Belimumab (Benlysta®)
Intravenous

Place of Service
Office Administration
Home Health Administration
Infusion Center Administration
Outpatient Facility Administration*
[*Prior authorization required – see section (1)]

HCPCS: J0490 per 10 mg (Intravenous)

Conditions listed in policy (*see criteria for details*)
- Lupus nephritis
- Systemic lupus erythematosus (SLE)

AHFS therapeutic class: Immunosuppressive agent

Mechanism of action: Belimumab, a human immune globulin G1 lambda monoclonal antibody, is a BLyS-specific inhibitor that blocks the binding of soluble BLyS, a B-cell survival factor, to its receptors on B cells.

(1) Special Instructions and Pertinent Information

Benlysta (J0490), given by intravenous (IV) injection is managed under the Medical Benefit, please submit clinical information for prior authorization review.

**** CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION****

AAAAI Guidelines 2011, MCG™ Care Guidelines, 19th edition, 2015, Benlysta PI, GSK, 12/16

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, Medi-Cal, 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.

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

1. **Patient is receiving their first infusion 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.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Benlysta® (belimumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Lupus nephritis

1. Being prescribed by a rheumatologist or nephrologist, **AND**
2. Patient is at least 18 years old, **AND**
3. Patient has received standard therapy (e.g., corticosteroids, mycophenolate, cyclophosphamide, azathioprine), **AND**
4. Will not be used in combination with rituximab or other biologics

Covered Doses
Up to 10 mg/kg IV on day 0, 14, 28 in month 1 of treatment, followed by up to 10 mg/kg IV every 4 weeks thereafter

Coverage Period
Indefinite

ICD-10:
M32.14

Systemic lupus erythematosus (SLE), seropositive disease

1. Prescribed by or in consultation with a rheumatologist, **AND**
2. Patient is ≥ 5 years of age, **AND**
3. Patient is currently taking one or more of the following drugs: azathioprine, chloroquine, hydroxychloroquine, methotrexate, methylprednisolone, mycophenolate, or prednisone, **AND**
4. Patient does not have severe CNS lupus, **AND**
5. Drug will not be used in combination with rituximab, other biologics, or IV cyclophosphamide

Covered Doses
Up to 10 mg/kg IV on day 0, 14, 28 in month 1 of treatment, followed by up to 10 mg/kg IV every 4 weeks thereafter

Coverage Period
Indefinite

ICD-10:
M32.0, M32.10-M32.19, M32.8, M32.9

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Benlysta® (belimumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

- 120 mg (5 mL single-use vial)
- 400 mg (20 mL single-use vial)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- American Academy of Allergy Asthma and Immunology. Guidelines for the Site of Care for Administration of IGIV Therapy. December 2011.
- Benlysta (belumumab) [Prescribing information]. Philadelphia, PA: GlaxoSmithKline; 2023.
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Fanouriakis A, Kostopoulou M, Alunno A et al. 2019 update of the EULAR recommendations for the management of systemic lupus erythematosus. Ann Rheum Dis 2019;78:736–745.
- 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.
- MCG™ Care Guidelines, 19th edition, 2015, Home Infusion Therapy, CMT: CMT-0009(SR)
- 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

(7) Policy Update

Date of last review: 4Q2023
Date of next review: 4Q2024
Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee