# 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) [NDC Unit]:**

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

**B. Max Units (per dose and over time) [HCPCS Unit]:**

- Loading Dose:
  - 120 billable units on days 1, 15 and 29
- Maintenance Dose:
  - 120 billable units per 28 days

## III. Initial Approval Criteria [1]

Site of care specialty infusion program requirements are met (refer to Moda Site of Care Policy).

- Patient is at least 5 years of age; **AND**

Universal Criteria [1]

- Patient must not have an active infection; **AND**
- Patient will not receive live vaccines during therapy or within 30 days prior to starting treatment; **AND**
- Patient does not have severe active central nervous system lupus; **AND**

- Will be used in combination with standard therapy (e.g., anti-malarials, corticosteroids, non-steroidal anti-inflammatory drugs, immunosuppressives); **AND**
- Will not be used in combination with rituximab, anifrolumab, or IV cyclophosphamide*****; **AND**

**** Note**: May be used in combination with IV cyclophosphamide for Lupus Nephritis.*

**Systemic Lupus Erythematosus (SLE) † [1,9,11,12, 22-27,29]**

- Patient has a confirmed diagnosis of SLE as evidenced by all of the following:
  - Confirmed SLE classification criteria score ≥10***** (*Note: must include clinical and immunologic domains criteria)*
  - Anti-nuclear antibody (ANA) titer of ≥1:80 measured via indirect immunofluorescence (IIF) on human epithelial (HEp-2) cells (or an equivalent ANA positive test) at least once; **AND**
- Patient has documented active disease; **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool (i.e., Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI 2K), British Isles Lupus Assessment Group-2004 (BILAG 2004), and/or Physician's Global Assessment (PGA) score); **AND**
- Patient has failed to respond adequately to at least one (1) standard therapy such as anti-malarials, corticosteroids, non-steroidal anti-inflammatory drugs, immunosuppressives******

***** Note:** For patients already established on biologic therapy, trial and failure of standard therapy is not required.*

**Lupus Nephritis (LN) † [1,9,11,12,19,22,28-30]**

- Patient has active lupus nephritis Class III, IV, or V as confirmed by renal biopsy; **AND**
- Patient has a confirmed diagnosis of SLE as evidenced by all of the following******:
  - Confirmed SLE classification criteria score ≥10***** (*Note: must include clinical and immunologic domains criteria)*
  - Anti-nuclear antibody (ANA) titer of ≥1:80 measured via indirect immunofluorescence (IIF) on human epithelial (HEp-2) cells (or an equivalent ANA positive test) at least once; **AND**
- Physician has obtained a baseline measurement of one or more of the following: urine protein:creatinine ratio (uPCR), estimated glomerular filtration rate (eGFR), or urine protein

********Patients with class III, IV, or V disease that do not meet the SLE diagnostic criteria will be reviewed on a case-by-case basis*

| ***Classification Criteria for Systemic Lupus Erythematosus (SLE) [22]** | |
|---|---|
| **Clinical Score Δ** (range: 0-39) | **Clinical Domains and Criteria** |
| 2 | **Constitutional:** Unexplained fever > 101°F |

| | |
|---|---|
| 3<br>4 | **Hematologic:**<br>White blood cell count < 4,000/mm$^3$<br>Platelet count < 100,000/mm$^3$ or Autoimmune hemolysis |
| 2<br>3<br>5 | **Neuropsychiatric:**<br>Delirium<br>Psychosis<br>Primary generalized seizure or partial/focal seizure |
| 2<br>4<br>6 | **Mucocutaneous +:**<br>Non-scarring alopecia or oral ulcers<br>Subacute cutaneous or discoid lupus<br>Acute cutaneous lupus |
| 5<br>6 | **Serosal:**<br>Pleural or pericardial effusion<br>Acute pericarditis |
| 6 | **Musculoskeletal:**<br>Joint involvement with either synovitis involving 2 or more joints with swelling or effusion OR tenderness in 2 or more joints with at least 30 minutes of morning stiffness |
| 4<br>8<br>10 | **Renal:**<br>Proteinuria > 0.5g/24 hr by a 24-hour urine or equivalent spot urine protein-to-creatinine ratio<br>Renal biopsy class II or V lupus nephritis<br>Renal biopsy Class III or IV lupus nephritis |
| **Immunologic Score** ∆<br>(range: 0-12) | **Immunologic Domains and Criteria** |
| 2 | **Presence of antiphospholipid antibodies** (i.e., positive lupus anticoagulant, positive anti-ß2GP1 antibodies, and/or anti-cardiolipin antibodies at medium or high titer) |
| 3<br>4 | **Presence of low complement proteins** (below lower limit of normal):<br>Low C3 OR low C4<br>Low C3 AND C4 |
| 6 | **Presence of anti-Sm and/or anti-dsDNA antibodies** |
| *****A web-based scoring calculator as well as further definitions of each criterion are available at: https://rheumatology.org/criteria<br>∆ Occurrence on at least one occasion is sufficient to count toward score when all other causes have been ruled out. Count only the highest weighted score within each of the 10 domains (7 clinical and 3 immunologic) and any additional criteria within the same domain will not count.<br>**+** Observed by a physician via clinical exam or photograph review | |

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

## IV. Renewal Criteria [1]

Coverage can be renewed based on the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: depression, suicidal thoughts, serious infections, suspected or confirmed progressive

multifocal leukoencephalopathy (PML), malignancy, severe hypersensitivity reactions/anaphylaxis, serious infusion-related reactions, etc.; **AND**

**Systemic Lupus Erythematosus (SLE)** [1,9,21-27,29]

- 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-2K; **OR**
  - Reduction of baseline BILAG-2004 (e.g. reduction from A to B or from B to C/D, and no BILAG-2004 worsening in other organ systems, as defined by ≥2 new BILAG-2004 B or ≥1 new BILAG A); **OR**
  - No worsening (<0.30-point increase) in Physician's Global Assessment (PGA) score; **OR**
  - Seroconverted (negative)

**Lupus Nephritis (LN)** [1,19,22,30]

- Adequate documentation of disease stability and/or improvement as indicated by one or more of the following when compared to pre-treatment baseline:
  - Urine protein:creatinine ratio (uPCR); **OR**
  - Estimated glomerular filtration rate (eGFR); **OR**
  - Urine protein

## V. Dosage/Administration [1]

| Indication | Dose |
|---|---|
| Systemic Lupus Erythematosus (SLE) or Lupus Nephritis (LN) | • Loading Dose: 10 mg/kg intravenously (by a healthcare provider) every 2 weeks for the first 3 doses (days 1, 15 and 29)<br>• Maintenance Dose: 10 mg/kg intravenously (by a healthcare provider) every 4 weeks |

## VI. Billing Code/Availability Information

HCPCS Code:

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

NDC(s):

- Benlysta 120 mg/5 mL single-dose vial for injection: 49401-0101-xx
- Benlysta 400 mg/20 mL single-dose vial 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 |
| 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)

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

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

| 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 |

| Medicare Part B Administrative Contractor (MAC) Jurisdictions | | |
|---|---|---|
| **Jurisdiction** | **Applicable State/US Territory** | **Contractor** |
| 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 |
| M (11) | NC, SC, WV, VA (excluding below) | Palmetto GBA |
| 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 |