

Title: belimumab (Benlysta)

Origination: 08/24/11	Revised:	Annual Review: 12/15/11
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Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Background Information:

Reference Statement

- Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

Medication Summary

- Belimumab is a human monoclonal antibody that inhibits B lymphocyte stimulator protein (BLyS). Inhibition of BLyS inhibits the survival of B cells (recent research suggests enhanced B cell function is the defining pathogenic event of SLE) including autoreactive B cells and reduces the differentiation of B cells into immunoglobulin-producing plasma cells. Belimumab is indicated as an adjunct to standard therapy for the treatment of active, autoantibody-positive, systemic lupus erythematosus (SLE).

Eligibility Criteria

- Member must be eligible and have applicable benefits.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

Exclusions

- Members with severe active lupus nephritis or severe active central nervous system lupus.
- Concurrent administration of other intravenous cyclophosphamide or biologics.
- Members who are autoantibody negative.

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Procedure:

- 1.0 Request for *initiation* with Benlysta for adult Members with **Active, Autoantibody-positive, systemic lupus erythematosus (SLE)** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying all of the following:
 - 1.1 Member's diagnosis of active systemic lupus erythematosus; **AND**
 - 1.2 Member has a serological test for SLE and is autoantibody (e.g. ANA, anti-ds-DNA, anti-Sm) positive evidenced by either:
 - 1.2.1 ANA>1:80 **OR**
 - 1.2.1 Anti-ds DNA≥30 IU/ml; **AND**
 - 1.3 Member does not have severe active lupus nephritis evidenced by:
 - 1.3.1 SrCr>2.5ml/dl; **OR**
 - 1.3.1 Proteinuria>6g/dl; **OR**
 - 1.3.2 Prednisone >100mg/day; **AND**
 - 1.4 Member does not have severe active central nervous system lupus; **AND**
 - 1.5 Has not had an active or chronic infection in the last 60 days; **AND**
 - 1.6 Member shows inadequate response to a three (3) to six (6) month minimum trial of an adequate dose of or is not a candidate for at least one (1) of the following standards of therapy:
 - 1.6.1 Corticosteroids; **OR**
 - 1.6.1 Immunosuppressive/cytotoxic agents; **OR**
 - 1.6.1 Antimalarials; **AND**
 - 1.7 Benlysta is prescribed in combination with standard therapy but not with intravenous cyclophosphamide or biologics; **AND**
 - 1.8 If the Member meets the above criteria, Benlysta may be approved for 10 mg/kg administered as an IV infusion over one (1) hour every two (2) weeks for the first three (3) doses and at every four (4) weeks thereafter for a total of four (4) months (6 doses).

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Procedure, continued:

- 2.0 Request for *continuation of therapy* beyond the initial authorization period for **Active, Autoantibody-positive, systemic lupus erythematosus (SLE)** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying a reduction in the Member's signs and symptoms of SLE as evidenced by medical progress notes:
- 2.1 If criteria are met, Benlysta may be approved for 10 mg/kg administered as an IV infusion over one (1) hour every four (4) weeks for six (6) months.

References:

1. Benlysta (belimumab) package insert. Rockville, MD: Human Genome Sciences, Inc.; 2011 Mar.
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3. Navarro 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;377:721-31.
4. Thomson MICROMEDEX, Thomson Healthcare, Inc. <http://www.micromedex.com/> . Accessed March 14, 2011.
5. Schur PH, Wallace DJ. Overview of the therapy and prognosis of systemic lupus erythematosus in adults. Available at: <http://www.uptodate.com>. Accessed March 14, 2011.
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8. Gladman DD, Urowitz MB, Esdaile JM, et al. Guidelines for referral and management of systemic lupus erythematosus in adults. *Arthritis Rheum* 1999;42:1785-1796.
9. Dubois EL. Antimalarials in the management of discoid and systemic lupus erythematosus. *Semin Arthritis Rheum* 1978;8:33-51.



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Disclaimer Information:

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.