Clinical Policy: Belimumab (Benlysta)

Reference Number: CP.PHAR.88
Effective Date: 10.11
Last Review Date: 11.17
Line of Business: Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Belimumab (Benlysta®) is B-lymphocyte stimulator specific inhibitor.

FDA Approved Indication

Benlysta is indicated for the treatment of adult patients with active, autoantibody-positive, systemic lupus erythematosus (SLE) who are receiving standard therapy.

Limitations of use: The efficacy of Benlysta has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus. Benlysta has not been studied in combination with other biologics or intravenous cyclophosphamide. Use of Benlysta is not recommended in these situations.

Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation® that Benlysta is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Systemic Lupus Erythematosus (must meet all)**:**

1. Diagnosis of SLE;
2. Age ≥ 18 years;
3. Documentation confirms that member is positive for anti-nuclear antibody and/or anti-double-stranded DNA (deoxyribonucleic acid);
4. Currently receiving standard therapy for SLE that includes one or more of the following agents, unless all agents are contraindicated: glucocorticoids (e.g., prednisone), antimalarial (e.g., hydroxychloroquine or chloroquine), non-biologic immunosuppressants (e.g., azathioprine, methotrexate, mycophenolate);
5. Member is not currently receiving treatment for a chronic infection;
6. Dose does not exceed 10 mg/kg/dose.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Systemic Lupus Erythematosus (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Documentation of positive response to therapy;
3. If request is for a dose increase, new dose does not exceed 10 mg/kg/dose.

Approval duration: 12 months

B. Other diagnoses/indications (1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PHAR.57 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
DNA: deoxyribonucleic acid
SLE: Systemic lupus erythematosus

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Systemic lupus erythematosus	10 mg/kg at 2 week intervals for the first 3 doses and at 4 week intervals thereafter	10 mg/kg/dose

VI. Product Availability

Injection: 120 mg and 400 mg lyophilized powder in single-dose vials for reconstitution

VII. References

1. Benlysta Prescribing Information. Research Triangle Park, NC: GlaxoSmithKline; November 2015. Available at http://www.benlysta.com. Accessed August 18, 2016.
2. 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.
3. Petri M, Orbai AM, Alarcon GS, et al. Derivation and validation of Systemic Lupus International Collaborating Clinics classification criteria for system lupus erythematosus. Arthritis Rheum. 2012 August; 64(8): 2677-2686. doi:10.1002/art.34473.
4. Bertsias G, Loannidis JPA, 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. doi:10.1136/ard.2007.070367.

5. Van Vollenhoven RF, Mosca M, Bertsias G, et al. Treat-to-target in systemic lupus erythematosus: recommendation from an international task force. Ann Rheum Dis. 2014; 73: 958-967. doi: 10.1136/annrheumdis-2013-205139
6. Romero-Diaz J, Isenberg D, Ramsey-Goldman R. Measures of adult systemic lupus erythematosus: Updated Version of British Isles Lupus Assessment Group (BILAG 2004), European Consensus Lupus Activity Measurements (ECLAM), Systemic Lupus Activity Measure, Revised (SLAM-R), Systemic Lupus Activity Questionnaire for Population Studies (SLAQ), Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K), and Systemic Lupus International Collaborating Clinics/American College of Rheumatology Damage Index (SDI). Arthritis Care Res (Hoboken). 2011 November; 63(11). doi:10.1002/acr.20572.

Reviews, Revisions, and Approvals	Date	Approval Date
Updated background information Updated safety information. Appendix B: Cyclophosphamide added	12.13	12.13
Algorithm modified to include current prescribing recommendations for lab testing, and question regarding chronic infection	12.14	12.14
Converted policy to new format. In criteria, broadened question around disease activity in initial and re-auth; included live vaccine limitation in the safety appendix. Shortened narrative; limited appendices to abbreviation key, safety appendix, appendix of disease activity instruments. Limited references to package insert (updated), guidelines, and a review of validated disease activity instruments.	11.15	11.15
Converted policy to new template; modified approval criteria to 6 month and 12 months for initial and renewal criteria respectively. Added anaphylaxis with prior Benlysta administration as contraindication in initial and continuation criteria.	09.16	11.16
Converted to new template. Safety criteria applied according to the safety guidance discussed at CPAC and endorsed by Centene Medical Affairs.	09.17	11.17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.