



## Benlysta® (belimumab)

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### Definition

Benlysta is a human IgG1 lambda monoclonal antibody that inhibits the binding of soluble B lymphocyte stimulator protein (BlyS) to its B cell receptors.

### Length of Authorization

Coverage will be provided for 12 months and may be renewed.

### Dosing Limits

#### Max Units (per dose and over time) [Medical Benefit]:

- Loading Dose (doses administered on days 1, 15 and 29):
  - 360 billable units per 29 days
- Maintenance Dose:
  - 120 billable units per 28 days

### Guideline

#### I. INITIAL APPROVAL CRITERIA

##### Systemic Lupus Erythematosus (SLE) †

- Adult patient (5 years or older); **AND**
- Patient has a positive autoantibody test (e.g., anti-nuclear antibody [ANA] greater than laboratory reference range and/or anti-double-stranded DNA [anti-dsDNA] greater than 2 fold the laboratory reference range if tested by ELISA); **AND**

- Patient has failed to respond adequately to at least two (2) standard therapies (anti-malarials, corticosteroids, non-steroidal anti-inflammatory drugs, immunosuppressives (excluding intravenous cyclophosphamide); **AND**
- Patient has one of the following:
  - Safety of Estrogen in Lupus National Assessment – Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score of 6-12
  - British Isles Lupus Assessment Group (BILAG) A organ domain score  $\geq 1$
  - BILAG B organ domain score  $\geq 2$ ; **AND**
- Patient must not have an active infection; **AND**
- Patient has not received a live vaccine within 30 days before starting or concurrently with Benlysta; **AND**
- Patient does not have any of the following exclusion criteria:
  - Severe active central nervous system lupus
  - Severe active lupus nephritis
  - Individuals who are on other biologics or IV cyclophosphamide

† FDA Approved Indication(s)

## II. RENEWAL CRITERIA

Authorizations can be renewed based on the following criteria:

- Patient continues to meet the criteria identified in section III; **AND**
- Adequate documentation of disease stability and/or improvement as indicated by one or more of the following when compared to pre-treatment baseline:
  - Improvement in the SELENA-SLEDAI score of  $\geq 4$  points; **OR**
  - No new BILAG-A organ domain score or 2 new BILAG-B organ domain scores; **OR**
  - No worsening ( $< 0.30$ -point increase) in Physician’s Global Assessment (PGA) score; **OR**
  - Seroconverted (negative) or had a 20% reduction in autoantibody level; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: depression, suicidal thoughts, serious infections, signs or symptoms of progressive multifocal leukoencephalopathy (PML), malignancy, severe hypersensitivity reaction, etc.

## Dosing/Administration

Indication	Dose
Systemic lupus erythematosus (SLE)	<ul style="list-style-type: none"> <li>• Loading Dose: 10 mg/kg intravenously (by a healthcare provider) every 2 weeks x 3 doses (days 1, 15 and 29)</li> <li>• Maintenance Dose: 10 mg/kg intravenously (by a healthcare provider) every 4 weeks</li> </ul>

## Authorization

### Applicable Procedure Codes

J0490	Injection, belimumab, 10 mg; 1 billable unit = 10 mg
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### Applicable NDC's

49401-0101-xx	Benlysta 120 mg/5 mL SDV for injection
49401-0102-xx	Benlysta 400 mg/20 mL SDV for injection

ICD-10	ICD-10 Description
M32.10	Systemic lupus erythematosus organ or system involvement unspecified
M32.11	Endocarditis in systemic lupus erythematosus
M32.12	Pericarditis in systemic lupus erythematosus
M32.13	Lung involvement in systemic lupus erythematosus
M32.14	Glomerular disease in systemic lupus erythematosus
M32.15	Tubulo-interstitial nephropathy in systemic lupus erythematosus
M32.19	Other organ or system involvement in systemic lupus erythematosus
M32.8	Other forms of systemic lupus erythematosus
M32.9	Systemic lupus erythematosus, unspecified

### Revision History

8/12/2019	Updated age range from 18 to 5 years of age and older for IV
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### References

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