



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: (based on AWP 2011)	\$3,097.50/dose. After loading dose cost is \$37,170/year. (based 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).

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 12/14/11