

Corporate Medical Policy

Belimumab (Benlysta)

File Name:	belimumab_benlysta
Origination:	6/2011
Last CAP Review:	2/2012
Next CAP Review:	2/2013
Last Review:	2/2012

Description of Procedure or Service

Belimumab (Benlysta) 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 by binding BLyS, belimumab inhibits the survival of B cells, including autoreactive B cells, and reduces the differentiation of B cells into immunoglobulin-producing plasma cells.

Systemic lupus erythematosus (SLE) is chronic autoimmune disorder that can affect multiple organ systems and is a disease primarily of working and reproductive-age women.

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will provide coverage for belimumab (Benlysta) for the treatment of autoantibody-positive systemic lupus erythematosus when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Belimumab (Benlysta) is covered

Belimumab may be considered medically necessary for patients:

1. 18 years of age or older; **and**
2. For the treatment of active, autoantibody-positive, systemic lupus erythematosus.

Belimumab (Benlysta)

When Belimumab (Benlysta) is not covered

Belimumab is considered not medically necessary for use in patients with:

- Severe active lupus nephritis
- Severe active central nervous system lupus

Belimumab is considered not medically necessary when used in combination with other biologics or intravenous cyclophosphamide.

Belimumab is considered **investigational** for all other indications, including but not limited to use in children.

Policy Guidelines

Belimumab is for intravenous infusion only. The recommended dosage regimen is 10mg/kg at 2 week intervals for the first 3 doses and at 4 week intervals thereafter.

The efficacy of belimumab has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus. Belimumab has not been studied in combination with other biologics or intravenous cyclophosphamide.

Serious and sometimes fatal infections have been reported in patients receiving immunosuppressive agents, including belimumab (Benlysta). Caution should be exercised when considering use in patients with a history of chronic infections. Patients receiving therapy for a chronic infection should not receive belimumab (Benlysta).

The safety and effectiveness of belimumab has not been established in children.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: J0490

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

U.S. Food and Drug Administration (FDA). Belimumab (Benlysta) injection. Highlights of prescribing information. March 2011. Available at:

Belimumab (Benlysta)

http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/125370s00001bl.pdf

Benlysta (belimumab). Product information. GlaxoSmithKline 2011.

Specialty Matched Consultant Advisory Panel- 2/2012

Policy Implementation/Update Information

- 7/1/11 New medical policy issued. Belimumab is considered medically necessary for treatment of active, autoantibody-positive, systemic lupus erythematosus. Notification date 7/1/2011 for effective date 10/1/2011. PPA implementation 10/1/2011. Medical director review 6/2011. (lpr)
- 12/6/11 Deleted statement: “who are not immunocompromised” under When Covered section. Added statement: “Serious and sometimes fatal infections have been reported in patients receiving immunosuppressive agents, including Benlysta. Caution should be exercised when considering use in patients with a history of chronic infections. Patients receiving therapy for a chronic infection should not receive Benlysta” to Policy Guidelines section. Reviewed with medical director. Removed HCPCS code Q2044 from the Billing/Coding section and added J0490 effective 1/1/2012. (lpr)
- 3/20/12 Under “When Not Covered” first two statements changed to read “not medically necessary” Instead of “investigational” and the last statement continues to read “investigational for all Other indications, including but not limited to use in children.” Specialty Matched Consultant Advisory Panel review meeting 2/29/12. No change to policy statement. (lpr)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.