Benlysta (belimumab)

**Line(s) of Business:**
HMO; PPO; QUEST Integration
Akamai Advantage

**Original Effective Date:**
10/01/2015

**Current Effective Date:**
10/18/2016 TBD 01/01/2018

**POLICY**

**A. INDICATIONS**

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no contraindications or exclusions to the prescribed therapy.

**FDA-Approved Indication**

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

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

**B. REQUIRED DOCUMENTATION**

The following information is necessary to initiate the prior authorization review (where applicable):

- A completed Systemic Lupus Erythematosus Disease Activity Index SELENA Modification Form documenting member’s SELENA-SLEDAI* score (available from: https://www.rheumatology.org/Practice/Clinical/Indexes/Systemic_Lupus_Erythematosus_Disease_Activity_Index_SELENA_Modification/)
- Autoantibody test results

*Abbreviation: SELENA-SLEDAI = Safety of Estrogens in Lupus Erythematosus National Assessment – Systemic Lupus Erythematosus Disease Activity Index

**C. CRITERIA FOR APPROVAL**

1. **Systemic Lupus Erythematosus**

   Authorization of 6 months may be granted to members who meet ALL of the following criteria:
   
   a. Member is 18 years of age or older.
   
   b. Member has a diagnosis of active systemic lupus erythematosus.
c. Prior to initiation of Benlysta therapy, member’s disease is active as evidenced by Safety of SELENA-SLEDAI score of 6 or greater.
d. Prior to initiating Benlysta therapy, member is autoantibody-positive as demonstrated by anti-nuclear antibody (ANA) titer ≥1:80 and/or anti-double-stranded DNA (anti-dsDNA) ≥30 IU/mL.
e. Member meets either of the following:
   i. Member is currently receiving standard therapy for SLE (e.g., corticosteroids, azathioprine, leflunomide, methotrexate, mycophenolate, hydroxychloroquine).
   ii. Member has had an inadequate response or intolerance to standard therapy for SLE.
f. Member does NOT have severe active lupus nephritis or severe active central nervous system (CNS) lupus.
g. Benlysta will NOT be given in combination with other biologics or intravenous cyclophosphamide.

D. CONTINUATION OF THERAPY

All members, including new members, requesting authorization for therapy must meet ALL initial authorization criteria.

Members who were previously approved for Benlysta by HMSA may request reauthorizations after their initial approval. Approval for an additional 24 months may be granted for members with active SLE who achieve clinical benefit from Benlysta therapy (e.g., reduction in SELENA-SLEDAI score).

1. No previous authorization/precertification:
   All members (including members currently receiving treatment without prior authorization) must meet criteria for initial approval in section C.

2. Reauthorization:
   Authorization of 24 months may be granted to members with active SLE requesting authorization for continuation of therapy if Benlysta was previously authorized by HMSA/CVS and member achieved clinical benefit from Benlysta therapy (e.g., reduction in SELENA-SLEDAI score).

E. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

F. ADMINISTRATIVE GUIDELINES

Precertification is required. Please refer to the HMSA medical policy web site for the fax form.

G. IMPORTANT REMINDER

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.
This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that CVS/caremark reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

H. REFERENCES