Benlysta® (belimumab)
(Intravenous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 12 months (365 days).
- Renewal: Prior authorization validity may be renewed every 12 months (365 days) thereafter.

II. Dosing Limits

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

- Loading Dose: 116 billable units on days 1, 15 and 29
- Maintenance Dose: 116 billable units per 28 days

III. Initial Approval Criteria

Prior authorization validity is provided in the following conditions:

- If the member has an FDA labeled indication, then ONE of the following:
  - The member's age is within FDA labeling for the requested indication for the requested agent; **OR**
  - There is support for using the requested agent for the member's age for the requested indication; **AND**

Universal Criteria

- The prescriber is a specialist in the area of the member's diagnosis (e.g., rheumatologist, nephrologist), or the prescriber has consulted with a specialist in the area of the member's diagnosis; **AND**
- The member does NOT have severe active central nervous system (CNS) lupus; **AND**
- The member does NOT have any FDA labeled contraindications to the requested agent; **AND**

Indication Specific Criteria

- ONE of the following:
  - The member has a diagnosis of active systemic lupus erythematosus (SLE) WITHOUT active lupus nephritis (LN); **AND**
    - The member has ONE of the following:

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        - Tried and had an inadequate response, intolerance, or hypersensitivity to hydroxychloroquine; **OR**
        - An FDA labeled contraindication to hydroxychloroquine; **AND**
    - The member has ONE of the following:
        - Tried and had an inadequate response, intolerance, or hypersensitivity to ONE corticosteroid OR immunosuppressive agent (i.e., azathioprine, methotrexate, mycophenolate, cyclophosphamide); **OR**
        - An FDA labeled contraindication to ALL corticosteroids AND immunosuppressive agents (i.e., azathioprine, methotrexate, mycophenolate, cyclophosphamide); **AND**
    - The member will continue standard SLE therapy (i.e., corticosteroid, hydroxychloroquine, azathioprine, methotrexate, mycophenolate, cyclophosphamide) in combination with the requested agent; **OR**
- The member has a diagnosis of active lupus nephritis (LN); **AND**
    - The member has Class III, IV, or V lupus nephritis confirmed via kidney biopsy; **AND**
    - The member will be using background immunosuppressive LN therapy (e.g., corticosteroid plus mycophenolate, azathioprine, or cyclophosphamide) in combination with the requested agent; **AND**
    - If the member will be using the requested agent in combination with Lupkynis, then ALL of the following:
        - The member has tried and had an inadequate response to TWO standard therapy courses (e.g., corticosteroids and Benlysta plus mycophenolate, azathioprine, or cyclophosphamide; corticosteroids and Lupkynis plus mycophenolate); **AND**
        - The member will be using Benlysta in combination with Lupkynis plus mycophenolate; **AND**

- ONE of the following:
    - The member will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors, etc.); **OR**
    - The member will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors, etc.) and BOTH of the following:
        - The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent; **AND**
        - There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, or guidelines required)

IV. Renewal Criteria

Prior authorization validity may be renewed based upon the following conditions:

- The member continues to meet the universal criteria and indication specific concomitant therapy requirements (not including prerequisite therapy) identified in section III; **AND**

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- The member has had clinical benefit with the requested agent

V. Dosage/Administration

Indication	Dose
Systemic Lupus Erythematosus (SLE)	Adults and Pediatrics 5 years of age and older: • Loading Dose: Administer 10 mg/kg intravenously every 2 weeks for the first 3 doses • Maintenance Dose: Administer 10 mg/kg intravenously every 4 weeks
Lupus Nephritis (LN)	Adults and Pediatrics 5 years of age and older: • Loading Dose: Administer 10 mg/kg intravenously every 2 weeks for the first 3 doses • Maintenance Dose: Administer 10 mg/kg intravenously every 4 weeks
Note: *If applicable, refer to the package insert for specific details regarding suggested dosing and schedules if transitioning between intravenous and subcutaneous routes of therapy*	

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 A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

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Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

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
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	Wellpoint Federal
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)

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Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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	Wellpoint Federal
15	KY, OH	CGS Administrators, LLC

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