blue california
Promise Health Plan

belimumab (Benlysta)

Medical Benefit Drug Policy

Place of Service

Home Health Infusion
Infusion Center Administration
Office Administration
Outpatient Facility Infusion Administration

Drug Details

USP Category: IMMUNOLOGICAL AGENTS
Mechanism of Action: BLyS-specific inhibitor that blocks the binding of soluble BLyS, a B-cell survival factor, to its receptors on B cells.
HCPCS:
J0490:Injection, belimumab, 10 mg
How Supplied:
Intravenous:
120 mg (5 mL single-use vial)
400 mg (20 mL single-use vial)

Condition(s) listed in policy *(see coverage criteria for details)*

- Lupus Nephritis
- Systemic lupus erythematosus (SLE)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Lupus Nephritis
Meets medical necessity if all the following are met:

1. Being prescribed by or in consultation with a rheumatologist or nephrologist
2. Age is consistent with the FDA-approved indication (5 years and older)
3. Patient does not have severe CNS lupus

4. Patient has and will continue to use standard therapy (e.g., corticosteroids, mycophenolate, cyclophosphamide, azathioprine)
5. Will not be used in combination with rituximab or other biologics
6. Dose does not exceed the FDA-approved maximum

Covered Doses:
Intravenous: 10 mg/kg given intravenously on day 0, 14, 28 in month 1 of treatment, followed by 10 mg/kg given intravenously every 4 weeks thereafter

Coverage Period:
Yearly, based on continued response to therapy

ICD-10:
M32.14

Systemic lupus erythematosus (SLE)
Meets medical necessity if all the following are met:

1. Prescribed by or in consultation with a rheumatologist
2. Age is consistent with the FDA-approved indication (5 years and older)
3. Patient is currently taking one or more of the following drugs: azathioprine, chloroquine, hydroxychloroquine, methotrexate, methylprednisolone, mycophenolate, or prednisone
4. Patient does not have severe CNS lupus
5. Drug will not be used in combination with rituximab or other biologics
6. Dose does not exceed the FDA-approved maximum

Covered Doses:
Intravenous:10 mg/kg given intravenously on day 0, 14, 28 in month 1 of treatment, followed by 10 mg/kg given intravenously every 4 weeks thereafter

Coverage Period:
Yearly, based on continued response to therapy

ICD-10:
M32.0, M32.10, M32.11, M32.12, M32.13, M32.14, M32.15, M32.19, M32.8, M32.9

References

1. AHFS. Available by subscription at http://www.lexi.com
2. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. Benlysta (belimumab) [prescribing information]. Durham, NC: GlaxoSmithKline LLC; May 2024.

4. Fanouriakis A, Kostopoulou M, Andersen J, et al. EULAR recommendations for the management of systemic lupus erythematosus: 2023 upate. Ann Rheum Dis. 2024 Jan 2;83(1):15-29.
5. Ginzler EM, Wallace DJ, Merrill JT, et al. Disease control and safety of belimumab plus standard therapy over 7 years on patients with systemic lupus erythematosus J Rheumatol 2014;41(2):300-9.
6. Merrill JT, Ginzler EM, Wallace DJ, et al. Long term safety profile of belimumab plus standard therapy in patients with systemic lupus erythematosus. Arthritis Rheum 2012;64(10):3364-73.

Review History

Date of Last Annual Review: 4Q2025
Changes from previous policy version:

- Clarify combination use with belimumab to remove IV Cyclophosphamide

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee