Benlysta® (belimumab) (Intravenous)

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I. Length of Authorization

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

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Loading Dose (doses administered on days 1, 15 and 29):
  - Benlysta 120 mg SDV for injection: 9 vials per 29 days
  - Benlysta 400 mg SDV for injection: 9 vials per 29 days
- Maintenance Dose:
  - Benlysta 120 mg SDV for injection: 3 vials per 28 days
  - Benlysta 400 mg SDV for injection: 3 vials per 28 days

B. 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

III. Initial Approval Criteria

- For patients age 18 years and older, patient must have tried and failed, or have a documented contraindication to, subcutaneous Benlysta before the intravenous infusion will be authorized.

Systemic Lupus Erythematosus (SLE) †

- Patient is 5 years of age or older; **AND**
- Patient has a confirmed diagnosis of SLE with at least 4 diagnostic features (see list of diagnostic SLE criteria below)***** one of which must include a positive autoantibody test (e.g., anti-nuclear antibody [ANA] greater than laboratory reference range and/or anti-double-

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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 such as 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) B organ domain score ≥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**
- Used in combination with standard therapy (e.g. anti-malarials, corticosteroids, non-steroidal anti-inflammatory drugs, immunosuppressives); **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)

*Systemic Lupus Erythematosus Diagnostic Criteria
Patient must have at least 4 out of 11 diagnostic SLE features: 1. Malar rash 2. Discoid rash 3. Photosensitivity 4. Oral ulcers 5. Nonerosive arthritis (involving 2 or more peripheral joints) 6. Pleuritis/pericarditis • Pleuritis - history of pleuritic pain or rubbing heard by a physician or evidence of pleural effusion • Pericarditis - documented by electrocardiogram or rubbing heard by a physician or evidence of pericardial effusion 7. Renal disorder • Persistent proteinuria > 0.5 grams/day or > 3+ on urine dipstick • Cellular casts (red cell, hemoglobin, granular, tubular, or mixed) 8. Seizures/psychosis 9. Hematologic disorder • Hemolytic anemia with reticulocytosis • Leukopenia < 4,000/mm^3 on ≥ 2 occasions • Lymphopenia < 1,500/mm^3 on ≥ 2 occasions • Thrombocytopenia < 100,000/mm^3 in the absence of offending drugs 10. Immunologic disorder • Presence of anti-Sm or antiphospholipid antibodies • Presence of anti-double-stranded DNA [anti-dsDNA] greater than 2 fold the laboratory reference range if tested by ELISA

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11. Positive anti-nuclear antibody [ANA] greater than laboratory reference range

IV. 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 ≥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 reactions, etc.

V. Dosage/Administration

Indication	Dose
Systemic lupus erythematosus (SLE)	• Loading Dose: 10 mg/kg intravenously (by a healthcare provider) every 2 weeks x 3 doses (days 1, 15 and 29) • Maintenance Dose: 10 mg/kg intravenously (by a healthcare provider) every 4 weeks

VI. Billing Code/Availability Information

Jcode:

- J0490 – Injection, belimumab, 10 mg; 1 billable unit = 10 mg

NDC:

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

VII. References

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Appendix 1 – Covered Diagnosis Codes

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

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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

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): 5, 8	**NCD/LCD Document (s):** L34741
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34741&bc=gAAAAAAAAAAAAA==	

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

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