

Pharmacy PRIOR AUTHORIZATION FORM

For Prior Authorization, please fax toll-free (877) 974-4411, or local number (616) 942-8206

This form applies to: Commercial Plan Medicaid Plan Medicare Plan

Benlysta[®] (belimumab)

URGENT (life threatening)

Non-Urgent (standard review)

A claim involving "urgent care" applies when then standard review time will seriously jeopardize the life or health of the member, or subject the member to severe pain that cannot be managed without the care or treatment requested in the subject of this request. **Priority Health averages between 1 and 3 business days for our standard review response time.**

Member Information

Member Name:	Member No.:
DOB:	Gender: Wt: lb/kg (circle)
Member's PCP:	

Provider Information

Provider Name:	
Office Contact Name:	Provider Phone:
Provider NPI:	Provider Fax:
Provider Address:	

Provider Signature

Date

PRODUCT INFORMATION

NOTE: Benlysta[®] is a preferred specialty benefit. Benlysta[®] is covered for patients with active, autoantibody-positive systemic lupus erythematosus (SLE) who are receiving standard therapy and meet all prior authorization criteria.

Benlysta[®] 120 mg/5 mL 400 mg/20 mL

Dosage: 10 mg/kg = _____ mg **Starting Dose:** every 2 weeks x 3 doses, then every 4 weeks

Continuation: every 4 weeks

Start Date: _____

Expected Duration: _____

BILLING INFORMATION

Place of administration:

Infusion Center: _____
 Provider's Office

Billing Options:

Physician buy and bill (preferred)
 Preferred Specialty Vendor
 Other: _____

PRIORITY HEALTH PRECERTIFICATION REQUIREMENTS

Authorization for Benlysta[®] (belimumab) requires the following information to certify:

New therapy – Patients must meet all of the following criteria to certify:

1. Patient must have active, auto-antibody positive SLE.
2. Patient must have a baseline SELENA-SLEDAI score of 6 or more.
3. Patient must be free of severe nephritis, CNS manifestations, and chronic infections.
4. Patient must currently be receiving standard therapy for at least 3 months.
5. Patient must not be receiving any biologic therapy or intravenous cyclophosphamide.

Continuation of therapy – Patients must meet at least 3 of the 6 following criteria to certify:

1. Patient must have a SELENA-SLEDAI score point reduction of 4 or more (based on a 30 day assessment).
2. Patient must have a Physician Global Assessment change indicating no worsening of disease from baseline treatment with belimumab.
3. Patient must have a British Isles Lupus Assessment Group (BILAG) indicating a score of zero in Category A (very active disease) and a score of less than or equal to one in Category B (moderately active, in any organ system in last 4 weeks).
4. Patient has experienced a dose reduction of steroid therapy.
5. Patient has seroconverted (negative) or had a 20% reduction in autoantibody levels from baseline therapy.
6. Patient is free of significant clinical flares requiring a steroid boost during treatment with belimumab.

Note: continuation of therapy requires patient to meet all of the requirements for initial prior authorization.

NEW THERAPY – SECTION A

PRIORITY HEALTH PRECERTIFICATION DOCUMENTATION

Authorization for Benlysta[®] (belimumab) requires the following information to certify:

A. What is the patient’s diagnosis?

- Systemic Lupus Erythematosis ICD code: _____
- Other: _____ ICD code: _____
- Rationale for use: _____

Note: Authorization for indications not approved by the Food and Drug Administration (FDA) or recognized in CMS-accepted compendia (e.g. DrugDex, AHFS, and also Clinical Pharmacology for oncology indications only) require supporting evidence for coverage. Please provide two published peer-reviewed literature articles supporting the drug’s use for the identified indication.

B. What is the patient’s baseline SELENA-SLEDAI score? _____ (see pp 5-6)

C. Does the patient have an ANA titre \geq 1:80?

- Yes
- No
- Date of test: _____

D. Does the patient have an anti-dsDNA level \geq 30 L/mL ?

- Yes
- No
- Date of test: _____

E. **Does the patient have severe active lupus nephritis?**
 (defined as proteinuria > 6 g/24 hr, serum creatinine > 2.5 mg/dL, active nephritis, hemodialysis, or high dose prednisone (> 100mg/day) use within the past 90 days)

- Yes
 No

F. **Does the patient have severe active CNS lupus?**
 (defined as seizures, psychosis, organic brain syndrome, CVA, cerebritis, or CNS vasculitis within the past 60 days)

- Yes
 No

G. **Is the patient receiving other biologics or intravenous cyclophosphamide?**

- Yes
 No

H. **Please indicate which of the following apply to the patient:**

- No live vaccines within 30 days before initiation, or at any time while patient is receiving therapy.
 No chronic infection is present in patient

I. **Has the patient received standard therapy and has been on stable doses for at least 3 months?**

- Yes
- | | |
|---|--|
| <input type="checkbox"/> Corticosteroid (dose/day: _____) | <input type="checkbox"/> Duration: _____ |
| <input type="checkbox"/> hydroxychloroquine | <input type="checkbox"/> Duration: _____ |
| <input type="checkbox"/> Azathioprine | <input type="checkbox"/> Duration: _____ |
| <input type="checkbox"/> mycophenolate | <input type="checkbox"/> Duration: _____ |
| <input type="checkbox"/> methotrexate | <input type="checkbox"/> Duration: _____ |
| <input type="checkbox"/> oral cyclophosphamide | <input type="checkbox"/> Duration: _____ |
| <input type="checkbox"/> NSAIDs | <input type="checkbox"/> Duration: _____ |
| <input type="checkbox"/> Other: _____ | <input type="checkbox"/> Duration: _____ |
- No

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

CONTINUATION OF THERAPY – SECTION B

PRIORITY HEALTH PRECERTIFICATION DOCUMENTATION

Authorization for Benlysta[®] (belimumab) requires the following information to certify continuation of therapy:

A. **What is the patient's current Selena-Sledai Score? Current Score:** _____
 (Although the Selena-Sledai score asks for only for the last 10 days, please include your assessment for the last 30 days).

B. **Has the patient had a change in Physician Global Assessment indicating disease worsening?**

- Yes, disease progression has occurred (authorization will be denied).
 No, patient maintains or has shown improvement from baseline therapy with belimumab

C. What is the patient's British Isles Lupus Assessment Group (BILAG) score?

Category A score: 0
 ≥ 1

Category B score: 0-1
 ≥ 2

D. Has the patient had a reduction in steroid dose?

Yes – Percent reduction: _____
 No

Has there been any change in other immunosuppressant doses? Yes No

What was the change? _____

E. Has the patient seroconverted from positive to negative?

Yes
 No

If no, has the patient had a 20% reduction in autoantibody levels compared to baseline?

Yes
 No

F. Has the patient experienced any significant clinical flares requiring steroid boost during treatment:

Yes
 No

Optional: Please provide any other clinically meaningful changes not already noted above that should be considered for the review for continuation of therapy: _____

Table 1. Dose and Duration of Authorization

Initial Authorization	Continuing Authorization
<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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

*** All fields must be complete and legible for Prior Authorization Review***

**Please fax this request to: (877)974-4411 toll free or (616)942-8206
 YOUR OFFICE WILL RECEIVE A RESPONSE VIA FAX**

SYSTEMIC LUPUS ERYTHEMATOSUS DISEASE ACTIVITY INDEX SELENA MODIFICATION

Physicians Global Assessment _____

0 1 2 3
 None Mild Med 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	<input type="checkbox"/>	Seizure	Recent onset. Exclude metabolic, infectious or drug cause
8	<input type="checkbox"/>	Psychosis	Altered ability to function in normal activity due to severe disturbance of the perception of reality. Include hallucinations, incoherent loose associations, impoverished thought content, marked thinking, bizarre, disorganized, or catatonic behavior. Exclude drug causes.
8	<input type="checkbox"/>	Organic Brain Syndrome	Altered mental function with impaired orientation, memory, intelligent function, with rapid onset fluctuating clinical features, clouding of consciousness with reduced capacity to focus, an inability to sustain attention to environment, plus at least two of the following: perceptual disturbance, incoherent speech, insomnia, drowsiness, or increased or decreased psychomotor activity. Exclude metabolic, infectious or drug causes.
8	<input type="checkbox"/>	Visual Disturbance	Retinal changes of SLE. Include cytoid bodies, retinal lesions, serious exudate or hemorrhages in the choroids, or optic neuritis. Exclude hypertension, infection, or drug causes.
8	<input type="checkbox"/>	Cranial Nerve Disorder	New onset of sensory or motor neuropathy involving cranial nerves
8	<input type="checkbox"/>	Lupus Headache	Severe persistent headache: may be migrainous, but must be responsive to narcotic analgesia.
8	<input type="checkbox"/>	CVA	New onset of cerebrovascular accident(s). Exclude arteriosclerosis
8	<input type="checkbox"/>	Vasculitis	Ulceration, gangrene, tender finger nodules, periungual splinter hemorrhages, or biopsy or angiogram proof of vasculitis
4	<input type="checkbox"/>	Arthritis	More than 2 joints with pain and signs of inflammation (i.e. swelling, or effusion).
4	<input type="checkbox"/>	Myositis	Proximal muscle aching/weakness, associated with elevated phosphokinase/creatine phosphokinase or electromyogram changes or a biopsy proof of myositis.
4	<input type="checkbox"/>	Urinary Casts	Heme-granular or red blood cell casts
4	<input type="checkbox"/>	Hematuria	>5 red blood cells/high power field. Exclude stone, infection, or drug cause.
4	<input type="checkbox"/>	Proteinuria	>0.5 gm/24 hours. New onset or recent increase of more than 0.5 gm/24 hours.
4	<input type="checkbox"/>	Pyuria	>5 white blood cells/high power field. Exclude infection.
2	<input type="checkbox"/>	New Rash	New onset or recurrence of inflammatory type rash.
2	<input type="checkbox"/>	Alopecia	New onset or recurrence of abnormal, patchy or diffuse loss of hair
2	<input type="checkbox"/>	Mucosal Ulcers	New onset or recurrence of oral or nasal ulcerations

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

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

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