

## PHARMACY POLICY STATEMENT

### Georgia Medicaid

DRUG NAME	Benlysta (belimumab)
BILLING CODE	For medical - J0490 For Rx - must use valid NDC
BENEFIT TYPE	Medical or Pharmacy
SITE OF SERVICE ALLOWED	Outpatient/Office/Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT – N/A
LIST OF DIAGNOSES CONSIDERED <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

Benlysta (belimumab) is a **non-preferred** product and will only be considered for coverage under the **medical or pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

### SYSTEMIC LUPUS ERYTHEMATOSUS

For **initial** authorization:

1. Member is 18 years of age or older; AND
2. Medication must be prescribed by a rheumatologist; AND
3. Member must have active disease with SELENA-SLEDAI score of 6 or greater (documented in chart notes) prior to initiating Benlysta; AND
4. Member is autoantibody-positive with chart notes documentation of anti-nuclear antibody (ANA) titer  $\geq 1:80$  and/or anti-double-stranded DNA (anti-dsDNA)  $\geq 30$  IU/mL; AND
5. Member meets ALL of the following:
  - a) Member requires daily use of oral corticosteroids, unless contraindicated, or previously ineffective or not tolerated;
  - b) Member has tried and failed to respond to treatment with at least **two** of the following: chloroquine, hydroxychloroquine, methotrexate, azathioprine, cyclophosphamide, or mycophenolate mofetil for at least 12 weeks;
  - c) Member is not currently on intravenously administered cyclophosphamide or another biologic agent.
6. **Dosage allowed:** Intravenously 10 mg/kg at 2 week intervals for first 3 doses and at 4 week intervals thereafter. Subcutaneously 200 mg once weekly.

***If member meets all the requirements listed above, the medication will be approved for 6 months.***

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Member has SELENA-SLEDAI score improvement documented in chart notes; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***



**CareSource considers Benlysta (belimumab) not medically necessary for the treatment of the diseases that are not listed in this document.**

DATE	ACTION/DESCRIPTION
10/18/2017	New policy for Benlysta created. Length of approval was increased, system involvement limitations were removed and improvement of SELENA-SLEDAI score was added in reauthorization.

References:

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2. FDA Briefing Document for the Arthritis Advisory Committee Meeting: Benlysta/Belimumab. November 16, 2010. Available at: <http://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/drugs/arthritisdrugsadvisorycommittee/ucm233579.pdf>.
3. Furie R, Petri M, Zamani O, et al. A phase III, randomized, placebo-controlled study of belimumab, a monoclonal antibody that inhibits B lymphocyte stimulator, in patients with systemic lupus erythematosus. *Arthritis Rheum.* 2011; 63 (12): 3918 – 30.
4. Navarra SV, Guzman RM, Gallacher AE, et al. Efficacy and safety of belimumab in patients with active systemic lupus erythematosus: a randomized, placebo-controlled, phase 3 trial. *Lancet.* 2011; 26 (377): 721 – 31.
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6. American College of Rheumatology Ad Hoc Committee on Systemic Lupus Erythematosus Guidelines. Guidelines for referral and management of systemic lupus erythematosus in adults. *Arthritis Rheum.* 1999; 42 (9): 1785 – 1796.
7. Gold Standard, Inc. Benlysta. Clinical Pharmacology [database online]. Available at: <http://www.clinicalpharmacology.com>.
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9. Bertsias G, Ioannidis JP, Boletis J, et al. EULAR recommendations for the management of systemic lupus erythematosus. Report of a Task Force of the EULAR Standing Committee for International Clinical Studies Including Therapeutics. *Ann Rheum Dis.* 2008; 67 (2): 195 – 205.
10. Belimumab. Lexi-Drugs Online [database on internet]. Hudson, OH: Lexi-Comp, Inc.; 2007. Available from: <http://online.lexi.com>
11. American College of Rheumatology Ad Hoc Committee on Systemic Lupus Erythematosus Response Criteria. The American College of Rheumatology response criteria for systemic lupus erythematosus clinical trials: measures of overall disease activity. *Arthritis Rheum.* 2004; 50 (11): 3418 – 26.
12. Petri M. Disease activity assessment in SLE: do we have the right instruments? *Ann Rheum Dis.* 2007; 66 (suppl III):iii61 – iii64.

Effective date: 11/08/2017

Revised date: 10/18/2017