

**EFFECTIVE DATE:** 01|01|2012  
**POLICY LAST UPDATED:** 01|09|2014

### OVERVIEW

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

### PRIOR AUTHORIZATION

Prior authorization is required for BlueCHiP for Medicare and recommended for Commercial Products

### POLICY STATEMENT

#### BlueCHiP for Medicare and Commercial

Belimumab (Benlysta) is medically necessary when the criteria below has been met.

For contracts with specialty drug coverage, please refer to the member agreement for benefit guidelines

### MEDICAL CRITERIA

#### BlueCHiP for Medicare and Commercial

Belimumab (Benlysta) is **medically necessary** all of the following criteria has been met:

- Patient has a diagnosis of active SLE AND
- Patient is positive for autoantibodies prior to initiating therapy AND
- Patient does not have severe active lupus nephritis or severe active CNS lupus AND
- Patient is receiving standard therapy for SLE (eg, corticosteroids) AND
- Patient will not receive Benlysta in combination with other biologics or intravenous cyclophosphamide AND
- Patient is benefiting from Benlysta therapy for renewals

Initial approval may be granted for six months. After six months, approval for twelve months may be granted when treatment has been shown to benefit the member

### BACKGROUND

#### Systemic lupus erythematosus (SLE):

Systemic lupus erythematosus (SLE) 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 (also known as Benlysta™) 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 (BLyS) 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 FDA has recently approved the use of Belimumab in the treatment of Lupus.

## COVERAGE

### BlueCHiP for Medicare and Commercial

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement, or Benefit Booklet for applicable section regarding prescription drugs dispensed and administered by a licensed health care provider (other than a pharmacist) coverage/benefits.

For contracts with specialty drug coverage, please refer to the member agreement for benefit guidelines.

## CODING

### BlueCHiP for Medicare and Commercial

The following code is covered when the above criteria has been met:

**J0490** Injection, Belimumab, 10 MG

## RELATED POLICIES

None

## PUBLISHED

Provider Update Mar 2014

Provider Update Nov 2012

Provider Update Jan 2012

## REFERENCES

- I. Aran AA, Putterman C. Treatment of lupus nephritis: Facing the era of immunotherapy. *Panminerva Medica*; 2008;50(3):235-245.
- II. Furie R, Stohl W, Ginzler EM, et al. *Belimumab Study Group. Biologic activity and safety of belimumab, a neutralizing anti-B-lymphocyte stimulator (BLyS) monoclonal antibody: A phase I trial in patients with systemic lupus erythematosus.* *Arthritis Research & Therapy*;2008;10(5)1-15.
- III. GlaxoSmithKline Medication Guide. Benlysta (belimumab) injection for intravenous use. Issued: March 2011.
- IV. Navarra SV, Guzmán RM, Gallacher AE, et al; BLISS-52 Study Group. Efficacy and safety of belimumab in patients with active systemic lupus erythematosus: A randomised, placebo-controlled, phase 3 trial. *Lancet.* 2011;377(9767):721-731.

Wallace DJ. Advances in drug therapy for systemic lupus erythematosus *BioMed Central Medicine*;2010, 8:77. <http://www.biomedcentral.com/1741-7015/8/77>.

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