Government of District of Columbia Department of Health Care Finance

Benlysta (Belimumab) for Systemic Lupus Erythematosus

Prior Authorization Request

REQUEST DATE: / /

PATIENT INFORMATION

PATIENT'S MEDICAID ID NUMBER

PATIENT'S DATE OF BIRTH / /

PATIENT'S FULL NAME

PRESCRIBER INFORMATION

PRESCRIBER'S FULL NAME

PRESCRIBER PHONE NUMBER: - -

PRESCRIBER FAX NUMBER: - -

PRESCRIBER SPECIALTY:

(WRITE IN ABOVE)

PRESCRIBER NPI #: -

Please refer to FDA www.fda.gov for prescribing details and approved indications.

INFORMATION REQUIRED FOR PRIOR AUTHORIZATION APPROVAL

1A. **Select treatment option(s): The patient is 5 years of age or older (IV formulation)** ☐ Yes ☐ No

1B. **The patient is 18 years of age or older (SubQ formulation)** ☐ Yes ☐ No

2. **The patient is supervised by:** ☐ Rheumatologist ☐ Primary Care Provider/Internal medicine ☐ Nephrologist ☐ Other Provider (_____) Please list

3. Check all that apply: **Patient has a diagnosis of** (please attach a "letter of medical necessity" with documentation)

☐ Systemic Lupus Erythematosus (SLE) _____ (date of onset)

☐ Lupus Nephritis_____ (date of onset) Note *diagnostic criteria in appendix to this form*

4. Patient is currently receiving at least one standard of care treatment for active systemic lupus erythematosus to include corticosteroids AND either cyclophosphamide or mycophenolate mofetil ☐ Yes ☐ No

4A. If YES, list agents here/duration of treatment:

5. Special population certification**: Is the patient African American?** ☐ Yes ☐ No

If "no" skip to question 6.

5A. ***If "yes***," please certify and review clinical trial data and package insert regarding insignificant efficacy as add on therapy in the African American population. Have patient review and certify on ***Benlysta Patient Education Form***

5B. Certification is noting that clinical trials on these populations were inconclusive or ineffective. I understand that "in the treatment of SLE and acute lupus nephritis, Benlysta has limited data in the African American/Black population and its improvement in response rates versus standard treatment has not been established."

6) a. Has the patient received a live vaccine within 30 days before starting or concurrently with Benlysta? (Live vaccines should not be given for 30 days before or concurrently with Benlysta as clinical ☐ Yes ☐ No

	safety has not been established). Live vaccines= flu vaccine through your nose, measles, mumps, rubella, polio by mouth, BCG (TB vaccine), yellow fever, chicken pox (varicella), or typhoid		
b.	Will the Benlysta be used in combination with standard therapy (e.g., anti-malarials, corticosteroids, non-steroidal anti-inflammatory drugs, immunosuppressives?	☐ Yes	☐ No
c.	Is the patient using voclosporin? (Benlysta has not been studied in combination with other biologic therapies, voclopsorin, or intravenous cyclophosphamide, and is not recommended to be used with other biologic therapy or IV Cyclophosphamide)	☐ Yes	☐ No
	Is the patient of reproductive age or considering becoming pregnant?	☐ Yes	☐ No
	Benlysta is recommended to be discontinued once pregnancy is confirmed, and *women of reproductive potential should use effective contraception during treatment and for at least 4 months after the final treatment.*		

7. **If this drug is to be used for pregnant women, certify that you have and will contact the Benlysta pregnancy registry at phone:** 1-877-681-6296

I certify that the information provided is accurate and complete to the best of my knowledge and I understand that any falsification, omission, or concealment of material fact(s) may subject me to civil or criminal liability.

PRESCRIBER'S SIGNATURE: _____ **DATE**: _____

APPENDIX A

*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