Medical 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
  Facility: _____ NPI: _____ Fax: _____

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

ICD-10 Diagnosis code(s): _____

Drug cost information

The annual cost of treatment with this drug will vary depending on the patient's circumstances. For most individuals, the wholesale acquisition cost is more than $39,000 each year. Cost effectiveness is an important consideration for clinicians and patients in successful management of systemic lupus erythematosus. In the interest of making the best use of healthcare dollars, Priority Health requires the use of specific dosage formulations based on weight.

All fields must be complete and legible for review. Your office will receive a response via fax. No changes made since 09/2017
Last reviewed 03/2019

PriorityHealth

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. Must have active, autoantibody-positive systemic lupus erythematosus (SLE)
2. Must have a SELENA-SLEDAI score of 6 or more before starting Benlysta
3. Must not have severe nephritis, central nervous system manifestations, or chronic infection
4. Must currently be taking TWO of: corticosteroids, immunosuppressants, and hydroxychloroquine for at least 12 weeks each.
5. Must not use any other biologic drug or intravenous cyclophosphamide
6. Must have an anti-dsDNA antibody ≥30 IU/ml or ANA≥1:80

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

1. Must have a SELENA-SLEDAI score point reduction of 4 or more based on a 30-day assessment
2. Must have a Physician Global Assessment change indicating showing no disease progression (worsening) compared to baseline treatment with Benlysta
3. 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)
4. A reduction in dose of steroid therapy
5. A negative seroconversion or a 20% reduction in autoantibody levels from baseline
6. Free of significant clinical flares that require steroid boost treatment with Benlysta

***** 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.

New request
Priority Health Precertification Documentation

A. What condition is this drug being requested for?

☐ SLE (autoantibody positive)
☐ 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.)

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

- ☐ Will also receive intravenous cyclophosphomide
- ☐ Will also receive other biologic drug treatment
- ☐ Has a chronic infection
- ☐ None of the above apply

D. Which of the following drugs is the patient currently taking? And 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. Which of the following describes the patients weight?

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

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

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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 o Consider using a vial size calculator: https://www.gsksource.com/pharma/content/micro-sites/BenVialCalculator/calc.html	• Approved for an additional 6 months if patient meets 3 of 6 criteria demonstrating a positive response to therapy. • Reauthorization is required every 6 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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PriorityHealth

SYSTEMIC LUPUS ERYTHEMATOSUS DISEASE ACTIVITY INDEX
SELENA MODIFICATION

Physicians Global Assessment _____

0 None 1 Mild 2 Med 3 Severe

SLEDAI SCORE

Check box: If descriptor is present at the time of visit or in the proceeding 10 days

Wt	Present	Descriptor	Definition
8	☐	Seizure	Recent onset. Exclude metabolic, infectious or drug cause
8	☐	Psychosis	Altered ability to function in normal activity due to severe disturbance in the perception of reality. Include hallucinations, incoherence, marked loose associations, impoverished thought content, marked illogical thinking, bizarre, disorganized, or catatonic behavior. Excluded uremia and drug causes.
8	☐	Organic Brain Syndrome	Altered mental function with impaired orientation, memory or other intelligent function, with rapid onset fluctuating clinical features. Include clouding of consciousness with reduced capacity to focus, and inability to sustain attention to environment, plus at least two of the following: perceptual disturbance, incoherent speech, insomnia or daytime drowsiness, or increased or decreased psychomotor activity. Exclude metabolic, infectious or drug causes.
8	☐	Visual Disturbance	Retinal changes of SLE. Include cytoid bodies, retinal hemorrhages, serious exodate or hemorrhages in the choroids, or optic neuritis. Exclude hypertension, infection, or drug causes.
8	☐	Cranial Nerve Disorder	New onset of sensory or motor neuropathy involving cranial nerves.
8	☐	Lupus Headache	Severe persistent headache: may be migrainous, but must be non-responsive to narcotic analgesia.
8	☐	CVA	New onset of cerebrovascular accident(s). Exclude arteriosclerosis
8	☐	Vasculitis	Ulceration, gangrene, tender finger nodules, periungual, infarction, splinter hemorrhages, or biopsy or angiogram proof of vasculitis
4	☐	Arthritis	More than 2 joints with pain and signs of inflammation (i.e. tenderness, swelling, or effusion).
4	☐	Myositis	Proximal muscle aching/weakness, associated with elevated creatine phosphokinase/adolase or electromyogram changes or a biopsy showing myositis.
4	☐	Urinary Casts	Heme-granular or red blood cell casts
4	☐	Hematuria	>5 red blood cells/high power field. Exclude stone, infection or other cause.
4	☐	Proteinuria	>0.5 gm/24 hours. New onset or recent increase of more than 0.5 gm/24 hours.
4	☐	Pyuria	>5 white blood cells/high power field. Exclude infection.
2	☐	New Rash	New onset or recurrence of inflammatory type rash.
2	☐	Alopecia	New onset or recurrence of abnormal, patchy or diffuse loss of hair.
2	☐	Mucosal Ulcers	New onset or recurrence of oral or nasal ulcerations

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2	◻	Pleurisy	Pleuritic chest pain with pleural rub or effusion, or pleural thickening.
2	◻	Pericarditis	Pericardial pain with at least 1 of the following: rub, effusion, or electrocardiogram confirmation.
2	◻	Low Complement	Decrease in CH50, C3, or C4 below the lower limit of normal for testing laboratory.
2	◻	Increased DNA binding	>25% binding by Farr assay or above normal range for testing laboratory.
1	◻	Fever	>38°C. Exclude infectious cause
1	◻	Thrombocytopenia	<100,000 platelets/mm3
1	◻	Leukopenia	<3,000 White blood cell/mm3. Exclude drug causes.

_____ TOTAL SCORE (Sum of weights next to descriptors marked present)

Mild or Moderate Flare ◻	**Severe Flare** ◻
◻ Change in SLEDAI > 3 points	◻ Change in SLEDAI > 12
◻ New/worse discoid, photosensitive, profundus, cutaneous vasculitis, bullous lupus Nasopharyngeal ulcers Pleuritis Pericarditis Arthritis Fever (SLE)	◻ New/worse CNS-SLE Vasculius Nephritis Myositis Pk < 60.000 Home anemia: Hb <7% or decrease in Hb > 3% **Requiring:** double prednisone Prednisone>0.5 mg/kg/day hospitalization
◻ Increase in Prednisone, but not to >0.5 mg/kg/day	◻ Prednisone >0.5 mg/kg/day
◻ Added NSAID or Plaquenil	◻ New Cytoxan, Azathioprine, Methotrexate, Hospitalization (SLE)
◻ ≥1.0 Increase in PGA, but not to more than 2.5	◻ Increase in PGA to > 2.5

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