Clinical Policy: Belimumab (Benlysta)

Reference Number: ERX.SPA.213
Effective Date: 12.01.15
Last Review Date: 11.17 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(s)
Benlysta is indicated for the treatment of adult patients with active, autoantibody-positive, systemic lupus erythematosus who are receiving standard therapy.

Limitation(s) 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 Envolve Pharmacy Solutions™ 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 systemic lupus erythematosus (SLE);
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years;
4. Documentation confirms that member is positive for anti-nuclear antibody (ANA) and/or anti-double-stranded DNA [anti-dsDNA]);
5. 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 agents (e.g., hydroxychloroquine or chloroquine), non-biologic immunosuppressants (e.g., azathioprine, methotrexate, mycophenolate);
6. Dose does not exceed:
   a. IV: 10 mg/kg/dose;
   b. SC: 200 mg per week.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 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 a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed:
   a. IV: 10 mg/kg/dose;
   b. SC: 200 mg per week.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 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 – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
SLE: systemic lupus erythematosus

Appendix B: Therapeutic Alternatives
N/A

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
SLE	IV: 10 mg/kg at 2 week intervals for the first 3 doses and at 4 week intervals thereafter SC: 200 mg once weekly	IV: 10 mg/kg/dose SC: 200 mg per week

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; July 2017. Available at http://www.benlysta.com. Accessed September 17, 2017.
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).

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	11.15	12.15
Converted to new template. Removed age restriction and references to contraindications.	11.16	12.16
4Q17 Annual Review No significant changes. References updated and added age per PI.	09.17.17	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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.

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