MEDICAL MUTUAL®

Drug Policy

Policy:	**201107**	**Initial Effective Date: 05/31/2011**
Code(s):	**HCPCS J0490, J3590**	**Annual Review Date: 01/16/2025**
SUBJECT:	**Benlysta® (belimumab injection for intravenous use)* Benlysta® (belimumab injection for subcutaneous use)**	**Last Revised Date: 01/16/2025**

Subject to: ☒Site of Care
☒Medication Sourcing

***MMO requires that prior Authorization requests for Benlysta IV are submitted under the medical benefit.**

Initial and renewal requests for the medication(s) listed in this policy are subject to site of care management. When billed under the medical benefit, administration of the medication will be restricted to a non-hospital facility-based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center) unless the member meets the site of care exception criteria. To view the exception criteria and a list of medications subject to site of care management please click here.

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

POLICY STATEMENT

This policy involves the use of Benlysta. Prior authorization is recommended for pharmacy and medical benefit coverage of Benlysta. Approval is recommended for those who meet the conditions of coverage in the **Criteria, Dosing, Initial/Extended Approval, Duration of Therapy**, and **Labs/Diagnostics** for the diagnosis provided. **Waste Management** applies for all covered conditions that are administered by a healthcare professional. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria and Waste Management section. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Benlysta as well as the monitoring required for AEs and long-term efficacy, initial approval requires Benlysta be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Benlysta is recommended in those who meet the following criteria:

FDA Approved Indication

1. **Systemic Lupus Erythematosus.** *Patient must meet the following criteria*

I. Patient meets one of the following: (A OR B)
   A. If the request is Belimumab for intravenous administration, the patient's age is ≥ 5 years; OR
   B. If the request is Belimumab for subcutaneous administration, the patient's age is ≥ 18 years; AND
II. The patient has active, autoantibody[†]-positive systemic lupus erythematosus despite ≥6 weeks trial of conventional medical therapy; and
III. SLE is active as documented by a SELENA-SLEDAI score greater than or equal to 6 while on current treatment regimen; AND
IV. Belimumab will be used in combination with conventional medical therapy (e.g., corticosteroids, antimalarials, or other immunosuppressants with or without nonsteroidal anti-inflammatories); AND
V. Severe active central nervous system lupus erythematosus is not present; AND
VI. Belimumab will not be used in combination with another biologic agent; AND
VII. Site of care medical necessity is met*.

[†]Positive antinuclear antibody (ANA) [titer ≥1:80] or positive double-stranded DNA (anti-dsDNA) level ≥30 IU/mL

Dosing in Systemic Lupus Erythematosus. *Dosing must meet the following:*

Intravenous Dosing for Adults and Pediatric Patients: The recommended dosage regimen is 10 mg/kg at 2-week intervals for the first 3 doses and at 4-week intervals thereafter. Reconstitute, dilute, and administer as an intravenous infusion only, over a period of 1 hour.

Subcutaneous dosing for Adult Patients: 200 mg once weekly

Subcutaneous Dosing for Pediatric Patients:
- Weighing greater than or equal to 40 kg: 200 mg once weekly
- Weighing 15 kg to less than 40 kg: 200 mg once every 2 weeks

Initial Approval/ Extended Approval.
A) *Initial Approval:* 6 months

B) *Extended Approval:* Approve for an additional 12 months of therapy if the patient has responded to therapy as determined by the prescribing physician.

2. Lupus Nephritis. *Patient must meet the following criteria*

Initial Approval Criteria: *Patient must meet the following criteria (I, II, III, IV, V, VI, VII, VIII, **AND** IX)*
I. Patient meets one of the following: (A OR B)
   a. If the request is Belimumab for intravenous administration, the patient's age is ≥ 5 years; OR
   b. If the request is Belimumab for subcutaneous administration, the patient's age is ≥ 18 years; AND
II. Severe active central nervous system lupus erythematosus is not present; **AND**
III. Belimumab will not be used in combination with another biologic agent; **AND**
IV. Belimumab will be used in combination with conventional medical therapy (e.g., corticosteroids, antimalarials, or other immunosuppressants with or without nonsteroidal anti-inflammatories); **AND**

V. Patient has active lupus nephritis Class III, IV, or V as confirmed by renal biopsy; **AND**

VI. Patient has a confirmed diagnosis of SLE with at least 4 diagnostic features (see Table 1 SLE diagnosis criteria below) one of which must include a positive autoantibody test (e.g., anti-nuclear antibody [ANA] greater than laboratory reference range and/or anti-double-stranded DNA [anti-dsDNA] greater than 2 fold the laboratory reference range if tested by ELISA); **AND**

VII. Patient has failed to respond adequately to standard therapies including corticosteroids AND either cyclophosphamide or mycophenolate mofetil; **AND**

VIII. Baseline measurement of one or more of the following: urine protein:creatinine ratio (uPCR), estimated glomerular filtration rate (eGFR), or urine protein; **AND**

IX. Site of care medical necessity is met*.

Renewal Criteria: *Patient must meet the following criteria (I, II, **AND** III)*

I. For initial renewal (after 6 months), the patient has responded to therapy as determined by the prescribing physician.

II. The patient has disease stability and/or improvement as indicated by one or more of the following when compared to pre-treatment baseline after 12 months: *(a, b, **OR** c)*

a. Urine protein:creatinine ratio (uPCR); **OR**

b. Estimated glomerular filtration rate (eGFR); **OR**

c. Urine protein

III. There is an absence of unacceptable toxicity or side effects from the drug

Dosing in Lupus Nephritis. *Dosing must meet the following:*

Intravenous Dosage for Adults and Pediatric Patients: The recommended dosage regimen is 10 mg/kg at 2-week intervals for the first 3 doses and at 4-week intervals thereafter. Reconstitute, dilute, and administer as an intravenous infusion only, over a period of 1 hour.

Subcutaneous Dosage for Adults: 400 mg (two 200 mg injections) subcutaneously once weekly for 4 doses, then 200 mg once weekly thereafter. Patient may transition from intravenous therapy to subcutaneous therapy any time after the patient completes the first 2 intravenous doses. Administer the first subcutaneous dose 1 to 2 weeks after the last IV dose

Initial Approval/ Extended Approval.

A) *Initial Approval:* 6 months

B) *Extended Approval:* 12 months

Table 1. Systemic Lupus Erythematosus Diagnostic Criteria
Patient must have at least 4 out of 11 diagnostic SLE features: 1. Malar rash 2. Discoid rash 3. Photosensitivity 4. Oral ulcers 5. Nonerosive arthritis (involving 2 or more peripheral joints) 6. Pleuritis/pericarditis • Pleuritis - history of pleuritic pain or rubbing heard by a physician or evidence of pleural effusion • Pericarditis - documented by electrocardiogram or rubbing heard by a physician or evidence of pericardial effusion 7. Renal disorder • Persistent proteinuria > 0.5 grams/day or > 3+ on urine dipstick • Cellular casts (red cell, hemoglobin, granular, tubular, or mixed) 8. Seizures/psychosis 9. Hematologic disorder • Hemolytic anemia with reticulocytosis • Leukopenia < 4,000/mm^3 on ≥ 2 occasions • Lymphopenia < 1,500/mm^3 on ≥ 2 occasions • Thrombocytopenia < 100,000/mm^3 in the absence of offending drugs 10. Immunologic disorder • Presence of anti-Sm or antiphospholipid antibodies • Presence of anti-double-stranded DNA [anti-dsDNA] greater than 2 fold the laboratory reference range if tested by ELISA 11. Positive anti-nuclear antibody [ANA] greater than laboratory reference range

Waste Management for All Indications.

Intravenous Infusion

For injection: 120 mg or 400 mg lyophilized powder in single-dose vials for reconstitution and dilution prior to intravenous infusion.

Subcutaneous Injection

Injection: 200 mg/mL as a clear to opalescent, and colorless to pale yellow solution in a single-dose prefilled autoinjector or a single-dose prefilled glass syringe.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Benlysta has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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