erethmatosus. Annals of the Rheumatic Diseases 2019;78:736-745. Available at: https://ard.bmj.com/content/78/6/736
3. Lam NC, Ghetu MV, and Bieniek M. Systemic Lupus Erythematosus: Primary Care Approach to Diagnosis and Management. Am Fam Physician. 2016 Aug 15;94(4):284-294. Available at: https://www.aafp.org/afp/2016/0815/p284.html

Policy Implementation/Update:

Date Created	September 2017
Date Effective	November 2017
Last Updated	November 2019
Last Reviewed	11/2017, 11/2019

Action and Summary of Changes	**Date**
Criteria transitioned into policy with the following updates made: addition of supporting evidence and investigational section, removal of active infection question, removal of vaccine question, updated renewal question relating to symptom improvement into one question, and removing specific symptom improvement parameters to be consistent with the market.	11/2019