

**EFFECTIVE DATE:** 06|01|2018

**POLICY LAST UPDATED:** 05|15|2018

## OVERVIEW

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

This policy is applicable to BlueCHiP for Medicare products only. For Commercial Products, see related policy section.

## MEDICAL CRITERIA

### Initial Evaluation

**Benlysta® (belimumab)** will be approved when ALL of the following are met:

1. ONE of the following:
  - A. There is documentation that the patient is currently being treated with the requested agent for an FDA approved indication

**OR**

  - B. The prescriber states that the patient is using the requested agent for an FDA approved indication AND is at risk if therapy is changed

**OR**

  - A. ALL of the following:
    - i. The patient has a diagnosis of active systemic lupus erythematosus (SLE) disease

**AND**

    - ii. The patient is 18 years of age or older

**AND**

    - iii. BOTH of the following:
      - a. The patient has a history of positive autoantibody test results [positive antinuclear antibody (ANA  $\geq$ 1:80) and/or anti-dsDNA ( $\geq$ 30 IU/mL)]

**AND**

      - b. The patient has a history of 3 other SLE diagnostic criteria (i.e. malar rash, discoid rash, photosensitivity, oral ulcers, nonerosive arthritis, serositis (e.g. pleuritis/pericarditis), renal disorder [e.g. persistent proteinuria  $>$ 0.5 grams/day or cellular casts], hematologic disorder [e.g. hemolytic anemia (with reticulocytosis), leukopenia, lymphopenia, or thrombocytopenia], and/or immunologic disorder (e.g. positive finding of antiphospholipid antibodies or anti-Sm antibodies)

**AND**

    - iv. ONE of the following:
      - a. The patient is currently on a standard of care SLE treatment regimen comprised of at least one of the following: corticosteroids, antimalarials (hydroxychloroquine, chloroquine), nonsteroidal anti-inflammatory drugs (NSAIDS), aspirin, and/or immunosuppressives (azathioprine, methotrexate, cyclosporine, oral cyclophosphamide, or mycophenolate)

**OR**

      - b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to ALL the standard of care drug classes listed above

**OR**

D. The patient has another FDA labeled diagnosis

**AND**

2. The patient does NOT have or has not had severe active lupus nephritis [proteinuria >6 g/24 hour or equivalent or serum creatinine >2.5 mg/dL OR required hemodialysis or high-dose prednisone >100 mg/day] within the past 90 days

**AND**

3. The patient does NOT have or has not had severe active central nervous system lupus [e.g. seizures, psychosis, organic brain syndrome, cerebrovascular accident, cerebritis, CNS vasculitis requiring therapeutic intervention] within the past 60 days

**AND**

4. The patient has NOT been treated with intravenous cyclophosphamide in the previous 6 months

**AND**

5. The patient is NOT currently using another biologic agent

**AND**

6. The patient is NOT currently being treated for a chronic infection

**AND**

7. The patient does not have any FDA labeled contraindications to the requested agent

**AND**

8. The dose is within the FDA labeled dosage (e.g. 10 mg/kg intravenously at 2-week intervals for the first 3 doses and at 4-week intervals thereafter for SLE).

**Length of Approval:** 12 months

The requested agent will also be approved when the following are met:

1. The patient has NOT been treated with intravenous cyclophosphamide in the previous 6 months

**AND**

2. The patient is NOT currently using another biologic agent

**AND**

3. The patient is NOT currently being treated for a chronic infection

4. **AND**

5. The patient does not have any FDA labeled contraindications to the requested agent

#### **Renewal Evaluation**

**Benlysta® (belimumab)** will be approved when ALL of the following are met:

1. The patient has been previously approved for Benlysta through the BCBSRI Medical Drug Review process

**AND**

2. ONE of the following:

A. The patient is currently on a standard of care SLE treatment regimen comprised of at least one of the following: corticosteroids, antimalarials (hydroxychloroquine, chloroquine), nonsteroidal anti-inflammatory drugs (NSAIDs), aspirin, and/or immunosuppressives (azathioprine, methotrexate, cyclosporine, oral cyclophosphamide, or mycophenolate)

**OR**

B. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to ALL the standard of care drug classes listed above

**AND**

1. The patient has had a decrease in symptoms or stabilization in at least one SLE diagnostic criteria (e.g. serositis, oral ulcers, arthritis, photosensitivity, blood disorders, renal involvement, antinuclear antibodies, immunologic phenomena, neurologic disorder, malar rash, discoid rash)

**AND**

2. The patient does NOT have or has not had severe active lupus nephritis [proteinuria >6 g/24 hour or equivalent or serum creatinine >2.5 mg/dL OR required hemodialysis or high-dose prednisone >100 mg/day] within the past 90 days  
**AND**
3. The patient does NOT have or has not had severe active central nervous system lupus [e.g. seizures, psychosis, organic brain syndrome, cerebrovascular accident, cerebritis, CNS vasculitis requiring therapeutic intervention] within the past 60 days  
**AND**
4. The patient has NOT been treated with intravenous cyclophosphamide in the previous 6 months  
**AND**
5. The patient is NOT currently using another biologic agent  
**AND**
6. The patient is NOT currently being treated for a chronic infection  
**AND**
7. The patient does not have any FDA labeled contraindications to the requested agent  
**AND**
8. The dose is within the FDA labeled dosage (e.g. 10 mg/kg intravenously at 2-week intervals for the first 3 doses and at 4-week intervals thereafter)

**Length of Approval:** 12 months

The requested agent will also be approved when the following are met:

1. The patient has been previously approved for Benlysta through the BCBSRI Medical Drug Review process  
**AND**
1. The patient has NOT been treated with intravenous cyclophosphamide in the previous 6 months  
**AND**
2. The patient is NOT currently using another biologic agent  
**AND**
3. The patient is NOT currently being treated for a chronic infection  
**AND**
4. The patient does not have any FDA labeled contraindications to the requested agent

**Length of Approval:** 12 months

### **PRIOR AUTHORIZATION**

Prior authorization is required for BlueCHiP for Medicare.

### **POLICY STATEMENT**

#### **BlueCHiP for Medicare**

Benlysta (Belimumab) is medically necessary when the criteria above have been met.

### **COVERAGE**

Benefits may vary between groups/contracts. Please refer to the appropriate, Evidence of Coverage for applicable physician administered drug benefits.

### **BACKGROUND**

#### **Systemic lupus erythematosus (SLE)**

Systemic lupus erythematosus is a chronic autoimmune disorder that can affect multiple organ systems and is a disease primarily found in working and reproductive-age women.

#### **Belimumab (also known as Benlysta):**

Belimumab is in a class of treatments referred to as monoclonal antibodies, and has been tested for potential use in Lupus patients. Belimumab is a B-lymphocyte stimulator (BlvS) specific inhibitor indicated for the

treatment of adult patients with active, autoantibody-positive, systemic lupus erythematosus who are receiving standard therapy.

Belimumab is a BlyS-specific inhibitor that blocks the binding of soluble BlyS, a B-cell survival factor to its receptors on B cells. Belimumab does not bind B cells directly, but works by binding BlyS, belimumab inhibits survival of B cells, including autoreactive B cells and reduces the differentiation of B cells into immunoglobulin-producing plasma cells.

The U.S. Food and Drug Administration (FDA) has approved the use of Belimumab in the treatment of lupus.

### **CODING**

#### **BlueCHiP for Medicare**

The following HCPCS code is covered when the medical criteria have been met:

**J0490** Injection, Belimumab, 10 mg

### **RELATED POLICIES**

Prior Authorization of Drugs

### **PUBLISHED**

Provider Update, June 2018

Provider Update, January 2018

Provider Update, December 2016

Provider Update December 2015

Provider Update, March 2014

Provider Update, November 2012

Provider Update, January 2012

### **REFERENCES**

1. Benlysta Prescribing Information. GlaxoSmithKline. January 2017.
2. Goldberg A, Katzap E. Belimumab for the Treatment of Systemic Lupus Erythematosus. *International Journal of Clinical Rheumatology*. 2010; 5(4):407-413.
3. FDA Arthritis advisory committee meeting briefing document BLA 125370. October 2010. Available at: [www.fda.gov/.../CommitteesMeetingMaterials/Drugs/ArthritisDrugsAdvisoryCommittee/UCM233581.pdf](http://www.fda.gov/.../CommitteesMeetingMaterials/Drugs/ArthritisDrugsAdvisoryCommittee/UCM233581.pdf). Accessed April 12, 2011.
4. American College of Rheumatology and Ad Hoc Committee on Systemic Lupus Erythematosus Guidelines. Guidelines for referral and management of systemic lupus erythematosus in adults. *Arthritis Rheum*. 1999; 42:1785-96.
5. Bertsias G, Ioannidis J, Boletis J, et al. EULAR recommendations for the management of systemic lupus erythematosus (SLE) report of a task force of the European Standing Committee for International Clinical Studies Including Therapeutics (ESCSIT). *Ann Rheum Dis*. 2008; 67:195-205.

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