Prior Authorization Approval Criteria

**Benlysta (belimumab)**

**Generic name:** belimumab

**Brand name:** Benlysta

**Medication class:** monoclonal antibody

**FDA-approved uses:** Treatment of adult patients with active, autoantibody-positive, systemic lupus erythematosus who are receiving standard therapy.

**Available dosage forms:** single use vials of belimumab lyophilized powder 120mg/vial, 400mg/vial

**Usual dose:** 10mg/kg at 2 week intervals for the first 3 doses and at 4 week intervals thereafter.

**Approximate monthly cost:** $3,097.50/dose. After loading dose cost is $37,170/year. (based on AWP 2011) on a 70kg patient

**Duration of therapy:** indefinitely

**Criteria for use (bullet points below are all inclusive unless otherwise noted):**

- The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records.
- Must be clinically diagnosed with systemic lupus erythematosus (SLE).
- Must be receiving standard therapy such as NSAIDs, glucocorticoids, antimalarials, and/or immunosuppressives
- Must only have involvement of the musculoskeletal and mucocutaneous system.
- Patient must not have severe active lupus nephritis or severe active CNS lupus.
- Must not be on other biologics or IV cyclophosphamide.
- Must be 18 years of age or older.
- Must be prescribed by a rheumatologist.

**Caution:**

- Should not be administered with live vaccines

**Contraindication:**

- Belimumab is contraindicated in patients with a history of anaphylaxis to belimumab

**Not approved if:**

- Patient has severe active lupus nephritis or severe active CNS lupus.
- Patient is on other biologics or IV cyclophosphamide.
- Have any contraindications.
- Does not meet the above stated criteria.
Special considerations:

- Belimumab has not been assessed in patients with severe active lupus nephritis or severe active CNS lupus, or in combination with other biologics or intravenous (IV) cyclophosphamide; therefore, belimumab is not recommended in these situations.

- Drug therapy depends on the level of severity of a patient's symptoms, but may include
  - nonsteroidal anti-inflammatory drugs (NSAIDs), antimalarials (primarily hydroxychloroquine), glucocorticoids, and immunosuppressive agents (including cyclophosphamide, cyclosporine, tacrolimus, leflunomide, methotrexate, azathioprine, and mycophenolate).