Commercial/Healthcare Exchange PA Criteria

Effective: April 2011

Prior Authorization: Benlysta SQ

Products Affected:

- Benlysta (belimumab) Subcutaneous Solution

Medication Description:

Benlysta (belimumab) has been approved by the U.S. Food and Drug Administration (FDA) for the adjunctive treatment of active, autoantibody-positive, systemic lupus erythematosus (SLE).

Benlysta (belimumab) is a human IgG1λ monoclonal antibody that specifically recognizes and inhibits the biological activity of soluble human B-lymphocyte stimulator protein (BLyS). BLyS is a cytokine that belongs to the tumor necrosis factor (TNF) ligand family. It is expressed as transmembrane protein on various cell types including monocytes and bone marrow stromal cells and is required for the development of B-lymphocyte cells into mature plasma B cells (produce anti-bodies).

In systemic lupus erythematosus (SLE) elevated levels of BLyS are believed to contribute to the production of autoantibodies –antibodies that attack and destroy the body's own healthy tissues and the presence of autoantibodies appears to correlate with disease severity. Belimumab blocks the binding of soluble BLyS to its receptors on B cells and inhibits their survival, including autoreactive B cells, and reduces the differentiation of B cells into immunoglobulin-producing plasma cells.

Covered Uses:

- Systemic lupus erythematosus, active, autobody-positive, receiving standard therapy

Exclusion Criteria:

1. Pediatric patients
2. Severe active central nervous system lupus
3. Severe active lupus nephritis
4. Concomitant use of Benlysta SQ with other biologics or intravenous cyclophosphamide

Required Medical Information:

1. Diagnosis
2. Dose and frequency
3. Previous therapies tried
4. Patient has active, autobody-positive, systemic lupus erythematosus and is receiving standard therapy (anti-malarials, corticosteroids, non-steroidal anti-inflammatory drugs, immunosuppressives {excluding intravenous cyclophosphamide}) [documentation required]

Age Restrictions:

- Systemic lupus erythematosus: 18 years of age and older

Prescriber Restrictions: Prescribed by, or in consultation with, a rheumatologist, or a physician that specializes in diseases of joints and muscles

Coverage Duration: 12 months

Other Criteria:

Systemic lupus erythematosus:

Approve Benlysta SQ if the patient meets the following criteria (A, B, and C):

A. The patient has a documented diagnosis of active, autobody-positive, systemic lupus erythematosus; **AND**
B. Patient is receiving standard therapy (anti-malarials, corticosteroids, non-steroidal anti-inflammatory drugs, immunosuppressives {excluding intravenous cyclophosphamide}) [documentation required]); **AND**
C. Patient is 18 years of age or older; **AND**
D. Benlysta is being prescribed by, or in consultation with, a rheumatologist, or a physician that specializes in diseases of joints and muscles

References:

1. Benlysta [package insert]. Research Triangle Park, NC: GlaxoSmithKline; October 2017.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	10/31/2017
2	Update	CCI adopted EH Policy & Template; CCI P&T Review History:4/11, 12/11, 10/12, 10/13, 10/14, 11/15, 5/16, 5/17, 11/17, 5/18, 5/19 CCI Revision Record: 11/12, 2/16, 5/17, 11/17, 5/18	All	11/21/2019