EFFECTIVE DATE: 01|01|2012
POLICY LAST UPDATED: 11|21|2017

OVERVIEW

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

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 ≥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
4. **AND**
5. The patient does not have any FDA labeled contraindications to the requested agent
AND

1. The use of the target agent is for an indication that is supported by compendia. (NCCN Compendium™[level of evidence 1, 2A], AHFS, DrugDex [FDA approved Class I or Class IIa]), or the prescriber has submitted additional documentation (the use is supported by clinical research in 2 or more peer reviewed medical journals) supporting the requested therapeutic use (approval by the Clinical Review Pharmacist required).
AND
2. The requested dose is within FDA labeling or dose is supported by compendia. (NCCN Compendium™[level of evidence 1, 2A], AHFS, DrugDex [FDA approved Class I or Class IIa]), or the prescriber has submitted additional documentation (the dose is supported by clinical research in 2 or more peer reviewed medical journals) supporting the requested therapeutic dose.

Length of Approval: 12 months

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

AND

5. The use of the target agent is for an indication that is supported by compendia. (NCCN Compendium™ [level of evidence 1, 2A], AHFS, DrugDex [FDA approved Class I or Class IIa]), or the prescriber has submitted additional documentation (the use is supported by clinical research in 2 or more peer reviewed medical journals) supporting the requested therapeutic use (approval by the Clinical Review Pharmacist required).

AND

6. The requested dose is within FDA labeling or dose is supported by compendia. (NCCN Compendium™ [level of evidence 1, 2A], AHFS, DrugDex [FDA approved Class I or Class IIa]), or the prescriber has submitted additional documentation (the dose is supported by clinical research in 2

or more peer reviewed medical journals) supporting the requested therapeutic dose (approval by the Clinical Review Pharmacist required)

Length of Approval: 12 months

PRIOR AUTHORIZATION
Prior authorization is required for BlueCHiP for Medicare and recommended for Commercial products.

POLICY STATEMENT
BlueCHiP for Medicare and Commercial Products
Belimumab is medically necessary when the criteria above have been met.

COVERAGE
Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable physician administered drug benefits.

Specialty Pharmacy
For contracts with specialty drug coverage, please refer to the member agreement for benefits and preauthorization guidelines.

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 lyupus erythematosus who are receiving standard therapy.

Belimumab is a BLyS-specific inhibitor that blocks the binding of soluable 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 and Commercial Products
The following HCPCS code is medically necessary when the medical criteria have been met:
J0490 Injection, Belimumab, 10 mg

RELATED POLICIES
None

PUBLISHED
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. 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 (ESCISIT). *Ann Rheum Dis*. 2008; 67:195–205.

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