CareSource

PHARMACY POLICY STATEMENT
Ohio 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	Office/Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— see **Dosage allowed** below
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

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 5 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 ≥1:80 and/or anti-double-stranded DNA (anti-dsDNA) ≥ 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 (for adult and pediatric members) 10 mg/kg at 2 week intervals for first 3 doses and at 4 week intervals thereafter. Subcutaneously (only for adult members) 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 following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

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

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.
07/28/2019	Age coverage expanded from adult population (18 years old and older) to pediatric population of 5 years old and older.

References:

1. Benlysta [package insert]. Rockville, MD: Human Genome Sciences, Inc.; April, 2019.
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.
5. Wallace DJ, Sohl W, Furie RA, et al, A phase II, randomized, double-blind, placebo-controlled, dose-ranging study of belimumab in patients with active systemic lupus erythematosus. Arthritis Rheum. 2009; 61 (9): 1168 – 78.
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.
8. American College of Rheumatology. Belimumab for systemic lupus erythematosus. March 15, 2011.
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.
13. ClinicalTrials.gov. Identifier: NCT01649765. Pediatric Lupus Trial of Belimumab Plus Background Standard Therapy (PLUTO). Available at: https://clinicaltrials.gov/ct2/show/NCT01649765?term=01649765&rank=1.

Effective date: 09/26/2019
Revised date: 07/28/2019