belimumab (Benlysta)

Commercial 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)

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.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Benlysta (J0490) vials (given by intravenous injection) is managed under the Medical Benefit policy. Benlysta (C9399 / J3490 / J3590) prefilled autoinjector or prefilled syringe (given by subcutaneous injection) can be obtained through the patient's pharmacy benefit. Please refer to the "Self-Administered Drugs" medical benefit drug policy for more information.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct)** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

MCG Care Guidelines, 19th edition, 2015

ADMINISTRATION OF THIS DRUG IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted)*

1. Patient is receiving their first two infusions of Benlysta or is being re-initiated on Benlysta after at least 6 months off therapy. *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

OR

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. Patient has experienced a previous severe adverse event on Benlysta based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on Benlysta based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
4. Patient is clinically unstable based on documentation submitted.
5. Patient is physically or cognitively unstable based on documentation submitted.

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