

Belimumab (Benlysta®)

Goal(s):

- Promote use that is consistent with national clinical practice guidelines and medical evidence.

Length of Authorization:

- 6 months

Requires PA:

- Benlysta® (belimumab) pharmacy or provider administered claims.

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Table 1: FDA approved ages

Indication	Approved formulation	
	Intravenous (IV) powder for solution	Subcutaneous (SC) Injection
Systemic Lupus Erythematosus (SLE)	5 years and older	5 years and older
Lupus Nephritis	5 years and older	5 years and older

IV (usual adult dosage): SLE or Lupus Nephritis: 10 mg/kg IV infusion over 1 hour every 2 weeks for the first 3 doses, then every 4 weeks thereafter

SC (usual adult dosage): SLE: 200 mg SC once weekly

Lupus Nephritis: 400 mg (two 200-mg injections) SC once weekly into abdomen or thigh for 4 doses, then 200 mg SC once weekly thereafter

Approval Criteria

1. What diagnosis is being treated?	Record ICD-10 code.	
2. Does the patient have severe active central nervous system lupus?	Yes: Pass to RPh. Deny; medical appropriateness	No: Go to #3
3. Is this a request for continuation of therapy previously approved by fee-for-service (FFS)?	Yes: Go to Renewal Criteria	No: Go to #4
4. Is the patient diagnosed with lupus nephritis or systemic lupus erythematosus (SLE)?	Yes: Go to #5	No: Pass to RPh. Deny; medical appropriateness

Approval Criteria

<p>5. Is belimumab dosed appropriately and with an approved formulation for patient's age as outlined in Table 1?</p>	<p>Yes: Go to #6</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
<p>6. Is the patient currently on other targeted immune modulators?</p>	<p>Yes: Pass to RPh. Deny; medical appropriateness. Belimumab has not been studied in combination with other targeted immune modulators</p>	<p>No: Go to #7</p>
<p>7. Is the drug being prescribed by or in consultation with a rheumatologist, nephrologist, or a provider with experience treating SLE or lupus nephritis?</p>	<p>Yes: Go to #8</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
<p>8. Does the patient have active autoantibody-positive SLE or lupus nephritis and is a baseline assessment of SLE disease activity available using one of the following functional assessment tools:</p> <ul style="list-style-type: none"> • SLE Index Score (SIS) • British Isles Lupus Assessment Group (BILAG) • Systemic Lupus Activity Measure (SLAM) • Systemic Lupus Erythematosus Disease Activity Score (SLEDAI or modified versions, e.g. SLEDAI-2K, SELENA-SLEDAI) • Physicians Global Assessment (PGA) • Systemic Lupus International Collaborating Clinic (SLICC) Damage Index • Urinary protein to creatinine ratio • Most recent estimated Glomerular Filtration Rate (eGFR) 	<p>Yes: Go to #9 Document baseline assessment _____.</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
<p>9. Is the patient currently taking or have a contraindication to BOTH of the following:</p> <ul style="list-style-type: none"> • Hydroxychloroquine • Glucocorticoids (e.g. prednisone) 	<p>Yes: Go to #10</p>	<p>No: Pass to RPh. Deny; medical appropriateness. Belimumab has not been studied as monotherapy in patients with SLE.</p>

Approval Criteria		
10. Does the patient have lupus nephritis AND a urine protein: creatinine ratio of >500 mg/g?	Yes: Go to #11	No: Approve for 6 months
11. Is the patient currently taking, or have a contraindication to, either an angiotensin-converting enzyme inhibitor (ACEI) OR an angiotensin II receptor blocker (ARB)?	Yes: Approve for 6 months	No: Pass to RPh. Deny; medical appropriateness.

Renewal Criteria		
1. Is the patient currently on another therapeutic immune modulator? Note: Belimumab has not been studied in combination with other therapeutic immune modulators.	Yes: Pass to RPh. Deny; medical appropriateness.	No: Go to #2
2. Has the patient's SLE disease activity improved or stabilized as assessed by one of the following functional assessment tools: <ul style="list-style-type: none"> • SLE Index Score (SIS) • British Isles Lupus Assessment Group (BILAG) • Systemic Lupus Activity Measure (SLAM) • Systemic Lupus Erythematosus Disease Activity Score (SLEDAI or modified versions, e.g. SLEDAI-2K, SELENA-SLEDAI) • Physicians Global Assessment (PGA) • Systemic Lupus International Collaborating Clinic (SLICC) Damage Index • Urinary protein to creatinine ratio • eGFR 	Yes: Approve for 6 months.	No: Pass to RPh; Deny; medical appropriateness.

P&T/DUR Review: 02/22 (SF); 8/21 (DM) 2/20, 5/18
Implementation: 4/1/22; 3/1/2020; 7/1/18