PriorityHealth

Medical and Pharmacy Prior Authorization Form

Fax completed form to: 877.974.4411 toll free, or 616.942.8206

This form applies to: ☒ **Commercial (Traditional)** ☒ **Commercial (Individual/Optimized)** ☐ **Medicaid**

This request is: ☐ **Urgent** (life threatening) ☐ **Non-Urgent** (standard review)

Urgent means the standard review time may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function.

Benlysta® (belimumab)

Member

Last Name: _____ First Name: _____

ID #: _____ DOB: _____ Gender: _____

Primary Care Physician: _____

Requesting Physician: _____ Phone: _____ Fax: _____

Physician Address: _____

Physician NPI: _____ Contact Name: _____

Physician Signature: _____ Date: _____

Product and Billing Information

☐ New request ☐ Continuation request

Drug product:
- ☐ Benlysta® 120 mg vial
- ☐ Benlysta® 400 mg vial
- ☐ Benlysta® 200 mg syringe

Dose (mg/kg): _____
Dose Frequency: _____
Weight: _____
Date of last dose: _____
Date of next dose: _____

Place of administration:
- ☐ Patient to self-administer
- ☐ Physician's office
- ☐ Outpatient infusion
  - Facility: _____ NPI: _____ Fax: _____
- ☐ Home infusion
  - Agency: _____ NPI: _____

Fax: _____

Billing:
- ☐ Physician to buy and bill
- ☐ Facility to buy and bill
- ☐ Specialty Pharmacy
  - Pharmacy: _____ NPI: _____ Fax: _____

ICD-10 Diagnosis code(s): _____

All fields must be complete and legible for review. Your office will receive a response via fax. No changes made since 05/2021

Last reviewed 05/2021

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BENLYSTA COVERAGE POLICY

Precertification Requirements

On and after 12/1/2017, infusion of Benlysta® is not covered at hospital-affiliated infusion centers. First infusions of a drug may be covered in a hospital outpatient infusion center when physician supervision is desired. Patients age 17 and younger may choose to have this drug administered at a hospital-affiliated infusion center.

Patient must meet all of the following criteria:

1. For active, autoantibody-positive systemic lupus erythematosus (SLE):
    a. Must be at least 5 years of age; and
    b. Must be autoantibody-positive with one of the following:
        i. Anti-nuclear antibody (ANA) titer ≥ 1:80, or
        ii. Anti-double-stranded DNA (anti-dsDNA) level ≥ 30 IU/mL; and
    c. SLE is active as demonstrated by a score greater than 6 (as documented by a SELENA-SLEDAI) while on treatment with standard therapy (e.g., corticosteroids, immunosuppressants, and hydroxychloroquine) for at least 12 weeks each.

2. For biopsy-proven lupus nephritis Class III through V:
    a. Must be at least 18 years of age; and
    b. Must be autoantibody-positive with one of the following:
        i. Anti-nuclear antibody (ANA) titer ≥ 1:80, or
        ii. Anti-double-stranded DNA (anti-dsDNA) level ≥ 30 IU/mL; and
    c. Must have active renal disease requiring use of standard therapy (e.g., corticosteroids, immunosuppressants).
    d. Must not have estimated glomerular filtration rate (eGFR) <30 mL/min/1.73m^2

3. Benlysta is not covered in combination with other biologic drug therapy or in patients with central nervous system manifestations.

For continuation, patient must have met 3 of 6 of the following requirements:

1. For active, autoantibody-positive systemic lupus erythematosus (SLE):
    a. Must have a SELENA-SLEDAI score point reduction of 4 or more based on a 30-day assessment
    b. Must have a Physician Global Assessment change indicating showing no disease progression (worsening) compared to baseline treatment with Benlysta®
    c. Must have a British Lupus Assessment Group (BILAG) score of zero in Category A (very active disease) –and– a score of one or less in Category B (moderately active, in any organ system in the last 4 weeks)
    d. A reduction in dose of steroid therapy
    e. A negative seroconversion or a 20% reduction in autoantibody levels from baseline
    f. Free of significant clinical flares that require steroid boost treatment with Benlysta®

2. For biopsy-proven lupus nephritis Class III through V:
    a. Must have evidence of efficacy (defined as urinary protein creatinine ratio ≤0.7, eGFR ≤20% below the pre-flare or at least 60mL/min/1.73m2), and no use of rescue therapy for treatment failure.

***** The formulation of Benlysta® (subcutaneous syringe vs. intravenous vial) that is approved depends on the member's weight. The intravenous formulation will be required for members who weigh less than 80 kg. Member's that weigh 80 kg or more are required to use the subcutaneous syringe.***

Note: Authorization for indications, dosing, or a route of administration not approved by the Food and Drug Administration (FDA) or recognized in CMS-accepted compendia (e.g. DrugDex, AHFS, U.S. Pharmacopeia, and also Clinical Pharmacology for oncology indications only) require supporting evidence for coverage. Please provide two published peer-reviewed literature articles supporting the appropriateness of the drug, the dosing of the drug, or the route of administration to be used for the identified indication.

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New request
Priority Health Precertification Documentation

A. What condition is this drug being requested for?

- ☐ SLE (autoantibody positive)
- ☐ Lupus nephritis
- ☐ Other – the patient's condition is: _____
  Rationale for use: _____

Does the patient have severe active SLE? ☐ Yes ☐ No
(Severe active SLE is proteinuria of 6g/24 hours or more, serum creatinine more than 2.5 mg/dL, active nephritis, required hemodialysis, *or* use of prednisone at doses more than 100 mg each day for more than 90 days.)

Does the patient have severe active CNS SLE? ☐ Yes ☐ No
(Severe active CNS SLE is history of seizures, psychosis, organic brain syndrome, CVA, cerebritis, or CNS in the last 60 days.)

B. What is the patient's SELENA-SLEDAI score prior to starting Benlysta®? _____
(See the last two pages of this prior authorization form for the index.)

C. Which, if any, of the following apply to this patient?

- ☐ Will also receive other biologic drug treatment
- ☐ None of the above apply

D. Which of the following drugs is the patient currently taking? How long has the patient been taking the drug?

- ☐ azathioprine
- ☐ corticosteroid **Drug name:** _____ **Daily dose**: _____
- ☐ cyclophosphamide (by mouth)
- ☐ hydroxychloroquine
- ☐ methotrexate
- ☐ mycophenolate
- ☐ Non-steroidal anti-inflammatory drug (NSAID) **Drug name:** _____
- ☐ Other, the patient is treating his or her SLE with: _____

How long has the patient been taking the above drug? _____

E. For lupus nephritis, does the patient have active disease with renal biopsy classification III – V?

- ☐ Yes
- ☐ No

F. For lupus nephritis, does the patient have an eGFR <30 mL/min/1.73m^2?

- ☐ Yes
- ☐ No

G. Which of the following describes the patient's weight?

- ☐ Less than 80 kg – *requires the use of Benlysta IV vials*
- ☐ 80 kg or higher – *requires the use of Benlysta subcutaneous syringe*

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Request to continue a previously authorized approval - Priority Health Precertification Documentation

Only 3 of the following 6 criteria are required to show patient's successful response to treatment.

A. What is the patient's current SELENA-SLEDAI score? _____
(Your assessment should include the last 30 days, not the last 10 days.)

B. What is the patient's PGA response to therapy?
☐ The patient maintains or has shown improvement of his or her condition since starting Benlysta®
☐ The patient is experiencing disease progression

C. What is the patient's BILAG score?

Category A	Category B
☐ 0	☐ 0
☐ 1 or more	☐ 1
	☐ 2 or more

D. What is the percent reduction in steroid treatment the patient had since starting Benlysta®? _____
If applicable, has the patient been able to lower his or her dose for immunosuppressive treatment? _____

E. Did the patient seroconvert from positive to negative?
☐ Yes ☐ No
If no, what percent reduction of autoantibody level has the patient had since starting Benlysta®? _____

F. Did the patient have a significant clinical flare that required steroid boost treatment with Benlysta®?
☐ Yes ☐ No

H. For lupus nephritis, which of the following applies?
☐ Urinary protein creatinine ratio ≤0.7
☐ eGFR ≤20% below the pre-flare or at least 60mL/min/1.73m2
☐ No use of rescue therapy (e.g., high-dose corticosteroids plus cyclophosphamide/mycophenolate) for treatment failure

Additional information

Note: Response to Benlysta® in clinical trials was less than placebo in the African American patient population.

Dosing and duration of authorization information

Initial Authorization	Continuing Authorization
• Approved for 24 weeks • Approved dose is 10 mg/kg every 2 weeks for 3 doses, followed by 10 mg/kg every 4 weeks. • Subject to a quantity limit of 3-120 mg vials and 6-400mg vials every 28 days ○ Consider using a vial size calculator: https://www.gsksource.com/pharma/content/micro-sites/BenVialCalculator/calc.html	• Approved for 12 months if patient meets 3 of 6 criteria demonstrating a positive response to therapy. • Reauthorization is required every 12 months to confirm continued patient response. • Approved dose is 10 mg/kg every 4 weeks. • Subject to a quantity limit of 3-120 mg vials and 6-400mg vials every 28 days

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