BCRenal
Provincial Health Services Authority

Application for Coverage of Belimumab for Lupus Nephritis

Adjunct treatment for class III or IV +/- class V lupus nephritis within 4 months of induction treatment and eGFR < 30 mL/min/1.73m^2 or on dialysis

▶ PLEASE SIGN, DATE AND FAX THIS FORM TO: BC Renal (604) 875-7366

PATIENT INFORMATION LABEL

Name: _____

Address: _____

Phone: _____

Date of Birth (MM/DD/YYYY): _____

PHN: _____

INSTRUCTIONS

1. Ensure the patient is registered in PROMIS under the Provincial Renal Agency and under the care of a nephrologist within a BC Renal Health Authority program.
   a) Choose the most appropriate GN diagnosis under the available list of primary renal diagnoses.
   b) Ensure the patient address and contact information are accurate as these are needed for medication distribution.
2. Complete the appropriate section below, **fax this form to the BC Renal at (604) 875-7366.**
   a) Please note applications at 12 or 24 months should use the same type of form that was selected for initiation.
3. This application will be reviewed by the BC Renal Pharmacy Services Committee; you will be contacted once approval is decided.
4. If approved, fax the approval letter along with the Benlysta Monarch Patient Support Program enrollment form with the Lupus Nephritis section completed to the **Monarch Patient Support Program at (1-855-788-3140)**, to inform them of BCR coverage. The Patient Support Program will then arrange intravenous infusion or teaching for subcutaneous self-administration.
5. All approvals are valid for 12 months from the approval date, you will need to reapply after that.

THE FOLLOWING ARE REQUIRED FOR MEDICATION APPROVAL:

GN Diagnosis with PROMIS codes (pick one):

- ☐ Lupus nephritis (84), class III
- ☐ Lupus nephritis (84), class III + V
- ☐ Lupus nephritis (84), class IV
- ☐ Lupus nephritis (84), class IV + V
- ☐ Lupus nephritis (84), class V
- ☐ Additional details about diagnosis, if needed _____

Weight:_____ **Age:**_____

Intravenous Administration

- ☐ 10 mg/kg = _____ mg IV every 2 weeks x first 3 doses, then every 4 weeks thereafter
- ☐ 10 mg/kg = _____ mg IV every 4 weeks
- ☐ Other: _____

Subcutaneous Administration

- ☐ 400 mg subcutaneous weekly x first 4 doses, then 200 mg weekly thereafter
- ☐ 200 mg subcutaneous weekly
- ☐ Other: _____

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Initiation criteria

☐ Adults with class III or IV, with or without class V, lupus nephritis on a kidney biopsy within the last 6 months:

- Provide date of biopsy (MM/DD/YYYY): _____
- Provide evidence of disease activity on the biopsy: _____
- If a biopsy can't be performed:
  - Justify why: _____
  - Justify a clinical diagnosis of class III or IV with or without V lupus nephritis disease flare: _____

☐ Started induction therapy for the treatment of lupus nephritis within the prior 4 months, and have not already entered remission

- Provide details of drugs used for current induction therapy and their start dates and doses:
- Provide the following laboratory values:

Labs:	Prior to the onset of the most recent flare	At the time of the onset of current induction treatment	The most recent values
creatinine			
eGFR			
proteinuria			
urinalysis			

☐ Has not previously failed both cyclophosphamide and mycophenolate (both with corticosteroids) as induction therapies for lupus nephritis

- Provide details of previous induction therapy used in the past and the therapeutic response observed:

☐ Provide evidence of **acute kidney injury** with current eGFR < 30 mL/min/1.73m^2 or on dialysis, and with a baseline eGFR prior to the onset of lupus nephritis ≥ 30 mL/min/1.73m^2

- Provide the following laboratory values:

Labs:	Prior to the onset of the most recent flare
creatinine	
eGFR	

- If patient is on dialysis, provide dialysis start date: _____

Note: Patients with advanced CKD and baseline eGFR < 30 mL/min/1.73m^2 prior to the onset of most recent lupus nephritis flare do not qualify for belimumab.

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Continuation criteria at 12 months

☐ Has not started any new immunosuppression therapies for the treatment of lupus nephritis (other than those that were initially part of induction or maintenance therapy)

☐ Has reduced corticosteroids to ≤ 10 mg/day of prednisone or equivalent (other than short-term increases for non-lupus nephritis indications)

And satisfies either 1 or 2 below:

☐ 1) If patient did not require dialysis during the treatment of the current lupus nephritis flare, demonstrate an improvement in eGFR in the previous 12 months, and has not received a kidney transplant.

- Provide the following laboratory values:

Labs:	12 months ago	Onset of current flare	The most recent values
creatinine			
eGFR			

OR

☐ 2) If the patient was on dialysis during the treatment of the current lupus nephritis flare, demonstrate that the patient has recovered sufficient kidney function to come off dialysis, and has not received a kidney transplant

- Provide dialysis start and stop dates: _____
- Provide the following laboratory values:

Labs:	The most recent values
creatinine	
eGFR	

Continuation criteria at 24 months and every 12 months thereafter

☐ Has not started any new immunosuppression therapies for the treatment of lupus nephritis (other than those that were initially part of the induction or maintenance therapy)

☐ Has reduced corticosteroids to ≤ 10 mg/day of prednisone or equivalent (other than short-term increases for non-lupus nephritis indications)

☐ An eGFR that has been stable or improved in the prior 12 months and is currently eGFR ≥ 15 mL/min/1.73m^2, has not started dialysis and has not received a kidney transplant

- Provide the following laboratory values:

Labs:	Prior to onset of most recent flare	At time of most recent flare	12 months ago	The most recent values
creatinine				
eGFR				

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- If eGFR is declining due to reasons other than active lupus nephritis, provide a detailed explanation to justify ongoing treatment with belimumab:

_____
_____
_____

And satisfies either 1 or 2 or 3 below:

☐ 1) Has continued to show clinical improvement but is not yet in remission, as evidenced by proteinuria improvement by ≥ 25% in the prior 12 months and is ≥ 0.7 g/day.

- Provide the following laboratory values:

Labs:	12 months ago	The most recent value
proteinuria		

OR

☐ 2) Has achieved remission but has a history of lupus nephritis flare on maximum maintenance therapy, as evidenced by proteinuria < 0.7 g/day and there is a history of previous lupus nephritis flare (biopsy proven class III or IV with or without class V) while on maximum maintenance dose of mycophenolate (or has a contraindication to mycophenolate and has had a flare on maximum dose of azathioprine).

- Provide details of maintenance therapy, with drug dosing at time of prior flares, and details of biopsy dates and findings that confirmed the lupus nephritis flare:

_____
_____
_____

- If current proteinuria is ≥ 0.7 g/day, a kidney biopsy showing resolution of class III or IV active lesions (i.e. histologic remission) can be used instead, provide biopsy date and details:

_____
_____
_____

OR

☐ 3) Has a history of requiring belimumab in addition to maximum maintenance therapy to maintain remission, as evidenced by previously using belimumab for the treatment of lupus nephritis and achieved remission and has had a flare of class III or IV with or without class V lupus nephritis confirmed on kidney biopsy within 6 months of discontinuing belimumab while on maximum maintenance dose of mycophenolate (or on maximum dose of azathioprine if has a contraindication to mycophenolate).

- Provide details regarding the belimumab drug history, details regarding achieving remission while on belimumab, the drug type and dosing used for maintenance therapy at the time of the lupus nephritis flare that occurred after stopping belimumab and the details of the kidney biopsy date and findings that confirmed the lupus nephritis flare:

_____
_____
_____

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PATIENTS WHO ACHIEVE REMISSION AND WHO DO NOT HAVE A COMPLICATED HISTORY OF LUPUS NEPHRITIS (BASED ON CRITERIA 1, 2 OR 3 ABOVE) DO NOT QUALIFY FOR ONGOING USE OF BELIMUMAB.

Fax number for approval notification (mandatory): _____

If you do not receive a response to your application within 72 hours, or if you'd like to check on the status of your application, please email medications@bcrenal.ca.

Name: _____ Signature: _____

Phone: _____ Date: _____