Clinical Policy: Belimumab (Benlysta)

Reference Number: PA.CP.PHAR.88
Effective Date: 01/18
Last Review Date: 07/17/19

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for belimumab (Benlysta®).

FDA Approved Indication(s)
Benlysta is indicated for the treatment of adult patients with active, autoantibody-positive, systemic lupus erythematosus (SLE) 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
It is the policy of Pennsylvania Health and Wellness that Benlysta is **medically necessary** when one of the following criteria are met:

I. Initial Approval Criteria

A. Systemic lupus erythematosus (must meet all):

1. Diagnosis of SLE;
2. Prescribed by or in consultation with a rheumatologist;
3. Documentation confirms that member is positive for autoantibody (e.g., anti-nuclear antibody (ANA), anti-double-stranded DNA (anti-ds-DNA), anti-Smith antigen (anti-Sm), anti-ribonucleoprotein (anti-RNP), anti-Ro/SSA, anti-La/SSB);
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. Dose does not exceed 10 mg/kg/dose IV or 200 mg/week SC.

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. Systemic lupus erythematosus (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Documentation supports that member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 10 mg/kg/dose IV or 200 mg/week SC.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53

Background

Description/Mechanism of Action:

Belimumab is a human IgG1λ monoclonal antibody specific for soluble human B lymphocyte stimulator protein (BLyS). It is produced by recombinant DNA technology in a mammalian cell expression system. Belimumab blocks the binding of soluble BLyS, a B-cell survival factor, to its receptors on B cells. Belimumab does not bind B cells directly, but by binding BLyS, belimumab inhibits the survival of B cells, including autoreactive B cells, and reduces the differentiation of B cells into immunoglobulin-producing plasma cells.

Formulations:

Benlysta is available in 120mg and 400mg per single-use vial as a lyophilized powder for intravenous injection or 200mg/ml single dose subcutaneous auto injector or single-dose prefilled syringe.

Appendices

Appendix A: Abbreviation Key

SLE: Systemic lupus erythematosus
ANA: anti-nuclear antibody
Anti-dsDNA: anti-double-stranded deoxyribonucleic acid
BLyS: B-lymphocyte stimulator

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J0490	Injection, belimumab, 10 mg

Reviews, Revisions, and Approvals	Date	Approval Date
added prescriber requirement, removed requirement to confirm lack of chronic infection treatment, expanded list of accepted autoantibodies; references reviewed and updated.	05.18	

Reviews, Revisions, and Approvals	Date	Approval Date
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/17/19	

References

i. Benlysta Prescribing Information. Research Triangle Park, NC: GlaxoSmithKline; July 2017. Available at http://www.benlysta.com. Accessed May 9, 2018.
ii. 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.
iii. 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.
iv. 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.
v. 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
vi. 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.