

Application for Coverage of Belimumab for Lupus Nephritis

Pure class V lupus nephritis

Revised: May/25

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► **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 pure class V lupus nephritis on a kidney biopsy within the last 6 months:
 - Provide date of biopsy (MM/DD/YYYY): _____
 - Provide evidence of active class V on the biopsy: _____

 - If a biopsy can't be performed:
 - Justify why: _____
 - Justify a clinical diagnosis of class V lupus nephritis disease flare: _____

- ☐ Has been resistant to all other therapies for class V lupus nephritis, including corticosteroids, mycophenolate, calcineurin inhibitors, and mycophenolate with calcineurin inhibitors, and has an eGFR ≥ 30 mL/min/1.73m² and proteinuria ≥ 3.5 g/day
 - Provide details of all **prior** induction therapies, with drugs, doses, dates and demonstrate a lack of clinical improvement after a sufficient trial of each induction therapy (i.e., 4 to 6 months):

 - Provide details of drugs used for **current** treatment of class V lupus nephritis, and their start dates and doses: _____

 - Provide the following laboratory values:

Labs:	Prior to treatment	Most recent values demonstrating a lack of improvement after a sufficient trial of treatment
creatinine		
eGFR		
proteinuria		
urinalysis		

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)
- ☐ Current eGFR ≥ 30 mL/min/1.73m², has not started dialysis and has not received a kidney transplant

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- Provide the following laboratory values:

Labs:	The most recent values
creatinine	
eGFR	

- ☐ Proteinuria has reduced by $\geq 25\%$ in the previous 12 months

- Provide the following laboratory values:

Labs:	Prior to treatment with belimumab	The most recent values
proteinuria		

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 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 $\text{eGFR} \geq 30$ mL/min/1.73m², 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				

- 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 $\geq 25\%$ in the prior 12 months and is ≥ 3.5 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 < 3.5 g/day and there is a previous history of lupus nephritis flare

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(biopsy proven class III or IV with or without class V or pure class V) while on maximum maintenance dose of mycophenolate, calcineurin inhibitors, and mycophenolate with calcineurin inhibitors (or has a contraindication to mycophenolate, and has a flare on maximum dose of azathioprine in the aforementioned combinations)

- Provide details of prior 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 > 3.5 g/day, a kidney biopsy showing resolution of class III or IV active lesions and resolution of class V disease (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 or pure class V confirmed on kidney biopsy within 6 months of discontinuing belimumab while on maximum maintenance dose of mycophenolate + calcineurin inhibitors (or has a contraindication to mycophenolate and has a flare on maximum dose of azathioprine + calcineurin inhibitors)
- 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:

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: _____