EFFECTIVE DATE: 01|01|2012
POLICY LAST UPDATED: 10|04|2016

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
BlueCHiP for Medicare and Commercial Products
Belimumab is **medically necessary** when all of the following criteria have 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 (e.g., corticosteroids) AND
- Patient will not receive Belimumab in combination with other biologics or intravenous cyclophosphamide AND
- Patient is benefitting from Belimumab therapy for renewals.

- Initial approval may be granted for six months. After 6 months, approval for 12 months may be granted when treatment has been shown to benefit the member.

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 section regarding prescription drugs dispensed and administered by a licensed health care provider (other than a pharmacist) coverage/benefits.

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

RELATED POLICIES

None

PUBLISHED

Provider Update, December 2016
Provider Update December 2015
Provider Update, March 2014
Provider Update, November 2012
Provider Update, January 2012

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3. GlaxoSmithKline Medication Guide. Benlysta (belimumab) injection for intravenous use. Issued: March 2011.

4. 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.

5. 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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