

## Pharmacy Policy Bulletin

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**Title:** Belimumab (Benlysta®)

**Policy #:** Rx.01.203

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***Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.***

***This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.***

***Members are advised to use participating pharmacies in order to receive the highest level of benefits.***

### ▸ Intent:

The intent of this policy is to communicate the medical necessity criteria for belimumab (Benlysta®) as provided under the member's prescription drug benefit.

### ▸ Description:

Systemic lupus erythematosus (SLE) is an autoimmune disorder that is very heterogeneous with respect to its severity and the organs affected. Approximately 1.5 million Americans, primarily women of childbearing age, have a form of lupus. SLE represents approximately 70% of all lupus cases. Common clinical manifestations of SLE include pain, extreme fatigue, hair loss, cognitive issues, rashes (often the classic "butterfly rash"), arthritis and arthralgias. More severe clinical manifestations include renal, hematologic, or central nervous system involvement. SLE is often associated with relapses (which can be acute or chronic) and remissions.

BLyS, a B-cell survival factor, is overexpressed in patients with systemic lupus erythematosus (SLE) and other autoimmune diseases. Belimumab is an inhibitor that targets B-lymphocyte stimulator (BLyS) protein, which may reduce the number of abnormal B cells by blocking the binding of BLyS to its receptors on B-cells. An intravenous (IV) formulation of belimumab was approved by the FDA in 2011.

A subcutaneous formulation of the medication was approved by the FDA in July 2017.

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. Use of belimumab is not recommended in these situations.

### ▸ Policy:

Belimumab (Benlysta®) is approved when ALL of the following are met:

- A. Diagnosis of active systemic lupus erythematosus; and
- B. Autoantibody positive (ie, anti-nuclear antibody [ANA] titer greater than or equal to 1:80 or anti-dsDNA level greater than or equal to 30 IU/mL), antibodies to DNA [Anti-dsDNA], Anti-Smith [Anti-Sm]); and
- C. Currently receiving at least one standard of care treatment for active systemic lupus erythematosus (eg, antimalarials [eg, hydroxychloroquine], corticosteroids, NSAIDs, or immunosuppressants); and
- D. Prescribed by or in consultation with a rheumatologist.

▸ **Black Box Warning:**

N/A

▸ **Guidelines:**

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

**BENEFIT APPLICATION**

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

▸ **References:**

Benlysta® [Package Insert]. Rockville, MD: Human Genome Sciences, Inc.; June 2018. Available at [www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing\\_Information/Benlysta/pdf/BENLYSTA-PI-MG-IFU-COMBINED.PDF](http://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Benlysta/pdf/BENLYSTA-PI-MG-IFU-COMBINED.PDF). Accessed October 26, 2018.

Gladman DD, Pisetski DS, Curtis MR. Overview of the clinical manifestations of systemic lupus erythematosus in adults. UpToDate. Waltham, MA: UpToDate Inc. [https://www.uptodate.com.proxy1.lib.tju.edu/contents/overview-of-the-clinical-manifestations-of-systemic-lupus-erythematosus-in-adults?source=search\\_result&search=lupus&selectedTitle=1~150](https://www.uptodate.com.proxy1.lib.tju.edu/contents/overview-of-the-clinical-manifestations-of-systemic-lupus-erythematosus-in-adults?source=search_result&search=lupus&selectedTitle=1~150). Accessed on October 26, 2018.

Lupus facts and statistics. Lupus Foundation of America Web Site. <https://resources.lupus.org/entry/facts-and-statistics>. Published 2017. Accessed October 26, 2018.

▸ **Applicable Drugs:**

**i** Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Benlysta®	belimumab

 **Cross References:**

N/A

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<b>Policy Version Number:</b>	2.00
<b>P&amp;T Approval Date:</b>	October 11, 2018
<b>Policy Effective Date:</b>	January 1, 2019
<b>Next Required Review Date:</b>	October 12, 2019

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The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.