Exception Drug Status (EDS) Request

Benlysta (belimumab) for active lupus nephritis

Ministry of Health
Drug Plan and Extended Benefits
3475 Albert Street
Regina SK S4S 6X6
Phone: 1-800-667-2549
Fax: 306-798-1089
E-mail: DPEB@health.gov.sk.ca

- Requests MUST be submitted by prescribers (or their clinics) or pharmacies.
- Requests from patients or Patient Support Programs (PSPs) will NOT be accepted.
- INCOMPLETE FORMS may result in a delay in processing the request. Please ensure each section is completed.

Section 1 - Requester Information

Name (first & last): _____ Address (or clinic/pharmacy name): _____

Telephone Number: _____ Fax Number: _____

Requester Type **(required)**:

☐ Physician ☐ Pharmacist ☐ Nurse ☐ Other Health Professional (please specify): _____

Prescriber Name (if different than requester) and Telephone Number: _____

Section 2 - Patient Information

Name (first & last): _____

Health Services Number (HSN): _____ Date of Birth: _____

Section 3 - Initial Request for EDS

1. Does the patient have a diagnosis of active lupus nephritis (LN)? ☐ Yes ☐ No
2. Does this patient have an international Society of Nephrology/Renal Pathology Society class III (with or without class V), class IV (with or without class V) or class V? ☐ Yes ☐ No
3. Has this patient started standard induction therapy within the previous 60 days? ☐ Yes ☐ No
4. Has this patient previously failed both cyclophosphamide and mycophenolate as induction? ☐ Yes ☐ No
5. Has this patient had an eGFR that is less than 30mL/min/1.73m^2? ☐ Yes ☐ No
6. Is this patient is under the care of a rheumatologist or nephrologist experienced in the management of lupus nephritis? ☐ Yes ☐ No
7. **Please provide the following baseline measurement**:
   24-hour proteinuria measurement: _____

Section 4 – EDS Renewal Request

1. Has this patient had a reduction in their oral corticosteroid dose to less than or equal to 7.5mg/day (prednisone equivalent) **OR** a 50% or more decrease from their baseline oral corticosteroid dose? ☐ Yes ☐ No
2. Is this patient's eGFR greater than or equal to 60mL/min/1.73m^2 or no more than 20% less than the value before the renal flare (i.e., preflare value)? ☐ Yes ☐ No
3. Has this patient had an eGFR that is less than 30mL/min/1.73m^2? ☐ Yes ☐ No

4. Has this patient had improvement in proteinuria to no greater than 0.7g/24 hours?* ☐ Yes ☐ No

24-hour proteinuria: _____ **Date:** _____(mm-dd-yyyy)

**If baseline 24-hour proteinuria was in the nephrotic range (greater than 3.5 g/24 hours), this value will be assessed at second (and subsequent) renewals, allowing for 18-24 months of treatment to reach the treatment target of 0.7g/24 hours, as long as the other renewal parameters are met at first renewal.*

5. Has this patient had the addition of other immunosuppressant agents, corticosteroid use outside of the limits, anti-tumour necrosis factor therapy, or other biologics. ☐ Yes ☐ No

6. Is the patient under the care of a rheumatologist or nephrologist experienced in the management of lupus nephritis. ☐ Yes ☐ No

Section 5 – Additional Information

Requester Signature: _____ Date: _____