MEDICAL MUTUAL®

Drug Policy

Policy:	**201107**	**Initial Effective Date: 05/31/2011**
Code(s):	**HCPCS J0490**	**Annual Review Date: 08/16/2018**
SUBJECT:	**Benlysta® (belimumab injection for intravenous use)** **Benlysta® (belimumab injection for subcutaneous use)**	**Last Revised Date: 08/16/2018**

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

OVERVIEW

Belimumab (Benlysta®, Human Genome Sciences, Inc., Rockville, MD) is a fully human IgG1λ monoclonal antibody specific for soluble human B lymphocyte stimulator protein (BLyS). The drug blocks the binding of soluble human B lymphocyte stimulator to its receptors on B cells, thereby inhibiting activity of B cell activating factor (BAFF). Belimumab has been approved by the U.S. Food and Drug Administration (FDA) for treatment of active, autoantibody†-positive, systemic lupus erythematosus (SLE) in combination with conventional medical therapy.

POLICY STATEMENT

This policy involves the use of BENLYSTA. Prior authorization is recommended for pharmacy and medical benefit coverage of BENLYSTA. Approval is recommended for those who meet the conditions of coverage in the **Criteria, Dosing, Initial/Extended Approval, Duration of Therapy**, and **Labs/Diagnostics** for the diagnosis provided. **Waste Management** applies for all covered conditions that are administered by a healthcare professional. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria and Waste Management section. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with BENLYSTA as well as the monitoring required for AEs and long-term efficacy, initial approval requires BENLYSTA be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

The Site of Care Medical Necessity Criteria applies to initial therapy and reauthorizations under the medical benefit.

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RECOMMENDED AUTHORIZATION CRITERIA
Coverage of BENLYSTA is recommended in those who meet the following criteria:

1. **FDA Approved Indication**
   Systemic Lupus Erythematosus. *Patient must meet the following criteria*

   The Company considers belimumab **(HCPCS Code J0490) medically necessary** and eligible for reimbursement providing that ***all*** of the following medical criteria are met:

   a. Age ≥18 years; and
   b. Active, autoantibody[†]-positive systemic lupus erythematosus despite ≥6 weeks trial of conventional medical therapy; and
   c. SLE is active as documented by a SELENA-SLEDAI score greater than or equal to 6 while on current treatment regimen; AND
   d. Used in combination with conventional medical therapy (e.g., corticosteroids, antimalarials, or other immunosuppressants with or without nonsteroidal anti-inflammatories); AND
   e. Severe active systemic lupus erythematosus nephritis and/or severe active central nervous system lupus erythematosus are not present; AND
   f. Belimumab will not be used in combination with another biologic agent or intravenous cyclophosphamide; AND
   g. Site of care medical necessity is met*.

   [†]Positive antinuclear antibody (ANA) [titer ≥1:80] or positive double-stranded DNA (anti-dsDNA) level ≥30 IU/mL

Dosing in Systemic Lupus Erythematosus. *Dosing must meet the following:*
IV: The recommended dosage regimen is 10 mg/kg at 2-week intervals for the first 3 doses and at 4-week intervals thereafter. Reconstitute, dilute, and administer as an intravenous infusion only, over a period of 1 hour. The infusion rate may be slowed or interrupted if the patient develops an infusion reaction. The infusion must be discontinued immediately if the patient experiences a serious hypersensitivity reaction. Consider administering premedication for prophylaxis against infusion reactions and hypersensitivity reactions.

SC: 200 mg once weekly

Initial Approval/ Extended Approval.
A) *Initial Approval:* 6 months
B) *Extended Approval:* Approve for an additional 12 months of therapy if the patient has responded to therapy as determined by the prescribing physician.

Waste Management for All Indications.

Intravenous Infusion

For injection: 120 mg or 400 mg lyophilized powder in single-dose vials for reconstitution and dilution prior to intravenous infusion.

Subcutaneous Injection

Injection: 200 mg/mL as a clear to opalescent, and colorless to pale yellow solution in a single-dose prefilled autoinjector or a single-dose prefilled glass syringe.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

BENLYSTA has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. American College of Rheumatology Ad Hoc Committee on System Lupus Erythematosus Guidelines. (1999). Guidelines for referral and management of systemic lupus erythematosus in adults. Arthritis Rheum, 42(9), 1785-1796.
2. Benlysta (belimumab) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; June 2018.
3. Bertsias, G., Ioannidis, J. P., Boletis, J., Bombardien, S., Cervera, R., Dostal, C., … Boumpas, D.T. (2008). EULAR recommendations for the management of systemic lupus erythematosus (SLE). Report of a Task Force of the EULAR Standing Committee for International Clinical Studies Including Therapeutics (ESCISIT). Ann Rheum Dis, 67(2), 195-205.
4. Centers for Medicare & Medicaid Services: belimumab. No national or local coverage determination found in the coverage database. May 19, 2011.
5. 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 Dec;63(12):3918-30.
6. Hayes, Inc. (2011, March). Benlysta® (belimumab). Lansdale, PA: Author.

7. Jacobi, A. M., Huang, W., Wang, T., Freimuth, W., Sanz, I., Furie, R, Davidson, A. (2010). Effect of long-term belimumab treatment on B cells in systemic lupus erythematosus: extension of a phase II, double-blind, placebo-controlled, dose-ranging study. Arthritis Rheum, 62(1), 201-210.
8. Navarra, S. V., Guzmán, R. M., Gallacher, A. E., Hall, S., Levy, R. A., Jimenez, R. E.,Petri, M. A. (2011). Efficacy and safety of belimumab in patients with active systemic lupus erythematosus: a randomized, placebo-controlled, phase 3 trial. The Lancet, 377(9767), 721-731.
9. Wallace, D. J., Stohl, W., Furie, R. A., Lisse, J. R., McKay, J. D., Merrill, J. T., Freimuth, W. W. (2009). A phase II, randomized, double-blind, placebo-controlled, dose-ranging study of belimumab in patients with active systemic lupus erythematosus. Arthritis Rheum, 61(9), 1168-1178.
10. Borba HH, Wiens A, de Souza TT, Correr CJ, Pontarolo R. BioDrugs. 2014 Apr;28(2):211-28. Efficacy and safety of biologic therapies for systemic lupus erythematosus treatment: systematic review and meta-analysis.
11. Shida Y, Takahashi N, Sakamoto T, Ino H, Endo A, Hirama T.The pharmacokinetics and safety profiles of belimumab after single subcutaneous and intravenous doses in healthy Japanese volunteers. J Clin Pharm Ther. 2014. Feb;39(1):97-101.
12. Merrill JT, Ginzler EM, Wallace DJ, et al. Long-term safety profile of belimumab plus standard therapy in patients with systemic lupus erythematosus. Arthritis Rheum. 2012 Oct;64(10):3364-73.
13. Navarra SV, Guzmán RM, Gallacher AE,et al. Efficacy and safety of belimumab in patients with active systemic lupus erythematosus: a randomised, placebo-controlled, phase 3 trial. Lancet. 2011 Feb 26;377(9767):721-31.

FOR MEDICAL BENEFIT COVERAGE REQUESTS:

MMO Site of Care Medical Necessity Criteria:

Medications in this policy will be administered in a place of service that identifies the location to be a non-hospital facility based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center) unless *at least one* of the following are met[†]:

1. Age less than 21 years; or
2. Clinically unstable based upon documented medical history (e.g., patient is hemodynamically unstable); or
3. History of a severe adverse event from previous administration of the prescribed medication; or
4. Requested medication is being administered as follows:
   - part of a chemotherapy regimen (e.g., anti-neoplastic agent, colony stimulating factor, erythropoiesis-stimulating agent, anti-emetic) for treatment of cancer; or
   - administered with dialysis; or
5. Physical or cognitive impairment and caregiver is not available to assist with safe administration of prescribed medication in the home; or
6. Benlysta IV: Up to 3 dose of medication or re-initiation after at least 12 months; or
7. Benlysta SC: No doses in a hospital based outpatient facility doses. All doses need to be at NHFBL
8. Experiencing adverse events that are not managed by premedication or resources available at a non-hospital facility based location.

[†]This criterion does not apply to Medicare or Medicare Advantage members.

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Prior approval is required for HCPCS Code J0490

HCPCS Code(s):	
J0490	Injection, belimumab, 10 mg