

PHARMACY POLICY STATEMENT

Indiana Medicaid

DRUG NAME	Benlysta (belimumab)
BENEFIT TYPE	Medical (IV) or Pharmacy (subQ)
STATUS	Prior Authorization Required

Benlysta is a B-lymphocyte stimulator (BLyS)-specific inhibitor indicated for the treatment of patients aged 5 years and older with active systemic lupus erythematosus (SLE) who are receiving standard therapy and for patients aged 5 years and older with active lupus nephritis who are receiving standard therapy. Benlysta is not recommended in patients with severe active central nervous system lupus.

SLE is the most common type of lupus. It is a chronic autoimmune disease with periods of flares and remissions that causes inflammation and damage throughout the body. LN is a complication of SLE and can progress to end stage renal disease (ESRD). Proteinuria is often the first sign of LN.

Benlysta (belimumab) will be considered for coverage when the following criteria are met:

Systemic Lupus Erythematosus (SLE)

For **initial** authorization:

1. Member is at least 5 years of age; AND
2. Medication must be prescribed by or in consultation with a rheumatologist; AND
3. Member has a documented diagnosis of active, autoantibody-positive SLE as confirmed by documentation of at least one of the following:
 - a) Anti-
 - b) Elevated (above normal) anti-double-stranded DNA (anti-dsDNA)
 - c) Elevated (above normal) anti-Smith (anti-Sm) antibody; AND
4. Member has tried and failed hydroxychloroquine OR is unable to reduce steroid to an acceptable dose for chronic use (5 mg prednisone per day or less); AND
5. Standard therapy (e.g., hydroxychloroquine) will be continued unless contraindicated; AND
6. Member does NOT have severe active central nervous system (CNS) lupus.
7. Benlysta will NOT be used with other biologic therapies.
8. **Dosage allowed/Quantity limit:**
 - IV (Adult or Pediatric): 10mg/kg every 2 weeks for 3 doses and every 4 weeks thereafter
 - SubQ (Adult only): 200 mg once weekly
 - QL: 4 syringes per 28 days

If all the above requirements are met, the medication will be approved for 6 months.

References:

1. Benlysta [package insert]. Research Triangle Park, NC: GlaxoSmithKline LLC; 2023.
2. Furie R, Petri M, Zamani O, et al. A phase III, randomized, placebo-controlled study of belimumab, a monoclonal antibody that inhibits B lymphocyte stimulator, in patients with systemic lupus erythematosus. *Arthritis Rheum.* 2011; 63 (12): 3918-3928.
3. Navarra SV, Guzman RM, Gallacher AE, et al. Efficacy and safety of belimumab in patients with active systemic lupus erythematosus: a randomised, controlled trial. *Lancet.* 2010; 375 (9738): 734-743.



Effective date: 07/01/2024
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