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
   C. 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 ≥1:80) and/or anti-dsDNA (≥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

AND

4. 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 and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable physician administered drug benefits/coverage.

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, July 2019  
Provider Update, June 2018  
Provider Update, January 2018  
Provider Update, December 2016  
Provider Update December 2015

**REFERENCES**