Benlysta (belimumab)

Benlysta Monarch Patient Support Program

Systemic Lupus Erythematosus/ Lupus Nephritis

Send completed form by fax (1-855-788-3140) or email (support@benlysta-monarch.ca)

DO NOT SEND THIS FORM TO GSK

Enrollment Form

Patient Information

First Name:	Last Name:	Date of Birth (DD/MM/YYYY):
Address:	City:	Province:
Postal Code:	Preferred Language:	Home #:
Mobile #:	Email:	

Permission to leave a message/SMS: Y ☐ N ☐

Allergies:

Patient Authorization (Select one form of consent)

☐ I have read, understand, and agree to the patient authorization statement on the reverse side of this form

Signature Date (DD/MM/YYYY)

OR

Verbal consent obtained

☐ My patient has certified that they have read, understand, and agree to the Patient Authorization statement on the reverse side of this form

Signature Date (DD/MM/YYYY)

By Whom

Additional Information

	Prednisone	Methotrexate	Azathioprine	Hydroxychloroquine	Mycophenolate mofetil	Cyclophosphamide	Other (specify)
Recent dose							
Duration of treatment							
Current therapy	☐	☐	☐	☐	☐	☐	☐

SELENA-SLEDAI score:

Kidney Biopsy (Patients with LN only): Y ☐ N ☐

Is the patient medically cleared to start BENLYSTA once coverage is secured Y ☐ N ☐

Other:

For Systemic Lupus Erythematosus (SLE)

☐ BENLYSTA for subcutaneous (SC) injection with the autoinjector for patients with SLE. Dose 200 mg once weekly.

Duration of order (weeks): ☐ 26 ☐ 52 ☐ See R_x attached ☐ Other:

OR

☐ BENLYSTA for IV infusion (dose 10 mg/kg) for patients.

Frequency of administration:

☐ **Initial order:** Weeks 0, 2, and 4, then every 4 weeks

Weight: ..... kg

Dose: Give ..... mg
Infuse over at least 1 hour as per BENLYSTA Product Monograph.

Pre-treatment order Medication(s) administered prior to infusion at clinic (e.g., oral antihistamine, antipyretic).

☐ No premeds required

☐ **Premed:** .....

Dose: ..... **mg, min** ..... **prior to infusion** ☐ **PO** ☐ **IV**

Duration of order (weeks): ☐ 26 ☐ 52 ☐ See R_x attached ☐ Other:

For Lupus Nephritis (LN)

☐ BENLYSTA for subcutaneous (SC) injection with the autoinjector for patients with lupus nephritis. Dose 400 mg (two 200 mg injections) once weekly for 4 doses, then 200 mg once weekly thereafter.

Duration of order (weeks): ☐ 26 ☐ 52 ☐ See R_x attached ☐ Other:

OR

☐ BENLYSTA for IV infusion (dose 10 mg/kg) for patients.

Frequency of administration:

☐ **Initial order:** Weeks 0, 2, and 4, then every 4 weeks

Weight: ..... kg

Dose: Give ..... mg
Infuse over at least 1 hour as per BENLYSTA Product Monograph.

Pre-treatment order Medication(s) administered prior to infusion at clinic (e.g., oral antihistamine, antipyretic).

☐ No premeds required

☐ **Premed:**

Dose: ..... **mg, min** ..... **prior to infusion** ☐ **PO** ☐ **IV**

Duration of order (weeks): ☐ 26 ☐ 52 ☐ See R_x attached ☐ Other:

Physician Information

First name:	Last name:	
Address:		
City:	Province:	Postal code:
Phone:	Fax:	Email:
Nurse/PSP coordinator name:	Phone/fax:	Email:

Physician Authorization

By signing I certify that I have read, understand, and agree to the Physician Authorization statement on the reverse side of this form

Physician Signature | Physician License | Date (DD/MM/YYYY)

For more information please call the Benlysta Monarch Program Toll Free 1-855 788 3135. Mon-Fri 8am-8pm EST
visit BENLYSTA.ca for all your BENLYSTA and lupus needs

BENLYSTA Monarch Program
Consent Information and Patient Disclosure

Product Indication

BENLYSTA (Belimumab for injection, belimumab injection) is indicated in addition to standard therapy for:

- Reducing disease activity in adult patients with active, autoantibody-positive, systemic lupus erythematosus (SLE)
- Treatment of active lupus nephritis in adult patients

Consult the Product Monograph at https://ca.gsk.com/media/6151/benlysta.pdf for important information on contraindications, warnings, precautions, adverse reactions, interactions, dosing, and conditions of clinical use. To request a Product Monograph or report an adverse event please call 1-800-387-7374.

Physician Authorization

Please read the information included in the Patient Authorization section to obtain a full description of the **Benlysta Monarch** Patient Support Program ("Program") and if you agree, sign where indicated.

- I certify that this Product has been prescribed for this patient based on my independent medical judgment and the patient's informed consent. I acknowledge that the patient's participation in this Program will be terminated in the event of use that is inconsistent with the Product Monograph.
- I agree to be contacted by **NavieGo Patient Programs** ("Service Provider") and/or GSK about the patient, the Product, or Product complaints. I consent to the use of my prescribing information for the purpose of administering, monitoring, and assessing the Program.
- I authorize the Service Provider in the context of the Program to be my designated agent to forward the prescription by fax or other mode of delivery to the pharmacy chosen by the above-named patient.
- I understand that my information, including my prescribing information may be shared with GSK for the purpose of assessing the Program.
- I acknowledge that adverse events may be reported about my patient participating in the Program and understand that I may be contacted by GSK or its agents and/or the Service Provider to provide follow up information to Health Canada.

Patient Authorization

By signing this form (or providing verbal consent) you agree to enroll into the **Benlysta Monarch** Patient Support Program and have read and fully understand the information below:

- The **Benlysta Monarch** Patient Support Program ("Program") is designed to facilitate access and provide assistance to qualifying patients that have been prescribed **BENLYSTA** The services under the Program may include: (i) reimbursement investigation and/or financial assistance (ii) assistance with drug administration or medication dispensing or delivery and (iii) disease and medication resources.
- I acknowledge that, the Service Provider, on behalf of GSK, may collect and store (i) personal information such as my name, address, phone number, date of birth; (ii) medical information as it relates to my medical condition for which **BENLYSTA** has been prescribed, including patient-reported outcome data and (iii) insurance information such as information related to my health insurance coverage, collectively referred to as "My Information or Your Information". I consent to the collection, use and disclosure of My Information for the services provided under the Program.
- The Program is a GlaxoSmithKline Inc. ("GSK") Program and administered by a third-party service providers ("Service Provider") selected by GSK. In the event that GSK appoints a new Service Provider, I understand that My Information may be transferred to the new Service Provider in order to ensure the continuity of the Program services.
- I authorize the Service Provider, on behalf of GSK, to contact as well as to collect further information from me, my caregiver(s), my prescribing practitioner, pharmacist, nurse, and other healthcare professionals involved in my care as well as any insurer, or government agency, as deemed necessary to ensure the accuracy and completeness of this application and to administer the Program.
- GSK does not, in the normal course, access Your Information and relies on Service Provider to do so when administering the Program however, GSK may directly access Your Information in limited circumstances, for example, to transfer your personal information to a new Service Provider, to perform audits of the Program in order to evaluate or improve the Program, or for regulatory reporting purposes (e.g., reporting adverse reactions to a government agency).
- At times insurers may require the collection of medical information associated with the administration of **BENLYSTA** and that such data may be disclosed to insurers and regulatory bodies as required to enable reimbursement. I agree to be contacted by the Service Provider as needed to complete questionnaires or provide feedback on the services I receive pertaining to my medical condition or **BENLYSTA** for the purpose of market research and assessing the quality of services provided under the Program.
- I acknowledge the Service Provider may provide GSK with anonymize or aggregate information collected during the Program, which may be used by GSK for clinical or health outcomes research, market research or internal evaluation purposes, and disclosed by GSK to third parties in accordance with GSK's Privacy Notice https://privacy.gsk.com/en-ca/privacy-notice/general.
- I understand My information will be stored in a secure database, with access restricted to authorized personnel. Safeguards are used to protect My Information against unauthorized access, disclosure, copying, use or modification. I have the right to request access to My Information that GSK and/or its third-party service providers have on file, subject to applicable legal restrictions, which includes the right to correct that information and to receive an account of how it has been used and a list of the organizations to whom it has been disclosed. I may request access to or make inquiries or complaints I can contacting the Service Provider at **1-855-788-3135** or by email at **support@benlysta-monarch.ca** I understand and accept that My Information may be stored or processed outside of my province/territory or country and that the laws of those regions regarding privacy may be less stringent than the laws of Canada and its provinces. In addition, I understand, accept, and agree that My Information may be used or disclosed to any party to the extent such disclosure is required by applicable law, regulation, or court order.
- I understand that, (i) I do not have to consent to this Authorization but, if I do not, I will not be able to participate in the Program; (ii) consenting to this Authorization is not a requirement for insurance coverage and will not affect my insurance enrollment; (iii) participation in the Program is not required for me to have access to **BENLYSTA** (iv) acceptance into the Program is based on predefined criteria. If criteria is not met I may be withdrawn or declined from the Program; (v) GSK may cancel or revise the Program at any time; (vi) I may revoke this Authorization at any time by emailing a letter to: **support@benlysta-monarch.ca** or such other address as Service Provider may advise, but, if I do so, I will no longer be able to participate in the Program; (vii) revoking the Authorization will prohibit use and disclosures of My Information AFTER the date my letter of revocation is received and processed, but will not affect GSK's ability to use the disclosed information already received, solely for the purposes of the Program.

This document is not intended to promote the use of any drug. It contains information related to the patient assistance program intended to help patients access their medication prescribed by a healthcare professional.

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12/23

MEMBER OF INNOVATIVE MEDICINES CANADA

Benlysta (belimumab)

The Benlysta monarchprogram

GSK